# National Cancer Drugs Fund List

**This document contains treatment criteria for use of:**



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## 26-Mar-26

# National Cancer Drugs Fund (CDF) List

| NHS England INFORMATION READER BOX | | |
|---|---|---|
| **Directorate** | | |
| Medical | Operations and Information | **Specialised Commissioning** |
| Nursing | Trans. & Corp. Ops. | Commissioning Strategy |
| Finance | | |

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| **Description** | |
| **Cross Reference** | National Cancer Drug Fund decision summaries |
| **Superseded Docs** (if applicable) | National Cancer Drug Fund List (as updated July 2015) |
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## Document Status

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# National Cancer Drugs Fund (CDF) List

## A. National CDF List

**Notes:** This list should be read in conjunction with 'Appraisal and Funding of Cancer Drugs from July 2016 (including the new Cancer Drugs Fund) A new deal for patients, taxpayers and industry' published by NHS England on 8 July 2016 at www.england.nhs.uk/ourwork/cancer/cdf

| Blueteq Form ref: | Drug | Indication | Criteria for use | Available to new patients | | | Transition Drug (Old CDF) Indication (Yes or No) | Transition Funding agreed by manufacturer (Agreed, Rejected, Pending) | Eligible for Interim Funding (Yes, No, Not currently applicable (NCA)) | Interim Funding agreed by manufacturer (Agreed, Rejected, Pending, Not currently applicable (NCA)) | CDF Managed Access Scheme (Yes, No, Not currently applicable (NCA)) | Expected Entry into Baseline Commissioning (Date if known or Not currently applicable (NCA)) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Yes | Yes (but notice of removal served) | No | | | | | | |
| AMI1 | **Amivantamab** in combination with lazertinib | For the first line treatment of locally advanced or metastatic non-small cell lung cancer in adults whose tumours have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with amivantamab with lazertinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br><br>2. The patient has a histologically or cytologically documented non-small cell lung cancer (NSCLC) that has been shown to exhibit an epidermal growth factor (EGFR) exon 19 deletion or exon 21 (L858R) substitution mutation OR there is documented agreement by the lung MDT that the radiological appearances are in keeping with recurrent/locally advanced/metastatic NSCLC AND there is an informative circulating free DNA test result confirming the presence of an exon 19 deletion or exon 21 (L858R) substitution mutation.<br><br>Please mark below on which basis the diagnosis of EGFR mutation positive NSCLC has been made in this patient:<br>- Histological or cytological evidence and tissue/ctDNA testing, or<br>- Documented agreement by the lung MDT that the radiological appearances are in keeping with locally advanced or metastatic NSCLC and there is an informative circulating free DNA test result confirming the presence of an exon 19 deletion or exon 21 (L858R) substitution mutation.<br><br>3. The patient has locally advanced or metastatic disease, and that for this disease indication, the patient has not received any previous cytotoxic chemotherapy or immunotherapy.<br><br>4. The patient has had no prior treatment with an EGFR inhibitor unless osimertinib has had to be stopped within 6 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression, or osimertinib has been received as adjuvant treatment for resected stages IB to N2 only IIIB NSCLC with either an EGFR exon 19 deletion or exon 21 substitution mutation and the patient did not progress whilst still receiving adjuvant Osimertinib, or within 12 months of the last dose of osimertinib being taken.<br><br>Please mark below which scenario applies to this patient:<br>- no prior treatment with an EGFR inhibitor<br>- previous treatment with Osimertinib **(in the locally advanced or metastatic setting)** but treatment has had to be stopped within 6 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of progressive disease<br>- previously received **adjuvant** osimertinib for resected stages IB to N2 only IIIB NSCLC, and did not progress whilst still receiving adjuvant Osimertinib, or within 12 months of the last dose of osimertinib being taken.<br><br>Please state in box below how many months have elapsed since discontinuation of adjuvant osimertinib (or enter 'n/a' if not applicable):_____<br><br>5. The patient has an ECOG performance status (PS) of 0 or 1.<br><br>6. The patient will be treated until loss of clinical benefit or excessive toxicity or patient choice to discontinue treatment, whichever is the sooner.<br><br>If a patient experiences severe toxicity specifically related to amivantamab, lazertinib can be continued as a single agent<br><br>Note: the use of amivantamab and lazertinib should be stopped if there is disease progression in the CNS that cannot be treated with surgery or stereotactic radiotherapy.<br><br>7. Where a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment, which MUST be approved before treatment is recommenced.<br><br>8. Amivantamab and lazertinib will be used as set out in its Summary of Product Characteristics (SPC). | From 18-Dec-2025 | | | No | n/a | Yes | Agreed | No | 21-Apr-26 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | Indication | Criteria for use | Available to new patients | | | Transition Drug (Old CDF) Indication (Yes or No) | Transition Funding agreed by manufacturer (Agreed, Rejected, Pending) | Eligible for Interim Funding (Yes, No, Not currently applicable (NCA)) | Interim Funding agreed by manufacturer (Agreed, Rejected, Pending, Not currently applicable (NCA)) | CDF Managed Access Scheme (Yes, No, Not currently applicable (NCA)) | Expected Entry into Baseline Commissioning (Date if known or Not currently applicable (NCA)) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Yes | Yes (but notice of removal served) | No | | | | | | |
| AXI02a_v1.0 | **Axicabtagene ciloleucel** | Axicabtagene ciloleucel for treating relapsed/refractory diffuse large B-cell lymphoma (DLBCL) or high grade B-cell lymphoma and either in patients who relapse within 12 months of completion of 1st line chemoimmunotherapy AND who would otherwise be intended for potential stem cell transplantation or who are refractory to 1st line chemoimmunotherapy AND who would otherwise be intended for potential stem cell transplantation where the following criteria are met:<br><br>*This form is for the approval of leucapheresis and manufacture of CAR-T cells. There is a second part to this form which relates to the subsequent infusion of CAR-T cells and this will be available after submission of the first part. The second part of the form (AXI02b) can only be completed as a continuation of this first part of the form (AXI02a) and must be completed on infusion of CAR-T cells otherwise the treating Trust will not be reimbursed for the cost of axicabtagene ciloleucel* | 1. This application is being made by and that leucapheresis for and treatment with axicabtagene ciloleucel-modified CAR-T cells will be initiated by a consultant haematologist or medical oncologist specifically trained and accredited in the use of systemic anti-cancer therapy and working in an accredited CAR-T cell treatment centre **and** who is a member of the National CAR-T Clinical Panel for DLBCL and HGBCL **and** a member of the treating Trust's DLBCL and HGBCL CAR-T cell multidisciplinary team.<br><br>2. The patient is an adult (age 18 years or over) on the date of approval for axicabtagene ciloleucel by the National CAR-T Clinical Panel for DLBCL and HGBCL.<br><br>3. The patient has a confirmed histological diagnosis of DLBCL or HGBCL.<br>Please tick appropriately below as to which type of lymphoma the patient has:<br>- Diffuse large B-cell lymphoma (DLBCL) NOS (including ABC and GCB types) **or**<br>- High grade B-cell lymphoma (HGBCL) with or without MYC and BCL2 (double hit) and BCL6 (triple hit) re-arrangements **or**<br>- Transformed follicular lymphoma (TFL) to DLBCL and this diagnosis of TFL was made prior to embarking on any chemotherapy for DLBCL **or**<br>- T cell/histiocyte-rich large B-cell lymphoma **or**<br>- Primary cutaneous DLBCL of leg type **or**<br>- HHV8 positive DLBCL **or**<br>- DLBCL associated with chronic inflammation **or**<br>- EB virus positive DLBCL<br>Note: Patients with Burkitt lymphoma or primary mediastinal B cell lymphoma or primary CNS lymphoma or Richter's transformation to DLBCL are not eligible for treatment with axicabtagene ciloleucel in this indication.<br><br>4. The histological diagnosis of DLBCL or HGBCL or transformed lymphoma to DLBCL has been either made by or reviewed and confirmed by a designated lymphoma stem cell transplant centre.<br><br>5. Prior to consideration of CAR-T cell therapy the patient's disease has been re-biopsied unless **either** the patient had outright progressive disease on standard 1st line chemo-immunotherapy **or** a biopsy is unsafe in which case the patient must have progressive disease at previously known sites of active disease. In such situations the original diagnostic biopsy review is acceptable.<br>All patients with transformed follicular lymphoma to DLBCL who fulfil criteria 6 below must have a re-biopsy and have confirmation of DLBCL histology prior to consideration of CAR-T cell therapy.<br>Please enter appropriately below as to which scenario applies to this patient:<br>- no biopsy necessary as the patient had outright progressive disease during 1st line chemo-immunotherapy **or**<br>- re-biopsy has confirmed DLBCL or HGBCL **or**<br>- re-biopsy has confirmed transformed follicular lymphoma to DLBCL **or**<br>- re-biopsy is unsafe for the patient and the patient has progressive disease at previously known sites of active disease and the previous histology was DLBCL or HGBCL<br><br>6. The patient fulfils one of the following clinical scenarios relating to these definitions of relapsed or refractory lymphoma as applied to the failure of 1st line standard chemo-immunotherapy: please tick the appropriate box below.<br>Refractory disease is defined as progressive disease as the best response to 1st line standard chemo-immunotherapy after at least 2 cycles of chemo-immunotherapy **or** stable disease as the best response after at least 4 cycles of 1st line standard chemo-immunotherapy **or** a partial response as the best response after at least 6 cycles of 1st line standard chemo-immunotherapy with biopsy-proven residual disease **or** a partial response with biopsy-proven progressive disease within 12 months or less from completion of treatment.<br>Relapsed disease is defined as disease that was in complete remission following 1st line standard chemo-immunotherapy and has been followed by a biopsy-proven disease relapse within 12 months or less from completion of treatment.<br>Progressive disease should be defined radiologically as per RECIST version 1.1 and be based on CT or MR scans and aided if necessary, after discussion at the National CAR T Clinical Panel, with the use of Lugano lymphoma response criteria.<br>Please tick the box below which applies to this patient:<br>- progressive disease after at least 2 cycles of chemo-immunotherapy as the best response to 1st line standard chemo-immunotherapy OR<br>- stable disease as the best response after at least 4 cycles of 1st line standard chemo-immunotherapy with biopsy-proven residual disease OR<br>- a partial response as the best response after at least 6 cycles of 1st line standard chemo-immunotherapy with biopsy-proven residual disease OR<br>- a partial response to 1st line standard chemo-immunotherapy with biopsy-proven progressive disease within 12 months or less from completion of treatment OR<br>- a complete response to 1st line standard chemo-immunotherapy with biopsy-proven disease relapse within 12 months or less from completion of treatment.<br><br>7. The patient has been previously treated with a full dose 1st line anthracycline-containing standard regimen for his/her DLBCL or high grade lymphoma or with the Marietta protocol if presenting with CNS involvement.<br>Note: acceptable anthracycline-containing regimens include R-CHOP, Pola-R-CHP, R-CODOX-M/R-IVAC, DA-EPOC-R and the Marietta protocol.<br>Note: patients with transformed follicular lymphoma must have received the full dose 1st line anthracycline-containing standard regimen for the known DLBCL component and this regimen must have been the 1st ever chemotherapy regimen for the transformed lymphoma (i.e. patients who receive 1st line anthracycline-based chemotherapy for follicular lymphoma and then subsequently transform are not eligible for axicabtagene in this indication).<br><br>8. The patient has been previously treated with a regimen containing an anti-CD20 monoclonal antibody unless there is clear documentation of the determination of CD20 negative disease.<br><br>9. On the date that the patient was confirmed as having refractory or relapsed disease according to the above definitions, the patient had only received 1st line of therapy for the DLBCL or HGBCL or TFL to DLBCL.<br>Note: in the case of patients who have transformed from FL to DLBCL, 1st line therapy refers to the treatment of TFL to DLBCL once transformation has been documented.<br>Note: it is recognised that some patients at the time of the demonstration of refractory or relapsed disease have very rapidly progressive disease and thus have to commence urgent 2nd line treatment. It is therefore acceptable for patients to have received a maximum of 2 cycles of standard 2nd line chemotherapy regimens with one of the following regimens ('anticipatory bridging therapy'): R-GDP, R-GemCarbo, R-ESHAP, R-ICE, R-IVE, R-BendaPola and the Marietta protocol.<br>Please enter below whether the rate of disease progression as outlined above required urgent 2nd line salvage chemotherapy ('anticipatory bridging therapy') in this patient:<br>- no urgent chemotherapy required prior to this application **or**<br>- a maximum of 2 cycles of one of the above standard salvage chemotherapy regimens have been given prior to this application on grounds of urgent need and all other treatment criteria on this form are fulfilled<br><br>10. In the absence of the availability of axicabtagene ciloeucel for this 2nd line indication the patient would have been fit and intended for **both** standard 2nd line salvage chemotherapy (see note below) **and potential stem cell transplantation**.<br>Note: Second line treatment regimens which are appropriate include: R-GDP, R-GemCarbo, R-ESHAP, R-ICE, R-IVE, R-BendaPola and the Marietta protocol.<br><br>11. The patient has not previously been treated with an anti-CD19 antibody-drug conjugate.<br><br>12. There is no current suspicion of CNS involvement by the lymphoma.<br><br>***Continued on the next page*** | From 27-Apr-23 | | | No | n/a | Yes | Agreed | Yes | NCA |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Yes | Yes (but notice of removal served) | No | | | | | | |
| AXI02a_v1.0 | **Axicabtagene ciloleucel** | Axicabtagene ciloleucel for treating relapsed/refractory diffuse large B-cell lymphoma (DLBCL) or high grade B-cell lymphoma and either in patients who relapse within 12 months of completion of 1st line chemoimmunotherapy AND who would otherwise be intended for potential stem cell transplantation or who are refractory to 1st line chemoimmunotherapy AND who would otherwise be intended for potential stem cell transplantation where the following criteria are met:<br><br>*This form is for the approval of leucapheresis and manufacture of CAR-T cells. There is a second part to this form which relates to the subsequent infusion of CAR-T cells and this will be available after submission of the first part. The second part of the form (AXI02b) can only be completed as a continuation of this first part of the form (AXI02a) and must be completed on infusion of CAR-T cells otherwise the treating Trust will not be reimbursed for the cost of axicabtagene ciloleucel* | 13. The patient has an ECOG performance score of 0 or 1. Please enter below as to the patient's current ECOG performance status (PS):<br>The ECOG performance status scale is as follows:<br>PS 0 The patient is fully active and able to carry on all pre-disease performance without restriction<br>PS 1 The patient is restricted in physically strenuous activity but is ambulatory and able to carry out work of a light or sedentary nature eg light housework, office work<br>PS 2 The patient is ambulatory and capable of all selfcare but unable to carry out any work activities and is up and about more than 50% of waking hours<br>PS 3 The patient is capable of only limited selfcare and is confined to bed or chair more than 50% of waking hours<br>PS 4 The patient is completely disabled, cannot carry out any selfcare and is totally confined to bed or chair<br>The patient currently has a performance status of **either**<br>- ECOG PS 0 **or**<br>- ECOG PS 1 | From 27-Apr-23 | | | No | n/a | Yes | Agreed | Yes | NCA |
| | | | 14. The patient has sufficient end organ function to tolerate treatment with CAR-T cell therapy. | | | | | | | | | |
| | | | 15. The patient has **either** had no previous therapy with any genetically modified autologous or allogeneic T cell immunotherapy or the patient has been treated with doses of genetically modified autologous or allogeneic T cell immunotherapy within an abandoned dosing cohort in a first in human dose-escalation phase I clinical trial.<br>Please tick appropriate box as to which type of previous treatment the patient has had:<br>- No previous therapy with any genetically modified autologous or allogeneic T cell immunotherapy **or**<br>- Previously treated with doses of genetically modified autologous or allogeneic T cell immunotherapy within an abandoned dosing cohort in a first in human dose-escalation phase I clinical trial | | | | | | | | | |
| | | | 16. Prior to infusion 2 doses of tocilizumab are available for use in this patient in the event of the development of cytokine release syndrome. | | | | | | | | | |
| | | | 17. Axicabtagene ciloleucel-modified CAR-T cell therapy will otherwise be used as set out in its Summary of Product Characteristics (SPC). | | | | | | | | | |
| | | | 18. Approval for the use of axicabtagene ciloleucel has been formally given by the National DLBCL/HGBCL CAR-T cell Clinical Panel.<br>Please state date of approval (DD/MM/YYYY) | | | | | | | | | |
| | | | 19. Following national approval for use of axicabtagene ciloleucel there has been local CAR-T cell multidisciplinary team agreement that this patient continues to have the necessary fitness for treatment and fulfils all of the treatment criteria listed here. | | | | | | | | | |
| AXI02b_v1.0 | **Axicabtagene ciloleucel** | Axicabtagene ciloleucel for treating relapsed/refractory diffuse large B-cell lymphoma (DLBCL) or high-grade B-cell lymphoma and in adult patients either who relapse within 12 months of completion of 1st line chemoimmunotherapy AND who would otherwise be intended for potential stem cell transplantation or who are refractory to 1st line chemoimmunotherapy AND who would otherwise be intended for potential stem cell transplantation where the following criteria are met:<br><br>*This second part of the form is to document the date of infusion of CAR-T cell therapy and for registration of this infusion with NHS England so that the treating Trust is reimbursed for the cost of axicabtagene ciloleucel. There is a first part of the form for the approval of leucapheresis and manufacture of CAR-T cells which has already been completed (AXI02a). This second part of the form (AXI02b) should only be completed as a continuation form once the date of CAR-T cell infusion is known.* | 1. This application for continuation is being made by and treatment with axicabtagene ciloleucel-modified CAR-T cells will be initiated by a consultant haematologist/medical oncologist specifically trained and accredited in the use of systemic anti-cancer therapy and working in an accredited CAR-T cell treatment centre **and** who is a member of the National CAR-T Clinical Panel for DLBCL and HGBCL **and** a member of the treating Trust's DLBCL and HGBCL and CAR-T cell multidisciplinary teams. | From 27-Apr-23 | | | No | n/a | Yes | Agreed | Yes | NCA |
| | | | 2. The patient has an ECOG performance score of 0 or 1 or 2. Please tick one of the boxes below as to the patient's current ECOG performance status (PS):<br>The ECOG performance status scale is as follows:<br>PS 0 The patient is fully active and able to carry on all pre-disease performance without restriction<br>PS 1 The patient is restricted in physically strenuous activity but is ambulatory and able to carry out work of a light or sedentary nature eg light housework, office work<br>PS 2 The patient is ambulatory and capable of all selfcare but unable to carry out any work activities and is up and about more than 50% of waking hours<br>PS 3 The patient is capable of only limited selfcare and is confined to bed or chair more than 50% of waking hours<br>PS 4 The patient is completely disabled, cannot carry out any selfcare and is totally confined to bed or chair<br>The patient currently has a performance status of:<br>- ECOG PS 0 **or**<br>- ECOG PS 1 **or**<br>- ECOG PS 2 | | | | | | | | | |
| | | | 3. Whether the patient has required bridging therapy in between leucapheresis and CAR-T cell infusion. Please indicate what type(s) of bridging therapy have been required by ticking the most appropriate option below:<br>- no bridging therapy at all **or**<br>- corticosteroids only **or**<br>- chemo(immuno)therapy only with intensive salvage-type therapy (eg R-GDP, R-GemCarbo, R-ESHAP, R-ICE, R-IVE, R-BendaPola and the Marietta protocol) **or**<br>- chemo(immuno)therapy only with BR-polatuzumab **or**<br>- other chemo(immuno)therapy only **or**<br>- radiotherapy only **or**<br>- corticosteroids and chemo(immuno)therapy **or**<br>- corticosteroids and radiotherapy **or**<br>- chemo(immuno)therapy and radiotherapy ± corticosteroids | | | | | | | | | |
| | | | 4. The nature of any imaging procedure performed to assess response to bridging therapy below:<br>- no bridging therapy and so no radiological assessment performed **or**<br>- PET-CT scan performed **or**<br>- CT or MR scan performed **or**<br>- had bridging therapy but no radiological assessment performed. | | | | | | | | | |
| | | | 5. The response assessment to bridging therapy below:<br>- no bridging therapy and so no radiological assessment performed **or**<br>- complete response (CR) or complete metabolic response (CMR) **or**<br>- partial response (PR) or partial metabolic response (PMR) **or**<br>- stable disease (SD) **or**<br>- progressive disease (PD) **or**<br>- had bridging therapy but no radiological assessment performed | | | | | | | | | |
| | | | 6. The dominant reason for the decision to employ bridging therapy if used: please tick one box.<br>- no bridging therapy used at all or<br>- the need to relieve local symptoms **or**<br>- the need to relieve systemic symptoms **or**<br>- the need to relieve both local and systemic symptoms **or**<br>- the belief that toxicity and long-term outcomes will be better with bridging therapy | | | | | | | | | |
| | | | 7. The time gap (as measured by the number of days) between the date of leucapheresis and the start of any bridging therapy. If no bridging therapy has been used, please enter 0.<br>Number of days between date of leucapheresis and start of bridging therapy: _____ | | | | | | | | | |
| | | | 8. The patient has sufficient end organ function to tolerate treatment with CAR-T cell therapy. | | | | | | | | | |
| | | | 9. Prior to infusion 2 doses of tocilizumab are available for use in this patient in the event of the development of cytokine release syndrome. | | | | | | | | | |
| | | | 10. Axicabtagene ciloleucel-modified CAR-T cell therapy will otherwise be used as set out in its Summary of Product Characteristics (SPC). | | | | | | | | | |
| | | | 11. Following national approval for use of axicabtagene ciloleucel there has been local CAR-T cell multidisciplinary team agreement that this patient continues to have the necessary fitness for infusion and fulfils all of the treatment criteria listed here. | | | | | | | | | |

# National Cancer Drugs Fund (CDF) List

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Yes | Yes (but notice of removal served) | No | | | | | | |
| BELA1 | **Belantamab mafodotin** in combination with bortezomib and dexamethasone | Belantamab mafodotin in combination with bortezomib and dexamethasone as 2nd line treatment of relapsed or refractory myeloma in adult patients who previously received lenalidomide as part of 1st line systemic therapy where the following criteria have been met: | 1. This application for belantamab mafodotin in combination with bortezomib and dexamethasone is being made by and the first cycle of systemic anti-cancer therapy with belantamab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a confirmed diagnosis of multiple myeloma.<br><br>Note: patients with amyloidosis or POEMS syndrome are not eligible for belantamab mafodotin.<br>3. This patient has received **1 and only 1** prior line of systemic therapy for myeloma and that the numbering of a line of treatment is in accordance with the International Myeloma Workshop Consensus recommendations for the uniform reporting of clinical trials (http://doi.org/10.1182/blood-2010-10-299487).<br>A line of therapy is defined as one or more cycles of a planned treatment program. This may consist of one or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner (eg 1st line induction chemotherapy/chemotherapies when followed by stem cell transplantation and maintenance therapy is considered as 1 line of therapy).<br>A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse or toxicity, the exception to this being the need to attain a sufficient response for stem cell transplantation to proceed. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease.<br><br>Note: although the marketing authorisation is for patients with myeloma who have had at least 1 prior therapy, the company has initially sought a NICE recommendation for patients who have had only 1 prior line of treatment. **Patients who have had more than 1 prior line of therapy are <u>not eligible</u> for treatment with this belantamab mafodotin combination.**<br>4. This patient has been previously treated with a 1st line lenalidomide-containing regimen which is commissioned by NHS England or is part of a 1st line treatment regimen in a NIHR-badged clinical trial.<br><br>Please confirm below which 1st line treatment was received by the patient:<br><br>- 1st line daratumumab plus lenalidomide and dexamethasone for transplant ineligible disease<br>- 1st line lenalidomide and dexamethasone for transplant ineligible disease<br>- maintenance lenalidomide post stem cell transplant as part of 1st line therapy<br>- lenalidomide was part of a 1st line treatment regimen in a NIHR-badged clinical trial<br>- 1st line isatuximab plus bortezomib, lenalidomide and dexamethasone for untreated multiple myeloma when a stem cell transplant is unsuitable<br><br>Note: patients who have not received lenalidomide as part of their 1st line therapy are not eligible for treatment with this belantamab mafodotin combination.<br>5. The reason for discontinuing the 1st line lenalidomide was because of either disease progression on treatment or intolerance of lenalidomide.<br><br>Please indication the reason for discontinuing the 1st line lenalidomide:<br>- disease progression on treatment or<br>- intolerance of lenalidomide<br>6. This patient has been previously treated with bortezomib or another proteasome inhibitor as part of 1st line therapy.<br><br>Please tick the appropriate box which applies to this patient:<br><br>- No, the patient has not been previously treated with bortezomib or any other proteasome inhibitor or<br>- Yes, the patient has been previously treated with a 1st line bortezomib-containing regimen or<br>- Yes, the patient has been previously treated with another 1st line proteasome inhibitor-containing regimen in a clinical trial<br>7. This patient has been previously treated with an anti-CD38 antibody as part of 1st line therapy.<br><br>Please tick the appropriate box which applies to this patient:<br>- No, the patient has not been previously treated with an anti-CD38 antibody or<br>- Yes, the patient has been previously treated with a 1st line anti-CD38 antibody or<br>- Yes, the patient has been previously treated with another 1st line anti-CD38 antibody-containing regimen in a clinical trial<br>8. The patient has been previously treated as part of 1st line therapy with stem cell transplantation.<br><br>Please tick the appropriate box which applies to this patient:<br>- No, the patient has not been previously treated as part of 1st line treatment with stem cell transplantation or<br>- Yes, the patient has been previously treated as part of 1st line treatment with stem cell transplantation<br>9. The patient has progressive disease during or following 1st line systemic anti-myeloma therapy.<br>10. The patient has an ECOG performance status of 0 or 1 or 2:<br><br>Please record below the patient's ECOG performance status:<br>PS 0 or PS 1 or<br>PS 2<br><br>***Continued on the next page*** | From 12-Jun-25 | | | No | nca | Yes | Agreed | No | nca |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | Indication | Criteria for use | Available to new patients | | | Transition Drug (Old CDF) Indication (Yes or No) | Transition Funding agreed by manufacturer (Agreed, Rejected, Pending) | Eligible for Interim Funding (Yes, No, Not currently applicable (NCA)) | Interim Funding agreed by manufacturer (Agreed, Rejected, Pending, Not currently applicable (NCA)) | CDF Managed Access Scheme (Yes, No, Not currently applicable (NCA)) | Expected Entry into Baseline Commissioning (Date if known or Not currently applicable (NCA)) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Yes | Yes (but notice of removal served) | No | | | | | | |
| BELA1 | **Belantamab mafodotin** in combination with bortezomib and dexamethasone | Belantamab mafodotin in combination with bortezomib and dexamethasone as 2nd line treatment of relapsed or refractory myeloma in adult patients who previously received lenalidomide as part of 1st line systemic therapy where the following criteria have been met: | 11. Belantamab mafodotin will be used **only** in combination with bortezomib and dexamethasone and not with any other anti-myeloma agents.<br>12. The prescribing clinician is aware of the risk of corneal adverse reactions with belantamab mafodotin and that an ophthalmic examination including visual acuity and slit lamp examination must be performed by an eye care professional prior to each of cycles 1, 2, 3 and 4 and then during treatment as indicated.<br>13. Arrangements have been put in place for the eye care professional to categorize both the degree of any corneal damage and the best corrected visual acuity in the most severely affected eye and for these results to be communicated to the myeloma team.<br>14. Since belantamab mafodotin dose modifications are partly based on corneal examination findings and/or changes in best corrected visual acuity, the patient's ophthalmic examination findings will be reviewed before dosing and will determine the belantamab mafodotin dose based on the highest category from the corneal examination and/or best corrected visual acuity finding in the most severely affected eye.<br>15. The patient will be advised to administer preservative-free artificial tears for use at least 4 times daily throughout the time of treatment with belantamab mafodotin.<br>16. The patient should avoid using contact lenses until the end of belantamab mafodotin treatment unless bandage contact lenses are used under the direction of an ophthalmologist.<br>17. The patient will be treated with belantamab mafodotin until disease progression or the occurrence of excessive toxicity or the withdrawal of patient consent, whichever is the sooner.<br>18. The prescribing clinician understands that given the potentially necessary frequency and duration of treatment breaks during treatment with belantamab mafodotin, this indication is exempt from NHS England's treatment break policy.<br><br>Note: if there is disease progression during a treatment break from belantamab mafodotin, treatment with belantamab mafodotin must be discontinued.<br>19. The use of belantamab mafodotin will otherwise be as described in the drug's Summary of Product Characteristics (SPC). | From 12-Jun-25 | | | No | nca | Yes | Agreed | No | nca |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | Indication | Criteria for use | Available to new patients | | | Transition Drug (Old CDF) Indication (Yes or No) | Transition Funding agreed by manufacturer (Agreed, Rejected, Pending) | Eligible for Interim Funding (Yes, No, Not currently applicable (NCA)) | Interim Funding agreed by manufacturer (Agreed, Rejected, Pending, Not currently applicable (NCA)) | CDF Managed Access Scheme (Yes, No, Not currently applicable (NCA)) | Expected Entry into Baseline Commissioning (Date if known or Not currently applicable (NCA)) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Yes | Yes (but notice of removal served) | No | | | | | | |
| BELZUT1a | **Belzutifan monotherapy** | For adult patients with von Hippel-Lindau (VHL) disease who require systemic therapy for VHL associated renal cell carcinoma, central nervous system haemangioblastomas or pancreatic neuroendocrine tumours, AND for whom localised procedures are unsuitable or undesirable where the following criteria have been met:<br><br>This form BELZUT1a is for the FIRST ever application for a patient to commence belzutifan for the above indication. The form BELZUT1b is for either continuation of belzutifan beyond disease progression in one dominant tumour but with continued benefit in other equally dominant VHL associated tumours or a subsequent restart of belzutifan for a different VHL associated tumour to the one which previously resulted in the original indication for belzutifan treatment, and for which localised procedures are unsuitable or undesirable. | 1. This application is both being made by and the first cycle of systemic anti-cancer therapy with belzutifan will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient is an adult with a VHL germline alteration.<br>Please state the type of VHL relevant to this patient:<br>- this patient has VHL type 1 disease<br>- this patient has VHL type 2A disease<br>- this patient has VHL type 2B disease<br>- this patient has VHL type 2C disease<br>3. This patient's case has been discussed at a VHL multidisciplinary team meeting which has recommended the use of belzutifan for a VHL associated renal cell carcinoma or a CNS haemangioblastoma or a pancreatic neuroendocrine tumour, AND for which localised procedures are unsuitable or undesirable.<br>Please state the tumour which is the dominant indication for systemic therapy with belzutifan or whether the patient has multisystem involvement which requires systemic therapy for more than one type of VHL cancer and for which 2 or more unsuitable or undesirable procedures would be required:<br>- the dominant indication for treatment with belzutifan is for **renal cell carcinoma** with or without other VHL associated tumours which are not yet indicated for localised treatment<br>- the dominant indication for treatment with belzutifan is for **CNS haemangioblastoma** with or without other VHL associated tumours which are not yet indicated for localised treatment<br>- the dominant indication for treatment with belzutifan is for **pancreatic neuroendocrine tumour** with or without other VHL associated tumours which are not yet indicated for localised treatment<br>- this patient has multisystem disease **with 2 or more** of these 3 VHL associated types of cancer which are currently equally dominant as to the need for localised treatment<br>4. In the absence of systemic therapy with belzutifan the patient would otherwise proceed to treatment for VHL associated tumour(s) with a localised procedure/procedures which is/are considered by the patient and clinician to be unsuitable or undesirable.<br>Please tick the box below as to the type of localised treatment which would otherwise be employed (surgery or ablative procedure or radiotherapy) and then state the procedure(s) in the free text box below (eg partial nephrectomy, radical nephrectomy, CNS resection, partial pancreatectomy, total pancreatectomy, microwave ablation of RCC, cryoablation of RCC, radiotherapy to brainstem etc):<br>- surgery is the unsuitable or undesirable localised procedure<br>- ablation is the unsuitable or undesirable localised procedure<br>- radiotherapy is the unsuitable or undesirable localised procedure<br>Please write in the box below the type(s) of localised procedure(s) which is/are considered to be unsuitable or undesirable:<br>_____<br>5. The patient's status with regard to any VHL associated renal cell carcinoma (RCC) by ticking one of the following:<br>- the RCC(s) is/are the dominant tumour(s) for which belzutifan is indicated<br>- the patient has RCC(s) present but no localised treatment is currently indicated<br>- the patient has had RCC(s) in the past but these have been treated and none are known to be currently present<br>- this patient has never had any RCC(s)<br>6. The patient's status with regard to any VHL associated CNS haemangioblastoma by ticking one of the following:<br>- the **cerebellar** CNS haemangioblastoma(s) is/are the dominant tumour(s) for which belzutifan is indicated<br>- the **brainstem** CNS haemangioblastoma(s) is/are the dominant tumour(s) for which belzutifan is indicated<br>- the **spinal cord** CNS haemangioblastoma(s) is/are the dominant tumour(s) for which belzutifan is indicated<br>- the patient has CNS haemangioblastoma(s) present but no localised treatment is currently indicated<br>- the patient has had CNS haemangioblastoma(s) in the past but these have been treated and none are known to be currently present<br>- this patient has never had any CNS haemangioblastoma(s)<br>7. The patient's status with regard to any VHL associated pancreatic neuroendocrine tumour (pNET) by ticking one of the following:<br>- the pNET(s) is/are the dominant tumour(s) for which belzutifan is indicated<br>- the patient has pNET(s) present but no localised treatment is currently indicated<br>- the patient has had pNET(s) in the past but these have been treated and none are known to be currently present<br>- this patient has never had any pNET(s)<br>8. The patient's status with regard to any VHL associated retinal haemangioblastoma(s) by ticking one of the following:<br>- the patient has retinal haemangioblastom(s) present but no localised treatment is currently indicated<br>- the patient has had retinal haemangioblastoma(s) in the past but these have been treated and none are known to be currently present<br>- this patient has never had any retinal haemangioblastoma(s)<br>9. The patient has not been previously treated with belzutifan or any hypoxia-inducible factor 2 alpha (HIF-2α) inhibitor unless the patient was receiving belzutifan via a company compassionate access scheme and all other criteria on this form are fulfilled.<br>Please enter below as to which scenario applies to this patient:<br>- no previous treatment with belzutifan or a HIF-2α inhibitor or<br>- previous treatment with belzutifan via a company compassionate access scheme and all other criteria on this form are fulfilled.<br>10. Whether there is any evidence of metastatic disease or not of one of the VHL associated tumours of RCC, CNS haemangioblastoma or pNET.<br>Please state whether there is any evidence of such metastatic disease:<br>- yes, the patient has metastatic disease<br>- no, the patient does not have metastatic disease<br>Note: if there is such metastatic disease, there must still be a localised procedure which is currently indicated and in the absence of treatment with belzutifan is considered to be unsuitable or undesirable.<br>***Continued on the next page*** | From 05-Sep-24 | | | No | nca | Yes | Agreed | Yes | nca |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | Indication | Criteria for use | Available to new patients | | | Transition Drug (Old CDF) Indication (Yes or No) | Transition Funding agreed by manufacturer (Agreed, Rejected, Pending) | Eligible for Interim Funding (Yes, No, Not currently applicable (NCA)) | Interim Funding agreed by manufacturer (Agreed, Rejected, Pending, Not currently applicable (NCA)) | CDF Managed Access Scheme (Yes, No, Not currently applicable (NCA)) | Expected Entry into Baseline Commissioning (Date if known or Not currently applicable (NCA)) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Yes | Yes (but notice of removal served) | No | | | | | | |
| BELZUT1a | **Belzutifan monotherapy** | For adult patients with von Hippel-Lindau (VHL) disease who require systemic therapy for VHL associated renal cell carcinoma, central nervous system haemangioblastomas or pancreatic neuroendocrine tumours, AND for whom localised procedures are unsuitable or undesirable where the following criteria have been met:<br><br>This form BELZUT1a is for the FIRST ever application for a patient to commence belzutifan for the above indication. The form BELZUT1b is for either continuation of belzutifan beyond disease progression in one dominant tumour but with continued benefit in other equally dominant VHL associated tumours or a subsequent restart of belzutifan for a different VHL associated tumour to the one which previously resulted in the original indication for belzutifan treatment, and for which localised procedures are unsuitable or undesirable. | 11. The prescribing oncologist confirms that the patient is of ECOG performance status 0 or 1 or 2.<br>Please tick one of the boxes below:<br>- performance status 0 or<br>- performance status 1 or<br>- performance status 2 | From 05-Sep-24 | | | No | nca | Yes | Agreed | Yes | nca |
| | | | 12. Belzutifan is only to be used as monotherapy for treating VHL associated RCC and/or CNS haemangioblastoma and/or pNET. | | | | | | | | | |
| | | | 13.For the dominant indication/tumour belzutifan is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment or the occurrence of an intervention with a localised procedure for that dominant indication/tumour.<br>Note: NHS England recognises that it may be desirable for treatment with belzutifan to continue beyond disease progression in one dominant tumour with the consequent need for intervention with a localised procedure for this progressing tumour IF there has nevertheless been continued benefit in other equally dominant VHL associated tumours and in the absence of continued belzutifan would also be subject to the need for an unsuitable/undesirable localised procedure. In such a patient, blueteq form BELZUT1b should be completed to continue treatment with belzutifan.<br>Note: NHS England also recognises that belzutifan which has been discontinued for disease progression or the occurrence of an intervention with a localised procedure for one particular tumour may be later indicated again for another tumour if a localised procedure for that other tumour is considered to be unsuitable or undesirable. In such a patient, blueteq form BELZUT1b should be completed to restart treatment with belzutifan.<br>Note: belzutifan cannot be restarted for patients who suffer unacceptable toxicity or choose to stop treatment. Patients in such circumstances should be counselled that belzutifan cannot be restarted.<br>Note: the intention to treat with belzutifan must be with a planned and continued administration of belzutifan until disease progression or unacceptable toxicity or patient choice to stop treatment or the occurrence of an intervention with a localised procedure. Belzutifan is not funded to be used electively in an intermittent treatment schedule with planned 'treatment holidays'. | | | | | | | | | |
| | | | 14. The prescribing clinician is aware of the need for monitoring of anaemia, the scheduling of such monitoring and the management of anaemia (including the use of erythropoietin) as set out in sections 4.4 and 4.8 of the belzutifan Summary of Product Characteristics (SPC). | | | | | | | | | |
| | | | 15. The prescribing clinician is aware of the need for monitoring of hypoxia, the scheduling of such monitoring and the management of hypoxia as set out in sections 4.4 and 4.8 of the belzutifan SPC. | | | | | | | | | |
| | | | 16. The prescribing clinician is aware of all the precautions necessary to prevent embryofoetal toxicity whilst patients are on treatment with belzutifan as set out in sections 4.4 and 4.6 of the belzutifan SPC. | | | | | | | | | |
| | | | 17. The prescribing clinician is aware of the potential drug interactions of belzutifan with other medications including hormonal contraceptives as set out in section 4.5 of the belzutifan SPC. | | | | | | | | | |
| | | | 18. A formal medical review as to whether treatment with belzutifan continues or not will be scheduled to occur at least by the end of the second month of treatment. | | | | | | | | | |
| | | | 19. When a treatment break of more than 6 weeks beyond the expected weekly cycle length is needed, a treatment break approval form will be completed to restart treatment. | | | | | | | | | |
| | | | 20. Belzutifan will be otherwise used as set out in its Summary of Product Characteristics. | | | | | | | | | |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | Indication | Criteria for use | Available to new patients | | | Transition Drug (Old CDF) Indication (Yes or No) | Transition Funding agreed by manufacturer (Agreed, Rejected, Pending) | Eligible for Interim Funding (Yes, No, Not currently applicable (NCA)) | Interim Funding agreed by manufacturer (Agreed, Rejected, Pending, Not currently applicable (NCA)) | CDF Managed Access Scheme (Yes, No, Not currently applicable (NCA)) | Expected Entry into Baseline Commissioning (Date if known or Not currently applicable (NCA)) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Yes | Yes (but notice of removal served) | No | | | | | | |
| BELZUT1b | **Belzutifan monotherapy** | For adult patients with von Hippel-Lindau (VHL) disease who require EITHER continuation of belzutifan beyond disease progression in one dominant tumour but who have continued benefit in other equally dominant VHL associated tumours OR a subsequent re-start of therapy for a different VHL associated tumour to the one which previously resulted in the original indication for belzutifan treatment, and AND for which localised procedures are unsuitable or undesirable where the following criteria have been met:<br><br>The Form BELZUT1a is for the FIRST ever application for a patient to commence belzutifan for a VHL associated tumour for which localised procedures are unsuitable or undesirable. This BELZUT1b form is for either continuation of belzutifan beyond disease progression in one dominant tumour but with continued benefit in other equally dominant VHL associated tumours or a subsequent restart of belzutifan for a different VHL associated tumour to the one which previously resulted in the indication for belzutifan treatment, and for which localised procedures are unsuitable or undesirable. | 1. This application is being made by and continuation of or a restart of systemic anti-cancer therapy with belzutifan will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br><br>2. The patient has already received treatment with belzutifan for one VHL associated tumour for which a localised procedure was unsuitable or undesirable.<br>Please state the dominant tumour type for which belzutifan was previously commenced:<br>- Renal cell carcinoma (RCC)<br>- CNS haemangioblastoma<br>- pancreatic neuroendocrine tumour (pNET)<br>- this patient required belzutifan for 2 or more dominant tumours/indications<br><br>3. **Either** disease progression in one dominant tumour but continued benefit in other equally dominant VHL associated tumours or the patient previously discontinued belzutifan on account of disease progression of a dominant tumour and this was followed by a localised procedure to treat this and the patient has now developed a new VHL associated tumour which would otherwise require a localised procedure which is unsuitable or undesirable.<br>Please tick the box below which applies to this patient:<br>- there has been disease progression in one dominant tumour but continued benefit in other equally dominant VHL associated tumours<br>- the patient previously discontinued belzutifan on account of disease progression of a dominant tumour and this was followed by a localised procedure to treat this and the patient has now developed a new VHL associated tumour which would otherwise require a localised procedure which is unsuitable or undesirable.<br><br>4. This patient's case has been discussed at a VHL multidisciplinary team meeting which has recommended the continued use or a re-start of belzutifan for a VHL associated renal cell carcinoma or a CNS haemangioblastoma or a pancreatic neuroendocrine tumour, AND for which localised procedures are unsuitable or undesirable.<br>Please state the tumour which is the dominant indication for systemic therapy with belzutifan or whether the patient has multisystem involvement which requires systemic therapy for more than one type of VHL cancer and for which 2 or more unsuitable or undesirable procedures would be required:<br>- the dominant indication for treatment with belzutifan is for **renal cell carcinoma** with or without other VHL associated tumours which are not yet indicated for localised treatment<br>- the dominant indication for treatment with belzutifan is for **CNS haemangioblastoma** with or without other VHL associated tumours which are not yet indicated for localised treatment<br>- the dominant indication for treatment with belzutifan is for **pancreatic neuroendocrine tumour** with or without other VHL associated tumours which are not yet indicated for localised treatment<br>- this patient has multisystem disease **with 2 or more** of these 3 VHL associated types of cancer which are currently equally dominant as to the need for localised treatment procedures<br><br>5. In the absence of systemic therapy with belzutifan the patient would otherwise proceed to treatment for VHL associated tumour(s) with a localised procedure/procedures which is/are considered by the patient and clinician to be unsuitable or undesirable.<br>Please tick the box below as to the type of localised treatment which would otherwise be employed (surgery or ablative procedure or radiotherapy) and then state the procedure(s) in the free text box below (eg partial nephrectomy, radical nephrectomy, CNS resection, partial pancreatectomy, total pancreatectomy, microwave ablation of RCC, cryoablation of RCC, radiotherapy to brainstem etc):<br>- surgery is the unsuitable or undesirable localised procedure<br>- ablation is the unsuitable or undesirable localised procedure<br>- radiotherapy is the unsuitable or undesirable localised procedure<br>Please write in the box below the type(s) of localised procedure(s) which is/are considered to be unsuitable or undesirable:<br>_____<br><br>6. The patient's status with regard to any VHL associated renal cell carcinoma (RCC) by ticking one of the following:<br>- the RCC(s) is/are the dominant tumour(s) for which belzutifan is indicated<br>- the patient has RCC(s) present but no localised treatment is currently indicated<br>- the patient has had RCC(s) in the past but these have been treated and none are known to be currently present<br>- this patient has never had any RCC(s)<br><br>7. The patient's status with regard to any VHL associated CNS haemangioblastoma by ticking one of the following:<br>- the cerebellar CNS haemangioblastoma(s) is/are the dominant tumour(s) for which belzutifan is indicated<br>- the brainstem CNS haemangioblastoma(s) is/are the dominant tumour(s) for which belzutifan is indicated<br>- the spinal cord CNS haemangioblastoma(s) is/are the dominant tumour(s) for which belzutifan is indicated<br>- the patient has CNS haemangioblastoma(s) present but no localised treatment is currently indicated<br>- the patient has had CNS haemangioblastoma(s) in the past but these have been treated and none are known to be currently present<br>- this patient has never had any CNS haemangioblastoma(s)<br><br>8. The patient's status with regard to any VHL associated pancreatic neuroendocrine tumour (pNET) by ticking one of the following:<br>- the pNET(s) is/are the dominant tumour(s) for which belzutifan is indicated<br>- the patient has pNET(s) present but no localised treatment is currently indicated<br>- the patient has had pNET(s) in the past but these have been treated and none are known to be currently present<br>- this patient has never had any pNET(s)<br><br>9. The patient's status with regard to any VHL associated retinal haemangioblastoma(s) by ticking one of the following:<br>- the patient has retinal haemangioblastom(s) present but no localised treatment is currently indicated<br>- the patient has had retinal haemangioblastoma(s) in the past but these have been treated and none are known to be currently present<br>- this patient has never had any retinal haemangioblastoma(s)<br><br>***Continued on the next page*** | | From 05-Sep-24 | | No | nca | Yes | Agreed | Yes | nca |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | Indication | Criteria for use | Available to new patients | | | Transition Drug (Old CDF) Indication (Yes or No) | Transition Funding agreed by manufacturer (Agreed, Rejected, Pending) | Eligible for Interim Funding (Yes, No, Not currently applicable (NCA)) | Interim Funding agreed by manufacturer (Agreed, Rejected, Pending, Not currently applicable (NCA)) | CDF Managed Access Scheme (Yes, No, Not currently applicable (NCA)) | Expected Entry into Baseline Commissioning (Date if known or Not currently applicable (NCA)) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Yes | Yes (but notice of removal served) | No | | | | | | |
| BELZUT1b | **Belzutifan monotherapy** | For adult patients with von Hippel-Lindau (VHL) disease who require EITHER continuation of belzutifan beyond disease progression in one dominant tumour but who have continued benefit in other equally dominant VHL associated tumours OR a subsequent re-start of therapy for a different VHL associated tumour to the one which previously resulted in the original indication for belzutifan treatment, and AND for which localised procedures are unsuitable or undesirable where the following criteria have been met:<br><br>The Form BELZUT1a is for the FIRST ever application for a patient to commence belzutifan for a VHL associated tumour for which localised procedures are unsuitable or undesirable. This BELZUT1b form is for either continuation of belzutifan beyond disease progression in one dominant tumour but with continued benefit in other equally dominant VHL associated tumours or a subsequent restart of belzutifan for a different VHL associated tumour to the one which previously resulted in the indication for belzutifan treatment, and for which localised procedures are unsuitable or undesirable. | 10. Whether there is any evidence of metastatic disease or not of one of the VHL associated tumours of RCC, CNS haemangioblastoma or pNET.<br>Please state whether there is any evidence of such metastatic disease:<br>- yes, the patient has metastatic disease<br>- no, the patient does not have metastatic disease<br>Note: if there is such metastatic disease, there must still be a localised procedure which is currently indicated and in the absence of treatment with belzutifan is considered to be unsuitable or undesirable. | From 05-Sep-24 | | | No | nca | Yes | Agreed | Yes | nca |
| | | | 11. The prescribing oncologist confirms that the patient is of ECOG performance status 0 or 1 or 2.<br>Please tick one of the boxes below:<br>- performance status 0 or<br>- performance status 1 or<br>- performance status 2 | | | | | | | | | |
| | | | 12. Belzutifan is only to be used as monotherapy for treating VHL associated RCC and/or CNS haemangioblastoma and/or pNET. | | | | | | | | | |
| | | | 13. For the dominant indication/tumour belzutifan is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment or the occurrence of an intervention with a localised procedure for that dominant indication/tumour.<br>Note: belzutifan cannot be restarted for patients who suffer unacceptable toxicity or choose to stop treatment. Patients in such circumstances should be counselled that belzutifan cannot be restarted.<br>Note: the intention to treat with belzutifan must be with a planned and continued administration of belzutifan until disease progression or unacceptable toxicity or patient choice to stop treatment or the occurrence of an intervention with a localised procedure. Belzutifan is not funded to be used electively in an intermittent treatment schedule with planned 'treatment holidays'. | | | | | | | | | |
| | | | 14. The prescribing clinician is aware of the need for monitoring of anaemia, the scheduling of such monitoring and the management of anaemia (including the use of erythropoietin) as set out in sections 4.4 and 4.8 of the belzutifan Summary of Product Characteristics (SPC). | | | | | | | | | |
| | | | 15. The prescribing clinician is aware of the need for monitoring of hypoxia, the scheduling of such monitoring and the management of hypoxia as set out in sections 4.4 and 4.8 of the belzutifan SPC. | | | | | | | | | |
| | | | 16. The prescribing clinician is aware of all the precautions necessary to prevent embryofoetal toxicity whilst patients are on treatment with belzutifan as set out in sections 4.4 and 4.6 of the belzutifan SPC. | | | | | | | | | |
| | | | 17. The prescribing clinician is aware of the potential drug interactions of belzutifan with other medications including hormonal contraceptives as set out in section 4.5 of the belzutifan SPC. | | | | | | | | | |
| | | | 18. A formal medical review as to whether treatment with belzutifan continues or not will be scheduled to occur at least by the end of the second month of treatment. | | | | | | | | | |
| | | | 19. When a treatment break of more than 6 weeks beyond the expected weekly cycle length is needed, a treatment break approval form will be completed to restart treatment. | | | | | | | | | |
| | | | 20. Belzutifan will be otherwise used as set out in its Summary of Product Characteristics. | | | | | | | | | |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | Indication | Criteria for use | Available to new patients | | | Transition Drug (Old CDF) Indication (Yes or No) | Transition Funding agreed by manufacturer (Agreed, Rejected, Pending) | Eligible for Interim Funding (Yes, No, Not currently applicable (NCA)) | Interim Funding agreed by manufacturer (Agreed, Rejected, Pending, Not currently applicable (NCA)) | CDF Managed Access Scheme (Yes, No, Not currently applicable (NCA)) | Expected Entry into Baseline Commissioning (Date if known or Not currently applicable (NCA)) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Yes | Yes (but notice of removal served) | No | | | | | | |
| KTE01a_v1.2 | **Brexucabtagene autoleucel (formerly known as KTE-X19 (Tecartus®))** | For treating mantle cell lymphoma (MCL) in adults previously treated with two or more lines of systemic therapy where the following criteria have been met:<br><br>This form is for the approval of leucapheresis and manufacture of CAR-T cells. There is a second part to this form which relates to the subsequent infusion of CAR-T cells and this will be available after submission of the first part. The second part of the form (KTE01b) can only be completed as a continuation of this first part of the form (KTE01a) and must be completed on infusion of CAR-T cells otherwise the treating Trust will not be reimbursed for the cost of brexucabtagene autoleucel. | 1. This application is being made by and that leucapheresis for and treatment with brexucabtagene autoleucel (formerly known as KTE-X19-modified CAR-T) will be initiated by a consultant haematologist or medical oncologist specifically trained and accredited in the use of systemic anti-cancer therapy and working in an accredited CAR-T cell treatment centre and who is a member of the National CAR-T Clinical Panel for MCL and a member of the treating Trust's MCL and CAR-T cell multidisciplinary teams.<br><br>2. The patient has a confirmed histological diagnosis of MCL with documentation of either cyclin D1 overexpression or the presence of the translocation t(11:14).<br>3. The histological diagnosis of MCL has either been made by or reviewed and confirmed by a designated lymphoma stem cell transplant centre.<br>4. The patient fulfils one of the following clinical scenarios relating to the definition of refractory or relapsed MCL: please tick appropriate box below.<br>**Refractory disease** is defined as being either progressive disease as the best response to the last line of systemic therapy or stable disease as the best response after at least 2 cycles of the last line of therapy with stable disease duration lasting no longer than 6 months from the last dose of the last line of systemic therapy.<br>**Relapsed disease** is defined as disease that responded partially or completely to the last line of therapy and has since progressed.<br>**Progressive disease** must be defined radiologically as per RECIST version 1.1 and be based on CT or MR scans. Progressive disease cannot be defined on just an increased SUV on a PET scan; in such a circumstance, RECIST version 1.1 criteria for progressive disease must be met.<br>Neither radiotherapy nor steroids can be counted as a line of therapy.<br>Please document the number of previous lines of therapy and whether the patient has refractory or relapsed disease:<br>- has received 2 or more lines of systemic therapy for MCL and was refractory to the last line of systemic therapy **or**<br>- has received 2 or more lines of systemic therapy for MCL and relapsed after the last line of systemic therapy.<br>5. That the patient has been previously treated for MCL with one of the following cytotoxic chemotherapy regimens: an anthracycline-containing regimen or a bendamustine-containing regimen or a regimen containing high dose cytarabine with or without cisplatin/carboplatin.<br>Please tick one of the boxes below as to previous cytotoxic chemotherapy for this patient:<br>- has been previously treated with an anthracycline-containing regimen **or**<br>- has been previously treated with a bendamustine-containing regimen **or**<br>- has been previously treated with a high dose cytarabine-containing regimen with or without cisplatin/carboplatin<br><br>6. The patient has been previously treated with at least one anti-CD20 monoclonal antibody unless there is clear documentation of the determination of CD20 negative disease.<br><br>7. Either the patient has not had stem cell transplantation (SCT) or has had an autologous or allogeneic SCT. Please tick one of the boxes below:<br>- has not had SCT **or**<br>- has had autologous SCT **or**<br>- has had allogeneic SCT<br><br>8. The patient has been previously treated for MCL with a Bruton's tyrosine kinase (BTK) inhibitor (such as ibrutinib or acalabrutinib) and that the patient progressed either during treatment or following discontinuation of the BTK inhibitor.<br>Please tick one of the boxes below:<br>- has been previously treated with ibrutinib **or**<br>- has been previously treated with acalabrutinib **or**<br>- has been previously treated with another BTK inhibitor<br><br>9. Either the patient has not previously been treated with an anti-CD19 antibody-drug conjugate or if previously treated with an anti-CD19 antibody-drug conjugate that a biopsy of the relapsed/refractory disease has been done and has been shown to be CD19 positive.<br>10. The patient does not have known active CNS involvement by the lymphoma.<br>11. The patient is aged 18 years or older on the date of approval for brexucabtagene autoleucel by the National MCL CAR-T Clinical Panel.<br>12. The patient has an ECOG performance score of 0 or 1. Please enter below as to the patient's current ECOG performance status (PS):<br>The ECOG performance status scale is as follows:<br>PS 0 - The patient is fully active and able to carry on all pre-disease performance without restriction<br>PS 1 - The patient is restricted in physically strenuous activity but is ambulatory and able to carry out work of a light or sedentary nature e.g. light housework, office work<br>PS 2 - The patient is ambulatory and capable of all selfcare but unable to carry out any work activities and is up and about more than 50% of waking hours<br>PS 3 - The patient is capable of only limited selfcare and is confined to bed or chair more than 50% of waking hours<br>PS 4 - The patient is completely disabled, cannot carry out any selfcare and is totally confined to bed or chair<br>The patient currently has an ECOG performance status of either<br>- ECOG PS 0 **or**<br>- ECOG PS 1<br><br>13. The patient has sufficient end organ function to tolerate treatment with CAR-T cell therapy.<br>14. The patient has either had no previous therapy with any genetically modified autologous or allogeneic T cell immunotherapy or the patient has been treated with doses of genetically modified autologous or allogeneic T cell immunotherapy within an abandoned dosing cohort in a first in human dose-escalation phase I clinical trial.<br>Please tick appropriate box as to which type of previous treatment the patient has had:<br>- No previous therapy with any genetically modified autologous or allogeneic T cell immunotherapy **or**<br>- Previously treated with doses of genetically modified autologous or allogeneic T cell immunotherapy within an abandoned dosing cohort in a first in human dose-escalation phase I clinical trial<br><br>15. Prior to infusion of brexucabtagene autoleucel, 2 doses of tocilizumab are available for use in this patient in the event of the development of cytokine release syndrome.<br><br>16. Brexucabtagene autoleucel modified CAR-T cell therapy will otherwise be used as set out in its Summary of Product Characteristics (SPC).<br><br>17. Approval for the use of brexucabtagene autoleucel has been formally given by the National MCL CAR-T cell Clinical Panel.<br>Please state date of approval (DD/MM/YYYY)<br><br>18. Following national approval for use of brexucabtagene autoleucel there has been local CAR-T cell multidisciplinary team agreement that this patient continues to have the necessary fitness for treatment and fulfils all the treatment criteria listed here. | | From 19-Jan-21 | | No | nca | Yes | Agreed | Yes | nca |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | Indication | Criteria for use | Available to new patients | | | Transition Drug (Old CDF) Indication (Yes or No) | Transition Funding agreed by manufacturer (Agreed, Rejected, Pending) | Eligible for Interim Funding (Yes, No, Not currently applicable (NCA)) | Interim Funding agreed by manufacturer (Agreed, Rejected, Pending, Not currently applicable (NCA)) | CDF Managed Access Scheme (Yes, No, Not currently applicable (NCA)) | Expected Entry into Baseline Commissioning (Date if known or Not currently applicable (NCA)) |
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| | | | | Yes | Yes (but notice of removal served) | No | | | | | | |
| KTE01b_v1.3 | **Brexucabtagene autoleucel (formerly known as KTE-X19 (Tecartus®))** | For treating relapsed/refractory mantle cell lymphoma (MCL) in patients aged 18 years and over where the following criteria have been met:<br><br>This second part of the form is to document the date of infusion of CAR-T cell therapy and for registration of this infusion with NHS England so that the treating Trust is reimbursed for the cost of brexucabtagene autoleucel. There is a first part of the form for the approval of leucapheresis and manufacture of CAR-T cells which has already been completed (KTE01a). This second part of the form (KTE01b) should only be completed as a continuation form once the date of CAR-T cell infusion is known. | 1. This application for continuation is made by and treatment with brexucabtagene autoleucel (formerly known as KTE-X19-modified CAR-T) will be initiated by a consultant haematologist/medical oncologist specifically trained and accredited in the use of systemic anti-cancer therapy and working in an accredited CAR-T cell treatment centre and who is a member of the National CAR-T Clinical Panel for MCL and a member of the treating Trust's MCL and CAR-T cell multidisciplinary teams. | From 19-Jan-21 | | | No | nca | Yes | Agreed | Yes | nca |
| | | | 2. The patient has an ECOG performance score of 0 or 1 or 2. Please tick one of the boxes below as to the patient's current ECOG performance status (PS):<br>The ECOG performance status scale is as follows:<br>PS 0 - The patient is fully active and able to carry on all pre-disease performance without restriction<br>PS 1 - The patient is restricted in physically strenuous activity but is ambulatory and able to carry out work of a light or sedentary nature e.g. light housework, office work<br>PS 2 - The patient is ambulatory and capable of all selfcare but unable to carry out any work activities and is up and about more than 50% of waking hours<br>PS 3 - The patient is capable of only limited selfcare and is confined to bed or chair more than 50% of waking hours<br>PS 4 - The patient is completely disabled, cannot carry out any selfcare and is totally confined to bed or chair<br>The patient currently has an ECOG performance status of:<br>- ECOG PS 0 **or**<br>- ECOG PS 1 **or**<br>- ECOG PS 2 | | | | | | | | | |
| | | | 3. The patient has either required bridging therapy in between leucapheresis and CAR-T cell infusion or not. Please indicate what type(s) of bridging therapy have been required by ticking the most appropriate option below:<br>- no bridging therapy at all **or**<br>- corticosteroids only **or**<br>- ibrutinib monotherapy (only for those patients who previously discontinued a Bruton's tyrosine kinase (BTK) inhibitor without disease progression) or another BTK inhibitor **or**<br>- chemo(immuno)therapy only **or**<br>- radiotherapy only **or**<br>- corticosteroids and ibrutinib (only for those patients who previously discontinued a BTK inhibitor without disease progression) or corticosteroids and another BTK inhibitor **or**<br>- corticosteroids and chemo(immuno)therapy **or**<br>- corticosteroids and radiotherapy **or**<br>- chemo(immuno)therapy and radiotherapy ± corticosteroids | | | | | | | | | |
| | | | 4. The patient does not have known active CNS involvement by the lymphoma. | | | | | | | | | |
| | | | 5. The patient has sufficient end organ function to tolerate treatment with CAR-T cell therapy. | | | | | | | | | |
| | | | 6. Prior to infusion of brexucabtagene autoleucel, 2 doses of tocilizumab are available for use in this patient in the event of the development of cytokine release syndrome. | | | | | | | | | |
| | | | 7. Brexucabtagene autoleucel will otherwise be used as set out in its Summary of Product Characteristics (SPC). | | | | | | | | | |
| | | | 8. Following national approval for use of brexucabtagene autoleucel there has been local CAR-T cell multidisciplinary team agreement that this patient continues to have the necessary fitness for infusion and fulfils all the treatment criteria listed here. | | | | | | | | | |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | Indication | Criteria for use | Available to new patients | | | Transition Drug (Old CDF) Indication (Yes or No) | Transition Funding agreed by manufacturer (Agreed, Rejected, Pending) | Eligible for Interim Funding (Yes, No, Not currently applicable (NCA)) | Interim Funding agreed by manufacturer (Agreed, Rejected, Pending, Not currently applicable (NCA)) | CDF Managed Access Scheme (Yes, No, Not currently applicable (NCA)) | Expected Entry into Baseline Commissioning (Date if known or Not currently applicable (NCA)) |
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| | | | | Yes | Yes (but notice of removal served) | No | | | | | | |
| BREX01a | **Brexucabtagene autoleucel** | Brexucabtagene autoleucel modified CAR-T cells for treating relapsed/refractory Philadelphia negative or positive B cell precursor acute lymphoblastic leukaemia in patients aged 26 years and older where the following criteria are met:<br><br>*This form is for the approval of leucapheresis and manufacture of CAR-T cells. There is a second part to this form which relates to the subsequent infusion of CAR-T cells and this will be available after submission of the first part. The second part of the form (BREX01b) can only be completed as a continuation of this first part of the form (BREX01a) and BREX01b must be completed on infusion of CAR-T cells otherwise the treating Trust will not be reimbursed for the cost of brexucabtagene autoleucel* | 1. This application is being made by and that leucapheresis for and treatment with brexucabtagene autoleucel-modified CAR-T cells will be initiated by a consultant haematologist specifically trained and accredited in the use of systemic anti-cancer therapy and working in an accredited CAR-T cell treatment centre **and** who is a member of the National CAR-T Clinical Panel for adult acute lymphoblastic leukaemia **and** a member of the treating Trust's adult acute lymphoblastic leukaemia and CAR-T cell multidisciplinary teams.<br>2. The patient has CD19 positive relapsed or refractory B lineage acute lymphoblastic leukaemia (ALL).<br>Please tick appropriate box as to which type of ALL the patient has:<br>- Philadelphia chromosome **negative** ALL **or**<br>- Philadelphia chromosome **positive** ALL previously treated with at least 1 tyrosine kinase inhibitor (TKI) or the patient is unsuitable for or intolerant of TKI therapy<br>Note: patients with Burkitt leukaemia/lymphoma or with chronic myeloid leukaemia lymphoid blast crisis are not eligible for treatment with brexucabtagene autoleucel.<br>3. The patient fulfils **one** of the following clinical scenarios relating to the definition of relapsed or refractory ALL.<br>Please tick the most appropriate box as to which applies to this patient:<br>- the patient has primary refractory disease i.e. did not achieve a complete remission after 2 cycles of combination systemic anti-cancer therapy for newly diagnosed ALL **or**<br>- the patient has a bone marrow relapse after allogeneic stem cell transplantation in 1st remission and is at least 3 months since allogeneic SCT with no active Graft versus Host Disease (GVHD) requiring systemic therapy **or**<br>- the patient has a bone marrow relapse after allogeneic stem cell transplantation in 2nd remission or beyond, and is at least 3 months since allogeneic SCT with no GvHD requiring systemic therapy **or**<br>- the patient is in 1st bone marrow relapse following a remission lasting 12 months or less (not had SCT) **or**<br>- the patient is refractory to or has relapsed after 2nd or more lines of systemic anti-cancer therapy (not had SCT) **or**<br>- relapsed disease and ineligible for allogeneic SCT due to comorbid disease (**but still fit enough for CAR-T cell therapy with brexucabtagene autoleucel**) or contraindicated to allogeneic SCT conditioning or lack of a suitable donor<br>4. Having fulfilled, and ticked one of the criteria in box 3 above, the patient at the time of demonstration of such refractory/relapsed disease and thus consideration for potential treatment with brexucabtagene autoleucel has a bone marrow with CD19+ B-ALL demonstrable by flow cytometry.<br>Measurable residual disease by molecular methods is insufficient to comply with access to brexucabtagene autoleucel.<br>5. The patient does **not** have an **isolated** extramedullary ALL relapse i.e. if the patient has extramedullary disease, then the patient must also have bone marrow disease as set out above in criterion 4.<br>6. At the time of this application for treatment with brexucabtagene autoleucel the patient does **not** have active CNS involvement by ALL whether this be CNS2 with neurological changes or CNS3.<br>7. Whether the patient has been previously treated with blinatumomab or not. If there has been previous therapy with blinatumomab, there must be CD19 expression on the lymphoblasts (bone marrow or blood) after the most recent line of treatment.<br>Please tick appropriate box as to whether the patient has received blinatumomab or not:<br>- No previous treatment with blinatumomab **or**<br>- Yes, previous treatment with blinatumomab<br>8. Whether the patient has been previously treated with inotuzumab or not.<br>Please tick appropriate box as to whether patient has received inotuzumab or not:<br>- No previous treatment with inotuzumab **or**<br>- Yes, previous treatment with inotuzumab<br>9. The patient has **either** had no previous therapy with any genetically modified autologous or allogeneic T cell immunotherapy **or** the patient has been treated with doses of genetically modified autologous or allogeneic T cell immunotherapy within an abandoned dosing cohort in a first in human dose-escalation phase I clinical trial.<br>Please tick appropriate box as to which type of previous treatment the patient has had:<br>- No previous therapy with any genetically modified autologous or allogeneic T cell immunotherapy **or**<br>- Previously treated with doses of genetically modified autologous or allogeneic T cell immunotherapy within an abandoned dosing cohort in a first in human dose-escalation phase I clinical trial.<br>10. The patient has an ECOG performance status of 0 or 1.<br>11. The patient has sufficient end organ function to tolerate treatment with brexucabtagene autoleucel.<br>12. The patient is aged 26 years or more on the date of approval for brexucabtagene autoleucel by the National CAR-T Adult ALL Clinical Panel.<br>13. Whether the current intent is for the patient to receive bridging therapy prior to the conditioning chemotherapy before CAR-T infusion.<br>Please mark in the box below:<br>- no, there is no current intent for the patient to undergo bridging systemic anti-cancer therapy **or**<br>- yes, there is an intent for the patient to undergo bridging systemic anti-cancer therapy<br>14. Prior to infusion 2 doses of tocilizumab are available for use in this patient in the event of the development of cytokine release syndrome.<br>15. Brexucabtagene autoleucel-modified CAR-T cells will otherwise be used as set out in its Summary of Product Characteristics (SPC).<br>16. approval for the use of brexucabtagene autoleucel has been formally given by the National adult acute lymphoblastic leukaemia CAR-T cell Clinical Panel.<br>17. Following national approval for use of brexucabtagene autoleucel there has been local CAR-T cell multidisciplinary team agreement that this patient continues to have the necessary fitness for treatment and fulfils all the treatment criteria listed here. | From 27-Apr-23 | | | No | n/a | Yes | Agreed | Yes | NCA |
| BREX01b_v1.0 | **Brexucabtagene autoleucel** | Brexucabtagene autoleucel for treating relapsed/refractory Philadelphia negative and positive B cell acute lymphoblastic leukaemia in patients aged 26 years and over where the following criteria are met:<br><br>*This second form is to document the date of infusion of CAR T cell therapy and for registration of this infusion with NHS England so that the treating Trust is reimbursed for the cost of brexucabtagene autoleucel. There is a first form for the approval of leucapheresis and manufacture of CAR T cells. This second form must use the same unique Blueteq identifier number generated when this patient was registered for leucapheresis and CAR T cell manufacture using the first form* | 1. This application is being made by and treatment with brexucabtagene autoleucel will be initiated by a consultant haematologist specifically trained and accredited in the use of systemic anti-cancer therapy and working in an accredited CAR-T cell treatment centre and who is a member of the National CAR T Clinical Panel for adult acute lymphoblastic leukaemia and a member of the treating Trust's adult acute lymphoblastic leukaemia and CAR-T cell multidisciplinary teams.<br>2. Whether the patient was treated with bridging therapy in between leucapheresis and CAR-T cell infusion. Please indicate what type(s) of bridging therapy have been required by ticking the most appropriate option below:<br>- no bridging therapy at all **or**<br>- corticosteroids only **or**<br>- TKI therapy with or without steroids **or**<br>- systemic cytotoxic chemotherapy with or without steroids **or**<br>- systemic cytotoxic chemotherapy plus TKI with or without steroids **or**<br>- inotuzumab with or without steroids **or**<br>- other<br>3. The patient has an ECOG performance status of 0 or 1 or 2.<br>Please mark in the box below the current performance status:<br>- PS 0 **or**<br>- PS 1 **or**<br>- PS 2<br>4. The patient has sufficient end organ function to tolerate treatment with brexucabtagene autoleucel.<br>5. Prior to infusion a minimum of 2 doses of tocilizumab are available for use in this patient in the event of the development of cytokine release syndrome.<br>6. Brexucabtagene autoleucel will otherwise be used as set out in its Summary of Product Characteristics (SPC).<br>7. Following national approval for use of brexucabtagene autoleucel there has been local CAR T cell multidisciplinary team agreement that this patient continues to have the necessary fitness for treatment and fulfils all the treatment criteria listed here. | From 27-Apr-23 | | | No | n/a | Yes | Agreed | Yes | NCA |

# National Cancer Drugs Fund (CDF) List

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| | | | | Yes | Yes (but notice of removal served) | No | | | | | | |
| DOS1 | **Dostarlimab** | Dostarlimab monotherapy for patients with microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR) recurrent/advanced endometrial carcinoma after prior platinum-based chemotherapy where the following criteria have been met: | 1. This application is being made by and also that the first cycle of systemic anti-cancer therapy with dostarlimab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The prescribing clinician is fully aware of the management of and the treatment modifications that may be required for immune-related adverse reactions due to anti-PD-1/PD-L1 treatments including pneumonitis, colitis, nephritis, endocrinopathies, hepatitis and skin toxicity.<br>3. The patient has a proven histological diagnosis of endometrial carcinoma.<br>Please mark below whether the histology in this patient is endometrioid or not:<br>- the histology is of endometrioid type or<br>- the histology is of non-endometrioid type<br>4. The patient has recurrent or locally advanced or metastatic disease.<br>Please mark below which of the following scenarios best describes the type of recurrent disease the patient has:<br>- the patient previously had a hysterectomy and relapsed with local recurrence only or<br>- the patient previously had a hysterectomy and relapsed with distant disease only or<br>- the patient previously had a hysterectomy and relapsed with both local recurrence and distant disease or<br>- the patient previously had locally advanced disease, did not have surgery and has relapsed with local recurrence only or<br>- the patient previously had locally advanced disease, did not have surgery and has relapsed with distant disease only or<br>- the patient previously had locally advanced disease, did not have surgery and has relapsed with both local recurrence and distant disease or<br>- the patient first presented with distant spread<br>5. The patient's tumour has a documented presence of microsatellite instability-high (MSI-H) or DNA mismatch repair deficiency (dMMR) confirmed by validated testing.<br>6. The patient has progressive disease during or following previous platinum-based therapy for recurrent/locally advanced/metastatic endometrial carcinoma.<br>Please mark below whether the patient has been previously treated with 1 course or >1 courses of treatment with platinum-based chemotherapy for recurrent/locally advanced/metastatic endometrial carcinoma:<br>- 1 previous course of treatment with platinum-based chemotherapy for recurrent/locally advanced/metastatic endometrial carcinoma or<br>- >1 previous courses of treatment with platinum-based chemotherapy for recurrent/locally advanced/metastatic endometrial carcinoma<br>NB A course of treatment consists of a series of cycles of chemotherapy.<br>7. The patient has an ECOG performance status (PS) of 0 or 1.<br>8. The patient has no symptomatic brain or leptomeningeal metastases.<br>9. The patient has not received any prior treatment with an anti-PD-1, anti-PD-L2, anti-CD137, or anti-Cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) antibody unless the patient has been treated with dostarlimab in a company early access scheme and all other treatment criteria on this form apply.<br>Please mark below which clinical scenario applies to this patient:<br>- the patient has not received any previous anti-PD-1, anti-PD-L2, anti-CD137, or anti-Cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) antibody therapy for endometrial carcinoma<br>- the patient has received dostarlimab for recurrent/locally advanced/metastatic endometrial carcinoma via a company early access scheme and all other treatment criteria on this form apply<br>10. Dostarlimab will be administered as monotherapy as follows: dostarlimab 500mg given for a maximum of 4 cycles every 3 weeks and then dostarlimab 1000mg is continued every 6 weeks.<br>11. Dostarlimab will be stopped on disease progression or unacceptable toxicity or withdrawal of patient consent, whichever occurs first.<br>Note: there is no stopping rule for dostarlimab in this endometrial carcinoma indication and hence patients continuing to benefit from dostarlimab after 2 years of treatment can continue on dostarlimab if the patient and clinician agree.<br>Note: once dostarlimab is stopped for disease progression or unacceptable toxicity or withdrawal of patient consent, dostarlimab cannot be re-started.<br>12. A formal medical review as to whether treatment with dostarlimab should continue will occur at least by the end of the 2nd 3-weekly cycle of treatment.<br>13. Where a treatment break of more than 12 weeks beyond the expected 3- or 6-weekly cycle length is needed, the prescribing clinician will complete a treatment break approval form to restart treatment, including indicating as appropriate if the patient had an extended break because of COVID 19.<br>14. Dostarlimab will be otherwise used as set out in its Summary of Product Characteristics (SPCs). | From 08-Feb-22 | | | No | n/a | Yes | Agreed | Yes | nca |

# National Cancer Drugs Fund (CDF) List

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| | | | | Yes | Yes (but notice of removal served) | No | | | | | | |
| DUR5 | **Durvalumab** in combination with platinum-containing chemotherapy (carboplatin and paclitaxel) | For the 1st line treatment of mismatch repair deficient (dMMR) or microsatellite instability-high endometrial carcinoma in adult patients who have recurrent or primary advanced disease and who are not candidates for potentially curative surgery or radiotherapy or chemoradiotherapy but are eligible for systemic therapy where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with durvalumab in combination with carboplatin and paclitaxel will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The prescribing clinician is fully aware of the management of, and the treatment modifications that may be required for, immune-related adverse reactions due to anti-PD-1 treatments including pneumonitis, colitis, nephritis, endocrinopathies, hepatitis, myocarditis and skin toxicity.<br>3. The patient has a histologically- or cytologically confirmed diagnosis of endometrial carcinoma (including clear cell and serous histologies).<br><br>Note: patients with carcinosarcoma (Mixed Mullerian tumour) are eligible but otherwise uterine sarcomas of any kind are NOT eligible for durvalumab in this indication.<br>4. The patient's tumour has a documented presence of mismatch repair deficiency (dMMR) or microsatellite instability (MSI-H) confirmed by validated testing.<br>5. The patient **either** has a 1st recurrence of endometrial carcinoma after surgery or radiotherapy or chemoradiotherapy **or** has presented with primary locally advanced or metastatic endometrial carcinoma **and** in whichever scenario is **not** a candidate for any potentially curative treatment with surgery or radiotherapy or chemoradiotherapy.<br><br>Please mark below which scenario applies to this patient:<br>- 1st recurrence after previous surgery, radiotherapy or chemoradiotherapy or<br>- presented with primary stage IIIA disease and has received no systemic therapy or<br>- presented with primary stage IIIB disease and has received no systemic therapy or<br>- presented with primary stage IIIC1 disease and has received no systemic therapy or<br>- presented with primary stage IIIC2 disease and has received no systemic therapy or<br>- presented with primary stage IV disease and has received no systemic therapy<br>6. The patient **either** has not previously received any systemic chemotherapy for the endometrial carcinoma, or the only systemic therapy has been as neoadjuvant or adjuvant chemotherapy or chemoradiotherapy and the patient has progressed or recurred at least 6 months since the completion of such chemotherapy.<br><br>Please mark below which scenario applies to this patient:<br>- the patient is treatment-naïve to chemotherapy for the endometrial cancer or<br>- the only systemic therapy has been as neoadjuvant or adjuvant chemotherapy or chemoradiotherapy and the patient has progressed or recurred at least 6 months since the completion of such chemotherapy<br>7. Durvalumab will be given in combination with carboplatin and paclitaxel unless there is a clear contraindication to the use of one or both of these cytotoxic agents.<br><br>Please mark below which scenario applies to this patient:<br>- the intent is to use the combination of carboplatin and paclitaxel as the chemotherapy partner to durvalumab or<br>- the patient has a clear contraindication to the use of carboplatin and/or paclitaxel and hence an alternative platinum-based combination therapy has to be used as the chemotherapy partner to durvalumab<br><br>Note: in patients who suffer a severe allergic reaction to paclitaxel or carboplatin which necessitates discontinuation of the drug causing the severe allergy, use of durvalumab can continue with carboplatin or paclitaxel in combination with whichever agent is considered appropriate by the clinician.<br>8. Unless the patient is contraindicated from starting with carboplatin and paclitaxel, the patient will commence combination chemotherapy with carboplatin at a dose of AUC 5mg/ml/min and paclitaxel at 175mg/m$^2$, planned to be given 3-weekly and for a maximum of 6 cycles of chemotherapy.<br>9. The patient has not received any prior antibody treatment which targets PD-1 or PD-L1 or PD-L2 or CD137 or OX40 or anti-cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) unless the patient has already received durvalumab for the same indication via a company sponsored early access scheme<br><br>Please mark below which scenario applies to this patient:<br>- the patient has not received any prior antibody treatment which targets PD-1 or PD-L1 or PD-L2 or CD137 or OX40 or anti-cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4)<br>- the patient has received durvalumab for the same indication via a company sponsored early access scheme and meets all other criteria on this form<br>10. The patient will be treated with a fixed dose of durvalumab 1120mg every 3 weeks when in combination with chemotherapy and then at a dose of 1500mg every 4 weeks as monotherapy.<br><br>Note: patients with a body weight of 30 kg or less during maintenance phase must receive weight-based dosing equivalent to durvalumab at 20 mg/kg<br>11. Treatment with durvalumab will be stopped at whichever of the following events occurs first: disease progression or loss of clinical benefit or unacceptable toxicity or withdrawal of patient consent or **after a maximum of 3 calendar years of treatment.**<br>12. The patient has an ECOG performance status (PS) of 0 or 1.<br><br>Note: NHS England does not fund this combination in patients of ECOG PS > 1<br>13. The patient has no symptomatically active brain metastases or leptomeningeal metastases.<br>14. A formal medical review as to how durvalumab and carboplatin and paclitaxel are being tolerated, and whether treatment with this combination should continue or not, will be scheduled to occur at least by the end of the first 6 weeks of treatment.<br>15. When a treatment break of more than 12 weeks beyond the expected 3 or 4 weekly cycle length is needed, I will complete a treatment break approval form to restart treatment.<br>16. Durvalumab will be otherwise used as set out in its Summary of Product Characteristics (SPC). | From 26-Mar-25 | | | No | n/a | Yes | Agreed | No | nca |

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| | | | | Yes | Yes (but notice of removal served) | No | | | | | | |
| DUR8 | **Durvalumab** with gemcitabine and cisplatin | For neoadjuvant treatment then alone for adjuvant treatment of muscle-invasive bladder cancer where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with durvalumab (in combination with gemcitabine and cisplatin chemotherapy) will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a histologically or cytologically determined diagnosis of **resectable** muscle-invasive bladder cancer, and the intent is to treat the patient with a radical cystectomy following systemic neo-adjuvant treatment.<br>3. The patient has disease which is staged as below<br>- T2-T4a **and**<br>- N0 or N1 **and**<br>- M0<br>4. The patient has not received any prior chemotherapy or immunotherapy for the treatment of muscle-invasive bladder cancer.<br>5. The patient has had no prior treatment with anti–CTLA-4, anti–PD-1, anti–PD-L1, or anti–PD-L2 antibodies for a bladder cancer indication.<br>6. In the **neo-adjuvant** phase, durvalumab will be given alongside gemcitabine and cisplatin chemotherapy, at a dose of 1,500mg every THREE weeks, for FOUR cycles prior to surgery.<br>7. Treatment with **adjuvant** durvalumab monotherapy will be given at a dose of 1,500mg every FOUR weeks.<br>8. Treatment with **adjuvant** durvalumab monotherapy will continue until disease progression or unacceptable toxicity or withdrawal of patient consent **or for a maximum of EIGHT doses post-surgery**, whichever occurs first.<br>9. The patient has a current ECOG performance status of 0 or 1.<br>10. When a treatment break of more than 12 weeks beyond the expected 3-, or 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment. This **must** be approved before durvalumab is re-commenced.<br>11. Durvalumab will be otherwise used as set out in its Summary of Product Characteristics (SPC). | From 10-Feb-26 | | | No | nca | Yes | Agreed | No | 31-May-26 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | Indication | Criteria for use | Available to new patients | | | Transition Drug (Old CDF) Indication (Yes or No) | Transition Funding agreed by manufacturer (Agreed, Rejected, Pending) | Eligible for Interim Funding (Yes, No, Not currently applicable (NCA)) | Interim Funding agreed by manufacturer (Agreed, Rejected, Pending, Not currently applicable (NCA)) | CDF Managed Access Scheme (Yes, No, Not currently applicable (NCA)) | Expected Entry into Baseline Commissioning (Date if known or Not currently applicable (NCA)) |
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| | | | | Yes | Yes (but notice of removal served) | No | | | | | | |
| ELR1 | **Elranatamab** | For the treatment of relapsed or refractory myeloma in adult patients who have relapsed or are refractory to their last anti-myeloma regimen AND have received at least 3 prior lines of systemic therapies which must have included at least one proteasome inhibitor, at least one immune-modulatory agent and at least one anti-CD38 antibody where the following criteria have been met: | 1. This application for elranatamab monotherapy is both being made by and the first cycle of systemic anti-cancer therapy with elranatamab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient is an adult with a proven diagnosis of multiple myeloma.<br><br>Note: patients with amyloidosis or POEMS syndrome are not eligible for elranatamab.<br>3. The prescribing clinician understands that elranatamab is not funded for amyloidosis patients (with the exception of patients who have a proven diagnosis of myeloma with an associated diagnosis of amyloidosis) and that NHS funding for elranatamab is only for the relapsed or refractory myeloma indication in the specific indication recommended by NICE.<br><br>Please tick the relevant box below:<br>- this patient does not have a diagnosis of primary amyloidosis or<br>- this patient has a proven diagnosis of progressive myeloma with an associated diagnosis of amyloidosis and elranatamab is being prescribed for the myeloma (and all other treatment criteria on this form apply)<br>4. This patient has been previously treated with at least one proteasome inhibitor.<br><br>Please confirm how many different proteasome inhibitors have been used to treat this patient's myeloma:<br>- 1 proteasome inhibitor or<br>- 2 or more different proteasome inhibitors<br>5. This patient has been previously treated with at least one immunomodulatory agent.<br><br>Please confirm how many different immunomodulatory agents have been used to treat this patient's myeloma:<br>- 1 immunomodulatory agent or<br>- 2 or more different immunomodulatory agents<br>6. This patient has previously received a pomalidomide-containing regimen or not.<br><br>- No, the patient has not been treated with a pomalidomide-containing regimen or<br>- Yes, the patient has been treated with a pomalidomide-containing regimen<br>7. This patient has been previously been treated with at least one anti-CD38 antibody.<br><br>Please confirm how many anti-CD38 antibodies have been used to treat this patient's myeloma:<br>- 1 anti-CD38 antibody or<br>- 2 or more different anti-CD38 antibodies<br>8. The patient has received at least 3 lines of treatment according to the definition below and also set out below which line of myeloma therapy elranatamab is being used for.<br><br>I confirm that numbering of a line of treatment is in accordance with the International Myeloma Workshop Consensus recommendations for the uniform reporting of clinical trials (http://doi.org/10.1182/blood-2010-10-299487). A line of therapy is defined as one or more cycles of a planned treatment program. This may consist of one or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner (ie induction chemotherapy/chemotherapies when followed by stem cell transplantation is considered to be 1 line of therapy). A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse or toxicity, the exception to this being the need to attain a sufficient response for stem cell transplantation to proceed. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease.<br><br>Please record at which line of therapy elranatamab is being given:<br>- as 4th line of therapy or<br>- as 5th line of therapy or<br>- as 6th line or subsequent line of therapy<br>9. The patient has **NOT** been previously treated with any bispecific antibody targeting both BCMA and CD3.<br><br>Note: patients previously treated with any bispecific antibody targeting BCMA and CD3 (e.g. teclistamab) are not eligible for elranatamab<br>10. Whether the patient has ever been treated with a CAR-T therapy such as idecabtagene vicleucel or ciltacabtagene autoleucel.<br><br>Please confirm which situation applies to this patient:<br>- this patient has not been previously treated with a CAR-T therapy or<br>- this patient has received prior CAR-T treatment (eg idecabtagene, ciltacabtagne).<br>**(continued on next page)** | From 21-Jun-24 | | | No | n/a | Yes | Agreed | Yes | nca |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | Indication | Criteria for use | Available to new patients | | | Transition Drug (Old CDF) Indication (Yes or No) | Transition Funding agreed by manufacturer (Agreed, Rejected, Pending) | Eligible for Interim Funding (Yes, No, Not currently applicable (NCA)) | Interim Funding agreed by manufacturer (Agreed, Rejected, Pending, Not currently applicable (NCA)) | CDF Managed Access Scheme (Yes, No, Not currently applicable (NCA)) | Expected Entry into Baseline Commissioning (Date if known or Not currently applicable (NCA)) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Yes | Yes (but notice of removal served) | No | | | | | | |
| ELR1 | **Elranatamab** | For the treatment of relapsed or refractory myeloma in adult patients who have relapsed or are refractory to their last anti-myeloma regimen AND have received at least 3 prior lines of systemic therapies which must have included at least one proteasome inhibitor, at least one immune-modulatory agent and at least one anti-CD38 antibody where the following criteria have been met: | 11. Whether the patient has been treated with a BCMA-targeted antibody drug conjugate (such as belantamab mafodotin).<br><br>Please confirm which situation applies to this patient:<br>- this patient has not been previously treated with a BCMA-targeted antibody drug conjugate or<br>- this patient has been treated with a BCMA-targeted antibody drug conjugate.<br><br>12. The patient has had progressive disease during or following the last received line of systemic anti-myeloma therapy.<br><br>13. The patient has an ECOG performance status of 0 or 1 or 2:<br><br>Please record below the ECOG performance status<br>- PS 0 or<br>- PS 1 or<br>- PS 2<br><br>14. The patient will be treated with elranatamab until loss of clinical benefit or the occurrence of excessive toxicity or the withdrawal of patient consent, whichever is the sooner.<br><br>Note: once elranatamab is electively stopped (ie for reasons other than temporary toxicity), it cannot be re-started.<br><br>15. When a treatment break of more than 6 weeks beyond the expected weekly, 2-weekly, or 4-weekly, cycle length (as appropriate) is needed, a treatment break approval form will be completed to restart treatment.<br><br>16. Elranatamab will be otherwise used as set out in its Summary of Product Characteristics (SPC). | From 21-Jun-24 | | | No | n/a | Yes | Agreed | Yes | nca |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | Indication | Criteria for use | Available to new patients | | | Transition Drug (Old CDF) Indication (Yes or No) | Transition Funding agreed by manufacturer (Agreed, Rejected, Pending) | Eligible for Interim Funding (Yes, No, Not currently applicable (NCA)) | Interim Funding agreed by manufacturer (Agreed, Rejected, Pending, Not currently applicable (NCA)) | CDF Managed Access Scheme (Yes, No, Not currently applicable (NCA)) | Expected Entry into Baseline Commissioning (Date if known or Not currently applicable (NCA)) |
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| | | | | Yes | Yes (but notice of removal served) | No | | | | | | |
| ENT1b_v1.0 | **Entrectinib** | Entrectinib response assessment and treatment continuation form in the treatment of patients who have solid tumours that have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion AND disease which is locally advanced or metastatic or for which surgical resection is likely to result in severe morbidity AND who have no satisfactory treatment options where the following criteria have been met:<br><br>This form ENT1b requires information as to the RECIST response assessment made at 10 weeks after initiation of entrectinib. In addition, form ENT1b must be completed for continuation of funding for entrectinib to occur beyond the initial 12 week period otherwise the dispensing Trust will not receive reimbursement for further entrectinib.<br><br>Note: the ENT1a form is for the initiation of treatment with entrectinib and is only for funding of the first TWELVE weeks of entrectinib treatment. A PET/CT/MR scan of index assessable/measureable disease and the brain must be done prior to commencing entrectinib and repeated at 10 weeks after the start of treatment (if not indicated before 10 weeks on account of assessing risk of disease progression). | 1. This record of response assessment and (as appropriate) this application to continue treatment with entrectinib is being made by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy. | From 25-Jun-20 | | | No | n/a | Yes | Agreed | Yes | n/a |
| | | | 2. A RECIST radiological assessment has been made of the index disease at 10 weeks after the start of entrectinib and I have indicated the outcome of this RECIST assessment below. This response assessment should exclude metastatic disease in the brain/CNS.<br>If the patient has a primary brain tumour, please use this box to indicate the response status.<br>- complete response of disease or<br>- partial response of disease or<br>- stable disease or<br>- progressive disease<br>Please indicate below how many weeks there were between date of start of entrectinib and date of above PET/CT/MR response assessment scan: | | | | | | | | | |
| | | | 3. A RECIST radiological assessment has been made of any metastatic intra-cerebral or CNS disease at 10 weeks after the start of entrectinib and I have indicated the outcome of this RECIST assessment below. If the patient does not have any metastatic intra-cerebral disease, please indicate in the relevant box. If the patient has a primary cerebral tumour, the response assessment should be done in the above box.<br>- the patient does not have any metastatic intracerebral disease or<br>- the patient has a primary brain tumour and the response assessment has been done in the above section of this form or<br>- complete response in the brain/CNS or<br>- partial response in the brain/CNS or<br>- stable disease in the brain/CNS or<br>- progressive disease in the brain/CNS<br>Please indicate how many weeks there were between date of start of entrectinib and date of above CT/MR response assessment scan: | | | | | | | | | |
| | | | 4. The current clinical decision to continue or discontinue treatment with entrectinib is as set out below:<br>- the patient will continue treatment with entrectinib ie has so far achieved a complete response or a partial response or has stable disease or<br>- the patient will discontinue or has discontinued treatment with entrectinib on account of progressive disease or<br>- the patient will discontinue or has discontinued treatment with entrectinib on account of unacceptable toxicity<br>Note: RECIST-documented partial/complete responses to entrectinib in some patients can occur later than at 10 weeks and so a patient with stable disease would be expected to continue entrectinib as long as the clinical assessment is that the patient is/may be benefitting. This 10 week treatment period is to assess the early response rate. | | | | | | | | | |
| | | | 5. No treatment breaks of more than 6 weeks beyond the expected cycle length are allowed (to allow any toxicity of current therapy to settle or intercurrent comorbidities to improve). | | | | | | | | | |
| | | | 6. Entrectinib is to be otherwise used as set out in its Summary of Product Characteristics | | | | | | | | | |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | Indication | Criteria for use | Available to new patients | | | Transition Drug (Old CDF) Indication (Yes or No) | Transition Funding agreed by manufacturer (Agreed, Rejected, Pending) | Eligible for Interim Funding (Yes, No, Not currently applicable (NCA)) | Interim Funding agreed by manufacturer (Agreed, Rejected, Pending, Not currently applicable (NCA)) | CDF Managed Access Scheme (Yes, No, Not currently applicable (NCA)) | Expected Entry into Baseline Commissioning (Date if known or Not currently applicable (NCA)) |
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| | | | | Yes | Yes (but notice of removal served) | No | | | | | | |
| EPC2 | **Epcoritamab** monotherapy | Epcoritamab monotherapy for previously treated adult patients with relapsed/refractory follicular lymphoma who have received 2 or more lines of systemic therapy where the following criteria have been met: | 1. This application is being made by, and the first cycle of systemic anti-cancer therapy with epcoritamab monotherapy will be prescribed by, a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a histologically confirmed diagnosis of follicular lymphoma that has either relapsed following, or is refractory to, 2 or more lines of standard routinely commissioned systemic therapies.<br>3. Below are the number of lines of systemic therapy that the patient has received for the treatment of follicular lymphoma.<br><br>***Note: patients who have had only 1 line of systemic therapy are not eligible for treatment with epcoritamab.***<br><br>**Please record the number of lines of previous systemic therapy below:**<br>2 previous lines OR<br>3 previous lines OR<br>4 or more previous lines<br>4. The patient has not been previously treated with epcoritamab unless epcoritamab monotherapy needs to be continued following an Abbvie compassionate access scheme and all other treatment criteria on this form are fulfilled.<br><br>Please record in the box below which of the following applies to this patient:<br>- no previous treatment with epcoritamab OR<br>- continuation of previous treatment with epcoritamab monotherapy via an Abbvie compassionate access scheme and all other criteria on this form are fulfilled<br>5. The patient has not received any previous treatment with a bispecific antibody targeting both CD20 and CD3 other than epcoritamab as specified above in criterion 4.<br>6. The patient has an ECOG performance status score of 0 or 1 or 2.<br>7. Epcoritamab is to be administered as monotherapy and not in combination with any other systemic therapies for lymphoma.<br>8. Treatment with epcoritamab monotherapy will be stopped at whichever of the following events occurs first: disease progression, unacceptable toxicity or maximum 3 years of treatment regardless of response status at that time. Once epcoritamab is electively stopped (ie not for reasons of toxicity), it cannot be re-started.<br><br>***Note: the NICE optimised recommendation requires that epcoritamab is stopped after a maximum of 3 years.***<br>9. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, a treatment break approval form will be completed to restart treatment.<br>10. Epcoritamab will otherwise be used as set out in its Summary of Product Characteristics. | From 23-Feb-26 | | | No | n/a | Yes | Agreed | No | 10-Apr-26 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | Indication | Criteria for use | Available to new patients | | | Transition Drug (Old CDF) Indication (Yes or No) | Transition Funding agreed by manufacturer (Agreed, Rejected, Pending) | Eligible for Interim Funding (Yes, No, Not currently applicable (NCA)) | Interim Funding agreed by manufacturer (Agreed, Rejected, Pending, Not currently applicable (NCA)) | CDF Managed Access Scheme (Yes, No, Not currently applicable (NCA)) | Expected Entry into Baseline Commissioning (Date if known or Not currently applicable (NCA)) |
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| | | | | Yes | Yes (but notice of removal served) | No | | | | | | |
| ISA1_v1.1 | **Isatuximab** in combination with pomalidomide and dexamethasone | Isatuximab in combination with pomalidomide and dexamethasone for the 4th line treatment of adult patients with relapsed/refractory multiple myeloma where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with isatuximab in combination with pomalidomide and dexamethasone will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a diagnosis of multiple myeloma.<br>3. The patient has received 3 and only 3 prior lines of treatment and that the numbering of a line of treatment is in accordance with the International Myeloma Workshop Consensus recommendations for the uniform reporting of clinical trials (http://doi.org/10.1182/blood-2010-10-299487). A line of therapy is defined as one or more cycles of a planned treatment program. This may consist of one or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner (e.g. induction chemotherapy/chemotherapies if followed by stem cell transplantation then maintenance is considered to be 1 line of therapy). A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse or toxicity. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease.<br>Note: the use of isatuximab in combination with pomalidomide and dexamethasone in patients who have had 3 and only 3 prior lines of therapy was primarily chosen by Sanofi in its NICE submission and thus provides the basis for NICE's specific recommendation to the CDF. The use of isatuximab in combination with pomalidomide and dexamethasone in the 1-prior, 2-prior, 4-prior and >4-prior patient groups is not permitted within the CDF.<br>4. The prescribing clinician understands that isatuximab in combination with pomalidomide and dexamethasone in this indication is not funded for amyloidosis patients (with the exception of patients who have a proven diagnosis of progressive myeloma and also have an associated diagnosis of amyloidosis) and that NHS funding for isatuximab in combination with pomalidomide and dexamethasone is only for the specific multiple myeloma indication recommended by NICE to the Cancer Drugs Fund.<br>Please tick box below<br>-this patient does not have a diagnosis of amyloidosis<br>- this patient has a proven diagnosis of progressive myeloma and also an associated diagnosis of amyloidosis and isatuximab in combination with pomalidomide and dexamethasone is being prescribed for myeloma<br>Note: For amyloidosis patients requiring systemic therapies, NHS England does fund those treatments in routine commissioning for myeloma. As this isatuximab with pomalidomide and dexamethasone combination is in the CDF and not routine commissioning, NHS England does not fund isatuximab in combination with pomalidomide and dexamethasone for patients with amyloidosis unless they have a proven diagnosis of progressive myeloma and also an associated diagnosis of amyloidosis.<br>5. The patient has received prior treatment with at least 2 consecutive cycles of lenalidomide given alone or in combination and has failed treatment with lenalidomide on account of disease progression, refractory disease or intolerance.<br>6. The patient has received prior treatment with at least 2 consecutive cycles of a proteasome inhibitor (e.g. bortezomib or carfilzomib or ixazomib) given alone or in combination and has failed treatment with a proteasome inhibitor on account of disease progression, refractory disease or intolerance.<br>7. This patient has responded to at least one previous line of treatment i.e. the patient does not have primary refractory myeloma.<br>8. The patient was refractory to the last line of therapy i.e. there was progression on or within 60 days of the end of the last line of active anti-myeloma systemic therapy.<br>9. The patient either has had no previous therapy with any anti-CD38 antibody (e.g. daratumumab) or if there has been previous treatment with an anti-CD38 antibody, then the patient has received isatuximab via the EAMS scheme or the Sanofi early access scheme or did not progress whilst still receiving an anti-CD38 therapy other than isatuximab or did not progress within 60 days of the last infusion of an anti-CD38 treatment other than isatuximab.<br>Please enter below as to which scenario applies to this patient:<br>- no previous treatment with any anti-CD38 antibody or<br>- previous treatment with isatuximab in the EAMS scheme or the Sanofi early access scheme<br>- previous treatment with an anti-CD38 antibody other than isatuximab and the patient did not progress whilst still receiving the anti-CD38 therapy or did not progress within 60 days of the last infusion of the anti-CD38 treatment.<br>Note: isatuximab is not permitted in patients who fulfil the definition of refractoriness to daratumumab/anti-CD38 treatment.<br>10. The patient has not received any prior treatment with pomalidomide either as monotherapy or within combination therapy.<br>11. Isatuximab is only to be used in combination with pomalidomide and dexamethasone and not with any other active systemic agents for myeloma.<br>12. Isatuximab is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment, whichever is the sooner.<br>13. The patient has an ECOG performance status of 0 or 1 or 2.<br>14. A formal medical review as to how isatuximab in combination with pomalidomide and dexamethasone is being tolerated and whether treatment with isatuximab in combination with pomalidomide and dexamethasone should continue or not will be scheduled to occur at least by the end of the second month of treatment.<br>15. Where a treatment break of more than 6 weeks beyond the expected cycle length is needed, I will complete a treatment break approval form to restart treatment, including indicating as appropriate if the patient had an extended break because of COVID19.<br>16. Isatuximab and pomalidomide will otherwise be used as set out in their respective Summary of Product Characteristics (SPCs). | From 15-Oct-20 | | | No | n/a | Yes | Agreed | Yes | nca |

# National Cancer Drugs Fund (CDF) List

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| | | | | Yes | Yes (but notice of removal served) | No | | | | | | |
| LAR1a_v1.1 | **Larotrectinib** | For the treatment of adults and children who have solid tumours (including primary cerebral tumours) that have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion AND disease which is locally advanced or metastatic or for which surgical resection is likely to result in severe morbidity AND who have no satisfactory treatment options where the following criteria have been met:<br><br>This LAR1a form is for the initiation of treatment with larotrectinib and is only for funding of the first TWELVE weeks of larotrectinib treatment. PET/CT/MR scans of index assessable/measureable disease and also of the brain must be done prior to commencing larotrectinib and repeated at 10 weeks after the start of treatment (if not indicated before 10 weeks on account of assessing risk of disease progression). A RECIST response on the repeated assessment must be made. Form LAR1b which requires information as to this RECIST response assessment must then be completed for continuation of funding for larotrectinib beyond the initial 12-week period otherwise the dispensing Trust will not receive reimbursement for further larotrectinib. | 1. This application is made by and the first cycle of systemic anti-cancer therapy with larotrectinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. This patient has a proven histological diagnosis of a malignant solid tumour (ie a carcinoma or a sarcoma or melanoma or a brain or spinal cord tumour) and does NOT have a leukaemia or a lymphoma or myeloma.<br>Please state the site of origin of the patient's cancer (NB if sarcoma, please enter sarcoma; if unknown primary, please state as such) and its specific histological type (eg for breast cancer: ductal carcinoma, lobular carcinoma, secretory carcinoma etc; eg for lung cancer: squamous NSCLC, non-squamous NSCLC etc; eg for sarcoma: fibrosarcoma, osteosarcoma, gastrointestinal stromal tumour etc).<br>3. This patient has disease that is locally advanced or metastatic or would require surgical resection likely to result in severe morbidity.<br>Please enter the type of disease that is being treated:<br>- locally advanced disease for which systemic therapy has been indicated **or**<br>- metastatic disease **or**<br>- locally advanced disease for which surgical resection is likely to result in severe morbidity. Please state the type of surgical resection which would otherwise have been needed and resulted in severe morbidity.<br>4. This patient has no satisfactory systemic therapy options. A satisfactory systemic treatment option is defined as one which is funded by NHS England for the disease and indication in question. By ticking the 'yes' box on the Blueteq form, I confirm that the patient has already been treated with all the systemic therapy options funded by NHS England for the disease in question.<br>As part of the evidence that NICE and NHS England wish to see at the NICE re-appraisal of larotrectinib in NTRK gene fusion positive patients, data will be specifically analysed as to systemic therapies before and after larotrectinib in order to test whether larotrectinib has been used after all NHS-funded systemic therapies have been used. Please enter the number of lines of systemic therapy the patient has received for the locally advanced/metastatic indication:<br>- 1 line of systemic therapy for locally advanced/metastatic disease **or**<br>- 2 lines of systemic therapy for locally advanced/metastatic disease **or**<br>- 3 or more lines of systemic therapy for locally advanced/metastatic disease.<br>- Larotrectinib is being used as first line therapy for locally advanced/metastatic disease, as the patient has no satisfactory systemic therapy options, as described above.<br>5. This patient HAS a documented NTRK gene fusion in the tumour and this has been determined with appropriate nucleic acid-based assay(s). Please enter which NTRK gene is involved in the gene fusion:<br>- in NTRK1 **or**<br>- in NTRK2 **or**<br>- in NTRK3<br>Please also enter the NTRK gene fusion partner and enter the name of the testing laboratory which performed the NTRK gene fusion test.<br>6. The patient has not previously received treatment with any tropomyosin receptor tyrosine kinase (TRK) inhibitor.<br>7. Larotrectinib will be used as monotherapy.<br>8. The patient has an ECOG performance status (PS) of 0 or 1 or 2.<br>Note: a patient with a performance status of 3 or more is not eligible for larotrectinib.<br>9. A PET/CT/MR scan of index assessable/measureable disease has been done prior to commencing larotrectinib and that this will be repeated 10 weeks after the start of treatment (if not indicated before 10 weeks on account of assessing risk of disease progression).<br>10. The patient has had a recent CT or MR scan of the brain and either has no brain metastases or, if the patient has brain metastases, the patient is symptomatically stable prior to starting larotrectinib.<br>Please enter below as to whether the patient has radiological evidence of brain metastases and the patient's previous treatment for brain metastases:<br>- the patient does not have brain metastases **or**<br>- the patient does have brain metastases and has not received any cerebral surgery and/or radiotherapy and is symptomatically stable **or**<br>- the patient does have brain metastases and has received previous cerebral surgery and/or radiotherapy and is symptomatically stable.<br>Note: repeat imaging of the brain is required at week 10 after commencing larotrectinib.<br>11. Larotrectinib is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment or potentially curative surgery takes place.<br>12. The prescribing clinician is fully aware of the likely toxicities of larotrectinib as listed in its SPC.<br>13. A formal medical review as to whether treatment with larotrectinib should continue or not (on basis of being fit to continue treatment) will be scheduled to occur by the start of the second cycle (month) of treatment.<br>14. No treatment breaks of more than 6 weeks beyond the expected cycle length are allowed (to allow any toxicity of current therapy to settle or intercurrent comorbidities to improve).<br>15. Larotrectinib is to be otherwise used as set out in its Summary of Product Characteristics | | From 21-Apr-20 | | No | nca | Yes | Agreed | Yes | nca |

# National Cancer Drugs Fund (CDF) List

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Yes | Yes (but notice of removal served) | No | | | | | | |
| LAR1b_v1.0 | **Larotrectinib** | Larotrectinib response assessment and treatment continuation form in the treatment of patients who have solid tumours that have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion AND disease which is locally advanced or metastatic or for which surgical resection is likely to result in severe morbidity AND who have no satisfactory treatment options<br><br>This form LAR1b requires information as to the RECIST response assessment made at 10 weeks after initiation of larotrectinib. In addition, form LAR1b must be completed for continuation of funding for larotrectinib to occur beyond the initial 12 week period otherwise the dispensing Trust will not receive reimbursement for further larotrectinib.<br><br>Note: the LAR1a form is for the initiation of treatment with larotrectinib and is only for funding of the first TWELVE weeks of larotrectinib treatment. A PET/CT/MR scan of index assessable/measureable disease and the brain must be done prior to commencing larotrectinib and repeated at 10 weeks after the start of treatment (if not indicated before 10 weeks on account of assessing risk of disease progression). | 1. This record of response assessment and (as appropriate) this application to continue treatment with larotrectinib is being made by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br><br>2. A RECIST radiological assessment has been made of the index disease at 10 weeks after the start of larotrectinib and I have indicated the outcome of this RECIST assessment below. This response assessment should exclude metastatic disease in the brain/CNS.<br>If the patient has a primary brain tumour, please use this box to indicate the response status.<br>- complete response of disease **or**<br>- partial response of disease **or**<br>- stable disease **or**<br>- progressive disease<br>Please also indicate how many weeks there were between date of start of larotrectinib and date of above PET/CT/MR response assessment scan.<br><br>3. A RECIST radiological assessment has been made of any metastatic intra-cerebral or CNS disease at 10 weeks after the start of larotrectinib and I have indicated the outcome of this RECIST assessment below. If the patient does not have any metastatic intra-cerebral disease, please indicate in the relevant box. If the patient has a primary cerebral tumour, the response assessment should be done in the above box.<br>- the patient does not have any metastatic intracerebral disease **or**<br>- the patient has a primary brain tumour and the response assessment has been done in the above section of this form **or**<br>- complete response in the brain/CNS **or**<br>- partial response in the brain/CNS **or**<br>- stable disease in the brain/CNS **or**<br>- progressive disease in the brain/CNS<br>Please indicate how many weeks there were between date of start of larotrectinib and date of above CT/MR response assessment scan.<br><br>4. The current clinical decision to continue or discontinue treatment with larotrectinib is as set out below:<br>- the patient will continue treatment with larotrectinib ie has so far achieved a complete response or a partial response or has stable disease **or**<br>- the patient will discontinue or has discontinued treatment with larotrectinib on account of progressive disease **or**<br>- the patient will discontinue or has discontinued treatment with larotrectinib on account of unacceptable toxicity<br>Note: RECIST-documented responses to larotrectinib in some patients can occur later than at 10 weeks and so a patient with stable disease would be expected to continue larotrectinib as long as the clinical assessment is that the patient is/may be benefitting. This 10 week treatment period is to assess the early response rate.<br><br>5. No treatment breaks of more than 6 weeks beyond the expected cycle length are allowed (to allow any toxicity of current therapy to settle or intercurrent comorbidities to improve).<br><br>6. Larotrectinib is to be otherwise used as set out in its Summary of Product Characteristics | From 21-Apr-20 | | | No | nca | Yes | Agreed | Yes | nca |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | Indication | Criteria for use | Available to new patients | | | Transition Drug (Old CDF) Indication (Yes or No) | Transition Funding agreed by manufacturer (Agreed, Rejected, Pending) | Eligible for Interim Funding (Yes, No, Not currently applicable (NCA)) | Interim Funding agreed by manufacturer (Agreed, Rejected, Pending, Not currently applicable (NCA)) | CDF Managed Access Scheme (Yes, No, Not currently applicable (NCA)) | Expected Entry into Baseline Commissioning (Date if known or Not currently applicable (NCA)) |
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| | | | | Yes | Yes (but notice of removal served) | No | | | | | | |
| SEL4 | **Selpercatinib** | Selpercatinib as monotherapy for the 1st line treatment of adult patients with previously untreated advanced non-small cell lung cancer (NSCLC) exhibiting a RET gene fusion where the following criteria have been met: | 1. This application for selpercatinib is being made by and the first cycle of systemic anti-cancer therapy with selpercatinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has locally advanced or metastatic non-small cell lung cancer.<br>3. The patient has a histologically or cytologically confirmed diagnosis of non-small cell lung cancer.<br>Please mark which type of NSCLC applies to this patient:<br>- non-squamous NSCLC **or**<br>- squamous NSCLC<br>4. This patient's NSCLC has been shown to harbour a RET gene fusion as determined on a tumour tissue biopsy or a plasma specimen (liquid biopsy) or both.<br>Please mark which type of specimen was positive for the presence of the RET gene fusion:<br>- tumour tissue biopsy **or**<br>- plasma specimen (liquid biopsy) **or**<br>- both tumour tissue and plasma specimen<br>5. This patient's RET fusion partner has been determined to be in one of the categories as set out below:<br>- KIF5B<br>- CCDC6<br>- NCOA4<br>- RELCH<br>- another fusion partner<br>- unknown fusion partner<br>6. This patient has NOT received any prior systemic therapy for this locally advanced or metastatic NSCLC indication.<br>7. The patient has not previously received selpercatinib or any other TKI which targets the RET receptor unless the patient has received selpercatinib via a company early access scheme **and** the patient meets all the other criteria listed here.<br>8. The patient has an ECOG performance status (PS) score of 0 or 1 or 2.<br>Please mark below the performance status of the patient:<br>- ECOG PS 0<br>- ECOG PS 1<br>- ECOG PS 2<br>9. The patient either has no known brain/CNS metastases or if the patient does have brain/CNS metastases then the patient is symptomatically stable before starting selpercatinib.<br>Please mark below the status with respect to known brain/CNS metastases:<br>- the patient does not have any known brain/CNS metastases<br>- the patient has had brain/CNS metastases treated before with surgery/radiotherapy and is currently symptomatically stable<br>- the patient has brain secondaries which have not been treated with surgery/radiotherapy and is currently symptomatically stable<br>10. Selpercatinib will be used as monotherapy.<br>11. The prescribing clinician is aware of the following issues as regards the administration of selpercatinib as detailed in its Summary of Product Characteristics (SPC):<br>- the dosage of selpercatinib is according to body weight<br>- selpercatinib has reduced solubility at a higher pH and hence precautions are necessary with the co-administration of proton pump inhibitors or H2 antagonists<br>- selpercatinib has clinically important interactions with CYP3A inhibitors or CYP3A inducers<br>12. The patient will be treated until loss of clinical benefit or excessive toxicity or patient choice to discontinue treatment whichever is the sooner.<br>13. A formal medical review as to how selpercatinib is being tolerated and whether treatment with selpercatinib should continue or not will be scheduled to occur at least by the start of the third 4-weekly cycle of treatment.<br>14. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, the prescribing clinician will complete a treatment break approval form to restart treatment.<br>15. Selpercatinib is to be otherwise used as set out in its Summary of Product Characteristics (SPC). | From 22-Jun-23 | | | No | n/a | Yes | Agreed | Yes | nca |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | Indication | Criteria for use | Available to new patients | | | Transition Drug (Old CDF) Indication (Yes or No) | Transition Funding agreed by manufacturer (Agreed, Rejected, Pending) | Eligible for Interim Funding (Yes, No, Not currently applicable (NCA)) | Interim Funding agreed by manufacturer (Agreed, Rejected, Pending, Not currently applicable (NCA)) | CDF Managed Access Scheme (Yes, No, Not currently applicable (NCA)) | Expected Entry into Baseline Commissioning (Date if known or Not currently applicable (NCA)) |
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| | | | | Yes | Yes (but notice of removal served) | No | | | | | | |
| PEMB34 | **Pembrolizumab** | Pembrolizumab for resectable, locally advanced, head and neck squamous cell carcinoma in adults whose tumours express PD-L1 with a combined positive score of 1 or more where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy will be prescribed by a consultant, or internally accredited oncology specialty trainee, specifically trained and assessed in the use of systemic anti-cancer therapy.<br>2. The patient has a documented, histologically confirmed, diagnosis of **non-metastatic**, resectable, squamous cell carcinoma of the **oral cavity, larynx, hypopharynx, or oropharynx**.<br>3. The patient has disease which is staged as below<br>Stage III or IVA according to the AJCC 8th Edition:<br>o **HPV-positive oropharyngeal**: Must be Stage III (T4, N0-2, M0). **OR**<br>o **HPV-negative oropharyngeal, larynx, hypopharynx, or oral cavity**: Stage III or IVA.<br>4. PD-L1 testing with an approved and validated test to determine the Combined Positive Score (CPS) has been done prior to this application and the CPS is >=1% and the result is set out below.<br>Please document the actual CPS below<br>CPS: _____<br>Note: pembrolizumab is not funded in this indication for patients with tumours without a documented >=1% positive PD-L1 CPS score.<br>5. The patient has an ECOG performance status of 0 or 1.<br>6. The patient is treatment naïve, in terms of systemic anti-cancer therapy (SACT) for this diagnosis of head and neck cancer.<br>7. The patient will receive 2 x 200mg doses of **intravenous** pembrolizumab in the neoadjuvant setting, given three weeks apart.<br><br>Note – Subcutaneous pembrolizumab is not yet licensed for this specific indication in the UK.<br>8. Post surgery, the patient will receive intravenous pembrolizumab at a dose of either 200mg every three weeks, or 400mg every six weeks, alongside adjuvant radiotherapy. Please specify below whether the patient will also receive concomitant cisplatin.<br>- The patient WILL receive concomitant cisplatin<br>- The patient WILL NOT receive concomitant cisplatin<br>9. Adjuvant pembrolizumab will continue until unacceptable toxicity, withdrawal of patient consent, progression of disease, or the completion of 15 x 3 weekly (or the equivalent number of 6 weekly) doses in the adjuvant phase, whichever of these events occurs first.<br>10. Where a treatment break of more than 12 weeks beyond the expected 3 or 6-weekly cycle length is needed, a treatment break approval form will be completeed to restart treatment, which MUST be approved before treatment with pembrolizumab is recommenced.<br>11. Pembrolizumab will otherwise be used as set out in its Summary of Product Characteristics (SPC). | From 24-Mar-26 | | | No | n/a | Yes | Agreed | No | tbc |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | Indication | Criteria for use | Available to new patients | | | Transition Drug (Old CDF) Indication (Yes or No) | Transition Funding agreed by manufacturer (Agreed, Rejected, Pending) | Eligible for Interim Funding (Yes, No, Not currently applicable (NCA)) | Interim Funding agreed by manufacturer (Agreed, Rejected, Pending, Not currently applicable (NCA)) | CDF Managed Access Scheme (Yes, No, Not currently applicable (NCA)) | Expected Entry into Baseline Commissioning (Date if known or Not currently applicable (NCA)) |
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| | | | | Yes | Yes (but notice of removal served) | No | | | | | | |
| SOT1_v1.2 | **Sotorasib** | Sotorasib as monotherapy for the treatment of adult patients with advanced non-small cell lung cancer (NSCLC) exhibiting a KRAS G12C mutation and who have been previously treated with at least 1 prior systemic therapy for advanced NSCLC where the following criteria have been met: | 1. This application for sotorasib is being made by and the first cycle of systemic anti-cancer therapy with sotorasib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has locally advanced or metastatic non-small cell lung cancer.<br>3. The patient has a histologically or cytologically confirmed diagnosis of non-small cell lung cancer that has been shown to exhibit a KRAS G12C mutation using a validated assay and determined on a tumour tissue biopsy or a plasma specimen (liquid biopsy) or both.<br>Please mark which type of specimen was positive for the presence of the KRAS G12C mutation:<br>- tumour tissue biopsy only **or**<br>- plasma specimen (liquid biopsy) only **or**<br>- both tumour tissue and plasma specimen<br>4. The prescribing clinician has completed below the status of the patient's lung cancer with respect to other actionable mutations in NSCLC if known to be present and that all commissioned targeted therapies have been fully explored for this mutation.<br>Please mark below whether another actionable mutation is known to be present and confirm that all relevant commissioned targeted treatment options have been explored for this mutation:<br>- no other actionable mutation is known to be present or<br>- the NSCLC has an EGFR mutation and all appropriate targeted therapies have been explored or<br>- the NSCLC has an ALK gene rearrangement and all appropriate targeted therapies have been explored or<br>- the NSCLC has a ROS1 gene rearrangement and all appropriate targeted therapies have been explored or<br>- the NSCLC has a BRAF mutation and appropriate targeted therapies have been explored if available or<br>- the NSCLC has a MET exon 14 skipping alteration and appropriate targeted therapies have been explored if available<br>- the NSCLC has a RET gene fusion rearrangement and appropriate targeted therapies have been explored if available<br>5. This patient has been treated with platinum doublet chemotherapy and/or PD-1/PD-L1 targeted immunotherapy.<br>Please mark which of these 5 scenarios below applies to this patient (for the purposes of this criterion, any targeted therapies for actionable mutations do not count as lines of therapy):<br>- the only treatment that the patient has received is platinum-based cytotoxic chemotherapy for locally advanced or metastatic NSCLC with or without 2nd line cytotoxic chemotherapy **or**<br>- the only treatment that the patient has received is 1st line immunotherapy monotherapy for locally advanced or metastatic NSCLC **or**<br>- the patient has received 1st line combination treatment of platinum doublet chemotherapy and immunotherapy for locally advanced or metastatic NSCLC with or without 2nd line cytotoxic chemotherapy **or**<br>- the patient has received 1st line immunotherapy monotherapy for locally advanced or metastatic NSCLC followed by 2nd line cytotoxic chemotherapy with or without 3rd line cytotoxic chemotherapy **or**<br>- the patient has received 1st line platinum-based cytotoxic chemotherapy for locally advanced or metastatic NSCLC followed by 2nd line immunotherapy with or without further cytotoxic chemotherapy<br>6. The patient has not been previously treated with a drug specifically targeting the KRAS G12C mutation unless the patient has received sotorasib via a company early access scheme and the patient meets all the other treatment criteria on this form.<br>Please mark below which scenario applies to this patient:<br>- the patient has not been previously treated with a drug specifically targeting the KRAS G12C mutation **or**<br>- the patient has received sotorasib via a company early access scheme and the patient meets all the other treatment criteria on this form<br>7. The patient has an ECOG performance status (PS) score of 0 or 1.<br>8. The patient either has no known brain metastases or if the patient does have brain metastases then the patient is symptomatically stable before staring sotorasib.<br>Please mark below the status with respect to known brain/CNS metastases:<br>- the patient has never had known brain/CNS metastases<br>- the patient has had brain/CNS metastases treated before with surgery/radiotherapy and is currently symptomatically stable<br>- the patient has brain secondaries which have not been treated with surgery/radiotherapy and is currently symptomatically stable<br>9. Sotorasib will be used as monotherapy.<br>10. The prescribing clinician is aware of the side-effects of sotorasib including the risks of developing interstitial lung disease and hepatotoxicity.<br>11. The prescribing clinician is aware that proton pump inhibitors and H2 receptor antagonists reduce absorption of sotorasib and should not be co-administered with sotorasib but if an acid-reducing agent cannot be avoided, sotorasib should be administered ≥4hrs before and ≥10hrs after a local antacid.<br>12. The patient will be treated until loss of clinical benefit or excessive toxicity or patient choice to discontinue treatment whichever is the sooner.<br>13. A formal medical review as to how sotorasib is being tolerated will be done before the start of the second month of treatment and the next review to determine whether treatment with sotorasib should continue or not will be scheduled to occur at least by the end of the second month of therapy.<br>14. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment, including as appropriate if the patient has had an extended break on account of Covid-19.<br>15. Sotorasib will be otherwise used as set out in its Summary of Product Characteristics (SPC). | From 03-Mar-22 | | | No | n/a | Yes | Agreed | Yes | nca |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | Indication | Criteria for use | Available to new patients | | | Transition Drug (Old CDF) Indication (Yes or No) | Transition Funding agreed by manufacturer (Agreed, Rejected, Pending) | Eligible for Interim Funding (Yes, No, Not currently applicable (NCA)) | Interim Funding agreed by manufacturer (Agreed, Rejected, Pending, Not currently applicable (NCA)) | CDF Managed Access Scheme (Yes, No, Not currently applicable (NCA)) | Expected Entry into Baseline Commissioning (Date if known or Not currently applicable (NCA)) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Yes | Yes (but notice of removal served) | No | | | | | | |
| TRAD1_v1.1 | **Trastuzumab deruxtecan** | For treating over-expressed HER2 positive unresectable locally advanced or metastatic breast cancer in patients who have received 2 or more anti-HER2 therapies and who have received trastuzumab emtansine in the advanced/metastatic disease setting where the following criteria have been met: | 1. This application for trastuzumab deruxtecan for the treatment of unresectable locally advanced or metastatic breast cancer is being made by and the first cycle of trastuzumab deruxtecan will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has unresectable locally advanced or metastatic breast cancer.<br>3. The patient has histologically documented breast cancer which is **HER2 3+** by immunohistochemistry and/or has a **HER2 amplification ratio of ≥2.0** by in situ hybridisation.<br>4. If this patient received a HER2-targeted **neoadjuvant** regimen and if so its nature.<br>Please tick which option applies to this patient:<br>- the patient was not treated with a HER2-targeted neoadjuvant regimen<br>- the patient was treated with a HER2-targeted neoadjuvant regimen which contained both pertuzumab and trastuzumab<br>- the patient was treated with a HER2-targeted neoadjuvant regimen which contained trastuzumab as the sole HER2-targeted agent<br>5. If the patient received a HER2-targeted **adjuvant** regimen and if so its nature.<br>Please tick which option applies to this patient:<br>- the patient was not treated with a HER2-targeted adjuvant regimen<br>- the patient was treated with a HER2-targeted adjuvant regimen which contained both pertuzumab and trastuzumab<br>- the patient was treated with a HER2-targeted adjuvant regimen which contained trastuzumab as the sole HER2-targeted agent<br>- the patient was treated with a HER2-targeted adjuvant regimen which contained trastuzumab emtansine<br>6. If the patient received a HER2-targeted regimen for locally advanced/metastatic disease which included **both** pertuzumab and trastuzumab.<br>Please tick which option applies to this patient:<br>- the patient was not treated with a HER2-targeted regimen for locally advanced/metastatic disease which included both pertuzumab and trastuzumab<br>- the patient was treated with a HER2-targeted regimen for locally advanced/metastatic disease which included both pertuzumab and trastuzumab<br>7. If the patient received a HER2-containing regimen for locally advanced/metastatic disease which included trastuzumab as the sole HER2-targeted agent.<br>Please tick which option applies to this patient:<br>- the patient was not treated with a HER2-targeted regimen for locally advanced/metastatic disease which included trastuzumab as the sole HER2-targeted agent<br>- the patient was treated with a HER2-targeted regimen for locally advanced/metastatic disease which contained trastuzumab as the sole HER2-targeted agent<br>8. The patient has previously been treated with trastuzumab emtansine for advanced/metastatic disease and is now either resistant or refractory to trastuzumab emtansine or had to discontinue trastuzumab emtansine due to intolerance.<br>9. The patient has received two or more anti-HER2 therapies which must have included trastuzumab and trastuzumab emtansine.<br>Please tick below how many anti-HER2 therapies this patient has received in all clinical settings (neoadjuvant, adjuvant and locally advanced/metastatic indications; eg a treatment pathway of neoadjuvant pertuzumab plus trastuzumab regimen followed by adjuvant trastuzumab and then a 1st relapse treated with a pertuzumab plus trastuzumab regimen and a 2nd relapse treated with trastuzumab emtansine counts as 4 anti-HER2 therapies):<br>- 2 anti-HER2 therapies<br>- 3 anti-HER2 therapies<br>- 4 anti-HER2 therapies<br>- 5 or more anti-HER2 therapies<br>10. Prior to consideration of treatment with trastuzumab deruxtecan the patient has a baseline left ventricular ejection fraction (LVEF) of at least 50%.<br>11. The patient has an ECOG performance status of 0 or 1.<br>12. The status as to the presence of brain metastases/leptomeningeal spread and its symptomatic and treatment status:<br>- the patient has never had any known brain metastases or leptomeningeal spread<br>- the patient has active brain metastases/leptomeningeal spread and has not received any active treatment for this CNS spread<br>- the patient has been previously treated with CNS radiotherapy/stereotactic radiosurgery/intrathecal chemotherapy and the metastatic CNS disease is stable<br>- the patient has been previously treated with CNS radiotherapy/stereotactic radiosurgery/intrathecal chemotherapy and the metastatic CNS disease is progressing<br>13. The patient has had no prior treatment with trastuzumab deruxtecan unless it has been received as part of the Daiichi Sankyo early access scheme and the patient meets all the other criteria set out here.<br>14. Trastuzumab deruxtecan will be used as monotherapy and commencing at a dose of 5.4 mg/Kg administered every 3 weeks.<br>15. Trastuzumab deruxtecan will be given until disease progression or unacceptable toxicity or patient choice to stop treatment.<br>Note: trastuzumab deruxtecan is not to be used beyond first disease progression outside the CNS.<br>Note: it is advised that trastuzumab deruxtecan is not (at least initially) discontinued if disease progression is within the CNS alone.<br>16. The prescribing clinician is aware that cases of interstitial lung disease/pneumonitis have been reported with trastuzumab deruxtecan and fatal outcomes have been observed. The prescribing clinician also confirms that an appropriate imaging schedule is being used to detect early interstitial lung disease and will ensure that all patients are aware of the need to immediately report cough, dyspnoea, fever, and/or any new or worsening respiratory symptoms. In addition, the prescribing clinician confirms that if a diagnosis is made of interstitial lung disease/pneumonitis, management will include dose interruptions and modifications of trastuzumab deruxtecan as described in sections 4.2 and 4.4 of the drug's Summary of Product Characteristics (SmPC).<br>17. When a treatment break of more than 6 weeks beyond the expected 3-weekly cycle length is needed, I confirm that I will complete a treatment break approval form to restart treatment, including as appropriate if the patient had an extended break on account of Covid-19.<br>18. Trastuzumab deruxtecan will be otherwise used as set out in its Summary of Product Characteristics (SmPC). | From 20-Apr-21 | | | No | n/a | Yes | Agreed | Yes | nca |

# National Cancer Drugs Fund (CDF) List

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Yes | Yes (but notice of removal served) | No | | | | | | |
| TRAD2_v1.1 | **Trastuzumab deruxtecan** | For treating over-expressed HER2 positive unresectable locally advanced or metastatic breast cancer in patients who have received 1 or more anti-HER2 therapies and who are treatment-naïve for trastuzumab emtansine in the advanced/metastatic disease setting where the following criteria have been met: | 1. This application for trastuzumab deruxtecan for the treatment of unresectable locally advanced or metastatic breast cancer is being made by and the first cycle of trastuzumab deruxtecan will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has unresectable locally advanced or metastatic breast cancer.<br>3. The patient has histologically documented breast cancer which is **HER2 3+** by immunohistochemistry and/or has a **HER2 amplification ratio of ≥2.0** by in situ hybridisation.<br>4. If this patient received a HER2-targeted **neoadjuvant** regimen and if so its nature.<br>Please tick which option applies to this patient:<br>- the patient was not treated with a HER2-targeted neoadjuvant regimen or<br>- the patient was treated with a HER2-targeted neoadjuvant regimen which contained both pertuzumab and trastuzumab or<br>- the patient was treated with a HER2-targeted neoadjuvant regimen which contained trastuzumab as the sole HER2-targeted agent<br>5. If the patient received a HER2-targeted **adjuvant** regimen and if so its nature.<br>Please tick which option applies to this patient:<br>- the patient was not treated with a HER2-targeted adjuvant regimen or<br>- the patient was treated with a HER2-targeted adjuvant regimen which contained both pertuzumab and trastuzumab or<br>- the patient was treated with a HER2-targeted adjuvant regimen which contained trastuzumab as the sole HER2-targeted agent or<br>- the patient was treated with a HER2-targeted adjuvant regimen which contained trastuzumab emtansine<br>6. If the patient received a HER2-targeted regimen for locally advanced/metastatic disease which included **both** pertuzumab and trastuzumab.<br>Please tick which option applies to this patient:<br>- the patient was not treated with a HER2-targeted regimen for locally advanced/metastatic disease which included both pertuzumab and trastuzumab or<br>- the patient was treated with a HER2-targeted regimen for locally advanced/metastatic disease which included both pertuzumab and trastuzumab<br>7. If the patient received a HER2-containing regimen for locally advanced/metastatic disease which included trastuzumab as the sole HER2-targeted agent.<br>Please tick which option applies to this patient:<br>- the patient was not treated with a HER2-targeted regimen for locally advanced/metastatic disease which included trastuzumab as the sole HER2-targeted agent or<br>- the patient was treated with a HER2-targeted regimen for locally advanced/metastatic disease which contained trastuzumab as the sole HER2-targeted agent<br>8. The patient has been treated with a prior regimen which contained at least trastuzumab and a taxane OR trastuzumab and capecitabine for advanced /metastatic breast cancer **or** developed disease recurrence during or within 6 months of completing an adjuvant or neoadjuvant treatment regimen which contained at least trastuzumab and a taxane or adjuvant treatment with trastuzumab emtansine.<br>Please tick which option applies to this patient:<br>- the patient was treated with a prior regimen for advanced/metastatic breast cancer which contained at least trastuzumab and a taxane OR trastuzumab and capecitabine<br>- the patient has not yet been treated for advanced/metastatic breast cancer and has relapsed during or within 6 months of completing adjuvant or neoadjuvant therapy containing at least trastuzumab and a taxane<br>- the patient has not yet been treated for advanced/metastatic breast cancer and has relapsed during or within 6 months of completing adjuvant therapy with trastuzumab emtansine<br>9. The patient has received one or more anti-HER2 therapies which must have included trastuzumab.<br>Please tick below how many anti-HER2 therapies this patient has received in all clinical settings (neoadjuvant, adjuvant and locally advanced/metastatic indications; e.g a treatment pathway of neoadjuvant pertuzumab plus trastuzumab regimen followed by adjuvant trastuzumab and then a 1st relapse treated with a pertuzumab plus trastuzumab regimen counts as 3 separate anti-HER2 therapies):<br>- 1 anti-HER2 therapy<br>- 2 anti-HER2 therapies<br>- 3 anti-HER2 therapies<br>- 4 anti-HER2 therapies<br>10. The patient has **NOT** been previously treated with trastuzumab emtansine for advanced/metastatic breast cancer.<br>11. Prior to consideration of treatment with trastuzumab deruxtecan the patient has a baseline left ventricular ejection fraction (LVEF) of at least 50%.<br>12. The patient has an ECOG performance status of 0 or 1.<br>13. The status as to the presence of brain metastases/leptomeningeal spread and its symptomatic and treatment status:<br>- the patient has never had any known brain metastases or leptomeningeal spread<br>- the patient has active brain metastases/leptomeningeal spread and has not received any active treatment for this CNS spread<br>- the patient has been previously treated with CNS radiotherapy/stereotactic radiosurgery/intrathecal chemotherapy and the metastatic CNS disease is stable<br>- the patient has been previously treated with CNS radiotherapy/stereotactic radiosurgery/intrathecal chemotherapy and the metastatic CNS disease is progressing<br>14. The patient has had no prior treatment with trastuzumab deruxtecan unless it has been received as part of the Daiichi Sankyo early access scheme and the patient meets all the other criteria set out here.<br>15. Trastuzumab deruxtecan will be used as monotherapy and will commence at a dose of 5.4 mg/Kg administered every 3 weeks.<br>16. Trastuzumab deruxtecan will be given until disease progression or unacceptable toxicity or patient choice to stop treatment.<br>Note: trastuzumab deruxtecan is not to be used beyond first disease progression outside the CNS.<br>Note: it is advised that trastuzumab deruxtecan is not (at least initially) discontinued if disease progression is within the CNS alone.<br>17. The prescribing clinician is aware that cases of interstitial lung disease/pneumonitis have been reported with trastuzumab deruxtecan and fatal outcomes have been observed. The prescribing clinician also confirms that an appropriate imaging schedule is being used to detect early interstitial lung disease and will ensure that all patients are aware of the need to immediately report cough, dyspnoea, fever, and/or any new or worsening respiratory symptoms. In addition, the prescribing clinician confirms that if a diagnosis is made of interstitial lung disease/pneumonitis, management will include dose interruptions and modifications of trastuzumab deruxtecan as described in sections 4.2 and 4.4 of the drug's Summary of Product Characteristics (SmPC).<br>18. When a treatment break of more than 6 weeks beyond the expected 3-weekly cycle length is needed, the prescribing clinician confirm that the prescribing clinician will complete a treatment break approval form to restart treatment.<br>19. Trastuzumab deruxtecan will be otherwise used as set out in its Summary of Product Characteristics (SmPC). | From 20-Dec-22 | | | No | n/a | Yes | Agreed | Yes | nca |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | Indication | Criteria for use | Available to new patients | | | Transition Drug (Old CDF) Indication (Yes or No) | Transition Funding agreed by manufacturer (Agreed, Rejected, Pending) | Eligible for Interim Funding (Yes, No, Not currently applicable (NCA)) | Interim Funding agreed by manufacturer (Agreed, Rejected, Pending, Not currently applicable (NCA)) | CDF Managed Access Scheme (Yes, No, Not currently applicable (NCA)) | Expected Entry into Baseline Commissioning (Date if known or Not currently applicable (NCA)) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Yes | Yes (but notice of removal served) | No | | | | | | |
| VEN7_v1.1 | **Venetoclax** in combination with obinutuzumab | For the treatment of patients with previously untreated chronic lymphatic leukaemia in whom chemotherapy with the combinations of either FCR or BR would otherwise have been SUITABLE where the following criteria have been met: | 1. This application for venetoclax plus obinutuzumab is being made by and the first cycle of this systemic anti-cancer therapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has been diagnosed with chronic lymphatic leukaemia (CLL) or small lymphocytic lymphoma (SLL).<br>3. The patient has been tested for 17p deletion and the result is negative.<br>4. The patient has been tested for TP53 mutation and the result is negative.<br>5. The patient has symptomatic disease which requires systemic therapy.<br>6. The patient has not received any previous systemic therapy for CLL/SLL.<br>7. The patient has a performance status of 0 or 1 or 2.<br>8. In the absence of this venetoclax plus obinutuzumab treatment option, the patient would otherwise have been treated with the combination of fludarabine, cyclophosphamide and rituximab (FCR) or the combination of bendamustine and rituximab (BR).<br>Please record below as to which combination you would have treated the patient with in the absence of this CDF access to venetoclax plus obinutuzumab:<br>- FCR **or**<br>- BR<br>9. Venetoclax will be given in combination with obinutuzumab and that the venetoclax dose titration schedule will only be commenced after the patient has received the first 3 doses of obinutuzumab in cycle 1 (on days 1±2, 8 and 15) i.e. the venetoclax dose titration schedule is planned to commence on cycle 1 day 22 and be completed on cycle 2 day 28.<br>10. All of the following for the prevention and treatment of tumour lysis syndrome:<br>- that the patient has been prospectively assessed for the risk of the development of tumour lysis syndrome (TLS) with venetoclax<br>- that appropriate TLS risk mitigation strategies have been put in place as outlined in the updated venetoclax Summary of Product Characteristics<br>- that there is a robust system in place for measuring appropriate blood chemistries both at the specified timings of blood chemistries according to TLS risk status and at the venetoclax dose levels described in Section 4.2 Table 3 of the Summary of Product Characteristics. See https://www.medicines.org.uk/emc/medicine/32650 or https://products.mhra.gov.uk/substance/?substance=VENETOCLAX<br>- that there is a robust system in place for ensuring the rapid review in real time of these blood chemistry results by a senior clinician with experience in the management of TLS<br>- that there is a robust system in place for the withholding of the next days dose of each scheduled dose escalation until the blood chemistry results have been confirmed as being satisfactory by a senior clinician<br>11. The patient has been assessed specifically for potential drug interactions with venetoclax.<br>12. The maximum treatment duration of venetoclax in this indication is until day 28 of the 12th cycle of treatment i.e. the maximum duration of venetoclax treatment is for 45 weeks, consisting of 1 week from cycle 1 day 22 followed by 11 cycles of 4-weekly cycles of venetoclax in cycles 2-12.<br>13. The treatment duration of obinutuzumab is for a maximum of 6 cycles of obinutuzumab.<br>14. Venetoclax is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment or for the maximum treatment duration of 12 cycles (as measured above), whichever of these events is the sooner.<br>15. A formal medical review as to whether treatment with venetoclax in combination with obinutuzumab should continue or not will be scheduled to occur at least by the end of the first 8 weeks of treatment.<br>16. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment, including as appropriate if the patient had an extended break on account of Covid-19.<br>17. Venetoclax and obinutuzumab will be otherwise used as set out in their respective Summary of Product Characteristics (SPCs). | From 10-Nov-20 | | | No | n/a | Yes | Agreed | Yes | nca |

# National Cancer Drugs Fund (CDF) List

## B. NICE approved and baseline funded drugs/indications from 1st April 2016

**Notes:** If no Blueteq approval criteria are set this is because this was not considered necessary at the time of approval. However Blueteq registration will be required for all cancer drugs moving from the CDF to baseline as a result of positive final NICE guidance from 7th December 2016.

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| ABEM1_v1.2 | **Abemaciclib** (in combination with an aromatase inhibitor) | The treatment of previously untreated, hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer where the following criteria have been met: | 1. This application for abemaciclib in combination with an aromatase inhibitor is made by and the first cycle of systemic anti-cancer therapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy<br>2. The patient has histologically or cytologically documented oestrogen receptor positive and her-2 negative breast cancer<br>3. The patient has had no prior treatment with a CDK 4/6 inhibitor unless either palbociclib or ribociclib has had to be stopped within 6 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression or a CDK 4/6 inhibitor has been previously received as adjuvant therapy and treatment was completed without disease progression at least **12** months prior to the first diagnosis of recurrent or metastatic disease.<br><br>Please mark below which one of these 4 scenarios applies to this patient:<br>- no prior treatment with a CDK 4/6 inhibitor or<br>- previous treatment with the 1st line CDK4/6 inhibitor palbociclib but treatment has had to be stopped within 6 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of progressive disease or<br>- previous treatment with the 1st line CDK4/6 inhibitor ribociclib but treatment has had to be stopped within 6 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of progressive disease or<br>- previously received a CDK4/6 inhibitor with endocrine therapy in the adjuvant setting for high risk early breast cancer either via NHS England commissioned care or via a clinical trial and treatment with the CDK 4/6 inhibitor was completed without disease progression at least 12 months prior to the first diagnosis of recurrent or metastatic disease<br>4. The patient has metastatic breast cancer or locally advanced breast cancer which is not amenable to curative treatment<br>5. The patient is male or is female and if female is either post-menopausal or if pre- or peri-menopausal has undergone ovarian ablation or suppression with LHRH agonist treatment<br>6. The patient has had no previous hormone therapy for locally advanced or metastatic disease i.e. is hormone therapy naïve for locally advanced/metastatic breast cancer.<br><br>**Note:** previous hormone therapy with anastrazole or letrozole whether as adjuvant therapy or as neoadjuvant treatment is allowed as long as the patient has had a disease-free interval of 12 months or more since completing treatment with neoadjuvant or adjuvant anastrazole or letrozole.<br>7. Abemaciclib will only be given in combination with an aromatase inhibitor<br>8. The patient has an ECOG performance status of 0 or 1 or 2<br>9. Treatment will continue until there is progressive disease or excessive toxicity or until the patient chooses to discontinue treatment, whichever is the sooner<br>10. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, the prescribing clinician will complete a treatment break approval form to restart treatment.<br>11. Abemaciclib will be otherwise used as set out in its Summary of Product Characteristics (SPC) | No | TA563 | 27-Feb-19 | 28-May-19 |
| ABEM2 | **Abemaciclib** (in combination with fulvestrant) | The treatment of hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer where the following criteria have been met: | 1. This application for abemaciclib in combination with fulvestrant is being made by and the first cycle of abemaciclib plus fulvestrant will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has histologically or cytologically documented oestrogen receptor positive and HER-2 negative breast cancer<br>3. The patient has metastatic breast cancer or locally advanced breast cancer which is not amenable to curative treatment<br>4. The patient is male or is female and if female is either post-menopausal or if pre- or peri-menopausal has undergone ovarian ablation or suppression with LHRH agonist treatment<br>5. The patient has an ECOG performance status of 0 or 1 or 2<br>6. The patient has received previous endocrine therapy according to one of the three populations as set out below as these are the only groups for which there was evidence submitted to NICE for the use of abemaciclib plus fulvestrant. Please record which population the patient falls into:<br>- has progressive disease whilst still receiving adjuvant or neoadjuvant endocrine therapy for early breast cancer with no subsequent endocrine therapy received following disease progression **or**<br>- has progressive disease within 12 or less months of completing adjuvant endocrine therapy for early breast cancer with no subsequent endocrine therapy received following disease progression **or**<br>- has progressive disease on 1st line endocrine therapy for advanced/metastatic breast cancer with no subsequent endocrine therapy received following disease progression<br>7. The patient has had no prior treatment with a CDK 4/6 inhibitor unless either palbociclib (in combination with fulvestrant) or ribociclib (in combination with fulvestrant) has had to be stopped within 6 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression or a CDK 4/6 inhibitor has been previously received as adjuvant therapy and treatment was completed without disease progression at least **12** months prior to the first diagnosis of recurrent or metastatic disease.<br><br>Please mark below which one of the 4 scenarios applies to this patient:<br>- no prior treatment with a CDK 4/6 inhibitor or<br>- previous treatment with the CDK4/6 inhibitor palbociclib in combination with fulvestrant but treatment has had to be stopped within 6 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of progressive disease or<br>- previous treatment with the CDK4/6 inhibitor ribociclib in combination with fulvestrant but treatment has had to be stopped within 6 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of progressive disease or<br>- previously received a CDK4/6 inhibitor with endocrine therapy in the adjuvant setting for high risk early breast cancer either via NHS England commissioned care or via a clinical trial and treatment with the CDK 4/6 inhibitor was completed without disease progression at least 12 months prior to the first diagnosis of recurrent or metastatic disease<br>8. The patient has had no prior treatment with fulvestrant<br>9. The patient has had no prior treatment with everolimus<br>10. Abemaciclib will only be given in combination with fulvestrant<br>11. Treatment will continue until there is progressive disease or excessive toxicity or until the patient chooses to discontinue treatment, whichever is the sooner<br>12. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, the prescribing clinician will complete a treatment break approval form to restart treatment.<br>13. Abemaciclib and fulvestrant will be otherwise used as set out in its Summary of Product Characteristics (SPC) | No | TA725 | 15-Sep-21 | 14-Dec-21 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| ABEM3 | **Abemaciclib** in combination with endocrine therapy | As adjuvant treatment for high-risk hormone receptor-positive and HER2-negative early breast cancer where the following criteria have been met: | 1. This application for abemaciclib in combination with endocrine therapy is being made by and the first cycle of abemaciclib plus endocrine therapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has early breast cancer.<br>3. The patient has histologically or cytologically documented hormone receptor-positive and HER-2 negative breast cancer.<br>4. The patient has high risk early breast cancer as defined by having **either** 4 or more positive axillary lymph nodes **or** 1-3 positive axillary lymph nodes and a primary tumour size of ≥5cm and/or histologically grade 3 disease.<br>Please mark in the box below which category applies to this patient:<br>- ≥4 positive axillary lymph nodes **or**<br>- 1-3 positive axillary lymph nodes and a primary tumour size ≥5cm **or**<br>- 1-3 positive axillary lymph nodes and histological grade 3 disease **or**<br>- 1-3 positive axillary lymph nodes and a primary tumour size ≥5cm and histological grade 3 disease<br>5. The patient has completed definitive locoregional therapy (surgery with or without radiotherapy).<br>6. The patient has completed any adjuvant or neoadjuvant chemotherapy.<br>Please mark in the box below the relevant treatment that the patient did or did not receive:<br>- the patient did not receive any adjuvant or neoadjuvant chemotherapy **or**<br>- the patient received adjuvant chemotherapy only **or**<br>- the patient received neoadjuvant chemotherapy<br>7. The patient has received no more than 12 weeks of adjuvant endocrine therapy after completion of the last non-endocrine therapy (surgery or chemotherapy or radiotherapy).<br>8. The patient is male or female and if female, pre- or peri-menopausal and having adjuvant aromatase inhibitor therapy that the patient has undergone ovarian ablation or suppression with LHRH agonist treatment.<br>Please mark in the box below which category applies to this patient:<br>- female on adjuvant tamoxifen or<br>- post-menopausal female on adjuvant aromatase inhibitor therapy or<br>- pre- or peri-menopausal female on adjuvant aromatase inhibitor therapy and LHRH agonist treatment/ovarian ablation or<br>- male<br>9. The patient has an ECOG performance status of 0 or 1.<br>10. Abemaciclib is being given in combination with standard endocrine therapy.<br>11. The patient has had no prior treatment with a CDK 4/6 inhibitor unless the patient has suffered unacceptable toxicity on adjuvant ribociclib plus an aromatase inhibitor without any evidence of disease progression on treatment and fulfils the involved nodal and other criteria in criterion 4 above and the patient is transferring to treatment with adjuvant abemaciclib plus endocrine therapy. The treatment plan should be for a maximum CDK4/6 inhibitor treatment duration of 2 calendar years in all (time on ribociclib plus that on abemaciclib).<br><br>Please mark in the box below which scenario applies to this patient:<br>- the patient has never received any prior therapy with any CDK4/6 inhibitor or<br>- the patient has suffered unacceptable toxicity on ribociclib plus an aromatase inhibitor without any evidence of disease progression and fulfils the involved nodal criteria in criterion 4 above and is transferring to treatment with adjuvant abemaciclib plus an endocrine therapy with a treatment plan for a maximum CDK4/6 inhibitor treatment duration of 2 calendar years in all.<br><br>**Note:** patients who have commenced adjuvant ribociclib for disease stages which do not comply with criterion 4 are NOT eligible to switch to abemaciclib.<br>12. Treatment with abemaciclib will continue until there is progressive disease or excessive toxicity or until the patient chooses to discontinue treatment or for a maximum of 2 calendar years, whichever is the sooner.<br>For patients switching from ribociclib, the maximum total CDK4/6 inhibitor treatment duration is for 2 calendar years (time on ribociclib plus time on abemaciclib).<br>13. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, the prescribing clinician will complete a treatment break approval form to restart treatment.<br>14. Abemaciclib will be otherwise used as set out in its Summary of Product Characteristics (SPC). | No | TA810 | 20-Jul-22 | 18-Oct-22 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| ABI1 | **Abiraterone** | Abiraterone for treating metastatic hormone-relapsed prostate cancer before chemotherapy is indicated | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with abiraterone will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. This patient either has a proven histological or cytological diagnosis of adenocarcinoma of the prostate or has presented with a clinical picture consistent with metastatic prostate cancer with both widespread bone metastases radiologically typical of prostate cancer and a serum PSA of ≥50 ng/mL.<br>3. This patient has hormone-relapsed (castrate-resistant) metastatic prostate cancer.<br>4. The patient has no or only mild symptoms after androgen deprivation therapy has failed.<br>5. Chemotherapy is not yet indicated.<br>6. One of the following applies to this patient as regards any previous use of 2nd generation receptor inhibitors (such as enzalutamide, darolutamide or apalutamide) or CYP17 enzyme inhibitors (such as abiraterone).<br>Please enter below as to which scenario applies to this patient:<br>- the patient has not previously received any treatment with enzalutamide or darolutamide or apalutamide or abiraterone or<br>- the patient has previously received enzalutamide for this same pre-chemotherapy indication in hormone-relapsed (castrate-resistant) prostate cancer but it was stopped due to dose-limiting toxicity and in the clear absence of disease progression<br>7. Abiraterone is to be given in combination with prednisolone<br>8. The patient has an ECOG performance status (PS) of 0 or 1 or 2.<br>9. Abiraterone is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment.<br>10. Where a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break approval form requesting a restart to treatment.<br>11. Abiraterone is to be otherwise used as set out in its Summary of Product Characteristics. | Yes | TA387 | 27-Apr-16 | 26-Jul-16 |
| ABI2 | **Abiraterone** | For the treatment of patients with hormone-relapsed (castrate-resistant) metastatic prostate cancer with disease progression during or following treatment with docetaxel-containing chemotherapy where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with abiraterone will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. This patient either has a proven histological or cytological diagnosis of adenocarcinoma of the prostate or has presented with a clinical picture consistent with metastatic prostate cancer with both widespread bone metastases radiologically typical of prostate cancer and a serum PSA of ≥50 ng/mL.<br>3. This patient has hormone-relapsed (castration-resistant) metastatic prostate cancer.<br>4. The patient has been treated with docetaxel-containing chemotherapy and has progressed during or following treatment.<br>5. One of the following applies to this patient as regards any previous use of 2nd generation receptor inhibitors (such as enzalutamide, darolutamide or apalutamide) or CYP17 enzyme inhibitors (such as abiraterone).<br>Please enter below as to which scenario applies to this patient:<br>- the patient has not previously received any treatment with enzalutamide or darolutamide or apalutamide or abiraterone or<br>- the patient has previously received enzalutamide for this same post-chemotherapy indication in hormone-relapsed (castrate-resistant) prostate cancer but it was stopped due to dose-limiting toxicity and in the clear absence of disease progression<br>6. Abiraterone is to be given in combination with prednisolone<br>7. The patient has an ECOG performance status (PS) of 0 or 1 or 2.<br>8. Abiraterone is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment.<br>9. Where a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break approval form requesting a restart to treatment.<br>10. Abiraterone is to be otherwise used as set out in its Summary of Product Characteristics. | Yes | TA259 | 27-Jun-12 | 25-Sep-12 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| ABI4 | **Abiraterone**<br>In combination with androgen deprivation therapy (ADT) | For the treatment of newly diagnosed high risk metastatic hormone-sensitive prostate cancer where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with abiraterone will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br><br>2. The patient either has a proven histological or cytological diagnosis of adenocarcinoma of the prostate or has presented with a clinical picture consistent with metastatic prostate cancer with both widespread bone metastases radiologically typical of prostate cancer and a serum PSA of at least 50 ng/mL.<br><br>3. The patient has newly diagnosed high risk metastatic prostate cancer that is hormone sensitive.<br><br>Note: patients who fulfil the clinical picture of metastatic prostate cancer as outlined in criterion 2 above but who do not have histological or cytological confirmation are considered to have high risk metastatic disease.<br><br>Note: an exception to this criterion is for the maintained supply of abiraterone following trial closure for patients who entered the STAMPEDE prostate cancer trial (ISRCTN78818544) and who continue to benefit from abiraterone treatment.<br><br>4. The patient has an ECOG performance status of either 0 or 1 or 2.<br><br>5. This patient has **either** not been treated with docetaxel and has currently received androgen deprivation therapy (ADT) for no longer than 3 months before starting an androgen receptor targeted agent or has been treated with docetaxel and has currently received ADT for no more than 9 months.<br>Please enter below as to which scenario applies to this patient<br>- the patient has not yet received any ADT for metastatic prostate cancer or<br>- the patient has not been treated with docetaxel and has currently received no more than 3 months of ADT before starting an androgen receptor targeted agent or<br>- the patient has been treated with docetaxel and has currently received no more than 9 months of ADT before starting an androgen receptor targeted agent<br><br>6. The prescribing clinician has assessed this patient's status as regards receiving upfront docetaxel and have concluded that the patient completed planned docetaxel therapy or discontinued docetaxel before completion of planned treatment duration or should not have been treated with docetaxel or chose not to be treated with docetaxel.<br><br>Please mark below which of these 4 clinical scenarios applies to this patient:<br>- the patient was treated with docetaxel and completed a planned treatment duration of 6 cycles of docetaxel<br>- the patient commenced docetaxel and discontinued docetaxel prior to completion of 6 cycles on account of excessive toxicity (i.e. the patient COULD NOT complete the planned treatment duration with docetaxel)<br>- the patient had significant comorbidities which precluded treatment with docetaxel (i.e. the patient SHOULD NOT be treated with docetaxel) and this has been fully discussed with the patient. It is recommended that validated systems of scoring clinical frailty are used as part of the oncology assessment as to explaining the benefits and risks of the treatment options of chemotherapy and abiraterone<br>- the patient is fit for chemotherapy with docetaxel and has chosen not to be treated with docetaxel. The patient has been fully consented regarding all of the following: the advantages and disadvantages of upfront docetaxel chemotherapy vs upfront abiraterone; that the use of upfront abiraterone would result in there being no further possible treatment with any androgen receptor targeted agents when the patient's disease progresses; and that the patient may not be fit enough to receive docetaxel when the patient's disease progresses. After such informed consent, I confirm that the patient has chosen to receive upfront abiraterone (i.e. the patient is fit for chemotherapy with docetaxel and has CHOSEN NOT to be treated with docetaxel)<br><br>Note: an exception to this criterion is for the maintained supply of abiraterone following trial closure for patients who entered the STAMPEDE prostate cancer trial (ISRCTN78818544) and who continue to benefit from abiraterone treatment.<br><br>7. The patient has not previously received any androgen receptor targeted agent unless the patient has received enzalutamide or apalutamide or darolutamide for newly diagnosed metastatic hormone-sensitive prostate cancer which had to be stopped because of dose-limiting toxicity in the clear absence of disease progression and the patient meets all the other criteria listed here or the patient has progressive disease following treatment with 2 years of ADT plus abiraterone with or without enzalutamide for high risk non-metastatic disease as part of the STAMPEDE trial (ISRCTN78818544) and did not progress whilst on such treatment and the patient meets all the other criteria listed on this form or the patient has high risk hormone sensitive prostate cancer treated with abiraterone as part of the STAMPEDE trial and has not progressed whilst on such treatment and the patient meets all the other criteria listed on this form.<br><br>Please mark below which of these 4 clinical scenarios applies to this patient:<br>- the patient has not previously received any androgen receptor targeted agent<br>- the patient commenced enzalutamide/apalutamide/darolutamide which had to be stopped because of dose-limiting toxicity in the clear absence of disease progression and the patient meets all the other criteria listed here.<br>- the patient was treated with 2 years of ADT plus abiraterone with or without enzalutamide for high risk non-metastatic disease as part of the STAMPEDE trial and did not progress whilst on such treatment and the patients meets all the other criteria listed here<br>- the patient has high risk hormone sensitive prostate cancer treated with abiraterone as part of the STAMPEDE trial and has not progressed whilst on such treatment and the patient meets all the other criteria listed on this form<br><br>8. Abiraterone plus prednisolone is being given in combination with ADT.<br><br>9. Abiraterone is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment.<br><br>10. Where a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment, which MUST be approved before treatment is recommenced.<br><br>11. Abiraterone is to be otherwise used as set out in its Summary of Product Characteristics. | No | with reference to NHSE Urgent Interim Commissioning Policy Proposition 2424 | 13-Dec-24 | 13-Dec-24 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| ABI5 | **Abiraterone acetate** | For the treatment of high-risk, hormone sensitive, non-metastatic prostate cancer where the following criteria have been met: | 1. This application is being made by and that abiraterone acetate will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br><br>2. The patient has newly diagnosed high-risk, hormone sensitive prostate cancer or relapsing prostate cancer with high-risk features planned for standard of care treatment with radiotherapy (unless contraindicated). NOTE – patients who have already commenced treatment with abiraterone in this indication, funded locally, or using self-funding can transfer to NHSE commissioned drug **as long as all other criteria on this form are met.**<br><br>3. The patient meets the following eligibility criteria:<br>•WHO performance status 0-2<br>**AND**<br>•Non-metastatic (M0)<br>**AND EITHER**<br>•Pelvic node positive (N1)<br>**OR**<br>•In **NEWLY DIAGNOSED** high-risk prostate cancer<br>•Node negative (N0) with at least **two** of:<br>otumour stage T3 or T4<br>oGleason score 8-10<br>oProstate specific antigen (PSA) ≥ 40 nanograms/ml<br><br>•In **RELAPSING** prostate cancer with high-risk features<br>•Node negative (N0) with **one** of either<br>oA PSA of equal to or greater than 4 nanograms/ml with a doubling time of <6 months<br>oA PSA of greater than or equal to 20 nanograms/ml<br><br>4. The patient is aged 18 years or over.<br><br>5. The patient does not meet **any** of the following exclusion criteria:<br><br>• patients with contraindications to abiraterone acetate, as outlined in the summary of product characteristics (SmPC)<br>• patients with confirmed clinically significant cardiovascular disease<br><br>6. The patient has been discussed at an appropriate multidisciplinary team (MDT) meeting prior to starting treatment (for patients who are transferring from alternative funding streams, as in criteria 2, a further MDT discussion is NOT required).<br><br>7. The patient has been started on androgen deprivation therapy (ADT) prior to starting abiraterone acetate, and that ADT has been given for a MAXIMUM of three months before abiraterone is commenced.<br><br>8. The patient will receive the recommended dose of abiraterone acetate as suggested in the NHS England Clinical Commissioning Policy.<br><br>9. The stopping / exit criteria have been explained and agreed with the patient able to receive abiraterone until whichever of the following events occur<br><br>• a serious adverse event or intolerance related to treatment **OR**<br>• evidence of disease progression **OR**<br>• withdrawal of patient consent **OR**<br>• a treatment duration of TWO years is reached, at which point abiraterone **must be stopped**<br><br>10. Trust policy regarding off-label treatments has been followed as abiraterone is not licensed for this indication.<br><br>11. Abiraterone acetate will be otherwise used as set out in its Summary of Product Characteristics (SPC). | No | NHS Policy - URN 2312 | N/A | 16-Jan-26 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| ACA1_v1.2 | **Acalabrutinib monotherapy** | For the treatment of patients with previously untreated chronic lymphatic leukaemia which has a 17p deletion or TP53 mutation where the following criteria have been met: | 1. This application for acalabrutinib is being made by and the first cycle of this systemic anti-cancer therapy with acalabrutinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has been diagnosed with chronic lymphatic leukaemia (CLL) or small lymphocytic lymphoma (SLL).<br>3. The patient has been tested for 17p deletion and for TP53 mutation and the results are positive for 17p deletion or TP53 mutation or both.<br>Please indicate the result of these tests below:<br>- positive for 17p deletion and negative for TP53 mutation **or**<br>- negative for 17 deletion and positive for TP53 mutation **or**<br>- positive for both 17p deletion and TP53 mutation.<br>4. The patient has symptomatic disease which requires systemic therapy.<br>5. The patient has not received any previous systemic therapy for CLL/SLL unless 1st line acalabrutinib was previously commenced via an AstraZeneca early access scheme or 1st line ibrutinib has had to be stopped as a consequence of dose-limiting toxicity and in the clear absence of disease progression.<br>Please mark which of the 3 scenarios below applies to this patient:<br>- the patient has not received any systemic therapy for CLL/SLL i.e. is completely treatment-naive or<br>- the patient previously commenced 1st line acalabrutinib via an AstraZeneca early access scheme and all other treatment criteria on this form are fulfilled or<br>- the patient previously commenced 1st line zanubrutinib and the zanubrutinib has had to be stopped solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression<br>- the patient previously commenced 1st line ibrutinib and the ibrutinib has had to be stopped solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression<br>6. The patient has an ECOG performance status of 0 or 1 or 2.<br>7. Use of acalabrutinib in this indication will be as **monotherapy.**<br><br>Note: AstraZeneca did not submit evidence to NICE for consideration of acalabrutinib in combination with an anti-CD20 monoclonal antibody in this indication.<br>8. The prescribing clinician is aware that whereas the bioavailability of acalabrutinib CAPSULES is reduced by co-administration of an antacid or a proton pump inhibitor, acalabrutinib TABLETS can be safely co-administered with gastric acid reducing agents such as proton pump inhibitors, H2-receptor antagonists and antacids (see acalabrutinib's Summary of Product Characteristics).<br><br>Note: this distinction between acalabrutinib capsules and tablets is also important as stocks of acalabrutinib capsules will no longer be available from mid November 2023; existing stocks of acalabrutinib capsules should be used as soon as possible. Acalabrutinib tablets are currently available.<br>9. Acalabrutinib is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment, whichever is the sooner.<br>10. A formal medical review as to whether treatment with acalabrutinib should continue or not will be scheduled to occur at least by the end of the first 8 weeks of treatment.<br>11. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, a treatment break approval form will be completed to restart treatment.<br>12. Acalabrutinib will be otherwise used as set out in its Summary of Product Characteristics (SPC). | No | TA689 | 21-Apr-21 | 20-Jul-21 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| ACA2_v1.4 | **Acalabrutinib monotherapy** | For the treatment of patients with previously treated chronic lymphatic leukaemia where the following criteria have been met: | 1. This application for acalabrutinib is being made by and the first cycle of this systemic anti-cancer therapy with acalabrutinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has been previously diagnosed with chronic lymphatic leukaemia (CLL) or small lymphocytic lymphoma (SLL).<br>3. The patient has been tested for 17p deletion and for TP53 mutation and the results are as shown below:<br>negative for both 17p deletion and TP53 mutation<br>- positive for 17p deletion and negative for TP53 mutation **or**<br>- negative for 17p deletion and positive for TP53 mutation **or**<br>- positive for both 17p deletion and TP53 mutation<br>4. The patient has symptomatic disease which requires systemic therapy.<br>5. The patient has been previously treated with systemic therapy for CLL/SLL.<br>6. The patient is treatment naïve to a Bruton's kinase inhibitor or the patient has been previously commenced on zanubrutinib or ibrutinib monotherapy for previously treated CLL/SLL and the zanbrutinib or ibrutinib has had to be discontinued solely because of dose-limiting toxicity and in the clear absence of disease progression or the patient has previously been treated with the 1st line combination of ibrutinib plus venetoclax and was still in response on completion of treatment but has since relapsed and this application will be the first use of a BTK inhibitor since the 1st line combination of ibrutinib plus venetoclax.<br>Please mark which of the 4 scenarios below applies to this patient:<br>- the patient has not received any previous therapy for CLL/SLL with a Bruton's kinase inhibitor **or**<br>- the patient previously commenced zanubrutinib for relapsed/refractory CLL/SLL and zanubrutinib has had to be stopped solely because of dose-limiting toxicity and in the clear absence of disease progression **or**<br>- the patient previously commenced ibrutinib for relapsed/refractory CLL/SLL and ibrutinib has had to be stopped solely because of dose-limiting toxicity **and** in the clear absence of disease progression **or**<br>- the patient has previously been treated with the 1st line combination of ibrutinib plus venetoclax and was still in response on completion of treatment but has since relapsed and this application will be the first use of a BTK inhibitor since the 1st line combination of ibrutinib plus venetoclax<br>7. The patient has an ECOG performance status of 0 or 1 or 2.<br>8. Use of acalabrutinib in this indication will be as **monotherapy**.<br><br>Note: AstraZeneca did not submit evidence to NICE for consideration of acalabrutinib in combination with an anti-CD20 monoclonal antibody in this indication.<br>9. The prescribing clinician is aware that whereas the bioavailability of acalabrutinib CAPSULES is reduced by co-administration of an antacid or a proton pump inhibitor, acalabrutinib TABLETS can be safely co-administered with gastric acid reducing agents such as proton pump inhibitors, H2-receptor antagonists and antacids (see acalabrutinib's Summary of Product Characteristics).<br><br>Note: this distinction between acalabrutinib capsules and tablets is also important as stocks of acalabrutinib capsules will no longer be available from mid November 2023; existing stocks of acalabrutinib capsules should be used as soon as possible. Acalabrutinib tablets are currently available.<br>10. Acalabrutinib is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment, whichever is the sooner.<br><br>Note: Patients entered into the NIHR STATIC trial (NIHR ref: 52879) may be randomised to receive intermittent treatment as part of the trial protocol<br>11. A formal medical review as to whether treatment with acalabrutinib should continue or not will be scheduled to occur at least by the end of the first 8 weeks of treatment.<br>12. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, a treatment break approval form will be completed to restart treatment.<br>13. Acalabrutinib will be otherwise used as set out in its Summary of Product Characteristics (SPC). | No | TA689 | 21-Apr-21 | 20-Jul-21 |
| ACA3_v1.3 | **Acalabrutinib monotherapy** | For the treatment of patients with previously untreated chronic lymphatic leukaemia which does not have a 17p deletion or a TP53 mutation and in whom chemotherapy with FCR or BR is unsuitable where the following criteria have been met: | 1. This application for acalabrutinib is being made by and the first cycle of this systemic anti-cancer therapy with acalabrutinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has been diagnosed with chronic lymphatic leukaemia (CLL) or small lymphocytic lymphoma (SLL).<br>3. The patient has been tested for 17p deletion and the result is negative.<br>4. The patient has been tested for TP53 mutation and the result is negative.<br>5. The patient has symptomatic disease which requires systemic therapy.<br>6. In the absence of this acalabrutinib treatment option, the patient would otherwise have been considered as UNSUITABLE for treatment with the combination of fludarabine, cyclophosphamide and rituximab (FCR) or the combination of bendamustine and rituximab (BR).<br>Note: AstraZeneca did not make a submission to NICE for the assessment of clinical and cost effectiveness of 1st line acalabrutinib in patients suitable for chemotherapy and hence NICE was unable to make a recommendation for this patient population.<br>7. The patient has not received any previous systemic therapy for CLL/SLL unless 1st line acalabrutinib was previously commenced via an AstraZeneca early access scheme or the patient commenced 1st line zanubrutinib and the zanubrutinib has had to be stopped solely because of dose-limiting toxicity and in the clear absence of disease progression.<br>Please mark which of the 3 scenarios below applies to this patient:<br>- the patient has not received any systemic therapy for CLL/SLL i.e. is completely treatment-naive or<br>- the patient previously commenced 1st line acalabrutinib via an AstraZeneca early access scheme and all other treatment criteria on this form are fulfilled<br>- the patient previously commenced 1st line zanubrutinib and the zanubrutinib has had to be stopped solely because of dose-limiting toxicity and in the clear absence of disease progression<br>8. The patient has an ECOG performance status of 0 or 1 or 2.<br>9. Use of acalabrutinib in this indication will be as **monotherapy**.<br>Note: AstraZeneca did not submit evidence to NICE for consideration of acalabrutinib in combination with an anti-CD20 monoclonal antibody in this indication.<br>10. The prescribing clinician is aware that whereas the bioavailability of acalabrutinib CAPSULES is reduced by co-administration of an antacid or a proton pump inhibitor, acalabrutinib TABLETS can be safely co-administered with gastric acid reducing agents such as proton pump inhibitors, H2-receptor antagonists and antacids (see acalabrutinib's Summary of Product Characteristics).<br><br>Note: this distinction between acalabrutinib capsules and tablets is also important as stocks of acalabrutinib capsules will no longer be available from mid November 2023; existing stocks of acalabrutinib capsules should be used as soon as possible. Acalabrutinib tablets are currently available.<br>11. Acalabrutinib is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment, whichever is the sooner.<br>12. A formal medical review as to whether treatment with acalabrutinib should continue or not will be scheduled to occur at least by the end of the first 8 weeks of treatment.<br>13. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, a treatment break approval form will be completed to restart treatment.<br>14. Acalabrutinib will be otherwise used as set out in its Summary of Product Characteristics (SPC). | No | TA689 | 21-Apr-21 | 20-Jul-21 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| ALE1_v1.5 | **Alectinib monotherapy** | For anaplastic lymphoma kinase-positive advanced non-small cell lung cancer previously untreated with an ALK inhibitor where the following criteria are met: | 1. This application for alectinib is being made by and the first cycle of systemic anti-cancer therapy with alectinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has locally advanced or metastatic non-small cell lung cancer.<br>3. The patient has histological or cytological evidence of NSCLC that carries an anaplastic lymphoma kinase (ALK) rearrangement based on a validated test **OR** there is documented agreement by the lung MDT that the radiological appearances are in keeping with locally advanced or metastatic NSCLC **AND** there is an informative circulating free DNA test result confirming the presence of an activating anaplastic lymphoma kinase (ALK) rearrangement.<br>Please mark below on which basis the diagnosis of ALK positive NSCLC has been made in this patient:<br>- Histological or cytological evidence.<br>- Documented agreement by the lung MDT that the radiological appearances are in keeping with locally advanced or metastatic NSCLC and there is an informative circulating free DNA test result confirming the presence of an activating anaplastic lymphoma kinase (ALK) rearrangement<br>4. patient has not previously received any ALK inhibitor for the advanced NSCLC indication unless 1st line treatment with lorlatinib, brigatinib, ceritinib or crizotinib has had to be stopped within 6 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression or the patient was treated with adjuvant alectinib and had disease progression more than 6 months after completing treatment with adjuvant alectinib.<br>Please mark below which of the five scenarios applies to this patient:<br>- the patient has never previously received an ALK inhibitor **or**<br>- the patient has previously received **lorlatinib** as 1st line ALK-targeted therapy and this has had to be stopped within **6** months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression **or**<br>- the patient has previously received **brigatinib** as 1st line ALK-targeted therapy and this has had to be stopped within **6** months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression **or**<br>- the patient has previously received **crizotinib or ceritinib** as 1st line ALK-targeted therapy and this has had to be stopped within **6** months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression **or**<br>- the patient was previously treated with adjuvant alectinib and had disease progression more than 6 months after completing treatment with adjuvant alectinib<br>5. The patient is treatment-naïve to 1st line cytotoxic chemotherapy-containing systemic treatment for this locally advanced or metastatic NSCLC indication.<br><br>Note: the only previous cytotoxic treatment allowed for patients to be treated with 1st line alectinib is adjuvant or neoadjuvant chemotherapy or chemotherapy given concurrently with radiotherapy.<br>6. The patient has an ECOG performance status of 0 or 1 or 2.<br>7. The patient either has no known brain metastases or if the patient has brain metastases, the patient is symptomatically stable prior to starting alectinib.<br>8. The patient will be treated until loss of clinical benefit or excessive toxicity or patient choice to discontinue treatment, whichever is the sooner<br>9. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, the prescribing clinician will complete a treatment break approval form to restart treatment.<br>10. The prescribing clinician is aware that<br>a) none of brigatinib or ceritinib or crizotinib are to be used following disease progression on alectinib as there is no current clear evidence to support treatment with any of these agents after disease progression on alectinib<br>and<br>b) after disease progression on alectinib, the only subsequent ALK inhibitor commissioned by NHS England as next line therapy is lorlatinib.<br>and<br>c) after disease progression during treatment with adjuvant alectinib or within 6 months of completion of treatment with adjuvant alectinib, re-treatment with alectinib is not commissioned.<br>11. Alectinib will otherwise be used as set out in its Summary of Product Characteristics (SPC). | No | TA536 | 08-Aug-18 | 07-Sep-18 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| ALE2 | **Alectinib** | Alectinib monotherapy for adjuvant treatment in adults after complete tumour resection in patients with UICC/AJCC 8th TNM edition stage IIA or IIB or IIIA or N2 only IIIB non-small cell lung cancer whose tumours have an ALK gene rearrangement where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with adjuvant alectinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy. | No | TA1014 | 13-Nov-24 | 11-Feb-25 |
| | | | 2. The patient has a histologically documented non-small cell lung cancer (NSCLC). | | | | |
| | | | 3. The patient has undergone a complete resection of the NSCLC with all surgical margins negative for tumour. | | | | |
| | | | 4. The pathological stage determined on this patient's surgical NSCLC specimen was a stage IIA or IIB or IIIA or N2 only IIIB tumour according to the UICC/AJCC TNM 8th edition.<br><br>Please mark below which stage applies to this patient:<br>- stage IIA disease (T2b N0)<br>- stage IIB disease (T1a N1 or T1b N1 or T1c N1 or T2a N1 or T2b N1 or T3 N0)<br>- stage IIIA disease (T1a N2 or T1b N2 or T1c N2 or T2a N2 or T2b N2 or T3 N1 or T4 N0 or T4 N1)<br>- N2 only stage IIIB disease (T3 N2 or T4 N2) | | | | |
| | | | 5. The patient's NSCLC has been documented **on the tumour specimen** (biopsy or surgical specimen) as exhibiting an anaplastic lymphoma kinase (ALK) gene arrangement. | | | | |
| | | | 6. The patient did **not** receive any pre-operative systemic therapy (cytotoxic chemotherapy, immunotherapy, ALK-targeted tyrosine kinase inhibitors) for the NSCLC. | | | | |
| | | | 7. The patient did not receive any pre-operative or post-operative radiation therapy for the NSCLC. | | | | |
| | | | 8. No more than 12 weeks have elapsed since surgery | | | | |
| | | | 9. The patient has had no prior treatment with an ALK-targeted drug. | | | | |
| | | | 10. The patient has an ECOG performance status (PS) of 0 or 1. | | | | |
| | | | 11. The patient does not have brain metastases on CT or MR imaging of the brain done either before surgery or prior to this application. | | | | |
| | | | 12. Alectinib will be administered as monotherapy. | | | | |
| | | | 13. The patient will be treated with alectinib for whichever is the sooner of: disease progression or unacceptable toxicity or withdrawal of patient consent or **for a total treatment duration of 2 calendar years.** | | | | |
| | | | 14. A formal medical review as to how alectinib is being tolerated and whether treatment with alectinib should continue or not will be scheduled to occur at least by the end of the second 4-weekly cycle of treatment. | | | | |
| | | | 15. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, the prescribing clinician will complete a treatment break approval form to restart treatment. | | | | |
| | | | 16. Alectinib will be used as set out in its Summary of Product Characteristics (SPC). | | | | |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| ALP1 | **Alpelisib** in combination with fulvestrant | For treatment of hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer in patients previously treated with a CDK4/6 inhibitor and an aromatase inhibitor where the following criteria have been met: | 1. This application for alpelisib in combination with fulvestrant is being made by and the first cycle of alpelisib plus fulvestrant will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has histologically or cytologically documented hormone receptor positive and HER-2 negative breast cancer.<br>3. The patient's breast cancer has a PIK3CA mutation identified in a tumour or plasma specimen using a validated test.<br><br>Note: patients with an AKT1 or PTEN genomic alteration but without a PIK3CA genomic alteration are not eligible for alpelisib plus fulvestrant.<br>4. The patient has metastatic or locally advanced breast cancer which is not amenable to curative treatment.<br>5. The patient is male or female and if female is either post-menopausal or if pre- or peri-menopausal has undergone ovarian ablation or suppression with LHRH agonist treatment.<br>6. The patient has progressive disease after previous endocrine-based therapy.<br>7. The patient has been previously treated with an aromatase inhibitor.<br>Please record in which places in the treatment pathway the patient had aromatase inhibitor therapy:<br>- solely for early breast cancer **or**<br>- solely for locally advanced/metastatic breast cancer **or**<br>- in both early and advanced breast cancer settings<br>8. The patient has been previously treated with a CDK4/6 inhibitor.<br>Please record in which places in the treatment pathway the patient had CDK4/6 inhibitor therapy:<br>- solely for early breast cancer **or**<br>- solely for locally advanced/metastatic breast cancer **or**<br>- in both early and advanced breast cancer settings<br>Note: the company submitted a case to NICE for consideration of clinical and cost effectiveness **only** in patients previously treated with a CDK4/6 inhibitor. This population is narrower than that in the marketing authorisation.<br>9. The patient has had no prior treatment with fulvestrant for any indication unless this patient is switching from treatment with capivasertib plus fulvestrant due to toxicity (see criterion 10 below).<br><br>Note: the marketing authorisation of alpelisib states that the efficacy of alpelisib in combination with fulvestrant is not considered to be established in patients previously treated with fulvestrant.<br>10. The patient has not previously received any treatment with a PIK3CA-targeted drug (such as capivasertib) unless this patient has received previous treatment with capivasertib plus fulvestrant but such treatment with capivasertib plus fulvestrant has had to be stopped within 6 months of its start solely as a consequence of excessive toxicity and in the clear absence of disease progression and if all other treatment criteria on this form apply.<br><br>Please record which scenario applies to this patient:<br>- the patient has not previously received any treatment with a PIK3CA-targeted drug or<br>- the patient has received previous treatment with capivasertib plus fulvestrant but such treatment with capivasertib plus fulvestrant has had to be stopped within 6 months of its start solely as a consequence of excessive toxicity and in the clear absence of disease progression and all other treatment criteria on this form apply<br>11. The patient has an ECOG performance status of 0 or 1.<br>12. Alpelisib will only be given in combination with fulvestrant.<br>13. Treatment with alpelisib will continue until there is progressive disease or excessive toxicity or until the patient chooses to discontinue treatment, whichever is the sooner.<br>14. Because the absorption of alpelisib is affected by food, the patients will be advised to take alpelisib immediately after food and at approximately the same time each day.<br>15. The prescribing clinician is aware of the potentially serious side-effects of alpelisib (e.g. hyperglycaemia, cutaneous reactions, diarrhoea, and pneumonitis) and of the necessary alpelisib dose adjustments for these toxicities, as outlined in alpelisib's Summary of Product Characteristics.<br>16. The prescribing clinician is aware that patients with a diagnosis of diabetes mellitus require a treatment consultation with a diabetic specialist or a healthcare professional experienced in the management of hyperglycaemia **prior to the start of treatment with alpelisib**.<br>17. Should the patient develop hyperglycaemia, a consultation with a healthcare professional experienced in the management of hyperglycaemia should be considered for all non-diabetic patients and is recommended for those patients who are any of the following: pre-diabetic or in those with a fasting blood glucose level >250mg/dL **or** >13.9 mmol/L **or** those have a BMI ≥30 **or** those of age ≥75 years.<br>18. The prescribing clinician is aware of the potential drug interactions between alpelisib and human Breast Cancer Resistance protein (BCRP) inhibitors and various cytochrome P450 enzyme systems, as outlined in alpelisib's Summary of Product Characteristics.<br>19. When a treatment break of up to 6 weeks beyond the expected 4-weekly cycle length is needed, the prescribing clinician will complete a treatment break approval form to restart treatment, including as appropriate if the patient had an extended break on account of Covid-19.<br>20. Alpelisib and fulvestrant will be otherwise used as set out in their respective Summaries of Product Characteristics (SPCs). | No | TA816 | 10-Aug-22 | 08-Nov-22 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| APA1 | **Apalutamide** in combination with androgen deprivation therapy (ADT) | For the treatment of non-metastatic hormone-resistant (castration-resistant) prostate cancer in patients who are at high risk of developing metastatic disease where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with apalutamide will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. This patient has a proven histological or cytological diagnosis of adenocarcinoma of the prostate without neuroendocrine differentiation or features of a small cell carcinoma.<br>3. This patient has non-metastatic prostate cancer as defined by recent imaging with conventional imaging with both a whole body isotope bone scan and a CT/MR scan of the chest, abdomen and pelvis.<br>Note: patients with the sole abnormality of pelvic lymph nodes measuring <2cm in short axis diameter and which are below the aortic bifurcation are eligible for apalutamide in this indication.<br>4. The patient has hormone-resistant (castrate-resistant) disease as defined by 3 rising PSA levels (after the nadir PSA level) and taken at least 1 week apart during androgen deprivation therapy.<br>5. The patient's serum testosterone level is <1.7nmol/L on gonadotrophin releasing hormone agonist/antagonist therapy or after bilateral orchidectomy.<br>6. The current PSA level is ≥2ng/ml.<br>7. The patient is at high risk of developing metastatic disease as defined by a PSA doubling time of ≤10 months during continuous ADT.<br>Please document the actual PSA doubling time in the box below:<br>8. The patient has an ECOG performance status of either 0 or 1 or 2.<br>9. The patient has not previously received any 2nd generation androgen receptor inhibitors (such as enzalutamide, darolutamide, apalutamide) or CYP17 enzyme inhibitors (such as abiraterone) unless the patient received darolutamide for non-metastatic hormone-resistant (castration-resistant) which had to be stopped because of dose-limiting toxicity in the clear absence of disease progression and the patient meets all the other criteria listed on this form.<br>Please mark below which of these 2 clinical scenarios applies to this patient:<br>- the patient has not previously received any androgen receptor targeted agent<br>- the patient received darolutamide for non-metastatic hormone-resistant (castration-resistant) which had to be stopped because of dose-limiting toxicity in the clear absence of disease progression and the patient meets all the other criteria listed on this form<br>10. Apalutamide is being given only in combination with androgen deprivation therapy.<br>11. Apalutamide is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment.<br>12. A formal medical review as to how apalutamide is being tolerated and whether treatment with apalutamide should continue or not will be scheduled to occur at least by the start of the third 4-weekly cycle of treatment.<br>13. Where a treatment break of more than 6 weeks beyond the expected 4-week cycle length is needed, I will complete a treatment break approval form to restart treatment, including indicating as appropriate if the patient had an extended break because of COVID 19.<br>14. Apalutamide is to be otherwise used as set out in its Summary of Product Characteristics | No | TA740 | 28-Oct-21 | 26-Jan-22 |
| APA2 | **Apalutamide** in combination with androgen deprivation therapy (ADT) | For the treatment of patients with newly diagnosed metastatic hormone-sensitive prostate cancer who are ineligible for chemotherapy with docetaxel where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with apalutamide will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. This patient either has a proven histological or cytological diagnosis of adenocarcinoma of the prostate or has presented with a clinical picture consistent with metastatic prostate cancer with both widespread bone metastases radiologically typical of prostate cancer and a serum PSA of ≥50 ng/mL.<br>3. This patient has newly diagnosed metastatic prostate cancer that is hormone sensitive and has currently received androgen deprivation therapy (ADT) for no longer than 3 months before starting an androgen receptor targeted agent.<br>Please enter below as to which scenario applies to this patient:<br>- the patient has not yet received any ADT for metastatic prostate cancer or<br>- the patient has received no more than 3 months of ADT before starting an androgen receptor targeted agent<br>4. The patient has not received any upfront docetaxel chemotherapy for metastatic hormone sensitive prostate cancer.<br>5. The patient has an ECOG performance status (PS) of 0 or 1 or 2.<br>6. The prescribing clinician has assessed this patient's status as regards receiving upfront docetaxel and have concluded that the patient is ineligible for docetaxel on the grounds of either having significant comorbidities (i.e. the patient should not be treated with docetaxel) or the patient is fit for upfront docetaxel but after fully informed consent has chosen not to receive upfront docetaxel.<br>Please mark below which of these 3 clinical scenarios applies to this patient:<br>- the patient has significant comorbidities which preclude treatment with docetaxel (i.e. **the patient SHOULD NOT be treated with docetaxel**) and this has been fully discussed with the patient. It is recommended that validated systems of scoring clinical frailty are used as part of the oncology assessment as to explaining the benefits and risks of the treatment options of chemotherapy and apalutamide<br>- the patient is fit for chemotherapy with docetaxel and has chosen not to be treated with docetaxel. The patient has been fully consented regarding all of the following: the advantages and disadvantages of upfront docetaxel chemotherapy vs upfront apalutamide; that the use of upfront apalutamide would result in there being no further possible treatment with any androgen receptor targeted agents when the patient's disease progresses; and that the patient may not be fit enough to receive docetaxel when the patient's disease progresses. After such informed consent, I confirm that the patient has chosen to receive upfront apalutamide (i.e. **the patient is fit for chemotherapy with docetaxel and has CHOSEN NOT to be treated with docetaxel**)<br>7. Apalutamide is being given only in combination with ADT.<br>8. The patient has not previously received any androgen receptor targeted agent unless the patient has ***either*** received darolutamide, enzalutamide or abiraterone for newly diagnosed metastatic hormone-sensitive prostate cancer which had to be stopped because of dose-limiting toxicity <u>in the clear absence of disease progression</u> **and** the patient meets all the other criteria listed on this form ***or*** the patient has progressive disease following treatment with 2 years of ADT plus abiraterone with or without enzalutamide for high risk non-metastatic disease as part of the STAMPEDE trial (ISRCTN78818544) and did not progress whilst on such treatment and the patient meets all the other criteria listed on this form **or** the patient has progressive disease following treatment with 2 years of ADT plus abiraterone for high risk non-metastatic disease, did not progress whilst on such treatment, and meets all the other criteria listed on this form.<br><br>Please mark below which of these 6 clinical scenarios applies to this patient:<br>- the patient has not previously received any androgen receptor targeted agent<br>- patient commenced darolutamide which had to be stopped because of dose-limiting toxicity in the clear absence of disease progression and the patient meets all the other criteria listed here<br>- the patient commenced enzalutamide which had to be stopped because of dose-limiting toxicity in the clear absence of disease progression and the patient meets all the other criteria listed here.<br>- the patient commenced abiraterone which had to be stopped because of dose-limiting toxicity in the clear absence of disease progression and the patient meets all the other criteria listed here<br>- the patient was treated with 2 years of ADT plus abiraterone with or without enzalutamide for high-risk non-metastatic disease as part of the STAMPEDE trial and did not progress whilst on such treatment and the patients meets all the other criteria listed here<br>- the patient has progressive disease following treatment with 2 years of ADT plus abiraterone for high risk non-metastatic disease, did not progress whilst on such treatment, and meets all the other criteria listed on this form<br>9. The patient has not previously received any apalutamide or any other androgen receptor targeted agent unless the patient has received apalutamide via a company early access scheme and the patient meets all the other criteria listed here.<br>10. Where a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment, which MUST be approved before treatment is re-commenced.<br>11. Apalutamide is to be otherwise used as set out in its Summary of Product Characteristics. | No | TA741 | 28-Oct-21 | 26-Jan-22 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| ARS1 | **Arsenic trioxide** | Arsenic trioxide for treating newly diagnosed low to intermediate risk acute promyelocytic leukaemia in ADULTS where all the following criteria are met: | 1. An application is made by and the start of systemic anti-cancer therapy with arsenic trioxide will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy<br>2. The patient is an ADULT and has a confirmed diagnosis of acute promyelocytic leukaemia characterised by the presence of the t(15;17) translocation and/or the presence of the Pro-Myelocytic Leukaemia/Retinoic-Acid-Receptor-alpha (PML/RAR-alpha) gene<br>3. The patient is newly diagnosed with acute promyelocytic leukaemia<br>4. The patient has low to intermediate risk acute promyelocytic leukaemia (white cell count ≤10 x $10^9$/L) and has not received any chemotherapy for this.<br>Patients with high risk acute promyelocytic leukaemia are not funded for treatment with arsenic trioxide<br>5. The patient will be treated with induction treatment of arsenic trioxide in combination with all-trans-retinoic acid (ATRA)<br>6. Induction treatment with arsenic trioxide will be continued until complete remission is achieved but if complete remission is not achieved by day 60, arsenic trioxide will be discontinued<br>7. As consolidation therapy, a maximum of 4 cycles of arsenic trioxide will be prescribed, each cycle being 4 weeks on treatment followed by 4 weeks off therapy<br>8. The dosing and schedule of administration of arsenic trioxide will be either in accordance with that described in the Summary of Product Characteristics (SPC) or that used in the UK NCRI AML17 trial as reported in Lancet Oncology 2015; 16:1295-1305.<br><br>If the AML17 dosing and schedule is used, hospital Trust policy regarding unlicensed treatments should be followed<br>9. The treating team is aware of the risk of and the treatment for<br>* APL differentiation syndrome<br>* QT interval prolongation and the need for monitoring of electrolytes<br>* Liver toxicity<br>The use of arsenic trioxide is excluded from the NHS England Treatment Break Policy<br>10. Arsenic trioxide is to be otherwise used as set out in its SPC | No | TA526 | 13-Jun-18 | 11-Sep-18 |
| ARS2 | **Arsenic trioxide** | Arsenic trioxide for treating relapsed/refractory acute promyelocytic leukaemia in ADULTS where the following criteria are met: | 1. An application is made by and the start of systemic anti-cancer therapy with arsenic trioxide will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy<br>2. This patient is an ADULT and has a confirmed diagnosis of acute promyelocytic leukaemia characterised by the presence of the t(15;17) translocation and/or the presence of the Pro-Myelocytic Leukaemia/Retinoic-Acid-Receptor-alpha (PML/RAR-alpha) gene<br>3. The patient has acute promyelocytic leukaemia which is EITHER refractory to or relapsed after previous treatment which included a retinoid and chemotherapy OR has relapsed after a complete remission which lasted at least 2 years following previous arsenic trioxide and all-trans-retinoic acid treatment<br>4. The patient will be treated with induction and consolidation treatment of arsenic trioxide in combination with all-trans-retinoic acid (ATRA)<br>As combination therapy with ATRA is unlicensed in this relapsed/refractory setting, hospital Trust policy regarding unlicensed treatments should be followed<br>5. Induction treatment with arsenic trioxide will be continued until complete remission is achieved but if complete remission is not achieved by day 50 if the dosing and schedule is used as in the Summary of Product Characteristics or by day 60 if the UK NCRI AML 17 protocol is used (Lancet Oncology 2015; 16: 1295-1305), arsenic trioxide will be discontinued<br>6. As consolidation therapy, either the dosing and schedule in the Summary of Product Characteristics is used for a maximum of 5 weeks or the dosing and scheduling of the UK NCRI AML17 protocol (Lancet Oncology 2015; 16: 1295-1305) is used for a maximum of 4 cycles of arsenic trioxide, each cycle being 4 weeks on treatment followed by 4 weeks off therapy<br>7. The dosing and schedule of administration of arsenic trioxide will be either in accordance with that described in the Summary of Product Characteristics (SPC) or that used in the UK NCRI AML17 protocol.<br>If the AML17 dosing and schedule is used, hospital Trust policy regarding unlicensed treatments should be followed<br>8. The treating team is aware of the risk of and the treatment for<br>* APL differentiation syndrome<br>* QT interval prolongation and the need for monitoring of electrolytes<br>* Liver toxicity<br>Arsenic trioxide is excluded from the NHS England Treatment Break Policy<br>9. That arsenic trioxide is to be otherwise used as set out in its SPC | No | TA526 | 13-Jun-18 | 11-Sep-18 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| ARS3 | **Arsenic trioxide** | Arsenic trioxide for treating newly diagnosed low to intermediate risk acute promyelocytic leukaemia in CHILDREN where the following criteria are met: | 1. An application is made by and the start of systemic anti-cancer therapy with arsenic trioxide will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy<br>2. The patient is a CHILD and has a confirmed diagnosis of acute promyelocytic leukaemia characterised by the presence of the t(15;17) translocation and/or the presence of the Pro-Myelocytic Leukaemia/Retinoic-Acid-Receptor-alpha (PML/RAR-alpha) gene<br>3. The patient is newly diagnosed with acute promyelocytic leukaemia<br>4. The patient has low to intermediate risk acute promyelocytic leukaemia (white cell count ≤10 x $10^9$/L) and has not received any chemotherapy for this.<br>Patients with high risk acute promyelocytic leukaemia are not funded for treatment with arsenic trioxide<br>5. The patient will be treated with induction treatment of arsenic trioxide in combination with all-trans-retinoic acid (ATRA)<br>6. Induction treatment with arsenic trioxide will be continued until complete remission is achieved but if complete remission is not achieved by day 60, arsenic trioxide will be discontinued<br>7. As consolidation therapy, a maximum of 4 cycles of arsenic trioxide will be prescribed, each cycle being 4 weeks on treatment followed by 4 weeks off therapy<br>8. The patient is a pre-pubescent or post-pubescent child and will be treated with the dosing and schedule of administration of arsenic trioxide either in accordance with that described in the Summary of Product Characteristics (SPC) or that used in the UK NCRI AML17 trial as reported in Lancet Oncology 2015; 16: 1295-1305.<br>9. The use of arsenic trioxide has been discussed at a multi-disciplinary team (MDT) meeting which must include two consultants in the subspecialty with active and credible expertise in the relevant field of whom at least one must be a consultant paediatrician. The MDT should include a paediatric pharmacist and other professional groups appropriate to the disease area<br>10. The hospital Trust policy regarding unlicensed treatments has been followed as arsenic trioxide is not licensed in this indication in children<br>11. The treating team is aware of the risk of and the treatment for<br>* APL differentiation syndrome<br>* QT interval prolongation and the need for monitoring of electrolytes<br>* Liver toxicity<br>Arsenic trioxide is excluded from the NHS England Treatment Break Policy<br>12. Arsenic trioxide is to be otherwise used as set out in its SPC | No | TA526 | 13-Jun-18 | 11-Sep-18 |
| ARS4 | **Arsenic trioxide** | Arsenic trioxide for treating relapsed/refractory acute promyelocytic leukaemia in CHILDREN where the following criteria have been met: | 1. An application is made by and the start of systemic anti-cancer therapy with arsenic trioxide will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy<br>2. The patient is a CHILD and has a confirmed diagnosis of acute promyelocytic leukaemia characterised by the presence of the t(15;17) translocation and/or the presence of the Pro-Myelocytic Leukaemia/Retinoic-Acid-Receptor-alpha (PML/RAR-alpha) gene<br>3. The patient has acute promyelocytic leukaemia which is EITHER refractory to or relapsed after previous treatment which included a retinoid and chemotherapy OR has relapsed after a complete remission which lasted at least 2 years following previous arsenic trioxide and all-trans-retinoic acid treatment<br>4. The patient will be treated with induction and consolidation treatment of arsenic trioxide in combination with all-trans-retinoic acid (ATRA)<br>As combination therapy with ATRA is unlicensed in this relapsed/refractory setting, hospital Trust policy regarding unlicensed treatments should be followed<br>5. Induction treatment with arsenic trioxide will be continued until complete remission is achieved but if complete remission is not achieved by day 50 if the dosing and schedule is used as in the Summary of Product Characteristics or by day 60 if the UK NCRI AML 17 protocol is used (Lancet Oncology 2015; 16: 1295-1305), arsenic trioxide will be discontinued<br>6. As consolidation therapy, either the dosing and schedule in the Summary of Product Characteristics is used for a maximum of 5 weeks or the dosing and scheduling of the UK NCRI AML17 protocol (Lancet Oncology 2015; 16: 1295-1305) is used for a maximum of 4 cycles of arsenic trioxide, each cycle being 4 weeks on treatment followed by 4 weeks off therapy<br>7. The patient is a pre-pubescent or post-pubescent child and will be treated with the dosing and schedule of administration of arsenic trioxide either in accordance with that described in the Summary of Product Characteristics (SPC) or that used in the UK NCRI AML17 protocol as reported in Lancet Oncology 2015; 16: 1295-1305.<br>8. The use of arsenic trioxide has been discussed at a multi-disciplinary team (MDT) meeting which must include two consultants in the subspecialty with active and credible expertise in the relevant field of whom at least one must be a consultant paediatrician. The MDT should include a paediatric pharmacist and other professional groups appropriate to the disease area<br>9. The hospital Trust policy regarding unlicensed treatments has been followed as arsenic trioxide is not licensed in this indication in children<br>10. The treating team is aware of the risk of and the treatment for<br>* APL differentiation syndrome<br>* QT interval prolongation and the need for monitoring of electrolytes<br>* Liver toxicity<br>Arsenic trioxide is excluded from the NHS England Treatment Break Policy<br>11. Arsenic trioxide is to be otherwise used as set out in its SPC. | No | TA526 | 13-Jun-18 | 11-Sep-18 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| ARS5 | **Arsenic trioxide** in combination with all-trans retinoic acid (ARTA) | Arsenic trioxide in combination with all-trans retinoic acid (ARTA) for the treatment of high-risk acute promyelocytic leukaemia (>=18 years old) where the following criteria are met: | 1. An application has been made by and the first cycle of arsenic trioxide will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy. | No | NHSE Policy: URN2320 | N/A | 05-Mar-25 |
| | | | 2. The patient is aged >=18 years old and has a diagnosis of newly diagnosed high risk acute promyelocytic leukaemia (APML) as confirmed by:<br>• a white cell count >=10,000/µl (or 10 x $10^9$/L) AND<br>• fusion of the PML/RARa gene (confirmed by fluorescence in situ hybridisation (FISH) analysis or PCR | | | | |
| | | | 3. The patient does not meet any of the following exclusion criteria:<br><br>• patient with isolated myeloid sarcoma but without evidence of APL by bone marrow or peripheral blood morphology<br>• patients with a pre-existing diagnosis of a prolonged QT syndrome, a history or presence of significant ventricular or atrial tachyarrhythmia, right bundle branch block plus left anterior hemiblock, bifascicular block<br>• patients on active dialysis for renal dysfunction<br>• female patients who are pregnant<br>• hypersensitivity to arsenic trioxide or ATRA | | | | |
| | | | 4. The use of the arsenic trioxide will be discussed at a multi-disciplinary team (MDT) meeting which must include at least two haematology consultants. | | | | |
| | | | 5. The patient will receive the recommended dose and treatment regimen for arsenic trioxide as suggested in the NHS England Clinical Commissioning Policy. | | | | |
| | | | 6. The stopping / exit criteria have been explained and agreed with the patient and/or carer before the treatment is started and this has been documented in the patient records. | | | | |
| | | | 7. The Trust policy regarding unlicensed treatments has been followed.<br><br>**NB. The use of arsenic trioxide in this indication is off-label, therefore Trust policy regarding unlicensed medicines should apply.** | | | | |
| | | | 8. The patient has not previously received arsenic trioxide. | | | | |
| | | | 9. Arsenic trioxide will be otherwise used as set out in its Summary of Product Characteristics (SPC). | | | | |
| ARS6 | **Arsenic trioxide** in combination with all-trans retinoic acid (ARTA) | Arsenic trioxide in combination with all-trans retinoic acid (ARTA) for the treatment of high-risk acute promyelocytic leukaemia (Children aged 12 months to <18 years old) where the following criteria have been met: | 1. An application has been made by and the first cycle of arsenic trioxide will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy. | No | NHSE Policy: URN2320 | N/A | 05-Mar-25 |
| | | | 2. The patient is aged 12 months or older and has a diagnosis of newly diagnosed high risk acute promyelocytic leukaemia (APML) as confirmed by:<br>• a white cell count >=10,000/µl (or 10 x $10^9$/L) AND<br>• fusion of the PML/RARa gene (confirmed by fluorescence in situ hybridisation (FISH) analysis or PCR | | | | |
| | | | 3. The patient does not meet any of the following exclusion criteria:<br><br>• patient with isolated myeloid sarcoma but without evidence of APL by bone marrow or peripheral blood morphology<br>• patients with a pre-existing diagnosis of a prolonged QT syndrome, a history or presence of significant ventricular or atrial tachyarrhythmia, right bundle branch block plus left anterior hemiblock, bifascicular block<br>• patients on active dialysis for renal dysfunction<br>• female patients who are pregnant<br>• hypersensitivity to arsenic trioxide or ATRA | | | | |
| | | | 4. The use of the drug has been discussed at a specialised multidisciplinary team (MDT) meeting involving at least two paediatric haematological consultants who agree that continued treatment with arsenic trioxide is the most appropriate treatment plan. The MDT should also include a paediatric pharmacist and other professional groups appropriate to the disease area.<br><br>Patients should be discussed at a multidisciplinary team (MDT) prior to initiating treatment where time permits. However, in urgent cases where this is not possible, patients should be subsequently discussed at a local MDT meeting. | | | | |
| | | | 5. The patient will receive the recommended dose and treatment regimen for arsenic trioxide as suggested in the NHS England Clinical Commissioning Policy. | | | | |
| | | | 6. The stopping / exit criteria have been explained and agreed with the patient and/or carer before the treatment is started and this has been documented in the patient records. | | | | |
| | | | 7. The Trust policy regarding unlicensed treatments has been followed.<br><br>**NB. The use of arsenic trioxide in this indication is off-label, therefore Trust policy regarding unlicensed medicines should apply.** | | | | |
| | | | 8. The use of arsenic trioxide in this indication is being requested and administered in Principal Treatment Centres only. | | | | |
| | | | 9. The patient has not previously received arsenic trioxide. | | | | |
| | | | 10. Arsenic trioxide will be otherwise used as set out in its Summary of Product Characteristics (SPC). | | | | |
| | | | 11. Idarubicin chemotherapy will only be used during induction therapy and will follow the treatment regimen as suggested in the NHS England Clinical Commissioning Policy. | | | | |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| ASC1 | **Asciminib** | For the treatment of patients with chronic phase Philadelphia chromosome-positive chronic myeloid leukaemia previously treated with two or more tyrosine kinase inhibitors where the following criteria have been met: | 1. This application for asciminib is being made by and the first cycle of systemic anti-cancer therapy with asciminib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has Philadelphia chromosome-positive chronic myeloid leukaemia (CML).<br>3. The CML remains in chronic phase.<br>4. The patient has received previous treatment with 2 or more TKIs for CML.<br>Please tick the appropriate option below as to the total number of different TKIs received by this patient:<br>- 2 previous different TKIs<br>- 3 previous different TKIs<br>- 4 or more previous different TKIs<br>5. The patient has been previously treated with ponatinib or not:<br>- the patient has received treatment with ponatinib<br>- the patient has not received treatment with ponatinib<br>6. The last line of TKI therapy was **either** discontinued due to resistant disease in which case the T315I mutation test has been done and is negative or the last line of therapy was stopped due to patient intolerance of treatment in which case the previous T315I mutation test was negative.:<br>- the patient had resistant disease on the last line of TKI therapy and the T315I mutation test is negative<br>- the patient was intolerant of the last line of TKI therapy and the previous T315I mutation test was negative<br>7. The patient has an ECOG performance status score of 0 or 1.<br>8. The patient has not received prior treatment with asciminib unless the patient has started treatment via the EAMS scheme or via the Novartis compassionate use scheme and all other treatment criteria on this form are fulfilled.<br>Please mark below which of these 3 clinical scenarios applies to this patient<br>- the patient has NOT received prior treatment with asciminib<br>- the patient started treatment with asciminib via the EAMS scheme and all other treatment criteria on this form are fulfilled<br>- the patient started treatment with asciminib via the Novartis compassionate use scheme and all other treatment criteria on this form are fulfilled<br>9. Asciminib will be given until the development of disease resistance or patient intolerance or withdrawal of patient consent.<br>10. The prescribing clinician understands that the daily dose of asciminib at the initiation of treatment for this indication is **80mg daily**.<br>11. The prescribing clinician is aware of the potential drug interactions of asciminib with CYP3A4 inhibitors, CYP3A4 inducers, certain CYP3A4 substrates, CYP2C9 substrates and certain P-gp substrates.<br>12. The prescribing clinician is aware that asciminib absorption and bioavailability may be significantly reduced by concurrent administration with food (in particular high fat meals) and by some drugs (e.g. itraconazole) as described in asciminib' s Summary of Product Characteristics).<br>13. A formal medical review as to how asciminib is being tolerated and whether treatment with asciminib should continue or not will be scheduled to occur at least by the end of the second 4-weekly cycle of treatment.<br>14. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment.<br>15. Asciminib will otherwise be used as set out in its Summary of Product Characteristics (SPC). | No | TA813 | 03-Aug-22 | 02-Sep-22 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| ATE1 | **Atezolizumab** | The first line treatment of locally advanced or metastatic urothelial cancer in patients who are ineligible for cisplatin-based chemotherapy and whose tumours have PD-L1 expression of 5% or more where all the following criteria are mett: | 1. An application is being made by and the first cycle of systemic anti-cancer therapy with atezolizumab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br><br>2. The prescribing clinician is fully aware of the management of and the treatment modifications that may be required for immune-related adverse reactions due to anti-PD-L1 treatments including pneumonitis, colitis, nephritis, endocrinopathies, hepatitis and skin toxicities.<br><br>3. The patient has histologically or cytologically documented transitional cell carcinoma of the urothelial tract<br><br>4. The patient has disease that is either locally advanced (ie T4b any N or any T N2-3 disease) or metastatic (any T any N M1 disease)<br><br>5. The patient has not received previous chemotherapy for inoperable locally advanced or metastatic urothelial cancer<br><br>6. The patient has EITHER not received previous adjuvant chemotherapy, neoadjuvant chemotherapy or chemo-radiotherapy OR if previously treated with platinum-based chemotherapy whether as adjuvant chemotherapy or as neoadjuvant chemotherapy or with chemo-radiotherapy, has relapsed more than 12 months since completing the platinum-based chemotherapy*.<br><br>* Patients meeting this criterion are eligible to be considered as treatment naïve for locally advanced/ metastatic disease but must satisfy all other criteria.<br><br>7. The patient has an ECOG performance status (PS) of 0, 1 or 2.<br><br>Note: treatment of patients of performance status 2 should only proceed with caution as there is limited safety data on PS 2 patients with urothelial cancer treated with atezolizumab.<br><br>8. The patient is ineligible for platinum-based chemotherapy, due to **one or more of the following**:<br>* impaired renal function (EDTA-assessed glomerular filtration rate >30 and <60mls/min)<br>* hearing loss of 25dB as assessed by formal audiometry<br>* NCI CTCAE grade 2 or worse peripheral neuropathy<br>* ECOG PS 2<br><br>9. The patient's urothelial tumour has undergone PD-L1 testing<br><br>10. A PD-L1 expression of >=5% has been recorded and the measurement used for PD-L1 testing is defined as the presence of discernible >=5% of tumour area occupied by tumour cells, associated intra-tumoural and contiguous peri-tumoural desmoplastic stroma.<br>Please document the actual score for tumour infiltrating immune cell PD-L1 expression:_____<br><br>11. The patient has not received prior treatment with an anti PD-1, anti-PD-L1, anti-PD-L2, anti-CD137 or anti-cytotoxic T-lymphocyte-associated antigen-4 (CTL-4) antibody unless the patient completed or discontinued checkpoint inhibitor immunotherapy as part of adjuvant or neoadjuvant therapy **without disease progression on treatment and at least 12 months elapsed between the date of last immunotherapy treatment and the date of first diagnosis of relapse with recurrent or metastatic disease.**<br><br>Note: NHS England does not commission any re-treatment with checkpoint inhibitor therapy for patients who have discontinued or completed previous checkpoint inhibitor therapy for the locally advanced/metastatic indication.<br><br>Please mark below if the patient has received previous checkpoint inhibitor therapy and in which setting:<br>- the patient has never received any immunotherapy for urothelial cancer. If so, please type 'n/a' in the 'Time gap' box below<br>- the patient has previously been treated with adjuvant immunotherapy for urothelial cancer and discontinued immunotherapy without disease progression and at least 12 months prior to the first diagnosis of disease relapse. Please document in the box below the time gap in months between completion of previous adjuvant immunotherapy and first diagnosis of disease relapse stable disease at the end of 1st line chemotherapy<br>- the patient has previously been treated with neoadjuvant treatment containing immunotherapy for urothelial cancer and discontinued immunotherapy without disease progression and at least 12 months prior to the first diagnosis of disease relapse. Please document in the box below the time gap in months between completion of previous neoadjuvant immunotherapy and first diagnosis of disease relapse<br><br>Time gap in months after completion of previous adjuvant or neoadjuvant or maintenance checkpoint inhibitor immunotherapy and first diagnosis of disease relapse:_____<br><br>12. The patient has no symptomatically active brain metastases or leptomeningeal metastases<br><br>13. Atezolizumab will be administered as monotherapy either **subcutaneously** at a dose of 1875mg every 3 weeks or **intravenously** at a dose of 1200mg every 3 weeks or 1680 mg every 4 weeks.<br><br>14. A formal medical review as to whether treatment with atezolizumab should continue or not will be scheduled to occur at least by the end of the third cycle of treatment.<br><br>15. The patient will be treated until loss of clinical benefit or excessive toxicity or patient choice to discontinue treatment, whichever is the sooner.<br><br>Note: there is no stopping rule for this indication.<br><br>16. When a treatment break of more than 3 months beyond the expected 3- or 4-weekly cycle is needed, a treatment break approval form will be completed to restart treatment.<br><br>17. Atezolizumab will otherwise be used as set out in its Summary of Product Characteristics (SPC). | No | TA739 | 27-Oct-21 | 25-Jan-22 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| ATE2 | **Atezolizumab** | Atezolizumab monotherapy for the treatment of PD-L1 positive or negative locally advanced or metastatic non-small cell lung cancer after chemotherapy where all the following criteria are met: | 1. An application has been made by and the first cycle of systemic anti -cancer therapy with atezolizumab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br><br>2. The prescribing clinician is fully aware of the management of and the treatment modifications that may be required for immune-related adverse reactions due to anti-PD-L1 treatments including pneumonitis, colitis, nephritis, endocrinopathies, hepatitis and skin toxicities.<br><br>3. The patient has a histologically- or cytologically-confirmed diagnosis of non-small cell lung cancer (squamous or non-squamous).<br><br>4. The patient has stage IIIB or IIIC or IV NSCLC or disease that recurred after previous potentially curative local management of NSCLC with surgery/chemoradiotherapy/radiotherapy.<br><br>5. PD-L1 testing with an approved and validated test to determine the Tumour Proportion Score (TPS) has been attempted prior to this application and the result is set out below.<br>Please document the actual TPS below (if negative, record '0') or enter 'n/a' if the TPS cannot be documented and the reason why below:<br>TPS_____<br>If n/a, please indicate below the reason why the actual TPS cannot be documented:<br>- the TPS result was unquantifiable OR<br>- PD-L1 testing was not possible as the pathologist has documented that there is insufficient tissue for PD-L1 analysis<br><br>6. The patient has progressed **either** after treatment with at least two cycles of platinum-based doublet chemotherapy for stage IIIB or IIIC or IV or recurrent NSCLC after previous potentially curative local management or has progressed within 6 months of completing platinum-based adjuvant or neoadjuvant therapy or chemoradiation and if appropriate that the patient has had all appropriate targeted treatments if the patient has a tumour which is positive for an actionable genomic change in relation to EGFR or ALK or ROS1 or MET exon 14 or KRAS G12C or RET or BRAF V600 status.<br><br>7. The patient has not received prior treatment with an anti PD-1, anti-PD-L1, anti-PD-L2, anti-CD137 or anti-cytotoxic T-lymphocyte-associated antigen-4 (CTL-4) antibody unless the patient discontinued or completed checkpoint inhibitor immunotherapy as part of adjuvant/neoadjuvant/maintenance therapy **without disease progression and at least 6 months elapsed between the date of the last immunotherapy treatment and the date of first diagnosis of relapse with recurrent or metastatic disease**.<br>Note: NHS England does not commission re-treatment with checkpoint inhibitor therapy for patients who have discontinued or completed previous checkpoint inhibitor therapy for the locally advanced/metastatic indication.<br><br>Please mark below if the patient received previous checkpoint inhibitor therapy and in which setting:<br>- the patient has never received any immunotherapy for NSCLC. If so, please type 'n/a' in the 'Time gap' box below or<br>- the patient has previously been treated with adjuvant immunotherapy for NSCLC and discontinued immunotherapy without disease progression and at least 6 months prior to the first diagnosis of relapse. Please document in the box below the time gap in months between completion of previous adjuvant immunotherapy and first diagnosis of disease relapse or<br>- the patient has previously been treated with neoadjuvant immunotherapy for NSCLC and discontinued immunotherapy without disease progression and at least 6 months prior to the first diagnosis of relapse. Please document in the box below the time gap in months between completion of previous neoadjuvant immunotherapy and first diagnosis of disease relapse or<br>- the patient has previously been treated with maintenance immunotherapy post chemoradiotherapy for NSCLC and discontinued immunotherapy without disease progression and at least 6 months prior to the first diagnosis of relapse. Please document in the box below the time gap in months between completion of previous maintenance immunotherapy and first diagnosis of disease relapse<br><br>Time gap in months after completion of previous adjuvant or neoadjuvant or maintenance checkpoint inhibitor immunotherapy and first diagnosis of disease relapse:_____<br>Note: the mandatory interval between the last date of administration of any prior adjuvant/neoadjuvant/maintenance immunotherapy and the date of first relapse is **at least 6 months**. For patients suffering a first relapse within 6-12 months of previous immunotherapy, clinicians should bear in mind the long elimination half-lives of immunotherapies and make individual assessments of the overall benefit/risk ratio of re-treatment with immunotherapy.<br><br>8. Treatment with atezolizumab will continue for a total of 2 years* or until disease progression or unacceptable toxicity or withdrawal of patient consent, whichever occurs first.<br>*2 years treatment is defined as a maximum of 35 x 3-weekly cycles or the equivalent number is 26 cycles iff 4-weekly dosing is used.<br><br>9. Atezolizumab will be administered as monotherapy either **subcutaneously** at a dose of 1875mg every 3 weeks or **intravenously** at a dose of 1200mg every 3 weeks or 1680 mg every 4 weeks.<br><br>10. The patient has an ECOG performance status (PS) of 0 or 1.<br><br>11. The patient has no symptomatically active brain metastases or leptomeningeal metastases.<br><br>12. Atezolizumab will be administered as monotherapy.<br><br>13. A formal medical review as to whether treatment with atezolizumab should continue or not will be scheduled to occur at least by the end of the second cycle of treatment.<br><br>14. When a treatment break of more than 12 weeks beyond the expected cycle length is needed, a treatment break form will be completed to restart treatment, including an indication as appropriate if the patient had an extended break because of COVID 19.<br><br>15. Atezolizumab will otherwise be used as set out in its Summary of Product Characteristics (SPC) | No | TA520 | 16-May-18 | 14-Aug-18 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| ATE3 | **Atezolizumab** | Atezolizumab for locally advanced or metastatic urothelial cancer previously treated with platinum-based chemotherapy where all the following criteria are met: | 1. The application is made by and the first cycle of systemic anti-cancer therapy with atezolizumab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy<br><br>2. The prescribing clinician is fully aware of the management of and the treatment modifications that may be required for the immune-related adverse reactions due to anti-PD-L1 treatments including pneumonitis, colitis, nephritis, endocrinopathies, hepatitis and skin toxicities.<br><br>3. The patient has histologically or cytologically documented transitional cell carcinoma of the urothelial tract<br><br>4. The patient's disease is either locally advanced (ie T4b any N or any T N2-3 disease) or metastatic (any T any N M1 disease).<br><br>5. The patient has **either** not received previous adjuvant chemotherapy, neoadjuvant chemotherapy or chemo-radiotherapy, **or** if previously treated with platinum-based chemotherapy whether as adjuvant chemotherapy or as neoadjuvant chemotherapy or with chemo-radiotherapy, has relapsed =< 12 months since completing the platinum-based chemotherapy*.<br><br>* Patients meeting this criterion are eligible to be considered as previously treated for locally advanced/ metastatic disease (see below for criterion 6) but must satisfy all other criteria.<br><br>* Patients meeting this criterion are eligible to be considered as previously treated for locally advanced/ metastatic disease (and can answer "Yes" to criteria 6 below) but must satisfy all other criteria<br><br>6. There has been disease progression during or following previous platinum-based combination chemotherapy for inoperable locally advanced or metastatic urothelial cancer.<br><br>7. The patient has an ECOG performance status (PS) score of 0 or 1<br><br>8. The patient has not received prior treatment with an anti PD-1, anti-PD-L1, anti-PD-L2, anti-CD137 or anti-cytotoxic T-lymphocyte-associated antigen-4 (CTL-4) antibody unless the patient completed or discontinued checkpoint inhibitor immunotherapy as part of adjuvant or neoadjuvant therapy **without disease progression on treatment and at least 12 months elapsed between the date of last immunotherapy treatment and the date of first diagnosis of relapse with recurrent or metastatic disease.**<br>Note: NHS England does not commission any re-treatment with checkpoint inhibitor therapy for patients who have discontinued or completed previous checkpoint inhibitor therapy for the locally advanced/metastatic indication.<br><br>Please mark below if the patient has received previous checkpoint inhibitor therapy and in which setting:<br>- the patient has never received any immunotherapy for urothelial cancer. If so, please type 'n/a' in the 'Time gap' box below<br>- the patient has previously been treated with adjuvant immunotherapy for urothelial cancer and discontinued immunotherapy without disease progression and at least 12 months prior to the first diagnosis of disease relapse. Please document in the box below the time gap in months between completion of previous adjuvant immunotherapy and first diagnosis of disease relapse stable disease at the end of 1st line chemotherapy<br>- the patient has previously been treated with neoadjuvant treatment containing immunotherapy for urothelial cancer and discontinued immunotherapy without disease progression and at least 12 months prior to the first diagnosis of disease relapse. Please document in the box below the time gap in months between completion of previous neoadjuvant immunotherapy and first diagnosis of disease relapse<br>Time gap in months after completion of previous adjuvant or neoadjuvant checkpoint inhibitor immunotherapy and first diagnosis of disease relapse:_____<br><br>9. Atezolizumab will be administered as monotherapy either **subcutaneously** at a dose of 1875mg every 3 weeks or **intravenously** at a dose of 1200mg every 3 weeks or 1680 mg every 4 weeks.<br><br>10. A formal medical review as to whether treatment with atezolizumab should continue or not will be scheduled to occur at least by the end of the third cycle of treatment.<br><br>11. The patient is to be treated until disease progression and loss of clinical benefit or excessive toxicity or patient choice or **for a maximum treatment duration of 2 years of uninterrupted treatment** (ie a maximum of 35 administrations if given 3-weekly or a maximum of 26 administrations if given 4-weekly).<br><br>12. When treatment break of more than 3 months beyond the expected 3- or 4-weekly cycle length, a treatment break approval form will be completed.<br><br>13. The patient has no symptomatically active brain metastases or leptomeningeal metastases<br><br>14. Atezolizumab will otherwise be used as set out in its Summary of Product Characteristics (SPC) | No | TA525 | 13-Jun-18 | 13-Jul-18 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| ATE4 | **Atezolizumab** (in combination with bevacizumab, carboplatin and paclitaxel) | The first line treatment of adult patients with locally advanced or metastatic non-squamous non-small cell lung cancer with a PD-L1 tumour proportion score of 0-49% and without EGFR and ALK mutations where the following criteria are met: | 1. This application has been made by and the first cycle of systemic anti -cancer therapy with the combination of atezolizumab, bevacizumab, carboplatin and paclitaxel will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br><br>2. As the prescribing clinician I am fully aware of the management of and the treatment modifications that may be required for immune-related adverse reactions due to anti-PD-L1 treatments including pneumonitis, colitis, nephritis, endocrinopathies, hepatitis and skin toxicities.<br><br>3. The patient has a histologically- or cytologically-confirmed diagnosis of non-squamous non-small cell lung cancer (NSCLC).<br><br>4. The patient has stage IIIB or IIIC or IV NSCLC or has disease that has recurred after potentially curative treatment with local management of NSCLC with surgery/chemoradiotherapy/radiotherapy.<br><br>5. EGFR and ALK testing have been done and both are negative.<br><br>6. PD-L1 testing with an approved and validated test to determine the Tumour Proportion Score (TPS) has been performed prior to this application and the result is set out below.<br>Note: for fully informed patient consent of all the potential 1st line treatment options, PD-L1 testing must be done. This is also because Roche's submission to NICE sought recommendation only for patients with a PD-L1 TPS of 0-49%. The combination of atezolizumab, bevacizumab, carboplatin and paclitaxel is not approved or funded if the TPS is 50-100%.<br>Please document the actual TPS below (if negative, record '0'):<br>TPS_____<br><br>7. Either the patient has not received any previous systemic therapy for NSCLC or the patient **completed the last treatment** with chemotherapy or chemoradiotherapy or checkpoint inhibitor immunotherapy as part of adjuvant/neoadjuvant/maintenance therapy at least **6** months prior to the first diagnosis of locally recurrent or metastatic disease.<br>Please indicate below whether the patient has received any previous adjuvant or neoadjuvant or maintenance systemic therapy for NSCLC:<br>- the patient has not been previously treated with any adjuvant or neoadjuvant or maintenance systemic therapy for NSCLC or<br>- the patient has been previously treated with **adjuvant** systemic therapy for NSCLC and this was completed more than 6 months before first diagnosis of recurrent or metastatic disease or<br>- the patient has been previously treated with **neoadjuvant** systemic therapy for NSCLC and this was completed more than 6 months before first diagnosis of recurrent or metastatic disease or<br>- the patient has been previously treated with **maintenance** systemic therapy for NSCLC and this was completed more than 6 months before first diagnosis of recurrent or metastatic disease<br><br>8. The patient has not received prior treatment with an anti PD-1, anti-PD-L1, anti-PD-L2, anti-CD137 or anti-cytotoxic T-lymphocyte-associated antigen-4 (CTL-4) antibody unless the patient discontinued or completed checkpoint inhibitor immunotherapy as part of adjuvant/neoadjuvant/maintenance therapy **without disease progression and at least 6 months elapsed between the date of the last immunotherapy treatment and the date of first diagnosis of relapse with recurrent or metastatic disease**.<br>Note: NHS England does not commission re-treatment with checkpoint inhibitor therapy for patients who have discontinued or completed previous checkpoint inhibitor therapy for the locally advanced/metastatic indication.<br><br>Please mark below if the patient received previous checkpoint inhibitor therapy and in which setting:<br>- the patient has never received any immunotherapy for NSCLC. If so, please type 'n/a' in the 'Time gap' box below or<br>- the patient has previously been treated with adjuvant immunotherapy for NSCLC and discontinued immunotherapy without disease progression and at least 6 months prior to the first diagnosis of relapse. Please document in the box below the time gap in months between completion of previous adjuvant immunotherapy and first diagnosis of disease relapse or<br>- the patient has previously been treated with neoadjuvant immunotherapy for NSCLC and discontinued immunotherapy without disease progression and at least 6 months prior to the first diagnosis of relapse. Please document in the box below the time gap in months between completion of previous neoadjuvant immunotherapy and first diagnosis of disease relapse or<br>- the patient has previously been treated with maintenance immunotherapy post chemoradiotherapy for NSCLC and discontinued immunotherapy without disease progression and at least 6 months prior to the first diagnosis of relapse. Please document in the box below the time gap in months between completion of previous maintenance immunotherapy and first diagnosis of disease relapse<br><br>Time gap in months after completion of previous adjuvant or neoadjuvant or maintenance checkpoint inhibitor immunotherapy and first diagnosis of disease relapse:_____<br>Note: the mandatory interval between the last date of administration of any prior adjuvant/neoadjuvant/maintenance immunotherapy and the date of first relapse is **at least 6 months**. For patients suffering a first relapse within 6-12 months of previous immunotherapy, clinicians should bear in mind the long elimination half-lives of immunotherapies and make individual assessments of the overall benefit/risk ratio of re-treatment with immunotherapy.<br><br>9. The patient does not have a contra-indication to being treated with bevacizumab.<br><br>10. The patient will be treated with a maximum of 4 x 3-weekly cycles of the combination of atezolizumab, bevacizumab (15mg/Kg), carboplatin (AUC 6mg/ml/min) and paclitaxel (200mg/m$^2$).<br><br>Note: a lower starting dose of paclitaxel 175mg/m$^2$should be used in patients of Asian origin as per the SPC.<br><br>11. After completion of the combination of atezolizumab, bevacizumab, carboplatin and paclitaxel and in the absence of disease progression, maintenance treatment with atezolizumab and bevacizumab will continue until loss of clinical benefit or unacceptable toxicity or withdrawal of patient consent or for a maximum treatment duration of 2* years, whichever occurs first.<br>*2 years treatment is defined as a maximum of 35 x 3-weekly cycles of atezolizumab and bevacizumab including the initial 4 induction cycles of treatment.<br><br>Note: atezolizumab in this maintenance treatment will be administered either **subcutaneously** at a dose of 1875mg every 3 weeks or **intravenously** at a dose of 1200mg every 3 weeks.<br><br>12. The patient has a performance status of 0 or 1 and is fit for the combination of atezolizumab, bevacizumab, carboplatin (AUC 6mg/ml/min) and paclitaxel (200mg/m$^2$).<br>Note: the chemotherapy doses in this regimen are higher than may be the case in common practice and so careful selection of patients is required to ensure that patients can tolerate these higher doses of chemotherapy.<br><br>13. The patient has no symptomatically active brain metastases or leptomeningeal metastases.<br><br>14. A formal medical review as to whether treatment with the combination of atezolizumab, bevacizumab, carboplatin and paclitaxel should continue or not will be scheduled to occur at least by the end of the first 6 weeks of treatment.<br><br>15. Where a treatment break of more than 12 weeks beyond the expected cycle length is needed, a treatment break form will be completed to restart treatment, including an indication as appropriate if the patient had an extended break because of COVID 19.<br><br>16. Atezolizumab and bevacizumab will be otherwise used as set out in their respective Summaries of Product Characteristics. | No | TA584 | 05-Jun-19 | 03-Sep-19 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| ATE5 | **Atezolizumab** (in combination with bevacizumab, carboplatin and paclitaxel) | The treatment of adult patients with EGFR or ALK or ROS1 or MET exon 14 or KRAS G12C or RET or BRAF mutation positive locally advanced or metastatic non-squamous non-small cell lung cancer after failure of appropriate targeted therapy where the following criteria are met: | 1. This application is being made by and the first cycle of systemic anti -cancer therapy with the combination of atezolizumab, bevacizumab, carboplatin and paclitaxel will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The prescribing clinician is fully aware of the management of and the treatment modifications that may be required for immune-related adverse reactions due to anti-PD-L1 treatments including pneumonitis, colitis, nephritis, endocrinopathies, hepatitis and skin toxicities.<br>3. The patient has a histologically- or cytologically-confirmed diagnosis of non-squamous non-small cell lung cancer (NSCLC).<br>4. The patient has stage IIIB ***or*** IIIC ***or*** IV NSCLC ***or*** disease that recurred after potentially curative treatment with local management of NSCLC with surgery/chemoradiotherapy/radiotherapy.<br>5. The patient's lung cancer has shown an actionable mutation for which there is funded NHS England therapy and that the patient has been treated with such targeted therapy.<br>Please mark which actionable mutation has been identified and for which the patient has been treated:<br>- EGFR activating mutation except exon 20 insertion mutation or<br>- EGFR exon 20 insertion mutation or<br>- ALK gene rearrangement or<br>- ROS1 gene rearrangement or<br>- MET exon 14 skipping mutation or<br>- KRAS G12C mutation or<br>- RET gene fusion or<br>- BRAF V600 mutation<br>6. The patient has not received prior treatment with an anti PD-1, anti-PD-L1, anti-PD-L2, anti-CD137 or anti-cytotoxic T-lymphocyte-associated antigen-4 (CTL-4) antibody unless the patient discontinued or completed checkpoint inhibitor immunotherapy as part of adjuvant/neoadjuvant/maintenance therapy **without disease progression and at least 6 months elapsed between the date of the last immunotherapy treatment and the date of first diagnosis of relapse with recurrent or metastatic disease**.<br>Note: NHS England does not commission re-treatment with checkpoint inhibitor therapy for patients who have discontinued or completed previous checkpoint inhibitor therapy for the locally advanced/metastatic indication.<br><br>Please mark below if the patient received previous checkpoint inhibitor therapy and in which setting:<br>- the patient has never received any immunotherapy for NSCLC. If so, please type 'n/a' in the 'Time gap' box below or<br>- the patient has previously been treated with adjuvant immunotherapy for NSCLC and discontinued immunotherapy without disease progression and at least 6 months prior to the first diagnosis of relapse. Please document in the box below the time gap in months between completion of previous adjuvant immunotherapy and first diagnosis of disease relapse or<br>- the patient has previously been treated with neoadjuvant immunotherapy for NSCLC and discontinued immunotherapy without disease progression and at least 6 months prior to the first diagnosis of relapse. Please document in the box below the time gap in months between completion of previous neoadjuvant immunotherapy and first diagnosis of disease relapse or<br>- the patient has previously been treated with maintenance immunotherapy post chemoradiotherapy for NSCLC and discontinued immunotherapy without disease progression and at least 6 months prior to the first diagnosis of relapse. Please document in the box below the time gap in months between completion of previous maintenance immunotherapy and first diagnosis of disease relapse<br><br>Time gap in months after completion of previous adjuvant or neoadjuvant or maintenance checkpoint inhibitor immunotherapy and first diagnosis of disease relapse:_____<br>Note: the mandatory interval between the last date of administration of any prior adjuvant/neoadjuvant/maintenance immunotherapy and the date of first relapse is **at least 6 months**. For patients suffering a first relapse within 6-12 months of previous immunotherapy, clinicians should bear in mind the long elimination half-lives of immunotherapies and make individual assessments of the overall benefit/risk ratio of re-treatment with immunotherapy.<br>7. The patient does not have a contra-indication to being treated with bevacizumab.<br>8. The patient will be treated with a maximum of 4 x 3-weekly cycles of the combination of atezolizumab, bevacizumab (15mg/Kg), carboplatin (AUC 6mg/ml/min) and paclitaxel (200mg/m²).<br><br>Note: a lower starting dose of paclitaxel 175mg/m²should be used in patients of Asian origin as per the SPC.<br>9. After completion of the combination of atezolizumab, bevacizumab, carboplatin and paclitaxel and in the absence of disease progression, maintenance treatment with atezolizumab and bevacizumab will continue until loss of clinical benefit or unacceptable toxicity or withdrawal of patient consent or for a maximum treatment duration of 2* years, whichever occurs first.<br>*2 years treatment is defined as a maximum of 35 x 3-weekly cycles of atezolizumab and bevacizumab including the initial 4 induction cycles of treatment.<br><br>Note: atezolizumab in this maintenance treatment will be administered either **subcutaneously** at a dose of 1875mg every 3 weeks or **intravenously** at a dose of 1200mg every 3 weeks.<br>10. The patient has a performance status of 0 or 1 and is fit for the combination of atezolizumab, bevacizumab, carboplatin (AUC 6mg/ml/min) and paclitaxel (200mg/m²).<br>Note: the chemotherapy doses in this regimen are higher than may be the case in common practice and so careful selection of patients is required to ensure that patients can tolerate these higher doses of chemotherapy.<br>11. The patient has no symptomatically active brain metastases or leptomeningeal metastases.<br>12. A formal medical review as to whether treatment with the combination of atezolizumab, bevacizumab, carboplatin and paclitaxel should continue or not will be scheduled to occur at least by the end of the first 6 weeks of treatment.<br>13. Where a treatment break of more than 12 weeks beyond the expected cycle length is needed, a treatment break form will be completed to restart treatment, including an indication as appropriate if the patient had an extended break because of COVID 19.<br>14. Atezolizumab and bevacizumab will be otherwise used as set out in their respective Summaries of Product Characteristics. | No | TA584 | 05-Jun-19 | 05-Jul-19 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| ATE6_v1.1 | **Atezolizumab** in combination with nab-paclitaxel | For treating untreated PD-L1-positive, triple negative, unresectable, locally advanced or metastatic breast cancer for patients whose tumours express PD-L1 at a level of 1% or more where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with atezolizumab in combination with nab-paclitaxel will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The prescribing clinician is fully aware of the management of and the treatment modifications that may be required for immune-related adverse reactions due to anti-PD-L1 treatments including pneumonitis, colitis, nephritis, endocrinopathies and hepatitis and skin toxicities.<br>3. The patient has a histologically- or cytologically-confirmed diagnosis of locally advanced and unresectable or metastatic breast cancer.<br>4. The patient's breast cancer has had receptor analysis performed and this is negative for all of the following: the HER2 receptor, oestrogen receptor and progesterone receptor i.e. the patient has triple negative disease.<br>5. The patient's tumour has been tested for PD-L1 expression and demonstrates PD-L1 expression of 1% or more by an approved and validated test.<br>Note: the measurement used for PD-L1 testing in the registration trial was defined as the presence of discernible PD-L1 staining of any intensity in tumour infiltrating immune cells covering 1% or more of the tumour area occupied by tumour cells, associated intra-tumoural and contiguous peri-tumoural desmoplastic stroma.<br>Please document the actual PD-L1 expression below:<br>PD-L1 expression: _____<br>6. The patient has had no prior systemic therapy for the unresectable and locally advanced or metastatic breast cancer indication.<br>7. **Either** the patient has never had any prior treatment with anti-PD-L1/PD-1 therapy for the breast cancer **or** the only previous anti-PD-1/PD-L1 treatment that the patient has received was with prior neoadjuvant and adjuvant therapy **and** there was no disease progression during such treatment and for at least 12 months after completion of anti-PD-1/PD-L1 therapy.<br><br>Please mark below which of these clinical scenarios applies to this patient:<br>- the patient has never had any prior treatment with anti-PD-1/PD-L1 therapy for the breast cancer or<br>- the only previous anti-PD-1/PD-L1 treatment that the patient has received was prior neoadjuvant and adjuvant therapy **and** there was no disease progression during such treatment and for at least 12 months after completion of anti-PD-1/PD-L1 therapy<br><br>Please document in the box below the time gap in months between completion of the previous neoadjuvant and adjuvant anti-PD-1/PD-L1 immunotherapy and the first diagnosis of disease relapse. If the patient has never had such immunotherapy, please type 'n/a'.<br>Time gap in months after the completion of previous neoadjuvant and adjuvant anti-PD-1/PD-L1 immunotherapy and the first diagnosis of disease relapse:<br>8. The patient is eligible for taxane monotherapy as 1st line treatment for locally advanced/metastatic breast cancer and that only the combination of atezolizumab plus nab-paclitaxel is being used as 1st line treatment.<br>9. The patient will be treated with either intravenous atezolizumab 840mg on days 1 and 15 or 1680mg on day 1 of a 28 day treatment cycle in combination with chemotherapy and in the absence of disease progression, treatment with these doses and schedules of atezolizumab will continue until disease progression or unacceptable toxicity or withdrawal of patient consent, whichever occurs first.<br><br>Note: there is no formal stopping rule for atezolizumab in benefitting patients as regards the duration of treatment with atezolizumab.<br><br>Note: Atezolizumab may be continued as a single agent if nab-paclitaxel has to be discontinued due to toxicity in which case atezolizumab may be given as monotherapy either **subcutaneously** at a dose of 1875mg every 3 weeks or **intravenously** at a dose of 1200mg every 3 weeks or 1680 mg every 4 weeks.<br>10. The patient will be treated with nab-paclitaxel at an initial dose of 100mg/m$^2$ on days 1, 8 and 15 of a 28 day treatment cycle with a target of at least 6 cycles and with no maximum number of cycles as long as in the absence of disease progression, unacceptable toxicity or withdrawal of patient consent.<br>It is important to note that this dose and schedule of nab-paclitaxel is not currently the licensed dose and schedule in metastatic breast cancer.<br>11. The patient has an ECOG performance status (PS) of 0 or 1.<br>12. The patient has no symptomatically active brain metastases or leptomeningeal metastases.<br>13. A formal medical review as to how atezolizumab and nab-paclitaxel are being tolerated and whether treatment with the combination of atezolizumab and nab-paclitaxel should continue or not will be scheduled to occur at least by the end of the first 8 weeks of treatment.<br>14. Where a treatment break of more than 12 weeks beyond the expected 4 weekly cycle length is needed, I will complete a treatment break approval form to restart treatment, including indicating as appropriate if the patient had an extended break because of COVID 19.<br>15. Atezolizumab and nab-paclitaxel will be otherwise used as set out in their respective Summary of Product Characteristics (SPCs). | No | TA639 | 01-Jul-20 | 31-Jul-20 |
| ATE7 | **Atezolizumab** in combination with carboplatin and etoposide | For the first-line treatment of adult patients with extensive-stage small cell lung cancer where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti -cancer therapy with atezolizumab in combination with carboplatin and etoposide will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The prescribing clinician is fully aware of the management of and the treatment modifications that may be required for immune-related adverse reactions due to anti-PD-L1 treatments including pneumonitis, colitis, nephritis, endocrinopathies, hepatitis and skin toxicity.<br>3. The patient has a histologically or cytologically determined diagnosis of small cell lung cancer (SCLC).<br>4. The patient has been staged as having extensive stage small cell lung cancer.<br>5. The patient has not received previous systemic therapy for his/her extensive stage disease. Previous treatment with concurrent chemoradiotherapy for limited stage SCLC is allowed as long as therapy was completed at least 6 months prior to the diagnosis of recurrent and extensive stage disease.<br>6. The patient has an ECOG performance status score of 0 or 1.<br>7. The patient will be treated with a maximum of four 3-weekly cycles of atezolizumab in combination with carboplatin (AUC 5mg/ml/min) and etoposide (100mg/m$^2$ IV on days 1-3 or oral equivalent on days 2-3).<br>8. On completion of 4 cycles of atezolizumab in combination with carboplatin and etoposide and in the absence of disease progression, treatment with atezolizumab maintenance monotherapy will continue until disease progression or symptomatic deterioration or unacceptable toxicity or withdrawal of patient consent, whichever occurs first.<br>9. Atezolizumab will be administered either **subcutaneously** at a dose of 1875mg every 3 weeks or **intravenously** at a dose of 1200mg every 3 weeks or 1680 mg every 4 weeks.<br>10. The patient has no symptomatically active brain metastases or leptomeningeal metastases.<br>11. The patient has had no prior treatment with anti-PD-L1/PD-1 therapy for small cell lung cancer.<br>12. A formal medical review as to how treatment with atezolizumab in combination with carboplatin plus etoposide is being tolerated and whether treatment with atezolizumab plus chemotherapy should continue or not will be scheduled to occur at least by the end of the first 6 weeks of treatment<br>13. Where treatment break of more than 12 weeks beyond the expected 3-weekly or 4-weekly cycle length is needed, I confirm that I will complete a treatment break approval form to restart treatment.<br>14. Atezolizumab, carboplatin and etoposide will be otherwise used as set out in their respective Summary of Product Characteristics (SPCs). | No | TA638 | 01-Jul-20 | 31-Jul-20 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| ATE8 | **Atezolizumab** in combination with bevacizumab | For the first-line systemic treatment of adult patients with locally advanced or metastatic and/or unresectable hepatocellular carcinoma where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with atezolizumab in combination with bevacizumab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a diagnosis of hepatocellular carcinoma and that one of the following applies to the patient (please tick appropriate box below as to which option applies):<br><br>- either option 1 applies in which case the patient has a confirmed histological diagnosis of hepatocellular carcinoma (HCC)<br>-or option 2 applies in which case a biopsy is deemed to be very high risk or technically not feasible in the patient and both the criteria a and b below are also both met:<br>**a:** the decision not to biopsy has been made and documented by a specialist HCC multi-disciplinary team meeting<br>**and b:** the tumour meets the non-invasive diagnostic criteria of HCC as set out below*.<br><br>It is expected that option 2 will only apply in exceptional circumstances.<br><br>Please mark below which of these 2 clinical scenarios applies to this patient:<br>Option 1: the patient has a confirmed histological diagnosis of hepatocellular carcinoma or<br>Option 2: the patient cannot be biopsied on account of high risk or technical lack of feasibility and the above criteria for option 2 all apply.<br><br>*EASL-EORTC Clinical Practice Guidelines: Management, Journal of Hepatology 2012 vol 56 p908-943. Non-invasive criteria can only be applied to cirrhotic patients and are based on imaging techniques obtained by 4-phase multidetector CT scan or dynamic contrast-enhanced MRI. Diagnosis should be based on the identification of the typical hallmark of HCC (hypervascular in the arterial phase with washout in the portal venous or delayed phases). While one imaging technique is required for nodules beyond 1cm in diameter, a more conservative approach with 2 techniques is recommended in suboptimal settings.<br>3. The patient has metastatic or locally advanced disease that is ineligible for or has failed surgical or loco-regional therapies.<br>4. The patient has Child-Pugh A liver function.<br>5. The patient has not received previous systemic therapy for his/her hepatocellular carcinoma.<br>Note: previous systemic treatment with sorafenib or lenvatinib or regorafenib or any immunotherapy or any systemic chemotherapy is not allowed.<br>6. The patient has an ECOG performance status score of 0 or 1.<br>7. Treatment with atezolizumab in combination with bevacizumab will continue until loss of clinical benefit or unacceptable toxicity or withdrawal of patient consent, whichever occurs first.<br>If either atezolizumab or bevacizumab has to be discontinued on account of toxicity and the patient is otherwise benefitting from therapy, treatment should continue with the remaining agent until loss of clinical benefit or unacceptable toxicity or withdrawal of patient consent.<br>8. The patient has no symptomatically active brain metastases or leptomeningeal metastases.<br>9. The patient has not received prior treatment with an anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CD137, or anti-Cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) antibody.<br>10. Atezolizumab will be administered either **subcutaneously** at a dose of 1875mg every 3 weeks or **intravenously** at a dose of 1200mg every 3 weeks or 1680 mg every 4 weeks.<br>11. When a treatment break of more than 12 weeks beyond the expected 3-weekly cycle length is needed, I will complete a treatment break form to restart treatment.<br>12. On discontinuation of the combination of atezolizumab and bevacizumab on account of loss of clinical benefit or treatment intolerance and if the patient is fit for further systemic therapy, the next line of treatment would be a<br>13. Atezolizumab and bevacizumab will otherwise be used as set out in their respective Summary of Product Characteristics (SPCs). | No | TA666 | 16-Dec-20 | 15-Jan-21 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| ATE9 | **Atezolizumab** | Atezolizumab monotherapy for the first line treatment of locally advanced or metastatic non-small cell lung cancer which has PD-L1 expression in at least 50% of tumour cells or in at least 10% of tumour-infiltrating immune cells where all the following criteria are met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with atezolizumab monotherapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a histologically- or cytologically-confirmed diagnosis of non-small cell lung cancer (squamous or non-squamous).<br>Please mark below which histology applies to this patient:<br>- squamous NSCLC<br>- non-squamous NSCLC<br>3. The patient has stage IIIB or IIIC or IV NSCLC or has disease that has recurred after previous potentially curative local management of NSCLC with surgery/chemoradiotherapy/radiotherapy.<br>4. An approved and validated test has demonstrated that there is PD-L1 expression in **at least 50% of tumour cells or in at least 10% of tumour-infiltrating immune cells.**<br>Please document the tumour PD-L1 expression in this box:_____<br>or the PD-L1 expression in tumour-infiltrating immune cells:_____<br>5. **Either** the patient has been documented as NOT having a NSCLC which harbours an EGFR 19 or 21 mutation or an ALK gene fusion or the patient has a squamous cell carcinoma and a decision to not test for an EGFR 19 or 21 mutation or an ALK gene fusion and proceed with atezolizumab has been discussed with the patient during the consenting process, i.e. the patient has consented to be treated with an unknown EGFR/ ALK status.<br>Please mark below which option applies to this patient:<br>- Documented as NOT having a NSCLC which harbours an EGFR 19 or 21 mutation or an ALK gene fusion<br>- Patient has squamous NSCLC and a decision to not test for an EGFR 19 or 21 mutation or an ALK gene fusion and proceed with atezolizumab has been discussed with the patient during the consenting process.<br>6. **Either** the patient has not received any previous systemic therapy for NSCLC or the patient completed the last treatment with chemotherapy or chemoradiotherapy or checkpoint inhibitor immunotherapy as part of adjuvant/neoadjuvant/maintenance therapy at least 6 months prior to the first diagnosis of locally recurrent or metastatic disease or the patient has a BRAFV600 mutation, or MET alteration, and has received 1st line therapy with a suitable targeted agent, and has now progressed on, or was unable to tolerate, the targeted agent.<br>Please indicate below whther the patient has received any previous systematic therapy for NSCLC:<br>- the patient has not been previously treated with any adjuvant or neoadjuvant or maintenance systemic therapy for NSCLC or<br>- the patient has been previously treated with adjuvant systemic therapy for NSCLC and this was completed more than 6 months before first diagnosis of recurrent or metastatic disease or<br>- the patient has been previously treated with neoadjuvant systemic therapy for NSCLC and this was completed more than 6 months before first diagnosis of recurrent or metastatic disease or<br>- the patient has been previously treated with maintenance systemic therapy for NSCLC and this was completed more than 6 months before first diagnosis of recurrent or metastatic disease<br>- the patient has a BRAFV600 mutation, or MET alteration, and has received 1st line therapy with a suitable targeted agent, and has now progressed on, or was unable to tolerate, the targeted agent.<br>7. The patient has not received prior treatment with an anti PD-1, anti-PD-L1, anti-PD-L2, anti-CD137 or anti-cytotoxic T-lymphocyte-associated antigen-4 (CTL-4) antibody unless the patient discontinued or completed checkpoint inhibitor immunotherapy as part of adjuvant/neoadjuvant/maintenance therapy **without disease progression and at least 6 months elapsed between the date of the last immunotherapy treatment and the date of first diagnosis of relapse with recurrent or metastatic disease.**<br><br>Note: NHS England does not commission re-treatment with checkpoint inhibitor therapy for patients who have discontinued or completed previous checkpoint inhibitor therapy for the locally advanced/metastatic indication.<br><br>Please mark below if the patient received previous checkpoint inhibitor therapy and in which setting:<br>- the patient has never received any immunotherapy for NSCLC. If so, please type 'n/a' in the 'Time gap' box below or<br>- the patient has previously been treated with adjuvant immunotherapy for NSCLC and discontinued immunotherapy without disease progression and at least 6 months prior to the first diagnosis of relapse. Please document in the box below the time gap in months between completion of previous adjuvant immunotherapy and first diagnosis of disease relapse or<br>- the patient has previously been treated with neoadjuvant immunotherapy for NSCLC and discontinued immunotherapy without disease progression and at least 6 months prior to the first diagnosis of relapse. Please document in the box below the time gap in months between completion of previous neoadjuvant immunotherapy and first diagnosis of disease relapse or<br>- the patient has previously been treated with maintenance immunotherapy post chemoradiotherapy for NSCLC and discontinued immunotherapy without disease progression and at least 6 months prior to the first diagnosis of relapse. Please document in the box below the time gap in months between completion of previous maintenance immunotherapy and first diagnosis of disease relapse<br><br>Time gap in months after completion of previous adjuvant or neoadjuvant or maintenance checkpoint inhibitor immunotherapy and first diagnosis of disease relapse:_____<br>Note: the mandatory interval between the last date of administration of any prior adjuvant/neoadjuvant/maintenance immunotherapy and the date of first relapse is **at least 6 months**. For patients suffering a first relapse within 6-12 months of previous immunotherapy, clinicians should bear in mind the long elimination half-lives of immunotherapies and make individual assessments of the overall benefit/risk ratio of re-treatment with immunotherapy.<br>8. Atezolizumab will be administered either subcutaneously at a dose of 1875mg every 3 weeks or intravenously at a dose of 1200mg every 3 weeks or 1680 mg every 4 weeks.<br>9. Atezolizumab will be stopped at disease progression or unacceptable toxicity or withdrawal of patient consent, whichever occurs first.<br>Note: there is **NO** stopping rule for atezolizumab in this indication and hence patients continuing to benefit from atezolizumab after 2 years of treatment can continue if the patient and clinician agree. Note: once atezolizumab is stopped for disease progression or unacceptable toxicity or withdrawal of patient consent, atezolizumab cannot be re-started.<br>10. The patient has an ECOG performance status (PS) of 0 or 1.<br>11. The patient has no symptomatically active brain metastases or leptomeningeal metastases.<br>12. When a treatment break of more than 12 weeks beyond the expected 3- or 4-weekly cycle length is needed, I will complete a treatment break approval form, which must be approved **BEFORE** treatment with atezolizumab is re-started<br>13. Atezolizumab will otherwise be used as set out in its Summary of Product Characteristics (SPC). | No | TA705 | 02-Jun-21 | 31-Aug-21 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| ATE10 | **Atezolizumab** | Atezolizumab monotherapy for adjuvant treatment after complete tumour resection in adult patients with UICC/AJCC 8th edition stage IIB or IIIA or N2 only IIIB non-small cell lung cancer and whose disease is all of the following: has PD-L1 expression on ≥50% of tumour cells, is not EGFR mutant or ALK-positive and has not progressed on recently completed adjuvant platinum-based chemotherapy where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with adjuvant atezolizumab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The prescribing clinician is fully aware of the management of and the treatment modifications that may be required for immune-related adverse reactions due to anti-PD-L1 treatments including pneumonitis, colitis, nephritis, endocrinopathies, hepatitis and skin toxicity.<br>3. The patient has a histologically documented diagnosis of non-small cell lung cancer (NSCLC).<br>Please mark below which histology applies to this patient:<br>- squamous NSCLC<br>- non-squamous NSCLC<br>4. The patient's NSCLC has been documented as exhibiting PD-L1 expression on ≥50% of tumour cells as determined by an approved and validated PD-L1 assay.<br>Please document below the actual PD-L1 expression on tumour cells (e.g. if 80%, please type just the number 80):<br>5. The patient either has been documented as NOT having a NSCLC which harbours an EGFR 19 or 21 mutation or an ALK gene fusion or the patient has a squamous cell carcinoma and a decision to not test for an EGFR 19 or 21 mutation or an ALK gene fusion and proceed with neoadjuvant atezolizumab has been made following discussion at the Lung Cancer MDT and consideration of the relevant patient characteristics (including age and smoking status).<br><br>Please mark below which option applies to this patient:<br>- Documented as NOT having a NSCLC which harbours an EGFR 19 or 21 mutation or an ALK gene fusion<br>- Patient has squamous NSCLC and a decision to not test for an EGFR 19 or 21 mutation or an ALK gene fusion and proceed with atezolizumab has been made following discussion at the Lung Cancer MDT.<br><br>Note: the marketing authorisation for adjuvant atezolizumab in this indication changed in November 2024 to exclude NSCLCs bearing EGFR mutations and ALK gene rearrangements.<br>6. The patient either has been documented as having any other actionable NSCLC mutation or not: ROS1, RET, KRAS G12C, MET14 or BRAF.<br><br>Please mark in the box below whether such an actionable mutation has been found or not:<br>- only testing for an EGFR mutations and ALK gene rearrangements have been done and the results are negative<br>- genomic testing has not been done for all the other genomic alterations listed below and any results so far have been negative<br>- genomic testing has been done for all the other genomic alterations listed below and results are all negative<br>- the patient's NSCLC is positive for a ROS1 gene rearrangement<br>- the patient's NSCLC is positive for a RET gene fusion<br>- the patient's NSCLC is positive for a KRAS G12C mutation<br>- the patient's NSCLC is positive for a MET exon 14 skipping mutation<br>- the patient's NSCLC is positive for a BRAF mutation<br>7. The patient had M0 disease prior to surgery and has undergone a complete resection of the primary NSCLC with all surgical margins negative for tumour i.e. a R0 resection has taken place.<br>8. The pathological TNM stage determined on this patient's surgical NSCLC specimen was a stage IIB or IIIA or N2 only IIIB tumour according to the UICC/AJCC TNM 8th edition.<br>Please mark below which stage applies to this patient:<br>- stage IIB disease (T1a N1 or T1b N1 or T1c N1 or T2a N1 or T2b N1 or T3 N0)<br>- stage IIIA disease (T1a N2 or T1b N2 or T1c N2 or T2a N2 or T2b N2 or T3 N1 or T4 N0 or T4 N1)<br>- N2 only stage IIIB disease (T3 N2 or T4 N2)<br>Note: the trial included patients staged using the UICC/AJCC TNM 7th edition and hence the marketing authorisation uses the 7th edition staging system. As NSCLC surgical resection specimens are now reported using the UICC/AJCC TNM 8th edition, the corresponding 7th edition stages included in the marketing authorisation have been translated into those of the 8th edition.<br>9. The patient commenced adjuvant platinum-based chemotherapy within 12 weeks of resection of the NSCLC.<br>NB The marketing authorisation of atezolizumab in this adjuvant NSCLC indication stipulates that patients must have received adjuvant chemotherapy prior to commencing adjuvant atezolizumab.<br>10. The patient has received a maximum of 4 cycles of adjuvant platinum-based chemotherapy.<br>Please mark below how many cycles of adjuvant chemotherapy were received by this patient:<br>- 1 cycle of adjuvant chemotherapy<br>- 2 cycles of adjuvant chemotherapy<br>- 3 cycles of adjuvant chemotherapy<br>- 4 cycles of adjuvant chemotherapy<br>11. The patient has been radiologically re-staged after completion of adjuvant chemotherapy and continues to have no evidence of residual or metastatic disease.<br>12. No more than 12 weeks have elapsed since the start of the last cycle of adjuvant platinum-based chemotherapy.<br>13. The patient has not received prior treatment with an anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CD137, or anti-Cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) antibody.<br>14. The patient has an ECOG performance status (PS) of 0 or 1.<br>**(continues on next page)** | No | TA1071 | 19-Jun-25 | 21-Jul-25 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| ATE10 | **Atezolizumab** | Atezolizumab monotherapy for adjuvant treatment after complete tumour resection in adult patients with UICC/AJCC 8th edition stage IIB or IIIA or N2 only IIIB non-small cell lung cancer and whose disease is all of the following: has PD-L1 expression on ≥50% of tumour cells, is not EGFR mutant or ALK-positive and has not progressed on recently completed adjuvant platinum-based chemotherapy where the following criteria have been met: | 15. Atezolizumab will be stopped at whichever of the following events occurs first: disease progression or unacceptable toxicity or withdrawal of patient consent **or on completion of 1 year in total duration of treatment with atezolizumab** (i.e. after a maximum of 17 x 3-weekly or 13 x 4-weekly cycles).<br>Note: NHS England appreciates that the registration trial had a total treatment duration of 48 weeks but the maximum total treatment duration of 1 year is stated in atezolizumab's Summary of Product Characteristics. | No | TA1071 | 19-Jun-25 | 21-Jul-25 |
| | | | 16. Atezolizumab will be administered as monotherapy either subcutaneously at a dose of 1875mg every 3 weeks or intravenously at a dose of 1200mg every 3 weeks or 1680 mg every 4 weeks. | | | | |
| | | | 17. A formal medical review as to how atezolizumab is being tolerated and whether treatment with atezolizumab should continue or not will be scheduled to occur at least by the end of the second month of treatment. | | | | |
| | | | 18. When a treatment break of more than 3 months beyond the expected 3- or 4-weekly (or exceptionally 2- or 3-weekly) cycle length is needed, I will complete a treatment break approval form to restart treatment. | | | | |
| | | | 19. Atezolizumab will be otherwise used as set out in its Summary of Product Characteristics (SPC). | | | | |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| AVA1 | **Avapritinib monotherapy** | For the treatment of aggressive systemic mastocytosis or aggressive systemic mastocytosis with an associated haematological neoplasm or mast cell leukaemia where the following criteria have been met: | 1. This application for avapritinib monotherapy is being made by and the first cycle of systemic anti-cancer therapy with avapritinib monotherapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient is an adult and has a pathologically-confirmed diagnosis of aggressive systemic mastocytosis (ASM) or aggressive systemic mastocytosis with an associated haematological neoplasm (ASM-AHN) or mast cell leukaemia.<br>3. The patient has advanced disease and requires systemic therapy for this condition.<br>4. The patient has previously received systemic therapy for this condition or not.<br><br>Please mark below whether the patient has/has not previously received any systemic therapy for this condition:<br>- no, this patient has not received any previous systemic therapy for this condition<br>- yes, this patient has been previously treated with systemic therapy for this condition<br>5. The patient has previously received midostaurin or not.<br><br>Please mark below whether the patient has previously received treatment with midostaurin or not:<br>- no, this patient has not received previous midostaurin<br>- yes, this patient has received previous midostaurin<br>6. The patient has not previously received treatment with avapritinib unless this was via a company early access scheme and all treatment criteria on this form are complied with.<br>7. The patient has an ECOG performance status (PS) of 0 or 1 or 2 or 3 and is fit enough for treatment with avapritinib.<br>8. Avapritinib will be administered as monotherapy.<br>9. Avapritinib will be continued until loss of clinical benefit or the development of unacceptable toxicity or withdrawal of patient consent, whichever occurs first.<br>10. The prescribing clinician is aware of the need for caution and potential dose changes in the prescribing of avapritinib with strong or moderate CYP3A inhibitors and inducers, as set out in the avapritinib Summary of Product Characteristics (SPC).<br>11. The prescribing clinician is aware that before initiating treatment with avapritinib the risk of intracranial haemorrhage should be carefully considered in patients with relevant risk factors such as severe thrombocytopenia, vascular<br>12. The prescribing clinician is aware that 2-weekly full blood counts are necessary for the first 8 weeks of treatment, then 2-weekly if the platelet count is <75 x $10^9$/L, 4-weekly if the platelet count is 75-100 x $10^9$/L and as required if the platelet count is >100 x $10^9$/L.<br>13. A formal medical review as to how avapritinib is being tolerated and whether avapritinib should continue or not will be scheduled to occur at least by the end of the second 4-weekly cycle of treatment.<br>14. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, a treatment break approval form will be completed to restart treatment.<br>15. Avapritinib will otherwise be used as set out in its Summary of Product Characteristics (SPC). | No | TA1012 | 06-Nov-24 | 04-Feb-25 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| AVE1 | **Avelumab** | The treatment of previously untreated (with systemic therapy) metastatic Merkel cell carcinoma where all the following criteria are met: | 1. An application is made by and the first cycle of systemic anti-cancer therapy with avelumab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy | No | TA691 | 21-Apr-21 | 20-Jul-21 |
| | | | 2. The prescribing clinician is fully aware of the management of and the treatment modifications that may be required for the immune-related adverse reactions due to anti-PD-L1 treatments including pneumonitis, colitis, nephritis, endocrinopathies and hepatitis | | | | |
| | | | 3. The patient has a confirmed histological or cytological diagnosis of Merkel cell carcinoma | | | | |
| | | | 4. The patient has metastatic disease | | | | |
| | | | 5. The patient is treatment naïve to any systemic anti-cancer therapy for Merkel cell carcinoma and in particular has not received any prior treatment with any anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CD137 or anti-cytotoxic T-lymphocyte-associated antigen-4 [CTLA-4] antibody | | | | |
| | | | 6. The patient has an ECOG performance status of either 0 or 1. Note: a patient with a performance status of 2 or more is not eligible for avelumab | | | | |
| | | | 7. If the patient has brain metastases, then these have been treated and are stable | | | | |
| | | | 8. Avelumab is to be used as monotherapy only | | | | |
| | | | 9. Avelumab is to be continued until loss of clinical benefit or unacceptable toxicity or patient choice to stop treatment. I also confirm that patients with radiological disease progression not associated with significant clinical deterioration (defined as no new or worsening symptoms **and** no change in performance status for greater than 2 weeks **and** no need for salvage therapy: all 3 conditions must apply) can continue treatment | | | | |
| | | | 10. A formal medical review as to whether treatment with avelumab should continue or not will be scheduled to occur at least by the end of the first 8 weeks of treatment | | | | |
| | | | 11. Where a treatment break of more than 12 weeks beyond the expected cycle length of avelumab is needed, I will complete a treatment break approval form to restart treatment, including indicating as appropriate if the patient had an extended break because of COVID 19. | | | | |
| | | | 12. Avelumab will otherwise be used as set out in its Summary of Product Characteristics (SPC). | | | | |
| AVE2 | **Avelumab** | The treatment of previously treated (with systemic cytotoxic chemotherapy) metastatic Merkel cell carcinoma where all the following criteria are met: | 1. An application is made by and the first cycle of systemic anti-cancer therapy with avelumab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy | No | TA517 | 11-Apr-18 | 10-Jul-18 |
| | | | 2. The prescribing clinician is fully aware of the management of and the treatment modifications that may be required for the immune-related adverse reactions due to anti-PD-L1 treatments including pneumonitis, colitis, nephritis, endocrinopathies and hepatitis | | | | |
| | | | 3. The patient has a confirmed histological or cytological diagnosis of Merkel cell carcinoma | | | | |
| | | | 4. The patient has metastatic disease | | | | |
| | | | 5. I confirm that the patient has previously been treated with cytotoxic chemotherapy for metastatic Merkel cell carcinoma and has not received any prior treatment with any anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CD137 or anti-cytotoxic T-lymphocyte-associated antigen-4 [CTLA-4] antibody | | | | |
| | | | 6. The patient has an ECOG performance status of either 0 or 1. Note: a patient with a performance status of 2 or more is not eligible for avelumab | | | | |
| | | | 7. If the patient has brain metastases, then these have been treated and are stable | | | | |
| | | | 8. Avelumab is to be used as monotherapy only | | | | |
| | | | 9. Avelumab is to be continued until loss of clinical benefit or unacceptable toxicity or patient choice to stop treatment. I also confirm that patients with radiological disease progression not associated with significant clinical deterioration (defined as no new or worsening symptoms **and** no change in performance status for greater than 2 weeks **and** no need for salvage therapy: all 3 conditions must apply) can continue treatment | | | | |
| | | | 10. A formal medical review as to whether treatment with avelumab should continue or not will be scheduled to occur at least by the end of the first 8 weeks of treatment | | | | |
| | | | 11. Treatment breaks of up to 12 weeks beyond the expected cycle length of avelumab are allowed but solely to allow immune toxicities to settle | | | | |
| | | | 12. Avelumab will otherwise be used as set out in its Summary of Product Characteristics (SPC) | | | | |

# National Cancer Drugs Fund (CDF) List

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| AVE3 | **Avelumab** in combination with axitinib | For use in treatment-naïve patients with advanced, favourable risk, renal cell carcinoma where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with the combination of avelumab and axitinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has unresectable locally advanced or metastatic renal cell carcinoma (RCC) which has either a clear cell component or is one of the types of RCC as indicated below.<br>Please indicate below which RCC histology applies to this patient:<br>- RCC with a clear cell component **or**<br>- Papillary RCC **or**<br>- Chromophobe RCC **or**<br>- Collecting duct RCC (Bellini collecting duct RCC) **or**<br>- Medullary RCC **or**<br>- Mucinous tubular and spindle cell RCC **or**<br>- Multilocular cystic RCC **or**<br>- XP11 translocation RCC **or**<br>- Unclassified RCC<br>3. The prescribing clinician confirms that the risk status as assessed by the International Metastatic RCC Database Consortium (IMDC) system for this patient is FAVOURABLE-RISK (i.e. no risk factors present, and therefore an IMDC score of zero)<br><br>Note: The combination of avelumab and axitinib **CANNOT** be used for patients who have an IMDC risk status of intermediate or poor.<br>4. The patient is either completely treatment naïve for systemic immune-modulatory therapy for RCC or if the patient has received prior systemic immune-modulatory therapy in the context of adjuvant/neoadjuvant therapy, then such treatment was completed 12 or more months previously and the patient meets all other criteria listed here.<br>Please mark below whether or not previous systemic immune-modulatory therapy has been received in the adjuvant/neoadjuvant setting:<br>- **no previous adjuvant/neoadjuvant** systemic immune-modulatory therapy of any kind and the patient is treatment naïve for the locally advanced/metastatic RCC indication or<br>- **prior adjuvant/neoadjuvant therapy** with immune-modulatory therapies for RCC anti-Programmed Death receptor-1 (PD-1), anti-Programmed Death-1 ligand-1 (PD-L1), anti-PD L2, anti-CD137 or anti-cytotoxic T lymphocyte associated antigen-4 (anti-CTLA-4) antibodies and last dose received by the patient was 12 or more months prior to this application and the patient is treatment-naïve for the locally advanced/metastatic RCC indication<br>Please mark in the box the time since end of treatment with adjuvant/neoadjuvant immune-modulatory therapy:<br>_____<br>5. The patient has an ECOG performance status of 0 or 1.<br>6. The patient has no symptomatic brain metastases or leptomeningeal metastases currently requiring steroids for symptom control.<br>7. The patient is to be treated until loss of clinical benefit or excessive toxicity or patient choice, whichever is the sooner.<br>Note: there is no stopping rule as to the maximum treatment duration of avelumab plus axitinib in this indication.<br>Note: if either avelumab or axitinib has to be permanently discontinued on account of toxicity, treatment with the other drug can be continued as monotherapy as long as there is no evidence of progressive disease.<br>8. Avelumab and axitinib will otherwise be prescribed and administered as outlined in their respective Summary of Product Characteristics (SPCs).<br>9. When a treatment break of more than 12 weeks beyond the expected 4-weekly cycle length is needed, the prescribing clinician will complete a treatment break approval form to restart treatment, which MUST be approved before treatment is recommenced.<br>10. If the disease progresses on the avelumab and axitinib combination and further systemic therapy is appropriate, the next line of treatment will be chosen from those options which are routinely commissioned ie for the next line of systemic therapy, there will be use of one choice of the following (mainly incorporating TKI options which have multiple modes of action [so-called 'dirty' TKIs)]: the currently commissioned 2nd line options of **cabozantinib** or **lenvatinib plus everolimus** or **everolimus monotherapy** or the currently commissioned 1st line options of **sunitinib** (still on label as 2nd line treatment) or **pazopanib** (off label as 2nd line treatment, or **tivozanib** (off-label as 2nd line treatment). | No | TA1120 | 08-Jan-26 | 07-Feb-26 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| AVE4 | **Avelumab** | Avelumab monotherapy for the maintenance treatment of adult patients with locally advanced or metastatic urothelial carcinoma who have just completed and not progressed on 1st line platinum-containing combination chemotherapy where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with avelumab monotherapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a histologically confirmed diagnosis of locally advanced or metastatic urothelial carcinoma.<br>3. The patient has recently completed 1st line combination chemotherapy with either the combination of gemcitabine plus cisplatin or gemcitabine plus carboplatin.<br><br>Please enter below whether the patient commenced 1st line chemotherapy with either gemcitabine plus cisplatin or gemcitabine plus carboplatin:<br>- 1st line commenced with gemcitabine plus cisplatin<br>- 1st line chemotherapy commenced with gemcitabine plus carboplatin.<br>4. The patient has completed at least 3 cycles and no more than 6 cycles of combination chemotherapy with gemcitabine plus cisplatin or gemcitabine plus carboplatin.<br>5. The patient had a CT or MR scan after completing this chemotherapy and has been shown to have no evidence of progressive disease compared with the scans performed prior to chemotherapy and with any scans whilst on chemotherapy.<br><br>Please enter below the response status of the tumour as assessed radiologically at the end of chemotherapy:<br>- complete response to treatment at the end of 1st line chemotherapy<br>- partial response to treatment at the end of 1st line chemotherapy<br>- stable disease at the end of 1st line chemotherapy.<br><br>Note: patients who have responded to chemotherapy as demonstrated on an interval scan during chemotherapy but whose scans at the end of chemotherapy show progressive disease are NOT eligible for maintenance avelumab therapy.<br>6. The patient will commence treatment with avelumab within 4 to 10 weeks of receiving the last dose of chemotherapy.<br>7. The patient has an ECOG performance status score of 0 or 1.<br>8. Maintenance treatment with avelumab monotherapy will continue until disease progression or symptomatic deterioration or unacceptable toxicity or withdrawal of patient consent or **after a maximum of 5 calendar years of avelumab treatment** (as measured from cycle 1 day 1 of avelumab administration), whichever of these events occurs first.<br>9. The patient has no symptomatically active brain metastases or leptomeningeal metastases.<br>10. The patient has not received prior treatment with an anti PD-1, anti-PD-L1, anti-PD-L2, anti-CD137 or anti-cytotoxic T-lymphocyte-associated antigen-4 (CTL-4) antibody unless the patient completed or discontinued checkpoint inhibitor immunotherapy as part of adjuvant or neoadjuvant therapy **without disease progression on treatment and at least 12 months elapsed between the date of last immunotherapy treatment and the date of first diagnosis of relapse with recurrent or metastatic disease.**<br>Note: NHS England does not commission any re-treatment with checkpoint inhibitor therapy for patients who have discontinued or completed previous checkpoint inhibitor therapy for the locally advanced/metastatic indication.<br><br>Please mark below if the patient has received previous checkpoint inhibitor therapy and in which setting:<br>- the patient has never received any immunotherapy for urothelial cancer. If so, please type 'n/a' in the 'Time gap' box below or<br>- the patient has previously been treated with adjuvant immunotherapy for urothelial cancer and discontinued immunotherapy without disease progression and at least 12 months prior to the first diagnosis of disease relapse. Please document in the box below the time gap in months between completion of previous adjuvant immunotherapy and first diagnosis of disease relapse or<br>- the patient has previously been treated with neoadjuvant treatment containing immunotherapy for urothelial cancer and discontinued immunotherapy without disease progression and at least 12 months prior to the first diagnosis of disease relapse. Please document in the box below the time gap in months between completion of previous neoadjuvant immunotherapy and first diagnosis of disease relapse<br><br>Time gap in months after completion of previous adjuvant or neoadjuvant or maintenance checkpoint inhibitor immunotherapy and first diagnosis of disease relapse: _____<br>11. When a treatment break of more than 12 weeks beyond the expected 2-weekly cycle length is needed, I will complete a treatment break form to restart treatment which MUST be approved before treatment is restarted.<br>12. Avelumab will otherwise be used as set out in its Summary of Product Characteristics (SPC). | No | TA788 | 11-May-22 | 10-Jun-22 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| AXI01a | **Axicabtagene ciloleucel** | Axicabtagene ciloleucel for treating relapsed/refractory diffuse large B-cell lymphoma (DLBCL), primary mediastinal B-cell lymphoma (PMBCL) and transformed lymphoma to DLBCL in patients previously treated with two or more lines of systemic therapy where the following criteria are met:<br><br>*This form is for the approval of leucapheresis and manufacture of CAR-T cells. There is a second part to this form which relates to the subsequent infusion of CAR-T cells and this will be available after submission of the first part. The second part of the form (AXI01b) can only be completed as a continuation of this first part of the form (AXI01a) and must be completed on infusion of CAR-T cells otherwise the treating Trust will not be reimbursed for the cost of axicabtagene ciloleucel* | 1. This application is being made by and that leucapheresis for and treatment with axicabtagene ciloleucel-modified CAR-T cells will be initiated by a consultant haematologist or medical oncologist specifically trained and accredited in the use of systemic anti-cancer therapy and working in an accredited CAR-T cell treatment centre **and** who is a member of the National CAR-T Clinical Panel for DLBCL, PMBCL and transformed lymphoma **and** a member of the treating Trust's DLBCL, PMBCL and transformed lymphoma and CAR T cell multidisciplinary teams.<br>2. The patient is either an adult (age 18 years or over) or a post-pubescent child (age <18 years) on the date of approval for axicabtagene ciloleucel by the National CAR-T Clinical Panel.<br>Please mark below whether the patient is an adult or a post-pubescent child:<br>- the patient is an adult OR<br>- the patient is a post-pubescent child*<br>*Please note that the use of axicabtagene ciloleucel is unlicensed in patients who are under 18 years old and so the Trust policy regarding the use of unlicensed medicines should be followed.<br>3. The patient has a confirmed histological diagnosis of DLBCL or PMBCL or transformed lymphoma to DLBCL or post-transplant lymphoproliferative disorder or follicular lymphoma (FL) grade IIIB.<br>Please tick appropriately below as to which type of lymphoma the patient has:<br>- Diffuse large B-cell lymphoma (DLBCL) **or**<br>- Primary mediastinal B-cell lymphoma (PMBCL) **or**<br>- Transformed follicular lymphoma (TFL) to DLBCL **or**<br>- Transformed marginal zone lymphoma (MZL) to DLBCL **or**<br>-Transformed lymphoplasmacytoid lymphoma (LPL) to DLBCL **or**<br>- Transformation of CLL to DLBCL (Richter's transformation) **or**<br>- Transformation of nodular lymphocyte predominant Hodgkin lymphoma (NLPHL) to DLBCL **or**<br>- Post-transplant lymphoproliferative disease (PTLD) of DLBCL type and EBV positive **or**<br>- Post-transplant lymphoproliferative disease (PTLD) of DLBCL type and EBV negative **or**<br>- Follicular lymphoma grade 3B and as axicabtagene ciloleucel is unlicensed in this subtype of lymphoma, I also confirm that the Trust policy regarding the use of unlicensed medicines will be followed<br>Note: Patients with Burkitt lymphoma or primary CNS lymphoma are not eligible for treatment with axicabtagene ciloleucel.<br>4. The histological diagnosis of DLBCL or PMBCL or transformed lymphoma to DLBCL or post-transplant lymphoproliferative disorder of DLBCL type or FL grade 3B has been either made by or reviewed and confirmed by a designated lymphoma stem cell transplant centre.<br>5. Prior to consideration of CAR-T cell therapy the patient's disease has been re-biopsied unless **either** a biopsy at first relapse has shown DLBCL and there is progressive disease at second relapse at the same site **or** a biopsy is unsafe in which case the patient must have progressive disease at previously known sites of active disease. In such situations the original diagnostic biopsy review is acceptable.<br>All patients with transformed lymphoma to DLBCL (TFL, MZL, CLL, NLPHL) or PTLD of DLBCL type or FL grade 3B who fulfil criteria 6 below must have a re-biopsy and have confirmation of DLBCL or FL grade 3B histology prior to consideration of CAR-T cell therapy.<br>Please enter appropriately below as to which scenario applies to this patient:<br>- re-biopsy at first relapse confirmed DLBCL or PMBCL and the patient has progressive disease at the same site **or**<br>- re-biopsy at second relapse has confirmed DLBL or PMBCL **or**<br>- re-biopsy at first or second relapse was/is unsafe plus there is progressive disease at previously documented sites of active disease and the previous histology was DLBCL or PMBCL **or**<br>- re-biopsy at second relapse has again confirmed transformed lymphoma (TFL, MZL, CLL, NLPHL) to DLBCL **or**<br>- re-biopsy at second relapse has again confirmed PTLD of DLBCL type **or**<br>- re-biopsy at second relapse has again confirmed FL grade 3B<br>6. The patient fulfils one of the following clinical scenarios relating to the definition of relapsed or refractory lymphoma and also the need for the patient to have received at least 2 previous lines of systemic therapy: please tick the appropriate box below.<br>Refractory disease is defined as either progressive disease as the best response to the last line of systemic therapy or stable disease as the best response after at least 2 cycles of the last line of therapy with stable disease duration lasting no longer than 6 months from the last dose of the last line of systemic therapy.<br>Relapsed disease is defined as disease that responded partially or completely to the last line of therapy and has since progressed.<br>Progressive disease should be defined radiologically as per RECIST version 1.1 and be based on CT or MR scans and aided if necessary, after discussion at the National CAR T Clinical Panel, with the use of Lugano lymphoma response criteria.<br>Second line treatment regimens which are appropriate include: R-GDP, R-GemOx, R-GemCarbo, R-ESHAP, R-ICE, R-IVE, R-BendaPola and the Marietta protocol.<br>Neither radiotherapy nor steroids can be counted as a line of therapy.<br>Please tick the box below which applies to this patient:<br>- has DLBCL and received 2 or more lines of systemic therapy and relapsed after or was refractory to the last line of systemic therapy OR<br>- had DLBCL with CNS involvement at first diagnosis and treated with first line systemic therapy (eg Marietta protocol) followed by stem cell transplantation as part of first line therapy and has relapsed after or was refractory to this first line of systemic therapy OR<br>- has PMBCL and received 2 or more lines of systemic therapy and relapsed after or was refractory to the last line of systemic therapy OR<br>- has transformed lymphoma to DLBCL (TFL, MZL, CLL, NLPHL) and received 2 or more lines of systemic therapy since diagnosis of transformation and relapsed after or was refractory to the last line of systemic therapy OR<br>- has transformed lymphoma to DLBCL (TFL, MZL, NLPHL), received an anthracycline-containing regimen before transformation, and after transformation then received 1 or more lines of systemic therapy and relapsed after or was refractory to the last line of systemic therapy OR<br>- has PTLD of DLBCL type and received 2 or more lines of systemic therapy since diagnosis of PTLD of DLBCL type and relapsed after or was refractory to the last line of systemic therapy OR<br>- has FL grade 3B and received 2 or more lines of systemic therapy and relapsed after or was refractory to the last line of systemic therapy<br>7. The patient has been previously treated with at least 3 cycles (2 cycles is allowed if there is outright refractory disease) of full dose anthracycline-containing regimen for his/her lymphoma or with the Marietta protocol if presenting with CNS involvement.<br>Note: acceptable anthracycline-containing regimens include R-CHOP, Pola-R-CHP, R-CODOX-M/R-IVAC, DA-EPOC-R and the Marietta protocol.<br>8. The patient has been previously treated with at least one anti-CD20 monoclonal antibody unless there is clear documentation of the determination of CD20 negative disease.<br>9. Either the patient has not had stem cell transplantation (SCT) or has had an autologous or allogeneic SCT. Please tick one of the boxes below:<br>- has not had SCT **or**<br>- has had autologous SCT **or**<br>- has had allogeneic SCT<br>10. Either the patient has not previously been treated with an anti-CD19 antibody-drug conjugate or if previously treated with an anti-CD19 antibody-drug conjugate that a biopsy of the relapsed/refractory disease has been done and has been shown to be CD19 positive.<br>11. Whether the patient has active CNS involvement by the lymphoma or not and if present whether this is in addition to systemic disease progression or not.<br>Please tick one of the boxes below:<br>- currently no known CNS involvement **or**<br>- currently has both active CNS and systemic disease **or**<br>- currently has isolated CNS disease only<br>Note: patients with primary CNS lymphoma are not eligible for treatment with axicabtagene ciloleucel.<br>***Continued on the next page*** | Yes | TA872 | 28-Feb-23 | 29-May-23 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| AXI01a | **Axicabtagene ciloleucel** | Axicabtagene ciloleucel for treating relapsed/refractory diffuse large B-cell lymphoma (DLBCL), primary mediastinal B-cell lymphoma (PMBCL) and transformed lymphoma to DLBCL in patients previously treated with two or more lines of systemic therapy where the following criteria are met:<br><br>*This form is for the approval of leucapheresis and manufacture of CAR-T cells. There is a second part to this form which relates to the subsequent infusion of CAR-T cells and this will be available after submission of the first part. The second part of the form (AXI01b) can only be completed as a continuation of this first part of the form (AXI01a) and must be completed on infusion of CAR-T cells otherwise the treating Trust will not be reimbursed for the cost of axicabtagene ciloleucel* | 12. The patient has an ECOG performance score of 0 or 1. Please enter below as to the patient's current ECOG performance status (PS):<br>The ECOG performance status scale is as follows:<br>PS 0 The patient is fully active and able to carry on all pre-disease performance without restriction<br>PS 1 The patient is restricted in physically strenuous activity but is ambulatory and able to carry out work of a light or sedentary nature eg light house work, office work<br>PS 2 The patient is ambulatory and capable of all selfcare but unable to carry out any work activities and is up and about more than 50% of waking hours<br>PS 3 The patient is capable of only limited selfcare and is confined to bed or chair more than 50% of waking hours<br>PS 4 The patient is completely disabled, cannot carry out any selfcare and is totally confined to bed or chair<br>The patient currently has a performance status of **either**<br>- ECOG PS 0 **or**<br>- ECOG PS 1 | Yes | TA872 | 28-Feb-23 | 29-May-23 |
| | | | 13. The patient has sufficient end organ function to tolerate treatment with CAR-T cell therapy. | | | | |
| | | | 14. The patient has **either** had no previous therapy with any genetically modified autologous or allogeneic T cell immunotherapy **or** the patient has been treated with doses of genetically modified autologous or allogeneic T cell immunotherapy within an abandoned dosing cohort in a first in human dose-escalation phase I clinical trial.<br>Please tick appropriate box as to which type of previous treatment the patient has had:<br>- No previous therapy with any genetically modified autologous or allogeneic T cell immunotherapy **or**<br>- Previously treated with doses of genetically modified autologous or allogeneic T cell immunotherapy within an abandoned dosing cohort in a first in human dose-escalation phase I clinical trial | | | | |
| | | | 15. Prior to infusion 2 doses of tocilizumab are available for use in this patient in the event of the development of cytokine release syndrome. | | | | |
| | | | 16. Axicabtagene ciloleucel-modified CAR-T cell therapy will otherwise be used as set out in its Summary of Product Characteristics (SPC). | | | | |
| | | | 17. Approval for the use of axicabtagene ciloleucel has been formally given by the National DLBCL/PMBCL/TFL CAR-T cell Clinical Panel.<br>Please state date of approval (DD/MM/YYYY) | | | | |
| | | | 18. Following national approval for use of axicabtagene ciloleucel there has been local CAR-T cell multidisciplinary team agreement that this patient continues to have the necessary fitness for treatment and fulfils all of the treatment criteria listed here. | | | | |
| AXI01b | **Axicabtagene ciloleucel** | Axicabtagene ciloleucel for treating relapsed/refractory diffuse large B cell lymphoma (DLBCL), primary mediastinal B cell lymphoma (PMBCL) and transformed follicular lymphoma (TFL) to DLBCL in patients aged 18 years and over where the following criteria are met:<br><br>*This second part of the form is to document the date of infusion of CAR-T cell therapy and for registration of this infusion with NHS England so that the treating Trust is reimbursed for the cost of axicabtagene ciloleucel. There is a first part of the form for the approval of leucapheresis and manufacture of CAR-T cells which has already been completed (AXI01a). This second part of the form (AXI01b) should only be completed as a continuation form once the date of CAR-T cell infusion is known.* | 1. This application for continuation is being made by and treatment with axicabtagene ciloleucel-modified CAR-T cells will be initiated by a consultant haematologist/medical oncologist specifically trained and accredited in the use of systemic anti-cancer therapy and working in an accredited CAR-T cell treatment centre **and** who is a member of the National CAR-T Clinical Panel for DLBCL, PMBCL and TFL **and** a member of the treating Trust's DLBCL, PMBCL and TFL and CAR-T cell multidisciplinary teams. | Yes | TA872 | 28-Feb-23 | 29-May-23 |
| | | | 2. The patient has an ECOG performance score of 0 or 1 or 2. Please tick one of the boxes below as to the patient's current ECOG performance status (PS):<br>The ECOG performance status scale is as follows:<br>PS 0 The patient is fully active and able to carry on all pre-disease performance without restriction<br>PS 1 The patient is restricted in physically strenuous activity but is ambulatory and able to carry out work of a light or sedentary nature eg light house work, office work<br>PS 2 The patient is ambulatory and capable of all selfcare but unable to carry out any work activities and is up and about more than 50% of waking hours<br>PS 3 The patient is capable of only limited selfcare and is confined to bed or chair more than 50% of waking hours<br>PS 4 The patient is completely disabled, cannot carry out any selfcare and is totally confined to bed or chair<br>The patient currently has a performance status of:<br>- ECOG PS 0 **or**<br>- ECOG PS 1 **or**<br>- ECOG PS 2 | | | | |
| | | | 3. If the patient has required bridging therapy in between leucapheresis and CAR-T cell infusion, please indicate what type(s) of bridging therapy have been required by ticking the most appropriate option below:<br>- no bridging therapy at all **or**<br>- corticosteroids only **or**<br>- chemo(immuno)therapy only **or**<br>- radiotherapy only **or**<br>- corticosteroids and chemo(immuno)therapy **or**<br>- corticosteroids and radiotherapy **or**<br>- chemo(immuno)therapy and radiotherapy ± corticosteroids | | | | |
| | | | 4. The patient has sufficient end organ function to tolerate treatment with CAR-T cell therapy. | | | | |
| | | | 5. Prior to infusion 2 doses of tocilizumab are available for use in this patient in the event of the development of cytokine release syndrome. | | | | |
| | | | 6. Axicabtagene ciloleucel-modified CAR-T cell therapy will otherwise be used as set out in its Summary of Product Characteristics (SPC). | | | | |
| | | | 7. Following national approval for use of axicabtagene ciloleucel there has been local CAR-T cell multidisciplinary team agreement that this patient continues to have the necessary fitness for infusion and fulfils all of the treatment criteria listed here. | | | | |

# National Cancer Drugs Fund (CDF) List

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|---|---|---|---|---|---|---|---|
| AZA1 | **Azacitidine** | Oral azacitidine as maintenance therapy in newly diagnosed AML patients in remission following at least induction chemotherapy and who are not candidates for, or who choose not to proceed to, haemopoietic stem cell transplantation where the following treatment criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with oral azacitidine will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy. | No | TA827 | 05-Oct-22 | 02-Sep-22<br><br>(Supply available from 13-Oct-22) |
| | | | 2. The patient has newly diagnosed acute myeloid leukaemia (AML). | | | | |
| | | | 3. The patient has been treated with standard intensive cytarabine-based induction chemotherapy. | | | | |
| | | | 4. The patient has either received any consolidation chemotherapy or not. Please mark below whether consolidation chemotherapy was received or not:<br>- no consolidation chemotherapy was administered<br>- at least one cycle of consolidation chemotherapy was given | | | | |
| | | | 5. The patient is currently in complete remission (CR) or is in complete remission with incomplete blood count recovery (CRi).<br>Please mark below as to whether the patient is in CR or CRi.<br>- CR<br>- Cri | | | | |
| | | | 6. The patient is not a candidate for, or has chosen not to proceed to, haemopoietic stem cell transplantation (HSCT).<br>Please mark below the reason for not undergoing haemopietic stem cell transplantation:<br>- the patient is not medically fit for HSCT<br>- there is no suitable donor for HSCT<br>- the patient has chosen not to proceed to HSCT<br>- there is another reason for not proceeding to HSCT | | | | |
| | | | 7. Maintenance therapy with oral azacitidine will be as monotherapy. | | | | |
| | | | 8. Oral azacitidine maintenance therapy will be continued until disease progression up to a **maximum of 15% blasts** is observed in peripheral blood/bone marrow or until unacceptable toxicity occurs or there is withdrawal of patient consent, whichever is the sooner. | | | | |
| | | | 9. The prescribing clinician understands that the usual 300mg once daily 14-day treatment schedule every 28 days for oral azacitidine can be extended to a 21-day treatment schedule every 28 days if a disease relapse with a blast count of 5-15% is observed in the peripheral blood or bone marrow.<br>Note: oral azacitidine must be discontinued if the blast count exceeds 15% in the peripheral blood or bone marrow. | | | | |
| | | | 10. The patient is fit for treatment with oral azacitidine maintenance therapy and has an ECOG performance status (PS) of 0-3.<br>Please mark below the ECOG PS status:<br>- PS 0<br>- PS 1<br>- PS 2<br>- PS 3 | | | | |
| | | | 11. The prescribing clinician understands that oral azacitidine can only be prescribed in this maintenance indication in this group of AML patients and cannot be used interchangeably with injectable azacitidine. | | | | |
| | | | 12. A formal medical review as to whether treatment with oral azacitidine should continue will occur at least by the end of the second cycle of treatment. | | | | |
| | | | 13. Where a treatment break of more than 10 weeks beyond the expected cycle length is needed, the prescribing clinician will complete a treatment break approval form to restart treatment, including indicating as appropriate if the patient had an extended break because of COVID 19. | | | | |
| | | | 14. Azacitidine will be otherwise used as set out in its Summary of Product Characteristics (SPC). | | | | |

# National Cancer Drugs Fund (CDF) List

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| BELA2 | **Belantamab mafodotin with pomalidomide and dexamethasone** | Belantamab mafodotin with pomalidomide and dexamethasone as 2nd line treatment of relapsed or refractory myeloma in adult patients who previously received lenalidomide as part of 1st line systemic therapy where the following criteria have been met: | 1. This application for belantamab mafodotin in combination with pomalidomide and dexamethasone is being made by and the first cycle of systemic anti-cancer therapy with belantamab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a confirmed diagnosis of multiple myeloma.<br><br>Note: patients with amyloidosis or POEMS syndrome are not eligible for belantamab mafodotin.<br>3. This patient has received **1 and only 1** prior line of systemic therapy for myeloma and that the numbering of a line of treatment is in accordance with the International Myeloma Workshop Consensus recommendations for the uniform reporting of clinical trials (http://doi.org/10.1182/blood-2010-10-299487).<br>A line of therapy is defined as one or more cycles of a planned treatment program. This may consist of one or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner (eg 1st line induction chemotherapy/chemotherapies when followed by stem cell transplantation and maintenance therapy is considered as 1 line of therapy).<br>A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse or toxicity, the exception to this being the need to attain a sufficient response for stem cell transplantation to proceed. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease.<br><br>Note: although the marketing authorisation is for patients with myeloma who have had at least one prior therapy including lenalidomide, the company has initially sought a NICE recommendation for patients who have had only one prior line of treatment. **Patients who have had more than one prior line of therapy are not eligible for treatment with this belantamab mafodotin combination.**<br>4. This patient has been previously treated with a 1st line lenalidomide containing regimen which is commissioned by NHS England or is part of a 1st line treatment regimen in a NIHR-badged clinical trial.<br>Please confirm below which 1st line treatment was received by the patient:<br>- 1st line daratumumab plus lenalidomide and dexamethasone for transplant ineligible disease<br>- 1st line lenalidomide and dexamethasone for transplant ineligible disease maintenance lenalidomide post stem cell transplant as part of 1st line therapy lenalidomide was part of a 1st line treatment regimen in a NIHR-badged clinical trial<br>- 1st line isatuximab plus bortezomib, lenalidomide and dexamethasone for untreated multiple myeloma when a stem cell transplant is unsuitable<br><br>Note: patients who have not received lenalidomide as part of their 1st line therapy are not eligible for treatment with this belantamab mafodotin combination.<br>5. The reason for discontinuing the 1st line lenalidomide was because of either disease progression on treatment or intolerance of lenalidomide.<br><br>Please indication the reason for discontinuing the 1st line lenalidomide:<br>- disease progression on treatment or<br>- intolerance of lenalidomide<br>6. This patient has been previously treated with bortezomib or another proteasome inhibitor as part of 1st line therapy.<br><br>Please tick the appropriate box which applies to this patient:<br>- No, the patient has not been previously treated with bortezomib or any other proteasome inhibitor or<br>- Yes, the patient has been previously treated with a 1st line bortezomib-containing regimen or<br>- Yes, the patient has been previously treated with another 1st line proteasome inhibitor containing regimen in a clinical trial<br>7. This patient has been previously treated with an anti-CD38 antibody as part of 1st line therapy.<br><br>Please tick the appropriate box which applies to this patient:<br>- No, the patient has not been previously treated with an anti-CD38 antibody or<br>- Yes, the patient has been previously treated with a 1st line anti-CD38 antibody or<br>- Yes, the patient has been previously treated with another 1st line anti-CD38 antibody containing regimen in a clinical trial<br>8. The patient has been previously treated as part of 1st line therapy with stem cell transplantation.<br><br>Please tick the appropriate box which applies to this patient:<br>- No, the patient has not been previously treated as part of 1st line treatment with stem cell transplantation or<br>- Yes, the patient has been previously treated as part of 1st line treatment with stem cell transplantation<br>9. The patient has progressive disease during or following 1st line systemic anti-myeloma therapy.<br>10. The patient has an ECOG performance status of 0 or 1 or 2:<br><br>Please record below the patient's ECOG performance status:<br>- PS 0 or<br>- PS 1 or<br>- PS 2<br><br>***Continued on the next page*** | No | TA1133 | 18-Feb-26 | 20-Mar-26 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| BELA2 (CONT) | **Belantamab mafodotin with pomalidomide and dexamethasone** | Belantamab mafodotin with pomalidomide and dexamethasone as 2nd line treatment of relapsed or refractory myeloma in adult patients who previously received lenalidomide as part of 1st line systemic therapy where the following criteria have been met: | 11. Belantamab mafodotin will be used only in combination with pomalidomide and dexamethasone and not with any other anti-myeloma agents. | No | TA1133 | 18-Feb-26 | 20-Mar-26 |
| | | | 12. The prescribing clinician is aware of the risk of corneal adverse reactions with belantamab mafodotin and that an ophthalmic examination including visual acuity and slit lamp examination must be performed by an eye care professional prior to each of cycles 1, 2, 3 and 4 and then during treatment as indicated. | | | | |
| | | | 13. Arrangements have been put in place for the eye care professional to categorize both the degree of any corneal damage and the best corrected visual acuity in the most severely affected eye and for these results to be communicated to the myeloma team. | | | | |
| | | | 14. Since belantamab mafodotin dose modifications are partly based on corneal examination findings and/or changes in best corrected visual acuity, the patient's ophthalmic examination findings will be reviewed before dosing and will determine the belantamab mafodotin dose based on the highest category from the corneal examination and/or best corrected visual acuity finding in the most severely affected eye. | | | | |
| | | | 15. The patient will be advised to administer preservative-free artificial tears for use at least 4 times daily throughout the time of treatment with belantamab mafodotin. | | | | |
| | | | 16. The patient should avoid using contact lenses until the end of belantamab mafodotin treatment unless bandage contact lenses are used under the direction of an ophthalmologist. | | | | |
| | | | 17. The patient will be treated with belantamab mafodotin until disease progression or the occurrence of excessive toxicity or the withdrawal of patient consent, whichever is the sooner. | | | | |
| | | | 18. The prescribing clinician understands that given the potentially necessary frequency and duration of treatment breaks during treatment with belantamab mafodotin, this indication is exempt from NHS England's treatment break policy.<br><br>Note: if there is disease progression during a treatment break from belantamab mafodotin, treatment with belantamab mafodotin must be discontinued. | | | | |
| | | | 19. The use of belantamab mafodotin will otherwise be as described in the drug's Summary of Product Characteristics (SPC). | | | | |
| BEN1 | **Bendamustine** | The first line treatment of low grade lymphoma where all the following criteria are met: | 1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy | Yes | n/a - NHS England clinical policy | - | 08-Jul-18 |
| | | | 2. Low grade non-Hodgkin's lymphoma | | | | |
| | | | 3. Option for 1st-line chemotherapy only | | | | |
| | | | 4. To be used within the treating Trust's governance framework, as Bendamustine is not licensed in this indication | | | | |
| | | | Note: Can be used in combination with Rituximab, which is commissioned by NHS England for this indication. | | | | |
| BEN2 | **Bendamustine** | The first line treatment of mantle cell non-Hodgkin's lymphoma where all the following criteria are met: | 1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy | Yes | n/a - NHS England clinical policy | - | 08-Jul-18 |
| | | | 2. Mantle cell non-Hodgkin's lymphoma | | | | |
| | | | 3. 1st-line treatment in patients unsuitable for standard treatment | | | | |
| | | | 4. To be used within the treating Trust's governance framework, as Bendamustine is not licensed in this indication | | | | |
| | | | Note: Can be used in combination with Rituximab, which is commissioned by NHS England for this indication. | | | | |
| BEN6 | **Bendamustine** | The treatment of relapsed low grade lymphoma where all the following criteria are met: | 1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy | Yes | n/a - NHS England clinical policy | - | 01-Apr-21 |
| | | | 2. Low grade non-Hodgkin's lymphoma | | | | |
| | | | 3. Relapsed disease | | | | |
| | | | 4. Unable to receive CHOP-R | | | | |
| | | | 5. Unable to receive FCR | | | | |
| | | | 6. Unable to receive high dose-therapy | | | | |
| | | | 7. No prior bendamustine | | | | |
| | | | 8. To be used within the treating Trust's governance framework, as Bendamustine is not licensed in this indication | | | | |
| | | | Note: Can be used in combination with Rituximab, which is commissioned by NHS England for this indication. | | | | |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| BEV2 | **Bevacizumab** | The first line treatment of recurrent or metastatic cervical cancer in combination with chemotherapy where all the following criteria are met: | 1. An application has been made and the first cycle of systemic anti -cancer therapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy<br>2. The patient has histologically confirmed carcinoma of the cervix<br>3. The indication will be for 1st line palliative chemotherapy<br>4. The patient has primary stage IVB, recurrent, or persistent disease not amenable to curative treatment with surgery and/or radiotherapy<br>5. Bevacizumab will be given with Paclitaxel and either Cisplatin or Carboplatin<br>6. The patient has an ECOG PS of 0 or 1<br>7. The patient has had no previous treatment with bevacizumab or other anti-VEGF therapy<br>8. The patient has no contraindications to the use of bevacizumab<br>9. Bevacizumab dose to be 15mg/kg every 3 weeks<br>10. No planned treatment breaks of more than 6 weeks beyond the expected cycle length are allowed (to allow any toxicity of current therapy to settle or intercurrent comorbidities to improve).<br>*Requests for continuation of treatment after unplanned treatment breaks over this duration should be made via the treatment break approval process<br>Note: Bevacizumab is ONLY approved for use in combination with combination chemotherapy and is not approved for use as a single agent maintenance therapy<br>Note: Bevacizumab should be discontinued for reasons of toxicity or disease progression, whichever occurs first. | Yes | n/a - NHS England clinical policy | - | 01-Apr-21 |
| BEV3 | **Bevacizumab** at a dose of 7.5mg/Kg | In combination with 1st line chemotherapy AS INDUCTION TREATMENT for patients with stage III or IV ovarian, fallopian tube or primary peritoneal carcinoma where the following criteria have been met:<br><br>Note: there is a separate form BEV9 for the use of bevacizumab at a dose of 15mg/Kg in combination with 1st line chemotherapy AS INDUCTION TREATMENT for advanced ovarian cancer<br><br>Note: there is a separate form BEV10 for the use of bevacizumab monotherapy at a dose of 7.5mg/Kg as MAINTENANCE treatment after completion of induction chemotherapy<br><br>Note: there is a separate form OLAP4 for the use of bevacizumab at a dose of 15mg/kg in combination with olaparib as MAINTENANCE treatment after completion of induction chemotherapy | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with bevacizumab in combination with induction chemotherapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. Bevacizumab **at a dose of 7.5mg/Kg** is to be used in combination with 1st line induction chemotherapy for previously untreated advanced epithelial ovarian, fallopian tube or primary peritoneal cancer.<br>3. One of the following criteria applies to this patient:<br>i) FIGO stage III disease and debulked but residual disease more than 1cm **or**<br>ii) FIGO stage III disease and unsuitable for debulking surgery **or**<br>iii) FIGO stage IV disease **or**<br>iv) FIGO stage III disease at presentation and requires neo-adjuvant chemotherapy due to low likelihood of optimal primary surgical cytoreduction<br>4. Bevacizumab is to be given in combination with carboplatin and paclitaxel chemotherapy.<br>5. Bevacizumab is to **start** with:<br>i) the 1st or 2nd cycle of chemotherapy following primary debulking surgery, **or**<br>ii) the 1st or 2nd cycle of chemotherapy following interval debulking surgery performed after 3 – 4 cycles of non-bevacizumab-containing neoadjuvant chemotherapy, **or**<br>iii) the 1st or 2nd cycle of chemotherapy for those patients who have inoperable stage IV disease or inoperable stage III disease or who are unable to undergo surgery due to increased risk during COVID19 **or**<br>iv) the 1st or 2nd cycle of neo-adjuvant chemotherapy<br>6. Bevacizumab is to be given at a dose of 7.5mg/Kg every 3 weeks.<br>7. A maximum of 6 cycles of bevacizumab will be given as part of induction chemotherapy.<br>8. As neither this dosage of bevacizumab nor its use in the neoadjuvant setting is licensed in ovarian cancer, this use of bevacizumab must be used within the treating Trust's governance framework.<br>Note: This policy relating to the use of bevacizumab 7.5mg/Kg is NOT for patients with stage I-III disease who have had optimal debulking<br>9. When a treatment break is needed of more than 6 weeks beyond the expected cycle length of 3-weekly treatment, I will complete a treatment break approval form to restart treatment, including as appropriate if the patient had an extended break on account of Covid-19.<br>10. Bevacizumab is to be otherwise used as set out in its Summary of Product Characteristics. | Yes | n/a - NHS England clinical policy | - | 01-Apr-21 |
| BEV8 | **Bevacizumab** | The third line treatment of low grade gliomas of childhood where all the following criteria are met: | 1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant paediatric specialist specifically trained and accredited in the use of systemic anti-cancer therapy<br>2. Progressive low grade glioma<br>3. No previous treatment with either irinotecan or bevacizumab<br>4. Irinotecan and bevacizumab to be the 3rd or further line of therapy<br>5. A maximum of 12 months duration of treatment to be used<br>6. Consent with the parent/guardian to specifically document the unknown long term toxicity of this combination, particularly on growth and ovarian function<br>7. To be used within the treating Trust's governance framework, as Bevacizumab and Irinotecan are not licensed in this indication in children<br>8. In the period immediately prior to the application for irinotecan and bevacizumab, the appropriate specialist MDT has considered the use of proton beam radiotherapy.<br>NOTE: Bevacizumab is ONLY approved for use in combination with combination chemotherapy and is not approved for use as a single agent maintenance therapy<br>NOTE: Additional data on long term toxicity must be collected by the paediatric oncology community | Yes | | - | 01-Apr-21 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| BEV9 | **Bevacizumab** at a dose of 15mg/Kg | in combination with 1st line chemotherapy AS INDUCTION TREATMENT patients with stage III or IV ovarian, fallopian tube or primary peritoneal carcinoma where the following criteria have been met:<br><br>Note: there is a separate form BEV3 for the use of bevacizumab at a dose of 7.5mg/Kg in combination with 1st line chemotherapy AS INDUCTION TREATMENT for advanced ovarian cancer<br><br>Note: there is a separate form BEV10 for the use of bevacizumab monotherapy at a dose of 7.5mg/Kg as MAINTENANCE treatment after completion of induction chemotherapy<br><br>Note: there is a separate form OLAP4 for the use of bevacizumab at a dose of 15mg/kg in combination with olaparib as MAINTENANCE treatment after completion of induction chemotherapy | 1. I confirm that this application is being made by and the first cycle of systemic anti-cancer therapy with bevacizumab in combination with induction chemotherapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. I confirm that bevacizumab **at a dose of 15mg/Kg** is to be used in combination with 1st line induction chemotherapy for previously untreated advanced epithelial ovarian, fallopian tube or primary peritoneal cancer.<br>3. I confirm that one of the following criteria applies to this patient:<br>i) FIGO stage III disease and debulked with no residual disease or residual disease less than 1cm **or**<br>ii) FIGO stage III disease and debulked with residual disease of more than 1cm **or**<br>iii) FIGO stage III disease and unsuitable for debulking surgery **or**<br>iii) FIGO stage IV disease and debulked with residual disease less than 1cm **or**<br>v) FIGO stage IV disease and debulked with residual disease of more than 1 cm **or**<br>vi) FIGO stage IV disease and unsuitable for debulking surgery **or**<br>vii) FIGO stage III disease at presentation and requires neo-adjuvant chemotherapy due to low likelihood of optimal primary surgical cytoreduction **or**<br>viii) FIGO stage IV disease at presentation and requires neo-adjuvant chemotherapy due to low likelihood of optimal primary surgical cytoreduction<br>4. I confirm that bevacizumab is to be given in combination with carboplatin and paclitaxel chemotherapy.<br>5. I confirm that bevacizumab is to start with:<br>i) the 1st or 2nd cycle of chemotherapy following primary debulking surgery, **or**<br>ii) the 1st or 2nd cycle of chemotherapy following interval debulking surgery performed after 3 – 4 cycles of non-bevacizumab-containing neoadjuvant chemotherapy, **or**<br>iii) the 1st or 2nd cycle of chemotherapy for those patients who have inoperable stage IV disease or inoperable stage III disease or who are unable to undergo surgery due to increased risk during COVID19 , **or**<br>iv) the 1st or 2nd cycle of neo-adjuvant chemotherapy<br>6. I confirm that bevacizumab is to be given at a dose of 15mg/Kg every 3 weeks.<br>7. I confirm that a maximum of 6 cycles of bevacizumab will be given as part of induction chemotherapy.<br>8. I confirm that as neither bevacizumab in stage IIIA disease nor its use in the neoadjuvant setting is licensed in ovarian cancer, this use of bevacizumab must be used within the treating Trust's governance framework.<br>Note: This policy relating to the use of bevacizumab 15mg/Kg is NOT for patients with stage I-II disease who have had optimal debulking<br>9. I confirm that when a treatment break is needed of more than 6 weeks beyond the expected cycle length of 3-weekly treatment, I will complete a treatment break approval form to restart treatment, including as appropriate if the patient had an extended break on account of Covid-19.<br>10. I confirm that bevacizumab is to be otherwise used as set out in its Summary of Product Characteristics. | Yes | n/a - NHS England clinical policy | - | 01-Apr-21 |
| BEV10 | **Bevacizumab** at a dose of 7.5mg/Kg | As MAINTENANCE monotherapy for patients with stage III or IV ovarian, fallopian tube or primary peritoneal carcinoma where the following criteria have been met:<br><br>Note: there is a separate form BEV3 for the use of bevacizumab at a dose of 7.5mg/Kg in combination with 1st line chemotherapy AS INDUCTION TREATMENT for advanced ovarian cancer<br><br>Note: there is a separate form BEV9 for the use of bevacizumab at a dose of 15mg/Kg in combination with 1st line chemotherapy AS INDUCTION TREATMENT for advanced ovarian cancer<br><br>Note: if an application is being made for the 1st line maintenance combination of olaparib plus bevacizumab, form OLAP4 should be used and will apply to the maintenance use of both drugs | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with maintenance bevacizumab monotherapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. Bevacizumab at a dose of 7.5mg/kg is to be used as maintenance monotherapy after completion of 1st line induction chemotherapy in combination with bevacizumab 7.5mg/kg or 15mg/kg for previously untreated advanced epithelial ovarian, fallopian tube or primary peritoneal cancer.<br>3. Bevacizumab is to be given as monotherapy for a maximum of 18 cycles in all, this figure including the number of cycles given in combination with 1st line induction chemotherapy.<br>4. Bevacizumab is to be given at a dose of 7.5mg/kg every 3 weeks.<br>5. The prescribing clinician understands that this dosage of bevacizumab is not licensed in ovarian cancer, this use of bevacizumab must be used within the treating Trust's governance framework.<br><br>Note: This policy relating to the use of maintenance bevacizumab 7.5mg/Kg is NOT for patients with stage I-III disease who have had optimal debulking<br>6. When a treatment break is needed of more than 6 weeks beyond the expected cycle length of 3-weekly treatment, I will complete a treatment break approval form to restart treatment which MUST be approved before treatment is restarted.<br>7. Bevacizumab is to be otherwise used as set out in its Summary of Product Characteristics. | Yes | n/a - NHS England clinical policy | - | 01-Apr-21 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| BEV11 | **Bevacizumab** with FIRST LINE fluoropyrimidine-based chemotherapy | For metastatic or locally advanced and inoperable colorectal cancer where the following criteria have been met: | 1. This application for bevacizumab is being made by, and the first cycle of systemic anti-cancer therapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has either metastatic or locally advanced and inoperable colorectal carcinoma and has not received any previous systemic therapy for this indication.<br><br>Note: patients may have received neoadjuvant systemic therapy for non-metastatic disease and/or adjuvant chemotherapy after surgery.<br>3. The patient's tumour has a documented presence of microsatellite stability (MSI-S) or DNA mismatch repair proficiency (pMMR) confirmed by validated testing, **OR** immunotherapy is not being used as first line therapy due to its unsuitability for this patient<br>- patient has MSI-S/pMMR tumour<br>- immunotherapy (e.g. ipilimumab/nivolumab/pembrolizumab) is not suitable for this patient<br>4. The primary reason for the patient **NOT** receiving either cetuximab or panitumumab alongside first line chemotherapy is as below<br>- the patient has a right sided primary tumour<br>- the patient's tumour has a mutant RAS status<br>- the patient's tumour has a BRAF V600E mutation<br>- the RAS test result not yet reported and the decision to proceed without knowing RAS status has been discussed with the patient during the consenting process<br>- Cetuximab or Panitumumab are not suitable for this patient due to pre-existing medical conditions or sensitivities<br>5. The patient will receive fluoropyrimidine based chemotherapy alongside bevacizumab as shown below<br>- the patient will receive irinotecan plus infusional 5FU (FOLFIRI)<br>- the patient will receive oxaliplatin plus infusional 5FU (FOLFOX)<br>- the patient will receive irinotecan, oxaliplatin, and fluoropyrimidine chemotherapy (e.g. FOLFOXIRI)<br>- the patient will receive single agent capecitabine or single agent infusional 5FU<br>- the patient will receive an alternative fluoropyrimidine based chemotherapy regimen<br>6. Bevacizumab will be stopped on disease progression or unacceptable toxicity or withdrawal of patient consent whichever occurs first.<br><br>Note – Patients who move to 2nd line fluoropyrimidine based chemotherapy may continue to receive bevacizumab with this 2nd line chemotherapy via form BEV12<br>7. When a treatment break of more than 6 weeks beyond the expected 2, or 3 - weekly cycle length is needed, a treatment break approval form will be completed to restart treatment. This **MUST** be approved before treatment is re-started.<br>8. Bevacizumab will be otherwise used as set out in its Summary of Product Characteristics (SPC). | No | TA1136 | 25-Feb-26 | 24-Dec-25 |
| BEV12 | **Bevacizumab** with SECOND LINE fluoropyrimidine-based chemotherapy | For metastatic or locally advanced and inoperable colorectal cancer where the following criteria have been met: | 1. This application for bevacizumab is being made by, and the first cycle of systemic anti-cancer therapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has either metastatic or locally advanced and inoperable colorectal carcinoma and has received **ONE** prior line of systemic therapy for this indication.<br><br>Note: patients may also/additionally have received neoadjuvant systemic therapy for non-metastatic disease and/or adjuvant chemotherapy after surgery.<br>3. The patient's tumour has a documented presence of microsatellite stability (MSI-S) or DNA mismatch repair proficiency (pMMR) confirmed by validated testing, **OR** the patient received immunotherapy as their first line treatment, **OR** immunotherapy is not being used as second line therapy due to its unsuitability for this patient<br>- patient has MSI-S/pMMR tumour<br>- patient received immunotherapy as their first line treatment<br>- immunotherapy (e.g. ipilimumab/nivolumab/pembrolizumab) is not suitable for this patient<br>4. The patient's tumour is either BRAF V600E mutation **NEGATIVE, or** the patient received cetuximab/panitumumab as part of first line therapy, **or** the patient is not suitable for 2nd line treatment with encorafenib in combination with cetuximab as per form ENC2<br>- patient has a tumour which is BRAF V600E mutation negative<br>- patient received cetuximab/panitumumab as part of 1st line therapy<br>- the combination of encorafenib and cetuximab is not suitable for this patient<br>5. The patient will receive **2nd line** fluoropyrimidine based chemotherapy alongside bevacizumab as shown below<br>- the patient will receive irinotecan plus infusional 5FU (FOLFIRI)<br>- the patient will receive oxaliplatin plus infusional 5FU (FOLFOX)<br>- the patient will receive oxaliplatin plus capecitabine (CAPOX)<br>- the patient will receive single agent capecitabine or single agent infusional 5FU<br>- the patient will receive an alternative fluoropyrimidine based chemotherapy regimen<br>6. Bevacizumab will be stopped on disease progression or unacceptable toxicity or withdrawal of patient consent whichever occurs first.<br><br>Note – Patients who move to 3rd line treatment may continue to receive bevacizumab with trifluridine plus tipiracil if this is the most appropriate third line regimen, and the patient meets all of the criteria on form TRI3<br>7. When a treatment break of more than 6 weeks beyond the expected 2, or 3 - weekly cycle length is needed, a treatment break approval form will be completed to restart treatment. This **MUST** be approved before treatment is re-started.<br>8. Bevacizumab will be otherwise used as set out in its Summary of Product Characteristics (SPC). | No | TA1136 | 25-Feb-26 | 24-Dec-25 |

# National Cancer Drugs Fund (CDF) List

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|---|---|---|---|---|---|---|---|
| BLI1 | **Blinatumomab** | The treatment of relapsed/refractory Philadelphia negative B-precursor acute lymphoblastic leukaemia in ADULT patients | 1. An application is being made and the first cycle of systemic anti-cancer therapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient is an adult.<br><br>**NB. There is a separate Blueteq form to be used for blinatumomab in this indication in children.**<br>3. The patient has relapsed or refractory Philadelphia negative acute lymphoblastic leukaemia (ALL).<br>4. The patient has been previously treated with intensive combination chemotherapy as initial treatment with or without subsequent salvage therapy.<br>5. Blinatumomab will only be requested by and administered in either bone marrow transplant centres or in major haematological centres that regularly treat patients with relapsed ALL and who have close and regular ALL multi-disciplinary team meetings and links with bone marrow transplant centres.<br>6. The patient has an ECOG performance status of 0 - 2.<br>7. A maximum of 5 cycles of treatment with blinatumomab will be administered.<br>8. Blinatumomab in this indication is exempt from the NHS England Treatment Break policy.<br>9. Blinatumomab will otherwise be used as set out in its Summary of Product Characteristics (SPC). | Yes | TA450 | 27-Apr-17 | 26-Sep-17 |
| BLI2 | **Blinatumomab** | The treatment of relapsed/refractory Philadelphia negative B-precursor acute lymphoblastic leukaemia in CHILD patients | 1. An application is being made and the first cycle of systemic anti-cancer therapy with blinatumomab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient is a child and ONE of the following applies:<br><br>OPTION 1 - The patient is post pubescent.<br>OPTION 2 - The patient is pre pubescent<br>**Please choose correct option**<br>- Option A<br>- Option B<br><br>**NB. There is a separate Blueteq form to be used for blinatumomab in this indication in adults.**<br>3. The patient has relapsed or refractory Philadelphia negative acute lymphoblastic leukaemia (ALL).<br>4. The patient has been previously treated with intensive combination chemotherapy as initial treatment with or without subsequent salvage therapy.<br>5. The first cycle of blinatumomab will only be requested by, prescribed, and commenced in Principal Treatment Centres (PTCs). Subsequent cycles (including the latter parts of the first 28-day treatment cycle) of blinatumomab may be administered at the PTC or in partnership with enhanced POSCUs under the direction of the PTCs and in agreement with relevant Operational Delivery Networks<br>6. The use of the blinatumomab has been discussed at a multidisciplinary team (MDT) meeting which must include at least two consultants in the subspecialty with active and credible expertise in the relevant field of whom at least one must be a consultant paediatrician. The MDT should include a paediatric pharmacist and other professional groups appropriate to the disease area.<br>7. The patient has a Karnofsky/Lansky performance score of 60 or more.<br>8. A maximum of 5 cycles of treatment with blinatumomab will be administered.<br>9. The use of blinatumomab in this indication is exempt from the NHS England Treatment Break policy.<br>10. Relevant Trust policy regarding off-label treatments will be followed for children less than 1 year of age, as blinatumomab is not licensed in this age group.<br>11. Blinatumomab should otherwise be used as set out in its Summary of Product Characteristics (SPC). | Yes | TA450 | 27-Apr-17 | 26-Sep-17 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| BLI3 | **Blinatumomab** | The treatment of patients in first complete haematological complete remission and with minimal residual disease post 1st line induction chemotherapy in B-precursor acute lymphoblastic leukaemia in ADULT patients where all the following criteria are met: | 1. This application has been made by and the first cycle of systemic anti-cancer therapy with blinatumomab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient is an adult*<br>*note there is a separate Bluteq form to be used for blinatumomab in this minimal residual disease indication in children.<br>3. The patient has CD19 positive acute lymphoblastic leukaemia (ALL).<br>Please indicate below whether the patient has Philadelphia negative or positive ALL:<br>- Philadelphia negative ALL (use is on-label) or<br>- Philadelphia positive ALL (use is off-label). By ticking this box for use in Philadelphia positive ALL, I confirm that my hospital Trust policy regarding unlicensed treatments is being followed as blinatumomab is not licensed in Philadelphia positive ALL.<br>4. The patient has been previously treated with intensive 1st line combination chemotherapy as initial induction treatment.<br>5. The patient is in complete haematological remission of ALL.<br>6. The patient's bone marrow has been shown to have a minimal residual disease level of ≥ 0.01% (≥10-4) leukaemic cells confirmed in a validated assay.<br><br>Note: a patient who has minimal residual disease (MRD) negativity defined as being less than 0.01% is potentially eligible for blinatumomab as part of consolidation therapy via form BLI5.<br>7. Blinatumomab will only be requested by and administered in either bone marrow transplant centres or in major haematological centres that regularly treat patients with MRD positive ALL and who have close and regular ALL multi-disciplinary team meetings and links with bone marrow transplant centres.<br>8. The patient has an ECOG performance status of 0-2.<br>9. A maximum of 4 cycles of blinatumomab will be administered to this patient.<br>10. Blinatumomab will be used as monotherapy.<br><br>Note: intrathecal chemotherapy and appropriate tyrosine kinase inhibitors may be continued as planned during any blinatumomab cycles.<br>11. No planned treatment breaks of more than SIX weeks beyond the expected cycle length are allowed (to allow any toxicity of current therapy to settle or intercurrent comorbidities to improve).*<br>*Requests for continuation of treatment after unplanned treatment breaks over this duration should be made via the treatment break approval process<br>12. Blinatumomab will otherwise be used as set out in its Summary of Product Characteristics (SPC). | No | TA589 | 24-Jul-19 | 22-Oct-19 |
| BLI4 | **Blinatumomab** | The treatment of patients in first complete haematological remission and with minimal residual disease post 1st line induction chemotherapy in B-precursor acute lymphoblastic leukaemia in CHILD patients where all the following criteria have been met: | 1. This application has been made by and the first cycle of systemic anti -cancer therapy with blinatumomab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient is a child* and please mark as to whether pre- or post-pubescent:<br>- is post-pubescent or<br>- is pre-pubescent and will receive blinatumomab at the paediatric dosage described in the blinatumomab summary of product characteristics (SmPC).<br>*note there is a separate Blueteq form to be used for blinatumomab in this indication in adults.<br>3. The patient has CD19 positive acute lymphoblastic leukaemia (ALL).<br>Please indicate below whether the patient has Philadelphia negative or positive ALL:<br>- Philadelphia negative ALL or<br>- Philadelphia positive ALL<br>4. The patient has been previously treated with 1st line intensive combination chemotherapy as initial induction treatment.<br>5. The patient is in complete haematological remission of ALL.<br>6. The patient's bone marrow has been shown to have minimal residual disease level of ≥ 0.01% (≥10-$^{4}$) confirmed in a validated assay.<br><br>Note: a patient who has minimal residual disease (MRD) negativity defined as being less than 0.01% is potentially eligible for blinatumomab as part of consolidation therapy via form BLI6.<br>7. The first cycle of blinatumomab will only be requested by, prescribed, and commenced in Principal Treatment Centres (PTCs). Subsequent cycles (including the latter parts of the first 28-day treatment cycle) of blinatumomab may be administered at the PTC or in partnership with enhanced POSCUs under the direction of the PTCs and in agreement with relevant Operational Delivery Networks.<br>8. The patient has a Karnofsky/Lansky performance score of 60 or more.<br>9. A maximum of 4 cycles of treatment with blinatumomab will be administered.<br>10. Blinatumomab will be used as systemic monotherapy.<br><br>Note: intrathecal chemotherapy and appropriate tyrosine kinase inhibitors may be continued as planned during any blinatumomab cycles.<br>11. Blinatumomab has been discussed at a multi-disciplinary team (MDT) meeting which must include at least two consultants in the subspecialty with active and credible expertise in the relevant field of whom at least one must be a consultant paediatrician. The MDT should include a paediatric pharmacist, and other professional groups appropriate to the disease area.<br>12. When a treatment break of more than SIX weeks beyond the expected cycle length is needed, I will complete a treatment break approval form to restart treatment.<br>13. Trust policy regarding unlicensed treatments has been followed as blinatumomab is not licensed in this indication in children.<br>14. Blinatumomab will otherwise be used as set out in its Summary of Product Characteristics (SPC). | No | TA589 | 24-Jul-19 | 22-Oct-19 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| BLI5 | **Blinatumomab** | The treatment of ADULT patients in first morphological complete remission and without minimal residual disease after 1st line intensive induction and intensification chemotherapy for Philadelphia chromosome negative B-cell precursor acute lymphoblastic leukaemiawhere all the following criteria are met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with blinatumomab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient is an adult.<br>3. The patient has Philadelphia chromosome negative CD19 positive B-cell precursor acute lymphoblastic leukaemia (ALL).<br>4. The patient has been previously treated with intensive 1st line induction and intensification combination chemotherapy.<br>5. The patient is in a morphological complete remission of ALL.<br>6. The prescribing clinician understands that this NICE recommendation for blinatumomab uses the E1910 trial definition of minimal residual disease negativity as the bone marrow exhibiting **<0.01% (<$10^{-4}$)** leukaemic cells confirmed in a validated assay and the prescibing clinician confirms that this patient's level of minimal residual disease fulfils this definition. For those patients in whom an assay sensitivity or QR of **$10^{-4}$** is not reached but sufficient to report minimal residual disease negativity to the maximum sensitivity of the available assay, blinatumomab will also be permitted.<br><br>Note: the company's case for the clinical and cost effectiveness of blinatumomab in this indication was based on the evidence base of the E1910 trial which in the key randomisation only included patients who had MRD negativity defined as being <0.01%.<br><br>Note: a level of minimal residual disease (MRD) of ≥0.01% means that blinatumomab is not recommended by NICE in this indication and is not funded by NHS England. Blinatumomab is however potentially funded in a MRD positive indication which can be accessed via form BLI3.<br>7. Blinatumomab will only be requested by and administered in either bone marrow transplant centres or in major haematological centres that regularly treat patients with MRD negative ALL and who have close and regular ALL multi-disciplinary team meetings and links with bone marrow transplant centres.<br>8. The patient has an ECOG performance status of 0-2.<br>9. The treatment intent for this patient is to be potentially treated with a **maximum of 4 cycles** of blinatumomab whether given in cycles 1, 2, 6 and 8 of consolidation treatment with chemotherapy planned to be given in cycles 3, 4, 5 and 7 of an 8 cycle consolidation treatment program **or** blinatumomab given in cycles 1, 2, 6 and 7 and chemotherapy in cycles 3, 4 and 5 of a 7 cycle consolidation treatment program **or** blinatumomab as sequenced with chemotherapy in other approved UK ALL Research Network consolidation treatment protocols.<br><br>Note: NHS England understands that patients in the E1910 trial could proceed to allogeneic transplantation after completing at least cycles 1 and 2 of the above potential program of consolidation therapy.<br>10. The patient has not yet commenced any consolidation therapy i.e. the patient has just finished the sequence of induction and intensification therapies.<br><br>Note: the company's case for the clinical and cost effectiveness of blinatumomab in this indication was based on the evidence base of the E1910 trial which only included patients who had not started any consolidation therapy.<br>11. Blinatumomab will be administered as monotherapy in accordance with treatment criterion 9 above.<br><br>Note: intrathecal chemotherapy and appropriate tyrosine kinase inhibitors (for patients with ABL-class mutations) may be continued as planned during any blinatumomab cycles.<br>12. The prescribing clinician understands that given the scheduling timetable of a potential maximum of 4 cycles of blinatumomab given interspersed with cycles of chemotherapy, this indication is exempted from NHS England's treatment break policy.<br>13. Blinatumomab will otherwise be used as set out in its Summary of Product Characteristics (SPC). | No | TA1049 | 26-Mar-25 | 24-Jun-25 |
| BLI6 | **Blinatumomab** | The treatment of POST PUBESCENT CHILDREN in first morphological complete remission and without minimal residual disease after 1st line intensive induction and any indicated intensification chemotherapy for Philadelphia chromosome negative B-cell precursor acute lymphoblastic leukaemia where all the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with blinatumomab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient is a **post pubescent** child.<br>3. The patient has Philadelphia chromosome negative CD19 positive B-cell precursor acute lymphoblastic leukaemia (ALL).<br>4. The patient has been previously treated with intensive 1st line induction and any indicated cytoreductive combination chemotherapy.<br>5. The patient is in a morphological complete remission of ALL.<br>6. The prescribing clinician understands that this NICE recommendation for blinatumomab uses the E1910 trial definition of minimal residual disease negativity as the bone marrow exhibiting **<0.01% (<$10^{-4}$)** leukaemic cells confirmed in a validated assay and the prescibing clinician confirms that this patient's level of minimal residual disease fulfils this definition. For those patients in whom an assay sensitivity or QR of **$10^{-4}$** is not reached but sufficient to report minimal residual disease negativity to the maximum sensitivity of the available assay, blinatumomab will also be permitted.<br><br>Note: the company's case for the clinical and cost effectiveness of blinatumomab in this indication was based on the evidence base of the E1910 trial which in the key randomisation only included patients who had MRD negativity defined as being <0.01%.<br><br>Note: a level of minimal residual disease (MRD) of >=0.01% means that blinatumomab is not recommended by NICE in this indication and is not funded by NHS England. Blinatumomab is however potentially funded in a MRD positive indication which can be accessed via form BLI4.<br>7. Blinatumomab will only be requested by, prescribed, and initially administered in, principal treatment centres (PTCs) who have close and regular ALL multi-disciplinary team meetings and links with bone marrow transplant centres. Subsequent cycles of blinatumomab (including the latter part of the first 28-day treatment cycle) may be administered at PTCs or in close partnership with enhanced POSCUs under the direction of PTCs and in agreement with relevant Operational Delivery Networks.<br>8. The patient has a Karnofsky/Lansky performance score of at least 60.<br>9. The treatment intent for this patient is to be potentially treated with a **maximum of 4 cycles** of blinatumomab as sequenced with chemotherapy in accordance with UK nationally approved CCLG protocols/guidelines.<br><br>Note: NHS England understands that patients in the E1910 trial could proceed to allogeneic transplantation after completing at least cycles 1 and 2 of blinatumomab consolidation therapy.<br>10. The patient has not yet commenced any consolidation therapy i.e. the patient has just finished the sequence of induction and any indicated cytoreductive therapies.<br><br>Note: the company's case for the clinical and cost effectiveness of blinatumomab in this indication was based on the evidence base of the E1910 trial which only included patients who had not started any consolidation therapy.<br>11. Blinatumomab will be administered as systemic **monotherapy** in accordance with treatment criterion 9 above.<br><br>Note: intrathecal chemotherapy, , and appropriate tyrosine kinase inhibitors, may continue as planned during blinatumomab cycles.<br>12. The prescribing clinician understands that given the scheduling timetable of a potential maximum of 4 cycles of blinatumomab given interspersed with cycles of chemotherapy, this indication is exempted from the NHS England's treatment break policy.<br>13. Trust policy regarding unlicensed treatments has been followed as blinatumomab is not licensed in this indication in post pubescent children. | No | TA1049 | 26-Mar-25 | 24-Jun-25 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| BOS1 | **Bosutinib** | Bosutinib for previously treated chronic myeloid leukaemia | 1. I confirm that an application has been made and the first cycle of systemic anti-cancer therapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. I confirm the patient has chronic, accelerated or blast phase Philadelphia chromosome positive chronic myeloid leukaemia.<br>3. I confirm the patient has had previous treatment with 1 or more tyrosine kinase inhibitor.<br>4. I confirm that treatment is not appropriate with either imatinib, nilotinib or dasatinib.<br>5. I confirm the patient will receive the licensed dose and frequency of bosutinib | Yes | TA401 | 24-Aug-16 | 22-Nov-16 |
| BRE3 (formerly BRE2) | **Brentuximab** | Treatment of brentuximab-naïve relapsed/refractory Hodgkin lymphoma following autologous stem cell transplant in ADULT patients where the following criteria are met: | 1. An application has been made by and the first cycle of systemic anti-cancer therapy is to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy<br>2. The patient is an adult.<br><br>**NB. There is a separate Blueteq form to be used for brentuximab in this indication in children.**<br>3. The patient has relapsed or refractory CD30+ Hodgkin lymphoma.<br>4. The patient has relapsed Hodgkin lymphoma after autologous stem cell transplant.<br>5. The patient has never received brentuximab unless having previously responded to brentuximab when treated with 1st line BV-AVD.<br>- No prior treatment with brentuximab<br>- Prior therapy brentuximab within 1st line BV-AVD<br>6. Treatment with brentuximab will be discontinued after 4 cycles if CT or PET-CT scans to assess response demonstrate a response status of less than a partial or a complete response<br>7. No planned treatment breaks of more than 6 weeks beyond the expected cycle length are allowed (to allow any toxicity of current therapy to settle or intercurrent comorbidities to improve).<br>*Requests for continuation of treatment after unplanned treatment breaks over this duration should be made via the treatment break approval process<br>8. No re-use of brentuximab will be used outside this indication unless previous partial/complete response to brentuximab and brentuximab is being used as a bridge to allogeneic stem cell transplant or donor lymphocyte infusion*<br>*note there is a separate blueteq form for such re-use of brentuximab<br>9. A maximum of 16 cycles of brentuximab will be administered to the patient<br>Note: administration of a full 6 cycles of 1st line use of BV plus AVD (12 doses of brentuximab at 1.2 mg/Kg) counts as 8 cycles of brentuximab monotherapy at 1.8mg/Kg.<br>10. Brentuximab will otherwise be used as set out in its Summary of Product Characteristics (SPC). | Yes | TA524 (formerly TA446) | 13-Jun-18 | 26-Sep-17 |
| BRE4 (formerly BRE2) | **Brentuximab** | Treatment of brentuximab-naïve relapsed/refractory Hodgkin lymphoma following autologous stem cell transplant in CHILD patients where the following criteria are met: | 1. An application has been made by and the first cycle of systemic anti-cancer therapy is to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy<br>2. The patient has relapsed or refractory CD30+ Hodgkin lymphoma.<br>3. The patient has relapsed Hodgkin lymphoma after autologous stem cell transplant<br>4. The patient has never received brentuximab<br>5. Treatment with brentuximab will be discontinued after 4 cycles if CT or PET-CT scans to assess response demonstrate a response status of less than a partial or a complete response<br>6.The patient is a child* and is either post pubescent or is pre pubescent and will receive brentuximab dosage described in the phase 2 part of the brentuximab trial protocol C25002 http://www.clinicaltrials.gov/ct2/show/NCT01492088?term=C25002&rank=1 and reported on http://www.bloodjournal.org/content/122/21/4378<br>*note there is a separate Bluteq form to be used for brentuximab in this indication in adults.<br>7. The use of the brentuximab has been discussed at a multi disciplinary team (MDT) meeting which must include at least two consultants in the subspecialty with active and credible expertise in the relevant field of whom at least one must be a consultant paediatrician. The MDT should include a paediatric pharmacist and other professional groups appropriate to the disease area.<br>8. No planned treatment breaks of more than 6 weeks beyond the expected cycle length are allowed (to allow any toxicity of current therapy to settle or intercurrent comorbidities to improve).<br>*Requests for continuation of treatment after unplanned treatment breaks over this duration should be made via the treatment break approval process<br>9. No re-use of brentuximab will be used outside this indication unless previous partial/complete response to brentuximab and brentuximab is being used as a bridge to allogeneic stem cell transplant or donor lymphocyte infusion*<br>*note there is a separate blueteq form for such re-use of brentuximab<br>10. A maximum of 16 cycles of brentuximab will be administered to the patient<br>11. Trust policy regarding unlicensed treatments has been followed as brentuximab is not licensed in this indication in children.<br>12. Brentuximab will otherwise be used as set out in its Summary of Product Characteristics (SPC). | Yes | TA524 (formerly TA446) | 13-Jun-18 | 26-Sep-17 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| BRE5 (formerly BRE2) | **Brentuximab** | Treatment of brentuximab-naïve relapsed/refractory Hodgkin lymphoma following at least 2 prior therapies when autologous stem cell transplant or multi-agent chemotherapy is not a treatment option in ADULT patients where the following criteria are met: | 1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy<br>2. The patient is an adult*<br>*note there is a separate blueteq form to be used for brentuximab in this indication in children<br>3. The patient has relapsed or refractory CD30+ Hodgkin lymphoma.<br>4. The patient has relapsed Hodgkin lymphoma after at least 2 prior systemic therapies when either autologous stem cell transplant or further multi-agent chemotherapy is not a treatment option.<br>5. The patient has had no previous stem cell transplant<br>6. The The patient has never received brentuximab unless having previously responded to brentuximab when treated with 1st line BV-AVD.<br>- No prior treatment with brentuximab<br>- Prior therapy brentuximab within 1st line BV-AVD<br>7. Treatment with brentuximab will be discontinued after 4 cycles if CT or PET-CT scans to assess response demonstrate a response status of less than a partial or a complete response<br>8. I confirm that no more than 16 cycles of brentuximab may be administered per patient<br>Note: administration of a full 6 cycles of 1st line use of BV plus AVD (12 doses of brentuximab at 1.2 mg/Kg) counts as 8 cycles of brentuximab monotherapy at 1.8mg/Kg.<br>9. No planned treatment breaks of more than 6 weeks beyond the expected cycle length are allowed (to allow any toxicity of current therapy to settle or intercurrent comorbidities to improve).<br>*Requests for continuation of treatment after unplanned treatment breaks over this duration should be made via the treatment break approval process<br>10. No re-use of brentuximab will be used outside this indication unless previous partial/complete response to brentuximab and brentuximab is being used as a bridge to allogeneic stem cell transplant or donor lymphocyte infusion*<br>*note there is a separate blueteq form for such re-use of brentuximab<br>11. Brentuximab will otherwise be used as set out in its Summary of Product Characteristics (SPC). | Yes | TA524 | 13-Jun-18 | 11-Sep-18 |
| BRE6 (formerly BRE2) | **Brentuximab** | Treatment of brentuximab-naïve relapsed/refractory Hodgkin lymphoma following at least 2 prior therapies when autologous stem cell transplant or multi-agent chemotherapy is not a treatment option in CHILD patients where the following criteria are met: | 1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy<br>2. The patient is a child* and is either post pubescent or is pre pubescent and will receive brentuximab dosage described in the phase 2 part of the brentuximab trial protocol C25002<br>http://www.clinicaltrials.gov/ct2/show/NCT01492088?term=C25002&rank=1 and reported on http://www.bloodjournal.org/content/122/21/4378<br>*note there is a separate Bluteq form to be used for brentuximab in this indication in adults.<br>3. The patient has relapsed or refractory CD30+ Hodgkin lymphoma.<br>4. The patient has relapsed Hodgkin lymphoma after at least 2 prior systemic therapies when either autologous stem cell transplant or further multi-agent chemotherapy is not a treatment option.<br>5. The patient has had no previous stem cell transplant<br>6. The patient has never received brentuximab<br>7. Treatment with brentuximab will be discontinued after 4 cycles if CT or PET-CT scans to assess response demonstrate a response status of less than a partial or a complete response<br>8. I confirm that no more than 16 cycles of brentuximab may be administered per patient<br>9. The use of the brentuximab has been discussed at a multi disciplinary team (MDT) meeting which must include at least two consultants in the subspecialty with active and credible expertise in the relevant field of whom at least one must be a consultant paediatrician. The MDT should include a paediatric pharmacist and other professional groups appropriate to the disease area.<br>10. No planned treatment breaks of more than 6 weeks beyond the expected cycle length are allowed (to allow any toxicity of current therapy to settle or intercurrent comorbidities to improve).<br>*Requests for continuation of treatment after unplanned treatment breaks over this duration should be made via the treatment break approval process<br>11. No re-use of brentuximab will be used outside this indication unless previous partial/complete response to brentuximab and brentuximab is being used as a bridge to allogeneic stem cell transplant or donor lymphocyte infusion*<br>*note there is a separate blueteq form for such re-use of brentuximab<br>12. Trust policy regarding unlicensed treatments has been followed as brentuximab is not licensed in this indication in children.<br>13. Brentuximab will otherwise be used as set out in its Summary of Product Characteristics (SPC). | Yes | TA524 | 13-Jun-18 | 11-Sep-18 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| BRE7 | **Brentuximab** | Re-use of brentuximab in relapsed/refractory Hodgkin lymphoma in ADULT patients: | 1. An application has been made by and the first cycle of systemic anti-cancer therapy is to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy<br>2. The patient has relapsed or refractory CD30+ Hodgkin lymphoma.<br>3. The patient has relapsed Hodgkin lymphoma after autologous stem cell transplant<br>4. Previous use of brentuximab achieved a partial/complete response to brentuximab<br>5. Brentuximab is being used as a bridge to allogeneic stem cell transplantation or donor lymphocyte infusion<br>6. Treatment with brentuximab will be discontinued after 4 cycles if CT or PET-CT scans to assess response demonstrate a response status of less than a partial or a complete response<br>7. The patient is an adult*<br>*note there is a separate blueteq form to be used for brentuximab in this indication in children<br>8. No planned treatment breaks of more than 6 weeks beyond the expected cycle length are allowed (to allow any toxicity of current therapy to settle or intercurrent comorbidities to improve).<br>*Requests for continuation of treatment after unplanned treatment breaks over this duration should be made via the treatment break approval process<br>9. A maximum of 16 cycles of brentuximab will be administered to the patient when combining this reuse and previous cycles of brentuximab<br>Note: administration of a full 6 cycles of 1st line use of BV plus AVD (12 doses of brentuximab at 1.2 mg/Kg) counts as 8 cycles of brentuximab monotherapy at 1.8mg/Kg.<br>10. Brentuximab will otherwise be used as set out in its Summary of Product Characteristics (SPC). | Yes | TA524 (formerly TA446) | 13-Jun-18 | 26-Sep-17 |
| BRE8 | **Brentuximab** | Re-use of brentuximab in relapsed/refractory Hodgkin lymphoma in CHILD patients: | 1. An application has been made by and the first cycle of systemic anti-cancer therapy is to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy<br>2. The patient has relapsed or refractory CD30+ Hodgkin lymphoma.<br>3. The patient has relapsed Hodgkin lymphoma after autologous stem cell transplant<br>4. Previous use of brentuximab achieved a partial/complete response to brentuximab<br>5. Brentuximab is being used as a bridge to allogeneic stem cell transplantation or donor lymphocyte infusion<br>6. Treatment with brentuximab will be discontinued after 4 cycles if CT or PET-CT scans to assess response demonstrate a response status of less than a partial or a complete response<br>7. The patient is a child* and is either post pubescent or is pre pubescent and will receive brentuximab dosage described in the phase 2 part of the brentuximab trial protocol C25002<br>http://www.clinicaltrials.gov/ct2/show/NCT01492088?term=C25002&rank=1 and reported on http://www.bloodjournal.org/content/122/21/4378<br>*note there is a separate Bluteq form to be used for brentuximab in this indication in adults.<br>8. The use of the brentuximab has been discussed at a multi disciplinary team (MDT) meeting which must include at least two consultants in the subspecialty with active and credible expertise in the relevant field of whom at least one must be a consultant paediatrician. The MDT should include a paediatric pharmacist and other professional groups appropriate to the disease area.<br>9. No planned treatment breaks of more than 6 weeks beyond the expected cycle length are allowed (to allow any toxicity of current therapy to settle or intercurrent comorbidities to improve).<br>*Requests for continuation of treatment after unplanned treatment breaks over this duration should be made via the treatment break approval process<br>10. A maximum of 16 cycles of brentuximab will be administered to the patient when combining this reuse and previous cycles of brentuximab<br>11. Trust policy regarding unlicensed treatments has been followed as brentuximab is not licensed in this indication in children.<br>12. Brentuximab will otherwise be used as set out in its Summary of Product Characteristics (SPC). | Yes | TA524 (formerly TA446) | 13-Jun-18 | 26-Sep-17 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| BRE9 (formerly BRE1) | **Brentuximab** | The treatment of relapsed or refractory systemic anaplastic large cell lymphoma in ADULT patients, where the following criteria have been met: | 1. This application is being made by and first cycle of systemic anti-cancer therapy with brentuximab vedotin will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has relapsed or refractory systemic anaplastic large cell lymphoma (sALCL) after front line chemotherapy.<br>NB. Brentuximab is not available for primary cutaneous anaplastic large cell lymphoma unless it has transformed into systemic anaplastic large cell lymphoma.<br>3. The patient has a proven histological diagnosis of CD30+ve systemic anaplastic large cell lymphoma.<br>4. Either the patient has never previously been treated with brentuximab vedotin or was previously treated with brentuximab vedotin in combination with cyclophosphamide, doxorubicin and prednisone and did not have refractory disease to this therapy.<br>Please mark which of these 2 clinical scenarios applies to this patient:<br>- No prior treatment with brentuximab vedotin<br>- Received prior treatment with brentuximab vedotin in combination with cyclophosphamide, doxorubicin and prednisone and did not have refractory disease to this therapy<br>5. Brentuximab is to be used as single-agent therapy.<br>6. The patient has an ECOG performance status of 0 or 1 or 2.<br>7. Treatment with brentuximab is to be discontinued after 4 cycles if the CT or PET-CT scans to assess response demonstrate a response status of less than a partial or a complete response.<br>8. A maximum of 16 cycles of brentuximab vedotin may be administered per patient (this total of 16 cycles includes any previous treatment with brentuximab vedotin as part of prior therapy).<br>9. A formal medical review as to how the brentuximab vedotin is being tolerated and whether treatment with brentuximab vedotin should continue or not will be scheduled to occur at least by the end of the first 6 weeks of treatment.<br>10. If a treatment break of more than 6 weeks beyond the expected 3 week cycle length occurs, I will complete a treatment break approval form to restart treatment.<br>11. Brentuximab will be otherwise used as set out in its Summary of Product Characteristics (SPC). | Yes | TA478 | 04-Oct-17 | 02-Jan-18 |
| BRE10 (formerly BRE1) | **Brentuximab** | The treatment of relapsed or refractory systemic anaplastic large cell lymphoma in CHILD patients, where the following criteria have been met: | 1. An application has been made and the first cycle of systemic anti-cancer therapy is to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy<br>2. The patient has relapsed or refractory **systemic** anaplastic large cell lymphoma after front line chemotherapy<br>Note: Brentuximab is not available for 1° cutaneous anaplastic large cell lymphoma unless it has transformed into **systemic** anaplastic large cell lymphoma<br>3. Histologically confirmed CD30 positive disease<br>4. The patient has never previously received brentuximab unless previously enrolled in the NCRI-adopted clinical trial called ECHELON-2<br>5. Brentuximab is to be used as single-agent therapy<br>6. The patient has an ECOG performance status of 0-1<br>7. The patient is a child* and either post pubescent or is pre pubescent and will receive brentuximab vedotin dosage as described in phase 2 of the trial protocol C25002<br>http://www.clinicaltrials.gov/ct2/show/NCT01492088?term=C25002&rank=1 and reported on http://www.bloodjournal.org/content/122/21/4378<br>Note: there is a separate Blueteq form to be used for brentuximab vedotin in this indication in adults<br>8. The use of brentuximab in this setting and in this patient has been discussed at a multi-disciplinary team (MDT) meeting which must include at least 2 consultants in the subspecialty with active and credible expertise in the relevant field of whom one must be a consultant paediatrician. The MDT should include a paediatric pharmacist and other professional groups appropriate to the disease area<br>9. Treatment with brentuximab to be discontinued after 4 cycles if CT or PET-CT scans to assess response demonstrate a response status of less than a partial or a complete response<br>10. No treatment breaks of more than 6 weeks beyond the expected cycle length are allowed (to allow any toxicity of current therapy to settle or intercurrent comorbidities to improve)*<br>*Note: Requests for continuation of treatment after unplanned treatment breaks over this duration should be made via the treatment break approval process<br>11. Brentuximab vedotin will only be requested by and administered in principal treatment centres<br>12.Trust policy regarding unlicensed treatments has been followed as brentuximab vedotin is not licensed in this indication in children<br>13. A maximum of 16 cycles of brentuximab may be administered per patient<br>14. Brentuximab will be otherwise used as set out in its Summary of Product Characteristics | Yes | TA478 | 04-Oct-17 | 02-Jan-18 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| BRE11 | **Brentuximab vedotin** | The treatment of CD30+ cutaneous T cell lymphoma following at least 1 prior systemic therapy in ADULT patients where the following criteria are met:<br><br>Note: there is a separate Blueteq form for the use of brentuximab vedotin in children with cutaneous T cell lymphoma | 1. This application has been made by and the first cycle of systemic anti -cancer therapy with brentuximab vedotin will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has relapsed or refractory CD30+ cutaneous T cell lymphoma, the type of which is one of the following: advanced stage IIB-IVB mycosis fungoides or primary cutaneous anaplastic large cell lymphoma or Sezary syndrome. Please mark in the tick box below which of these 3 types of cutaneous T cell lymphoma applies to this patient:<br>- stage IIB-IVB mycosis fungoides or<br>- primary cutaneous anaplastic large cell lymphoma or<br>- Sezary syndrome<br>Note: Takeda restricted its submission to NICE for the consideration of the clinical and cost effectiveness of brentuximab vedotin in only these 3 subtypes of cutaneous T cell lymphoma (CTCL) and NICE has optimised its recommendations in CTCL accordingly. Brentuximab vedotin is therefore not approved for use in patients with other types of cutaneous lymphoma such as lymphomatoid papulosis, subcutaneous panniculitis-like T cell NHL and primary cutaneous peripheral T cell lymphoma.<br>3. The patient has been treated with at least 1 prior systemic therapy for his/her CTCL.<br>4. The patient has never previously received treatment with brentuximab vedotin unless it has been given as part of any compassionate use scheme and the patient meets all the other criteria set out here including the maximum treatment duration of 16 cycles as set out in brentuximab vedotin's Summary of Product Characteristics.<br>5. No more than 16 cycles of brentuximab vedotin will be administered to this patient.<br>6. The patient has an ECOG performance status of 0 or 1 or 2.<br>7. No planned treatment breaks of more than 6 weeks beyond the expected cycle length are allowed (to allow any toxicity of current therapy to settle or intercurrent comorbidities to improve).<br><br>*Requests for continuation of treatment after unplanned treatment breaks over this duration should be made via the treatment break approval process<br>8. This sequence of cycles of treatment with brentuximab vedotin will be the sole sequence of cycles of treatment with bretuximab vedotin ie there will be no future re-treatment with brentuximab vedotin once this sequence of cycles (up to a maximum of 16 cycles) of brentuximab vedotin has ended.<br>9. Brentuximab will otherwise be used as set out in its Summary of Product Characteristics (SPC). | No | TA577 | 24-Apr-19 | 23-Jul-19 |
| BRE12 | **Brentuximab vedotin** | The treatment of CD30+ cutaneous T cell lymphoma following at least 1 prior systemic therapy in CHILD patients where the following criteria are met:<br><br>Note: there is a separate Blueteq form for the use of brentuximab vedotin in adults with cutaneous T cell lymphoma | 1. This application has been made by and the first cycle of systemic anti -cancer therapy with brentuximab vedotin will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient is a child* and please mark as to whether the chid is pre- or post-pubescent:<br>- is post-pubescent **or**<br>- is pre-pubescent and will receive brentuximab vedotin at the paediatric dosage described in the brentuximab vedotin literature in Hodgkin lymphoma.<br>*note there is a separate Blueteq form to be used for brentuximab vedotin in this indication in adults<br>3. The patient has relapsed or refractory CD30+ cutaneous T cell lymphoma which is advanced stage IIB-IVB mycosis fungoides or primary cutaneous anaplastic large cell lymphoma or Sezary syndrome.<br>Please mark in the tick box below which of these 3 types of cutaneous T cell lymphoma applies to this patient:<br>- stage IIB-IVB mycosis fungoides **or**<br>- primary cutaneous anaplastic large cell lymphoma **or**<br>- Sezary syndrome<br>Note: Takeda restricted its submission to NICE for the consideration of the clinical and cost effectiveness of only these 3 subtypes of cutaneous T cell lymphoma (CTCL) and NICE has restricted its recommendations in CTCL accordingly. Brentuximab vedotin is therefore not approved for use in patients with other types of cutaneous lymphoma such as lymphomatoid papulosis, subcutaneous panniculitis-like T cell NHL and primary cutaneous peripheral T cell lymphoma.<br>4. The patient has been treated with at least 1 prior systemic therapy for his/her CTCL.<br>5. The patient has never previously received brentuximab vedotin unless it has been given as part of a compassionate access scheme and the patient meets all the criteria set out here including the maximum treatment duration of 16 cycles as set out in brentuximab vedotin's Summary of Product Characteristics.<br>6. No more than 16 cycles of brentuximab vedotin will be administered to this patient<br>7. The patient has an ECOG performance status of 0 or 1 or 2<br>8. This sequence of cycles of treatment with brentuximab vedotin will be the sole sequence of cycles of treatment with brentuximab vedotin ie there will be no future re-treatment with brentuximab vedotin once this current sequence of cycles (up to 16 cycles) of brentuximab vedotin has ended.<br>9. The use of brentuximab has been discussed at a multi-disciplinary team (MDT) meeting which must include at least two consultants in the subspecialty with active and credible expertise in the relevant field of whom at least one must be a consultant paediatrician. The MDT should include a paediatric pharmacist and other professional groups appropriate to the disease area.<br>10. Brentuximab vedotin will only be requested by and administered in principal treatment centres.<br>11. No planned treatment breaks of more than 6 weeks beyond the expected cycle length are allowed (to allow any toxicity of current therapy to settle or intercurrent comorbidities to improve).<br>*Requests for continuation of treatment after unplanned treatment breaks over this duration should be made via the treatment break approval process<br>12. Trust policy regarding unlicensed treatments has been followed as brentuximab vedotin is not licensed in this indication in patients aged less than 18 years.<br>13. Brentuximab vedotin will otherwise be used as set out in its Summary of Product Characteristics (SPC). | No | TA577 | 24-Apr-19 | 23-Jul-19 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| BRE13 | **Brentuximab vedotin** in combination with cyclophosphamide, doxorubicin and prednisone | For previously untreated systemic anaplastic large cell lymphoma (sALCL) in an ADULT patient where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with brentuximab vedotin in combination with chemotherapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a proven histological diagnosis of CD30+ve systemic anaplastic large cell lymphoma (sALCL).<br>3. The patient is previously untreated for systemic anaplastic large cell lymphoma.<br>4. The patient has not received prior treatment with brentuximab vedotin.<br>5. The patient will be treated with brentuximab vedotin in combination with cyclophosphamide, doxorubicin and prednisone.<br>6. The patient will be treated with a maximum of 6 or 8 cycles of chemotherapy, 6 cycles being the usual maximum.<br>7. The patient has an ECOG performance status of 0 or 1 or 2.<br>8. A formal medical review as to how the combination of brentuximab vedotin and chemotherapy is being tolerated and whether treatment with the combination of brentuximab vedotin and chemotherapy should continue or not will be scheduled to occur at least by the end of the first 6 weeks of treatment.<br>9. When a treatment break of more than 6 weeks beyond the expected 3 week cycle length occurs, I will complete a treatment break approval form to restart treatment.<br>10. Brentuximab vedotin will otherwise be used as set out in its Summary of Product Characteristics (SPC) | No | TA641 | 12-Aug-20 | 10-Nov-20 |
| BRE14 | **Brentuximab vedotin** in combination with chemotherapy | For previously untreated systemic anaplastic large cell lymphoma (sALCL) in CHILD patients where the following criteria are met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with brentuximab vedotin in combination with chemotherapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a proven histological diagnosis of CD30+ve systemic anaplastic large cell lymphoma (sALCL).<br>3. The patient is previously untreated for systemic anaplastic large cell lymphoma.<br>4. The patient is a child* and the prescribing clinician understands that the Summary of Product Characteristics (SPC) states 'The safety and efficacy in children less than 18 years have not yet been established.'<br>Please mark as to whether pre- or post-pubescent:<br>- is post-pubescent<br>- is pre-pubescent<br>Please enter in the box below the patients age in years and months:<br>_____<br>*Note: there is a separate Blueteq form to be used for brentuximab in this indication in adults.<br>5. The patient has not received prior treatment with brentuximab vedotin or previous cytotoxic chemotherapy*.<br>*Note: patients who present with rapidly progressing disease may receive a single course of chemotherapy, as an emergency treatment given before final diagnosis is established.<br>6. the patient will be treated with brentuximab vedotin in combination with chemotherapy using the brentuximab vedotin dose (1.8mg/kg) and chemotherapy schedule described in the reference below and I understand that that the trial excluded patients less than 10Kg so brentuximab must only be given to patients who weigh 10kg or more.<br>*'Lowe E Reilly AF, Lim MS, Gross TG, Saguilig L, Brakasuskas D et al Brentuximab vedotin in combination with chemotherapy for pediatric patients with ALK1 ALCL: results of COG trial ANHL12P1: Blood 1 July 2021 Volume 137, Number 26,p3595-3603'*<br>7. The use of the brentuximab vedotin has been discussed at a multi-disciplinary team (MDT) meeting which must include at least two consultants in the subspecialty with active and credible expertise in the relevant field of whom at least one must be a consultant paediatrician. The MDT should include a paediatric pharmacist and other professional groups appropriate to the disease area.<br>8. The patient has an ECOG (or equivalent Karnofsky/Lansky Scale) performance status of 0 - 2.<br>9. The patient does not have disease isolated to the skin, stage I disease, or central nervous system involvement.<br>10. Trust policy regarding unlicensed treatments is being followed.<br>11. When a treatment break of more than 6 weeks beyond the expected 3 week cycle length occurs, a treatment break approval form will be completed to restart treatment.<br>*Requests for continuation of treatment after unplanned treatment breaks over this duration should be made via the treatment break approval process<br>12. Brentuximab vedotin will otherwise be used as set out in its Summary of Product Characteristics (SPC). | No | TA641 | 12-Aug-20 | 03-Feb-23 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| BRE15 | **Brentuximab vedotin** in combination with doxorubicin, vinblastine and dacarbazine | For treating adult patients with previously untreated stage III or IV Hodgkin lymphoma where the following criteria have been met: | 1. This application is being made by and the first cycle of brentuximab in combination with doxorubicin, vinblastine and dacarbazine will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient is an adult.<br>3. The patient has previously untreated CD30 positive Hodgkin lymphoma.<br>4. The patient has stage III or IV Hodgkin lymphoma.<br><br>Please mark below which stage applies to this patient:<br>- stage III disease or<br>- stage IV disease<br><br>Note: the use of brentuximab plus chemotherapy is not commissioned in stage I or II Hodgkin lymphoma.<br>5. Brentuximab will be given in combination with doxorubicin, vinblastine and dacarbazine (AVD).<br>6. A maximum of 6 x 28 day cycles of brentuximab plus AVD will be administered to this patient.<br><br>Note: there is no PET-adapted approach to treatment escalation or de-escalation with this brentuximab-AVD combination.<br>7. The prescribing clinician is aware that the scheduled brentuximab dose per day 1 and day 15 administrations is 1.2mg/Kg (ie not the dose used when brentuximab is given as monotherapy).<br>8. The prescribing clinician is aware that the brentuximab SPC recommends that primary prophylaxis with GCSF should begin with the first dose of brentuximab-AVD.<br>9. The patient has an ECOG performance status of 0 or 1 or 2.<br>10. The prescribing clinician is aware that when a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break approval form.<br>11. Brentuximab will be otherwise used as set out in its Summary of Product Characteristics (SPC). | No | TA1059 | 07-May-25 | 05-Aug-25 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| BRI1 | Brigatinib | Brigatinib for anaplastic lymphoma kinase-positive advanced non-small-cell lung cancer previously treated with crizotinib where all the following criteria have been met: | 1. This application is made by and the first cycle of systemic anti-cancer therapy with brigatinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has histological or cytological evidence of NSCLC that carries an anaplastic lymphoma kinase (ALK) rearrangement based on a validated test **OR** there is documented agreement by the lung MDT that the radiological appearances are in keeping with locally advanced or metastatic NSCLC **AND** there is an informative circulating free DNA test result confirming the presence of an activating anaplastic lymphoma kinase (ALK) rearrangement.<br>Please mark below on which basis the diagnosis of ALK positive NSCLC has been made in this patient:<br>- Histological or cytological evidence.<br>- Documented agreement by the lung MDT that the radiological appearances are in keeping with locally advanced or metastatic NSCLC and there is an informative circulating free DNA test result confirming the presence of an activating anaplastic lymphoma kinase (ALK) rearrangement<br>3. The only TKI treatment that the patient has progressed on is 1st line crizotinib or 2nd line crizotinib after 1st line chemotherapy and that the patient has not been treated with either 1st line alectinib or 1st line ceritinib.<br>**Second line brigatinib is only licensed, NICE-approved and funded in patients who have been treated with and progressed on crizotinib as their sole TKI treatment.**<br>4. The patient has not been treated with 2nd line ceritinib after 1st line crizotinib unless the ceritinib had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression<br>5. The patient has not been previously treated with brigatinib unless brigatinib has been received as part of any compassionate use scheme and the patient meets all the other criteria set out here.<br>6. Brigatinib will be used only as monotherapy.<br>7. The patient has an ECOG performance status of 0 or 1 or 2.<br>8. The patient either has no brain metastases or, if the patient has brain metastases, the patient is symptomatically stable prior to starting brigatinib<br>9. The patient will be treated with brigatinib until loss of clinical benefit or excessive toxicity or patient choice to discontinue treatment, whichever is the sooner.<br>10. Treatment breaks of up to 6 weeks are allowed but solely to allow toxicities to settle.<br>11. Brigatinib will be otherwise used as set out in its Summary of Product Characteristics | No | TA571 | 20-Mar-19 | 18-Jun-19 |
| BRI2_v1.3 | **Brigatinib monotherapy** | For anaplastic lymphoma kinase-positive advanced non-small cell lung cancer previously untreated with an ALK inhibitor where the following criteria have been met: | 1. This application for brigatinib is being made by and the first cycle of systemic anti-cancer therapy with brigatinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has locally advanced or metastatic non-small cell lung cancer.<br>3. The patient has histological or cytological evidence of NSCLC that carries an anaplastic lymphoma kinase (ALK) rearrangement based on a validated test **OR** there is documented agreement by the lung MDT that the radiological appearances are in keeping with locally advanced or metastatic NSCLC **AND** there is an informative circulating free DNA test result confirming the presence of an activating anaplastic lymphoma kinase (ALK) rearrangement.<br>Please mark below on which basis the diagnosis of ALK positive NSCLC has been made in this patient:<br>- Histological or cytological evidence.<br>- Documented agreement by the lung MDT that the radiological appearances are in keeping with locally advanced or metastatic NSCLC and there is an informative circulating free DNA test result confirming the presence of an activating anaplastic lymphoma kinase (ALK) rearrangement<br>4. The patient has not previously received any ALK inhibitor for the advanced NSCLC indication unless 1st line treatment with lorlatinib, alectinib, ceritinib or crizotinib has had to be stopped within 6 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression or the patient was treated with adjuvant alectinib and had disease progression more than 6 months after completing treatment with adjuvant alectinib.<br>Please mark below which of the five scenarios applies to this patient:<br>- the patient has never previously received an ALK inhibitor **or**<br>- the patient has previously received **lorlatinib** as 1st line ALK-targeted therapy and this has had to be stopped within **6** months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression **or**<br>- the patient has previously received **alectinib** as 1st line ALK-targeted therapy and this has had to be stopped within **6** months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression **or**<br>- the patient has previously received **crizotinib or ceritinib** as 1st line ALK-targeted therapy and this has had to be stopped within **6** months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression **or**<br>- the patient has previously received treatment with adjuvant alectinib and had disease progression more than 6 months after completing treatment with adjuvant alectinib<br>5. Either the patient is naïve to 1st line cytotoxic chemotherapy-containing systemic treatment for this locally advanced or metastatic NSCLC indication or the patient received 1st line cytotoxic chemotherapy-containing treatment for locally advanced/metastatic non-small cell lung cancer at a time when the ALK status was not known and the patient has since received no further therapy.<br>Please mark which of these 2 scenarios below applies to this patient:<br>- the patient has not received any previous 1st line cytotoxic chemotherapy-containing systemic treatment for the locally advanced or metastatic NSCLC indication **or**<br>- the patient previously received 1st line cytotoxic chemotherapy-containing systemic treatment for locally advanced or metastatic NSCLC at a time when the ALK status was not known.<br>6. The patient has an ECOG performance status of 0 or 1 or 2.<br>7. The patient either has no known brain metastases or if the patient has brain metastases, the patient is symptomatically stable prior to starting brigatinib.<br>8. The patient will be treated until loss of clinical benefit or excessive toxicity or patient choice to discontinue treatment, whichever is the sooner.<br>9. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment.<br>10. The prescribing clinician is aware that: a) none of alectinib or ceritinib or crizotinib are to be used following disease progression on brigatinib as there is no current clear evidence to support treatment with any of these agents after disease progression on brigatinib and<br>b) after disease progression whilst on brigatinib, the only subsequent ALK inhibitor commissioned by NHS England is lorlatinib.<br>c) after disease progression during treatment with adjuvant alectinib or within 6 months of completion of treatment with adjuvant alectinib, treatment with brigatinib is not commissioned<br>11. Brigatinib will otherwise be used as set out in its Summary of Product Characteristics (SPC). | No | TA670 | 27-Jan-21 | 27-Apr-21 |
| CABA1 | **Cabazitaxel** | Cabazitaxel for hormone-relapsed metastatic prostate cancer treated with docetaxel | 1. I confirm that an application has been made and the first cycle of systemic anti-cancer therapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. I confirm the patient has hormone-relapsed metastatic prostate cancer.<br>3. I confirm the patient has received 225mg/m/sq or more of docetaxel and the disease has progressed during or after docetaxel chemotherapy.<br>4. I confirm cabazitaxel is to be prescribed in combination with prednisone or prednisolone.<br>5. I confirm the patient has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1.<br>6. I confirm the patient has been informed that treatment with cabazitaxel will be stopped if the disease progresses or after a maximum of 10 cycles (whichever happens first).<br>7. I confirm the licensed dose and frequency of cabazitaxel will be used. | Yes | TA391 | 25-May-16 | 25-May-16 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| CABNIV1_v1.0 | **Cabozantinib** in combination with nivolumab | For use in treatment-naïve patients with intermediate or poor risk advanced renal cell carcinoma for whom combination treatment with either nivolumab plus ipilimumab or lenvatinib plus pembrolizumab would otherwise be suitable where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with the combination of cabozantinib plus nivolumab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br><br>2. The patient has unresectable locally advanced or metastatic renal cell carcinoma (RCC) which has either a clear cell component or is one of the types of RCC as indicated below.<br>Please indicate below which RCC histology applies to this patient:<br>- RCC with a clear cell component or<br>- Papillary RCC or<br>- Chromophobe RCC or<br>- Collecting duct RCC (Bellini collecting duct RCC) or<br>- Medullary RCC<br>- Mucinous tubular and spindle cell RCC or<br>- Multilocular cystic RCC or<br>- XP11 translocation RCC or<br>- Unclassified RCC<br><br>3. The patient has advanced RCC and the patient's disease is in the intermediate or poor risk category as assessed by the International Metastatic RCC Database Consortium (IMDC) system which scores 1 point for each of the 6 factors listed below – a score of 0 indicates good risk disease, a score of 1-2 indicates intermediate risk and a score of 3-6 denotes poor risk.<br>The IMDC factors are:<br>- less than 1 year from time of initial diagnosis of RCC to now<br>- a Karnofsky performance status of <80%<br>- the haemoglobin level is less than the lower limit of normal<br>- the corrected calcium level is >2.5mmol/L<br>- the platelet count is greater than the upper limit of normal<br>- the absolute neutrophil count is greater than the upper limit of normal.<br>Please indicate below whether the patient is in the intermediate or poor risk prognostic group:<br>- intermediate risk disease (IMDC score of 1 or 2) or<br>- poor risk disease (IMDC score of 3-6)<br>Note: cabozantinib plus nivolumab is not approved for patients with good risk RCC.<br><br>4. The patient is either completely treatment naïve for systemic immune-modulatory therapy for RCC or if the patient has received prior systemic immune-modulatory therapy in the context of adjuvant/neoadjuvant therapy, then such treatment was completed 12 or more months previously and the patient meets all other criteria listed here.<br>Please mark below whether or not previous systemic immune-modulatory therapy has been received in the adjuvant/neoadjuvant setting:<br>- **no previous adjuvant/neoadjuvant** systemic immune-modulatory therapy of any kind and the patient is treatment naïve for the locally advanced/metastatic RCC indication or<br>- **prior adjuvant/neoadjuvant therapy** with immune-modulatory therapies for RCC(anti-Programmed Death receptor-1 (PD-1), anti-Programmed Death-1 ligand-1 (PD-L1), anti-PD L2, anti-CD137 or anti-cytotoxic T lymphocyte associated antigen-4 (anti-CTLA-4) antibodies) and last dose received by the patient was 12 or more months prior to this application and the patient is treatment naïve for the locally advanced/metastatic RCC indication<br>Please mark in the box the time since end of treatment with adjuvant/neoadjuvant immune-modulatory therapy:<br>_____<br><br>5. In the absence of cabozantinib plus nivolumab, the patient would otherwise be suitable for combination treatment with either nivolumab plus ipilimumab or lenvatinib plus pembrolizumab.<br>Note: NICE recommended cabozantinib plus nivolumab as an option only in those patients who would otherwise be suitable for either nivolumab plus ipilimumab or lenvatinib plus pembrolizumab but not in patients suitable for single agent TKI therapy.<br><br>6. The patient has a Karnofsky performance status of at least 70 (ie an ECOG performance score of 0 or 1).<br><br>7. The patient has no symptomatic brain metastases or leptomeningeal metastases currently requiring steroids for symptom control.<br><br>8.The patient is to be treated with cabozantinib until loss of clinical benefit or excessive toxicity or withdrawal of patient consent, whichever is the sooner.<br>Note: there is no stopping rule as to the maximum treatment duration of the cabozantinib part of this indication.<br>Note: if cabozantinib is permanently discontinued on account of toxicity, treatment with nivolumab can be continued as monotherapy as long as there is no evidence of progressive disease and the patient has not already completed 2 years of treatment with nivolumab.<br><br>9. The patient will receive the licensed dose, frequency, and route of nivolumab for this indication, as shown below<br>• **Subcutaneously** – at a dose of 600mg every 2 weeks, or 1200mg every 4 weeks<br>• **Intravenously** – at a dose of 240mg every 2 weeks, or 480mg every 4 weeks<br><br>10. The patient is to be treated with nivolumab until loss of clinical benefit or excessive toxicity or withdrawal of patient consent or **completion of a total treatment duration of 2 calendar years***, whichever occurs first.<br>*2 calendar years of treatment is defined as a duration of treatment which does not have any cycles of nivolumab in the period commencing on or after a date which is 2 years after the date of first nivolumab treatment.<br>Note: if nivolumab is permanently discontinued on account of toxicity, treatment with cabozantinib can be continued as monotherapy as long as there is no evidence of progressive disease.<br><br>11. When a treatment break of more than 12 weeks beyond the expected 2- or 4-weekly cycle length is needed, I will complete a treatment break approval form requesting a restart of treatment. This **must** be approved before nivolumab and/or cabozantinib is re-commenced<br><br>12. If the disease progresses on the cabozantinib plus nivolumab combination and further systemic therapy is appropriate, the next line of treatment will be chosen from those options which are routinely commissioned ie for the next line of systemic therapy, there will be use of one choice of the following (mainly incorporating TKI options which have multiple modes of action): the currently commissioned 2nd line options of axitinib or lenvatinib plus everolimus or everolimus monotherapy or the currently commissioned 1st line options of sunitinib (still on label as 2nd line treatment) or pazopanib (off label as 2nd line treatment) or tivozanib (off label as 2nd line treatment).<br><br>13. Cabozantinib and nivolumab will be otherwise prescribed and administered as outlined in their respective Summary of Product Characteristics (SPCs). | No | TA964 | 10-Apr-24 | 09-Jul-24 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| CABO1 | **Cabozantinib** | The treatment of medullary thyroid cancer where all the following criteria are met: | 1. This application is made by and the first cycle of systemic anti-cancer therapy with cabozantinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy<br>2. This patient has a confirmed histological diagnosis of medullary thyroid carcinoma<br>3. The patient has either metastatic disease or inoperable locally advanced disease<br>4. The disease is progressive and is either symptomatic or imminently likely to become symptomatic<br>5. The patient is treatment naïve to both cabozantinib and vandetanib unless the patient has had to discontinue vandetanib within 3 months of starting vandetanib because of toxicity (i.e. there is vandetanib toxicity which cannot be managed by dose delay or dose modification) and there has been no disease progression whilst on vandetanib.<br>6. The patient has an ECOG performance status of 0 or 1 or 2.<br>7. Cabozantinib is to be continued as long as clinical benefit is observed or until there is unacceptable toxicity or patient choice to stop treatment<br>8. A formal medical review as to whether treatment with cabozantinib should continue or not will be scheduled to occur at least by the end of the first 8 weeks of treatment<br>9. No treatment breaks of more than 6 weeks beyond the expected cycle length are allowed (to allow any toxicity of current therapy to settle or intercurrent comorbidities to improve)<br>10. Cabozantinib is to be otherwise used as set out in its Summary of Product Characteristics | Yes | TA516 | 28-Mar-18 | 26-Jun-18 |
| CABO2 | **Cabozantinib** | The treatment of previously treated advanced renal cell carcinoma where the following criteria are met: | 1. This application is being made by and the first cycle of systemic anti -cancer therapy with cabozantinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy<br>2. The patient has a histologically- or cytologically-proven diagnosis of renal cell carcinoma (RCC) which either has a clear cell component or is one of the types of RCC as indicated below.<br>Please indicate below which RCC histology applies to this patient:<br>- RCC with a clear cell component or<br>- papillary RCC or<br>- chromophobe RCC or<br>- collecting duct RCC (Bellini collecting duct RCC) or<br>- medullary RCC or<br>- mucinous tubular and spindle cell RCC or<br>- multilocular cystic RCC or<br>- XP11 translocation RCC or<br>- unclassified RCC<br>3. The patient has either metastatic disease or inoperable locally advanced disease<br>4. The patient has previously received at least 1 vascular endothelial growth factor (VEGF)-targeted systemic therapy and has not been previously treated with cabozantinib.<br><br>**Note:** the patient may also have received prior treatment with an anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CD137, or anti-Cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) antibody for renal cancer.<br>5. The patient has progressed on previous treatment or within 6 months of most recent dose of VEGF inhibitor<br>6. The patient has a performance status of 0 or 1<br>7. If the patient has brain metastases then these have been treated and are stable<br>8. Cabozantinib is to be continued until loss of clinical benefit or unacceptable toxicity or patient choice to stop treatment or cabozantinib can be stopped with a planned treatment break following the protocol used in the STAR trial.<br><br>Note: following 24 weeks of continuous cabozantinib therapy, and if there is no evidence of disease progression on therapy, patients and clinicians may choose to stop treatment for a planned drug free interval/treatment break and then restart cabozantinib on disease progression as per the STAR trial design.<br><br>Note: all patients who undergo planned treatment breaks must have regular clinical and radiological assessments and then have the option of restarting cabozantinib on disease progression.<br><br>Note: if the patient benefits from restarting after the first planned treatment break, they can take further planned treatments breaks following the same strategy, i.e. after a further 24 weeks on treatment.<br>Ref for the STAR trial: Brown JE, Royle KA, Gregory W, Ralph C, Maraveyas A, Din O et al. 'Temporary treatment cessation versus continuation of first-line tyrosine kinase inhibitor in patients with advanced clear cell renal cell carcinoma (STAR): an open-label, non-inferiority, randomised, controlled, phase 2/3 trial.' The Lancet Oncology,2023, February 13 https://doi.org/10.1016/S1470-2045(22)00793-8.<br>9. A formal medical review as to whether treatment with cabozantinib should continue or not will be scheduled to occur at least by the end of the first 8 weeks of treatment<br>10. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, a treatment break approval form will be completed to restart treatment unless the patient is following a planned intermittent treatment schedule as evidenced by the STAR trial and described above.<br>11. Cabozantinib will otherwise be used as set out in its Summary of Product Characteristics (SPC). | Yes | TA463 | 08-Nov-17 | 08-Nov-17 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| CABO3 | **Cabozantinib** | The treatment of treatment-naïve to vascular endothelial growth factor (VEGF)-targeted therapy and with intermediate or poor risk advanced renal cell carcinomawhere the following criteria are met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with cabozantinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. This patient has a histologically- or cytologically-proven diagnosis of renal cell carcinoma (RCC) which either has a clear cell component or is one of the types of RCC as indicated below.<br><br>Please indicate below which RCC histology applies to this patient:<br>- RCC with a clear cell component or<br>- papillary RCC or<br>- chromophobe RCC or<br>- collecting duct RCC (Bellini collecting duct RCC) or<br>- medullary RCC or<br>- mucinous tubular and spindle cell RCC or<br>- multilocular cystic RCC or<br>- XP11 translocation RCC or<br>- unclassified RCC<br>3. The patient has either metastatic disease or inoperable locally advanced disease<br>4. Cabozantinib is either being used as 1st line treatment for renal carcinoma or as 2nd line treatment in patients previously treated with 1st line nivolumab plus ipilimumab.<br>Please mark below in which setting cabozantinib is being used in this patient:<br>- 1st line treatment or<br>- 2nd line treatment after 1st line therapy with nivolumab plus ipilimumab<br>Note: NHS England does not fund cabozantinib in this indication after disease progression with pembrolizumab plus lenvatinib or avelumab plus axitinib or nivolumab plus cabozantinib.<br>5. The patient has not previously received any vascular endothelial growth factor (VEGF)-targeted systemic therapy unless the patient commenced 1st line treatment with whichever of pazopanib or sunitinib or tivozanib as the immediate prior therapy and this had to be stopped within 3 months of its start and solely because of dose-limiting toxicity and in the clear absence of disease progression.<br><br>Please mark which of these 2 scenarios below applies to this patient:<br>- the patient has not previously received any vascular endothelial growth factor (VEGF)-targeted systemic therapy or<br>- has only previously received treatment with 1st line pazopanib or sunitinib or tivozanib as the immediate prior therapy and which had to be stopped within 3 months of its start solely because of dose-limiting toxicity and in the clear absence of disease progression<br>6. The patient has intermediate risk OR poor risk advanced renal cell carcinoma as defined by the International Metastatic Renal Cell Carcinoma Database Consortium. Good risk patients are not eligible for cabozantinib therapy.<br><br>Intermediate risk is defined as having 1 or 2 risk factors and poor risk as having >=3 factors, these factors being:<br>- Time from diagnosis of RCC to need for systemic therapy of <1 year<br>- Haemoglobin < lower limit of normal<br>- Corrected calcium > upper limit of normal<br>- Karnofsky performance status <80%<br>- Neutrophils > upper limit of normal<br>- Platelet count > upper limit of normal<br>**Please indicate whether patients has intermediate risk or poor risk disease:**<br>- intermediate risk poor risk<br>- poor risk<br>7. The patient has an ECOG performance status of either 0 or 1 or 2<br>8. If the patient has brain metastases, then these have been treated and are stable.<br>9. Cabozantinib is to be continued until loss of clinical benefit or unacceptable toxicity or patient choice to stop treatment or cabozantinib can be stopped with a planned treatment break following the protocol used in the STAR trial.<br><br>Note: following 24 weeks of continuous cabozantinib therapy, and if there is no evidence of disease progression on therapy, patients and clinicians may choose to stop treatment for a planned drug free interval/treatment break and then restart cabozantinib on disease progression as per the STAR trial design.<br><br>Note: all patients who undergo planned treatment breaks must have regular clinical and radiological assessments and then have the option of restarting cabozantinib on disease progression.<br><br>Note: if the patient benefits from restarting after the first planned treatment break, they can take further planned treatments breaks following the same strategy, i.e. after a further 24 weeks on treatment.<br>Ref for the STAR trial: Brown JE, Royle KA, Gregory W, Ralph C, Maraveyas A, Din O et al. 'Temporary treatment cessation versus continuation of first-line tyrosine kinase inhibitor in patients with advanced clear cell renal cell carcinoma (STAR): an open-label, non-inferiority, randomised, controlled, phase 2/3 trial.' The Lancet Oncology,2023, February 13 https://doi.org/10.1016/S1470-2045(22)00793-8.<br>10. A formal medical review as to whether treatment with cabozantinib should continue or not will be scheduled to occur at least by the end of the first 8 weeks of treatment<br>11. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, a treatment break approval form will be completed to restart treatment with cabozantinib, unless the patient is following a planned intermittent treatment schedule as evidenced by the STAR trial and described above.<br>12. Cabozantinib is to be otherwise used as set out in its Summary of Product Characteristics | Yes | TA542 | 03-Oct-18 | 01-Jan-19 |
| CABO4 | **Cabozantinib** | For the second line of tyrosine kinase inhibitor systemic therapy of Child-Pugh A locally advanced or metastatic hepatocellular carcinoma previously treated with sorafenib where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with cabozantinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has been previously treated with sorafenib for locally advanced or metastatic hepatocellular carcinoma.<br>3. The patient currently has Child-Pugh liver function class A.<br>4. The patient has an ECOG performance status of 0 or 1.<br>Note: NICE has not recommended cabozantinib in patients with an ECOG performance status of 2 or more.<br>5. The only other TKI with which the patient has been previously treated is sorafenib unless regorafenib has had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression.<br>6. The patient has not been previously treated with cabozantinib.<br>7. Cabozantinib is to be used only as monotherapy.<br>8. Cabozantinib is to be continued until loss of clinical benefit or unacceptable toxicity or patient choice to stop treatment, whichever is the sooner.<br>9. A formal medical review as to whether treatment with cabozantinib should continue or not will be scheduled to occur no later than by the end of the 2nd month of therapy.<br>10. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, a treatment break form will be completed to restart treatment, including an indication as appropriate if the patient had an extended break because of COVID 19.<br>11. Cabozantinib will be otherwise used as set out in its Summary of Product Characteristics. | Yes | TA849 | 14-Dec-22 | 14-Mar-23 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| CAP1 | **Capivasertib** in combination with fulvestrant | Capivasertib in combination with fulvestrant for hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer in patients previously treated with a CDK4/6 inhibitor and an aromatase inhibitor where the following criteria have been met: | 1. This application for capivasertib in combination with fulvestrant is being made by and the first cycle of capivasertib plus fulvestrant will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has histologically or cytologically documented hormone receptor positive and HER-2 negative breast cancer.<br>3. The patient's breast cancer has a PIK3CA or an AKT1 or a PTEN genomic alteration identified using a validated test.<br><br>Please set out below which genomic alteration(s) has/have been found on testing:<br>- solely a PIK3CA alteration or<br>- solely a AKT1 alteration or<br>- solely a PTEN alteration or<br>- 2 or more of these 3 genomic alterations<br>4. The patient has metastatic or locally advanced breast cancer which is not amenable to curative treatment.<br>5. If the patient is female and pre- or peri-menopausal, the patient has undergone ovarian ablation or suppression with LHRH agonist treatment and if the patient is male, consideration has been given to administration of LHRH agonist therapy.<br>6. The patient has progressive disease after previous endocrine-based therapy.<br>7. The patient has been previously treated with an aromatase inhibitor.<br><br>- solely for early breast cancer or<br>- solely for locally advanced/metastatic breast cancer or<br>- in both early and advanced breast cancer settings<br>8. The patient has been previously treated with a CDK4/6 inhibitor.<br><br>Please record in which places in the treatment pathway the patient had CDK4/6 inhibitor therapy:<br>- solely for early breast cancer or<br>- solely for locally advanced/metastatic breast cancer or<br>- in both early and advanced breast cancer settings<br><br>Note: the company submitted a case to NICE for consideration of clinical and cost effectiveness only in patients previously treated with a CDK4/6 inhibitor and an aromatase inhibitor. This population is narrower than that in the marketing authorisation.<br>9. The patient has had no prior treatment with fulvestrant for any indication unless this patient has either received capivasertib plus fulvestrant via the company early access programme and all other conditions on this form are complied with or this patient is switching from treatment with alpelisib plus fulvestrant due to toxicity (see criterion 10 below).<br>10. The patient has not previously received any treatment with a PIK3CA-targeted drug (such as alpelisib) unless this patient has received previous treatment with alpelisib plus fulvestrant but such treatment with alpelisib plus fulvestrant has had to be stopped within 6 months of its start solely as a consequence of excessive toxicity and in the clear absence of disease progression and if all other treatment criteria on this form apply.<br><br>Please record which scenario applies to this patient:<br>- the patient has not previously received any treatment with a PIK3CA-targeted drug or<br>- the patient has received previous treatment with alpelisib plus fulvestrant but such treatment with alpelisib plus fulvestrant has had to be stopped within 6 months of its start solely as a consequence of excessive toxicity and in the clear absence of disease progression and all other treatment criteria on this form apply<br>11. The patient has an ECOG performance status of 0 or 1.<br>12. Capivasertib will only be given in combination with fulvestrant.<br><br>Note: capivasertib is not commissioned in combination with elacestrant.<br>13. Treatment with capivasertib plus fulvestrant will continue until there is progressive disease or excessive toxicity or until the patient chooses to discontinue treatment, whichever is the sooner.<br>14. The prescribing clinician is aware of the potentially serious side-effects of capivasertib (particularly hyperglycaemia, cutaneous reactions, diarrhoea) and of the necessary capivasertib dose adjustments for these toxicities, as outlined in capivasertib's Summary of Product Characteristics.<br>15. Before starting treatment the patient will undergo testing for fasting blood sugar and HbA1C and should this patient develop hyperglycaemia, a consultation with a diabetologist will be considered when selecting the anti-diabetic medication because of the risk of hypoglycaemia particularly on non-dosing days of capivasertib.<br>16. The prescribing clinician is aware of the various potential drug interactions between capivasertib and other drugs, as outlined in section 4.5 of capivasertib's Summary of Product Characteristics.<br>17. When a treatment break of up to 6 weeks beyond the expected 4-weekly cycle length is needed, I as the prescribing clinician will complete a treatment break approval form to restart treatment.<br>18. Capivasertib and fulvestrant will be otherwise used as set out in their respective Summaries of Product Characteristics (SPCs). | No | TA1063 | 15-May-25 | 13-Aug-25 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| CAR1 | **Carfilzomib** | The treatment of previously treated multiple myeloma where all the following crtieria are met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with carfilzomib plus dexamethasone will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a diagnosis of multiple myeloma.<br>3. The patient has relapsed or progressing disease.<br>4. The patient has received 1 and only 1 prior line of treatment and that the numbering of a line of treatment is in accordance with the International Myeloma Workshop Consensus recommendations for the uniform reporting of clinical trials (http://doi.org/10.1182/blood-2010-10-299487). A line of therapy is defined as one or more cycles of a planned treatment program. This may consist of one or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner (eg induction chemotherapy/chemotherapies if followed by stem cell transplantation then maintenance is considered to be 1 line of therapy). A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse or toxicity. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease.<br>Note: the use of carfilzomib in combination with dexamethasone in patients who have had 1 and only 1 prior line of therapy is because of NICE's specific recommendation for routine commissioning. The use of carfilzomib in combination with dexamethasone in the 2- or more prior line patient groups is not permitted.<br>5. One of the following options applies as to any previous systemic therapy with bortezomib for this patient:<br>- the patient has not received any previous treatment with bortezomib or<br>- the patient has received prior bortezomib as part of 1st line treatment and there has been at least a 6- month proteasome inhibitor treatment-free interval from the last bortezomib dose.<br>6. The patient has an ECOG performance status (PS) of 0 or 1 or 2.<br>7. Carfilzomib will only be administered in combination with dexamethasone and with no other systemic anticancer therapies.<br>8. A formal medical review as to whether treatment with carfilzomib plus dexamethasone should continue or not will be scheduled to occur no later than by the end of the 2nd month of therapy.<br>9. Where a treatment break of more than 12 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break form to restart treatment, including an indication as appropriate if the patient had an extended break because of COVID 19.<br>10. Carfilzomib will otherwise be used as set out in its Summary of Product Characteristics (SPC). | Yes | TA657 (previously TA475) | 18-Nov-20 | 17-Oct-17 |
| CAR2 | **Carfilzomib** in combination with lenalidomide and dexamethasone | For the treatment of previously treated multiple myeloma in patients who have had 1 prior line of systemic therapy where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with carfilzomib in combination with lenalidomide and dexamethasone will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a diagnosis of multiple myeloma.<br>3. The patient has relapsed or progressing disease.<br>4. The patient has received 1 and only 1 prior line of treatment and that the numbering of a line of treatment is in accordance with the International Myeloma Workshop Consensus recommendations for the uniform reporting of clinical trials (http://doi.org/10.1182/blood-2010-10-299487). A line of therapy is defined as one or more cycles of a planned treatment program. This may consist of one or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner (eg induction chemotherapy/chemotherapies if followed by stem cell transplantation and maintenance therapy is considered to be 1 line of therapy). A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse or toxicity. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease.<br>Note: the use of carfilzomib in combination with lenalidomide and dexamethasone in patients who have had 1 and only 1 prior line of therapy is because of NICE's specific recommendation for this position in the myeloma treatment pathway. The use of carfilzomib in combination with lenalidomide and dexamethasone in the 2- or more prior line patient groups is not permitted.<br>5. The patient was treated with a bortezomib-containing regimen as part of 1st line treatment and the patient responded to this bortezomib-containing therapy.<br>Note: the company, when making its submission to NICE, stipulated that it wished consideration of a recommendation only in the group of patients who had been previously treated with bortezomib.<br>Note: the ASPIRE trial, on which the Amgen submission to NICE was based, included only patients who had responded to treatment. As Amgen restricted its submission to patients who had previously had 1 line of therapy, NICE's recommendation is based on patients who had responded to a bortezomib-containing 1st line regimen.<br>6. The patient has not been previously treated with lenalidomide unless lenalidomide was received in one of the specific scenarios listed below.<br>Please confirm whether the patient has received previous lenalidomide or not:<br>- the patient has not previously received any lenalidomide-containing therapy **or**<br>- the patient has received lenalidomide-containing chemotherapy but only as part of induction chemotherapy prior to a stem cell transplant<br>- the patient has received post-transplant lenalidomide maintenance, which was stopped due to patient choice (and therefore NOT stopped due to progressive disease or unmanageable toxicity)<br>Note: NICE's decision-making as to its recommendation of carfilzomib in combination with lenalidomide and dexamethasone was based on patients who did not have progressive disease on 1st line lenalidomide-containing therapy or who were intolerant of 1st line lenalidomide.<br>7. The patient has not been previously treated with carfilzomib.<br>8. 1st line treatment either included stem cell transplantation or not:<br>9. The patient has an ECOG performance status (PS) of 0 or 1 or 2.<br>10. The patient will receive a maximum of 18 cycles of carfilzomib and that a patient continuing to respond after completing 18 cycles of carfilzomib plus lenalidomide plus dexamethasone will continue on treatment with lenalidomide plus dexamethasone without carfilzomib.<br>11. Carfilzomib will only be administered in combination with lenalidomide and dexamethasone and with no other systemic anticancer therapies.<br>12. Carfilzomib (to a maximum of 18 cycles) plus lenalidomide plus dexamethasone is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment or patient proceeds to stem cell transplant*, whichever is the sooner<br>*Carfilzomib with lenalidomide and dexamethasone is intended to be used for transplant ineligible patients after relapse or progression of first line therapy. Any patient receiving carfilzomib with lenalidomide and dexamethasone in this indication who subsequently becomes transplant eligible and is then able to proceed to transplant cannot resume treatment post-transplant as carfilzomib with lenalidomide and dexamethasone is not funded as maintenance therapy post-transplant.<br>13. Where a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break form to restart treatment, , which MUST be approved before treatment is recommenced.<br>14. Carfilzomib will otherwise be used as set out in its Summary of Product Characteristics (SPC). | No | TA695 | 28-Apr-21 | 27-Jul-21 |

# National Cancer Drugs Fund (CDF) List

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| CEM1 | **Cemiplimab** | Cemiplimab monotherapy for the treatment of adult patients with locally advanced or metastatic cutaneous squamous cell carcinoma where the following treatment criteria have been met: | 1. This application has been made by and the first cycle of systemic anti -cancer therapy with cemiplimab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The prescribing clinician is fully aware of the management of and the treatment modifications that may be required for immune-related adverse reactions due to anti-PD-1 treatments including pneumonitis, colitis, nephritis, endocrinopathies, hepatitis and cutaneous reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis.<br>3. The patient has a histologically- or cytologically-confirmed diagnosis of cutaneous squamous cell carcinoma.<br>4. The patient has either locally advanced disease or metastatic disease and is not a candidate for curative surgery or curative radiotherapy.<br>Please record here whether the disease is locally advanced or metastatic and if metastatic, whether the disease is nodal only or includes distant spread:<br>- locally advanced disease which results in the patient not being a candidate for curative surgery or curative radiotherapy **or**<br>- metastatic disease with spread which is nodal only **or**<br>- metastatic disease with spread that includes distant metastasis (eg lung, liver, bone etc)<br>5. The patient does not have a contra-indication to being treated with cemiplimab and that I am aware that immunocompromised patients were not included in the main cemiplimab clinical study: exclusion criteria in this study excluded any patient with a previous solid organ transplant or autoimmune disease which required systemic therapy with immunosuppressive agents within the previous 5 years or a history of pneumonitis within the last 5 years.<br>Cemiplimab should therefore be used with caution in immunosuppressed patients. By ticking 'yes' in the adjacent box you are stating that if cemiplimab is being administered to an immunocompromised patient, then you have evaluated and fully discussed with the patient the benefits and the risks of treatment with cemiplimab (eg rejection of a solid organ transplant).<br>Please tick the correct box as to whether the patient fulfils the above definition of immunocompromise:<br>- no immunocompromise **or**<br>- a previous solid organ transplant or autoimmune disease which required systemic therapy with immunosuppressive agents within the previous 5 years or a history of pneumonitis within the last 5 years.<br>6. Cemiplimab is to be given solely as monotherapy<br>7. Treatment with cemiplimab will continue until loss of clinical benefit or unacceptable toxicity or withdrawal of patient consent or for a maximum treatment duration of 2 years (or 35 3-weekly cycles of cemiplimab), whichever occurs first.<br>In those patients transferring from the Sanofi early access scheme (see below in criterion 10), a maximum total treatment duration of 2 years of treatment applies.<br>8. The patient is fit for treatment with cemiplimab and has an ECOG performance status score of 0 or 1.<br>9. The patient has no symptomatically active brain metastases or leptomeningeal metastases.<br>10. The patient has not received prior treatment with an anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CD137, or anti-Cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) antibody unless the patient has been entered into the Sanofi cemiplimab early access scheme and all other treatment criteria on this form are fulfilled (eg ECOG performance status).<br>Please mark below whether the patient was previously enrolled in the Sanofi early access scheme:<br>- not enrolled in Sanofi early access scheme ie patient is cemiplimab-naive or<br>- previously enrolled in Sanofi early access scheme and all other treatment criteria on this form are fulfilled.<br>11. A formal medical review as to whether treatment with cemiplimab should continue or not will be scheduled to occur at least by the end of the first 6 weeks of treatment.<br>12. Treatment breaks of up to 12 weeks beyond the expected cycle length are allowed but solely to allow any immune toxicities to settle.<br>13. Cemiplimab will be otherwise used as set out in its Summary of Product Characteristics (SPC) | No | TA802 | 29-Jun-22 | 27-Sep-22 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| CER1 | **Ceritinib** | Ceritinib for anaplastic lymphoma kinase-positive advanced non-small-cell lung cancer previously treated with crizotinib where the following criteria are met: | 1. I confirm that this application is made by and the first cycle of systemic anti-cancer therapy with ceritinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has histological or cytological evidence of NSCLC that carries an anaplastic lymphoma kinase (ALK) rearrangement based on a validated test **OR** there is documented agreement by the lung MDT that the radiological appearances are in keeping with locally advanced or metastatic NSCLC **AND** there is an informative circulating free DNA test result confirming the presence of an activating anaplastic lymphoma kinase (ALK) rearrangement.<br>Please mark below on which basis the diagnosis of ALK positive NSCLC has been made in this patient:<br>- Histological or cytological evidence.<br>- Documented agreement by the lung MDT that the radiological appearances are in keeping with locally advanced or metastatic NSCLC and there is an informative circulating free DNA test result confirming the presence of an activating anaplastic lymphoma kinase (ALK) rearrangement<br>3. I confirm that the only TKI treatment that the patient has progressed on is 1st line crizotinib or 2nd line crizotinib after 1st line chemotherapy and that the patient has not been treated with either 1st line alectinib or 1st line ceritinib.<br>Ceritinib in this indication is only funded in patients who have been treated with and progressed on crizotinib as their sole TKI treatment.<br>4. I confirm that the patient has not been treated with 2nd line brigatinib after 1st line crizotinib unless the brigatinib had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression.<br>5. I confirm that the patient has not been previously treated with ceritinib.<br>6. I confirm that ceritinib will be used only as monotherapy.<br>7. I confirm that the patient has an ECOG performance status of 0 or 1 or 2.<br>8. I confirm that the patient either has no brain metastases or, if the patient has brain metastases, the patient is symptomatically stable prior to starting ceritinib.<br>9. I confirm that the patient will be treated with ceritinib until loss of clinical benefit or excessive toxicity or patient choice to discontinue treatment, whichever is the sooner.<br>10. I confirm that treatment breaks of up to 6 weeks are allowed but solely to allow toxicities to settle.<br>11. I confirm that ceritinib will be otherwise used as set out in its Summary of Product Characteristics | No | TA395 | 22-Jun-16 | 20-Sep-16 |
| CER2 | **Ceritinib** | For anaplastic lymphoma kinase-positive advanced non-small cell lung cancer previously untreated with an ALK inhibitor where the following criteria have been met: | 1. This application for ceritinib is being made by and the first cycle of systemic anti-cancer therapy with ceritinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has locally advanced or metastatic non-small cell lung cancer.<br>3. The patient has histological or cytological evidence of NSCLC that carries an anaplastic lymphoma kinase (ALK) rearrangement based on a validated test **OR** there is documented agreement by the lung MDT that the radiological appearances are in keeping with locally advanced or metastatic NSCLC **AND** there is an informative circulating free DNA test result confirming the presence of an activating anaplastic lymphoma kinase (ALK) rearrangement.<br>Please mark below on which basis the diagnosis of ALK positive NSCLC has been made in this patient:<br>- Histological or cytological evidence.<br>- Documented agreement by the lung MDT that the radiological appearances are in keeping with locally advanced or metastatic NSCLC and there is an informative circulating free DNA test result confirming the presence of an activating anaplastic lymphoma kinase (ALK) rearrangement<br>4. The patient has not previously received any ALK inhibitor unless 1st line alectinib or 1st line brigatinib or 1st line crizotinib has had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression.<br>Please mark below which of the four scenarios applies to this patient:<br>- the patient has never previously received an ALK inhibitor or<br>- the patient has previously received alectinib as 1st line ALK-targeted therapy and this has had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression or<br>- the patient has previously received brigatinib as 1st line ALK-targeted therapy and this has had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression or<br>- the patient has previously received crizotinib as 1st line ALK-targeted therapy and this has had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression.<br>5. The patient is treatment-naïve to 1st line cytotoxic chemotherapy-containing systemic treatment for this locally advanced or metastatic NSCLC indication.<br><br>Note: the only previous cytotoxic treatment allowed for patients to be treated with 1st line ceritinib is adjuvant or neoadjuvant chemotherapy or chemotherapy given concurrently with radiotherapy.<br>6. The patient has an ECOG performance status of 0 or 1 or 2.<br>7. The patient either has no known brain metastases or if the patient has brain metastases, the patient is symptomatically stable prior to starting ceritinib.<br>8. Ceritinib will be used as monotherapy.<br>9. The patient will be treated until loss of clinical benefit or excessive toxicity or patient choice to discontinue treatment, whichever is the sooner<br>10. A formal medical review as to whether treatment with ceritinib should continue or not will be scheduled to occur at least by the end of the first 8 weeks of treatment.<br>11. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment, including as appropriate if the patient had an extended break on account of Covid-19.<br>12. The prescribing clinician is aware that a) none of alectinib or brigatinib or crizotinib are to be used following disease progression on ceritinib as there is no current clear evidence to support treatment with any of these agents after disease progression on ceritinib and b) after disease progression on ceritinib, the only subsequent ALK inhibitor commissioned by NHS England is lorlatinib.<br>13. Ceritinib will otherwise be used as set out in its Summary of Product Characteristics (SPC). | No | TA500 | 24-Jan-18 | 24-Apr-18 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| CET4_v1.2 | **Cetuximab** in combination with FOLFIRINOX/ FOLFOXIRI (5-fluorouracil, irinotecan and oxaliplatin) chemotherapy | For chemotherapy-naïve metastatic or locally advanced and inoperable colorectal cancer where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with cetuximab in combination with FOLFIRINOX/FOLFOXIRI chemotherapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. This patient has RAS wild-type metastatic or locally advanced and inoperable colorectal cancer.<br>3. This patient has not received previous cytotoxic chemotherapy for metastatic disease unless there has been use of previous neoadjuvant combination cytotoxic chemotherapy for potentially resectable metastatic colorectal cancer.<br>Please mark below whether the patient has had neoadjuvant chemotherapy or not:<br>- the patient has not had previous neoadjuvant cytotoxic chemotherapy for metastatic colorectal cancer **or**<br>- the patient has been treated with previous neoadjuvant cytotoxic chemotherapy for potentially resectable metastatic colorectal cancer<br>4. Cetuximab in this FOLFIRINOX/FOLFOXIRI combination is being used as either 1st line treatment for metastatic colorectal cancer or as 2nd line treatment if treated with 1st line pembrolizumab for MSI-H/dMMR disease.<br>Please mark below in which line of therapy the patient is having cetuximab plus FOLFIRINOX/FOLFOXIRI chemotherapy:<br>- cetuximab + FOLFIRINOX/FOLFOXIRI is being used as 1st line treatment for metastatic colorectal cancer **or**<br>- cetuximab + FOLFIRINOX/FOLFOXIRI is being used as 2nd line treatment for metastatic colorectal cancer as the patient has MSI-H/dMMR disease and has been treated with 1st line pembrolizumab or 1st line nivolumab which was previously available as an Interim COVID option<br>5. The patient has not received prior treatment with cetuximab or panitumumab unless this was received as part of combination neoadjuvant chemotherapy for potentially resectable metastatic disease.<br>Patients with potentially resectable metastatic disease who have received a neoadjuvant cetuximab/panitumumab-containing combination chemotherapy with the intention of resection if the metastases become resectable, and who do not progress while on treatment with cetuximab/panitumumab but who then become unsuitable for surgery or have unsuccessful surgery, may continue treatment with the same cetuximab/panitumumab-containing combination chemotherapy.<br>Patients who have successful resection(s) after neoadjuvant cetuximab/panitumumab-containing combination chemotherapy for metastatic disease and who did not progress on such chemotherapy may receive cetuximab/panitumumab with subsequent first-line combination chemotherapy if they present later with progression of metastatic disease.<br>Please mark below the patient's treatment status in respect of previous cetuximab/panitumumab-containing neoadjuvant chemotherapy:<br>- the patient has not been treated with previous chemotherapy with either cetuximab or panitumumab-containing combination chemotherapy for metastatic disease **or**<br>- the only previous cetuximab/panitumumab-containing chemotherapy was with neoadjuvant treatment for potentially resectable disease which resulted in a lack of disease progression and the patient was then unable to proceed to surgery or had unsuccessful surgery **or**<br>- the only previous cetuximab/panitumumab-containing chemotherapy was with neoadjuvant treatment for potentially resectable disease which resulted in a lack of disease progression and the patient was then able to proceed to surgery but has since relapsed<br>6. The prescribing clinician is aware that if this patient has BRAF V600 mutation-positive disease, the patient will be ineligible for encorafenib plus cetuximab as a subsequent line of therapy if they receive a cetuximab/panitumumab-containing regimen now as first-line therapy.<br>7. The prescribing clinician is aware that from 1st December 2020 an NHS England Best Value framework is in operation for cetuximab and panitumumab in first line colorectal cancer. The choice of this cetuximab-containing regimen is therefore in line with the local application of the Best Value framework for these drugs within my organisation.<br>8. This patient will receive cetuximab in combination FOLFIRINOX/FOLFOXIRI (5-fluorouracil, irinotecan and oxaliplatin in combination) chemotherapy.<br>9. Cetuximab will be given as a 2-weekly regimen at a dose of 500mg/m2.<br>10. Trust policy regarding the use of unlicensed treatments has been followed as cetuximab is not licensed for 2-weekly administration.<br>11. Cetuximab in combination with FOLFIRINOX chemotherapy will be given until disease progression on this regimen and that cetuximab will be discontinued when this disease progression occurs.<br>If the patient experiences excessive toxicity with irinotecan and/or oxaliplatin, cetuximab can be subsequently continued in combination with a fluoropyrimidine without irinotecan and/or oxaliplatin until disease progression and then will be discontinued.<br>Note: continued use of cetuximab beyond 1st line therapy is not commissioned once disease progression has occurred with 1st line treatment.<br>12. When a treatment break of more than 6 weeks beyond the expected cycle length is needed, I will complete a treatment break form to restart treatment, including an indication as appropriate if the patient had an extended break because of COVID 19.<br>13. The use of cetuximab will be otherwise used as per its Summary of Product Characteristics (SPC). | Yes | TA439 | 29-Mar-17 | 27-Jun-17 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| CET1_v1.2 | **Cetuximab** in combination with irinotecan-based chemotherapy | For chemotherapy-naive metastatic or locally advanced and inoperable colorectal cancer where all the following criteria are met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with cetuximab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. This patient has RAS wild-type metastatic or locally advanced and inoperable colorectal cancer.<br>3. This patient has not received previous cytotoxic treatment for metastatic disease unless there has been use of previous neoadjuvant combination cytotoxic chemotherapy for potentially resectable metastatic colorectal cancer.<br>Please mark below whether the patient has had neoadjuvant cytotoxic chemotherapy or not:<br>- the patient has not had previous neoadjuvant cytotoxic chemotherapy for metastatic colorectal cancer **or**<br>- the patient has been treated with previous neoadjuvant cytotoxic chemotherapy for potentially resectable metastatic colorectal cancer<br>4. Cetuximab in this irinotecan-based combination is being used as either 1st line treatment for metastatic colorectal cancer or as 2nd line treatment if treated with 1st line pembrolizumab for MSI-H/dMMR disease.<br>Please mark below in which line of therapy the patient is having cetuximab plus an irinotecan-based combination chemotherapy:<br>- cetuximab + irinotecan-based chemotherapy is being used as 1st line treatment for metastatic colorectal cancer **or**<br>- cetuximab + irinotecan-based chemotherapy is being used as 2nd line treatment for metastatic colorectal cancer as the patient has MSI-H/dMMR disease and has been treated with 1st line pembrolizumab or 1st line nivolumab which was previously available as an Interim COVID option<br>5. The patient has not received prior treatment with cetuximab or panitumumab unless this was received as part of combination neoadjuvant chemotherapy for potentially resectable metastatic disease.<br>Patients with potentially resectable metastatic disease who have received a neoadjuvant cetuximab/panitumumab-containing combination chemotherapy with the intention of resection if the metastases become resectable, and who do not progress while on treatment with cetuximab/panitumumab but who then become unsuitable for surgery or have unsuccessful surgery, may continue treatment with the same cetuximab/panitumumab-containing combination chemotherapy.<br><br>Patients who have successful resection(s) after neoadjuvant cetuximab/panitumumab-containing combination chemotherapy for metastatic disease and who did not progress on such chemotherapy may receive cetuximab/panitumumab with subsequent first-line combination chemotherapy if they present later with progression of metastatic disease.<br><br>Please mark below the patient's treatment status in respect of previous cetuximab/panitumumab-containing neoadjuvant chemotherapy:<br>- the patient has not been treated with previous chemotherapy with either cetuximab or panitumumab-containing combination chemotherapy for metastatic disease **or**<br>- the only previous cetuximab/panitumumab-containing chemotherapy was with neoadjuvant treatment for potentially resectable disease which resulted in a lack of disease progression and the patient was then unable to proceed to surgery or had unsuccessful surgery **or**<br>- the only previous cetuximab/panitumumab-containing chemotherapy was with neoadjuvant treatment for potentially resectable disease which resulted in a lack of disease progression and the patient was then able to proceed to surgery but has since relapsed<br>6. The prescribing clinician is aware that if this patient has BRAF V600 mutation-positive disease, the patient will be ineligible for encorafenib plus cetuximab as a subsequent line of therapy if they receive a cetuximab/panitumumab-containing regimen now as first-line therapy.<br>7. The prescribing clinician is aware that from 1st December 2020 an NHS England Best Value framework is in operation for cetuximab and panitumumab in first line colorectal cancer. The choice of this panitumumab -containing regimen is therefore in line with the local application of the Best Value framework for these drugs within my organisation.<br>8. Cetuximab will be given in combination with irinotecan-based combination chemotherapy.<br>9. Cetuximab will be given in a 2-weekly regimen at a dose of 500mg/m$^2$.<br>10. As this dose and schedule of cetuximab is not licensed, this use of cetuximab must be used within the Trust's governance framework.<br>11. Cetuximab in combination with irinotecan-based chemotherapy will be given until disease progression on this regimen and that cetuximab will be discontinued when this disease progression occurs.<br>If the patient experiences excessive toxicity with irinotecan, cetuximab can be subsequently continued in combination with a fluoropyrimidine alone until disease progression and then will be discontinued.<br><br>Note: continued use of cetuximab beyond 1st line therapy is not commissioned once disease progression has occurred with 1st line treatment.<br>12. Where a treatment break of more than 6 weeks beyond the expected cycle length is needed, I will complete a treatment break form to restart treatment, including an indication as appropriate if the patient had an extended break because of COVID 19<br>13. The use of cetuximab will be as per the Summary of Product Characteristics (SPC). | Yes | TA439 | 29-Mar-17 | 27-Jun-17 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| CET2_v1.3 | **Cetuximab** in combination with oxaliplatin-based chemotherapy | For chemotherapy-naive metastatic or locally advanced and inoperable colorectal cancer where all the following criteria are met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with cetuximab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br><br>2. This patient has RAS wild-type metastatic or locally advanced and inoperable colorectal cancer.<br><br>3. This patient has not received previous cytotoxic chemotherapy for metastatic disease unless there has been use of previous neoadjuvant combination cytotoxic chemotherapy for potentially resectable metastatic colorectal cancer.<br>Please mark below whether the patient has had neoadjuvant chemotherapy or not:<br>- the patient has not had previous neoadjuvant cytotoxic chemotherapy for metastatic colorectal cancer **or**<br>- the patient has been treated with previous neoadjuvant cytotoxic chemotherapy for potentially resectable metastatic colorectal cancer<br><br>4. Cetuximab in this oxaliplatin-based combination is being used as either 1st line treatment for metastatic colorectal cancer or as 2nd line treatment if treated with 1st line pembrolizumab for MSI-H/dMMR disease.<br>Please mark below in which line of therapy the patient is having cetuximab plus an oxaliplatin-based combination chemotherapy:<br>- cetuximab + oxaliplatin-based chemotherapy is being used as 1st line treatment for metastatic colorectal cancer **or**<br>- cetuximab + oxaliplatin-based chemotherapy is being used as 2nd line treatment for metastatic colorectal cancer as the patient has MSI-H/dMMR disease and has been treated with 1st line pembrolizumab or 1st line nivolumab which was previously available as an Interim COVID option<br><br>5. The patient has not received prior treatment with cetuximab or panitumumab unless this was received as part of combination neoadjuvant chemotherapy for potentially resectable metastatic disease.<br>Patients with potentially resectable metastatic disease who have received a neoadjuvant cetuximab/panitumumab-containing combination chemotherapy with the intention of resection if the metastases become resectable, and who do not progress while on treatment with cetuximab/panitumumab but who then become unsuitable for surgery or have unsuccessful surgery, may continue treatment with the same cetuximab/panitumumab-containing combination chemotherapy.<br><br>Patients who have successful resection(s) after neoadjuvant cetuximab/panitumumab-containing combination chemotherapy for metastatic disease and who did not progress on such chemotherapy may receive cetuximab/panitumumab with subsequent first-line combination chemotherapy if they present later with progression of metastatic disease.<br><br>Please mark below the patient's treatment status in respect of previous cetuximab/panitumumab-containing neoadjuvant chemotherapy:<br>- the patient has not been treated with previous chemotherapy with either cetuximab or panitumumab-containing combination chemotherapy for metastatic disease **or**<br>- the only previous cetuximab/panitumumab-containing chemotherapy was with neoadjuvant treatment for potentially resectable disease which resulted in a lack of disease progression and the patient was then unable to proceed to surgery or had unsuccessful surgery **or**<br>- the only previous cetuximab/panitumumab-containing chemotherapy was with neoadjuvant treatment for potentially resectable disease which resulted in a lack of disease progression and the patient was then able to proceed to surgery but has since relapsed<br><br>6. The prescribing clinician is aware that if this patient has BRAF V600 mutation-positive disease, the patient will be ineligible for encorafenib plus cetuximab as a subsequent line of therapy if they receive a cetuximab/panitumumab-containing regimen now as first-line therapy.<br><br>7. The prescribing clinician is aware that from 1st December 2020 an NHS England Best Value framework is in operation for cetuximab and panitumumab in first line colorectal cancer. The choice of this cetuximab-containing regimen is therefore in line with the local application of the Best Value framework for these drugs within my organisation.<br><br>8. Cetuximab will be given in combination with oxaliplatin-based combination chemotherapy.<br><br>9. Cetuximab will be given as a 2-weekly regimen at a dose of 500mg/m2<br><br>10. Trust policy regarding the use of unlicensed treatments has been followed as cetuximab is not licensed for 2-weekly administration.<br><br>11. Cetuximab in combination with oxaliplatin-based chemotherapy will be given until disease progression on this regimen and that cetuximab will be discontinued when this disease progression occurs.<br>If the patient experiences excessive toxicity with oxaliplatin, cetuximab can be subsequently continued in combination with a fluoropyrimidine alone until disease progression and then will be discontinued.<br><br>Note: continued use of cetuximab beyond 1st line therapy is not commissioned once disease progression has occurred with 1st line treatment.<br><br>12. When a treatment break of more than 6 weeks beyond the expected cycle length is needed, I will complete a treatment break form to restart treatment, including an indication as appropriate if the patient had an extended break because of COVID 19.<br><br>13. The use of cetuximab will be otherwise used as per its Summary of Product Characteristics (SPC). | Yes | TA439 | 29-Mar-17 | 27-Jun-17 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| CET3_V1.1 | **Cetuximab** | Cetuximab in combination with chemotherapy for the first cytotoxic-containing treatment of recurrent/metastatic squamous cell cancer of the head and neck only originating in the oral cavity where the following criteria are met: | 1. An application has been made and the first cycle of systemic anti -cancer therapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a confirmed histological diagnosis of squamous cell carcinoma.<br>3.The patient has a primary tumour that originated in the oral cavity.<br>4. The patient has recurrent and/or metastatic disease.<br>5. The patient has not received any previous cytotoxic chemotherapy for this recurrent/metastatic oral cavity tumour unless it was part of multimodality treatment for locally advanced disease and was completed more than 6 months previously.<br>6. The patient has not received any systemic therapy for this recurrent/metastatic oral cavity tumour **or** the only systemic therapy for this recurrent/metastatic oral cavity tumour has been with pembrolizumab monotherapy.<br>7. The treatment will be given with palliative intent.<br>8. Cetuximab is to only be used in combination with a maximum of 6 cycles of platinum-based combination chemotherapy followed by single agent cetuximab as maintenance therapy.<br>9. The patient has received no previous treatment with cetuximab for head and neck cancer.<br>10. The patient has an ECOG performance status of 0 or 1.<br>11. Cetuximab is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment, whichever is the sooner.<br>12. When a treatment break of more than 6 weeks beyond the expected 3- or 4-weekly cycle length is needed, a treatment break approval from will be completed to restart treatment.<br>13. Consideration has been to be given to administration of cetuximab 500mg/m² every 2 weeks (e.g. if chemotherapy is scheduled on a 4 week cycle or during the maintenance phase of single agent cetuximab therapy).<br>14. Cetuximab will be otherwise used as set out in its Summary of Product Characteristics. | Yes | TA473 | 31-Aug-17 | 31-Aug-17 |
| CLO1 | **Clofarabine** | The treatment of relapsed/refractory acute lymphoblastic leukaemia where all the following criteria are met: | 1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy<br>2. Acute lymphoblastic leukaemia<br>3. Relapsed/ refractory disease with intent to use treatment to bridge to bone marrow transplant | Yes | n/a - NHS England clinical policy | - | 01-Apr-21 |
| CRI1 | **Crizotinib** | For anaplastic lymphoma kinase-positive advanced non-small cell lung cancer previously untreated with an ALK inhibitor where the following criteria have been met: | 1. This application for crizotinib is being made by and the first cycle of systemic anti-cancer therapy with crizotinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has locally advanced or metastatic non-small cell lung cancer.<br>3. The patient has histological or cytological evidence of NSCLC that carries an anaplastic lymphoma kinase (ALK) rearrangement based on a validated test **OR** there is documented agreement by the lung MDT that the radiological appearances are in keeping with locally advanced or metastatic NSCLC **AND** there is an informative circulating free DNA test result confirming the presence of an activating anaplastic lymphoma kinase (ALK) rearrangement.<br>Please mark below on which basis the diagnosis of ALK positive NSCLC has been made in this patient:<br>- Histological or cytological evidence.<br>- Documented agreement by the lung MDT that the radiological appearances are in keeping with locally advanced or metastatic NSCLC and there is an informative circulating free DNA test result confirming the presence of an activating anaplastic lymphoma kinase (ALK) rearrangement<br>4. The patient has not previously received any ALK inhibitor for the advanced NSCLC indication unless 1st line alectinib or 1st line brigatinib or 1st line ceritinib has had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression or the patient was treated with adjuvant alectinib and had disease progression more than 6 months after completing treatment with adjuvant alectinib.<br>Please mark below which of the four scenarios applies to this patient:<br>- the patient has never previously received an ALK inhibitor **or**<br>- the patient has previously received alectinib as 1st line ALK-targeted therapy and this has had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression **or**<br>- the patient has previously received brigatinib as 1st line ALK-targeted therapy and this has had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression **or**<br>- the patient has previously received ceritinib as 1st line ALK-targeted therapy and this has had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression.<br>- the patient has previously received treatment with adjuvant alectinib and had disease progression more than 6 months after completing treatment with adjuvant alectinib<br>5. Either the patient is naïve to 1st line cytotoxic chemotherapy-containing systemic treatment for this locally advanced or metastatic NSCLC indication or the patient received 1st line cytotoxic chemotherapy-containing treatment for locally advanced/metastatic non-small cell lung cancer at a time when the ALK status was not known and the patient has since received no further therapy.<br>Please mark which of these 2 scenarios below applies to this patient:<br>- the patient has not received any previous 1st line cytotoxic chemotherapy-containing systemic treatment for the locally advanced or metastatic NSCLC indication **or**<br>- the patient previously received 1st line cytotoxic chemotherapy-containing systemic treatment for locally advanced or metastatic NSCLC at a time when the ALK status was not known.<br>6. The patient has an ECOG performance status of 0 or 1 or 2.<br>7. The patient either has no known brain metastases or if the patient has brain metastases, the patient is symptomatically stable prior to starting crizotinib.<br>8. Crizotinib will be used as monotherapy.<br>9. The patient will be treated until loss of clinical benefit or excessive toxicity or patient choice to discontinue treatment, whichever is the sooner<br>10. A formal medical review as to whether treatment with crizotinib should continue or not will be scheduled to occur at least by the end of the first 8 weeks of treatment.<br>11. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment.<br>12. The prescribing clinician is aware that<br>a) alectinib is not to be used following disease progression on crizotinib as there is no current clear evidence to support treatment with alectinib after disease progression on crizotinib<br>and<br>b) after disease progression on crizotinib, the only subsequent ALK inhibitors commissioned by NHS England as next line therapy is a choice of brigatinib or ceritinib.<br>c) after disease progression during treatment with adjuvant alectinib or within 6 months of completion of treatment with adjuvant alectinib, treatment with crizotinib is not commissioned<br>13. Crizotinib will otherwise be used as set out in its Summary of Product Characteristics (SPC). | No | TA406<br>TA422 | 28-Sep-16 | 28-Dec-16 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| CRI3 | **Crizotinib** | 1st or subsequent line systemic therapy for ROS1-positive inoperable locally advanced/metastatic non squamous non-small cell lung cancer where the following criteria have been met: | 1. This application is made by and the first cycle of systemic anti-cancer therapy with crizotinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy<br>2. The patient has histological or cytological evidence of NSCLC that carries a ROS1 gene rearrangement based on a validated test OR there is documented agreement by the lung MDT that the radiological appearances are in keeping with locally advanced or metastatic NSCLC AND there is an informative circulating free DNA test result confirming the presence of a ROS1 gene rearrangement.<br>Please mark below on which basis the diagnosis of ROS1 positive NSCLC has been made in this patient:<br>- Histological or cytological evidence.<br>- Documented agreement by the lung MDT that the radiological appearances are in keeping with locally advanced or metastatic NSCLC and there is an informative circulating free DNA test result confirming the presence of a ROS1 gene rearrangement<br>3. This non squamous NSCLC carries a confirmed ROS1 gene rearrangement as demonstrated by an accurate and validated assay<br>4. The patient has received no previous ROS1-targeted therapy unless entrectinib has had to be stopped within 6 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression.<br>Please select one:<br>- no prior treatment with ROS1-targeted therapy or<br>- previous treatment with entrectinib has had to be stopped within 6 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of progressive disease<br>5. EITHER the patient has received no previous cytotoxic chemotherapy for locally advanced or metastatic non-small cell lung cancer OR has been previously treated with cytotoxic chemotherapy for locally advanced or metastatic disease<br><br>Note: NHS England has a strong preference for ROS1-positive patients to be treated with crizotinib as 1st line therapy for locally advanced/metastatic NSCLC though recognises that some patients have had to be treated with chemotherapy for urgent clinical reasons before the ROS1 result was known<br>6. Crizotinib will be used only as single-agent therapy<br>7. The patient has an ECOG performance status of 0 or 1 or 2<br>8. The patient either has no brain metastases or, if the patient has brain metastases, the patient is symptomatically stable prior to starting crizotinib<br>9. The patient will be treated until loss of clinical benefit or excessive toxicity or patient choice to discontinue treatment, whichever is the sooner<br>10. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment.<br>11. Crizotinib will be otherwise used as set out in its Summary of Product Characteristics (SPC) | No | TA1021 | 04-Dec-24 | 03-Jan-25 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| DABTRA3 | **Dabrafenib** in combination with trametinib | For the first line treatment of metastatic BRAF V600 mutation positive non-small cell lung cancer where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with dabrafenib in combination with trametinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a histologically confirmed diagnosis of non-small cell lung cancer (NSCLC).<br>3. The patient has histological or cytological evidence of NSCLC that contains a BRAF V600E mutation based on a validated test OR there is documented agreement by the lung MDT that the radiological appearances are in keeping with metastatic NSCLC AND there is an informative circulating free DNA test result confirming the presence of a BRAF V600E mutation.<br>Please mark below on which basis the diagnosis of BRAF V600E mutation positive NSCLC has been made in this patient:<br>- Histological or cytological evidence or<br>- Documented agreement by the lung MDT that the radiological appearances are in keeping with metastatic NSCLC and there is an informative circulating free DNA test result confirming the presence of a BRAF V600E mutation<br>4. The patient has metastatic non-small cell lung cancer.<br>5. I confirm that the patient is treatment naïve to BRAF and MEK inhibitors for the treatment of metastatic NSCLC.<br>6. I confirm that the patient has not received any previous systemic therapy for metastatic NSCLC.<br><br>Note: any prior adjuvant or neoadjuvant chemotherapy or immunotherapy for NSCLC does not count as previous systemic therapy in this regard.<br>7. The patient has an ECOG performance status of either 0 or 1 or 2.<br>Please enter below as to which ECOG performance status applies to this patient:<br>- ECOG PS 0 or<br>- ECOG PS 1 or<br>- ECOG PS 2<br>8. The patient either has no known brain metastases or if the patient has brain metastases, the patient is symptomatically stable prior to starting dabrafenib in combination with trametinib.<br>9. Treatment with dabrafenib in combination with trametinib will be continued until loss of clinical benefit or unacceptable toxicity or withdrawal of patient consent.<br>10. A formal medical review as to how the combination of dabrafenib and trametinib is being tolerated and whether treatment with the combination of dabrafenib and trametinib should continue or not will be scheduled to occur at least by the end of the first 8 weeks of treatment.<br>11. Where a treatment break of more than 6 weeks beyond the expected cycle length is needed, a treatment break approval form will be completed to restart treatment.<br>12. Dabrafenib in combination with trametinib is to be otherwise used as set out in their respective Summaries of Product Characteristics. | Yes | TA898 | 14-Jun-23 | 12-Sep-23 |
| DABTRA4 | **Dabrafenib (as Finlee®) in combination with trametinib (as Spexotras®)** | For the treatment of paediatric patients aged 1-17 years with BRAF V600E mutation positive glioma where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with dabrafenib in combination with trametinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient is currently aged between 1 and 17 years.<br>3. The patient has a histologically confirmed diagnosis of either a low grade or a high grade glioma and that a BRAF V600E mutation has been confirmed to be present in whichever glioma type.<br>4. The patient either has a low grade glioma with a BRAF V600E mutation and requires systemic therapy or the patient has a high grade glioma with a BRAF V600E mutation and has received at least one prior radiation therapy and/or chemotherapy.<br>Please mark below which scenario applies to this patient:<br>- low grade glioma requiring first ever systemic therapy or<br>- low grade glioma having previously had systemic therapy or<br>- high grade glioma having previously had radiotherapy only or<br>- high grade glioma having previously had radiotherapy and chemotherapy or<br>- high grade glioma having previously had chemotherapy only<br>5. The patient is either treatment naïve to BRAF and MEK inhibitors for the glioma or the patient is currently receiving dabrafenib in combination with trametinib via a company compassionate access scheme and all treatment criteria on this form are fulfilled.<br>Please indicate below which option applies:<br>- No prior BRAF and MEK inhibitors for the treatment of glioma or<br>- the patient is currently receiving dabrafenib in combination with trametinib via a company compassionate access scheme and all treatment criteria on this form are fulfilled.<br>6. The patient has a performance status of at least 50 on either the Karnofsky scale (for those 16 years and over) or the Lansky scale (for those <16 years of age).<br>Please enter below as to which ECOG performance status applies to this patient:<br>- performance score 50-60 or<br>- performance score 70-80 or<br>- performance score 90-100<br>7. The patient's dosing of dabrafenib (as Finlee®) and trametinib (as Spexotras®) will be according to the patient's weight as described in the respective drug's Summary of Product Characteristics (SPC).<br>8. The prescribing clinician is aware the many interactions of particularly dabrafenib (as Finlee®) and trametinib (as Spexotras®) with other medicines as outlined in the respective drug's SPCs.<br>9. Treatment with dabrafenib in combination with trametinib will be continued until loss of clinical benefit or unacceptable toxicity or withdrawal of patient consent.<br>Note: the intention to treat with dabrafenib plus trametinib must be with a planned and continued administration of this combination until disease progression or unacceptable toxicity or patient choice to stop treatment. Dabrafenib and trametinib are not funded to be used electively in an intermittent treatment schedule with planned 'treatment holidays'.<br>10. For paediatric patients who are still on treatment when they become 18 years of age, the SPC states that continued treatment into adulthood should be based on an assessment of the benefit and risks to the individual patient as evaluated by the oncologist.<br>If this combination is continued into adulthood, the treating oncologist understands that such use is off label and thus the treating Trust's procedures must be followed for the use of unlicensed medicines.<br>11. A formal medical review as to how the combination of dabrafenib and trametinib is being tolerated and whether treatment with the combination of dabrafenib and trametinib should continue or not will be scheduled to occur at least by the end of the first 8 weeks of treatment.<br>12. When a treatment break of more than 6 weeks beyond the expected cycle length is needed, the prescribing clinician will complete a treatment break approval form to restart treatment.<br>13. Dabrafenib (as Finlee®) in combination with trametinib (as Spexotras®) are to be otherwise used as set out in their respective Summaries of Product Characteristics. | No | TA977 | 29-May-24 | 27-Aug-24 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| DACO1 | **Dacomitinib** | The treatment of untreated EGFR mutation-positive non-small-cell lung cancer where all the following criteria have been met: | 1. This application is made by and the first cycle of systemic anti-cancer therapy with dacomitinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy | No | TA595 | 14-Aug-19 | 12-Nov-19 |
| | | | 2. The patient has a histologically or cytologically confirmed diagnosis of non-small cell lung cancer (NSCLC) that is either stage IIIB or stage IV NSCLC | | | | |
| | | | 3. This patient's NSCLC has been shown to express an EGFR-activating mutation as demonstrated by an accurate and validated assay | | | | |
| | | | 4. The patient has received no previous EGFR-targeted therapy unless this has had had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression. | | | | |
| | | | 5. The patient has received no previous cytotoxic chemotherapy for locally advanced or metastatic non-small cell lung cancer | | | | |
| | | | 6. Dacomitinib will be used only as monotherapy | | | | |
| | | | 7. The patient has an ECOG performance status of 0 or 1 | | | | |
| | | | 8. The prescribing clinician is aware of the potential drug interactions associated with dacomitinib therapy and the dose reductions or discontinuations required for the management of interstitial lung toxicity, diarrhoea and cutaneous toxicity. | | | | |
| | | | 9. The patient will be treated until loss of clinical benefit or excessive toxicity or patient choice to discontinue treatment, whichever is the sooner | | | | |
| | | | 10. Treatment breaks of up to 6 weeks are allowed but solely to allow toxicities to settle | | | | |
| | | | 11. Dacomitinib will be otherwise used as set out in its Summary of Product Characteristics (SPC) | | | | |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| DAR1 | **Daratumumab** | The treating of relapsed and refractory multiple myeloma where all the following criteria are met: | 1. This application is made by and the first cycle of systemic anti-cancer therapy with daratumumab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a diagnosis of multiple myeloma.<br>3. The prescribing clinician understands that daratumumab in this indication is not funded for amyloidosis patients (with the exception of patients who have a proven diagnosis of myeloma and also have an associated diagnosis of amyloidosis) and that NHS funding for daratumumab is only for the specific multiple myeloma indication recommended by NICE.<br>Please tick box below:<br>- this patient does not have a diagnosis of primary amyloidosis<br>- this patient has a proven diagnosis of progressive myeloma and also an associated diagnosis of amyloidosis and daratumumab is being prescribed for the myeloma<br>Note: For amyloidosis patients requiring systemic therapies, NHS England does fund treatments already in routine commissioning for myeloma. NHS England does not fund daratumumab in this indication for patients with amyloidosis unless they have a proven diagnosis of progressive myeloma and also an associated diagnosis of amyloidosis.<br>4. The patient has received 3 and no more than 3 prior lines of treatment and that the numbering of these lines of treatment is in accordance with the International Myeloma Workshop Consensus recommendations for the uniform reporting of clinical trials (http://doi.org/10.1182/blood-2010-10-299487). A line of therapy is defined as one or more cycles of a planned treatment program. This may consist of one or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner (eg induction chemotherapy and stem cell transplantation then maintenance is considered to be 1 line of therapy). A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse or toxicity. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease.<br>***Note*** : The use of daratumumab will be audited to confirm it is being used in accordance with these treatment criteria (particularly in respect of lines of therapy) and non-compliant use will be monitored and followed-up.<br>5. The patient has responded to at least 1 of these 3 lines of treatment.<br>6. In relation to the immediately previous line of systemic therapy, the patient has:<br>- documented relapse of disease after initial response or<br>- refractory disease<br>7. The patient has been previously treated with a proteasome inhibitor.<br>8. The patient has been previously treated with an immunomodulatory agent.<br>9. I have informed the CDF as to whether the patient has been treated with a previous stem cell transplant (SCT) or not:<br>- Yes - previous SCT<br>- No - previous SCT<br>10. The patient is of performance status 0 or 1 or 2.<br>- 0<br>- 1<br>- 2<br>11. The patient has not been previously treated with daratumumab or an anti-CD38 antibody unless they have been previously treated with daratumumab in which case the patient must have received the daratumumab as part of induction therapy pre-transplant and must have responded to that daratumumab-containing combination. The daratumumab-free period from previous therapy until now must be stated below.<br>Please enter below as to which scenario applies to this patient:<br>- no previous treatment with daratumumab or<br>- previous treatment with daratumumab in the transplant-eligible setting and disease responded to this. Please record the time since the start of the last cycle of daratumumab to now:<br>12. Daratumumab is only to be used as a single agent. It is not to be used in combination with other agents. The first administration of daratumumab can be given in split doses on different days if necessary.<br>13. A formal medical review as to whether treatment with daratumumab should continue or not will be scheduled to occur at least by the end of the first 8 weeks of treatment.<br>14. Daratumumab is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment.<br>15. Where a treatment break of more than 6 weeks beyond the expected cycle length is needed, I will complete a treatment break approval form to restart treatment, including indicating as appropriate if the patient had an extended<br>16. Daratumumab will be otherwise used as set out in its Summary of Product Characteristics. | No | TA783 | 13-Apr-22 | 12-Jul-22 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| DAR2 | **Daratumumab** (in combination with bortezomib and dexamethasone) | For treating relapsed multiple myeloma in patients who have had only 1 line of therapy and are transplant ineligible where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with daratumumab in combination with bortezomib and dexamethasone will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a diagnosis of multiple myeloma.<br>3. The prescribing clinician understands that daratumumab in this indication is not funded for amyloidosis patients (with the exception of patients who have a proven diagnosis of myeloma with an associated diagnosis of amyloidosis) and that NHS funding for daratumumab is only for the specific multiple myeloma indication recommended by NICE.<br>Please tick box below:<br>- this patient does not have a diagnosis of primary amyloidosis.<br>- this patient has a proven diagnosis of progressive myeloma with an associated diagnosis of amyloidosis and daratumumab is being prescribed for the myeloma<br>Note: NHS England does not fund daratumumab in this indication for patients with amyloidosis unless they have a proven diagnosis of progressive myeloma with an associated diagnosis of amyloidosis.<br>4. The patient has received 1 and no more than 1 prior line of treatment and that the numbering of a line of treatment is in accordance with the International Myeloma Workshop Consensus recommendations for the uniform reporting of clinical trials (http://doi.org/10.1182/blood-2010-10-299487). A line of therapy is defined as one or more cycles of a planned treatment program. This may consist of one or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner (ie induction chemotherapy/chemotherapies when followed by stem cell transplantation is considered to be 1 line of therapy). A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse or toxicity, the exception to this being the need to attain a sufficient response for stem cell transplantation to proceed. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease.<br>Patients who commenced on the Interim COVID option of ixazomib with lenalidomide and dexamethasone (Blueteq form code IXA2CV) as a **second** line therapy **instead of daratumumab bortezomib and dexamethasone** during the COVID19 pandemic to avoid hospital admissions can be granted an exception to the 1 prior line of therapy rule.<br>Please tick box below:<br>- this patient has received 1 and no more than 1 prior line of treatment or<br>- this patient has received 2 lines of treatment the 2nd of which was the temporary COVID-related option of 2nd line ixazomib with lenalidomide and dexamethasone (Blueteq form code IXA2CV)<br>Note: The use of daratumumab in combination with bortezomib and dexamethasone in the 1-prior treatment setting was the place in the treatment pathway chosen by Janssen for its submission to NICE for the appraisal of clinical and cost effectiveness of this daratumumab combination and thus is the basis of NICE's recommendation.<br>5. The patient responded to this 1-prior line of treatment (or if this patient received 2nd line ixazomib with lenalidomide and dexamethasone courtesy of Covid-related access IXA2CV, the patient must have responded to at least one of these 2 lines of therapy).<br>Note: the need for patients to have responded to their 1 prior line of treatment is as a consequence of the 1-prior subgroup chosen by Janssen for its submission to NICE for the appraisal of clinical and cost effectiveness of this daratumumab combination.<br>6. In relation to this 1-prior line of systemic therapy (or 2-prior in the case of patients accessing ixazomib with lenalidomide and dexamethasone via Covid-related access IXA2CV), the patient now has documented relapse of disease.<br>7. With respect to previous consideration of treatment with lenalidomide as part of previous therapy:<br>- this patient was treated with 1st line lenalidomide (either as 1st line therapy for transplant ineligible patients or as maintenance therapy in patients treated with stem cell transplantation as part of 1st line treatment) or<br>- the patient was treated with 2nd line ixazomib with lenalidomide and dexamethasone courtesy of the Covid-related access IXA2CV or<br>- treatment with 1st line lenalidomide in the transplant ineligible setting was considered unsuitable for this patient at the time or<br>- treatment with maintenance lenalidomide post stem cell transplantation was not available at the time of the transplant (i.e. before the NICE recommendation in January 2021) or was considered unsuitable for this patient<br>8. The patient has not been previously treated with daratumumab or an anti-CD38 antibody unless they have been previously treated with daratumumab in which case the patient must have received the daratumumab as part of induction therapy pre-transplant and must have responded to that daratumumab-containing combination. The daratumumab-free period from previous therapy until now must be stated below.<br>Please enter below as to which scenario applies to this patient:<br>- no previous treatment with daratumumab or<br>- previous treatment with daratumumab in the transplant-eligible setting and disease responded to this. Please record the time since the start of the last cycle of daratumumab to now<br>9. With respect to current consideration of treatment with lenalidomide as part of 2nd line therapy:<br>- the patient has already been treated with lenalidomide with 1st line lenalidomide (either as 1st line therapy for transplant ineligible patients or as maintenance therapy in patients treated with stem cell transplantation as part of 1st line treatment) or received 2nd line lenalidomide as part of the Covid-related access IXA2CV to ixazomib with lenalidomide and dexamethasone<br>- the patient is lenalidomide-naïve but 2nd line treatment with lenalidomide is currently considered as unsuitable for this patient<br>10. The patient has either not been treated with high dose chemotherapy and stem cell transplantation or has been previously treated with high dose chemotherapy and stem cell transplantation as part of 1st line therapy. Please fill in as appropriate below.<br>Please enter below as to which scenario applies to this patient:<br>- no previous treatment with high dose chemotherapy and stem cell transplantation or<br>- previous treatment with high dose chemotherapy and stem cell transplantation<br>11. the patient is of ECOG performance status 0 or 1 or 2.<br>Please tick one of the boxes below:<br>- performance status 0 or<br>- performance status 1 or<br>- performance status 2<br>12. Daratumumab is only to be used in combination with bortezomib and dexamethasone and that it is not to be used in combination with any other agents.<br>13. The dosage schedule of daratumumab will be for weekly treatment given in weeks 1-9 (a total of 9 doses), 3-weekly treatment in weeks 10 to 24 (a total of 5 doses) and 4-weekly treatment from week 25 onwards.<br>NHS England recommends that the subcutaneous formulation of daratumumab is used.<br>14. Daratumumab is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment.<br>15. A formal medical review as to whether treatment with daratumumab in combination with bortezomib and dexamethasone continues or not will be scheduled to occur at least by the end of the first 6 weeks of treatment.<br>16. When a treatment break of more than 6 weeks beyond the expected cycle length is needed, the prescribing clinician will complete a treatment break approval form to restart treatment.<br>17. Daratumumab will be otherwise used as set out in its Summary of Product Characteristics. | Yes | TA897 | 06-Jun-23 | 04-Sep-23 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| DAR3 | **Daratumumab** in combination with bortezomib, thalidomide and dexamethasone | For induction and consolidation therapy of transplant-eligible multiple myeloma where the following criteria have been met: | 1. This application is both being made by and the first cycle of systemic anti-cancer therapy with daratumumab in combination with bortezomib, thalidomide and dexamethasone will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has newly diagnosed multiple myeloma.<br>Note: this daratumumab indication is not funded for patients with primary amyloidosis.<br>Please confirm this by ticking the box below:<br>- this patient does not have a diagnosis of primary amyloidosis<br>3. The patient has not previously received any systemic anti-cancer therapy for myeloma except for an emergency use of a short course of corticosteroids before this treatment<br>4. The patient is eligible for an autologous stem cell transplant after this induction therapy with the combination of daratumumab, bortezomib, thalidomide and dexamethasone.<br>5. Daratumumab will be given in combination with bortezomib, thalidomide and dexamethasone in the four 28 day induction cycles pre-transplant and in the two 28 day cycles of post-transplant consolidation therapy.<br>Note: daratumumab is not funded for this transplant-eligible indication in combination with other anti-myeloma drugs.<br>6. The patient is of ECOG performance status 0 or 1 or 2.<br>Please tick one of the boxes below:<br>- performance status 0 or<br>- performance status 1 or<br>- performance status 2<br>7. The dosage schedule of daratumumab will be as:<br>- weekly treatment given in weeks 1-8 (a total of 8 doses)<br>- 2-weekly treatment in weeks 9-16 (a total of 4 doses)<br>- a pause for high-dose chemotherapy and stem cell transplantation<br>- and then 2-weekly treatment in the 2 consolidation cycles of daratumumab (a total of 4 doses).<br>The first administration of daratumumab can be given in split doses on different days if IV infusion is used instead of subcutaneous daratumumab.<br>8. There will be no prescription of maintenance daratumumab after completion of the 2 post-transplant consolidation cycles of daratumumab, bortezomib, thalidomide and dexamethasone.<br>Note: maintenance lenalidomide is funded to commence after completion of the 2 post-transplant consolidation cycles of daratumumab, bortezomib, thalidomide and dexamethasone.<br>9. Hepatitis B virus screening has been recently done and that if positive hepatitis B viral serology is found, the patient will be monitored for hepatitis B virus reactivation as outlined in the daratumumab Summary of Product Characteristics.<br>10. A formal medical review as to whether treatment with daratumumab in combination with bortezomib, thalidomide and dexamethasone continues or not will be scheduled to occur at least by the end of the second 4-weekly cycle of treatment.<br>11. When a treatment break of more than 6 weeks beyond the expected cycle length* is needed, I will complete a treatment break approval form to restart treatment, including indicating as appropriate if the patient had an extended break because of COVID-19.<br>*Note the treatment cycle includes transplant, so, the break in treatment due to transplant does not require completion of a treatment break form.<br>12. Daratumumab will be otherwise used as set out in its Summary of Product Characteristics. | No | TA763 | 02-Feb-22 | 03-May-22 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| DAR4 | **Daratumumab** in combination with lenalidomide and dexamethasone | For the treatment of newly diagnosed and treatment-naive patients with multiple myeloma who are INELIGIBLE for an autologous stem cell transplant where the following criteria have been met: | 1. This application is both being made by and the first cycle of systemic anti-cancer therapy with daratumumab in combination with lenalidomide and dexamethasone will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has newly diagnosed multiple myeloma.<br><br>Note: this daratumumab indication is not funded for patients with primary amyloidosis.<br><br>Please confirm this by ticking the box below:<br>- this patient does not have a diagnosis of primary amyloidosis<br>3. The patient has previously **not** received any systemic anti-cancer therapy for myeloma except for either an emergency use of a short course of corticosteroids before this treatment or the patient commenced induction therapy with the combination of daratumumab plus bortezomib, thalidomide and dexamethasone with the intention of proceeding to a stem cell transplant but despite responding to such treatment the patient is now ineligible for transplantation.<br><br>Please tick below which scenario applies to this patient:<br>- the patient has not received any prior systemic anti-cancer therapy<br>- the patient has only had an emergency use of a short course of corticosteroids<br>- the patient commenced induction therapy with the combination of daratumumab plus bortezomib, thalidomide and dexamethasone with the intention of proceeding to a stem cell transplant but despite responding to such treatment the patient is now ineligible for transplantation.<br><br>Note: patients who have not responded to induction therapy with daratumumab plus bortezomib, thalidomide and dexamethasone are NOT allowed to switch to daratumumab plus lenalidomide and dexamethasone.<br>4. The patient is ineligible for an autologous stem cell transplant.<br>5. Daratumumab will only be given in combination with lenalidomide and dexamethasone and that it is not to be used in combination with any other agents.<br>6. The patient is of ECOG performance status 0 or 1 or 2.<br>Please tick one of the boxes below:<br>- performance status 0 or<br>- performance status 1 or<br>- performance status 2<br>7. The dosage schedule of daratumumab will be as:<br>- weekly treatment given in weeks 1-8 (a total of 8 doses)<br>- 2-weekly treatment in weeks 9-24 (a total of 8 doses)<br>- and from then on 4-weekly.<br><br>Note: the first administration of daratumumab can be given in split doses on different days if IV infusion is used instead of the subcutaneous daratumumab formulation.<br>8. Daratumumab plus lenalidomide and dexamethasone will continue to be given until the development of progressive disease, unacceptable toxicity or patient choice to stop treatment, whichever occurs first.<br>9. Hepatitis B virus screening has been recently done and that if positive hepatitis B viral serology is found, the patient will be monitored for hepatitis B virus reactivation as outlined in the daratumumab Summary of Product Characteristics.<br>10. A formal medical review as to whether treatment with daratumumab in combination with lenalidomide and dexamethasone continues or not will be scheduled to occur at least by the end of the second 4-weekly cycle of treatment.<br>11. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, the prescribing clinician will complete a treatment break approval form to restart treatment.<br>12. Daratumumab will be otherwise used as set out in its Summary of Product Characteristics. | No | TA917 | 25-Oct-23 | 23-Jan-24 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| DAR5 | **Daratumumab** in combination with bortezomib, cyclophosphamide and dexamethasone | For the treatment of newly diagnosed and treatment-naive patients with systemic immunoglobulin light chain amyloidosis (AL) where the following criteria have been met: | 1. This application is both being made by and the first cycle of systemic anti-cancer therapy with daratumumab in combination with bortezomib, cyclophosphamide and dexamethasone will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a histopathological diagnosis of **newly diagnosed** systemic immunoglobulin light chain amyloidosis (AL).<br>3. The patient has previously not received any systemic anti-cancer therapy for systemic light chain amyloidosis except for an emergency use of a short course of corticosteroids before this treatment.<br>Note: patients who have already commenced any systemic therapy for light chain amyloidosis (AL) other than corticosteroids are not eligible for treatment with this daratumumab combination.<br>4. The patient is potentially eligible or not for a future autologous stem cell transplant. Please indicate this below:<br>- may be eligible for future stem cell transplantation or<br>- will not be eligible for future stem cell transplantation<br>Note: patients having stem cell transplantation during therapy with daratumumab will not be able to re-start with this daratumumab combination after the stem cell transplantation.<br>5. The patient has at least 1 form of organ involvement by the systemic light chain amyloidosis (AL). Forms of organ involvement could be cardiac, renal, hepatic, nervous system, gastrointestinal tract, lung and soft tissue.<br>Please tick one of the boxes below:<br>- 1 known form of organ involvement or<br>- 2 known forms of organ involvement or<br>- 3 or more known forms of organ involvement<br>6. The patient has known cardiac involvement by the amyloidosis or not:<br>- yes, there is known cardiac involvement or<br>- no, there is not known cardiac involvement<br>7. The patient has known renal involvement by the amyloidosis or not:<br>- yes, there is known renal involvement or<br>- no, there is not known renal involvement<br>8. The cardiac staging as described by the European adaptation of the Mayo Clinic Cardiac staging system which is based on the assessment of 2 serum biomarker risk factors being raised: the NT-proBNP above 332ng/L (N-terminal pro-B-type natriuretic peptide) and the high sensitivity cardiac troponin T above 54ng/L.<br>Stage I: no risk factors positive<br>Stage II: 1 risk factor positive<br>Stage III: both risk factors positive<br>Please mark below which above cardiac stage applies to this patient:<br>- Stage I or<br>- Stage II or<br>- Stage III<br>9. The patient has class I or II or IIIA or IIIB New York Heart Association class of heart failure (see below).<br>Note: NYHA class IV patients are not eligible for daratumumab in this indication.<br>Class I: no limitation in physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnoea or anginal pain.<br>Class II: slight limitation of physical activity. Patient is comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnoea or anginal pain.<br>Class IIIA: comfortable at rest. Less than ordinary activity results in fatigue, palpitation, dyspnoea or anginal pain.<br>Class IIIB: comfortable at rest. Shortness of breath with performance of activities of daily living (dressing, toileting, showering etc).<br>Class IV: shortness of breath at rest. Unable to carry on any physical activity without discomfort. Signs/symptoms of heart failure or anginal syndrome may be present at rest. If any physical activity is undertaken, discomfort is increased.<br>Please mark below which NYHA class is appropriate for this patient:<br>- Class I or<br>- Class II or<br>- Class IIIA or<br>- Class IIIB<br>10. The renal amyloidosis staging for this patient using recent measurements of urine albumin to creatinine ratio and estimated eGFR using the Cockcroft and Gault formula.<br>Stage I: both urine albumin to creatinine ratio (ACR) <500mg/mmol and eGFR ≥50mls/min per 1.73m²<br>Stage II: either urine albumin to creatinine ratio (ACR) =>500mg/mmol or eGFR <50mls/min per 1.73m²<br>Stage III: both urine albumin to creatinine ratio (ACR) >=500mg/mmol and eGFR <50mls/min per 1.73m²<br>Please mark below which renal staging applies to this patient:<br>- Stage I or<br>- Stage II or<br>- Stage III<br>**(continued on next page)** | No | TA959 | 27-Mar-24 | 25-Jun-24 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| DAR5 (CONT) | **Daratumumab** in combination with bortezomib, cyclophosphamide and dexamethasone | For the treatment of newly diagnosed and treatment-naive patients with systemic immunoglobulin light chain amyloidosis (AL) where the following criteria have been met: | 11. The the patient is of ECOG performance status 0 or 1 or 2.<br>Please tick one of the boxes below:<br>- performance status 0 or<br>- performance status 1 or<br>- performance status 2 | No | TA959 | 27-Mar-24 | 25-Jun-24 |
| | | | 12. Daratumumab will only be given in combination with bortezomib, cyclophosphamide and dexamethasone and that it is not to be used in combination with any other agents. | | | | |
| | | | 13. The dosage schedule of daratumumab will be as follows:<br>weekly treatment given in weeks 1-8 (a total of 8 doses in 2 x 4-weekly cycles)<br>2-weekly treatment in weeks 9-24 (a total of 8 doses in 4 x 4-weekly cycles)<br>and from then on 4-weekly.<br>Note: the first administration of daratumumab can be given in split doses on different days if IV infusion is used instead of the preferred subcutaneous daratumumab formulation. | | | | |
| | | | 14. A maximum of **6 cycles of the combination** of daratumumab plus bortezomib, cyclophosphamide and dexamethasone will be given unless there is development of progressive disease, unacceptable toxicity or patient choice to stop treatment. | | | | |
| | | | 15. Daratumumab **monotherapy** will continue to be given after completion of the combination therapy until whichever of the following events occurs first: the development of progressive disease, unacceptable toxicity or patient choice to stop treatment or **after completion of a total 24 x 4-weekly cycles of daratumumab counted from the first cycle of daratumumab in combination with bortezomib, cyclophosphamide and dexamethasone**.<br>Note: daratumumab cannot be continued with any other systemic therapy after completion of the initial combination of daratumumab, bortezomib, cyclophosphamide and dexamethasone.<br>Note: there is no funding for daratumumab after completion of a total of 24 x 4-weekly cycles. It is therefore important that at the time of consenting, patients are informed of this maximum daratumumab treatment duration. | | | | |
| | | | 16. Hepatitis B virus screening has been recently done and that if positive hepatitis B viral serology is found, the patient will be monitored for hepatitis B virus reactivation as outlined in the daratumumab Summary of Product Characteristics. | | | | |
| | | | 17. A formal medical review as to whether treatment with daratumumab in combination with bortezomib, cyclophosphamide and dexamethasone continues or not will be scheduled to occur at least by the end of the second 4-weekly cycle of treatment. | | | | |
| | | | 18. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, the prescribing clinician will complete a treatment break approval form to restart treatment. | | | | |
| | | | 19. The National Amyloidosis Centre is auditing the outcomes of treatment-naïve patients commencing this daratumumab combination for light chain amyloidosis and details of this audit can be obtained by emailing Darren Foard (Clinical Nurse Specialist) at darren.foard@nhs.net<br>Note: NHS England strongly recommends participation in this audit which will provide real world evidence of this combination including data in patients with renal and cardiac involvement (some groups of which were excluded from the registration trial). | | | | |
| | | | 20. Daratumumab will be otherwise used as set out in its Summary of Product Characteristics. | | | | |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| DARO1 | **Darolutamide** in combination with androgen deprivation therapy (ADT) | For the treatment of non-metastatic hormone-resistant (castration-resistant) prostate cancer in patients who are at high risk of developing metastatic disease where the following criteria have been met | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with darolutamide will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. This patient has a proven histological or cytological diagnosis of adenocarcinoma of the prostate without neuroendocrine differentiation or features of a small cell carcinoma.<br>3. This patient has non-metastatic prostate cancer as defined by recent imaging with conventional imaging with both a whole body isotope bone scan and a CT/MR scan of the chest, abdomen and pelvis.<br>Note: patients with the sole abnormality of pelvic lymph nodes measuring <2cm in short axis diameter and which are below the aortic bifurcation are eligible for darolutamide in this indication.<br>4. The patient has hormone-resistant (castrate-resistant) disease as defined by 3 rising PSA levels (after the nadir PSA level) and taken at least 1 week apart during androgen deprivation therapy.<br>5. The patient's serum testosterone level is <1.7nmol/L on gonadotrophin releasing hormone agonist/antagonist therapy or after bilateral orchidectomy.<br>6. The current PSA level is ≥2ng/ml.<br>7. The patient is at high risk of developing metastatic disease as defined by a PSA doubling time of ≤10 months.<br>Please document the actual PSA doubling time in the box below:<br>8. The patient has an ECOG performance status of either 0 or 1 or 2.<br>9. The patient has not previously received any 2nd generation androgen receptor inhibitors (such as enzalutamide, darolutamide, apalutamide) or CYP17 enzyme inhibitors (such as abiraterone) unless the patient received apalutamide for non-metastatic hormone-resistant (castration-resistant) which had to be stopped because of dose-limiting toxicity in the clear absence of disease progression and the patient meets all the other criteria listed on this form.<br>Please mark below which of these 2 clinical scenarios applies to this patient:<br>- the patient has not previously received any androgen receptor targeted agent<br>- the patient received apalutamide for non-metastatic hormone-resistant (castration-resistant) which had to be stopped because of dose-limiting toxicity in the clear absence of disease progression and the patient meets all the other criteria listed on this form<br>10. Darolutamide is being given only in combination with androgen deprivation therapy.<br>11. Darolutamide is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment.<br>12. A formal medical review as to how darolutamide is being tolerated and whether treatment with darolutamide should continue or not will be scheduled to occur at least by the start of the third 4-weekly cycle of treatment.<br>13. Where a treatment break of more than 6 weeks beyond the expected 4-week cycle length is needed, I will complete a treatment break approval form to restart treatment, including indicating as appropriate if the patient had an extended break because of COVID19.<br>14. Darolutamide is to be otherwise used as set out in its Summary of Product Characteristics | No | TA660 | 25-Nov-20 | 23-Feb-21 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| DARO2 | **Darolutamide** in combination with docetaxel and androgen deprivation therapy (ADT) | For the treatment of patients with newly diagnosed metastatic hormone-sensitive prostate cancer where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with darolutamide will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. This patient either has a proven histological or cytological diagnosis of adenocarcinoma of the prostate or has presented with a clinical picture consistent with metastatic prostate cancer with both widespread bone metastases radiologically typical of prostate cancer and a serum PSA of ≥50 ng/mL.<br>3. This patient has TNM M1 metastatic prostate cancer<br>4. This patient has newly diagnosed metastatic prostate cancer that is hormone sensitive and has currently received androgen deprivation therapy (ADT) for no longer than 12 weeks.<br>Please enter below as to which scenario applies to this patient:<br>- the patient has not yet received any ADT for metastatic prostate cancer<br>or<br>- the patient has received no more than 12 weeks of ADT for metastatic prostate cancer<br>5. The patient is fit enough for docetaxel chemotherapy, has consented such treatment and has not yet commenced upfront docetaxel chemotherapy for metastatic hormone sensitive prostate cancer.<br>6. The patient has an ECOG performance status (PS) of 0 or 1.<br>Please enter below as to which ECOG performance status applies to this patient:<br>- ECOG OS 0<br>or<br>- ECOG PS 1<br>7. Darolutamide is being given in combination with both docetaxel and ADT.<br>8. The patient has not previously received any androgen receptor targeted agent such as enzalutamide or apalutamide or abiraterone unless the patient has progressive metastatic disease following completion of treatment with 2 years of ADT plus abiraterone with or without enzalutamide for high risk non-metastatic disease as part of the STAMPEDE trial (ISRCTN78818544) and did not progress whilst on such treatment and the patient meets all the other criteria listed on this form.<br>Please mark below which of these 2 clinical scenarios applies to this patient:<br>- the patient has not previously received any androgen receptor targeted agent<br>- the patient has progressive metastatic disease following completion of treatment with 2 years of ADT plus abiraterone with or without enzalutamide for high risk non-metastatic disease as part of the STAMPEDE trial and did not progress whilst on such treatment and the patients meets all the other criteria listed here.<br>9. Darolutamide is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment.<br>Note: patients who discontinue docetaxel due to unacceptable toxicity may continue with darolutamide if that treatment-limiting toxicity is deemed to be due to the docetaxel.<br>10. The patient will receive a maximum of 6 cycles of docetaxel chemotherapy.<br>11. A formal medical review as to how darolutamide is being tolerated and whether treatment with darolutamide should continue or not will be scheduled to occur at least by the start of the third 3-weekly combination cycle of treatment.<br>12. Where a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, a treatment break approval form will be completed to restart treatment.<br>13. Darolutamide is to be otherwise used as set out in its Summary of Product Characteristics. | No | TA903 | 21-Jun-23 | 19-Sep-23 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| DARO3 | **Darolutamide** in combination with androgen deprivation therapy (ADT) | For the treatment of patients with newly diagnosed metastatic hormone-sensitive prostate cancer who are unsuitable for treatment with docetaxel where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with darolutamide will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br><br>2. The patient either has a proven histological or cytological diagnosis of adenocarcinoma of the prostate or has presented with a clinical picture consistent with metastatic prostate cancer with both widespread bone metastases radiologically typical of prostate cancer and a serum PSA of >= 50 ng/mL.<br><br>3. This patient has newly diagnosed metastatic prostate cancer that is hormone sensitive and has currently received androgen deprivation therapy (ADT) for no longer than 3 months before starting an androgen receptor targeted agent.<br><br>Please enter below as to which scenario applies to this patient<br>- the patient has not yet received any ADT for metastatic prostate cancer or<br>- the patient has received no more than 3 months of ADT before starting an androgen receptor targeted agent<br><br>4. The patient has not received any upfront docetaxel chemotherapy for metastatic hormone sensitive prostate cancer.<br><br>5. The patient has an ECOG performance status (PS) of 0 or 1 or 2.<br><br>Please enter below as to which ECOG performance status applies to this patient:<br>- ECOG PS 0<br>- ECOG PS 1<br>- ECOG PS 2<br><br>6. The prescribing clinician has assessed this patient's status as regards receiving upfront docetaxel and have concluded that the patient is ineligible for docetaxel on the grounds of either having significant comorbidities (i.e. the patient should not be treated with docetaxel) or the patient is fit for upfront docetaxel but after fully informed consent has chosen not to receive upfront docetaxel.<br><br>Please mark below which of these 2 clinical scenarios applies to this patient:<br>- the patient has significant comorbidities which preclude treatment with docetaxel (i.e. the patient SHOULD NOT be treated with docetaxel) and this has been fully discussed with the patient. It is recommended that validated systems of scoring clinical frailty are used as part of the oncology assessment as to explaining the benefits and risks of the treatment options of chemotherapy and darolutamide<br>- the patient is fit for chemotherapy with docetaxel and has chosen not to be treated with docetaxel. The patient has been fully consented regarding all of the following: the advantages and disadvantages of upfront docetaxel chemotherapy vs upfront darolutamide; that the use of upfront darolutamide would result in there being no further possible treatment with any androgen receptor targeted agents when the patient's disease progresses; and that the patient may not be fit enough to receive docetaxel when the patient's disease progresses. After such informed consent, I confirm that the patient has chosen to receive upfront darolutamide (i.e. the patient is fit for chemotherapy with docetaxel and has CHOSEN NOT to be treated with docetaxel)<br><br>7. Darolutamide is being given in combination with ADT.<br><br>8. The patient has not previously received any androgen receptor targeted agent unless the patient has either received enzalutamide, apalutamide, or abiraterone, for newly diagnosed metastatic hormone-sensitive prostate cancer which had to be stopped because of dose-limiting toxicity in the clear absence of disease progression and the patient meets all the other criteria listed on this form or the patient has progressive disease following treatment with 2 years of ADT plus abiraterone with or without enzalutamide for high risk non-metastatic disease as part of the STAMPEDE trial (ISRCTN78818544) and did not progress whilst on such treatment and the patient meets all the other criteria listed on this form.<br><br>Please mark below which of these 5 clinical scenarios applies to this patient:<br>- the patient has not previously received any androgen receptor targeted agent<br>- the patient commenced enzalutamide which had to be stopped because of dose-limiting toxicity in the clear absence of disease progression and the patient meets all the other criteria listed here<br>- the patient commenced apalutamide which had to be stopped because of dose-limiting toxicity in the clear absence of disease progression and the patient meets all the other criteria listed here<br>- the patient commenced abiraterone which had to be stopped because of dose-limiting toxicity in the clear absence of disease progression and the patient meets all the other criteria listed here<br>- the patient was treated with 2 years of ADT plus abiraterone with or without enzalutamide for high-risk non-metastatic disease as part of the STAMPEDE trial and did not progress whilst on such treatment and the patients meets all the other criteria listed here<br>- the patient has progressive disease following treatment with 2 years of ADT plus abiraterone for high risk non-metastatic disease, did not progress whilst on such treatment, and meets all the other criteria listed on this form.<br><br>9. Darolutamide is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment.<br><br>10. Where a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment, which MUST be approved before treatment is recommenced.<br><br>11. Darolutamide is to be otherwise used as set out in its Summary of Product Characteristics. | No | TA1109 | 12-Nov-25 | 12-Dec-25 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| DAS4 | **Dasatinib** | Dasatinib for treating imatinib-resistant or imatinib-intolerant Philadelphia chromosome positive chronic phase chronic myeloid leukaemia in children where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with dasatinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has Philadelphia chromosome positive CML in chronic phase.<br>3. The patient has been previously treated with imatinib which had to be discontinued due to resistance or intolerance.<br>Please mark below whether the patient was resistant to or intolerant of imatinib:<br>- resistant to imatinib or<br>- intolerant of imatinib<br>4. The use of dasatinib has been discussed by the relevant multi-disciplinary team (MDT) involved in chronic myeloid leukaemia (CML) decision making, which must include at least two consultants in the subspecialty with active and credible expertise in the relevant field of whom at least one must be a consultant paediatrician.<br>5. The patient is a child and I understand the Summary of Product Characteristics (SPC) states that 'there is no experience with treatment of paediatric patients below 2 years of age' and 'there is limited data in imatinib-resistant or intolerant paediatric patients below 6 years of age'.<br>6. Treatment with dasatinib will be as monotherapy and with dosing appropriate to the tablet formulation or the oral suspension as described in the separate tablet and oral suspension Summaries of Product Characteristics (SPCs).<br>7. The prescribing clinician understands the SPC cautions that in paediatric patients after at least 2 years of treatment, treatment-related adverse events associated with bone growth and development were reported and close monitoring of growth in paediatric patients under dasatinib treatment is therefore recommended.<br>8. When a treatment break of more than 6 weeks beyond the expected cycle length is needed, I will complete a treatment break approval form to restart treatment, including indicating as appropriate if the patient had an extended break because of COVID19.<br>9. Dasatinib will otherwise be used as outlined in the Summary of Product Characteristics (SPC). | No | As referenced in TA425 | 21-Dec-16 | 21-Mar-17 |
| DAS6 | **Dasatinib** | Dasatinib for the treatment of untreated chronic phase chronic myeloid leukaemia | 1. I confirm that an application has been made by and the first cycle of systemic anti-cancer therapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. I confirm that the patient has chronic phase myeloid leukaemia<br>3. I confirm that the patient has received no prior treatment unless it was dasatinib received as part of the SPIRIT 2 trial for this indication and the patient meets all other criteria listed here*<br>*In March 2018 patients previously entered into the Spirit 2 trial and receiving free-of-charge supplies of dasatinib can transition to NHS commercial supply.<br>4. . I confirm that imatinib is not appropriate for this patient and that this has been discussed and supported by the relevant MDT involved in CML decision making unless they are already receiving dasatinib as part of the SPIRIT 2 trial for this indication and the patient meets all other criteria listed here<br>5. I confirm that dasatinib will be used as outlined in the Summary of Product Characteristics (SPC). | No | TA426 | 21-Dec-16 | 21-Mar-17 |

# National Cancer Drugs Fund (CDF) List

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| DIN1 | **Dinutuximab beta** | Dinutuximab beta as part of 1st line therapy for high risk neuroblastoma in patients aged 12 months and above and who have both responded to induction chemotherapy and been treated with myeloablative therapy and stem cell transplantation where the following criteria are met: | 1. An application is being made by and the first cycle of systemic anti-cancer therapy with dinutuximab beta will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The prescribing clinician is fully aware of the management of and the treatment modifications that may be required for hypersensitivity reactions, capillary leak syndrome, neuropathic pain, peripheral neuropathy and ocular toxicity<br>3. The patient is currently aged 12 months or older and has histologically documented neuroblastoma according to the International Neuroblastoma Staging System (INSS)<br>4. The patient has high risk disease defined as either INSS stage 2, 3 , 4 and 4s with MYCN amplification or INSS stage 4 without MYCN amplification and aged >12 months at diagnosis<br>5. The patient achieved at least a partial response to induction chemotherapy (defined as whatever the sequence of therapies which subsequently led to myeloablative therapy).<br>6. The patient was treated with myeloablative therapy and stem cell transplantation<br>7. The patient remains free of disease progression following induction chemotherapy and stem cell transplantation<br>8. The patient has not received prior treatment with an anti-GD2 antibody antibody unless they were treated with dinutuximab beta as part of induction therapy (as defined above) in the SIOPEN HR-NBL-2 or SIOPEN Pilot studies and all other treatment criteria listed on this form are fulfilled.<br>9. Dinutuximab beta is not being given in combination with interleukin-2<br>10. A formal medical review as to whether treatment with dinutuximab beta should continue or not and at what dose will be scheduled to occur at least by the end of the first cycle of treatment<br>11. The patient will be treated until disease progression or excessive toxicity or completion of 5 cycles of therapy or patient/parent/guardian (as appropriate) choice to discontinue treatment, whichever is the sooner<br>12. Treatment breaks of up to 6 weeks beyond the expected cycle length are allowed<br>13. Dinutuximab beta will otherwise be used as set out in its Summary of Product Characteristics (SPC) | No | TA538 | 22-Aug-18 | 20-Nov-18 |
| DIN2 | **Dinutuximab beta** | Dinutuximab beta for the treatment of RELAPSED or REFRACTORY neuroblastoma in patients aged 12 months and above and who have then both responded to intensive induction chemotherapy used to treat high risk 1st line patients and been treated with myeloablative therapy and stem cell transplantation where the following criteria are met: | 1. An application has been made by and the first cycle of systemic anti -cancer therapy with dinutuximab beta will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The prescribing clinician is fully aware of the management of and the treatment modifications that may be required for hypersensitivity reactions, capillary leak syndrome, neuropathic pain, peripheral neuropathy and ocular toxicity<br>3. The patient is currently aged 12 months or older and has histologically documented neuroblastoma according to the International Neuroblastoma Staging System (INSS)<br>4. The patient has relapsed or refractory neuroblastoma and has disease that requires intensive induction chemotherapy (similar in type to that used in 1st line induction chemotherapy for high risk disease) and myeloablative chemotherapy and stem cell transplantation<br>5. The patient achieved at least a partial response to induction chemotherapy<br>6. The patient was treated with myeloablative therapy and stem cell transplantation<br>7. The patient remains free of disease progression following induction chemotherapy and stem cell transplantation<br>8. The patient has not received prior treatment with an anti-GD2 antibody other than dinutuximab beta received solely in the context of participation in the BEACON or MINIVAN trials<br>9. Dinutuximab beta is not being given in combination with interleukin-2<br>10. A formal medical review as to whether treatment with dinutuximab beta should continue or not and at what dose will be scheduled to occur at least by the end of the first cycle of treatment<br>11. The patient will be treated until disease progression or excessive toxicity or completion of 5 cycles of therapy or patient/parent/guardian (as appropriate) choice to discontinue treatment, whichever is the sooner<br>12. Treatment breaks of up to 6 weeks beyond the expected cycle length are allowed<br>13. Dinutuximab beta will otherwise be used as set out in its Summary of Product Characteristics (SPC) | No | TA538 | 22-Aug-18 | 20-Nov-18 |

# National Cancer Drugs Fund (CDF) List

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| DOS2 | **Dostarlimab** in combination with platinum-containing chemotherapy (carboplatin and paclitaxel) | For the 1st line treatment of adult patients with mismatch repair deficient or microsatellite instability-high endometrial carcinoma who have recurrent or primary advanced disease and who are not candidates for potentially curative surgery or radiotherapy or chemoradiotherapy but are eligible for systemic therapy where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with dostarlimab in combination with carboplatin and paclitaxel will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The prescribing clinician is fully aware of the management of, and the treatment modifications that may be required for, immune-related adverse reactions due to anti-PD-1 treatments including pneumonitis, colitis, nephritis, endocrinopathies, hepatitis, myocarditis and skin toxicity.<br>3. The patient has a histologically- or cytologically-confirmed diagnosis of endometrial carcinoma (including clear cell and serous histologies).<br>Note: patients with carcinosarcoma (Mixed Mullerian tumour) are eligible but otherwise uterine sarcomas of any kind are NOT eligible for dostarlimab in this indication.<br>4. The patient's tumour has a documented presence of mismatch repair deficiency (dMMR) or microsatellite instability (MSI-H) confirmed by validated testing.<br>5. The patient either has a 1st recurrence of endometrial carcinoma after surgery or radiotherapy or chemoradiotherapy or has presented with primary locally advanced or metastatic endometrial carcinoma and in whichever scenario is not a candidate for any potentially curative treatment with surgery or radiotherapy or chemoradiotherapy.<br><br>Please mark below which scenario applies to this patient:<br>- 1st recurrence after previous surgery, radiotherapy or chemoradiotherapy or<br>- presented with primary stage IIIA disease and has received no systemic therapy or<br>- presented with primary stage IIIB disease and has received no systemic therapy or<br>- presented with primary stage IIIC1 disease and has received no systemic therapy or<br>- presented with primary stage IIIC2 disease and has received no systemic therapy or<br>- presented with primary stage IV disease and has received no systemic therapy genomic<br>6. The patient either has not previously received any systemic chemotherapy for the endometrial carcinoma or the only systemic therapy has been as neoadjuvant or adjuvant chemotherapy or chemoradiotherapy and the patient has progressed or recurred at least 6 months since the completion of such chemotherapy.<br><br>Please mark below which scenario applies to this patient:<br>- the patient is treatment-naïve to chemotherapy for the endometrial cancer or<br>- the only systemic therapy has been as neoadjuvant or adjuvant chemotherapy or chemoradiotherapy and the patient has progressed or recurred at least 6 months since the completion of such chemotherapy<br>7. Dostarlimab will be given in combination with carboplatin and paclitaxel unless there is a clear contraindication to the use of one or both of these cytotoxic agents.<br><br>Please mark below which scenario applies to this patient:<br>- the intent is to use the combination of carboplatin and paclitaxel as the chemotherapy partner to dostarlimab or<br>- the patient has a clear contraindication to the use of carboplatin and/or paclitaxel and hence an alternative platinum-based combination therapy has to be used as the chemotherapy partner to dostarlimab<br>Note: in patients who suffer a severe allergic reaction to paclitaxel or carboplatin which necessitates discontinuation of the drug causing the severe allergy, use of dostarlimab can continue with carboplatin or paclitaxel in combination with whichever agent is considered appropriate by the clinician.<br>8. Unless the patient is contraindicated from starting with carboplatin and paclitaxel, the patient will commence combination chemotherapy with carboplatin at a dose of AUC 5mg/ml/min and paclitaxel at 175mg/m², planned to be given 3-weekly and for a maximum of 6 cycles of chemotherapy.<br>9. The patient has not received any prior antibody treatment which targets PD-1 or PD-L1 or PD-L2 or CD137 or OX40 or anti-cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) unless the patient has already received dostarlimab for the same indication via the EAMS scheme.<br><br>Please mark below which scenario applies to this patient:<br>- the patient has not received any prior antibody treatment which targets PD-1 or PD-L1 or PD-L2 or CD137 or OX40 or anti-cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4)<br>- the patient has received dostarlimab for the same indication via the EAMS scheme<br>10. The patient will be treated with a fixed dose of dostarlimab 500mg every 3 weeks when in combination with the chemotherapy and then at a dose of 1000mg every 6 weeks as monotherapy.<br>11. Treatment with dostarlimab will be stopped at whichever of the following events occurs first: disease progression or loss of clinical benefit or unacceptable toxicity or withdrawal of patient consent or **after a maximum of 3 calendar years of treatment.**<br>12. The patient has an ECOG performance status (PS) of 0 or 1.<br>Note: NHS England does not fund this combination in patients of ECOG PS 2.<br>13. The patient has no symptomatically active brain metastases or leptomeningeal metastases.<br>14. A formal medical review as to how dostarlimab and carboplatin and paclitaxel are being tolerated, and whether treatment with this combination should continue or not, will be scheduled to occur at least by the end of the first 6 weeks of treatment.<br>15. When a treatment break of more than 12 weeks beyond the expected 3 or 6 weekly cycle length is needed, the prescribing clinician will complete a treatment break approval form to restart treatment.<br>16. Dostarlimab will be otherwise used as set out in its Summary of Product Characteristics (SPC). | Yes | TA897 | 22-May-25 | 20-Aug-25 |

# National Cancer Drugs Fund (CDF) List

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|---|---|---|---|---|---|---|---|
| DOS3 | **Dostarlimab** in combination with platinum-containing chemotherapy (carboplatin and paclitaxel) | For the 1st line treatment of mismatch repair proficient (pMMR) or microsatellite stable endometrial carcinoma in adult patients who have recurrent or primary advanced disease and who are not candidates for potentially curative surgery or radiotherapy or chemoradiotherapy but are eligible for systemic therapy where the following criteria have been met: | 1. Both this application is being made by and the first cycle of systemic anti-cancer therapy with dostarlimab in combination with carboplatin and paclitaxel will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a histologically- or cytologically confirmed diagnosis of endometrial carcinoma (including clear cell and serous histologies).<br><br>Note: patients with carcinosarcoma (Mixed Mullerian tumour) are eligible but otherwise uterine sarcomas of any kind are NOT eligible for dostarlimab in this indication.<br>3. The patient's tumour has a documented presence of mismatch repair proficiency (pMMR) or microsatellite stability confirmed by validated testing.<br>4. Either the patient has a 1st recurrence of endometrial carcinoma after surgery or radiotherapy or chemoradiotherapy **or** has presented with primary locally advanced or metastatic endometrial carcinoma **and** in whichever scenario is **not** a candidate for any potentially curative treatment with surgery or radiotherapy or chemoradiotherapy.<br><br>Please mark below which scenario applies to this patient:<br>- 1st recurrence after previous surgery, radiotherapy or chemoradiotherapy or<br>- presented with primary stage IIIA disease and has received no systemic therapy or<br>- presented with primary stage IIIB disease and has received no systemic therapy or<br>- presented with primary stage IIIC1 disease and has received no systemic therapy or<br>- presented with primary stage IIIC2 disease and has received no systemic therapy or<br>- presented with primary stage IV disease and has received no systemic therapy<br>5. **Either** the patient has not previously received any systemic chemotherapy for the endometrial carcinoma, or the only systemic therapy has been as neoadjuvant or adjuvant chemotherapy or chemoradiotherapy and the patient has progressed or recurred at least 6 months since the completion of such chemotherapy.<br><br>Please mark below which scenario applies to this patient:<br>- the patient is treatment-naïve to chemotherapy for the endometrial cancer or<br>- the only systemic therapy has been as neoadjuvant or adjuvant chemotherapy or chemoradiotherapy and the patient has progressed or recurred at least 6 months since the completion of such chemotherapy<br>6. Dostarlimab will be given in combination with carboplatin and paclitaxel unless there is a clear contraindication to the use of one or both cytotoxic agents.<br><br>Please mark below which scenario applies to this patient:<br>- the intent is to use the combination of carboplatin and paclitaxel as the chemotherapy partner to dostarlimab or<br>- the patient has a clear contraindication to the use of carboplatin and/or paclitaxel and hence an alternative platinum-based combination therapy must be used as the chemotherapy partner to dostarlimab<br><br>Note: in patients who suffer a severe allergic reaction to paclitaxel or carboplatin which necessitates discontinuation of the drug causing the severe allergy, use of dostarlimab can continue with carboplatin or paclitaxel in combination with whichever agent is considered appropriate by the clinician.<br>7. Unless the patient is contraindicated from starting with carboplatin and paclitaxel, the patient will commence combination chemotherapy with carboplatin at a dose of AUC 5mg/ml/min and paclitaxel at 175mg/m², planned to be given 3-weekly and for a maximum of 6 cycles of chemotherapy.<br>8. The patient has not received any prior antibody treatment which targets PD-1 or PD-L1 or PD-L2 or CD137 or OX40 or anti-cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) unless the patient has already received dostarlimab for the same indication via a company sponsored early access scheme<br>9. Treatment with dostarlimab will be stopped at whichever of the following events occurs first: disease progression, or loss of clinical benefit, or unacceptable toxicity, or withdrawal of patient consent, **or after a maximum of 3 calendar years of treatment**.<br>10. The patient has an ECOG performance status (PS) of 0 or 1.<br>11. The patient has no symptomatically active brain metastases or leptomeningeal metastases.<br>12. When a treatment break of more than 12 weeks beyond the expected 3- or 6-weekly cycle length is needed, the prescribing clinician will complete a treatment break approval form to restart treatment.<br>13. Dostarlimab will be otherwise used as set out in its Summary of Product Characteristics (SPC). | No | TA1117 | 16-Dec-25 | 16-Mar-26 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| DUR1_v1.2 | **Durvalumab** | The treatment of PD-L1 ≥1% positive locally advanced and unresectable non-small-cell lung cancer which has not progressed following concurrent platinum-based chemoradiotherapy where all the following criteria are met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with durvalumab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The prescribing clinician is fully aware of the management of and the treatment modifications that may be required for immune-related adverse reactions due to anti-PD-L1 treatments including pneumonitis, colitis, nephritis, endocrinopathies, hepatitis and skin toxicity.<br>3. The patient has a histologically- or cytologically-confirmed diagnosis of non-small cell lung cancer.<br>4. PD-L1 testing with an approved and validated test to determine the PD-L1 Tumour Proportion Score (TPS) has been done prior to this application and **either** the result demonstrates a PD-L1 score of 1% or more and the result is set out below **or** the PD-L1 TPS cannot be ascertained despite a clear intent and a reasonable attempt to do so.<br>Please document the actual TPS below:<br>TPS: _____<br>or indicate below the reason that the actual PD-L1 TPS cannot be documented:<br>- the TPS result was unquantifiable for technical (assay) reasons or<br>- PD-L1 testing was not possible as the pathologist has documented that there is insufficient tissue for PD-L1 analysis and the Lung Cancer MDT has concluded and documented that the gaining of a further tumour sample is hazardous to the patient.<br>Note: durvalumab is not approved for use if the PD-L1 result is <1% or negative.<br>5. The patient has locally advanced and unresectable non small cell lung cancer which is either stage IIIA or stage IIIB or stage IIIC at the time of commencing concurrent chemoradiotherapy.<br>Please tick the correct box as to staging:<br>- stage IIIA disease **or**<br>- stage IIIB disease **or**<br>- stage IIIC disease<br>6. The patient has recently completed treatment with 2 or more cycles (defined according to local practice) of platinum-based combination chemotherapy given concurrently with definitive radical radiotherapy **which must have been at a dose of 54-66Gy (or a biologically equivalent dose of 54-66Gy)**.<br>Note: durvalumab is not approved by NICE for use after sequential chemotherapy and radiotherapy.<br>7. The patient has been re-staged since chemoradiotherapy was completed and does not have any evidence of disease progression or metastatic spread.<br>8. The patient will start his/her first treatment with durvalumab within 42 days of the last active treatment date of the concurrent chemoradiotherapy treatment program.<br>9. The patient has an ECOG performance status (PS) of 0 or 1.<br>10. The maximum treatment duration with durvalumab will be 12 months, this being measured from the date of first durvalumab treatment.<br>Note: the total active treatment period is a maximum of 12 months ie in those patients who have toxicity and thus have dose interruptions, the maximum number of treatment cycles is 26 2-weekly cycles or 13 x 4-weekly cycles.<br>11. Treatment with durvalumab will continue until loss of clinical benefit or excessive toxicity or the patient decision to stop therapy or the treatment duration of 12 months has been completed, whichever is the sooner.<br>Note: no re-treatment with durvalumab is allowed.<br>12. The patient has not received prior treatment with an anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CD137, or anti-Cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) antibody unless the patient was treated with neoadjuvant nivolumab plus chemotherapy and failed to have progressive disease after nivolumab plus chemotherapy and did not proceed to a resection or the patient was treated with neoadjuvant and/or adjuvant checkpoint inhibitor immunotherapy containing therapy and such treatment was completed without disease progression and the patient had an isolated local recurrence at least 6 months after completing immunotherapy treatment.<br>Please tick the correct box in relation to any previous immunotherapy:<br>- no previous immunotherapy for NSCLC or<br>- the only previous immunotherapy for NSCLC has been with neoadjuvant nivolumab plus chemotherapy and the patient failed to have progressive disease after nivolumab plus chemotherapy and did not proceed to a resection<br>- the only previous immunotherapy for NSCLC has been with neoadjuvant and/or adjuvant checkpoint inhibitor immunotherapy containing therapy and such treatment was completed without disease progression and the patients had an isolated local recurrence at least 6 months after completing immunotherapy treatment<br>13. A formal medical review as to whether treatment with durvalumab should continue or not will be scheduled to occur at least by the end of the first 3 cycles of treatment.<br>14. Treatment breaks of up to 12 weeks beyond the expected cycle length are allowed but solely to allow any immune toxicities to settle.<br>15. Durvalumab will be otherwise used as set out in its Summary of Product Characteristics (SPC). | No | TA798 | 22-Jun-22 | 20-Sep-22 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| DUR2_v1.0 | **Durvalumab** in combination with gemcitabine and cisplatin | For the 1st line treatment of patients with locally advanced or unresectable or recurrent or metastatic biliary tract cancer where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with durvalumab in combination with gemcitabine and cisplatin will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The prescribing clinician is fully aware of the management of and the treatment modifications that may be required for immune-related adverse reactions due to anti-PD-L1 treatments including pneumonitis, colitis, nephritis, endocrinopathies, hepatitis and skin toxicity.<br>3. The patient has a histologically- or cytologically-confirmed diagnosis of adenocarcinoma of the biliary tract which comprises intrahepatic cholangiocarcinoma or extrahepatic cholangiocarcinoma or gall bladder carcinoma.<br><br>Please mark below which of these 3 sites of disease applies to this patient:<br>- intrahepatic cholangiocarcinoma<br>- extrahepatic carcinoma<br>- gall bladder carcinoma<br><br>Note: a patient with a primary extrahepatic cholangiocarcinoma sited at the ampulla is eligible for treatment with durvalumab plus gemcitabine and cisplatin as the tumour arises from the biliary epithelium.<br><br>Note: a patient with a primary pancreatic or small bowel carcinoma which is sited at the ampulla is not eligible for access to durvalumab plus gemcitabine and cisplatin.<br>4. The patient has locally advanced or unresectable or recurrent or metastatic disease.<br>5. The patient has not received previous chemotherapy for the locally advanced or unresectable or recurrent or metastatic biliary tract cancer indication unless the patient has been enrolled on the SAFIR ABC-10 Precision Medicine clinical trial (see criterion 6 below for further detail).<br><br>Note: patients who have received prior adjuvant or neoadjuvant chemotherapy are eligible for durvalumab plus gemcitabine and cisplatin provided that the adjuvant or neoadjuvant chemotherapy did not contain the combination of gemcitabine and cisplatin.<br>6. The patient has not been previously treated with the combination of gemcitabine plus cisplatin unless the patient has been enrolled in the SAFIR ABC-10 Precision Medicine clinical trial and has been randomised to the experimental (targeted therapy) arm and has now progressed on or experienced unacceptable toxicity with the targeted agent and is fit for further treatment with gemcitabine plus cisplatin and durvalumab. Such patients must NOT have shown any evidence of disease progression during the initial four cycles of gemcitabine plus cisplatin and durvalumab.<br>7. The patient has an ECOG performance status (PS) of 0 or 1.<br><br>Note: NHS England does not fund this treatment in patients of ECOG PS 2.<br>8. The patient has no symptomatic brain or leptomeningeal metastases.<br>9. The patient has NOT received prior treatment with an anti-PD-1, anti-PD-L2, anti-CD137, or anti-Cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) antibody unless the patient has been enrolled in the SAFIR ABC-10 clinical trial as per criterion 6 and is fit for further treatment with gemcitabine plus cisplatin and durvalumab.<br>10. Durvalumab 1500mg will be administered in combination with gemcitabine and cisplatin every 3 weeks for a maximum of 8 cycles and then as monotherapy at a dose of 1500mg every 4 weeks.<br>11. Durvalumab will be stopped at whichever of the following events occurs first: disease progression or loss of clinical benefit or unacceptable toxicity or withdrawal of patient consent.<br><br>Note: there is no fixed duration stopping rule for durvalumab in this biliary tract indication.<br>12. A formal medical review as to whether treatment with durvalumab in combination with gemcitabine and cisplatin should continue will occur at least by the end of the 2nd cycle of treatment.<br>13. Where a treatment break of more than 12 weeks beyond the expected 3 or 4-weekly cycle length is needed, the prescribing clinician will complete a treatment break approval form to restart treatment.<br>14. Durvalumab will be otherwise used as set out in its Summary of Product Characteristics (SPC). | No | TA944 | 10-Jan-24 | 09-Apr-24 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| DUR3_v1.1 | **Durvalumab** in combination with chemotherapy | For the treatment of neoadjuvant treatment and then continued as adjuvant monotherapy in adults with previously untreated UICC/AJCC 8th edition stage IIA or IIB or IIIA or N2 only IIIB non-small cell lung cancer AND who are candidates for potentially curative surgery where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with neoadjuvant durvalumab in combination with chemotherapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a histologically documented diagnosis of non-small cell lung cancer (NSCLC).<br><br>Please mark below which histology applies to this patient:<br>- squamous NSCLC<br>- non-squamous NSCLC<br>3. The patient either has been documented as NOT having a NSCLC which harbours an EGFR 19 or 21 mutation or an ALK gene fusion or the patient has a squamous cell carcinoma and a decision to not test for an EGFR 19 or 21 mutation or an ALK gene fusion and proceed with neoadjuvant durvalumab has been made following discussion at the Lung Cancer MDT and consideration of the relevant patient characteristics (including age and smoking status).<br><br>Please mark below which option applies to this patient:<br>- Documented as NOT having a NSCLC which harbours an EGFR 19 or 21 mutation or an ALK gene fusion<br>- Patient has squamous NSCLC and a decision to not test for an EGFR 19 or 21 mutation or an ALK gene fusion and proceed with durvalumab has been made following discussion at the Lung Cancer MDT.<br>4. The clinical TNM staging has been agreed at the appropriate Lung Cancer MDT meeting to be stage IIA or IIB or IIIA or N2 only IIIB tumour according to the UICC/AJCC TNM 8th edition.<br><br>Please mark below which stage applies to this patient:<br>- stage IIA disease (T2b N0)<br>- stage IIB disease (T1a N1 or T1b N1 or T1c N1 or T2a N1 or T2b N1 or T3 N0)<br>- stage IIIA disease (T1a N2 or T1b N2 or T1c N2 or T2a N2 or T2b N2 or T3 N1 or T4 N0 or T4 N1)<br>- N2 only stage IIIB disease (T3 N2 or T4 N2)<br>5. The patient has been staged as having M0 disease and has been assessed by the thoracic surgical team to be eligible and fit for a potentially curative resection.<br>6. The intent is to treat the patient with a maximum of 4 cycles of 3-weekly neoadjuvant platinum-based chemotherapy in combination with 3-weekly durvalumab.<br>7. The chemotherapy partner to this neoadjuvant combination will be a 2-drug platinum-based combination with the platinum component being either cisplatin or carboplatin given at a dose of at least AUC of 5mg/ml/min.<br><br>Please mark below which will be the platinum-based component of the 2-drug combination:<br>- cisplatin<br>- carboplatin given with a drug dose of at least AUC 5mg/ml/min<br><br>Note: the partner cytotoxic drugs to cisplatin/carboplatin can be pemetrexed or paclitaxel or gemcitabine or vinorelbine.<br>8. The intent is for the patient to potentially undergo resection within 20 weeks of the 1st dose of neoadjuvant therapy.<br>9. The intent is for the patient to commence adjuvant durvalumab monotherapy no later than 12 weeks after surgery for a maximum of 12 x 4-weekly durvalumab doses and then discontinue treatment with durvalumab.<br>10. The intent for any patient requiring any form of post-operative radiotherapy is for this to start no later than 8 weeks after surgery and for adjuvant durvalumab to commence no later than 4 weeks after completion of radiotherapy.<br>11. The patient has not received any previous anticancer therapy of any kind for this NSCLC or any prior treatment with an anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CD137, or anti-Cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) antibody.<br>12. The patient has an ECOG performance status (PS) of 0 or 1.<br>13. Durvalumab will be stopped at whichever of the following events occurs first: any local or distant disease progression at any time in the neoadjuvant, peri-operative and adjuvant phases of treatment or unacceptable toxicity or withdrawal of patient consent or on completion of the maximum allowed duration of treatment with adjuvant durvalumab as outlined above.<br>14. When a treatment break of more than 12 weeks beyond the expected 3-weekly or 4-weekly cycle length (as appropriate) is needed, the prescribing clinician will complete a treatment break approval form to restart treatment, which MUST be approved before treatment is recommenced..<br>15. The prescribing clinician is aware of the following issues which relate to the subsequent management of this patient following neoadjuvant durvalumab plus chemotherapy:<br>i) if the patient has a resection, then post-operative radiotherapy or chemoradiotherapy can be given if indicated and in the absence of any progressive disease, the patient can proceed to adjuvant durvalumab<br>ii) if the patient does not have a resection, then post-operative radiotherapy or chemoradiotherapy can be given if indicated and in the absence of any progressive disease, the patient can proceed to adjuvant durvalumab<br>iii) if the patient does not have surgery or radiotherapy or chemoradiotherapy, no adjuvant durvalumab can be given<br>iv) if there is disease progression during neoadjuvant or adjuvant durvalumab, no further anti-PD1 or anti-PDL1 immunotherapy is funded in any indication<br>16. Durvalumab will be otherwise used as set out in its Summary of Product Characteristics (SPC). | Yes | TA1030 | 15-Jan-25 | 15-Apr-25 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| DUR4 | **Durvalumab** in combination with etoposide plus either carboplatin or cisplatin | For the first-line treatment of adult patients with extensive-stage small cell lung cancer where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with durvalumab in combination with etoposide plus carboplatin or cisplatin will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The prescribing clinician is fully aware of the management of and the treatment modifications that may be required for immune-related adverse reactions due to anti-PD-L1 treatments including pneumonitis, colitis, nephritis, endocrinopathies, hepatitis and skin toxicity.<br>3. The patient has a histologically or cytologically determined diagnosis of small cell lung cancer (SCLC).<br>4. The patient has been staged as having extensive stage small cell lung cancer (SCLC).<br>5. The patient has not received previous systemic therapy for his/her extensive stage SCLC. Previous treatment with concurrent chemoradiotherapy for limited stage SCLC is allowed as long as therapy was completed at least 6 months prior to the diagnosis of recurrent and extensive stage disease.<br>6. The patient has an ECOG performance status score of 0 or 1.<br>7. The patient will be treated with a maximum of four 3-weekly cycles of durvalumab in combination with etoposide (80-100mg/$m^2$ IV on days 1-3 or its oral equivalent on days 2-3) plus either carboplatin (AUC 5 or 6 mg/ml/min) or cisplatin (75-80mg/$m^2$).<br>8. On completion of durvalumab in combination with chemotherapy and in the absence of disease progression, treatment with durvalumab maintenance monotherapy will continue until disease progression or symptomatic deterioration or unacceptable toxicity or withdrawal of patient consent, whichever occurs first.<br>9. The dosing of durvalumab will be at an intravenous dose of 1500mg given every 3 weeks in combination with chemotherapy and at a dose of 1500mg given every 4 weeks as monotherapy maintenance therapy.<br>10. As part of informed consent the patient has been given the options of receiving either durvalumab plus chemotherapy and then maintenance intravenous 4-weekly durvalumab or atezolizumab plus chemotherapy and then maintenance subcutaneous 3-weekly atezolizumab and has chosen the intravenous 4-weekly durvalumab option.<br>11. The patient has no symptomatically active brain metastases or leptomeningeal metastases<br>12. The patient has had no prior treatment with anti-PD-L1/PD-1 therapy for small cell lung cancer, unless this was received for this indication via a company early access program and all treatment criteria on this form are fulfilled.<br>13. A formal medical review as to how treatment with durvalumab in combination with etoposide plus carboplatin or cisplatin is being tolerated and whether treatment with durvalumab plus chemotherapy should continue or not will be scheduled to occur at least by the end of the first 6 weeks of treatment.<br>14. Where a treatment break of more than 12 weeks beyond the expected 3- or 4-weekly cycle length is needed, I confirm that I will complete a treatment break approval form to restart treatment.<br>15. Durvalumab, etoposide and carboplatin or cisplatin will be otherwise used as set out in their respective Summary of Product Characteristics (SPCs). | No | TA1041 | 19-Feb-25 | 20-Mar-25 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| DUR6 | **Durvalumab** in combination with tremelimumab | For first-line systemic treatment of adult patients with locally advanced or metastatic and/or unresectable hepatocellular carcinoma where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with durvalumab in combination with tremelimumab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a diagnosis of hepatocellular carcinoma and that one of the following applies to the patient (please tick appropriate box below as to which option applies):<br><br>- either option 1 applies in which case the patient has a confirmed histological diagnosis of hepatocellular carcinoma (HCC)<br>- or option 2 applies in which case a biopsy is deemed to be very high risk or technically not feasible in the patient and both the criteria a and b below are also both met:<br>**a**: the decision not to biopsy has been made and documented by a specialist HCC multi-disciplinary team meeting<br>**and b**: the tumour meets the non-invasive diagnostic criteria of HCC as set out below*.<br><br>It is expected that option 2 will only apply in exceptional circumstances.<br><br>Please mark below which of these 2 clinical scenarios applies to this patient:<br>Option 1: the patient has a confirmed histological diagnosis of hepatocellular carcinoma or<br>Option 2: the patient cannot be biopsied on account of high risk or technical lack of feasibility and the above criteria for option 2 all apply.<br><br>*EASL-EORTC Clinical Practice Guidelines: Management, Journal of Hepatology 2012 vol 56 p908-943. Non-invasive criteria can only be applied to cirrhotic patients and are based on imaging techniques obtained by 4-phase multidetector CT scan or dynamic contrast-enhanced MRI. Diagnosis should be based on the identification of the typical hallmark of HCC (hypervascular in the arterial phase with washout in the portal venous or delayed phases). While one imaging technique is required for nodules beyond 1cm in diameter, a more conservative approach with 2 techniques is recommended in suboptimal settings.<br>3. The patient has metastatic or locally advanced disease that is ineligible for or has failed surgical or loco-regional therapies.<br>4. The patient has Child-Pugh A liver function.<br>5. The patient has not received previous systemic therapy for his/her hepatocellular carcinoma.<br><br>Note: previous systemic treatment with sorafenib or lenvatinib or regorafenib or any immunotherapy or any systemic chemotherapy is not allowed.<br>6. The patient has an ECOG performance status score of 0 or 1.<br>7.Treatment with durvalumab after its initial single dose in combination with tremelimumab will continue until loss of clinical benefit or unacceptable toxicity or withdrawal of patient consent, whichever occurs first.<br>8. The patient has no symptomatically active brain metastases or leptomeningeal metastases.<br>9. The patient has not received prior treatment with an anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CD137, or anti-Cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) antibody.<br>10. Durvalumab will be given intravenously at a dose of 1500 mg every 4 weeks.<br>11. When a treatment break of more than 12 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break form to restart treatment.<br>12. On discontinuation of the combination of durvalumab on account of loss of clinical benefit or treatment intolerance and if the patient is fit for further systemic therapy, the next line of treatment would be a choice of either sorafenib or lenvatinib.<br>13. Durvalumab and tremelmumab will otherwise be used as set out in their respective Summary of Product Characteristics (SPCs). | No | TA1090 | 19-Aug-25 | 17-Nov-25 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| DUR7 | **Durvalumab** | Durvalumab monotherapy for patients with limited- stage small cell lung cancer whose disease has not progressed following platinum-based chemoradiotherapy where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with durvalumab monotherapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy. | No | TA1099 | 01-Oct-25 | 30-Dec-25 |
| | | | 2. The patient has a histologically or cytologically determined diagnosis of small cell lung cancer (SCLC). | | | | |
| | | | 3. The patient has limited stage SCLC. | | | | |
| | | | 4. The patient has been treated with platinum-based chemoradiotherapy (etoposide plus either cisplatin or carboplatin) and there has been no evidence of disease progression following this.<br><br>Please mark below whether the radiotherapy was concurrent with chemotherapy or sequential after chemotherapy:<br>- concurrent radiotherapy and chemotherapy or<br>- sequential radiotherapy after chemotherapy<br><br>Note: NHS England expects concurrent chemoradiotherapy to be the preferred way of giving platinum-based chemotherapy and radiotherapy in line with the 2019 NICE Clinical Guideline for SCLC. | | | | |
| | | | 5. The patient has been treated with prophylactic cranial irradiation (PCI) or not:<br>- yes, the patient has received PCI or<br>- no, the patient has not been treated with PCI | | | | |
| | | | 6. Treatment with durvalumab maintenance monotherapy will continue until disease progression or symptomatic deterioration or unacceptable toxicity or withdrawal of patient consent or **for a maximum of 2 calendar years**, whichever occurs first. | | | | |
| | | | 7.The patient will start his/her first treatment with durvalumab **within 42 days** from the last day of the final cycle of chemotherapy (e.g. C4D21) or the last day of radiotherapy, whichever occurs later. | | | | |
| | | | 8. The patient has a current ECOG performance status of 0 or 1. | | | | |
| | | | 9. The patient has no symptomatically active brain metastases or leptomeningeal metastases. | | | | |
| | | | 10. The patient has had no prior treatment with anti-PD-L1/PD-1 therapy for small cell lung cancer, unless this was received for this indication via a company early access program and all treatment criteria on this form are fulfilled. | | | | |
| | | | 11. When a treatment break of more than 12 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment. This must be approved before durvalumab is re-commenced | | | | |
| | | | 12. Durvalumab will be otherwise used as set out in its Summary of Product Characteristics (SPC). | | | | |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| ELAC1 | **Elacestrant** monotherapy | For the treatment of oestrogen receptor-positive, HER2-negative, locally advanced or metastatic breast cancer in patients previously treated with at least 12 calendar months of therapy with a CDK4/6 inhibitor-based combination where the following criteria have been met: | 1. This application for elacestrant is being made by and the first cycle of elacestrant will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has histologically or cytologically documented diagnosis of oestrogen receptor positive and HER-2 negative breast cancer.<br>3. The patient's breast cancer has an activating ESR1 mutation identified using a validated test.<br><br>Note: elacestrant's SPC states that the presence of activating ESR1 mutation should be based on use of a plasma specimen.<br><br>Please document below whether the PIK3CA mutation status is known or not and if known whether the patient has a dual mutation positive cancer or one bearing just an ESR1 mutation<br>- the PIK3CA mutation test result is not currently known or<br>- the patient is known to be solely positive for an ESR1 mutation (ie the PIK3CA test is negative) or<br>- the patient has dual mutation positive disease (ie both ESR1 and PIK3CA tests are positive)<br>4. The patient has metastatic or locally advanced breast cancer which is not amenable to curative treatment.<br>5. The patient's menopausal status has been considered and if appropriate the patient has undergone ovarian ablation or suppression with LHRH agonist treatment.<br>6. The patient has progressive disease after previous endocrine-based therapy.<br>7. The patient has been previously treated with at least 1 prior line of endocrine therapy in combination with a CDK4/6 inhibitor.<br>8. The patient has been previously treated with at least 12 calendar months of treatment with a CDK4/6 inhibitor.<br><br>Please record in which places in the treatment pathway the patient had CDK4/6 inhibitor therapy:<br>- solely for early breast cancer or<br>- solely for locally advanced/metastatic breast cancer or<br>- in both early and advanced breast cancer settings<br><br>Note: the company submitted a case to NICE for consideration of elacestrant's clinical and cost effectiveness only in patients previously treated with at least 12 calendar months of therapy with a CDK4/6 inhibitor. This population is narrower than that in the marketing authorisation.<br><br>Note: NHS England does not commission the use of elacestrant in patients who have had less than 12 calendar months of prior therapy with a CDK4/6 inhibitor-based combination.<br>9. The patient has been previously treated with the combination of alpelisib plus fulvestrant or not:<br>- No, the patient has not received prior alpelisib plus fulvestrant **or**<br>- Yes, the patient has been previously treated with alpelisib plus fulvestrant<br>10. The patient has had no more than 1 prior line of cytotoxic chemotherapy for advanced/metastatic disease.<br>11. The patient is an appropriate candidate for the use of further endocrine therapy.<br>12. The patient has not previously received treatment with elacestrant unless this was via a company early access scheme and all treatment criteria on this form are complied with.<br>13. The patient has an ECOG performance status of 0 or 1.<br>14. Elacestrant will only be given as monotherapy.<br>16. The prescribing clinician is aware of both the potential drug interactions between elacestrant and CYP3A4 inhibitors/inducers/other enzyme systems and any consequent elacestrant dose adjustments that are required, as outlined in sections 4.2, 4.4 and 4.5 of elacestrant's Summary of Product Characteristics.<br>17. When a treatment break of up to 6 weeks beyond the expected 4-weekly cycle length is needed, I as the prescribing clinician will complete a treatment break approval form to restart treatment.<br>18. Elacestrant will be otherwise used as set out in their respective Summary of Product Characteristic (SPC). | No | TA1036 | 05-Feb-25 | 06-May-25 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| ENC1_v1.1 | **Encorafenib** (in combination with binimetinib) | The treatment of unresectable stage III or stage IV BRAF V600 mutation positive malignant melanoma where the following criteria are met: | 1. This application is made by and the first cycle of systemic anti-cancer therapy with encorafenib in combination with binimetinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy | No | TA562 | 27-Feb-19 | 28-May-19 |
| | | | 2. This patient has a confirmed histological diagnosis of malignant melanoma. | | | | |
| | | | 3. This patient's cancer has been shown to contain a BRAF V600 mutation. | | | | |
| | | | 4. The patient has unresectable stage III or stage IV disease that has been staged according to the AJCC 8th edition | | | | |
| | | | 5. The patient is treatment naïve to BRAF V600 and MEK inhibitors for malignant melanoma unless either the patient has previously received adjuvant dabrafenib and trametinib and did not progress during such therapy or has received a sufficient trial of dabrafenib plus trametinib for advanced disease and this has had to be stopped solely as a consequence of persistent dose-limiting toxicity and in the documented absence of disease progression.<br>Note: sequential treatment is not commissioned with dabrafenib plus trametinib and then on disease progression with encorafenib plus binimetinib. | | | | |
| | | | 6. The patient has sufficient ECOG performance status to tolerate treatment with the combination of encorafenib plus binimetinib | | | | |
| | | | 7. Treatment with encorafenib in combination with binimetinib will be continued until loss of clinical benefit or unacceptable toxicity or withdrawal of patient consent unless the patient is enrolled in the DyNAMIc clinical trial (trial reference CTA 21266/0255/001-0001) in which case an intermittent adaptive dosing schedule as guided by circulating tumour DNA levels can be used as per the trial protocol. | | | | |
| | | | 8. A formal medical review as to whether treatment with encorafenib in combination with binimetinib should continue or not will be scheduled to occur at least by the end of the first 8 weeks of treatment | | | | |
| | | | 9. Where a treatment break of more than 6 weeks beyond the expected cycle length is needed, the prescribing clinician will complete a treatment break approval form to restart treatment, including indicating as appropriate if the patient had an extended break because of COVID 19.<br>Note: patients in the DyNAMIc clinical trial (trial reference CTA 21266/0255/001-0001) who draw the adaptive intermittent treatment arm do not need to apply for approval to restart after treatment breaks that are a planned part of the trial schedule. | | | | |
| | | | 10. Encorafenib in combination with binimetinib is to be otherwise used as set out in their respective Summaries of Product Characteristics | | | | |
| ENC2_v1.2 | **Encorafenib** in combination with cetuximab | For previously treated BRAF V600E mutation positive metastatic or locally advanced and inoperable colorectal cancer where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with encorafenib in combination with cetuximab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy. | No | TA668 | 06-Jan-21 | 06-Apr-21 |
| | | | 2. The patient has a histologically proven diagnosis of colorectal adenocarcinoma. | | | | |
| | | | 3. This patient's colorectal cancer has been shown to be of RAS wild type. | | | | |
| | | | 4. This patient's colorectal cancer has been shown to contain a BRAF V600E mutation. | | | | |
| | | | 5. The patient has failed one or two prior regimens for either metastatic or locally advanced and inoperable disease. Note: if the patient progressed through adjuvant chemotherapy or within 6 months of completing adjuvant chemotherapy, the patient can be classed as having received one line of treatment for metastatic disease.<br>Please note below whether the patient has been previously treated with one or two prior regimens for advanced/metastatic disease:<br>- One prior regimen<br>- Two prior regimens | | | | |
| | | | 6. The has not received prior treatment with any BRAF inhibitor or MEK inhibitor unless this patient was treated with neoadjuvant encorafenib plus cetuximab prior to surgery for locally advanced but operable colon cancer within the FOxTROT 4 clinical trial (ISRCTN83842641).<br><br>Please mark below which of these 2 clinical scenarios applies to this patient:<br>- No prior treatment with any BRAF or MEK inhibitor<br>- Treated with neoadjuvant encorafenib plus cetuximab prior to surgery for locally advanced but operable colon cancer within the FOxTROT 4 clinical trial | | | | |
| | | | 7. The patient has not received prior treatment with cetuximab or panitumumab or any other EGFR inhibitors unless this patient was treated with neoadjuvant encorafenib plus cetuximab prior to surgery for locally advanced but operable colon cancer within the FOxTROT 4 clinical trial (ISRCTN83842641).<br><br>Please mark below which of these 2 clinical scenarios applies to this patient:<br>- No prior treatment with cetuximab or panitumumab or any other EGFR inhibitors<br>- Treated with neoadjuvant encorafenib plus cetuximab prior to surgery for locally advanced but operable colon cancer within the FOxTROT 4 clinical trial | | | | |
| | | | 8. The patient will be treated with encorafenib at an initial continuous dose of 300mg daily as part of a 28-day cycle. | | | | |
| | | | 9. The patient will be treated with cetuximab at a dose of 500mg/m2 every two weeks as part of a 28-day cycle. | | | | |
| | | | 10. The patient has an ECOG performance status (PS) of 0 or 1. | | | | |
| | | | 11. The patient has no active brain metastases or leptomeningeal metastases. | | | | |
| | | | 12. Encorafenib with cetuximab is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment, whichever is the sooner. | | | | |
| | | | 13. A formal medical review as to how the combination of encorafenib plus cetuximab is being tolerated and whether treatment with the combination of encorafenib plus cetuximab should continue or not will be scheduled to occur at least by the end of the first 8 weeks of treatment. | | | | |
| | | | 14. Where a treatment break of more than 6 weeks beyond the expected cycle length is needed, I will complete a treatment break approval form to restart treatment. | | | | |
| | | | 15. Encorafenib and cetuximab will be otherwise used as set out in their respective Summary of Product Characteristics (SPCs). | | | | |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| ENF1 | **Enfortumab vedotin** in combination with pembrolizumab | Enfortumab vedotin with pembrolizumab for untreated, unresectable or metastatic urothelial cancer, when platinum-based chemotherapy is suitable where the following criteria have been met: | 1. This application has been made by and the first cycle of systemic anti -cancer therapy with enfortumab vedotin & pembrolizumab will be/was prescribed by a consultant oncologist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a histologically- or cytologically confirmed diagnosis of unresectable or metastatic urothelial cancer (i.e., cancer of the bladder, renal pelvis, ureter, or urethra). Patients with squamous or sarcomatoid differentiation or mixed cell types are eligible.<br>3. In respect of his/her treatment for unresectable/advanced disease and at the time of starting enfortumab vedotin & pembrolizumab, the patient is/was treatment-naïve to systemic therapy<br>4. In the absence of enfortumab vedotin & pembrolizumab the patient would have been deemed eligible for treatment with cisplatin or carboplatin-based chemotherapy<br>5. The patient does not have ongoing sensory or motor neuropathy of grade 2 or higher<br>6. At the time of commencing pembrolizumab the patient has/had not received prior treatment with any of the following in respect of their urothelial cancer: anti-PD-1, anti-PD-L1, anti-PD-L2 and anti-CD137 treatments, unless these were given in a neo adjuvant and/or adjuvant setting and the most recent dose was given >12 months before recurrence was diagnosed<br>7. The patient has an ECOG performance status (PS) of 0, 1, or 2. Patients with a PS of 2 must have a haemoglobin of >10g/dl and a GFR >50ml/min<br>8. The patient does not have active central nervous system metastases – if the patient does have such metastases these must be clinically stable, and the patient must not have leptomeningeal disease<br>9. Enfortumab vedotin and pembrolizumab will be used in combination unless:<br>- The patient experiences unacceptable toxicity that is attributable only to pembrolizumab, then they may continue enfortumab vedotin monotherapy until one of the criteria in #10 is met<br>- The patient experiences unacceptable toxicity that is attributable only to enfortumab vedotin, then they may continue pembrolizumab monotherapy until one of the criteria in #11 is met<br>10. Treatment with enfortumab vedotin will be continued until disease progression, unacceptable toxicity, or withdrawal of patient consent, whichever of these events occurs first.<br>11. Treatment with pembrolizumab will be continued until disease progression, unacceptable toxicity, withdrawal of patient consent, or a maximum treatment duration of 35 cycles (if given 3-weekly, or its equivalent if 6-weekly dosing is used) whichever of these events occurs first.<br>12. When a treatment break of more than 12 weeks beyond the expected 3-weekly cycle length is needed, a treatment break form to restart treatment will be completed, which must be approved before treatment is re-commenced.<br>13. Enfortumab vedotin and pembrolizumab will be otherwise used as set out in their respective Summary of Product Characteristics (SPCs) | No | TA1097 | 11-Sep-25 | 10-Dec-25 |

# National Cancer Drugs Fund (CDF) List

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|---|---|---|---|---|---|---|---|
| ENT2 | **Entrectinib** | Entrectinib for ROS1-positive recurrent or locally advanced or metastatic non-small-cell lung cancer previously untreated with a ROS1 inhibitor therapy where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with entrectinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br><br>2. The patient has histological or cytological evidence of NSCLC that carries a ROS1 gene rearrangement based on a validated test **OR** there is documented agreement by the lung MDT that the radiological appearances are in keeping with locally advanced or metastatic NSCLC **AND** there is an informative circulating free DNA test result confirming the presence of a ROS1 gene rearrangement.<br>Please mark below on which basis the diagnosis of ROS1 positive NSCLC has been made in this patient:<br>- Histological or cytological evidence.<br>- Documented agreement by the lung MDT that the radiological appearances are in keeping with locally advanced or metastatic NSCLC and there is an informative circulating free DNA test result confirming the presence of a ROS1 gene rearrangement<br><br>3. The patient has not previously received a ROS1 inhibitor.<br>Previous treatment with crizotinib is not allowed. The NICE recommendation and the entrectinib Summary of Product Characteristics both state that entrectinib is indicated in the treatment of patients who have not been previously treated with ROS1 inhibitors. The only exception to this is for patients who have had dose- limiting toxicity with crizotinib and it has had to be stopped within 6 months of its start and in the clear absence of progressive disease<br><br>Please tick appropriately below as to whether the patient has been previously treated with systemic therapy for the recurrent/locally advanced/metastatic indication:<br>- no previous treatment with any systemic therapy for recurrent or locally advanced or metastatic NSCLC or<br>- Previous treatment with crizotinib has had to be stopped within 6 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of progressive disease<br><br>4. Entrectinib will be used only as monotherapy.<br>5. The patient has an ECOG performance status of 0 or 1 or 2.<br>6. The patient either has no brain metastases or, if the patient has brain metastases, the patient is symptomatically stable prior to starting entrectinib.<br>7. The patient will be treated with entrectinib until loss of clinical benefit or excessive toxicity or patient choice to discontinue treatment, whichever is the sooner.<br>8. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment.<br>9. Entrectinib will be otherwise used as set out in its Summary of Product Characteristics. | No | TA643 | 12-Aug-20 | 10-Nov-20 |
| ENZ3 | **Enzalutamide** in combination with androgen deprivation therapy (ADT) | For the treatment of patients with newly diagnosed metastatic hormone-sensitive prostate cancer where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with enzalutamide will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br><br>2. This patient either has a proven histological or cytological diagnosis of adenocarcinoma of the prostate or has presented with a clinical picture consistent with metastatic prostate cancer with both widespread bone metastases radiologically typical of prostate cancer and a serum PSA of ≥50 ng/mL.<br><br>3. This patient has newly diagnosed metastatic prostate cancer that is hormone sensitive and has either not been treated with docetaxel and has currently received androgen deprivation therapy (ADT) for no longer than 3 months or has been treated with docetaxel and has currently received ADT for no more than 9 months.<br>Please enter below as to which scenario applies to this patient:<br>- the patient has not yet received any ADT for metastatic prostate cancer or<br>- the patient has not been treated with docetaxel and has currently received no more than 3 months of ADT (before starting an androgen receptor targeted agent) or<br>- the patient has been treated with docetaxel and has currently received no more than 9 months of ADT before starting an androgen receptor targeted agent<br><br>4. The patient has an ECOG performance status (PS) of 0 or 1 or 2.<br>5. The prescribing clinician has assessed this patient's status as regards receiving upfront docetaxel and have concluded that the patient completed planned docetaxel therapy or discontinued docetaxel before completion of planned treatment duration or should not have been treated with docetaxel or chose not to be treated with docetaxel. Please mark which of these 4 clinical scenarios applies to this patient:<br>- the patient was treated with docetaxel and completed a planned treatment duration of 6 cycles of docetaxel<br>- the patient commenced docetaxel and discontinued docetaxel prior to completion of 6 cycles on account of excessive toxicity (i.e. **the patient COULD NOT complete planned treatment duration with docetaxel**)<br>- the patient had significant comorbidities which precluded treatment with docetaxel (i.e. **the patient SHOULD NOT be treated with docetaxel**) and this has been fully discussed with the patient. It is recommended that validated systems of scoring clinical frailty are used as part of the oncology assessment as to explaining the benefits and risks of the treatment options of chemotherapy and enzalutamide<br>- the patient is fit for chemotherapy with docetaxel and has chosen not to be treated with docetaxel. The patient has been fully consented regarding all of the following: the advantages and disadvantages of upfront docetaxel chemotherapy vs upfront enzalutamide; that the use of upfront enzalutamide would result in there being no further possible treatment with any androgen receptor targeted agents when the patient's disease progresses; and that the patient may not be fit enough to receive docetaxel when the patient's disease progresses. After such informed consent, I confirm that the patient has chosen to receive upfront enzalutamide (i.e. **the patient is fit for chemotherapy with docetaxel and has CHOSEN NOT to be treated with docetaxel**)<br><br>6. Enzalutamide is being given in combination with ADT.<br><br>7. The patient has not previously received any androgen receptor targeted agent unless the patient has received darolutamide, apalutamide or abiraterone for newly diagnosed metastatic hormone-sensitive prostate cancer which had to be stopped because of dose-limiting toxicity in the clear absence of disease progression and the patient meets all the other criteria listed here **or** the patient has progressive disease following treatment with 2 years of ADT plus abiraterone with or without enzalutamide for high risk non-metastatic disease as part of the STAMPEDE trial (ISRCTN78818544) and did not progress whilst on such treatment and the patient meets all the other criteria listed on this form **or** the patient has metastatic hormone sensitive prostate cancer treated with abiraterone or abiraterone plus enzalutamide as part of the STAMPEDE-1 trial and has not progressed whilst on such treatment and the patient meets all the other criteria listed on this form **or** the patient has progressive disease following treatment with 2 years of ADT plus abiraterone for high risk non-metastatic disease, did not progress whilst on such treatment, and meets all the other criteria listed on this form.<br><br>Please mark below which of these 6 clinical scenarios applies to this patient:<br>- the patient has not previously received any androgen receptor targeted agent<br>- the patient commenced darolutamide which had to be stopped because of dose-limiting toxicity in the clear absence of disease progression and the patient meets all the other criteria listed here<br>- the patient commenced apalutamide which had to be stopped because of dose-limiting toxicity in the clear absence of disease progression and the patient meets all the other criteria listed here<br>- the patient commenced abiraterone which had to be stopped because of dose-limiting toxicity in the clear absence of disease progression and the patient meets all the other criteria listed here<br>- the patient was treated with 2 years of ADT plus abiraterone with or without enzalutamide for high risk non-metastatic disease as part of the STAMPEDE trial and did not progress whilst on such treatment and the patients meets all the other criteria listed here<br>- the patient has progressive disease following treatment with 2 years of ADT plus abiraterone for high risk non-metastatic disease, did not progress whilst on such treatment, and meets all the other criteria listed on this form<br><br>8. Enzalutamide is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment.<br>9. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment, which MUST be approved before treatment is re-commenced.<br><br>10. Enzalutamide is to be otherwise used as set out in its Summary of Product Characteristics. | No | TA712 | 07-Jul-21 | 05-Oct-21 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| ENZ4 | **Enzalutamide** | Enzalutamide for the treatment of patients with hormone-relapsed (castrate-resistant) metastatic prostate cancer before chemotherapy is indicated where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with enzalutamide will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. This patient either has a proven histological or cytological diagnosis of adenocarcinoma of the prostate or has presented with a clinical picture consistent with metastatic prostate cancer with both widespread bone metastases radiologically typical of prostate cancer and a serum PSA of ≥50 ng/mL.<br>3. This patient has hormone-relapsed (castrate-resistant) metastatic prostate cancer.<br>4. The patient has no or only mild symptoms after androgen deprivation therapy has failed.<br>5. Chemotherapy is not yet indicated.<br>6. One of the following applies to this patient as regards any previous use of 2nd generation receptor inhibitors (such as enzalutamide, darolutamide or apalutamide) or CYP17 enzyme inhibitors (such as abiraterone).<br>Please enter below as to which scenario applies to this patient:<br>- the patient has not previously received any treatment with enzalutamide or darolutamide or apalutamide or abiraterone or<br>- the patient has previously received abiraterone for this same pre-chemotherapy indication in hormone-relapsed (castrate-resistant) prostate cancer but it was stopped due to dose-limiting toxicity and in the clear absence of disease progression<br>7. The patient has an ECOG performance status (PS) of 0 or 1 or 2.<br>8. Enzalutamide is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment.<br>9. Where a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment.<br>10. Enzalutamide is to be otherwise used as set out in its Summary of Product Characteristics. | Yes | TA377 | 27-Jan-16 | 26-Apr-16 |
| ENZ5 | **Enzalutamide** | Enzalutamide for the treatment of patients with hormone-relapsed (castrate-resistant) metastatic prostate cancer with disease progression during or following treatment with docetaxel-containing chemotherapy where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with enzalutamide will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. This patient either has a proven histological or cytological diagnosis of adenocarcinoma of the prostate or has presented with a clinical picture consistent with metastatic prostate cancer with both widespread bone metastases radiologically typical of prostate cancer and a serum PSA of ≥50 ng/mL.<br>3. This patient has hormone-relapsed (castration-resistant) metastatic prostate cancer.<br>4. The patient has been treated with docetaxel-containing chemotherapy and has progressed during or following treatment.<br>5. One of the following applies to this patient as regards any previous use of 2nd generation receptor inhibitors (such as enzalutamide, darolutamide or apalutamide) or CYP17 enzyme inhibitors (such as abiraterone).<br>Please enter below as to which scenario applies to this patient:<br>- the patient has not previously received any treatment with enzalutamide or darolutamide or apalutamide or abiraterone or<br>- the patient has previously received abiraterone for this same pre-chemotherapy indication in hormone-relapsed (castrate-resistant) prostate cancer but it was stopped due to dose-limiting toxicity and in the clear absence of disease progression<br>6. The patient has an ECOG performance status (PS) of 0 or 1 or 2.<br>7. Enzalutamide is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment.<br>8. Where a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment.<br>9. Enzalutamide is to be otherwise used as set out in its Summary of Product Characteristics. | No | TA316 | 23-Jul-14 | 21-Oct-14 |

# National Cancer Drugs Fund (CDF) List

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| EPC1 | **Epcoritamab monotherapy** | For the treatment of previously treated adult patients with diffuse large B-cell lymphoma who have received 2 or more lines of systemic therapy which have included polatuzumab vedotin unless the use of polatuzumab vedotin was contraindicated where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with epcoritamab monotherapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy. | No | TA954 | 06-Mar-24 | 04-Jun-24 |
| | | | 2. The patient has a histologically confirmed diagnosis of diffuse large B cell lymphoma (DLBCL) or transformed follicular lymphoma to DLBCL.<br>The definition of DLBCL includes the following:<br>- DLBCL not otherwise specified (NOS) [including germinal centre B-cell (GCB) and activated B-cell (ABC) subtypes]<br>- primary mediastinal large B cell lymphoma<br>- T cell rich B cell lymphoma<br>- Epstein-Barr virus (EBV) positive DLBCL<br>- intravascular large B cell lymphoma<br>- double hit and triple hit high grade B cell lymphoma<br>Note: Primary CNS lymphoma, Burkitt lymphoma and plasmablastic lymphoma are NOT included for treatment with epcoritamab.<br>Please record in the box below whether the patient has DLBCL according to one of the above types of DLBCL or has transformed follicular lymphoma:<br>- the patient has DLBCL according to one of the types within the above definition OR<br>- the patient has transformed follicular lymphoma (TFL) to DLBCL | | | | |
| | | | 3. The patient has DLBCL or TFL which has either relapsed following or is refractory to **2 or more** lines of standard routinely commissioned systemic therapies and that within these 2 lines of therapy there has been treatment with an anti-CD20 regimen and an anthracycline-containing regimen.<br>Note: patients with TFL must have received 2 or more lines of systemic therapy given specifically for the transformed follicular lymphoma. | | | | |
| | | | 4. The patient has either previously received systemic therapy with a regimen containing polatuzumab vedotin or the use of a polatuzumab vedotin-containing regimen was contraindicated.<br>Note: NICE preferred to assume equal efficacy between epcoritamab and polatuzumab plus bendamustine and rituximab (Pola-BR) and as treatment with epcoritamab was substantially more expensive than Pola-BR, NICE concluded that epcoritamab was not cost effective when compared with Pola-BR. Hence, epcoritamab was recommended by NICE for treating relapsed or refractory DLBCL in patients who have had 2 or more systemic therapies, but only if patients have received prior polatuzumab (whether relapsed following such treatment or refractory to it or if polatuzumab was not tolerated) or if treatment with polatuzumab was contraindicated.<br>Please record in the box below which of the following applies to this patient:<br>- previous treatment with 1st line polatuzumab vedotin-containing chemotherapy to which the patient had relapsed or refractory disease OR<br>- previous treatment with 2nd or greater line polatuzumab vedotin-containing chemotherapy to which the patient had relapsed or refractory disease OR<br>- previous treatment with a polatuzumab vedotin-containing chemotherapy which was not tolerated and hence treatment with polatuzumab vedotin was discontinued OR<br>- the use of a polatuzumab vedotin-containing chemotherapy was contraindicated and hence the patient has not been treated with polatuzumab vedotin for this reason | | | | |
| | | | 5. The number of lines of systemic therapy that the patient has received for the treatment of DLBCL.<br>Note: induction chemotherapy prior to and then followed by stem cell transplantation counts as 1 line of systemic therapy. Similarly, bridging chemotherapy prior to and then followed by CAR T therapy counts as 1 line of systemic therapy.<br>Note: patients who have had only 1 line of systemic therapy are not eligible for treatment with epcoritamab.<br>**Please record the number of lines of previous systemic therapy below:**<br>- 2 previous lines OR<br>- 3 previous lines OR<br>- 4 or more previous lines | | | | |
| | | | 6. Whether the patient has been previously treated with stem cell transplantation:<br>- No previous stem cell transplantation OR<br>- Yes, previous stem cell transplantation | | | | |
| | | | 7. Whether the patient has been previously treated with CAR T therapy and if so at which place in the treatment pathway:<br>- No previous CAR T therapy OR<br>- Yes, previous CAR T therapy as 2nd line therapy OR<br>- Yes, previous CAR T therapy as 3rd or more line of therapy | | | | |
| | | | 8. The patient has not been previously treated with epcoritamab unless **either** epcoritamab monotherapy needs to be continued following an Abbvie compassionate access scheme and all other treatment criteria on this form are fulfilled **or** the patient received and responded to no more than three 4-weekly cycles of epcoritamab monotherapy used specifically as bridging treatment prior to 3rd or more line of CAR T therapy.<br>Note: epcoritamab cannot be used as bridging therapy for 2nd line CAR T therapy.<br>Please record in the box below which of the following applies to this patient:<br>- no previous treatment with epcoritamab OR<br>- continuation of previous treatment with epcoritamab monotherapy via an Abbvie compassionate access scheme and all other criteria on this form are fulfilled OR<br>- previous treatment with no more than 3 cycles of epcoritamab monotherapy specifically used as bridging therapy prior to 3rd or more line CAR T therapy and the patient responded to this epcoritamab bridging therapy | | | | |
| | | | 9. The patient has not received any previous treatment with a bispecific antibody targeting both CD20 and CD3 other than epcoritamab as specified above in criterion 8.<br>Note: use of epcoritamab after previous treatment with glofitamab is NOT commissioned. | | | | |
| | | | 10. The patient has an ECOG performance status score of 0 or 1 or 2. | | | | |
| | | | 11. Epcoritamab is to administered as monotherapy and not in combination with any other systemic therapies for lymphoma. | | | | |
| | | | 12. The prescribing is aware that the planned dosing schedule of epcoritamab is in 4-weekly cycles and is as follows:<br>- in cycle 1 is 0.16mg on day 1, 0.8mg on day 8 and 48mg on days 15 and 22<br>- in cycles 2 and 3 is 48mg on days 1, 8, 15 and 22<br>- in cycles 4 to 9 is 48mg on days 1 and 15<br>- in cycle 10 and thereafter is 48mg on day 1 only. | | | | |
| | | | 13. Treatment with epcoritamab monotherapy will be stopped at whichever of the following events occurs first: disease progression or unacceptable toxicity or withdrawal of patient consent.<br>Note: there is no formal stopping rule for epcoritamab in this indication but once epcoritamab is electively stopped (ie not for reasons of toxicity), it cannot be re-started. | | | | |
| | | | 14. The prescribing clinician and the treating team are familiar with the grading of cytokine release syndrome and immune effector cell-associated neurotoxicity syndrome, its monitoring and management and the indications for use of tocilizumab and both I and the treating team have all undergone training in these clinical issues. | | | | |
| | | | 15. The prescribing clinician and the treating team are aware that the patient must be admitted overnight for at least the cycle 1 day 15 administration of epcoritamab and potentially for further epcoritamab administrations if grade 2 or greater cytokine release syndrome occurs with the previous epcoritamab injection. | | | | |
| | | | 16. 1 dose of tocilizumab is immediately available should tocilizumab be required for the treatment of cytokine release syndrome and access to an additional dose of tocilizumab within 8 hours of the previous tocilizumab must be ensured. | | | | |
| | | | 17. A formal medical review as to whether treatment with epcoritamab should continue or not will be scheduled to occur at least by the end of the first 8 weeks of treatment. | | | | |
| | | | 18. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, a treatment break approval form will be completed to restart treatment. | | | | |
| | | | 19. Epcoritamab will be otherwise used as set out in its Summary of Product Characteristics (SPC). | | | | |

# National Cancer Drugs Fund (CDF) List

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|---|---|---|---|---|---|---|---|
| ERD1 | **Erdafitinib** | Erdafitinib for unresectable locally advanced or metastatic urothelial carcinoma which has a susceptible fibroblast growth factor receptor 3 (FGFR3) genetic alteration in patients previously treated with at least one line of therapy containing a PD-1 or PD-L1 inhibitor administered in the unresectable locally advanced or metastatic treatment setting where the following criteria have been met: | 1. This application for erdafitinib is being made by and the first cycle of systemic anti-cancer therapy with erdafitinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy. | No | TA1062 | 12-May-25 | 09-Aug-25 |
| | | | 2. The patient is an adult with a histologically or cytologically confirmed diagnosis of urothelial carcinoma.<br><br>Please also indicate below whether the urothelial carcinoma is of upper tract or lower tract origin:<br>- the urothelial carcinoma is of upper tract origin Or<br>- the urothelial carcinoma is of lower tract origin | | | | |
| | | | 3. The urothelial carcinoma has been tested for FGFR3 genomic alterations and at least 1 of the following FGFR3 genetic alterations has been determined with a validated test and the result is positive: an FGFR3 gene mutation (R248C or S249C or G370C or Y373C) or a FGFR gene fusion (FGFR3-TACC3 or FGFR3- BAIAP2L1).<br><br>Please also indicate below which genetic alteration is positive:<br>- one of these FGFR3 gene mutations: R248C or S249C or G370C or Y373C Or<br>- one of these FGFR3 gene fusions: FGFR3-TACC3 or FGFR3- BAIAP2L1 Or<br>- both a FGFR3 mutation and a FGFR3 fusion are positive | | | | |
| | | | 4. The patient has unresectable locally advanced or metastatic disease. | | | | |
| | | | 5. The patient has been previously treated with at least 1 line of systemic therapy containing a PD-1 or PD-L1 inhibitor given in the unresectable locally advanced or metastatic treatment setting.<br><br>Note: neoadjuvant or adjuvant therapy containing a PD-1 or PD-L1 inhibitor with disease progression during or within 12 months of its completion counts as treatment in the advanced/metastatic disease setting. | | | | |
| | | | 6. The patient has an ECOG performance status of 0 or 1 or 2. | | | | |
| | | | 7. The patient either has no known brain metastases or if the patient has brain metastases, the patient is symptomatically stable prior to starting treatment with erdafitinib. | | | | |
| | | | 8. The patient has not previously received any specifically FGFR3-targeted therapy unless the patient has received erdafitinib via a company early access scheme and the patient meets all the criteria set out on this form. | | | | |
| | | | 9. Erdafitinib will be used as monotherapy. | | | | |
| | | | 10. The patient will be treated until loss of clinical benefit or excessive toxicity or patient choice to discontinue treatment, whichever is the sooner. | | | | |
| | | | 11. The prescribing clinician understands that erdafitinib can cause serious ocular toxicity and therefore formal opthalmological examinations are to be arranged prior to initiation of erdafitinib, monthly for the first 4 months of treatment, 3-monthly from then on and otherwise urgently as required.<br><br>Note: the baseline opthalmological examination should include an Amsler grid test, fundoscopy, visual acuity and if available optical coherence tomography. The monitoring opthalmological examinations should at least include an Amsler grid test. | | | | |
| | | | 12. The prescribing clinician is aware of the need for erdafitinib dose modifications and interruptions according to the development of hyper-phosphataemia and eye, nail, skin or mucosal adverse events related to erdafitinib as outlined in the erdafitinib SPC | | | | |
| | | | 13. The prescribing clinician is aware of the important drug interactions which can occur between erdafitinib and CYP2C9 and CYP3A4 inhibitors and CYP3A4 inducers as well as other clinically significant interactions as outlined in section 4.5 of the erdafitinib SPC. | | | | |
| | | | 14. A first formal medical review as to whether treatment with erdafitinib should continue or not will be scheduled to occur at least by the end of the first 8 weeks of treatment. | | | | |
| | | | 15. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment | | | | |
| | | | 16. Erdafitinib will be otherwise used as set out in its Summary of Product Characteristics (SPC). | | | | |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| ERIB1 | **Eribulin** | Eribulin for treating locally advanced or metastatic breast cancer after 2 or more lines of systemic anti-cancer treatment where the following criteria have been met: | 1. An application has been made by and the first cycle of systemic anti-cancer therapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy. | Yes | TA423 | 21-Dec-16 | 21-Dec-16 |
| | | | 2. The patient has advanced breast cancer | | | | |
| | | | 3. The patient has had at least 2 prior lines of systemic anti-cancer treatment for advanced disease | | | | |
| | | | 4. Eribulin is to be otherwise used as set out in its Summary of Product Characteristics | | | | |
| EVE1 | **Everolimus** | Everolimus with exemestane for treating advanced breast cancer after endocrine therapy | 1. I confirm that this application is being made by and the first cycle of systemic anti-cancer therapy of everolimus with exemestane will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy. | Yes | TA421 | 21-Dec-16 | 21-Dec-16 |
| | | | 2. I confirm that the patient has ER +ve, HER2 –ve metastatic breast cancer | | | | |
| | | | 3. I confirm that the patient has no symptomatic visceral disease | | | | |
| | | | 4. I confirm that everolimus will be given in combination with exemestane | | | | |
| | | | 5. I confirm that the patient has had previous treatment with a non-steroidal aromatase inhibitor | | | | |
| | | | 6. I confirm that the patient has had no previous treatment with exemestane for metastatic breast cancer | | | | |
| | | | 7. I confirm the patient has received no more than one line of cytotoxic chemotherapy for the treatment of advanced breast cancer. | | | | |
| | | | 8. I confirm the licensed dose and frequency of everolimus will be used. | | | | |
| EVE5 | **Everolimus** | Everolimus for advanced renal cell carcinoma after previous treatment | 1. I confirm that an application has been made by and the first cycle of systemic anti-cancer therapy is to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy | Yes | TA432 | 22-Feb-17 | 23-May-17 |
| | | | 2. I confirm that the patient has biopsy proven renal cell carcinoma | | | | |
| | | | 3. I confirm that the patient has progressed during or after treatment with vascular endothelial growth factor targeted therapy | | | | |
| | | | 4. I confirm that the use of everolimus will be as per the Summary of Product Characteristics (SPC) | | | | |
| EVE6 | **Everolimus** | The treatment of unresectable or metastatic neuroendocrine tumours of pancreatic origin with disease progression where all the following criteria are met: | 1. An application has been made by and the first cycle of systemic anti-cancer therapy is to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy | Yes | TA449 | 13-May-17 | 26-Sep-17 |
| | | | 2. The patient has histopathologically proven well differentiated neuroendocrine tumour of pancreatic origin | | | | |
| | | | 3. The patient has unresectable or metastatic disease | | | | |
| | | | 4. The patient has exhibited disease progression in past 12 months | | | | |
| | | | 5. The patient has a performance status of 0-1 | | | | |
| | | | 6. The patient has had no previous treatment with a mTOR inhibitor. | | | | |
| | | | 7. No planned treatment breaks of more than 6 weeks beyond the expected cycle length are allowed (to allow any toxicity of current therapy to settle or intercurrent comorbidities to improve).* | | | | |
| | | | 8. Everolimus will otherwise be used as set out in its Summary of Product Characteristics (SPC). | | | | |
| EVE7 | **Everolimus** | The treatment of unresectable or metastatic neuroendocrine tumours of gastrointestinal or lung origin with disease progression where all the following criteria are met: | 1. An application has been made by and the first cycle of systemic anti-cancer therapy is to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy | Yes | TA449 | 13-May-17 | 26-Sep-17 |
| | | | 2. The patient has histopathologically proven well differentiated neuroendocrine tumour of gastrointestinal or lung origin | | | | |
| | | | 3. The patient has unresectable or metastatic disease | | | | |
| | | | 4. The patient has no history of and no active symptoms to suggest a functional tumour | | | | |
| | | | 5. The patient has exhibited disease progression in past 12 months | | | | |
| | | | 6. The patient has a performance status of 0-1 | | | | |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| FED1 | **Fedratinib** | For the treatment of patients with myelofibrosis previously treated with ruxolitinib where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with fedratinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. This patient is an adult with a diagnosis of primary myelofibrosis (also known as chronic idiopathic myelofibrosis) or post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis.<br>Please enter below as to which type of myelofibrosis applies to this patient:<br>- primary myelofibrosis or<br>- post polycythaemia vera myelofibrosis or<br>- post essential thrombocythaemia myelofibrosis<br>3. This patient's myelofibrosis has a risk category that is either intermediate-2 or high risk.<br>Please enter below which myelofibrosis risk category applies to this patient:<br>- intermediate-2 or<br>- high risk<br>4. The patient has symptomatic disease-related splenomegaly and/or constitutional symptoms of myelofibrosis.<br>5. The patient has been previously treated with ruxolitinib and that momelotinib is unsuitable.<br>Please enter below the reason as to why the patient discontinued the ruxolitinib whether for disease progression or intolerance of ruxolitinib:<br>- disease progression on ruxolitinib or<br>- patient intolerance of ruxolitinib<br>Note: although the marketing authorisation of fedratinib includes patients who are either treatment naïve to JAK inhibitor therapy or who have been treated with ruxolitinib, the company's submission to NICE was only for patients previously treated with ruxolitinib<br>6. The patient has an ECOG performance status (PS) of 0 or 1 or 2.<br>7. The prescribing clinician is aware that patients must have thiamine (vitamin B1) levels tested both before and during fedratinib therapy and that thiamine deficiency must be corrected before treatment starts and during fedratinib therapy.<br>8. In terms of active systemic therapy fedratinib is being given as monotherapy.<br>9. Fedratinib is to be continued until loss of clinical benefit or unacceptable toxicity or patient choice to stop treatment.<br>10. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment.<br>11. Fedratinib is to be otherwise used as set out in its Summary of Product Characteristics. | Yes | TA1018 | 20-Nov-24 | 18-Feb-25 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| FRU1 | **Fruquintinib** | Fruquintinib for patients with either metastatic or locally advanced and inoperable colorectal cancer who have received 2 or more prior anticancer treatment regimens including fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapies with or without anti-VEGF agents and/or anti-EGFR-based agents AND for whom the combination of trifluridine plus tipiracil and bevacizumab is unsuitable where the following criteria have been met: | 1. This application is both being made by and the first cycle of systemic anti-cancer therapy with fruquintinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a histologically confirmed diagnosis of adenocarcinoma of the colon or rectum.<br>3. The patient has either metastatic disease or locally advanced and inoperable disease.<br>4. The patient has been previously treated for metastatic or locally advanced and inoperable disease with 2 or more prior anticancer regimens including fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapies. If disease has recurred during, or within, 6 months after the last administration of neoadjuvant or adjuvant therapy, this can be counted as a prior line of treatment for metastatic or locally advanced and inoperable disease.<br>5. The patient has been previously treated with anti-EGFR-containing chemotherapy or not.<br><br>Please tick which option applies to this patient:<br>- yes, the patient has been previously treated with anti-EGFR-containing chemotherapy or<br>- no, the patient has not been previously treated with anti-EGFR-containing chemotherapy<br>6. The patient has been previously treated with an anti-VEGF-containing chemotherapy or not.<br><br>Please tick which option applies to this patient:<br>- yes, the patient has been previously treated with an anti-VEGF-containing chemotherapy or<br>- no, the patient has not been previously treated with an anti-VEGF-containing chemotherapy<br>7. The patient has been previously treated with regorafenib or not.<br><br>Please tick which option applies to this patient:<br>- yes, the patient has been previously treated with regorafenib or<br>- no, the patient has not been previously treated with regorafenib<br>8. The patient is unsuitable for treatment with the combination of trifluridine plus tipiracil and bevacizumab for one of the reasons listed below – please tick the appropriate box:<br>- the patient has already been treated with the combination of trifluridine plus tipiracil and bevacizumab or<br>- the patient has already been treated with trifluridine plus tipiracil or<br>- the patient has a contraindication to treatment with trifluridine plus tipiracil or<br>- the patient has a contraindication to bevacizumab or<br>- the patient has previously had poor or no responses to cytotoxic therapy and hence further treatment with cytotoxic chemotherapy is considered inappropriate or<br>- the patient has previously tolerated cytotoxic chemotherapy poorly and hence further treatment with cytotoxic chemotherapy is inappropriate<br>9. The patient has not been previously treated with fruquintinib unless transferring from a company early access scheme and all other treatment criteria on this form are fulfilled.<br>10. The patient has an ECOG performance status of 0 or 1.<br>11. Fruquintinib is to be used as monotherapy.<br>12. Fruquintinib is to be continued until loss of clinical benefit or unacceptable toxicity or patient choice to stop treatment, whichever is the sooner.<br>13. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment.<br>14. Fruquintinib will be otherwise used as set out in its Summary of Product Characteristics (SPC). | Yes | TA1079 | 23-Jul-25 | 21-Oct-25 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| FUT1 | **Futibatinib** | For the treatment of patients for locally advanced or metastatic cholangiocarcinoma which has a fibroblast growth factor receptor 2 gene fusion/rearrangement in patients with disease progression during or after previous systemic therapy where the following criteria have been met: | 1. This application for futibatinib is being made by and the first cycle of systemic anti-cancer therapy with futibatinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a histologically or cytologically confirmed diagnosis of cholangiocarcinoma.<br><br>Please also indicate below whether the cholangiocarcinoma is of intrahepatic or extrahepatic origin:<br>- the cholangiocarcinoma is of intra-hepatic origin<br>- the cholangiocarcinoma is of extrahepatic origin<br>3. The cholangiocarcinoma has been tested for fibroblast growth factor receptor 2 (FGFR2) gene fusion or rearrangement with a validated test and the result is positive.<br>4. The patient has unresectable locally advanced or metastatic disease.<br>5. The patient has been previously treated with systemic therapy for cholangiocarcinoma and the disease has progressed during or after such therapy.<br><br>Please also indicate whether the patient has received 1 or >=2 lines of systemic therapy:<br>- the patient has been previously treated with 1 line of systemic therapy for cholangiocarcinoma<br>- the patient has been previously treated with >=2 lines of systemic therapy for cholangiocarcinoma<br>6. The patient has an ECOG performance status of 0 or 1.<br>7. The patient either has no known brain metastases or if the patient has brain metastases, the patient is symptomatically stable prior to starting treatment with futibatinib.<br>8. The patient has not previously received any specifically FGFR2-targeted therapy unless either the patient has received futibatinib via a company early access scheme and the patient meets all the criteria set out on this form or pemigatinib monotherapy has had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of progressive disease.<br><br>Please mark below which scenario applies to this patient:<br>- the patient has not been previously treated with a FGFR2-targeted therapy<br>- the patient has received futibatinib via a company early access scheme and the patient meets all the criteria set out on this form<br>- pemigatinib monotherapy has had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of progressive disease<br>9. Futibatinib will be used as monotherapy.<br>10. The patient will be treated until loss of clinical benefit or excessive toxicity or patient choice to discontinue treatment, whichever is the sooner.<br>11. The prescribing clinician understands that futibatinib can cause serous retinal detachment and therefore opthalmological examination has been arranged prior to initiation of futibatinib and at 6 weeks after initiation of treatment and from then on urgently as required.<br>12. The prescribing clinician is aware of the risk of the patient developing hyper-phosphataemia during treatment with futibatinib and understand all of the following: the requirement for monitoring of phosphate levels, the need for dietary restriction to limit phosphate intake, the management of hyper-phosphataemia as outlined in the futibatinib SPC and the need to review such measures if futibatinib treatment is deferred or discontinued.<br>13. The prescribing clinician is aware of the important drug interactions which can occur between futibatinib and CYP3A/P-gp inhibitors and inducers as outlined in sections 4.2 and 4.5 of the futibatinib SPC.<br>14. A first formal medical review as to whether treatment with futibatinib should continue or not will be scheduled to occur at least by the end of the first 8 weeks of treatment.<br>15. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment.<br>16. Futibatinib will be otherwise used as set out in its Summary of Product Characteristics (SPC). | No | TA1005 | 11-Sep-24 | 10-Dec-24 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| GEM1 | **Gemtuzumab ozogamicin** | Gemtuzumab ozogamicin as part of chemotherapy for previously untreated CD33 positive acute myeloid leukaemia in patients AGED 15 YEARS AND OVER where the following criteria are met: | 1. This application is made by and the first cycle of systemic anti-cancer therapy with gemtuzumab ozogamicin will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy<br>2. The prescribing clinician is fully aware of the potential for gemtuzumab ozogamicin inducing hepatotoxicity including veno-occlusive liver disease/sinusoidal obstruction syndrome<br>3. This patient has a confirmed diagnosis of CD33-positive acute myeloid leukaemia but does **NOT** have acute promyelocytic leukaemia<br>4. The patient has previously untreated acute myeloid leukaemia<br>5. The patient is aged 15 years and over<br>**Note**: there is a separate application form for those patients who are aged less than 15 years<br>6. This patient has had cytogenetics performed<br>7. The result of the cytogenetics test has shown that the patient has one of the following (please tick appropriate box):<br>- favourable risk stratification according to the 2017 ELN risk stratification OR<br>- intermediate risk stratification according to the 2017 ELN risk stratification OR<br>- the result of the cytogenetics test was unsuccessful OR<br>- the result of the cytogenetics test is awaited and there is a clinical need for urgent systemic therapy to be commenced. If this is the case, it is mandatory that gemtuzumab ozogamicin will be discontinued as soon as cytogenetic results indicate adverse cytogenetics. Such discontinuation of gemtuzumab ozogamicin may be before all of the 1st cycle of induction treatment has been administered. Ticking the 'Need for urgent treatment before cytogenetics known' box is confirmation that gemtuzumab ozogamicin will be stopped as soon as adverse cytogenetics are known.<br>8. The patient is fit for intensive induction chemotherapy<br>9. Gemtuzumab ozogamicin is to be given with the combination of daunorubicin and cytarabine (DA) regimen unless either the patient has been entered into the Optimise-FLT3 clinical trial (ISRCTN 34016918) in which case gemtuzumab ozogamicin can also be given in combination with midostaurin (with either DA or FLAG-Ida chemotherapy) for patients with a FLT3 mutation according to the trial protocol or the patient has been entered into the Myechild01 trial in which case gemtuzumab ozogamicin can be given according to the trial protocol.<br><br>Note: for patients entered into the VICTOR clinical trial, the dose and schedule of the daunorubicin plus cytarabine (DA) regimen used in combination with gemtuzumab ozogamicin should be that specified in the current trial protocol.<br><br>Note: For teenagers aged ≥15 years and young adults not entered into the Myechild01 trial, gemtuzumab ozogamicin can be combined with standard chemotherapy agents appropriate to the age of the patient.<br>10. The dose and schedule of administration of gemtuzumab ozogmaicin will be given as in the Summary of Product Characteristics i.e. in the 1st cycle of induction chemotherapy [but not in the 2nd cycle of induction chemotherapy] and, if the patient has attained complete remission, in up to 2 cycles of consolidation chemotherapy) unless the patient has been entered in the Optimise-FLT3 or Myechild01 or VICTOR trials in which cases the trial doses and schedules of gemtuzumab ozogamicin should be used.<br>11. Gemtuzumab ozogamicin is to be otherwise used as set out in its Summary of Product Characteristics<br>12. The use of gemtuzumab ozogamicin is exempt from the NHS England Treatment Break policy | No | TA545 | 14-Nov-18 | 12-Feb-19 |
| GEM2 | **Gemtuzumab ozogamicin** | Gemtuzumab ozogamicin as part of chemotherapy for previously untreated CD33 positive acute myeloid leukaemia in CHILD patients AGED LESS THAN 15 YEARS where the following criteria are met: | 1. An application has been made by and the first cycle of systemic anti -cancer therapy with gemtuzumab ozogamicin will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The prescribing clinician is fully aware of the potential for gemtuzumab ozogamicin inducing hepatotoxicity including veno-occlusive liver disease/sinusoidal obstruction syndrome<br>3. The patient has a confirmed diagnosis of CD33-positive acute myeloid leukaemia but does NOT have acute promyelocytic leukaemia<br>4. The patient has previously untreated acute myeloid leukaemia<br>5. The patient is a child* and:<br>- is post pubescent and less than 15 years of age<br>- is pre pubescent and if not going into a clinical trial will receive gemtuzumab ozogamicin at the dosage described in the results of the gemtuzumab ozogamicin COG AAML0531trial in children and reported in J Clin Oncol 2014; 32: 3021-3032 doi: 10.1200/JCO.2014.55.3628<br>*note there is a separate Bluteq form to be used for gemtuzumab ozogamicin in this indication in people aged 15 years and over.<br>6. This patient has had cytogenetics performed<br>7. The result of the cytogenetics test has shown that the patient has one of the following (please tick appropriate box):<br>favourable risk stratification according to the 2017 ELN risk stratification OR<br>intermediate risk stratification according to the 2017 ELN risk stratification OR<br>the result of the cytogenetics test was unsuccessful OR<br>the result of the cytogenetics test is awaited and there is a clinical need for urgent systemic therapy to be commenced. If this is the case, it is mandatory that gemtuzumab ozogamicin will be discontinued as soon as cytogenetic results indicate adverse cytogenetics. Such discontinuation of gemtuzumab ozogamicin may be before all of the 1st cycle of induction treatment has been administered. Ticking the 'Need for urgent treatment before cytogenetics known' box is confirmation that gemtuzumab ozogamicin will be stopped as soon as adverse cytogenetics are known<br>8. The patient is fit for intensive induction chemotherapy<br>9. Gemtuzumab ozogamicin will only be requested by and administered in principal treatment centres.<br>10. The use of the gemtuzumab ozogamicin has been discussed at a multi-disciplinary team (MDT) meeting which must include at least two consultants in the subspecialty with active and credible expertise in the relevant field of whom at least one must be a consultant paediatrician. The MDT should include a paediatric pharmacist and other professional groups appropriate to the disease area.<br>11. Gemtumumab ozogamicin will be used in combination with standard induction or intensification/consolidation therapy appropriate to the age of the patient.<br>Note for patients entered into the Myechild01 trial ,gemtuzumab ozogamicin can be given according to the trial protocol.<br>12. Trust policy regarding unlicensed treatments has been followed as gemtuzumab ozogamicin is not licensed in this indication in children.<br>13. Gemtuzumab ozogamicin will otherwise be used as set out in its Summary of Product Characteristics (SPC).<br>14. The use of gemtuzumab ozogamicin is exempt from the NHS England Treatment Break policy | No | TA545 | 14-Nov-18 | 12-Feb-19 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| GILT1 | **Gilteritinib** | For treating relapsed/refractory FLT3 mutation positive acute myeloid leukaemia in adults where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with gilteritinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a proven diagnosis of acute myeloid leukaemia.<br>3. The patient has a FMS-like tyrosine kinase 3 (FLT3) mutation (internal tandem duplication [ITD] or tyrosine kinase domain [TKD]) as determined by a validated test.<br>4. The patient has relapsed/refractory FLT3 positive acute myeloid leukaemia.<br>5. The patient has not received previous systemic therapy with other FLT3 inhibitors (with the exception of sorafenib or midostaurin or quizartinib used in first-line therapy or in clinical trials in 1st line therapy).<br>6. The patient has an ECOG performance status (PS) of 0, 1 or 2.<br>7. Use of gilteritinib will be as monotherapy.<br>8. Gilteritinib will be continued until disease progression or unacceptable toxicity or the time at which the patient is considered to be cured or until the patient receives a haematopoietic stem cell transplant whichever occurs first.<br>9. The prescribing clinician understands that patients whose disease responds to gilteritinib and who then go on to have a haematopoietic stem cell transplant cannot restart gilteritinib as maintenance therapy after the transplant. This is as a consequence of the optimised NICE recommendation.<br>Note: patients who receive a stem cell transplant for FLT3 AML and who have not previously received treatment with gilteritinib cannot commence maintenance gilteritinib. Such patients can only receive gilteritinib if they relapse post-SCT.<br>10. The prescribing clinician is fully aware of the management of and the treatment modifications that may be required for differentiation syndrome consequent to gilteritinib administration.<br>11. When a treatment break of more than 6 weeks beyond the expected cycle length is needed, I will complete a treatment break approval form to restart treatment, including indicating as appropriate if the patient had an extended break because of COVID 19.<br>12. Gilteritinib will be otherwise used as set out in its Summary of Product Characteristics (SmPC). | No | TA642 | 12-Aug-20 | 10-Nov-20 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| GLO1_ver1.2 | **Glofitamab monotherapy** | For the treatment of previously treated adult patients with diffuse large B-cell lymphoma who have received 2 or more lines of systemic therapy where the following criteria have been met: | 1. I confirm that this application is being made by, and drugs prescribed by, a consultant or senior resident doctor specifically trained and accredited in the use of systemic anti-cancer therapy. | Yes | TA927 | 17-Oct-23 | 16-Nov-23 |
| | | | 2. I confirm that the patient has a histologically confirmed diagnosis of diffuse large B cell lymphoma (DLBCL) or transformed follicular lymphoma to DLBCL.<br><br>The definition of DLBCL includes the following:<br>DLBCL not otherwise specified (NOS) [including germinal centre B-cell (GCB) and activated B-cell (ABC) subtypes]<br>primary mediastinal large B cell lymphoma<br>T cell rich B cell lymphoma<br>Epstein-Barr virus (EBV) positive DLBCL<br>intravascular large B cell lymphoma<br>double hit and triple hit high grade B cell lymphoma<br><br>Note: Primary CNS lymphoma, Burkitt lymphoma and plasmablastic lymphoma are NOT included for treatment with glofitamab.<br><br>Please record in the box below whether the patient has DLBCL according to one of the above types of DLBCL or has transformed follicular lymphoma:<br>- the patient has DLBCL according to one of the types within the above definition OR<br>- the patient has transformed follicular lymphoma (TFL) to DLBCL | | | | |
| | | | 3. I confirm that the patient has DLBCL or TFL which has either relapsed following or is refractory to **2 or more** lines of standard routinely commissioned systemic therapies and that within these 2 lines of therapy there has been treatment with an anti-CD20 regimen and an anthracycline-containing regimen, unless the use of an anthracycline is contraindicated or considered unsuitable due to a pre-existing condition.<br><br>Note: patients with TFL must have received 2 or more lines of systemic therapy given specifically for the transformed follicular lymphoma. | | | | |
| | | | 4. I confirm below the number of lines of systemic therapy that the patient has received for the treatment of DLBCL.<br><br>Note: induction chemotherapy prior to and then followed by stem cell transplantation counts as 1 line of systemic therapy. Similarly, bridging chemotherapy prior to and then followed by CAR T therapy counts as 1 line of systemic therapy.<br><br>Note: patients who have had only 1 line of systemic therapy are not eligible for treatment with glofitamab, in this setting.<br><br>**Please record the number of lines of previous systemic therapy below:**<br>- 2 previous lines OR<br>- 3 previous lines OR<br>- 4 or more previous lines | | | | |
| | | | 5. I confirm below whether the patient has been previously treated with stem cell transplantation:<br>- No previous stem cell transplantation OR<br>- Yes, previous stem cell transplantation | | | | |
| | | | 6. I confirm below whether the patient has been previously treated with CAR T therapy and if so at which place in the treatment pathway:<br>- No previous CAR T therapy OR<br>- Yes, previous CAR T therapy as 2nd line therapy OR<br>- Yes, previous CAR T therapy as 3rd or more line of therapy | | | | |
| | | | 7. I confirm that the patient has not been previously treated with glofitamab unless glofitamab monotherapy was used specifically as bridging treatment prior to 3rd or more line of CAR T therapy.<br><br>Note: glofitamab cannot be used as bridging therapy for 2nd line CAR T therapy.<br><br>Please record in the box below which of the following applies to this patient:<br>- no previous treatment with glofitamab OR<br>- previous treatment with no more than 3 cycles of glofitamab monotherapy specifically used as bridging therapy prior to 3rd or more line CAR T therapy and the patient responded to this glofitamab bridging therapy | | | | |
| | | | 8. I confirm that the patient has not received any treatment with a bispecific antibody targeting both CD20 and CD3 other than glofitamab as specified above in criterion 7.<br>Note: use of glofitamab after previous treatment with epcoritamab is NOT commissioned. | | | | |
| | | | 9. I confirm that the patient has an ECOG performance status score of 0 or 1. | | | | |
| | | | 10. I confirm that treatment with glofitamab monotherapy will be stopped at whichever of the following events occurs first: disease progression or unacceptable toxicity or withdrawal of patient consent **or after a maximum of twelve 3-weekly cycles of glofitamab.**<br><br>Note: once glofitamab is stopped after 12 cycles of treatment, it cannot be re-started. | | | | |
| | | | 11. I confirm that when a treatment break of more than 6 weeks beyond the expected 3-weekly cycle length is needed, a treatment break approval form will be completed to restart treatment. | | | | |
| | | | 12. I confirm that glofitamab will be otherwise used as set out in its Summary of Product Characteristics (SPC). | | | | |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| GLO2 | **Glofitamab** in combinaton with gemcitabine and oxaliplatin | Glofitamab with gemcitabine and oxaliplatin for treating relapsed or refractory diffuse large B- cell lymphoma where the following criteria have been met: | 1. This application is being made by, and drugs prescribed by, a consultant or senior resident doctor specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has histologically confirmed diffuse large B cell lymphoma (DLBCL) not otherwise specified (NOS), relapsed/refractory following first line treatment.<br><br>Note: Primary CNS lymphoma, Burkitt lymphoma, transformed follicular lymphoma and plasmablastic lymphoma are NOT eligible for treatment with glofitamab, gemcitabine and oxaliplatin.<br>3. The patient has received **one line of previous treatment only**.<br><br>Note: Glofitamab, gemcitabine and oxaliplatin cannot be given if the patient has had more than one prior course of treatment. Glofitamab, gemcitabine and oxaliplatin is intended as **second line only**.<br>4. First line treatment that was previously given for DLBCL.<br>- Pola R-CHP<br>- R-CHOP<br>- Other (specify)<br><br>If 'other' was ticked please specify: _____<br><br>Please indicate number of cycles of first line treatment given: _____<br>5. The patient has:<br>- Refractory/resistant DLBCL i.e. no response to first cycle of first line treatment.<br>- DLBCL that initially went into remission but subsequently relapsed.<br>6. The patient is not eligible for an autologous stem cell transplant.<br>7. The patient has not previously received a bispecific antibody treatment.<br>8. The patient has an ECOG performance status score of 0, 1 or 2.<br>9. Treatment with glofitamab, gemcitabine and oxaliplatin will be stopped at whichever of the following events occurs first:<br><br>- disease progression<br>- unacceptable toxicity<br>- withdrawal of patient consent<br>- a total of eight cycles of glofitamab, gemcitabine and oxaliplatin plus four additional cycles of glofitamab monotherapy<br>Note: once glofitamab is stopped after 12 cycles of treatment, it cannot be re-started.<br>10. When a treatment break of more than 6 weeks beyond the expected 3-weekly cycle length is needed, a treatment break approval form will be completed to restart treatment.<br>11. Glofitamab with gemcitabine and oxaliplatin will be used as per the Summary of Product Characteristics (SPC). | No | TA1113 | 03-Dec-25 | 03-Mar-26 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| IBR5 | **Ibrutinib** | For the treatment of relapsed/ refractory mantle cell lymphoma in patients who have either only received 1 prior line of systemic therapy or been treated with ≥2 prior lines if 2nd line therapy was initiated before NICE's recommendation in January 2018 where all the following criteria are met: | 1. This application has been made by and the first cycle of systemic anti-cancer therapy is to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a confirmed histopathological diagnosis of mantle cell lymphoma<br>3. The patient has previously been treated with one **and only one** prior line of rituximab-containing chemotherapy.<br><br>**Note: Patients treated with more than 1 line of prior therapy are not eligible for treatment with ibrutinib.**<br>4. The presence of relapsed/refractory mantle cell lymphoma with documented progression of disease during or following rituximab-containing 1st line systemic therapy.<br>5. The patient has never received any prior therapy with a BTK inhibitor (ibrutinib or zanubrutinib or another BTK inhibitor) unless the patient has suffered unacceptable toxicity on therapy with zanubrutinib without any evidence of disease progression and is transferring to treatment with ibrutinib.<br><br>Please enter below which of these scenarios applies to this patient:<br>- the patient is treatment-naïve to a BTK inhibitor or<br>- the patient has been receiving therapy with zanubrutinib but has suffered unacceptable toxicity without any evidence of disease progression and is transferring to treatment with ibrutinib<br>6. Ibrutinib is to be used as a single agent<br>7. Ibrutinib is to be continued until disease progression, unacceptable toxicity or the patient's choice to stop treatment.<br>8. The patient's performance status is 0 or 1 or 2<br>9. The patient is not on concurrent therapy with warfarin.<br>10. The rescribing clinician is aware that ibrutinib has clinically significant interactions with cytochrome P450 enzyme 3A4 (CYP3A4) inhibitors and inducers as described in ibrutinib's Summary of Product Characteristics.<br>11. When a treatment break of more than 6 weeks beyond the expected cycle length occurs, the prescribing clinician will complete a treatment break approval form to restart treatment.<br>12. Ibrutinib will be otherwise used as set out in its Summary of Product Characteristics | Yes | TA502 | 31-Jan-18 | 01-May-18 |
| IBR9_v1.1 | **Ibrutinib monotherapy** | Ibrutinib monotherapy for the treatment of patients with chronic lymphatic leukaemia which has a 17p deletion or TP53 mutation where the following criteria have been met: | 1. This application for ibrutinib is being made by and the first cycle of this systemic anti-cancer therapy with ibrutinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has been diagnosed with chronic lymphatic leukaemia (CLL) or small lymphocytic lymphoma (SLL).<br>3. The patient has been tested for 17p deletion and preferably for TP53 mutation as well and the results are positive for either 17p deletion or TP53 mutation or both.<br>Please indicate the result of these tests below:<br>- positive for 17p deletion and not tested for TP53 mutation or<br>- positive for 17p deletion and negative for TP53 mutation or<br>- negative for 17p deletion and positive for TP53 mutation or<br>- positive for both 17p deletion and TP53 mutation.<br>4. The patient has symptomatic disease which requires systemic therapy.<br>5. The patient has not received any previous BTK inhibitor therapy for CLL/SLL unless 1st line acalabrutinib or 1st line zanubrutinib has had to be stopped as a consequence of dose-limiting toxicity and in the clear absence of disease progression.<br>Please mark which of the 3 scenarios below applies to this patient:<br>- the patient has not received any previous BTK inhibitor therapy for CLL/SLL or<br>- the patient previously commenced 1st line acalabrutinib and the acalabrutinib has had to be stopped solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression<br>- the patient previously commenced 1st line zanubrutinib and the zanubrutinib has had to be stopped solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression<br>6. The patient has an ECOG performance status of 0 or 1 or 2.<br>7.Use of ibrutinib in this indication will be as **monotherapy**.<br>8. The prescribing clinician is aware that ibrutinib should not be administered concomitantly with warfarin or other vitamin K antagonists and that ibrutinib has clinically significant interactions with CYP3A4 inhibitors and inducers (see ibrutinib's Summary of Product Characteristics).<br>9. Ibrutinib is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment, whichever is the sooner.<br>10. A formal medical review as to whether treatment with ibrutinib should continue or not will be scheduled to occur at least by the end of the first 8 weeks of treatment.<br>11. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment, including as appropriate if the patient had an extended break on account of Covid-19.<br>12. Ibrutinib will be otherwise used as set out in its Summary of Product Characteristics (SPC). | Yes | TA429 | 25-Jan-17 | 25-Apr-17 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| IBR10_v1.2 | **Ibrutinib** | Ibrutinib monotherapy for the treatment of patients with previously treated chronic lymphatic leukaemia where the following criteria have been met: | 1. This application for ibrutinib is being made by and the first cycle of this systemic anti-cancer therapy with ibrutinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has been previously diagnosed with chronic lymphatic leukaemia (CLL) or small lymphocytic lymphoma (SLL).<br>3. The patient has been tested for 17p deletion and preferably for TP53 mutation and the results are as shown below:<br>- negative for 17p deletion and not tested for TP53 mutation<br>- positive for 17p deletion and not tested for TP53 mutation<br>- negative for 17p deletion and negative for TP53 mutation<br>- negative for 17p deletion and positive for TP53 mutation<br>- positive for 17p deletion and negative for TP53 mutation<br>- positive for 17p deletion and positive for TP53 mutation<br>4. The patient has symptomatic disease which requires systemic therapy.<br>5. The patient has been previously treated with systemic therapy for CLL/SLL.<br>6. The patient is treatment naïve to a Bruton's kinase inhibitor or the patient has been previously commenced on acalabrutinib monotherapy or zanubrutinib monotherapy for previously treated CLL/SLL and the acalabrutinib or zanubrutinib has had to be discontinued solely because of dose-limiting toxicity and in the clear absence of disease progression or the patient has previously been treated with the 1st line combination of ibrutinib plus venetoclax and was still in response on completion of treatment but has since relapsed and this application will be the first use of a BTK inhibitor since the 1st line combination of ibrutinib plus venetoclax.<br>Please mark which of the 4 scenarios below applies to this patient:<br>- the patient has not received any previous therapy for CLL/SLL with a Bruton's kinase inhibitor **or**<br>- the patient previously commenced acalabrutinib for relapsed/refractory CLL/SLL and acalabrutinib has had to be stopped solely because of dose-limiting toxicity **and** in the clear absence of disease progression **or**<br>- the patient previously commenced zanubrutinib for relapsed/refractory CLL/SLL and zanubrutinib has had to be stopped solely because of dose-limiting toxicity and in the clear absence of disease progression **or**<br>- the patient has previously been treated with the 1st line combination of ibrutinib plus venetoclax and was still in response on completion of treatment but has since relapsed and this application will be the first use of a BTK inhibitor since the 1st line combination of ibrutinib plus venetoclax<br>7. The patient has an ECOG performance status of 0 or 1 or 2.<br>8. Use of ibrutinib in this indication will be as **monotherapy**.<br>9. The prescribing clinician is aware that warfarin or other vitamin K antagonists should not be administered concomitantly with ibrutinib and that ibrutinib has clinically significant interactions with CYP3A4 inhibitors and inducers (see ibrutinib's Summary of Product Characteristics).<br>10. Ibrutinib is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment, whichever is the sooner.<br>**Note:** Patients entered into the NIHR STATIC trial (NIHR ref: 52879) may be randomised to receive intermittent treatment as part of the trial protocol.<br>11. A formal medical review as to whether treatment with ibrutinib should continue or not will be scheduled to occur at least by the end of the first 8 weeks of treatment.<br>12. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, a treatment break approval form will be completed to restart treatment.<br>13. Ibrutinib will be otherwise used as set out in its Summary of Product Characteristics (SPC). | Yes | TA429 | 25-Jan-17 | 25-Apr-17 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| IBR11 | **Ibrutinib** in combination with venetoclax | For the 1st line treatment of previously untreated chronic lymphatic leukaemia where the following criteria have been met: | 1. This application for ibrutinib in combination with venetoclax is being made by and the first cycle of ibrutinib plus venetoclax will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has been diagnosed with chronic lymphatic leukaemia or small lymphocytic lymphoma.<br>3. The patient has been tested for 17p deletion and TP53 mutation. Please indicate the result of these tests below:<br>- Negative for 17p deletion and negative for TP53 mutation<br>- Positive for 17p deletion and negative for TP53 mutation<br>- Negative for 17p deletion and positive for TP53 mutation<br>- Positive for 17p deletion and positive for TP53 mutation<br>4. The outcome of IGHV mutation testing if known:<br>Please indicate the result of this test below:<br>- IGHV unmutated<br>- IGHV mutated<br>- IGHV testing result not known or not done<br>5. The patient has symptomatic disease which requires systemic therapy.<br>6. The patient is treatment naïve for any systemic therapy for CLL/SLL i.e. ibrutinib and venetoclax treatment will be 1st line treatment.<br>7. The patient has an ECOG performance status of 0 or 1 or 2.<br>8. Ibrutinib will be given in combination with venetoclax and that the venetoclax will only be commenced after the patient has completed the first 3 x 4-weekly cycles of ibrutinib, i.e., addition of venetoclax at cycle 4.<br>9. Before the start of venetoclax therapy the patient will be prospectively assessed for the risk of the development of tumour lysis syndrome with venetoclax and that appropriate risk mitigation strategies will be put in place.<br>10. The patient has been assessed specifically for potential drug interactions with venetoclax.<br>11. The maximum treatment duration of ibrutinib in this indication is for a maximum of **15** x 4-weekly cycles.<br>12. The maximum treatment duration of venetoclax in this indication is for a maximum of **12** 4-weekly cycles.<br>13. Ibrutinib plus venetoclax are to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment or for the maximum treatment duration of 15 cycles of ibrutinib and 12 cycles of venetoclax.<br>14. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, a treatment break approval form will be completed to restart treatment.<br>15. Ibrutinib and venetoclax will be otherwise used as set out in their respective Summary of Product Characteristics (SPCs). | No | TA891 | 31-May-23 | 29-Aug-23 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| ISA2 | **Isatuximab** in combination with bortezomib, lenalidomide, and dexamethasone | For the treatment of UNTREATED multiple myeloma when a stem cell transplant is UNSUITABLE where the following criteria have been met: | 1. This application is both being made by and the first cycle of systemic anti-cancer therapy with isatuximab in combination with bortezomib, lenalidomide and dexamethasone, will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has **newly diagnosed** multiple myeloma.<br><br>Note: this isatuximab indication is not funded for patients with primary amyloidosis.<br>Please confirm this by ticking the box below:<br>- this patient does not have a diagnosis of primary amyloidosis<br>3. The patient has previously not received any systemic anti-cancer therapy for myeloma except for either an emergency use of a short course of corticosteroids before this treatment or the patient commenced induction therapy with the combination of daratumumab plus bortezomib, thalidomide and dexamethasone with the intention of proceeding to a stem cell transplant but despite responding to such treatment the patient is now ineligible for transplantation.<br><br>Please tick below which scenario applies to this patient:<br>- the patient has not received any prior systemic anti-cancer therapy<br>- the patient has only had an emergency use of a short course of corticosteroids<br>- the patient commenced induction therapy with the combination of daratumumab plus bortezomib, thalidomide and dexamethasone with the intention of proceeding to a stem cell transplant but despite responding to such treatment the patient is now ineligible for transplantation.<br><br>Note: patients who have not responded to induction therapy with daratumumab plus bortezomib, thalidomide and dexamethasone are **NOT** allowed to switch to the isatuximab combination regimen outlined in this Blueteq form<br>4. The patient is **ineligible** for an autologous stem cell transplant.<br>5. Isatuximab will only be given in combination with bortezomib, lenalidomide and dexamethasone and that it is not to be used in combination with any other agents.<br>6. The patient is of ECOG performance status 0, 1 or 2<br><br>Please tick one of the boxes below:<br>- performance status 0 or<br>- performance status 1 or<br>- performance status 2<br>7. Isatuximab in combination with bortezomib, lenalidomide and dexamethasone will continue to be given until the development of progressive disease, unacceptable toxicity, or patient choice to stop treatment, whichever occurs first.<br>8. When a treatment break of more than 6 weeks beyond the expected 4-, or 6- (cycle one and two only) weekly cycle length is needed, I will complete a treatment break approval form to restart treatment, which **MUST** be approved **before** treatment is re-commenced.<br>9. Isatuximab will be otherwise be used as set out in its Summary of Product Characteristics. | No | TA1098 | 24-Sep-25 | 23-Dec-25 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| INO1 | **Inotuzumab ozogamicin** | The treatment of relapsed/refractory Philadelphia positive and Philadelphia negative B cell precursor acute lymphoblastic leukaemia in ADULT patients where all the following criteria are met: | 1. An application is being made by and the first cycle of systemic anti-cancer therapy with inotuzumab ozogamicin for each part of the treatment pathway will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The prescribing clinician is fully aware of the risk factors for inotuzumab ozogamicin inducing hepatotoxicity including veno-occlusive liver disease/sinusoidal obstruction syndrome and that this risk rises as the number of cycles administered increases.<br>3. The patient has relapsed or refractory CD22-positive B cell precursor acute lymphoblastic leukaemia (ALL).<br><br>Please tick the appropriate box as to which type of ALL the patient has:<br>- Philadelphia chromosome negative ALL<br>- Philadelphia chromosome positive ALL in which case treatment with at least one TKI must have also failed<br>4. The patient has been previously treated with intensive combination chemotherapy as initial treatment with or without subsequent salvage chemotherapy or blinatumomab.<br>5. The patient is an adult*.<br>*Note: there is a separate Blueteq form to be used for inotuzumab ozogamicin in this indication in children.<br>6. Inotuzumab ozogamicin will only be requested by and administered in either bone marrow transplant centres or in major haematological centres that regularly treat patients with relapsed/refractory ALL and who have regular ALL multi-disciplinary team meetings and close links with bone marrow transplant centres.<br>7. The patient has an ECOG performance status of 0 or 1 or 2.<br>8. Inotuzumab is being used to treat relapsed or refractory ALL in one of the following settings: as a bridge to SCT or as a bridge to CAR T therapy or as treatment in a setting in which SCT and CAR T therapy are both inappropriate.<br><br>Please mark the appropriate box which describes the setting in which inotuzumab is being used:<br>- as a bridge to SCT or<br>- as a bridge to CAR T therapy or<br>- as treatment in a setting in which both SCT and CAR T therapy are inappropriate<br>9. Confirm below whether this use of inotuzumab is the first ever use of the drug in this patient or is as re-treatment in a different place in the treatment pathway to the one previously used and in which case the patient must have responded to the prior inotuzumab.<br><br>Please mark the appropriate box which indicates whether this is the first ever use of inotuzumab in this patient or is as re-treatment:<br>- first ever use of inotuzumab in this patient or<br>- is as re-treatment with inotuzumab in a different place in the treatment pathway and the patient responded to the prior inotuzumab<br>10. The following treatment duration policies will apply to the use of inotuzumab ozogamicin:<br><br>- for those patients proceeding to a stem cell transplant (SCT), the recommended duration of treatment is 2 cycles. A 3rd cycle may be considered for those patients who do not achieve a complete remission (CR) or a CR with incomplete haematological recovery (CRi) and minimal residual disease negativity after 2 cycles.<br>- for patients not proceeding to a SCT or CAR T therapy, a lifetime maximum of 6 cycles of inotuzumab treatment may be administered. Patients who do not achieve a CR or CRi within 3 cycles should discontinue treatment.<br>- for patients having re-treatment with inotuzumab, there is a lifetime maximum of 6 cycles of inotuzumab.<br>- for patients having re-treatment with inotuzumab which is being used as a bridge to SCT, it is recommended that no more than 3 cycles of inotuzumab are used across the entire pre-SCT pathway.<br>11. Inotuzumab ozogamicin will be used as monotherapy.<br>12. When a treatment break of more than 6 weeks beyond the expected 3- or 4-weekly cycle length is needed within each part of the treatment pathway as set out in criterion 8 above, the prescribing clinician will complete a treatment break approval form.<br>13. Inotuzumab ozogamicin will otherwise be used as set out in its Summary of Product Characteristics (SPC). | No | TA541 | 19-Sep-18 | 18-Dec-18 |
| INO2 | **Inotuzumab ozogamicin** | The treatment of relapsed/refractory Philadelphia positive and negative B cell precursor acute lymphoblastic leukaemia in CHILD patients where all the following criteria are met: | 1. An application has been made by and the first cycle of systemic anti-cancer therapy with inotuzumab ozogamicin will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy<br>2. The prescribing clinician is fully aware of the risk factors for inotuzumab ozogamicin inducing hepatotoxicity including veno-occlusive liver disease/sinusoidal obstruction syndrome and that this risk rises as the number of cycles administered increases<br>3. The patient has relapsed or refractory CD22-positive B cell precursor acute lymphoblastic leukaemia (ALL).<br>Please tick appropriate box as to which type of ALL the patient has:<br>* Philadelphia chromosome negative ALL **or**<br>* Philadelphia chromosome positive ALL in which case treatment with at least one second or third generation TKI must have also failed<br>4. The patient has been previously treated with intensive combination chemotherapy as initial treatment with or without subsequent salvage chemotherapy or blinatumomab<br>5. The patient is a child* and:<br>- is post pubescent **or**<br>- is pre-pubescent and will receive inotuzumab ozogamicin at the dosage described in the results of the inotuzumab ozogamicin trial in children and reported in Pediatric Blood Cancer 2014; 61: 369-372 doi: 10.1002/pbc.24721<br>*note there is a separate Blueteq form to be used for inotuzumab ozogamicin in this indication in adults.<br>6. Inotuzumab ozogamicin will only be requested by and administered in principal treatment centres<br>7. The use of the inotuzumab ozogamicin has been discussed at a multi-disciplinary team (MDT) meeting which must include at least two consultants in the subspecialty with active and credible expertise in the relevant field of whom at least one must be a consultant paediatrician. The MDT should include a paediatric pharmacist and other professional groups appropriate to the disease area<br>8. The patient has a performance status of 0 - 2<br>9. The following treatment duration policy will apply to the use of inotuzumab ozogamicin: for those patients proceeding to a stem cell transplant (SCT), the recommended duration of treatment is 2 cycles. A 3rd cycle may be considered for those patients who do not achieve a complete remission (CR) or a CR with incomplete haematological recovery (CRi) and minimal residual disease negativity after 2 cycles. For patients not proceeding to a SCT, a maximum of 6 cycles of treatment may be administered. Patients who do not achieve a CR or CRi within 3 cycles should discontinue treatment<br>10. Inotuzumab ozogamicin will be used as monotherapy<br>11. No planned treatment breaks of more than 6 weeks beyond the expected cycle length are allowed (to allow any toxicity of current therapy to settle or intercurrent comorbidities to improve).*<br>*Requests for continuation of treatment after unplanned treatment breaks over this duration should be made via the treatment break approval process<br>12. Trust policy regarding unlicensed treatments has been followed as inotuzumab ozogamicin is not licensed in this indication in children<br>13. Inotuzumab ozogamicin will otherwise be used as set out in its Summary of Product Characteristics (SPC). | No | TA541 | 19-Sep-18 | 18-Dec-18 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| IVO1_v1.0 | **Ivosidenib monotherapy** | For the treatment of patients with locally advanced or metastatic cholangiocarcinoma which has an isocitrate dehydrogenase-1 (IDH1) R132 mutation in patients with disease progression during or after previous systemic therapy and where the following criteria have been met: | 1. This application for ivosidenib is being made by and the first cycle of systemic anti-cancer therapy with ivosidenib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br><br>2. The patient has a histologically or cytologically confirmed diagnosis of cholangiocarcinoma.<br>Please also indicate below whether the cholangiocarcinoma is of intrahepatic or extrahepatic origin:<br>- the cholangiocarcinoma is of intra-hepatic origin Or<br>- the cholangiocarcinoma is of extrahepatic origin<br><br>3. The cholangiocarcinoma has been tested for isocitrate dehydrogenase-1 (IDH1) R132 mutation with a validated test and the result is **positive**.<br><br>4. The patient has unresectable locally advanced or metastatic disease.<br><br>5. The patient has been previously treated with systemic therapy for cholangiocarcinoma and the disease has progressed during or after such therapy. Such systemic therapy could have been in the adjuvant or neoadjuvant or advanced disease settings.<br>Please also indicate whether the patient has received 1 or ≥2 lines of systemic therapy:<br>- the patient has been previously treated with 1 line of systemic therapy for cholangiocarcinoma Or<br>- the patient has been previously treated with ≥2 lines of systemic therapy for cholangiocarcinoma<br><br>6. The patient has an ECOG performance status of 0 or 1.<br><br>7. The patient either has no known brain metastases or if the patient has brain metastases, the patient is symptomatically stable prior to starting treatment with ivosidenib.<br><br>8. Ivosidenib will be used as monotherapy.<br><br>9. The patient will be treated until loss of clinical benefit or excessive toxicity or patient choice to discontinue treatment, whichever is the sooner.<br><br>10. The prescribing clinician understands the following as regards the effect of ivosidenib on causing elongation of the heart rate corrected QT interval (QTc):<br><br>- an ECG prior to treatment initiation is necessary to check that the QTc interval is less than 450 msec and if the QTc interval is above 450 msec, management will be as stated in ivosidenib's Summary of Product Characteristics (SPC)<br>- an ECG must be done at least weekly during the first 3 weeks of treatment and then monthly thereafter if the QTc interval remains at or below 480 msec (see SPC)<br>- concomitant administration of medicinal products known to prolong the QTc interval, or moderate/strong CYP3A4 inhibitors should be avoided whenever possible (see SPC).<br><br>11. Ivosidenib has important interactions with CYP3A4 inhibitors and inducers and other drugs and the prescribing clinician has considered these when prescribing ivosidenib (see SPC) and will continue to do so during treatment with ivosidenib.<br><br>12. The prescribing clinician is aware that monitoring with full blood counts and blood chemistry will be performed as outlined in ivosidenib's SPC.<br><br>13. A first formal medical review as to whether treatment with ivosidenib should continue or not will be scheduled to occur at least by the end of the first 8 weeks of treatment<br><br>14. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, the prescribing clinician will complete a treatment break approval form to restart treatment.<br><br>15. Ivosidenib will be otherwise used as set out in its Summary of Product Characteristics (SPC). | No | TA948 | 31-Jan-24 | 30-Apr-24 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| IVO2_v1.0 | **Ivosidenib** in combination with azacitidine | For newly diagnosed and untreated adult acute myeloid leukaemia with an isocitrate dehydrogenease-1 (IDH1) R132 mutation in patients who are not eligible for standard induction chemotherapy where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with ivosidenib plus azacitidine will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has newly diagnosed acute myeloid leukaemia (AML).<br>3. The patient has a known IDH1 R132 mutation.<br>4. The patient has **previously untreated AML** and state below whether the patient has de novo AML or secondary AML.<br>- de novo AML<br>- secondary AML<br>5. The patient has the most recent bone marrow blast count:<br>- 20% to <30% blasts<br>- 30% to <50% blasts<br>- 50% or more blasts<br>6. The standard induction chemotherapy is unsuitable for this patient.<br><br>Please mark below the dominant reason as to why this patient is unsuitable for intensive chemotherapy:<br>- age<br>- fitness<br>- significant comorbidity or comorbidities<br>7. The patient is fit for treatment with ivosidenib plus azacitidine and has an ECOG performance status (PS) of 0-3.<br><br>Please mark below the ECOG PS status:<br>- PS 0<br>- PS 1<br>- PS 2<br>- PS 3<br>8. The prescribing clinician understands the following as regards the effect of ivosidenib on causing elongation of the heart rate corrected QT interval (QTc):<br><br>- an ECG prior to treatment initiation is necessary to check that the QTc interval is less than 450 msec and if the QTc interval is above 450 msec, management will be as stated in ivosidenib's Summary of Product Characteristics (SPC)<br>- an ECG must be done at least weekly during the first 3 weeks of treatment and then monthly thereafter if the QTc interval remains at or below 480 msec (see SPC)<br>- concomitant administration of medicinal products known to prolong the QTc interval, or moderate/strong CYP3A4 inhibitors should be avoided whenever possible (see SPC).<br>9. The prescribing clinician is aware that ivosidenib has important interactions with CYP3A4 inhibitors and inducers and other drugs and I have considered these when prescribing ivosidenib (see sections 4.4 and 4.5 of the SPC) and will continue to do so during treatment with ivosidenib.<br>10. Antifungal prophylaxis with posaconazole or voriconazole is to be given to this patient (unless there is intolerance of such antifungal prophylaxis) and thus the dosing of ivosidenib has taken this drug interaction into account with the ivosidenib daily dose prescribed at a reduced dose of 250mg as set out in section 4.5 of the Summary of Product Characteristics for ivosidenib.<br><br>Note: if the patient develops toxicities to posaconazole and voriconazole such that these anti-fungal agents are discontinued, ivosidenib dosing should be increased to a maximum daily dose of 500mg.<br><br>Note: for patients in the BioDrive AFS trial (NIHR trial ID 132674) who are randomised to the intervention biomarker arm, the requirement for antifungal prophylaxis with posaconazole or voriconazole is waived and ivosidenib dosing at a maximum daily dose of 500mg is funded.<br>11. Ivosidenib will be given in combination with azacitidine.<br>12. Ivosidenib plus azacitidine will be continued until disease progression or unacceptable toxicity or withdrawal of patient consent or an elective decision to discontinue treatment consequent to a sustained complete remission to therapy.<br><br>Note: if ivosidenib is stopped for any of the above reasons, no further ivosidenib can be prescribed.<br>13. A formal medical review as to whether treatment with ivosidenib should continue will occur at least by the end of the second cycle of treatment.<br>14. When a treatment break of more than 10 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment.<br>15. Ivosidenib and azacitidine will be otherwise used as set out in their respective Summaries of Product Characteristics (SPC). | Yes | TA979 | 05-Jun-24 | 03-Sep-24 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| IXA1_v1.1 | **Ixazomib** with lenalidomide and dexamethasone | The treament of relapsed or refractory multiple myeloma where all the following criteria are met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with ixazomib in combination with lenalidomide and dexamethasone will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy<br>2. The patient has an established diagnosis of multiple myeloma.<br>3. The prescribing clinician understands that this combination of ixazomib, lenalidomide and dexamethasone in this indication is not funded for amyloidosis patients (with the exception of patients with a proven diagnosis of progressive myeloma and who also have an associated diagnosis of amyloidosis) and that NHS funding for ixazomib is only for the specific myeloma indication recommended by NICE.<br>Please indicate below the appropriate status for this patient:<br>- this patient does not have a diagnosis of primary amyloidosis or<br>- this patient has a proven diagnosis of progressive myeloma and also has an associated diagnosis of amyloidoisis and this ixazomib combination is being prescribed for the myeloma<br>Note: for primary amyloidosis patients requiring systemic therapies, NHSE does fund other treatments already in routine commissioning for myeloma. NHSE does not fund this ixazomib combination in this indication for patients with amyloidosis unless they have a proven diagnosis of progressive myeloma and also have an associated diagnosis of amyloidosis.<br>4. The patient has received 2 or 3 prior lines of treatment (i.e. no lines less than 2 and no lines more than 3) and that the numbering of these lines of treatment is in accordance with the International Myeloma Workshop Consensus recommendations for the uniform reporting of clinical trials (http://doi.org/10.1182/blood-2010-10-299487). A line of therapy is defined as one or more cycles of a planned treatment program. This may consist of one or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner (eg induction chemotherapy and stem cell transplantation is considered to be 1 line of therapy). A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a consequence of disease progression, relapse or toxicity. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease. Please indicate the number of prior lines of treatment:<br>- 2 prior lines or<br>- 3 prior lines<br>5. The patient's disease is neither refractory to previous proteasome inhibitor-based nor to lenalidomide-based treatment at any line of therapy (in this context, refractory disease is defined as disease progression on treatment or disease progression within 60 days of the last dose of a proteasome inhibitor or lenalidomide).<br>6. The patient has either been refractory to 1 or more lines of therapy or has responded and relapsed after each line of therapy. Please indicate which scenario applies:<br>- the patient's disease has been refractory to at least 1 line of therapy<br>- the patient's disease has responded and relapsed to each line of therapy and has never been refractory to any line of therapy<br>7. The prior treatment status in respect of previous lenalidomide therapy:<br>- Patient is treatment naïve to lenalidomide<br>- Patient received lenalidomide as part of 1st line therapy and was not refractory to that lenalidomide-based treatment<br>- Patient received lenalidomide as part of 2nd line therapy and was not refractory to that lenalidomide-based treatment<br>- Patient received lenalidomide as part of 3rd line therapy and was not refractory to that lenalidomide-based treatment<br>8. The patient has been treated with a previous autologous or allogenic stem cell transplant or not. Please indicate which scenario applies:<br>- Patient has been treated with a previous stem cell transplant<br>- Patient has NOT been treated with previous stem cell transplant<br>9. The patient is treatment-naïve to any therapy with ixazomib unless the patient has been treated with ixazomib in a company early access scheme and all other treatment criteria on this form apply.<br>10. Ixazomib is only to be used in combination with lenalidomide and dexamethasone*.<br>*Note: all 3 drugs in the combination (i.e. ixazomib, lenalidomide and dexamethasone) must be commenced at the same time.<br>11. Ixazomib is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment, whichever is the sooner<br>*Note: the combination of ixazomib, lenalidomide and dexamethasone is not funded as maintenance therapy post-transplant. Therefore, if a patient on this treatment subsequently proceeds to transplantation, treatment with any of the component parts of this combination cannot be resumed post-transplant.<br>12. The performance status of the patient is 0 or 1 or 2.<br>13. I confirm that where a treatment break of more than 6 weeks beyond the expected cycle length is needed, a treatment break approval form will be completed to restart treatment.<br>14. Ixazomib and lenalidomide are to be otherwise used as set out in their respective Summary of Product Characteristics (SPCs). | Yes | TA870 | 22-Feb-23 | 23-May-23 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| LEN1 | **Lenalidomide** in combination with dexamethasone | The 1st line treatment in transplant ineligible patients with multiple myeloma in whom thalidomide is contraindicated or who cannot tolerate thalidomide where the following criteria have been met: | 1. This application is made by and the first cycle of systemic anti-cancer therapy with lenalidomide in combination with dexamethasone will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy. | No | TA587 | 26-Jun-19 | 24-Sep-19 |
| | | | 2. The patient has a confirmed diagnosis of multiple myeloma. | | | | |
| | | | 3. The patient is ineligible for stem cell transplantation | | | | |
| | | | 4. The patient has either a contraindication to being commenced on treatment with 1st line thalidomide-containing chemotherapy or has commenced treatment with thalidomide-containing treatment and toxicity has forced its discontinuation at a time when the patient had neither demonstrated refractory disease nor relapsed after responding to thalidomide-containing systemic therapy.<br><br>Please mark below which group this patient applies to:<br>- the patient is treatment naïve and the use of thalidomide is contraindicated **or**<br>- the patient has been commenced on 1st line thalidomide-containing chemotherapy and has had to discontinue on account of intolerance without evidence of disease refractoriness or progression<br><br>Note: The recommendation made by NICE to restrict the use of lenalidomide in combination with dexamethasone to the thalidomide-contraindicated and thalidomide-intolerant groups was directly as a consequence of the submission made by Celgene for the clinical and cost effectiveness of 1st line lenalidomide plus dexamethasone. Celgene did not submit a case for the combination of lenalidomide and dexamethasone to be used in a broader population as stated in its marketing authorisation ('lenalidomide as combination therapy is indicated for the treatment of adult patients with previously untreated multiple myeloma who are not eligible for transplant', in this indication the 'combination' referring to lenalidomide plus dexamethasone).<br>Note: lenalidomide is not commissioned for use in combination with melphalan. | | | | |
| | | | 5. The patient is of ECOG performance status 0 or 1 or 2.<br>Please tick one of the boxes below:<br>- performance status 0 **or**<br>- performance status 1 **or**<br>- performance status 2 | | | | |
| | | | 6. The patient has had no previous therapy with lenalidomide. | | | | |
| | | | 7. Lenalidomide is only to be used in combination with dexamethasone and that it is not to be used in combination with any other agents. | | | | |
| | | | 8. Lenalidomide plus dexamethasone is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment, whichever is the sooner. | | | | |
| | | | 9. A formal medical review as to whether treatment with lenalidomide in combination with dexamethasone continues or not will be scheduled to occur at least by the end of the first 8 weeks of treatment. | | | | |
| | | | 10. No treatment breaks of more than 6 weeks beyond the expected cycle length are allowed (to allow any toxicity of current therapy to settle or intercurrent comorbidities to improve). | | | | |
| | | | 11. Lenalidomide will be otherwise used as set out in its Summary of Product Characteristics. | | | | |
| LEN2 | **Lenalidomide** in combination with dexamethasone | The 2nd line treatment in transplant ineligible patients with multiple myeloma previously treated with a 1st line bortezomib-containing regimen where the following criteria have been met: | 1. This application is made by and the first cycle of systemic anti-cancer therapy with lenalidomide in combination with dexamethasone will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy. | No | TA586 | 26-Jun-19 | 24-Sep-19 |
| | | | 2. The patient has a confirmed diagnosis of multiple myeloma. | | | | |
| | | | 3. The patient is ineligible for stem cell transplantation | | | | |
| | | | 4. The patient has been treated with a 1st line regimen which contained bortezomib. | | | | |
| | | | 5. The patient has received 1 and no more than 1 prior line of treatment and that the numbering of a line of treatment is in accordance with the International Myeloma Workshop Consensus recommendations for the uniform reporting of clinical trials (http://doi.org/10.1182/blood-2010-10-299487). A line of therapy is defined as one or more cycles of a planned treatment program. This may consist of one or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner (ie induction chemotherapy/chemotherapies when followed by stem cell transplantation then maintenance is considered to be 1 line of therapy). A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse or toxicity, the exception to this being the need to attain a sufficient response for stem cell transplantation to proceed. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease. | | | | |
| | | | 6. The patient is of ECOG performance status 0 or 1 or 2.<br>Please tick one of the boxes below:<br>- performance status 0 **or**<br>- performance status 1 **or**<br>- performance status 2 | | | | |
| | | | 7. The patient has had no previous therapy with lenalidomide. | | | | |
| | | | 8. Lenalidomide is only to be used in combination with dexamethasone and that it is not to be used in combination with any other agents. | | | | |
| | | | 9. Lenalidomide plus dexamethasone is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment, whichever is the sooner. | | | | |
| | | | 10. A formal medical review as to whether treatment with lenalidomide in combination with dexamethasone continues or not will be scheduled to occur at least by the end of the first 8 weeks of treatment. | | | | |
| | | | 11. No treatment breaks of more than 6 weeks beyond the expected cycle length are allowed (to allow any toxicity of current therapy to settle or intercurrent comorbidities to improve). | | | | |
| | | | 12. Lenalidomide will be otherwise used as set out in its Summary of Product Characteristics. | | | | |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| LEN3 | **Lenalidomide** in combination with dexamethasone | The 3rd or later line of treatment in transplant ineligible patients with multiple myeloma previously treated with at least 2 prior regimens where the following criteria are met: | 1. This application is made by and the first cycle of systemic anti-cancer therapy with lenalidomide in combination with dexamethasone will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a confirmed diagnosis of multiple myeloma.<br>3. The patient is ineligible for stem cell transplantation<br>4. The patient has received at least 2 prior lines of treatment and that the numbering of a line of treatment is in accordance with the International Myeloma Workshop Consensus recommendations for the uniform reporting of clinical trials (http://doi.org/10.1182/blood-2010-10-299487). A line of therapy is defined as one or more cycles of a planned treatment program. This may consist of one or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner (ie induction chemotherapy/chemotherapies when followed by stem cell transplantation then maintenance is considered to be 1 line of therapy). A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse or toxicity, the exception to this being the need to attain a sufficient response for stem cell transplantation to proceed. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease.<br>5. The patient is of ECOG performance status 0 or 1 or 2.<br>Please tick one of the boxes below:<br>- performance status 0 **or**<br>- performance status 1 **or**<br>- performance status 2<br>6. The patient has had no previous therapy with lenalidomide.<br>7. Lenalidomide is to be used in combination with either dexamethasone or dexamethasone plus cyclophosphamide and that it is not to be used in combination with any other agents unless accompanied by a separate and specific blueteq treatment criteria form. If cyclophosphamide is used in combination with lenalidomide and dexamethasone, the cyclophosphamide must be initiated with the first cycle of lenalidomide plus dexamethasone and not as a result of disease progression whilst on lenalidomide and dexamethasone.<br>8. Lenalidomide plus dexamethasone is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment, whichever is the sooner.<br>9. A formal medical review as to whether treatment with lenalidomide in combination with dexamethasone continues or not will be scheduled to occur at least by the end of the first 8 weeks of treatment.<br>10. No treatment breaks of more than 6 weeks beyond the expected cycle length are allowed (to allow any toxicity of current therapy to settle or intercurrent comorbidities to improve).<br>11. Lenalidomide will be otherwise used as set out in its Summary of Product Characteristics. | No | TA171 | 18-Jun-09 | 16-Sep-09 |
| LEN4 | **Lenalidomide** | The treatment of myelodysplastic syndromes associated with an isolated deletion 5q cytogenetic abnormality where the following criteria are met: | 1. This application is made by and the first cycle of systemic anti-cancer therapy with lenalidomide will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a confirmed diagnosis of transfusion-dependent anaemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with an isolated deletion 5q cytogenetic abnormality<br>3. The other therapeutic options (e.g. best supportive care including regular red blood cell transfusions) are insufficient or inadequate.<br>4. When starting lenalidomide the ANC is greater than (>) 0.5 x 10^9/L and/or platelet counts greater than (>) 25 x 10^9/L.<br>5. The patient is of ECOG performance status 0 or 1 or 2.<br>Please tick one of the boxes below:<br>- performance status 0 **or**<br>- performance status 1 **or**<br>- performance status 2<br>6. The patient has had no previous therapy with lenalidomide.<br>7. Lenalidomide is only to be used as a single agent at a starting dose of 10mg daily as per the summary of product characteristics<br>8. Lenalidomide is to be discontinued if no response after 4 cycles. If patients are responding after 4 cycles, lenalidomide will be continued until loss of response (progression of MDS or need for RBC transfusion) or unacceptable toxicity or patient choice to stop treatment, whichever is the sooner.<br>9. A formal medical review as to whether treatment with lenalidomide continues or not will be scheduled to occur at least by the end of the first 4 cycles of treatment.<br>10. No treatment breaks of more than 6 weeks beyond the expected cycle length are allowed (to allow any toxicity of current therapy to settle or intercurrent comorbidities to improve).<br>11. Lenalidomide will be otherwise used as set out in its Summary of Product Characteristics. | No | TA322 | 24-Sep-14 | 23-Dec-14 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| LEN5 | **Lenalidomide** in combination with rituximab | For previously treated follicular lymphoma (grades 1-3a) where all the following criteria have been met: | 1. This application is made by and the first cycle of systemic anti-cancer therapy with lenalidomide in combination with rituximab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient is an adult and has a histological diagnosis of follicular lymphoma of grades 1-3.<br>3. The patient has been previously treated with at least 1 prior systemic therapy for follicular lymphoma and now requires further systemic treatment.<br>For patients who have received rituximab or obinutuzumab, please mark below as to whether the patient has disease that is anti-CD20 antibody sensitive or resistant:<br>- Anti-CD20 antibody sensitive i.e. responded to the last anti-CD20 antibody-containing regimen and had progressive disease more than 6 months after completion of that anti-CD20 antibody-containing regimen<br>- Anti-CD20 antibody -resistant i.e. failed to respond to the last anti-CD20 antibody-containing regimen or had progressive disease within 6 months of completion of that anti-CD20 antibody-containing regimen<br>4. The patient is of ECOG performance status 0 or 1 or 2.<br>5. The patient has had no previous therapy with lenalidomide.<br>6. The patient will be treated with a maximum of 12 4-weekly cycles of lenalidomide.<br>7. The rituximab schedule of administration of 375mg/m2 given intravenously (IV) on days 1, 8, 15 and 22 in cycle 1 and then either 375mg/m2 given intravenously (IV) or 1400mg given subcutaneously (SC) on D1 only in cycles 2-5 will be used<br>8. Lenalidomide is only to be used in combination with rituximab and that it is not to be used in combination with any other agents.<br>Note: if rituximab has to be discontinued for toxicity, lenalidomide can be continued up to the maximum of 12 cycles.<br>9. Prior to cycle 1 the patient will receive tumour lysis syndrome prophylaxis (allopurinol, rasburicase or equivalent as per institutional guideline) and that the patient will be counselled as to be well orally hydrated during the 1st week of the 1st cycle or longer if clinically indicated.<br>10. The patient will have routine biochemistry tests performed weekly during cycle 1 and as clinically indicated and these results will be reviewed on day of testing to check for tumour lysis syndrome and its consequences.<br>11. The patient will be treated for any Tumour Flare Reaction as set out in the Summary of Product Characteristics (SmPC) for lenalidomide.<br>12. A formal medical review as to whether treatment with lenalidomide in combination with rituximab should continue or not will be scheduled to occur at least by the end of the first 8 weeks of treatment.<br>13. No treatment breaks of more than 6 weeks beyond the expected cycle length are allowed (to allow any toxicity of current therapy to settle or intercurrent comorbidities to improve).<br>14. Lenalidomide and rituximab will be otherwise used as set out in their Summary of Product Characteristics (SmPC). | No | TA627 | 07-Apr-20 | 06-Jul-20 |
| LEN6_v1.3 | **Lenalidomide** | Lenalidomide monotherapy as maintenance treatment in newly diagnosed patients with multiple myeloma who have undergone autologous stem cell transplantation where the following criteria have been met: | 1. This application for maintenance lenalidomide is being made by and the first cycle of systemic anti-cancer therapy with maintenance lenalidomide monotherapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has newly diagnosed multiple myeloma.<br>3. The patient has recently undergone autologous stem cell transplantation.<br>4. The patient has had an adequate haematological recovery following autologous stem cell transplantation.<br>5. Just prior to this application the patient has been tested for and has no evidence of disease progression since the transplantation was done.<br>6. The prescribing clinician understands that maintenance lenalidomide is recommended to start at about day 100 after stem cell transplantation.<br>Please enter in the box below the number of days since stem cell transplantation:<br>7. The patient has had no previous therapy with lenalidomide unless the patient has been previously treated with 1st line lenalidomide allowed for transplant eligible patients via the interim treatment change options available during the coronavirus pandemic (blueteq form LEN1aCV will previously have been completed)<br>**or** if the patient has been receiving NHS approved free of charge supply of maintenance lenalidomide as part of the NIHR myeloma XI trial and is due to exit the trial on study closure<br>**or** if the patient has been receiving NHS approved free of charge supply of maintenance lenalidomide as part of the NIHR RADAR trial and whilst still in remission has chosen to exit the trial<br>**or** the patient chose to self-fund 'top-up' treatment with lenalidomide maintenance prior to now switching to NHS funding as long as he/she started maintenance lenalidomide treatment on or after the 18th February 2020*.<br>Please tick one of the boxes below:<br>- no previous therapy with lenalidomide or<br>- the patient has been previously treated with **1st line lenalidomide (only in combination with dexamethasone)** allowed for transplant eligible patients via the interim cancer treatment options available during the coronavirus pandemic (blueteq form LEN1aCV will previously have been completed) and this had been started before the 14th April 2022*.<br>- the patient has been receiving NHS approved free of charge supply of maintenance lenalidomide as part of the NIHR myeloma XI trial and is due to exit the trial on study closure<br>- the patient has been receiving NHS approved free of charge supply of maintenance lenalidomide as part of the NIHR RADAR trial and whilst still in remission has chosen to exit the trial<br>- the patient has been receiving lenalidomide maintenance treatment via 'top-up' self-funding and this was started on or after 18th February 2020**.<br><br>* Access to the Interim treatment option LEN1aCV was removed by NHS England on 14th April 2022.<br><br>** The appraisal was scoped by NICE in May 2012, but NICE terminated the appraisal as the manufacturer did not make an evidence submission as to the clinical and cost effectiveness of maintenance lenalidomide. Because of this termination, there was no expectation that this indication could potentially receive NHS funding until an evidence submission from the manufacturer was finally received by NICE on 18th February 2020. NHS England will not fund any patients who started maintenance lenalidomide treatment before 18th February 2020 as there was no expectation of NHS funding potentially occurring until then as NICE had not received a submission from the company. Patients who are receiving lenalidomide maintenance funded by their private healthcare insurance provider should continue receive the full treatment course of lenalidomide from their private healthcare insurance provider.<br>8. The patient has an ECOG performance status of 0 or 1 or 2.<br>9. The patient will start maintenance lenalidomide at a dosing schedule of 10mg daily given on days 1-21 of a 28-day cycle and that any dose delays and reductions will be according to the Myeloma XI protocol version 9.0 (dated 2 November 2017).<br>Note: this dosing schedule is not the licensed one as set out in the lenalidomide Summary of Product Characteristics but is the one on which NICE assessed the clinical and cost effectiveness of maintenance lenalidomide.<br>Note: the licensed dosing schedule of maintenance lenalidomide is not to be used.<br>10. My hospital Trust's governance policy regarding the use of unlicensed treatments has been followed as I understand that the above Myeloma XI dosing schedule of maintenance lenalidomide is unlicensed.<br>11. Lenalidomide is only to be used as monotherapy and that it is not to be used in combination with any other agents.<br>12. Lenalidomide is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment, whichever is the sooner.<br>13. A first formal medical review as to whether treatment with maintenance lenalidomide monotherapy continues or not will be scheduled to occur at least by the end of the first 8 weeks of treatment.<br>14. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment.<br>15. Lenalidomide will be otherwise used as set out in its Summary of Product Characteristics. | No | TA680 | 03-Mar-21 | 01-Jun-21 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| LNV1 | **Lenvatinib with everolimus** | The treatment of previously treated advanced renal cell carcinoma | 1. The application has been made by and the first cycle of systemic anti-cancer therapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy | No | TA498 | 24-Jan-18 | 24-Apr-18 |
| | | | 2. The patient has a confirmed histological diagnosis of renal cell carcinoma with a clear cell component<br>Note: papillary, chromophobe and Xp11 translocation sub types can be treated as per clear cell pathway | | | | |
| | | | 3. The patient has either metastatic disease or inoperable locally advanced disease | | | | |
| | | | 4. The patient has previously received only 1 vascular endothelial growth factor (VEGF)-targeted systemic therapy for advanced/metastatic renal cancer*<br><br>*Patients treated with more than 1 line of VEGF-targeted therapy for advanced/metastatic disease are not eligible for treatment using lenvatinib with everolimus | | | | |
| | | | 5. The patient has progressed on previous treatment or within 6 months of discontinuing previous treatment | | | | |
| | | | 6. The patient has an ECOG performance status of either 0 or 1*<br>*Patients with a performance status of 2 or more are not eligible for lenvatinib with everolimus | | | | |
| | | | 7. The patient has received no previous treatment with either lenvatinib or everolimus | | | | |
| | | | 8. The patient either has no brain metastases or, if the patient has brain metastases, then these have been treated and are symptomatically stable | | | | |
| | | | 9. Lenvatinib with everolimus will be continued until loss of clinical benefit or unacceptable toxicity or patient choice to stop treatment | | | | |
| | | | 10. Where a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, a treatment break approval form will be completed to restart treatment, which MUST be approved before treatment is recommenced | | | | |
| | | | 11. Lenvatinib and everolimus are to be otherwise used as set out in their Summaries of Product Characteristics | | | | |
| LNV2 | **Lenvatinib** | The treatment of differentiated thyroid cancer after radioactive iodine where all the following criteria are met: | 1. This application is made by and the first cycle of systemic anti-cancer therapy with lenvatinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy | No | TA535 | 08-Aug-18 | 06-Nov-18 |
| | | | 2. This patient has a confirmed histological diagnosis of differentiated thyroid carcinoma (papillary or follicular or Hurtle cell type) | | | | |
| | | | 3. The patient has either metastatic disease or inoperable locally advanced disease | | | | |
| | | | 4. The disease is refractory to radioactive iodine | | | | |
| | | | 5. The disease is progressive and is either symptomatic or imminently likely to become symptomatic | | | | |
| | | | 6. The patient is treatment naïve to both lenvatinib and sorafenib unless **either:**<br>a) previously enrolled in the company's lenvatinib compassionate access scheme and all other NHS England treatment criteria are fulfilled ie if treated with previous sorafenib, lenvatinib will only be accepted for NHS funding if the patient was intolerant of sorafenib according to the conditions set out in b) below **or**<br>b) the patient has had to discontinue sorafenib within 3 months of starting sorafenib because of toxicity (ie there is sorafenib toxicity which cannot be managed by dose delay or dose modification) and there has been no disease progression whilst on sorafenib<br><br>Note: Sequential use of lenvatinib and then sorafenib is only funded if the patient has to discontinue lenvatinib because of intolerance within 3 months of its start and if the disease has not progressed whilst the patient is on lenvatinib. The use of lenvatinib after disease progression on or after sorafenib is not funded and vice versa. | | | | |
| | | | 7. The patient has an ECOG performance status of 0 or 1 or 2 | | | | |
| | | | 8. Lenvatinib is to be continued as long as clinical benefit is observed or until there is unacceptable toxicity or patient choice to stop treatment | | | | |
| | | | 9. A formal medical review as to whether treatment with lenvatinib should continue or not will be scheduled to occur at least by the end of the first 8 weeks of treatment | | | | |
| | | | 10. No treatment breaks of more than 6 weeks beyond the expected cycle length are allowed (to allow any toxicity of current therapy to settle or intercurrent comorbidities to improve) | | | | |
| | | | 11. Lenvatinib is to be otherwise used as set out in its Summary of Product Characteristics | | | | |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| LNV3 | **Lenvatinib monotherapy** | Treatment of Child-Pugh A locally advanced or metastatic hepatocellular carcinoma where the following criteria are met: | 1. This application has been made by and the first cycle of systemic anti -cancer therapy with lenvatinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br><br>2. One of the following applies to the patient, **either**:<br>- option 1 in which the patient has a confirmed histological diagnosis of hepatocellular carcinoma (HCC) **or**<br>- option 2 in which a biopsy is deemed to be very high risk or technically not feasible in the patient and the criteria below are also all met:<br>a. the decision not to biopsy has been made and documented by a specialist HCC multi-disciplinary team meeting<br>b. the tumour meets the non-invasive diagnostic criteria of HCC*<br>c. data is submitted as part of the ongoing 'Systemic Therapy Audit, previously known as the Sorafenib Audit 2'.<br>It is expected that option 2 will only apply in exceptional circumstances and it should be noted that audit of non-biopsy rates will be reviewed regularly.<br>*EASL-EORTC Clinical Practice Guidelines: Management, Journal of Hepatology 2012 vol 56 p908-943. Non-invasive criteria can only be applied to cirrhotic patients and are based on imaging techniques obtained by 4-phase multidetector CT scan or dynamic contrast-enhanced MRI. Diagnosis should be based on the identification of the typical hallmark of HCC (hypervascular in the arterial phase with washout in the portal venous or delayed phases). While one imaging technique is required for nodules beyond 1cm in diameter, a more conservative approach with 2 techniques is recommended in suboptimal settings.<br><br>3. The patient has either metastatic disease or locally advanced disease that is ineligible for or failed surgical or loco-regional therapies<br><br>4. Either:<br>- the patient has not received any previous systemic therapy for hepatocellular carcinoma (option 1) **or**<br>- the patient has had to discontinue sorafenib within 3 months of starting sorafenib and solely because of toxicity (i.e. there was sorafenib toxicity which could not be managed by dose delay or dose modification) and there has been no disease progression whilst on sorafenib (option 2) **or**<br>- the patient has received atezolizumab/bevacizumab or durvalumab/tremelimumab as 1st line (option 3)<br><br>NOTE – If option 1 or option 3 is selected, patients will not be able to access regorafenib OR cabozantinib in any future line of therapy for HCC, as the licenses for both drugs clearly state that they can only be used in HCC which has previously been treated with sorafenib<br><br>5. The patient has Child-Pugh liver function class A<br><br>6. The patient has an ECOG performance status of 0 or 1.<br><br>7. Lenvatinib is to be continued until loss of clinical benefit or unacceptable toxicity or patient choice to stop treatment.<br><br>8. The prescribing clinician is aware that no treatment breaks of greater than six weeks beyond the expected cycle length of four weeks are permitted (to allow any toxicity of current therapy to settle or intercurrent comorbidities to improve).<br><br>9. Lenvatinib will be otherwise used as set out in its Summary of Product Characteristics. | No | TA551 | 19-Dec-18 | 19-Mar-19 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| LNV4 | **Lenvatinib** in combination with pembrolizumab | Lenvatinib in combination with pembrolizumab for use in treatment-naïve patients with intermediate or poor risk advanced renal cell carcinoma for whom treatment with nivolumab plus ipilimumab would otherwise be suitable where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with the combination of lenvatinib plus pembrolizumab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The prescribing clinician is fully aware of the management of and the treatment modifications that may be required for immune-related adverse reactions due to checkpoint inhibitor treatments including pneumonitis, colitis, nephritis, endocrinopathies, hepatitis, skin toxicity and other immune-related adverse reactions.<br>3. The patient has unresectable locally advanced or metastatic renal cell carcinoma (RCC) which has either a clear cell component or is one of the types of RCC as indicated below.<br>Please indicate below which RCC histology applies to this patient:<br>- RCC with a clear cell component or<br>- Papillary RCC or<br>- Chromophobe RCC or<br>- Collecting duct RCC (Bellini collecting duct RCC) or<br>- Medullary RCC<br>- Mucinous tubular and spindle cell RCC or<br>- Multilocular cystic RCC or<br>- XP11 translocation RCC or<br>- Unclassified RCC<br>4. The patient's disease is in the **intermediate** or **poor risk** category as assessed by the International Metastatic RCC Database Consortium (IMDC) system which scores 1 point for each of the 6 factors listed below – a score of 0 indicates good risk disease, a score of 1-2 indicates intermediate risk and a score of 3-6 denotes poor risk.<br>The IMDC factors are:<br>- less than 1 year from time of initial diagnosis of RCC to now<br>- a Karnofsky performance status of <80%<br>- the haemoglobin level is less than the lower limit of normal<br>- the corrected calcium level is >2.5mmol/L<br>- the platelet count is greater than the upper limit of normal<br>- the absolute neutrophil count is greater than the upper limit of normal.<br>Please indicate below whether the patient is in the intermediate or poor risk prognostic group:<br>- intermediate risk disease (IMDC score of 1 or 2) or<br>- poor risk disease (IMDC score of 3-6)<br>Note: Lenvatinib plus pembrolizumab is not approved for patients with good risk RCC.<br>5. The patient is either completely treatment naïve for systemic immune-modulatory therapy for RCC or if the patient has received prior systemic immune-modulatory therapy in the context of adjuvant/neoadjuvant therapy, then such treatment was completed 12 or more months previously and the patient meets all other criteria listed here.<br>Please mark below whether or not previous systemic immune-modulatory therapy has been received in the adjuvant/neoadjuvant setting:<br>- **no previous adjuvant/neoadjuvant** systemic immune-modulatory therapy of any kind and the patient is treatment naïve for the locally advanced/metastatic RCC indication or<br>- **prior adjuvant/neoadjuvant therapy** with immune-modulatory therapies for RCC anti-Programmed Death receptor-1 (PD-1), anti-Programmed Death-1 ligand-1 (PD-L1), anti-PD L2, anti-CD137 or anti-cytotoxic T lymphocyte associated antigen-4 (anti-CTLA-4) antibodies and last dose received by the patient was 12 or more months prior to this application and the patient is treatment-naïve for the locally advanced/metastatic RCC indication<br>Please mark in the box the time since end of treatment with adjuvant/neoadjuvant immune-modulatory therapy:<br>_____<br>6. In the absence of lenvatinib plus pembrolizumab, the patient would otherwise be suitable for treatment with nivolumab plus ipilimumab.<br>Note: NICE recommended lenvatinib plus pembrolizumab as an option only in those patients who would otherwise be suitable for nivolumab plus ipilimumab but not in patients suitable for single agent TKI therapy.<br>7. The patient has a Karnofsky performance status of at least 70 (ie an ECOG performance score of 0 or 1).<br>8. The patient has no symptomatic brain metastases or leptomeningeal metastases currently requiring steroids for symptom control.<br>9. The patient is to be treated with lenvatinib until loss of clinical benefit or excessive toxicity or withdrawal of patient consent, whichever is the sooner.<br>Note: there is no stopping rule as to the maximum treatment duration of the lenvatinib part of this indication.<br>Note: if lenvatinib is permanently discontinued on account of toxicity, treatment with pembrolizumab can be continued as monotherapy as long as there is no evidence of progressive disease and the patient has not already completed 2 years of treatment with pembrolizumab.<br>10. The patient is to be treated with pembrolizumab until loss of clinical benefit or excessive toxicity or withdrawal of patient consent or **completion of a total treatment duration of 2 years***, whichever occurs first.<br>*2 years treatment is defined as a maximum of 35 x 3-weekly cycles or the equivalent number of 6-weekly cycles.<br>Note: if pembrolizumab is permanently discontinued on account of toxicity, treatment with lenvatinib can be continued as monotherapy as long as there is no evidence of progressive disease.<br>11. A formal medical review to assess the tolerability of treatment with lenvatinib plus pembrolizumab will be scheduled to occur at least by the start of the 3rd 3-weekly cycle or 2nd 6-weekly cycle of treatment and thereafter on a regular basis.<br>12. Treatment breaks of up to 12 weeks beyond the expected 3- or 6-weekly cycle length are allowed but solely to allow any toxicities to settle.<br>13. If the disease progresses on the pembrolizumab and lenvatinib combination and further systemic therapy is appropriate, the next line of treatment will be chosen from those options which are routinely commissioned ie for the next line of systemic therapy, there will be use of one choice of the following (mainly incorporating TKI options which have multiple modes of action): the currently commissioned 2nd line options of cabozantinib or axitinib or everolimus monotherapy or the currently commissioned 1st line options of sunitinib (still on label as 2nd line treatment) or pazopanib (off label as 2nd line treatment) or tivozanib (off label as 2nd line treatment).<br>14. Lenvatinib and pembrolizumab will be otherwise prescribed and administered as outlined in their respective Summary of Product Characteristics (SPCs). | No | TA858 | 11-Jan-23 | 11-Apr-23 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| LIS01a | **Lisocabtagene maraleucel** | Lisocabtagene maraleucel for the treatment of relapsed/refractory diffuse large B-cell lymphoma (DLBCL) or high grade B-cell lymphoma or primary mediastinal large B-cell lymphoma or follicular lymphoma grade 3B either in patients who relapsed within 12 months of completion of 1st line chemoimmunotherapy AND who would otherwise be intended for potential stem cell transplantation or who are refractory to 1st line chemoimmunotherapy AND who would otherwise be intended for potential stem cell transplantation where the following criteria have been met:<br><br>This form is for the approval of leucapheresis and manufacture of CAR-T cells. There is a second part to this form which relates to the subsequent infusion of CAR-T cells and this will be available after submission of the first part. The second part of the form (LIS1b) can only be completed as a continuation of this first part of the form (LIS1a) and must be completed on infusion of CAR-T cells otherwise the treating Trust will not be reimbursed for the cost of lisocabtagene maraleucel | 1. This application is being made by and that leucapheresis for and treatment with lisocabtagene maraleucel-modified CAR-T cells will be initiated by a consultant haematologist or medical oncologist specifically trained and accredited in the use of systemic anti-cancer therapy and working in an accredited CAR-T cell treatment centre and who is a member of the National CAR-T Clinical Panel for lymphoma and a member of the treating Trust's lymphoma CAR-T cell multidisciplinary team.<br><br>2. The patient is an adult (age 18 years or over) on the date of approval for lisocabtagene maraleucel by the National CAR-T Clinical Panel for lymphoma.<br><br>3. The patient has a confirmed histological diagnosis of DLBCL or HGBCL or PMBCL or FL3B.<br><br>Please tick appropriately below as to which type of lymphoma the patient has:<br>- Diffuse large B-cell lymphoma (DLBCL) NOS (including ABC and GCB types) or<br>- High grade B-cell lymphoma (HGBCL) with or without MYC and BCL2 (double hit) and BCL6 (triple hit) re-arrangements or<br>- Primary mediastinal large B-cell lymphoma (PMBCL) or<br>- Follicular lymphoma grade 3B(FL3B) or<br>- T cell/histiocyte-rich large B-cell lymphoma or<br>- Primary cutaneous DLBCL of leg type or<br>- HHV8 positive DLBCL or<br>- DLBCL associated with chronic inflammation or<br>- EB virus positive DLBCL or<br>- Transformed follicular lymphoma (TFL) to DLBCL and this diagnosis of TFL was made prior to embarking on any chemotherapy for DLBCL or<br>- Transformed marginal zone lymphoma (TFL) to DLBCL and this diagnosis of transformation was made prior to embarking on any chemotherapy for DLBCL or<br>- Transformed lymphoplasmacytoid lymphoma (LPL) to DLBCL and this diagnosis of transformation was made prior to embarking on any chemotherapy for DLBCL or<br>- Transformation of CLL to DLBCL (Richter's transformation) and this diagnosis of transformation was made prior to embarking on any chemotherapy for DLBCL or<br>- Transformed nodular lymphocyte predominant Hodgkin lymphoma (NLPHL) to DLBCL and this diagnosis of transformation was made prior to embarking on any chemotherapy for DLBCL or<br>- Transformation of post-transplant lymphoproliferative disorder to DLBCL and EBV positive and this diagnosis of transformation was made prior to embarking on any chemotherapy for DLBCL or<br>- Transformation of post-transplant lymphoproliferative disorder to DLBCL type and EBV negative and this diagnosis of transformation was made prior to embarking on any chemotherapy for DLBCL<br><br>Note: Patients with Burkitt lymphoma or primary CNS lymphoma are not eligible for treatment with lisocabtagene maraleucel in this indication<br><br>4. The histological diagnosis of DLBCL or HGBCL or PMBCL or FL3B or transformed lymphoma to DLBCL has been either made by or reviewed and confirmed by a designated lymphoma stem cell transplant centre.<br><br>5. Prior to consideration of CAR-T cell therapy the patient's disease has been re-biopsied unless either the patient had outright progressive disease on standard 1st line chemo-immunotherapy or a biopsy is unsafe in which case the patient must have progressive disease at previously known sites of active disease. In such situations the original diagnostic biopsy review is acceptable.<br><br>All patients with any transformed condition to DLBCL who fulfil criteria 6 below must have a re-biopsy and have confirmation of DLBCL histology prior to consideration of CAR-T cell therapy.<br><br>Please enter appropriately below as to which scenario applies to this patient:<br>- no biopsy necessary as the patient had outright progressive disease during 1st line chemo-immunotherapy for DLBCL or HGBCL or PMBCL or FL3B or<br>- re-biopsy has confirmed DLBCL or HGBCL or PMBCL or FL3B or<br>- re-biopsy has confirmed transformed lymphoma or other condition to DLBCL or<br>- re-biopsy is unsafe for the patient and the patient has progressive disease at previously known sites of active disease and the previous histology was DLBCL or HGBCL or PMBCL or FL3B.<br><br>6. The patient fulfils one of the following clinical scenarios relating to these definitions of relapsed or refractory lymphoma as applied to the failure of 1st line standard chemo-immunotherapy: please tick the appropriate box below.<br><br>Refractory disease is defined as progressive disease as the best response to 1st line standard chemo-immunotherapy after at least 2 cycles of chemo-immunotherapy or stable disease as the best response after at least 4 cycles of 1st line standard chemo-immunotherapy or a partial response as the best response after at least 6 cycles of 1st line standard chemo-immunotherapy with biopsy-proven residual disease or a partial response with biopsy-proven progressive disease within 12 months or less from completion of treatment.<br><br>Relapsed disease is defined as disease that was in complete remission following 1st line standard chemo-immunotherapy and has been followed by a biopsy-proven disease relapse within 12 months or less from completion of treatment.<br><br>Progressive disease should be defined radiologically as per RECIST version 1.1 and be based on CT or MR scans and aided if necessary, after discussion at the National CAR T Clinical Panel, with the use of Lugano lymphoma response criteria.<br><br>Please tick the box below which applies to this patient:<br>- progressive disease after at least 2 cycles of chemo-immunotherapy as the best response to 1st line standard chemo-immunotherapy OR<br>- stable disease as the best response after at least 4 cycles of 1st line standard chemo-immunotherapy with biopsy-proven residual disease OR<br>- a partial response as the best response after at least 6 cycles of 1st line standard chemo-immunotherapy with biopsy-proven residual disease OR<br>- a partial response to 1st line standard chemo-immunotherapy with biopsy-proven progressive disease within 12 months or less from completion of treatment OR<br>- a complete response to 1st line standard chemo-immunotherapy with biopsy-proven disease relapse within 12 months or less from completion of treatment.<br><br>7. The patient has been previously treated with a full dose 1st line anthracycline-containing standard regimen for his/her DLBCL or HGBCL or PMBCL or FL3B or transformed condition to DLBCL or with the Marietta protocol if presenting with CNS involvement.<br><br>Note: acceptable anthracycline-containing regimens include R-CHOP, Pola-R-CHP, R-CODOX-M/R-IVAC, DA-EPOC-R and the Marietta protocol.<br><br>Note: patients with transformed lymphoma or other transformed conditions to DLBCL must have received the full dose 1st line anthracycline-containing standard regimen for the known DLBCL component and this regimen must have been the 1st ever chemotherapy regimen for the transformed lymphoma (e.g. patients who receive 1st line anthracycline-based chemotherapy for follicular lymphoma and then subsequently transform are not eligible for lisocabtagene in this indication).<br><br>**(continues on next page)** | No | TA1048 | 26-Mar-25 | 24-Jun-25 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| LIS01a | **Lisocabtagene maraleucel** | Lisocabtagene maraleucel for the treatment of relapsed/refractory diffuse large B-cell lymphoma (DLBCL) or high grade B-cell lymphoma or primary mediastinal large B-cell lymphoma or follicular lymphoma grade 3B either in patients who relapsed within 12 months of completion of 1st line chemoimmunotherapy AND who would otherwise be intended for potential stem cell transplantation or who are refractory to 1st line chemoimmunotherapy AND who would otherwise be intended for potential stem cell transplantation where the following criteria have been met:<br><br>This form is for the approval of leucapheresis and manufacture of CAR-T cells. There is a second part to this form which relates to the subsequent infusion of CAR-T cells and this will be available after submission of the first part. The second part of the form (LIS1b) can only be completed as a continuation of this first part of the form (LIS1a) and must be completed on infusion of CAR-T cells otherwise the treating Trust will not be reimbursed for the cost of lisocabtagene maraleucel | 8. The patient has been previously treated with a regimen containing an anti-CD20 monoclonal antibody unless there is clear documentation of the determination of CD20 negative disease. | No | TA1048 | 26-Mar-25 | 24-Jun-25 |
| | | | 9. On the date that the patient was confirmed as having refractory or relapsed disease according to the above definitions, the patient had only received 1st line of therapy for the DLBCL or HGBCL or PMBCL or FL3B or TFL to DLBCL or other transformed conditions to DLBCL.<br><br>Note: in the case of patients who have transformed from a lymphoma or other condition to DLBCL, 1st line therapy refers to the treatment of the disease (e.g. TFL to DLBCL) once transformation has been documented.<br><br>Note: it is recognised that some patients at the time of the demonstration of refractory or relapsed disease have very rapidly progressive disease and thus have to commence urgent 2nd line treatment. It is therefore acceptable for patients to have received a maximum of 2 cycles of standard 2nd line chemotherapy regimens with one of the following regimens ('anticipatory bridging therapy'): R-GDP, R-GemCarbo, R-ESHAP, R-ICE, R-IVE, R-BendaPola and the Marietta protocol.<br><br>Please enter below whether the rate of disease progression as outlined above required urgent 2nd line salvage chemotherapy ('anticipatory bridging therapy') in this patient:<br>- no urgent chemotherapy required prior to this application or<br>- a maximum of 2 cycles of one of the above standard salvage chemotherapy regimens have been given prior to this application on grounds of urgent need and all other treatment criteria on this form are fulfilled | | | | |
| | | | 10. In the absence of the availability of lisocabtagene maraleucel for this 2nd line indication the patient would have been fit and intended for both standard 2nd line salvage chemotherapy (see note below) **and potential stem cell transplantation.**<br><br>Note: Second line treatment regimens which are appropriate include: R-GDP, R-GemCarbo, R-ESHAP, R-ICE, R-IVE, R-BendaPola and the Marietta protocol. | | | | |
| | | | 11. The patient has not previously been treated with an anti-CD19 antibody-drug conjugate. | | | | |
| | | | 12. Whether the patient has active CNS involvement by the lymphoma or not and if present whether this is in addition to systemic disease progression or not.<br><br>Please tick one of the boxes below:<br>- currently no known CNS involvement or<br>- currently has both active CNS and systemic disease or<br>- currently has isolated CNS disease only<br><br>Note: patients with primary CNS lymphoma are not eligible for treatment with lisocabtagene maraleucel. | | | | |
| | | | 13. The patient has an ECOG performance score of 0 or 1. Please enter below as to the patient's current ECOG performance status (PS):<br><br>The ECOG performance status scale is as follows:<br>PS 0 The patient is fully active and able to carry on all pre-disease performance without restriction<br>PS 1 The patient is restricted in physically strenuous activity but is ambulatory and able to carry out work of a light or sedentary nature eg light housework, office work<br>PS 2 The patient is ambulatory and capable of all selfcare but unable to carry out any work activities and is up and about more than 50% of waking hours<br>PS 3 The patient is capable of only limited selfcare and is confined to bed or chair more than 50% of waking hours<br>PS 4 The patient is completely disabled, cannot carry out any selfcare and is totally confined to bed or chair<br><br>The patient currently has a performance status of either<br>- ECOG PS 0 or<br>- ECOG PS 1 | | | | |
| | | | 14. The patient has sufficient end organ function to tolerate treatment with CAR-T cell therapy. | | | | |
| | | | 15. The patient has either had no previous therapy with any genetically modified autologous or allogeneic T cell immunotherapy or the patient has been treated with doses of genetically modified autologous or allogeneic T cell immunotherapy within an abandoned dosing cohort in a first in human dose-escalation phase I clinical trial.<br><br>Please tick appropriate box as to which type of previous treatment the patient has had:<br>- No previous therapy with any genetically modified autologous or allogeneic T cell immunotherapy or<br>- Previously treated with doses of genetically modified autologous or allogeneic T cell immunotherapy within an abandoned dosing cohort in a first in human dose-escalation phase I clinical trial | | | | |
| | | | 16. Prior to infusion 2 doses of tocilizumab are available for use in this patient in the event of the development of cytokine release syndrome. | | | | |
| | | | 17. Lisocabtagene maraleucel-modified CAR-T cell therapy will otherwise be used as set out in its Summary of Product Characteristics (SPC). | | | | |
| | | | 18. Approval for the use of lisocabtagene maraleucel has been formally given by the National DLBCL/HGBCL CAR-T cell Clinical Panel.<br><br>Please state date of approval _____ | | | | |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| LIS01b | **Lisocabtagene maraleucel** | Lisocabtagene maraleucel for treating relapsed/refractory diffuse large B-cell lymphoma (DLBCL) or high grade B-cell lymphoma (HGBCL) or primary mediastinal large B-cell lymphoma (PMBCL) or follicular lymphoma grade 3B (FL3B) and in adult patients either who relapse within 12 months of completion of 1st line chemoimmunotherapy AND who would otherwise be intended for potential stem cell transplantation or who are refractory to 1st line chemoimmunotherapy AND who would otherwise be intended for potential stem cell transplantation where the following criteria have been met:<br><br>This second part of the form is to document the date of infusion of CAR-T cell therapy and for registration of this infusion with NHS England so that the treating Trust is reimbursed for the cost of lisocabtagene maraleucel. There is a first part of the form for the approval of leucapheresis and manufacture of CAR-T cells which has already been completed (LIS1a). This second part of the form (LIS1b) should only be completed as a continuation form once the date of CAR-T cell infusion is known. | 1. This application for continuation is being made by and treatment with lisocabtagene maraleucel-modified CAR-T cells will be initiated by a consultant haematologist/medical oncologist specifically trained and accredited in the use of systemic anti-cancer therapy and working in an accredited CAR-T cell treatment centre and who is a member of the National CAR-T Clinical Panel for lymphoma and a member of the treating Trust's lymphoma and CAR-T cell multidisciplinary teams.<br><br>2. The patient has an ECOG performance score of 0 or 1 or 2. Please tick one of the boxes below as to the patient's current ECOG performance status (PS):<br><br>The ECOG performance status scale is as follows:<br>PS 0 The patient is fully active and able to carry on all pre-disease performance without restriction<br>PS 1 The patient is restricted in physically strenuous activity but is ambulatory and able to carry out work of a light or sedentary nature eg light housework, office work<br>PS 2 The patient is ambulatory and capable of all selfcare but unable to carry out any work activities and is up and about more than 50% of waking hours<br>PS 3 The patient is capable of only limited selfcare and is confined to bed or chair more than 50% of waking hours<br>PS 4 The patient is completely disabled, cannot carry out any selfcare and is totally confined to bed or chair<br><br>The patient currently has a performance status of:<br>- ECOG PS 0 or<br>- ECOG PS 1 or<br>- ECOG PS 2<br><br>3. Whether the patient has required bridging therapy in between leucapheresis and CAR-T cell infusion. Please indicate what type(s) of bridging therapy have been required by ticking the most appropriate option below:<br><br>- no bridging therapy at all or<br>- corticosteroids only or<br>- chemo(immuno)therapy only with intensive salvage-type therapy (eg R-GDP, R-GemCarbo, R-ESHAP, R-ICE, R-IVE, R-BendaPola and the Marietta protocol) or<br>- chemo(immuno)therapy only with BR-polatuzumab or<br>- other chemo(immuno)therapy only or<br>- radiotherapy only or<br>- corticosteroids and chemo(immuno)therapy or<br>- corticosteroids and radiotherapy or<br>- chemo(immuno)therapy and radiotherapy ± corticosteroids<br><br>4. The nature of any imaging procedure performed to assess response to bridging therapy below:<br><br>no bridging therapy and so no radiological assessment performed or<br>- PET-CT scan performed or<br>- CT or MR scan performed or<br>- had bridging therapy but no radiological assessment performed<br><br>Note: a PET-CT scan is the most informative imaging for patients having bridging therapy and is therefore highly desirable in this situation but NHSE recognises that this is not always possible.<br><br>5. The response assessment to bridging therapy below:<br><br>- no bridging therapy and so no radiological assessment performed or<br>- complete response (CR) or complete metabolic response (CMR) or<br>- partial response (PR) or partial metabolic response (PMR) or<br>- stable disease (SD) or<br>- progressive disease (PD) or<br>- had bridging therapy but no radiological assessment performed<br><br>6. The dominant reason for the decision to employ bridging therapy if used: please tick one box.<br>- no bridging therapy used at all or<br>- the need to relieve local symptoms or<br>- the need to relieve systemic symptoms or<br>- the need to relieve both local and systemic symptoms or<br>- the belief that toxicity and long-term outcomes will be better with bridging therapy<br><br>7. In the box below the time gap (as measured by the number of days) between the date of leucapheresis and the start of any bridging therapy. If no bridging therapy has been used, please enter 0.<br><br>Number of days between date of leucapheresis and start of bridging therapy: _____<br><br>8. The patient has sufficient end organ function to tolerate treatment with CAR-T cell therapy.<br><br>9. Prior to infusion 2 doses of tocilizumab are available for use in this patient in the event of the development of cytokine release syndrome. | No | TA1048 | 26-Mar-25 | 24-Mar-25 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| LCD1 | **Liposomal cytarabine and daunorubicin** | The treatment of adults with newly diagnosed acute myeloid leukaemia (AML) that is secondary to therapy or myelodysplasia or chronic myelomonocytic leukaemia where the following criteria are met: | 1. I confirm that this application is made by and the first cycle of systemic anti-cancer therapy with liposomal cytarabine and daunorubicin will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy | No | TA552 | 19-Dec-18 | 19-Mar-19 |
| | | | 2. This patient is an adult and has a confirmed diagnosis of acute myeloid leukaemia with one of the following types:<br>- therapy-related AML (t-AML) with a documented history of prior cytotoxic therapy or ionising radiotherapy for an unrelated disease **or**<br>- chronic myelomonocytic leukaemia AML (CMMoL AML) with a documented history of CMMoL prior to transformation to AML **or**<br>- myelodysplasia AML (MDS AML) with a documented history of MDS prior to transformation to AML **or**<br>- de novo AML with karyotypic changes characteristic of MDS. | | | | |
| | | | 3. I confirm that the patient is newly diagnosed with one of the above types of AML and has not received any chemotherapy for this AML. | | | | |
| | | | 4. I confirm that the patient has an ECOG performance score of 0, 1 or 2. | | | | |
| | | | 5. I confirm that the patient is fit for induction chemotherapy with liposomal cytarabine and daunorubicin. | | | | |
| | | | 6. I confirm that the patient will be treated with liposomal cytarabine and daunorubicin with the doses and schedules for induction chemotherapy as outlined in the Summary of Product Characteristics of liposomal cytarabine and daunorubicin. | | | | |
| | | | 7. I note that the use of liposomal cytarabine and daunorubicin is exempt from the NHS England Treatment Break policy | | | | |
| | | | 8. I confirm that liposomal cytarabine and daunorubicin is to be otherwise used as set out in its Summary of Product Characteristics | | | | |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| LON1_v1.0 | **Loncastuximab tesirine monotherapy** | For the further treatment of adult patients with diffuse large B-cell lymphoma or high grade B-cell lymphoma who have received previous treatment with 2 or more lines of systemic therapy (which have included polatuzumab vedotin unless the use of polatuzumab vedotin was contra-indicated) and in addition are not candidates for any future CAR T cell therapy where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with loncastuximab tesirine monotherapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy. | No | TA947 | 31-Jan-24 | 30-Apr-24 |
| | | | 2. The patient has a histologically confirmed diagnosis of diffuse large B cell lymphoma (DLBCL) or high grade B cell lymphoma or transformed follicular lymphoma to DLBCL.<br>The definition of DLBCL includes the following:<br>- DLBCL not otherwise specified (NOS) [including germinal centre B-cell (GCB) and activated B-cell (ABC) subtypes]<br>- primary mediastinal large B cell lymphoma<br>- T cell rich B cell lymphoma<br>- Epstein-Barr virus (EBV) positive DLBCL<br>- intravascular large B cell lymphoma<br>- high grade B-cell lymphoma (double hit and triple hit high grade B cell lymphoma)<br>Note: Patients with primary CNS lymphoma, Burkitt lymphoma and plasmablastic lymphoma are NOT eligible for treatment with loncastuximab tesirine.<br>Please record in the box below whether the patient has DLBCL according to one of the above types of DLBCL or has transformed follicular lymphoma to DLBCL:<br>- the patient has DLBCL according to one of the types within the above definition OR<br>- the patient has transformed follicular lymphoma (TFL) to DLBCL | | | | |
| | | | 3. The patient has DLBCL or TFL to DLBCL either of which has relapsed following or during 2 or more lines of standard routinely commissioned systemic therapies and that within these 2 lines of therapy there has been treatment with an anti-CD20 regimen and an anthracycline-containing regimen.<br>Note: patients with TFL to DLBCL must have received 2 or more lines of systemic therapy given specifically for the transformed follicular lymphoma to DLBCL | | | | |
| | | | 4. The number of lines of systemic therapy that the patient has received for the treatment of DLBCL or TFL to DLBCL.<br>Note: induction chemotherapy prior to and then followed by stem cell transplantation counts as 1 line of systemic therapy. Similarly, bridging chemotherapy prior to and then followed by CAR T cell therapy counts as 1 line of systemic therapy.<br>Note: patients who have had only 1 line of systemic multi-agent therapy are NOT eligible for treatment with loncastuximab tesirine.<br>**Please record the number of lines of previous systemic therapy below:**<br>- 2 previous lines OR<br>- 3 previous lines OR<br>- 4 or more previous lines | | | | |
| | | | 5. The patient has been previously treated with stem cell transplantation:<br>- No previous stem cell transplantation OR<br>- Yes, previous stem cell transplantation | | | | |
| | | | 6. The patient has been previously treated with CAR T cell therapy and if so at which place in the treatment pathway:<br>- No previous CAR T cell therapy and the patient is unsuitable for CAR T cell therapy both now **and** in the future OR<br>- Yes, previous CAR T cell therapy as 2nd line therapy OR<br>- Yes, previous CAR T cell therapy as 3rd or more line of therapy<br>Note: Swedish Orphan Biovitrum (the company that markets loncastuximab tesirine) did not make an evidence submission to NICE for consideration of the use of loncastuximab tesirine in patients who are suitable for or might become eligible for CAR T cell therapy.<br>Note: loncastuximab tesirine must not be used as bridging therapy for CAR T cell therapy.<br>Note: patients who have had previous CD19-directed CAR T cell therapy **must be re-biopsied** prior to consideration of treatment with loncastuximab tesirine to ensure that the lymphoma retains CD19 protein expression (unless such a biopsy is unsafe for the patient and the patient has progressive disease at previously known sites of active disease and the previous histology was DLBCL or HGBCL). | | | | |
| | | | 7. The patient has either previously received systemic therapy with a regimen containing polatuzumab vedotin or the use of a polatuzumab vedotin-containing regimen was contraindicated.<br>Note: the NICE recommendation for access to loncastuximab tesirine stipulates that for treating relapsed or refractory DLBCL in patients who have had 2 or more systemic therapies, lonastuximab is only recommended if patients have received prior polatuzumab (whether relapsed following such treatment or refractory to it or if polatuzumab was not tolerated) or if treatment with polatuzumab was contraindicated.<br>Please record in the box below which of the following applies to this patient:<br>- previous treatment with 1st line polatuzumab vedotin-containing chemotherapy to which the patient had relapsed or refractory disease OR<br>- previous treatment with 2nd or greater line polatuzumab vedotin-containing chemotherapy to which the patient had relapsed or refractory disease OR<br>- previous treatment with a polatuzumab vedotin-containing chemotherapy which was not tolerated and hence treatment with polatuzumab vedotin was discontinued OR<br>- the use of a polatuzumab vedotin-containing chemotherapy was contraindicated and hence the patient has not been treated with polatuzumab vedotin for this reason | | | | |
| | | | 8. The patient has not been previously treated with loncastuximab tesirine unless loncastuximab tesirine has been accessed via a company compassionate access scheme and all other treatment criteria on this form are fulfilled. | | | | |
| | | | 9. The patient has an ECOG performance status score of 0 or 1 or 2. | | | | |
| | | | 10. Loncastuximab tesirine is to be administered as monotherapy and not in combination with any other systemic therapies for lymphoma. | | | | |
| | | | 11. The dosing schedule of loncastuximab tesirine differs in cycle 3 and beyond from that used in cycles 1 and 2. | | | | |
| | | | 12. Treatment with loncastuximab tesirine monotherapy will be stopped at whichever of the following events occurs first: disease progression or unacceptable toxicity or withdrawal of patient consent.<br>Note: there is no formal stopping rule for loncastuximab tesirine in this indication but once loncastuximab is electively stopped (ie not for reasons of toxicity), it cannot be re-started. | | | | |
| | | | 13. The prescribing clinician and the treating team are familiar with the dose modifications and delays required for the management of adverse reactions to loncastuximab tesirine, both haematological and non-haematological (eg for oedema, effusions, cutaneous toxicity and abnormal liver function tests). | | | | |
| | | | 14. A formal medical review as to whether treatment with loncastuximab tesirine should continue or not will be scheduled to occur at least by the end of the first 6 weeks of treatment. | | | | |
| | | | 15. When a treatment break of more than 6 weeks beyond the expected 3-weekly cycle length is needed, a treatment break approval form will be completed to restart treatment | | | | |
| | | | 16. Loncastuximab tesirine will be otherwise used as set out in its Summary of Product Characteristics (SPC) | | | | |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| LOR1 | **Lorlatinib** | For anaplastic lymphoma kinase positive advanced non-small-cell lung cancer previously treated with 1st line alectinib or 1st line brigatinib or 1st line ceritinib or 1st line crizotinib followed by a 2nd line ALK tyrosine kinase inhibitor therapy (brigatinib or ceritinib) or after disease progression during adjuvant alectinib or within 6 months of completion of adjuvant alectinib where the following criteria have been met: | 1. This application for lorlatinib is being made by and the first cycle of systemic anti-cancer therapy with lorlatinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy. | No | TA628 | 13-May-20 | 11-Aug-20 |
| | | | 2. The patient has a locally advanced or metastatic non-small cell lung cancer. | | | | |
| | | | 3. The patient has a histologically or cytologically confirmed diagnosis of non-small cell lung cancer that carries an anaplastic lymphoma kinase (ALK) rearrangement based on a validated test. | | | | |
| | | | 4. The only TKI treatment that the patient has progressed on is 1st line alectinib or 1st line brigatinib or 1st line ceritinib or 1st line crizotinib followed by one other second generation ALK tyrosine kinase therapy (brigatinib or ceritinib) or after disease progression during treatment with adjuvant alectinib or within 6 months of completion of adjuvant alectinib.<br>Please tick appropriately below as to which type of previous NHS England-commissioned treatment the patient has progressed on:<br>- 1st line alectinib or<br>- 1st line brigatinib or<br>- 1st line ceritinib or<br>- 1st line crizotinib followed by either brigatinib or ceritinib<br>- after disease progression during treatment with adjuvant alectinib<br>- after disease progression within 6 months of completion of adjuvant alectinib | | | | |
| | | | 5. The patient has not been previously treated with lorlatinib unless lorlatinib has been received as part of any compassionate use scheme and the patient meets all the other criteria set out here. | | | | |
| | | | 6. Lorlatinib will be used only as monotherapy. | | | | |
| | | | 7. The patient has an ECOG performance status of 0 or 1 or 2. | | | | |
| | | | 8. The patient either has no brain metastases or, if the patient has brain metastases, the patient is symptomatically stable prior to starting lorlatinib. | | | | |
| | | | 9. The patient will be treated with lorlatinib until loss of clinical benefit or excessive toxicity or patient choice to discontinue treatment, whichever is the sooner. | | | | |
| | | | 10. The prescribing clinician understands the need for regular monitoring of serum cholesterol and triglycerides before and during therapy with lorlatinib. | | | | |
| | | | 11. A formal medical review as to whether treatment with lorlatinib should continue or not will be scheduled to occur at least by the end of the first 8 weeks of treatment. | | | | |
| | | | 12. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment. | | | | |
| | | | 13. Lorlatinib will be otherwise used as set out in its Summary of Product Characteristics. | | | | |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| LOR2 | **Lorlatinib monotherapy** | Lorlatinib monotherapy for anaplastic lymphoma kinase-positive advanced non-small cell lung cancer previously untreated with an ALK inhibitor where the following criteria have been met: | 1. This application for lorlatinib is being made by and the first cycle of systemic anti-cancer therapy with lorlatinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has locally advanced or metastatic non-small cell lung cancer.<br>3. The patient has histological or cytological evidence of NSCLC that carries an anaplastic lymphoma kinase (ALK) rearrangement based on a validated test **OR** there is documented agreement by the lung MDT that the radiological appearances are in keeping with locally advanced or metastatic NSCLC **AND** there is an informative circulating free DNA test result confirming the presence of an activating anaplastic lymphoma kinase (ALK) rearrangement.<br>Please mark below on which basis the diagnosis of ALK positive NSCLC has been made in this patient:<br>- Histological or cytological evidence **or**<br>- Documented agreement by the lung MDT that the radiological appearances are in keeping with locally advanced or metastatic NSCLC and there is an informative circulating free DNA test result confirming the presence of an activating anaplastic lymphoma kinase (ALK) rearrangement<br>4. The patient has not previously received any ALK inhibitor for the advanced NSCLC indication unless 1st line treatment with alectinib, brigatinib, ceritinib or crizotinib has had to be stopped within **6** months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression or the patient was treated with adjuvant alectinib and had disease progression more than 6 months after completing treatment with adjuvant alectinib.<br>Please mark below which of the five scenarios applies to this patient:<br>- the patient has never previously received an ALK inhibitor **or**<br>- the patient has previously received **alectinib** as 1st line ALK-targeted therapy and this has had to be stopped within 6 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression **or**<br>- the patient has previously received **brigatinib** as 1st line ALK-targeted therapy and this has had to be stopped within 6 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression **or**<br>- the patient has previously received **crizotinib or ceritinib** as 1st line ALK-targeted therapy and this has had to be stopped within 6 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression **or**<br>- the patient was previously treated with **adjuvant alectinib** and had disease progression more than **6** months after completing treatment with adjuvant alectinib<br>5. The patient is treatment-naïve to 1st line cytotoxic chemotherapy-containing systemic treatment for this locally advanced or metastatic NSCLC indication.<br>**Note: the only previous cytotoxic treatment allowed for patients to be treated with 1st line lorlatinib is adjuvant or neoadjuvant chemotherapy or chemotherapy given concurrently with radiotherapy.**<br>6. The patient has an ECOG performance status of 0 or 1 or 2.<br>7. The patient either has no known brain metastases or if the patient has brain metastases, these must be asymptomatic (but can be treated or untreated.)<br>8. The patient will be treated until loss of clinical benefit or excessive toxicity or patient choice to discontinue treatment, whichever is the sooner.<br>9. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, the prescribing clinician will complete a treatment break approval form to restart treatment.<br>10. The prescribing clinician is aware that:<br>a) none of brigatinib or ceritinib or crizotinib are to be used following disease progression on lorlatinib as there is no current clear evidence to support treatment with any of these agents after disease progression on lorlatinib **and, therefore**<br>b) after disease progression on lorlatinib, no subsequent ALK inhibitor therapy is commissioned by NHS England<br>11. Lorlatinib will otherwise be used as set out in its Summary of Product Characteristics (SPC). | No | TA1103 | 21-Oct-25 | 19-Jan-26 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| LUT1 | **Lutetium oxodotreotide** | Lutetium oxodotreotide for unresectable or metastatic, progressive, well differentiated and somatostatin receptor positive gastroenteropancreatic neuroendocrine carcinoma where all the following criteria are met: | 1. This application is made by a consultant oncologist who is specifically trained and accredited in the use of systemic anti-cancer therapy and who is a core member of the relevant Neuroendocrine Carcinoma Multi-Disciplinary Team (MDT)<br>2. The Neuroendocrine Carcinoma MDT has confirmed the arrangements by which only persons authorised to handle radiopharmaceuticals (such as lutetium oxodotreotide) do so in authorised clinical settings and after evaluation of the patient by an appropriately trained and accredited physician<br>3. The patient has a histologically documented, well differentiated neuroendocrine carcinoma of the gastrointestinal tract or pancreas<br>Note: patients with primary bronchial neuroendocrine carcinomas are not eligible for treatment with lutetium oxodotreotide<br>4. The patient's disease is either unresectable or metastatic<br>5. The patient's disease is somatostatin receptor positive on imaging (on PET scanning but otherwise on scintigraphy if PET scanning not possible) and this imaging confirms overexpression of somatostatin receptors in the tumour tissue with the tumour uptake at least as high as normal liver uptake (tumour uptake grade score ≥ 2)<br>6. There has been recent demonstration in this patient of disease progression on CT or MR imaging over the course of a maximum period of 3 years<br>7. The patient has an ECOG performance status (PS) score of 0 or 1 or 2<br>8. The patient has not received prior treatment with lutetium oxodotreotide<br>Note: re-treatment with a further program of lutetium oxodotreotide treatments is not commissioned<br>9. Lutetium oxodotreotide is being given as monotherapy (bar somatostatin analogues in between treatments) and will involve a maximum of 4 infusions of 7400 MBq as long as there is no evidence of disease progression<br>10. A formal face to face medical review as to whether treatment with lutetium oxodotreotide should continue or not will be scheduled to occur before each of the 4 planned treatment administrations<br>11. The prescribing clinician notes that the use of lutetium oxodotreotide is exempt from the NHS England cancer drug Treatment Breaks policy<br>12. Lutetium oxodotreotide will otherwise be used as set out in its Summary of Product Characteristics (SPC) | No | TA539 | 29-Aug-18 | 27-Nov-18 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| MID1 | **Midostaurin** | Midostaurin for treating newly diagnosed FLT3 mutation positive acute myeloid leukaemia (FLT3-ITD or FLT3-TKD) in ADULTS where the following criteria are met: | 1. An application is being made by and the first cycle of systemic anti-cancer therapy with midostaurin will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy<br>2. This patient is an adult and has a confirmed diagnosis of acute myeloid leukaemia<br>3. The patient's AML has a FLT3 mutation (ITD or TKD) as determined by a validated test:<br><br>Please mark below which type of FLT3 mutation applies to this patient:<br>- ITD disease or<br>- TKD disease<br>4. The patient is newly diagnosed with FLT3 positive acute myeloid leukaemia and either has not received any induction chemotherapy or has only received a single cycle of induction chemotherapy whilst awaiting FLT3 status.<br><br>Please record the status as to induction chemotherapy:<br>- the patient has not yet received any induction chemotherapy or<br>- the patient has received only a single cycle of induction chemotherapy whilst awaiting the FLT3 result<br>5. The patient is fit for intensive induction chemotherapy<br>6. The patient will be treated with midostaurin only in combination with standard daunorubicin and cytarabine induction chemotherapy and then in combination with high dose cytarabine consolidation chemotherapyunless this patient has been entered into the NCRI Optimise-FLT3 Trial (ISRCTN 34016918) in which case midostaurin can also be given in combination with gemtuzumab ozogamicin with either DA or FLAG-Ida induction chemotherapy according to the Optimise-FLT3 trial protocol.<br><br>Note: midostaurin is excluded from the NHS England Treatment Breaks Policy.<br>7. As maintenance monotherapy, midostaurin is to be only used in patients in complete remission of their AML<br>8. In the maintenance monotherapy phase, a maximum of 12 x 28-day cycles of midostaurin will be used<br>9. If the patient proceeds to a stem cell transplant, midostaurin will be permanently discontinued prior to the stem cell transplant conditioning regimen.<br><br>Note: the use of midostaurin after a stem cell transplant is not commissioned.<br>10. Midostaurin is to be otherwise used as set out in its Summary of Product Characteristics | No | TA523 | 13-Jun-18 | 11-Sep-18 |
| MID2 | **Midostaurin** | For aggressive systemic mastocytosis or aggressive systemic mastocytosis with an associated haematological neoplasm or mast cell leukaemia where the following criteria have been met: | 1. This application for midostaurin monotherapy is being made by and the first cycle of systemic anti-cancer therapy with midostaurin monotherapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a pathologically-confirmed diagnosis of aggressive systemic mastocytosis (ASM) or aggressive systemic mastocytosis with an associated haematological neoplasm (ASM-AHN) or mast cell leukaemia.<br><br>Please mark below which type of disease applies to this patient:<br>- aggressive systemic mastocytosis (ASM)<br>- aggressive systemic mastocytosis with an associated haematological neoplasm (ASM-AHN)<br>- mast cell leukaemia<br>3. The patient has advanced disease and requires systemic therapy for this condition.<br>4. Either the patient has received previous systemic therapy for this condition or not.<br>Please mark below whether the patient has/has not previously received any systemic therapy for this condition:<br>- no, this patient has not received any previous systemic therapy for this condition<br>- yes, this patient has been previously treated with systemic therapy for this condition<br>5. Either the patient has received previous treatment with avapritinib or not.<br><br>Please mark below whether the patient has previously received avapritinib or not:<br>- no, this patient has not received any previous avapritinib<br>- yes, the patient has been previously treated with avapritinib<br>6. The patient has not previously received treatment with midostaurin .<br>Note: If patients were entered into the company's early access/compassionate use scheme for midostaurin for these indications they must continue to receive midostaurin from this scheme. These patients must not be transferred to CDF funded commercial stock and must not be registered on Blueteq.<br><br>Novartis will continue to provide free of charge stock for these patients.<br>7. The patient has an ECOG performance status (PS) of 0 or 1 or 2 or 3 and is fit enough for treatment with midostaurin.<br><br>Please mark below the ECOG performance status of the patient at the time of making this application for midostaurin therapy:<br>- this patient has an ECOG PS of 0<br>- this patient has an ECOG PS of 1<br>- this patient has an ECOG PS of 2<br>- this patient has an ECOG PS of 3 and is fit enough for treatment with midostaurin.<br>8. Midostaurin will be administered as monotherapy.<br><br>Note the recommended starting dose in ASM, SM-AHN and MCL is 100mg twice a day with food.<br>9. Midostaurin will be continued until loss of clinical benefit or the development of unacceptable toxicity or withdrawal of patient consent, whichever occurs first.<br>10. The prescribing clinician is aware of the need for caution in the prescribing of midostaurin with strong CYP3A4 inhibitors and inducers, as set out in the Summary of Product Characteristics (SPC).<br>11. The prescribing clinician is aware that midostaurin can cause hyperglycaemia and of the need for glycaemic level monitoring.<br>12. A formal medical review as to how midostaurin is being tolerated and whether midostaurin should continue or not will be scheduled to occur at least by the end of the second 4-weekly cycle of treatment.<br>13. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, a treatment break approval form will be completed to re-start treatment<br>14. Midostaurin will otherwise be used as set out in its Summary of Product Characteristics (SPC). | No | TA728 | 22-Sep-21 | 21-Dec-21 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| MID3 | **Midostaurin** | For treating newly diagnosed FLT3 mutation positive acute myeloid leukaemia (FLT3-ITD or FLT3-TKD) in POST PUBESCENT CHILDREN LESS THAN 18 YEARS OLD where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with midostaurin will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br><br>2. This patient is a post pubescent child less than 18 years old and has a confirmed diagnosis of acute myeloid leukaemia.<br>Note: midostaurin is not licensed for AML in this age group and hence completion of this form also confirms that Trust policy is being followed as regards the use of unlicensed medicines.<br>Note: For adults there is a separate blueteq form.<br><br>3. The patient's AML has a FLT3 mutation (ITD or TKD) as determined by a validated test.<br><br>Please mark below which type of FLT3 mutation applies to this patient:<br>- ITD disease or<br>- TKD disease<br><br>4. The patient is newly diagnosed with FLT3 positive acute myeloid leukaemia and either has not received any induction chemotherapy or has only received a single cycle of induction chemotherapy whilst awaiting FLT3 status.<br><br>Please record the status as to induction chemotherapy:<br>- the patient has not yet received any induction chemotherapy or<br>- the patient has received only a single cycle of induction chemotherapy whilst awaiting the FLT3 result<br><br>5. The patient is fit for intensive induction chemotherapy.<br><br>6. The patient will be treated with midostaurin only in combination with standard mitoxantrone and cytarabine induction chemotherapy and then in combination with high dose cytarabine consolidation chemotherapy unless this patient is eligible for and has been entered into the NCRI Optimise-FLT3 Trial (ISRCTN 34016918) in which case midostaurin can also be given in combination with gemtuzumab ozogamicin with either DA or FLAG-Ida induction chemotherapy according to the Optimise-FLT3 trial protocol.<br><br>Note: Midostaurin is excluded from the NHS England Treatment Breaks Policy.<br><br>7. As maintenance monotherapy, midostaurin is to be only used in patients in complete remission of their AML.<br><br>8. In the maintenance monotherapy phase, a maximum of 12 x 28-day cycles of midostaurin will be used.<br><br>9. If the patient proceeds to a stem cell transplant, midostaurin will be permanently discontinued prior to the stem cell transplant conditioning regimen.<br><br>10. Midostaurin is to be otherwise used as set out in its Summary of Product Characteristics. | No | TA523 | 13-Jun-18 | 03-Feb-23 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| MOG1 | **Mogamulizumab** | Mogamulizumab as 3rd line systemic therapy or beyond 3rd line systemic therapy for patients with stage IIB to IVB mycosis fungoides where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with mogamulizumab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy. | No | TA754 | 15-Dec-21 | 15-Mar-22 |
| | | | 2. The prescribing clinician is fully aware of the management of and the treatment modifications that may be required for adverse reactions to mogamulizumab and the prescribing clinician understands the need for testing for hepatitis B before mogamulizumab treatment commences and the risk of tumour lysis syndrome in patients with rapidly proliferating disease and high tumour burden. | | | | |
| | | | 3. The patient has a diagnosis of mycosis fungoides.<br>Please note that there is a separate form MOG2 for patients with Sezary syndrome. | | | | |
| | | | 4. The disease stage of mycosis fungoides is stage IIB to IVB.<br>Please mark below the stage of disease that applies to this patient:<br>- stage IIB mycosis fungoides<br>- stage IIIA mycosis fungoides<br>- stage IIIB mycosis fungoides<br>- stage IVA1 mycosis fungoides<br>- stage IVA2 mycosis fungoides<br>- stage IVB mycosis fungoides<br>Note: the company sought consideration from NICE of stage IIB to IVB mycosis fungoides and hence mogamulizumab is only recommended by NICE in stages IIB to IVB mycosis fungoides. | | | | |
| | | | 5. The patient has received at least 2 lines of systemic treatments for mycosis fungoides.<br>Note: mogamulizumab is only recommended by NICE if the patient has received at least 2 lines of systemic therapy. | | | | |
| | | | 6. The patient has received 1st line systemic therapy for mycosis fungoides and was one of the treatments listed below.<br>Please mark below which 1st line systemic therapy was received by the patient:<br>- bexarotene<br>- interferon<br>- methotrexate<br>- another type of chemotherapy<br>- extracorporeal photopheresis | | | | |
| | | | 7. The patient has received 2nd line systemic therapy for mycosis fungoides and was one of the treatments listed below.<br>Please mark below which 2nd line systemic therapy was received by the patient:<br>- bexarotene<br>- interferon<br>- methotrexate<br>- another type of chemotherapy<br>- extracorporeal photopheresis allogeneic stem cell transplantation<br>- brentuximab vedotin if the mycosis fungoides was CD30 positive | | | | |
| | | | 8. If the patient has CD30 positive mycosis fungoides, the patient has either been treated with brentuximab vedotin or its use in this patient is contraindicated.<br>Please mark below which of the following applies to this patient:<br>- the patient has CD30 negative disease and hence use of brentuximab vedotin is inappropriate<br>- the patient has CD30 positive disease and has been treated with brentuximab vedotin<br>- the patient has CD30 positive disease and the use of brentuximab vedotin in this patient is contraindicated. | | | | |
| | | | 9. The patient has an ECOG performance status (PS) of 0 or 1. | | | | |
| | | | 10. The patient has not received any prior treatment with mogamulizumab unless the patient has received mogamulizumab via a company early access scheme and the patient meets all the other treatment criteria on this form | | | | |
| | | | 11. Mogamulizumab will be used as monotherapy. | | | | |
| | | | 12. Mogamulizumab will be stopped at whichever of the following events occurs first: disease progression or unacceptable toxicity or withdrawal of patient consent. | | | | |
| | | | 13. A formal medical review as to how mogamulizumab is being tolerated and whether mogamulizumab should continue or not will be scheduled to occur at least by the end of the second month of treatment. | | | | |
| | | | 14. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, the prescribing clinician will complete a treatment break approval form to restart treatment, including as appropriate if the patient has had an extended break on account of Covid-19. | | | | |
| | | | 15. Mogamulizumab will otherwise be used as set out in its Summary of Product Characteristics (SPC) with the exception of criteria 4 and 5 above. | | | | |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| MOG2 | **Mogamulizumab** | Mogamulizumab as 2nd line systemic therapy or beyond 2nd line systemic therapy for patients with stage IVA to IVB Sezary syndrome where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with mogamulizumab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy. | No | TA754 | 15-Dec-21 | 15-Mar-22 |
| | | | 2. The prescribing clinician is fully aware of the management of and the treatment modifications that may be required for adverse reactions to mogamulizumab and the prescribing clinician understands the need for testing for hepatitis B before mogamulizumab treatment commences and the risk of tumour lysis syndrome in patients with rapidly proliferating disease and high tumour burden. | | | | |
| | | | 3. The patient has a diagnosis of Sezary syndrome.<br>Please note that there is a separate form MOG1 for patients with mycosis fungoides. | | | | |
| | | | 4. The disease stage of Sezary syndrome is stage IVA to IVB.<br>Please mark below the stage of disease that applies to this patient:<br>- stage IVA1 Sezary syndrome<br>- stage IVA2 Sezary syndrome<br>- stage IVB Sezary syndrome | | | | |
| | | | 5. The patient has received at least 1 line of systemic treatment for Sezary syndrome.<br>Note: mogamulizumab is only recommended by NICE if the patient has received at least 1 line of systemic therapy. | | | | |
| | | | 6. The patient has received 1st line systemic therapy for Sezary syndrome.<br>Please mark below which 1st line systemic therapy was received by the patient:<br>- bexarotene<br>- interferon<br>- methotrexate<br>- another type of chemotherapy<br>- extracorporeal photopheresis | | | | |
| | | | 7. If the patient has CD30 positive Sezary syndrome, the patient has either been treated with brentuximab vedotin or its use in this patient is contraindicated.<br>Please mark below which of the following applies to this patient:<br>- the patient has CD30 negative disease and hence use of brentuximab vedotin is inappropriate<br>- the patient has CD30 positive disease and has been treated with brentuximab vedotin<br>- the patient has CD30 positive disease and the use of brentuximab vedotin in this patient is contraindicated. | | | | |
| | | | 8. The patient has an ECOG performance status (PS) of 0 or 1. | | | | |
| | | | 9. The patient has not received any prior treatment with mogamulizumab unless the patient has received mogamulizumab via a company early access scheme and the patient meets all the other treatment criteria on this form | | | | |
| | | | 10. Mogamulizumab will be used as monotherapy. | | | | |
| | | | 11. Mogamulizumab will be stopped at whichever of the following events occurs first: disease progression or unacceptable toxicity or withdrawal of patient consent. | | | | |
| | | | 12. A formal medical review as to how mogamulizumab is being tolerated and whether mogamulizumab should continue or not will be scheduled to occur at least by the end of the second month of treatment. | | | | |
| | | | 13. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, the prescribing clinician will complete a treatment break approval form to restart treatment, including as appropriate if the patient has had an extended break on account of Covid-19. | | | | |
| | | | 14. Mogamulizumab will otherwise be used as set out in its Summary of Product Characteristics (SPC) with the exception of criteria 4 and 5 above. | | | | |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| MOM1 | **Momelotinib monotherapy** | For the treatment of moderately to severely anaemic patients with myelofibrosis and disease-related splenomegaly or symptoms where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with momelotinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy. | No | TA957 | 20-Mar-24 | 18-Jun-24 |
| | | | 2. The patient is an adult with a diagnosis of primary myelofibrosis (also known as chronic idiopathic myelofibrosis) or post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis.<br><br>Please enter below as to which type of myelofibrosis applies to this patient:<br>- primary myelofibrosis or<br>- post polycythaemia vera myelofibrosis or<br>- post essential thrombocythaemia myelofibrosis | | | | |
| | | | 3. The patient's myelofibrosis has a risk category that is either intermediate-2 or high risk.<br><br>Please enter below which myelofibrosis risk category applies to this patient:<br>- intermediate-2 risk or<br>- high risk | | | | |
| | | | 4. The patient has disease-related splenomegaly or symptoms. | | | | |
| | | | 5. The patient has moderate to severe anaemia. | | | | |
| | | | 6. The patient has been previously treated with ruxolitinib or not.<br><br>Please enter below whether the patient has been previously treated with ruxolitinib or not:<br>- no previous treatment with ruxolitinib or<br>- yes, the patient has been previously treated with ruxolitinib | | | | |
| | | | 7. The patient has an ECOG performance status (PS) of 0 or 1 or 2. | | | | |
| | | | 8. In terms of active systemic therapy momelotinib is being given as monotherapy. | | | | |
| | | | 9. The patient has not previously received momelotinib unless the patient has received momelotinib via a company early access scheme and the patient meets all the other criteria listed here. | | | | |
| | | | 10. Momelotinib is to be continued as long as the benefit-risk remains positive for the patient. | | | | |
| | | | 11. The prescribing clinician is aware that momelotinib has clinically important interactions with various drugs which can affect the CYP3A4 and other enzyme systems and also transporters (as set out in sections 4.4 and 4.5 of | | | | |
| | | | 12. The prescribing clinician is aware of the risks of infection including Hepatitis B reactivation that can occur during treatment with momelotinib. | | | | |
| | | | 13. A formal medical review as to how momelotinib is being tolerated and whether treatment with momelotinib should continue or not will be scheduled to occur at least by the start of the third 4-weekly cycle of treatment. | | | | |
| | | | 14. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, the prescribing clinician will complete a treatment break approval form to restart treatment. | | | | |
| | | | 15. Momelotinib is to be otherwise used as set out in its Summary of Product Characteristics. | | | | |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| NAB1 | **Nab-Paclitaxel** | Paclitaxel as albumin-bound nanoparticles (nab-paclitaxel) for breast cancer where the following criteria have been met: | 1. An application has been made by and the first cycle of systemic anti -cancer therapy with nab-paclitaxel will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy | No | | | |
| | | | 2. The patient has a confirmed histological or cytological diagnosis of breast cancer. | | | | |
| | | | 3. The patient is being switched to nab-paclitaxel from either paclitaxel or docetaxel **either** following a severe hypersensitivity reaction which precludes further exposure to paclitaxel **or** docetaxel or to reduce the risks of treatment in potentially vulnerable patients | | | | |
| | | | 4. Nab-paclitaxel is to be used either as a single agent or in combination for<br>- neoadjuvant treatment<br>- adjuvant treatment<br>- treatment of metastatic disease | | | | |
| | | | 5. The licensed dose of nab-paclitaxel at 260mg/m2 IV every 21 days will be used when given as monotherapy.<br>Note: The dose may be attenuated when given in combination with other chemotherapies. | | | | |
| | | | 6. The patient has an ECOG performance status of 0, 1 or 2. | | | | |
| | | | 7. Trust policy regarding the use of unlicensed treatments has been followed as nab-paclitaxel<br>is not licensed for use in early breast cancer. (It is only licensed for use in metastatic breast cancer) | | | | |
| | | | 8. Nab-paclitaxel will otherwise be used as set out in its Summary of Product Characteristics (SPC). | | | | |
| NAB2 | **Nab-paclitaxel with gemcitabine** | The treatment of untreated metastatic pancreatic cancer only if other combination chemotherapies are unsuitable and they would otherwise have gemcitabine monotherapy | 1. This application is being been made by and the first cycle of systemic anti-cancer therapy with nab-paclitaxel plus gemcitabine will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy. | No | TA476 | 06-Sep-17 | 05-Dec-17 |
| | | | 2. The patient has confirmed histological or cytological diagnosis of pancreatic adenocarcinoma. | | | | |
| | | | 3. The patient has metastatic disease (patients with locally advanced disease are ineligible). | | | | |
| | | | 4. The patient is either completely treatment naïve for systemic therapy for pancreatic cancer or the patient has received prior systemic anti-cancer therapy as neo-adjuvant or adjuvant therapy AND such treatment was completed at least 6 months previously.<br>Please mark below whether or not previous systemic anti-cancer therapy for pancreatic cancer has ever been received in the neoadjuvant or the adjuvant disease settings:<br>- no previous neoadjuvant/adjuvant systemic therapy of any kind and treatment naïve for metastatic pancreatic cancer<br>- prior neoadjuvant chemotherapy for non-metastatic disease and the last dose received by the patient was 6 or more months prior to this application<br>- prior chemotherapy in the adjuvant setting and the last dose received by the patient was 6 or more months prior to this application | | | | |
| | | | 5. Nab-paclitaxel is to be used only in combination with gemcitabine. | | | | |
| | | | 6. Nab-paclitaxel plus gemcitabine is to be used as 1st line treatment only. | | | | |
| | | | 7. The patient has a performance status of 0 or 1. | | | | |
| | | | 8. The patient is not considered to be a suitable candidate for oxaliplatin- and irinotecan-based combination chemotherapy and would otherwise receive gemcitabine monotherapy. | | | | |
| | | | 9. Nab-paclitaxel will otherwise be used as set out in its Summary of Product Characteristics (SPC). | | | | |
| NEL1 | **Nelarabine** | The treatment of refractory T-cell acute lymphoblastic leukaemia or refractory T-cell lymphoblastic non-Hodgkin's lymphoma where all the following criteria are met: | 1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy | Yes | n/a - NHS England clinical policy | - | 01-Apr-21 |
| | | | 2. a) Refractory T-cell acute lymphoblastic leukaemia, OR | | | | |
| | | | b) Refractory T-cell lymphoblastic non-Hodgkin's lymphoma | | | | |
| | | | 3. Treatment intent is to proceed to bone marrow transplantation | | | | |

# National Cancer Drugs Fund (CDF) List

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|---|---|---|---|---|---|---|---|
| NER1 | **Neratinib** | The extended adjuvant therapy for hormone receptor positive HER2-overexpressed early breast cancer after completion of adjuvant therapy with HER2 targeted monotherapy with trastuzumab where the following criteria have been met: | 1. This application for neratinib as extended adjuvant chemotherapy is made by and the first cycle of adjuvant neratinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has histologically documented breast cancer which is **BOTH** hormone receptor positive and HER2 overexpressed (HER2 3+ by immunohistochemistry and/or has a ratio of ≥2.0 by in situ hybridisation).<br>Note: neratinib is not licensed for extended adjuvant therapy in hormone receptor negative patients.<br>3. The patient has been diagnosed with early breast cancer and this has been adequately excised.<br>4. That either the patient did not receive neoadjuvant therapy or the patient was treated with neoadjuvant therapy **AND** there was residual invasive carcinoma in the breast and/or the axilla.<br>Please mark below which applies to this patient:<br>- patient did not receive neoadjuvant therapy **or**<br>- patient did receive neoadjuvant therapy and there was residual invasive disease in the breast and/or axillary nodes<br>Note: neratinib is not recommended by NICE if any neoadjuvant therapy resulted in a pathological complete remission or if there was only residual carcinoma in situ disease in the breast and a pathological complete remission in the axillary nodes (if the axillary lymph node status was positive prior to neoadjuvant treatment).<br>5. The patient has received chemotherapy in the management of the early breast cancer either as neoadjuvant treatment pre-definitive surgery or as adjuvant therapy post-surgery.<br>6. The patient has completed adjuvant therapy with trastuzumab as HER2-targeted monotherapy and is within 1 year of completing such trastuzumab monotherapy.<br>Note: NICE has not recommended use of neratinib if the patient received any pertuzumab as part of adjuvant therapy. Patients treated with neoadjuvant chemotherapy in combination with pertuzumab and trastuzumab are only eligible for neratinib therapy if the pertuzumab was solely used as part of neoadjuvant treatment and no pertuzumab was used as part of adjuvant therapy.<br>7. The patient has an ECOG performance status of 0 or 1.<br>8. The left ventricular ejection fraction prior to commencing extended adjuvant therapy with neratinib is ≥50%.<br>9. Before commencing neratinib the patient will be instructed to initiate prophylactic treatment with anti-diarrhoeal medication with the first dose of neratinib and maintain regular dosing of the anti-diarrhoeal medication during the first 1-2 months of neratinib treatment, titrating the anti-diarrhoeal medication to a frequency of 1-2 bowel movements per day.<br>10. A formal medical review as to whether extended adjuvant treatment with neratinib should continue and at what dose will be scheduled to occur at least by the start of the 2nd month of treatment.<br>11. Treatment breaks of up to 3 weeks (as per SmPC recommendations) are allowed, but solely to allow toxicities to settle. Note the SmPC recommends that treatment is discontinued for patients who:<br>• Fail to recover to Grade 0 to 1 from treatment-related toxicity,<br>• have toxicities that result in a treatment delay > 3 weeks, or<br>• For patients that are unable to tolerate 120 mg daily<br>Where an unplanned treatment break of more than 6 weeks beyond the expected 4-weekly cycle length occurs and is unrelated to settling of treatment toxicities, I will complete a treatment break approval form to restart treatment<br>12. Neratinib will be otherwise used as set out in its Summary of Product Characteristics (SPC) | No | TA612 | 20-Nov-19 | 18-Feb-20 |
| N/A | **Nilotinib** | Nilotinib for the treatment of untreated chronic phase chronic myeloid leukaemia | 1. I confirm that an application has been made and the first cycle of systemic anti-cancer therapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. I confirm that the patient has chronic phase myeloid leukaemia<br>3. I confirm that the patient has received no prior treatment<br>4. I confirm that imatinib is not appropriate for this patient and that this has been discussed and supported by the relevant MDT involved in CML decision making<br>5. I confirm that nilotinib will be used as outlined in the Summary of Product Characteristics (SPC). | No | TA426 | 21-Dec-16 | 21-Mar-17 |
| NIL4 | **Nilotinib** | For treating imatinib-resistant or imatinib-intolerant Philadelphia chromosome positive chronic phase chronic myeloid leukaemia in children where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with nilotinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has Philadelphia chromosome positive CML in chronic phase.<br>3. The patient has been previously treated with imatinib which had to be discontinued due to resistance or intolerance.<br>Please mark below whether the patient was resistant to or intolerant of imatinib:<br>- resistant to imatinib or<br>- intolerant of imatinib<br>4. The use of nilotinib has been discussed by the relevant multi-disciplinary team (MDT) involved in chronic myeloid leukaemia (CML) decision making, which must include at least two consultants in the subspecialty with active and credible expertise in the relevant field of whom at least one must be a consultant paediatrician.<br>5. The patient is a child and I understand the Summary of Product Characteristics (SPC) states that 'there is no experience with treatment of paediatric patients below 2 years of age' and 'there is limited data in imatinib-resistant or intolerant paediatric patients below 6 years of age'.<br>6. Treatment with nilotinib will be as monotherapy and with dosing as described in the Summary of Product Characteristics (SPC).<br>7. The prescribing clinician understands the SPC cautions that in paediatric patients after at least 2 years of treatment, treatment-related adverse events associated with bone growth and development were reported and close monitoring of growth in paediatric patients under nilotinib treatment is therefore recommended.<br>8. When a treatment break of more than 6 weeks beyond the expected cycle length is needed, I will complete a treatment break approval form to restart treatment, including indicating as appropriate if the patient had an extended break because of COVID19.<br>9. Nilotinib will otherwise be used as outlined in the Summary of Product Characteristics (SPC). | No | As referenced in TA425 | 21-Dec-16 | 21-Mar-17 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| NIR1 | **Niraparib** | Niraparib as maintenance treatment in patients with high grade epithelial ovarian, fallopian tube or primary peritoneal carcinoma who have a deleterious or suspected deleterious germline and/or somatic BRCA mutation and who have a recent FIRST RELAPSE of platinum-sensitive disease and who are now in response following a SECOND platinum-based chemotherapy where the following criteria have been met:<br><br>There is a separate form (NIR2) for niraparib as maintenance treatment in patients with high grade epithelial ovarian, fallopian tube or primary peritoneal carcinoma who do NOT have a deleterious or suspected deleterious germline and/or somatic BRCA mutation and who are in response following platinum-based SECOND or subsequent line chemotherapy. | 1. This application is made by and the first cycle of systemic anti-cancer therapy with niraparib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br><br>2. This patient has a proven histological diagnosis of predominantly high grade serous or high grade endometrioid or high grade clear cell ovarian, fallopian tube or primary peritoneal carcinoma.<br>Please enter below as to which is the predominant histology in this patient:<br>- high grade serous adenocarcinoma **or**<br>- high grade endometrioid adenocarcinoma **or**<br>- high grade clear cell carcinoma<br><br>3. This patient has had germline and/or somatic (tumour) BRCA testing.<br><br>4. This patient HAS a documented deleterious or suspected deleterious BRCA mutation(s) in the germline or in the tumour or in both.<br>Please enter below the type of testing done in this patient to determine the presence of deleterious or suspected deleterious BRCA mutation(s):<br>- in the germline only **or**<br>- in the tumour (somatic tissue) only **or**<br>- in both germline and somatic tissue.<br><br>5. This patient HAS a documented deleterious or suspected deleterious BRCA 1 or BRCA 2 mutation(s).<br>Please enter below as to which deleterious or suspected deleterious BRCA mutation(s) the patient has:<br>- BRCA 1 mutation **or**<br>- BRCA 2 mutation **or**<br>- both BRCA1 and BRCA 2 mutations.<br><br>6. The patient responded to initial (first line) platinum-based chemotherapy i.e. the recent FIRST relapse has occurred after a previous response to initial (first line) platinum-based treatment.<br><br>7. The patient has recently completed a SECOND platinum-based chemotherapy and has received a minimum of 4 cycles of platinum-based treatment.<br><br>8. This patient has responded to the recently completed SECOND platinum-based chemotherapy and has achieved a partial or complete response to treatment according to the definitions given below and there is no evidence of progressive disease on the post-treatment scan or a rising CA125 level.<br>Please enter below as to which response assessment applies to this patient:<br>- achieved a complete response at the end of the 2nd platinum-based chemotherapy i.e. has no measurable or non-measurable disease on the post-chemotherapy scan and the CA125 is normal<br>- achieved a partial response at the end of the 2nd platinum-based chemotherapy i.e. has had a at least 30% reduction in measurable or non-measurable disease from the start of to the completion of the 2nd platinum-based chemotherapy or the patient has a complete remission on the post-chemotherapy CT scan but the CA125 has not decreased to within the normal range.<br><br>9. The patient is currently less than 8 weeks from the date of the last infusion of the last cycle of the 2nd platinum-based chemotherapy.<br><br>10. The patient has not previously received any PARP inhibitor unless olaparib or rucaparib via the CDF has had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression.<br>Please mark below which of the three scenarios applies to this patient:<br>- the patient has never previously received a PARP inhibitor **or**<br>- the patient has previously received olaparib via the CDF and this has had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression<br>- the patient has previously received rucaparib via the CDF and this has had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression.<br><br>11. Niraparib will be used as monotherapy.<br><br>12. The prescribing clinician understands that though the licensed starting dose for niraparib in this 2nd line maintenance indication is 300mg daily (as opposed to the licensed starting dose of niraparib in the 1st line maintenance setting usually being 200mg daily), clinical experts informed NICE that the usual starting dose for niraparib in this 2nd line maintenance setting is 200mg daily.<br><br>13. The patient has an ECOG performance status of either 0 or 1.<br>Please enter below as to which ECOG performance status applies to this patient:<br>- ECOG PS 0 **or**<br>- ECOG PS 1.<br>Note: a patient with a performance status of 2 or more is not eligible for niraparib.<br><br>14. Niraparib is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment.<br><br>15. A formal medical review as to whether maintenance treatment with niraparib should continue or not will be scheduled to occur at least by the start of the second 4-weekly cycle of treatment (in view of the potential need for dose delay or dose reduction in the 2nd cycle of treatment).<br><br>16. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment, including as appropriate if the patient had an extended treatment break on account of Covid-19.<br><br>17. Niraparib is to be otherwise used as set out in its Summary of Product Characteristics. | No | TA784 | 20-Apr-22 | 19-Jul-22 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| NIR2 | **Niraparib** | Niraparib as maintenance treatment in patients with high grade epithelial ovarian, fallopian tube or primary peritoneal carcinoma who do NOT have a deleterious or suspected deleterious germline and/or somatic BRCA mutation and who have a recent FIRST OR SUBSEQUENT relapse of platinum-sensitive disease and who are now in response following a SECOND OR SUBSEQUENT platinum-based chemotherapy where the following criteria have been met:<br><br>There is a separate form (NIR1) for niraparib as maintenance treatment in patients with high grade epithelial ovarian, fallopian tube or primary peritoneal carcinoma who have a deleterious or suspected deleterious germline and/or somatic BRCA mutation and who are in response following a platinum-based SECOND line chemotherapy. | 1. This application is made by and the first cycle of systemic anti-cancer therapy with niraparib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br><br>2. This patient has a proven histological diagnosis of predominantly high grade serous or high grade endometrioid or high grade clear cell ovarian, fallopian tube or primary peritoneal carcinoma.<br>Please enter below as to which is the predominant histology in this patient:<br>- high grade serous adenocarcinoma **or**<br>- high grade endometrioid adenocarcinoma **or**<br>- high grade clear cell carcinoma<br><br>3. This patient has had germline and/or somatic (tumour) BRCA testing.<br>4. This patient DOES NOT HAVE a documented deleterious or suspected deleterious BRCA mutation(s) in the germline or in the tumour.<br>5. The patient had disease which was sensitive to the penultimate line of platinum-based chemotherapy (i.e. the disease responded to the line of platinum-based chemotherapy preceding the most recent line of platinum-based chemotherapy).<br>6. The patient has recently completed a further line of platinum-based chemotherapy and has received a minimum of 4 cycles of platinum-based treatment.<br>Please enter below what line of platinum-based treatment was the most recent line of treatment:<br>- 2nd line **or**<br>- 3rd line **or**<br>- 4th line or greater<br><br>7. This patient has responded to the recently completed SECOND OR SUBSEQUENT LINE platinum-based chemotherapy and has achieved a partial or complete response to treatment according to the definitions given below and there is no evidence of progressive disease on the post-treatment scan or a rising CA125 level.<br>Please enter below as to which response assessment applies to this patient:<br>- achieved a complete response at the end of the recent 2nd or subsequent line platinum-based chemotherapy i.e. has no measurable or non-measurable disease on the post-chemotherapy scan and the CA125 is normal<br>- achieved a partial response at the end of the recent 2nd or subsequent line platinum-based chemotherapy i.e. has had at least a 30% reduction in measurable or non-measurable disease from the start of to the completion of the 2nd platinum-based chemotherapy or the patient has a complete remission on the post-chemotherapy CT scan but the CA125 has not decreased to within the normal range<br><br>8. The patient is currently less than 8 weeks from the date of the last infusion of the last cycle of the recent 2nd or subsequent line platinum-based chemotherapy.<br>9. The patient has not previously received any PARP inhibitor unless rucaparib via the CDF has had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression.<br>Please mark below which of the two scenarios applies to this patient:<br>- the patient has never previously received a PARP inhibitor **or**<br>- the patient has previously received rucaparib via the CDF and this has had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression.<br><br>10. Niraparib will be used as monotherapy.<br>11. The prescribing clinician understands that though the licensed starting dose for niraparib in this 2nd/subsequent line maintenance indication is 300mg daily (as opposed to the licensed starting dose of niraparib in the 1st line maintenance setting usually being 200mg daily), clinical experts informed NICE that the usual starting dose for niraparib in this 2nd/subsequent line maintenance setting is 200mg daily.<br>12. The patient has an ECOG performance status of either 0 or 1.<br>Please enter below as to which ECOG performance status applies to this patient:<br>- ECOG PS 0 **or**<br>- ECOG PS 1.<br>Note: a patient with a performance status of 2 or more is not eligible for niraparib.<br><br>13. Niraparib is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment.<br>14. A formal medical review as to whether maintenance treatment with niraparib should continue or not will be scheduled to occur at least by the start of the second 4-weekly cycle of treatment (in view of the potential need for dose delay or dose reduction in the 2nd cycle of treatment).<br>15. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment, including as appropriate if the patient had an extended treatment break on account of Covid-19.<br>16. Niraparib is to be otherwise used as set out in its Summary of Product Characteristics. | No | TA1129 | 20-Apr-22 | 19-Jul-22 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| NIR3 | **Niraparib** | Niraparib monotherapy as maintenance treatment in patients with high grade epithelial stage III or IV ovarian, fallopian tube or primary peritoneal carcinoma who are in response following platinum-based FIRST line chemotherapy AND who HAVE a deleterious or suspected deleterious BRCA germline and/or somatic BRCA mutation [NICE TA673] where the following criteria have been met:<br><br>There is a separate form NIR4 for use of niraparib monotherapy as maintenance treatment in patients with high grade epithelial stage III or IV ovarian, fallopian tube or primary peritoneal carcinoma who are in response following platinum-based FIRST line chemotherapy and who DO NOT HAVE a deleterious or suspected deleterious BRCA germline and/or somatic BRCA mutation | 1. This application for maintenance niraparib is being made by and the first cycle of systemic anti-cancer therapy with niraparib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. This patient has a proven histological diagnosis of predominantly high grade serous or high grade endometrioid or high grade clear cell ovarian, fallopian tube or primary peritoneal carcinoma.<br>Please enter below as to which is the predominant histology in this patient:<br>- high grade serous adenocarcinoma **or**<br>- high grade endometrioid adenocarcinoma **or**<br>- high grade clear cell carcinoma<br>3. This patient has had germline and/or somatic (tumour) BRCA testing.<br>Please enter below the type of tissue on which BRCA mutation testing results are known at the time of this application:<br>- proven germline BRCA mutation **or**<br>- proven somatic BRCA mutation only i.e. somatic BRCA mutation positive and germline BRCA mutation negative **or**<br>- somatic BRCA mutation positive and germline BRCA mutation test not yet known<br>4. This patient HAS a documented deleterious or suspected deleterious BRCA 1 or BRCA 2 mutation(s).<br>5. The patient has recently diagnosed FIGO stage III or IV ovarian, fallopian tube or primary peritoneal carcinoma and has just completed 1st line platinum-based chemotherapy.<br>Note: maintenance niraparib in this 1st line maintenance indication is not funded for patients with recently diagnosed and treated stage I-IIC disease.<br>6. One of the following scenarios applies to the surgical management of the patient in relation to the stage of the disease:<br>- the patient has stage III disease and had an upfront attempt at optimal cytoreductive surgery and had no visible residual disease at the end of surgery **or**<br>- the patient has stage III disease and had an upfront attempt at optimal cytoreductive surgery and had visible residual disease at the end of surgery **or**<br>- the patient has stage III disease and had an interval attempt at optimal cytoreductive surgery and had no visible disease at the end of surgery **or**<br>- the patient has stage III disease and had an interval attempt at optimal cytoreductive surgery and had visible disease at the end of surgery **or**<br>- the patient has stage III disease and has had a biopsy only with no upfront or interval attempt at cytoreductive surgery **or**<br>- the patient has stage IV disease and had an upfront attempt at optimal cytoreductive surgery and had no visible disease at the end of surgery **or**<br>- the patient has stage IV disease and had an upfront attempt at optimal cytoreductive surgery and had visible residual disease at the end of surgery **or**<br>- the patient has stage IV disease and had an interval attempt at optimal cytoreductive surgery and had no visible disease at the end of surgery **or**<br>- the patient has stage IV disease and had an interval attempt at optimal cytoreductive surgery and had visible disease at the end of surgery **or**<br>- the patient has stage IV disease and has had a biopsy only with no upfront or interval attempt at cytoreductive surgery<br>7. The patient has been treated with platinum-based 1st line chemotherapy and has received a minimum of 4 cycles of platinum-based treatment.<br>8. The patient has either received bevacizumab as part of 1st line platinum-based chemotherapy or not:<br>Please indicate below whether bevacizumab was used in combination with the 1st line chemotherapy:<br>- bevacizumab 7.5mg/Kg given in combination with platinum-based chemotherapy or<br>- bevacizumab 15mg/Kg given in combination with platinum-based chemotherapy or<br>- no bevacizumab used in combination with chemotherapy<br>***Criteria continue over the page*** | Yes | TA1129 | 12-Feb-26 | 14-Mar-26 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| NIR3 (CONT) | **Niraparib** | Niraparib monotherapy as maintenance treatment in patients with high grade epithelial stage III or IV ovarian, fallopian tube or primary peritoneal carcinoma who are in response following platinum-based FIRST line chemotherapy AND who HAVE a deleterious or suspected deleterious BRCA germline and/or somatic BRCA mutation [NICE TA673] where the following criteria have been met:<br><br>There is a separate form NIR4 for use of niraparib monotherapy as maintenance treatment in patients with high grade epithelial stage III or IV ovarian, fallopian tube or primary peritoneal carcinoma who are in response following platinum-based FIRST line chemotherapy and who DO NOT HAVE a deleterious or suspected deleterious BRCA germline and/or somatic BRCA mutation | 9. This patient is in response to the recently completed 1st line platinum-based chemotherapy and has achieved a partial or complete response to treatment according to the definitions given below and has no evidence of progressive disease on the post-treatment scan or a rising CA125 level.<br>Please enter below as to which response assessment applies to this patient:<br>- achieved a complete response at the end of 1st line platinum-based chemotherapy i.e. has no measurable or non-measurable disease on the post-chemotherapy scan and the CA125 is normal or<br>- achieved a complete response at the end of 1st line platinum-based chemotherapy i.e. has no measurable or non-measurable disease on the post-chemotherapy scan and the CA125 has not decreased to within the normal range or<br>- achieved a partial response at the end of 1st line platinum-based chemotherapy i.e. has had a ≥30% reduction in measurable or non-measurable disease from the start of to the completion of 1st line chemotherapy and the CA125 is normal or<br>- achieved a partial response at the end of 1st line platinum-based chemotherapy i.e. has had a ≥30% reduction in measurable or non-measurable disease from the start of to the completion of 1st line chemotherapy and the CA125 has not decreased to within the normal range. | Yes | TA1129 | 12-Feb-26 | 14-Mar-26 |
| | | | 10. The patient will commence maintenance niraparib within 12 weeks from the date of the first day of the last cycle of 1st line chemotherapy unless the patient was previously entered into the company's early access scheme for maintenance niraparib after 1st line chemotherapy and all the other treatment criteria set out in this form are fulfilled. | | | | |
| | | | 11. The patient has not previously received any PARP inhibitor unless either the patient has received niraparib as part of a company early access scheme for this 1st line maintenance indication and the patient meets all the other criteria set out in this form or 1st line maintenance olaparib monotherapy has had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression.<br>Please mark below which scenario applies to this patient:<br>- the patient has never previously received a PARP inhibitor or<br>- the patient has received niraparib as part of a company early access scheme for this 1st line maintenance indication and all the other criteria set out in this form are fulfilled or<br>- the patient has previously received olaparib monotherapy as 1st line maintenance therapy and this has had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression | | | | |
| | | | 12. Niraparib will be used as monotherapy. | | | | |
| | | | 13. Maintenance niraparib is not being administered concurrently with maintenance bevacizumab. | | | | |
| | | | 14. The patient has an ECOG performance status of either 0 or 1.<br>Note: a patient with a performance status of 2 or more is not eligible for niraparib | | | | |
| | | | 15. Niraparib is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment, whichever is the sooner.<br>Note: NICE heard evidence during the niraparib appraisal that clinicians would wish to discuss with patients in continued complete remission when it would be an appropriate time to discontinue maintenance niraparib therapy and that this time was likely to be after approximately 3 years of maintenance treatment. | | | | |
| | | | 16. The prescribing clinician understands that the recommended starting dose for niraparib is 200mg daily unless the patient weighs ≥77Kg and has a platelet count ≥150,000 x $10^9$/uL in which case the recommended starting dose is 300mg daily.<br>Please indicate below the starting dose for this patient:<br>- niraparib 200mg daily or<br>- niraparib 300mg daily | | | | |
| | | | 17. The prescribing clinician understands that the marketing authorisation for niraparib recommends that full blood counts are performed weekly for the 1st month of treatment with niraparib, monthly for the next 10 months of therapy and then periodically thereafter during drug treatment with niraparib. | | | | |
| | | | 18. The prescribing clinician understands that the marketing authorisation for niraparib recommends that the patient's blood pressure is monitored weekly for the first 2 months of treatment, monthly for the 1st year of therapy and | | | | |
| | | | 19. A first formal medical review as to whether maintenance treatment with niraparib should continue or not will be scheduled to occur at least by the start of the third 4-weekly cycle of treatment. | | | | |
| | | | 20. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment, including as appropriate if the patient had an extended break on account of Covid-19. | | | | |
| | | | 21. Niraparib is to be otherwise used as set out in its Summary of Product Characteristics | | | | |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| NIR4 | **Niraparib** | Niraparib monotherapy as maintenance treatment in patients with high grade epithelial stage III or IV ovarian, fallopian tube or primary peritoneal carcinoma who are in response following platinum-based FIRST line chemotherapy AND who DO NOT HAVE a deleterious or suspected deleterious BRCA germline and/or somatic BRCA mutation [NICE TA673]<br><br>There is a separate form NIR3 for use of niraparib monotherapy as maintenance treatment in patients with high grade epithelial stage III or IV ovarian, fallopian tube or primary peritoneal carcinoma who are in response following platinum-based FIRST line chemotherapy and who HAVE a deleterious or suspected deleterious BRCA germline and/or somatic BRCA mutation | 1. This application for maintenance niraparib is being made by and the first cycle of systemic anti-cancer therapy with niraparib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. This patient has a proven histological diagnosis of predominantly high grade serous or high grade endometrioid or high grade clear cell ovarian, fallopian tube or primary peritoneal carcinoma.<br>Please enter below as to which is the predominant histology in this patient:<br>- high grade serous adenocarcinoma **or**<br>- high grade endometrioid adenocarcinoma **or**<br>- high grade clear cell carcinoma<br>3. This patient has had germline and/or somatic (tumour) BRCA testing.<br>Please enter below the type of tissue on which BRCA mutation testing has been done:<br>- negative germline BRCA mutation test with somatic BRCA mutation test not done or<br>- negative somatic BRCA mutation test<br>4. This patient DOES NOT HAVE a documented deleterious or suspected deleterious BRCA 1 or BRCA 2 mutation(s).<br>5. The patient has recently diagnosed FIGO stage III or IV ovarian, fallopian tube or primary peritoneal carcinoma and has just completed 1st line platinum-based chemotherapy.<br>Note: maintenance niraparib in this 1st line maintenance indication is not funded for patients with recently diagnosed and treated stage I-IIC disease.<br>6. One of the following scenarios applies to the surgical management of the patient in relation to the stage of the disease:<br>- the patient has stage III disease and had an upfront attempt at optimal cytoreductive surgery and had no visible residual disease at the end of surgery **or**<br>- the patient has stage III disease and had an upfront attempt at optimal cytoreductive surgery and had visible residual disease at the end of surgery **or**<br>- the patient has stage III disease and had an interval attempt at optimal cytoreductive surgery and had no visible disease at the end of surgery **or**<br>- the patient has stage III disease and had an interval attempt at optimal cytoreductive surgery and had visible disease at the end of surgery **or**<br>- the patient has stage III disease and has had a biopsy only with no upfront or interval attempt at cytoreductive surgery **or**<br>- the patient has stage IV disease and had an upfront attempt at optimal cytoreductive surgery and had no visible disease at the end of surgery **or**<br>- the patient has stage IV disease and had an upfront attempt at optimal cytoreductive surgery and had visible residual disease at the end of surgery **or**<br>- the patient has stage IV disease and had an interval attempt at optimal cytoreductive surgery and had no visible disease at the end of surgery **or**<br>- the patient has stage IV disease and had an interval attempt at optimal cytoreductive surgery and had visible disease at the end of surgery **or**<br>- the patient has stage IV disease and has had a biopsy only with no upfront or interval attempt at cytoreductive surgery<br>7. The patient has been treated with platinum-based 1st line chemotherapy and has received a minimum of 4 cycles of platinum-based treatment.<br>8. The patient has either received bevacizumab as part of 1st line platinum-based treatment or not:<br>Please indicate below whether bevacizumab was used in combination with the 1st line chemotherapy:<br>- bevacizumab 7.5mg/Kg given in combination with platinum-based chemotherapy **or**<br>- bevacizumab 15mg/Kg given in combination with platinum-based chemotherapy **or**<br>- no bevacizumab used in combination with chemotherapy<br>9. This patient is in response to the recently completed 1st line platinum-based chemotherapy and has achieved a partial or complete response to treatment according to the definitions given below and has no evidence of progressive disease on the post-treatment scan or a rising CA125 level.<br>Please enter below as to which response assessment applies to this patient:<br>- achieved a complete response at the end of 1st line platinum-based chemotherapy i.e. has no measurable or non-measurable disease on the post-chemotherapy scan and the CA125 is normal **or**<br>- achieved a complete response at the end of 1st line platinum-based chemotherapy i.e. has no measurable or non-measurable disease on the post-chemotherapy scan and the CA125 has not decreased to within the normal range **or**<br>- achieved a partial response at the end of 1st line platinum-based chemotherapy i.e. has had a ≥30% reduction in measurable or non-measurable disease from the start of to the completion of 1st line chemotherapy and the CA125 is normal **or**<br>- achieved a partial response at the end of 1st line platinum-based chemotherapy i.e. has had a ≥30% reduction in measurable or non-measurable disease from the start of to the completion of 1st line chemotherapy and the CA125 has not decreased to within the normal range.<br><br>***Criteria continue over the page*** | Yes | TA1129 | 12-Feb-26 | 14-Mar-26 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| NIR4 (CONT) | **Niraparib** | Niraparib monotherapy as maintenance treatment in patients with high grade epithelial stage III or IV ovarian, fallopian tube or primary peritoneal carcinoma who are in response following platinum-based FIRST line chemotherapy AND who DO NOT HAVE a deleterious or suspected deleterious BRCA germline and/or somatic BRCA mutation<br><br>There is a separate form NIR3 for use of niraparib monotherapy as maintenance treatment in patients with high grade epithelial stage III or IV ovarian, fallopian tube or primary peritoneal carcinoma who are in response following platinum-based FIRST line chemotherapy and who HAVE a deleterious or suspected deleterious BRCA germline and/or somatic BRCA mutation | 10. The patient will commence maintenance niraparib monotherapy within 12 weeks from the date of the first day of the last cycle of 1st line chemotherapy unless the patient was previously entered into the company's early access scheme for maintenance niraparib after 1st line chemotherapy and all the other treatment criteria set out in this form are fulfilled. | Yes | TA1129 | 12-Feb-26 | 14-Mar-26 |
| | | | 11. The patient has not previously received any PARP inhibitor unless the patient received 1st line maintenance rucaparib which has had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression.<br><br>Please mark below which scenario applies to this patient:<br>- the patient has never previously received a PARP inhibitor<br>- the patient has a positive status for homologous recombination deficient disease and received 1st line maintenance rucaparib which has had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression.<br>- the patient has a negative status for homologous recombination deficient disease and received 1st line maintenance rucaparib which has had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression. | | | | |
| | | | 12. Niraparib will be used as monotherapy. | | | | |
| | | | 13. Maintenance niraparib is not being administered concurrently with maintenance bevacizumab. | | | | |
| | | | 14. The patient has an ECOG performance status of either 0 or 1.<br>Note: a patient with a performance status of 2 or more is not eligible for niraparib | | | | |
| | | | 15. Niraparib is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment, whichever is the sooner.<br>Note: NICE heard evidence during the niraparib appraisal that clinicians would wish to discuss with patients in continued complete remission when it would be an appropriate time to discontinue maintenance niraparib therapy and that this time was likely to be after approximately 3 years of maintenance treatment. | | | | |
| | | | 16. The prescribing clinician understands that the recommended starting dose for niraparib is 200mg daily unless the patient weighs ≥77Kg and has a platelet count ≥150,000 x $10^9$/uL in which case the recommended starting dose is 300mg daily.<br>Please indicate below the starting dose for this patient:<br>- niraparib 200mg daily **or**<br>- niraparib 300mg daily | | | | |
| | | | 17. The prescribing clinician understands that the marketing authorisation for niraparib recommends that full blood counts are performed weekly for the 1st month of treatment with niraparib, monthly for the next 10 months of therapy and then periodically thereafter during drug treatment with niraparib. | | | | |
| | | | 18. The prescribing clinician understands that the marketing authorisation for niraparib recommends that the patient's blood pressure is monitored weekly for the first 2 months of treatment, monthly for the 1st year of therapy and then periodically thereafter during drug treatment with niraparib. | | | | |
| | | | 19. A first formal medical review as to whether maintenance treatment with niraparib should continue or not will be scheduled to occur at least by the start of the third 4-weekly cycle of treatment. | | | | |
| | | | 20. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment, including as appropriate if the patient had an extended break on account of Covid-19. | | | | |
| | | | 21. Niraparib is to be otherwise used as set out in its Summary of Product Characteristics | | | | |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| NIV1 | **Nivolumab** | Nivolumab for previously treated advanced renal cell carcinoma | 1. This application is being made by and the first cycle of systemic anti-cancer therapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br><br>2. The patient has unresectable locally advanced or metastatic renal cell carcinoma (RCC) which has either a clear cell component or is one of the types of RCC as indicated below.<br>Please indicate below which RCC histology applies to this patient:<br>- RCC with a clear cell component or<br>- Papillary RCC or<br>- Chromophobe RCC or<br>- Collecting duct RCC (Bellini collecting duct RCC) or<br>- Medullary RCC or<br>- Mucinous tubular and spindle cell RCC or<br>- Multilocular cystic RCC or<br>- XP11 translocation RCC or<br>- Unclassified RCC<br><br>3. The patient has been previously treated with only 1 or 2 previous lines of antiangiogenic therapy for advanced or metastatic disease.<br>Please indicate below the number of prior lines of antiangiogenic therapy with which the patient has been treated:<br>- 1 prior line<br>- 2 prior lines<br><br>4. The patient is either completely treatment naïve for immune-modulatory therapies (anti-Programmed Death receptor-1 (PD-1), anti-Programmed Death-1 ligand-1 (PD-L1), anti-PD L2, anti-CD137 or anti-cytotoxic T lymphocyte associated antigen-4 (anti-CTLA-4) antibodies) of any kind for RCC or if the patient has received prior immune-modulatory therapies in the context of adjuvant/neoadjuvant therapy, then such treatment was completed 12 or more months prior to the first relapse and the patient meets all other criteria listed here.<br>Please mark below whether or not previous systemic immune-modulatory therapy for RCC has ever been received in the adjuvant/neoadjuvant/advanced disease setting:<br>- no previous therapy with immune-modulatory therapies (anti-Programmed Death receptor-1 (PD-1), anti-Programmed Death-1 ligand-1 (PD-L1), anti-PD L2, anti-CD137 or anti-cytotoxic T lymphocyte associated antigen-4 (anti-CTLA-4) antibodies) of any kind or<br>- prior adjuvant/neoadjuvant therapy with immune-modulatory therapies for RCC (anti-Programmed Death receptor-1 (PD-1), anti-Programmed Death-1 ligand-1 (PD-L1), anti-PD L2, anti-CD137 or anti-cytotoxic T lymphocyte associated antigen-4 (anti-CTLA-4) antibodies) and last dose received by the patient was 12 or more months prior to first relapse<br>Please mark in the box the time between the end of treatment with adjuvant/neoadjuvant immune-modulatory therapy and first relapse:<br>_____<br><br>5. The patient's Karnofsky performance status (KPS) is 70 or more.<br><br>6. The patient will receive the licensed dose, frequency, and route of nivolumab for this indication, as shown below<br>•**Subcutaneously** – at a dose of 600mg every 2 weeks, or 1200mg every 4 weeks<br>•**Intravenously** – at a dose of 240mg every 2 weeks, or 480mg every 4 weeks<br><br>7. The patient is to be treated until loss of clinical benefit or excessive toxicity or withdrawal of patient consent, whichever is the sooner.<br><br>8. When a treatment break of more than 12 weeks beyond the expected 2- or 4-weekly cycle length is needed, I will complete a treatment break approval form requesting a restart of treatment. This **must** be approved before nivolumab is re-commenced<br><br>9. Nivolumab will otherwise be prescribed and administered as outlined in its Summary of Product Characteristics (SPC). | No | TA417 | 23-Nov-16 | 23-Dec-16 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| NIV2 | **Nivolumab** | The treatment of relapsed or refractory classical Hodgkin Lymphoma in ADULT patients where all the following criteria are met: | 1. An application has been made by and the first cycle of systemic anti-cancer therapy is to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy<br>2. The prescribing clinician is aware of the management of and the treatment modifications that may be required for immune-related adverse reactions due to anti-PD-L1 treatments including pneumonitis, colitis, nephritis, endocrinopathies and hepatitis<br>3. The patient has a histologically confirmed diagnosis of classical Hodgkin's Lymphoma<br>4. The patient has relapsed or refractory disease<br>5. The patient has received prior high-dose conditioning chemotherapy followed by autologous stem cell transplant (ASCT) as part of previous therapy for classical Hodgkin's Lymphoma<br>6. The patient has had prior treatment with brentuximab vedotin<br>7. The patient has an ECOG performance status (PS) 0-1<br>8. The patient is an adult*.<br>*note there is a separate Blueteq form to be used for nivolumab in this indication in children.<br>9. Nivolumab will be given as monotherapy.<br>10. The patient has no known central nervous system lymphoma.<br>11. The patient has not received prior treatment with an anti-PD-1, anti-PD-L2, anti-CD137, or anti-Cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) antibody unless received as part of the nivolumab EAMS programme for this indication and meeting all other criteria listed.<br>12. The patient will receive a maximum treatment duration of 2 years of uninterrupted treatment or 52 administrations (where administered every 2 weeks) or 26 administrations (where administered every 4 weeks) with nivolumab, whichever is the later.<br>13. When a treatment break of more than 12 weeks beyond the expected cycle length is needed, a treatment break approval form will be completed to restart treatment.<br>14. Nivolumab will otherwise be used as set out in its Summary of Product Characteristics (SPC)*<br>* Nivolumab can also be administered as 480mg every 4 weeks | Yes | TA462 | 26-Aug-17 | 26-Aug-17 |
| NIV3 | **Nivolumab** | The treatment of relapsed or refractory classical Hodgkin Lymphoma in PAEDIATRIC patients where all the following criteria are met: | 1. An application has been made by and the first cycle of systemic anti-cancer therapy is to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy<br>2. The prescribing clinician is aware of the management of and the treatment modifications that may be required for immune-related adverse reactions due to anti-PD-L1 treatments including pneumonitis, colitis, nephritis, endocrinopathies and hepatitis.<br>3. The patient has a histologically confirmed diagnosis of classical Hodgkin's Lymphoma<br>4. The patient has relapsed or refractory disease<br>5. The patient has received prior high-dose conditioning chemotherapy followed by autologous stem cell transplant (ASCT) as part of previous therapy for classical Hodgkin's Lymphoma<br>6. The patient has had prior treatment with brentuximab vedotin<br>7. The patient has an ECOG performance status (PS) 0-1<br>8. The patient is a child* and either post pubescent or is pre pubescent and will receive nivolumab dosage as described in the publication Blood 2016; 128: 5414<br>*note there is a separate Bluteq form to be used for nivolumab in this indication in adults.<br>9. Nivolumab will be given as monotherapy.<br>10. The patient has no known central nervous system lymphoma.<br>11. Nivolumab will only be requested by and administered in principal treatment centres.<br>12. The use of the nivolumab has been discussed at a multi disciplinary team (MDT) meeting which must include at least two consultants in the subspecialty with active and credible expertise in the relevant field of whom at least one must be a consultant paediatrician. The MDT should include a paediatric pharmacist and other professional groups appropriate to the disease area.<br>13. I confirm that Trust policy regarding unlicensed treatments has been followed as nivolumab is not licensed in this indication in children.<br>14. The patient has not received prior treatment with an anti-PD-1, anti-PD-L2, anti-CD137, or anti-Cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) antibody.<br>15. The patient will receive a maximum treatment duration of 2 years of uninterrupted treatment or 52 administrations (where administered every 2 weeks) or 26 administrations (where administered every 4 weeks) with nivolumab, whichever is the later.<br>16. When a treatment break of more than 12 weeks beyond the expected cycle length is needed, a treatment break approval form will be completed to restart treatment.<br>17. Nivolumab will otherwise be used as set out in its Summary of Product Characteristics (SPC). | Yes | - | 26-Aug-17 | 26-Aug-17 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| NIV4 | **Nivolumab** | Nivolumab monotherapy for the treatment of PD-L1 positive NON-SQUAMOUS locally advanced or metastatic disease non-small cell lung cancer after chemotherapy where the following criteria have been met: | 1. An application has been made by and the first cycle of systemic anti -cancer therapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The prescribing clinician is fully aware of the management of and the treatment modifications that may be required for immune-related adverse reactions due to anti-PD-L1 treatments including pneumonitis, colitis, nephritis, endocrinopathies, hepatitis and skin toxicities.<br>3. The patient has a histologically or cytologically confirmed diagnosis of non-squamous non-small cell lung cancer (NSCLC).<br>4. The patient has stage IIIB or IIIC or IV NSCLC or disease that recurred after previous potentially curative local management of NSCLC with surgery/chemoradiotherapy/radiotherapy.<br>5. An approved and validated test has shown that the patient's tumour expresses PD-L1 with a positive tumour proportion score (TPS) of at least 1%.<br>6. The patient has progressed either after treatment with at least two cycles of platinum-based doublet chemotherapy for stage IIIB or IIIC or IV or recurrent NSCLC after previous potentially curative local management or has progressed within 6 months of completing platinum-based adjuvant or neoadjuvant therapy or chemoradiation and if appropriate that the patient has had all appropriate targeted treatments if the patient has a tumour which is positive for an actionable genomic change in relation to EGFR or ALK or ROS1 or MET exon 14 or KRAS G12C or RET or BRAF V600 status.<br>7. The patient has not received prior treatment with an anti PD-1, anti-PD-L1, anti-PD-L2, anti-CD137 or anti-cytotoxic T-lymphocyte-associated antigen-4 (CTL-4) antibody unless the patient discontinued or completed checkpoint inhibitor immunotherapy as part of adjuvant/neoadjuvant/maintenance therapy without disease progression and at least 6 months elapsed between the date of the last immunotherapy treatment and the date of first diagnosis of relapse with recurrent or metastatic disease.<br>Note: NHS England does not commission re-treatment with checkpoint inhibitor therapy for patients who have discontinued or completed previous checkpoint inhibitor therapy for the locally advanced/metastatic indication.<br><br>Please mark below if the patient received previous checkpoint inhibitor therapy and in which setting:<br>- the patient has never received any immunotherapy for NSCLC. If so, please type 'n/a' in the 'Time gap' box below or<br>- the patient has previously been treated with adjuvant immunotherapy for NSCLC and discontinued immunotherapy without disease progression and at least 6 months prior to the first diagnosis of relapse. Please document in the box below the time gap in months between completion of previous adjuvant immunotherapy and first diagnosis of disease relapse or<br>- the patient has previously been treated with neoadjuvant immunotherapy for NSCLC and discontinued immunotherapy without disease progression and at least 6 months prior to the first diagnosis of relapse. Please document in the box below the time gap in months between completion of previous neoadjuvant immunotherapy and first diagnosis of disease relapse or<br>- the patient has previously been treated with maintenance immunotherapy post chemoradiotherapy for NSCLC and discontinued immunotherapy without disease progression and at least 6 months prior to the first diagnosis of relapse. Please document in the box below the time gap in months between completion of previous maintenance immunotherapy and first diagnosis of disease relapse<br><br>Time gap in months after completion of previous adjuvant or neoadjuvant or maintenance checkpoint inhibitor immunotherapy and first diagnosis of disease relapse:_____<br>Note: the mandatory interval between the last date of administration of any prior adjuvant/neoadjuvant/maintenance immunotherapy and the date of first relapse is **at least 6 months**. For patients suffering a first relapse within 6-12 months of previous immunotherapy, clinicians should bear in mind the long elimination half-lives of immunotherapies and make individual assessments of the overall benefit/risk ratio of re-treatment with immunotherapy.<br>8. Treatment with nivolumab will continue for a total of 2 years* or until disease progression or unacceptable toxicity or withdrawal of patient consent, whichever occurs first.<br>*2 years treatment is defined as a maximum of 52 x 2-weekly nivolumab administrations or 26 x 4-weekly administrations.<br>9. Nivolumab will be administered as monotherapy at a dose of 240mg every 2 weeks or 480mg every 4 weeks.<br>Note: nivolumab 480mg every 4 weeks is unlicensed, therefore Trust policy regarding the use of unlicensed treatments must be followed if using this dosing schedule.<br>10. The patient has an ECOG performance status of 0 or 1.<br>11. The patient has no symptomatically active brain metastases or leptomeningeal metastases.<br>12. A formal review as to whether treatment with nivolumab should continue or not will be scheduled to occur at least by the end of the first 8 weeks of treatment.<br>13. When a treatment break of more than 12 weeks beyond the expected 2 or 4-weekly cycle length is needed, the prescribing clinician will complete a treatment break approval form to restart treatment, including as appropriate if the patient had an extended break on account of Covid-19.<br>14. Nivolumab will be otherwise used as set out in its Summary of Product Characteristics (SPC). | Yes | TA713 | 07-Jul-21 | 05-Oct-21 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| NIV5 | **Nivolumab** | Nivolumab monotherapy for the treatment of SQUAMOUS locally advanced or metastatic non-small cell lung cancer after chemotherapy where the following criteria have been met: | 1. An application has been made by and the first cycle of systemic anti -cancer therapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br><br>2. The patient has a histologically or cytologically confirmed diagnosis of squamous non-small cell lung cancer (NSCLC).<br><br>3. The patient has stage IIIB or IIIC or IV NSCLC or disease that recurred after previous potentially curative local management of NSCLC with surgery/chemoradiotherapy/radiotherapy.<br><br>4. PD-L1 testing with an approved and validated test to determine the Tumour Proportion Score (TPS) has been attempted prior to this application and the result is set out below.<br>Please document the actual TPS below (if negative, record '0') or enter 'n/a' if the TPS cannot be documented and the reason why below:<br>TPS_____<br>If n/a, please indicate below the reason why the actual TPS cannot be documented:<br>- the TPS result was unquantifiable OR<br>- PD-L1 testing was not possible as the pathologist has documented that there is insufficient tissue for PD-L1 analysis<br><br>5. The patient has progressed either after treatment with at least two cycles of platinum-based doublet chemotherapy for stage IIIB or IIIC or IV or recurrent NSCLC after previous potentially curative local management or has progressed within 6 months of completing platinum-based adjuvant or neoadjuvant therapy or chemoradiation and if appropriate that the patient has had all appropriate targeted treatments if the patient has a tumour which is positive for an actionable genomic change in relation to EGFR or ALK or ROS1 or MET exon 14 or KRAS G12C or RET or BRAF V600 status.<br><br>6. The patient has not received prior treatment with an anti PD-1, anti-PD-L1, anti-PD-L2, anti-CD137 or anti-cytotoxic T-lymphocyte-associated antigen-4 (CTL-4) antibody unless the patient discontinued or completed checkpoint inhibitor immunotherapy as part of adjuvant/neoadjuvant/maintenance therapy without disease progression and at least 6 months elapsed between the date of the last immunotherapy treatment and the date of first diagnosis of relapse with recurrent or metastatic disease.<br>Note: NHS England does not commission re-treatment with checkpoint inhibitor therapy for patients who have discontinued or completed previous checkpoint inhibitor therapy for the locally advanced/metastatic indication.<br><br>Please mark below if the patient received previous checkpoint inhibitor therapy and in which setting:<br>- the patient has never received any immunotherapy for NSCLC. If so, please type 'n/a' in the 'Time gap' box below or<br>- the patient has previously been treated with adjuvant immunotherapy for NSCLC and discontinued immunotherapy without disease progression and at least 6 months prior to the first diagnosis of relapse. Please document in the box below the time gap in months between completion of previous adjuvant immunotherapy and first diagnosis of disease relapse or<br>- the patient has previously been treated with neoadjuvant immunotherapy for NSCLC and discontinued immunotherapy without disease progression and at least 6 months prior to the first diagnosis of relapse. Please document in the box below the time gap in months between completion of previous neoadjuvant immunotherapy and first diagnosis of disease relapse or<br>- the patient has previously been treated with maintenance immunotherapy post chemoradiotherapy for NSCLC and discontinued immunotherapy without disease progression and at least 6 months prior to the first diagnosis of relapse. Please document in the box below the time gap in months between completion of previous maintenance immunotherapy and first diagnosis of disease relapse<br><br>Time gap in months after completion of previous adjuvant or neoadjuvant or maintenance checkpoint inhibitor immunotherapy and first diagnosis of disease relapse:_____<br>Note: the mandatory interval between the last date of administration of any prior adjuvant/neoadjuvant/maintenance immunotherapy and the date of first relapse is at least 6 months. For patients suffering a first relapse within 6-12 months of previous<br>immunotherapy, clinicians should bear in mind the long elimination half-lives of immunotherapies and make individual assessments of the overall benefit/risk ratio of re-treatment with immunotherapy.<br><br>7. Treatment with nivolumab will continue for a total of 2 years* or until disease progression or unacceptable toxicity or withdrawal of patient consent, whichever occurs first.<br>*2 years treatment is defined as a maximum of 52 x 2-weekly nivolumab administrations or 26 x 4-weekly administrations.<br><br>8. The patient will receive the licensed* dose, frequency, and route of nivolumab for this indication, as shown below<br>•**Subcutaneously** – at a dose of 600mg every 2 weeks, or 1200mg every 4 weeks<br>•**Intravenously** – at a dose of 240mg every 2 weeks, or 480mg every 4 weeks (*4 weekly IV dosing is unlicensed).<br><br>9. The patient has an ECOG performance status of 0 or 1.<br><br>10. The patient has no symptomatically active brain metastases or leptomeningeal metastases.<br><br>11. When a treatment break of more than 12 weeks beyond the expected 2- or 4-weekly cycle length is needed, I will complete a treatment break approval form requesting a restart of treatment. This **must** be approved before nivolumab is re-commenced.<br><br>12. Nivolumab will be otherwise used as set out in its Summary of Product Characteristics (SPC). | Yes | TA655 | 21-Oct-20 | 19-Jan-21 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| NIV6 | **Nivolumab** | The treatment of recurrent or metastatic **squamous**-cell carcinoma of the head and neck after platinum-based chemotherapy where all the following crtieria are met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with nivolumab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a histologically or cytologically confirmed diagnosis of **squamous** cell carcinoma of the head and neck.<br>3. The patient has recurrent or metastatic head and neck cancer that is not amenable to local therapy with curative intent (surgery and/or radiation therapy with or without chemotherapy).<br>4. The patient's disease has progressed or recurred during or within 6 months of the last dose of previously received platinum-based chemotherapy.<br>Please indicate below in which disease setting this previous platinum-based chemotherapy was given:<br>- in the adjuvant setting or<br>- in the neoadjuvant setting or<br>- concurrently with radiotherapy or<br>- in the palliative setting for recurrent or metastatic disease<br>(Note: Patients progressing more than 6 months after completing platinum-based chemotherapy are not eligible for nivolumab).<br>5. The patient has an ECOG performance status of 0 or 1 and would otherwise be potentially fit for docetaxel-based chemotherapy.<br>6. The patient has not received prior treatment with an anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CD137, or anti-Cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) antibody.<br>7. Every effort has been made for the patient to have PD-L1 testing with an approved and validated test to determine the Tumour Proportion Score (TPS). Please document the TPS results below:<br>TPS result on tissue (if negative enter zero):_____<br>- The TPS has been documented above<br>- The TPS cannot be quantified<br>- PD-L1 testing was not possible as the pathologist has documented that these was insufficient tissue<br>Please explain why TPS could not be provided:_____<br>8. The patient will receive the licensed* dose, frequency, and route of nivolumab for this indication, as shown below<br>• **Subcutaneously** – at a dose of 600mg every 2 weeks, or 1200mg every 4 weeks<br>• **Intravenously** – at a dose of 240mg every 2 weeks, or 480mg every 4 weeks (*4 weekly IV dosing is unlicensed)<br>9. The patient has no symptomatically active brain metastases or leptomeningeal metastases.<br>10. The patient is to be treated with nivolumab until loss of clinical benefit or excessive toxicity or patient choice to discontinue therapy, whichever is the sooner.<br>11. When a treatment break of more than 12 weeks beyond the expected 2- or 4-weekly cycle length is needed, the prescribing clinician will complete a treatment break approval form requesting a restart of treatment. This must be approved before nivolumab is re-commenced.<br>12. Nivolumab will otherwise be used as set out in its Summary of Product Characteristics (SPC) with the exception of criterion 8 and 11. | No | TA736 | 20-Oct-21 | 18-Jan-22 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| NIV7 | **Nivolumab** | Nivolumab for the adjuvant treatment of newly diagnosed and completely resected stage III or completely resected stage IV malignant melanoma where the following criteria are met: | 1. This application is made by and the first cycle of systemic anti-cancer therapy with nivolumab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy | No | TA684 | 17-Mar-21 | 15-Jun-21 |
| | | | 2. This patient has a confirmed histological diagnosis of malignant melanoma.<br>Please indicate whether the melanoma is BRAF V600 mutation positive or not:<br>- BRAF V600 mutation positive **or**<br>- BRAF V600 mutation negative | | | | |
| | | | 3. The patient has melanoma which has been staged according to the AJCC 8th edition as stage III disease or completely resected stage IV disease.<br>Please state which stage disease the patient has:<br>- Stage IIIA disease **or**<br>- Stage IIIB disease **or**<br>- Stage IIIC disease **or**<br>- Stage IIID disease **or**<br>- Stage IV disease that has been completely resected | | | | |
| | | | 4. If stage III melanoma, the disease has been completely resected via sentinel node biopsy ('sentinel lymphadenectomy') or when indicated via completion lymph node dissection and/or there has been complete resection of intransit metastases; if stage IV melanoma, the distant metastatic disease has been completely resected | | | | |
| | | | 5. The patient is treatment naïve to systemic therapy for malignant melanoma and in particular has not previously received any BRAF V600 inhibitors or MEK inhibitors or immunotherapy with any check point inhibitors. | | | | |
| | | | 6. The prescribing clinician has discussed with the patient the benefits and toxicities of adjuvant nivolumab in stage III or completely resected stage IV disease and if stage III disease, has used the expected median figures below in relation to the risk of disease relapse if a routine surveillance policy is followed:<br>- for stage IIIA disease, the 5 and 10 year melanoma-specific survival probabilities with routine surveillance are 93% and 88%, respectively<br>- for stage IIIB disease, the 5 and 10 year figures are 83% and 77%, respectively<br>- for stage IIIC disease, the 5 and 10 year figures are 69% and 60%, respectively<br>- for stage IIID disease, the 5 and 10 year figures are 32% and 24%, respectively | | | | |
| | | | 7. The patient has an ECOG performance status of either 0 or 1 | | | | |
| | | | 8. Treatment with nivolumab will be continued for a maximum of 12 months (or a maximum of 26 cycles if given 2-weekly) or 13 administrations (when administered every 4 weeks) from the start of treatment in the absence of disease recurrence, unacceptable toxicity or withdrawal of patient consent. | | | | |
| | | | 9. The patient will receive the licensed dose, frequency, and route of nivolumab for this indication, as shown below<br>• **Subcutaneously** – at a dose of 600mg every 2 weeks, or 1200mg every 4 weeks<br>• **Intravenously** – at a dose of 240mg every 2 weeks, or 480mg every 4 weeks | | | | |
| | | | 10. When a treatment break of more than 12 weeks beyond the expected 2- or 4-weekly cycle length is needed, I will complete a treatment break approval form requesting a restart of treatment. This **must** be approved before nivolumab is re-commenced | | | | |
| | | | 11. Nivolumab is to be otherwise used as set out in its Summary of Product Characteristics | | | | |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| NIV8a | **Nivolumab** | Nivolumab monotherapy (with or without initial combination treatment with ipilimumab) for treating unresectable or advanced malignant melanoma **(form a)**: REGISTRATION OF START OF NIVOLUMAB MONOTHERAPY OR OF PREVIOUSLY COMMENCED AND CURRENTLY CONTINUED NIVOLUMAB MONOTHERAPY (WITHOUT INITIAL COMBINATION WITH IPILIMUMAB) OR OF PREVIOUSLY COMMENCED AND CURRENTLY CONTINUED NIVOLUMAB MONOTHERAPY AFTER INITIAL COMBINATION WITH IPILIMUMAB (clinicians starting patients on nivolumab plus ipilimumab combination treatment should only use this form after the ipilimumab part of the treatment has been completed).<br>This form comes in 3 parts<br>1. The first part is for patients who are either scheduled to commence nivolumab monotherapy or who commenced and continue to receive nivolumab monotherapy or who continue to receive nivolumab monotherapy after initial combination treatment with ipilimumab. The second part of the form which must use the same unique Blueteq identifier is for those benefitting patients who choose to electively discontinue nivolumab after 2 or more years of treatment.<br>2. The second part (patient details will be automatically entered) will only appear once the first part of the form is approved and should be completed at the time of elective discontinuation of nivolumab. The third part of the form which must use the same unique Blueteq identifier is for those patients registered as having electively and previously stopped nivolumab and in whom there is disease progression for which the clinician wishes to re-commence nivolumab monotherapy.<br>3. The third part of the form (patient details will be automatically entered) will only appear once the second part of the form has been approved. | 1. This application has been made by and the first cycle of systemic anti -cancer therapy with nivolumab will be/was prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>Note: if treatment with nivolumab has already commenced, it is vital that the first treatment start date has been entered in the box above.<br><br>2. The patient has a histologically- or cytologically-confirmed diagnosis of malignant melanoma.<br><br>3. The patient has unresectable or advanced melanoma.<br><br>4. In respect of his/her treatment for unresectable/advanced disease and at the time of starting nivolumab, the patient is/was treatment-naïve to systemic therapy, or<br>•Has/had previously only received BRAF/MEK-targeted therapy, or ipilimumab monotherapy, or both BRAF/MEK-targeted treatment and ipilimumab monotherapy.<br>•has a diagnosis of uveal melanoma, and has received treatment with tebentafusp in the first line setting, and has stopped this therapy due to disease progression, or lack of tolerance<br><br>5. At the time of commencing nivolumab the patient has/had not received prior treatment with any of the following: anti-PD-1, anti-PD-L1, anti-PD-L2 and anti-CD137 treatments unless the patient has received adjuvant immunotherapy with nivolumab or pembrolizumab in which case the patient must have relapsed after the discontinuation of such adjuvant immunotherapy.<br>Please tick appropriate box:<br>- No prior immunotherapy with anti-PD-1, anti-PD-L1, anti-PD-L2 or anti-CD137 treatments **or**<br>- Prior adjuvant immunotherapy with nivolumab or pembrolizumab **or**<br>- Nivolumab initially started in combination with ipilimumab (see question 9 below)<br><br>6. There is the future opportunity for patients continuing in a stable disease or a response disease state after 2 or more years of planned treatment to choose to discontinue nivolumab and then to re-start nivolumab monotherapy on disease progression as the next systemic therapy and should this option be chosen that both the date of discontinuation must be registered on the second part of this form and the application to re-start nivolumab be made on the third part of this form.<br><br>7. The patient has a sufficient performance status (PS) to be fit to receive treatment with immunotherapy.<br><br>8. Nivolumab will be or is administered as monotherapy. Note: clinicians starting nivolumab plus ipilimumab combination treatment should only use this form after the ipilimumab part of the treatment has been completed.<br><br>Please tick appropriate box:<br>- Nivolumab given as monotherapy from start of nivolumab therapy **or**<br>- Nivolumab initially given in combination with ipilimumab and then continued as monotherapy<br><br>9. Unless the patient chooses to electively discontinue treatment as outlined in criterion 6, the licensed dose, frequency, and route of nivolumab for this indication will be used, as shown below<br>• **Subcutaneously** – at a dose of 600mg every 2 weeks, or 1200mg every 4 weeks<br>• **Intravenously** – at a dose of 240mg every 2 weeks, or 480mg every 4 weeks<br>• 480mg IV every 8 weeks **ONLY** if the patient is participating in the REFINE trial (NIHR CPMS 50169).<br>• 1200mg SC every 8 weeks **ONLY** if the patient is participating in the REFINE trial (NIHR CPMS 50169).<br><br>10.When a treatment break of more than 12 weeks beyond the expected 2- or 4-weekly cycle length is needed, I will complete a treatment break approval form requesting a restart of treatment. This **must** be approved before nivolumab is re-commenced<br><br>***Form b and c are shown on the next page*** | No | TA384 & TA400 | 18-Feb-16 & 27-Jul-16 | 18-May-16 (Blueteq approval required from 01-Feb-19) |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| NIV8b | **Nivolumab** | Nivolumab for treating unresectable or advanced malignant melanoma **(form b)**: REGISTRATION OF DISCONTINUATION OF NIVOLUMAB<br><br>This second part of the form which must use the same unique Blueteq identifier is for those patients in stable or response remission who have chosen to electively discontinue nivolumab; this second part must be completed at the time of discontinuation of nivolumab. The third part of the form which must use the same unique Blueteq identifier is for those patients registered as having electively and previously stopped nivolumab and in whom there is disease progression for which the clinician wishes to re-commence nivolumab; this third part of the form (patient details will be automatically entered) will only appear once the second part of the form has been approved. | 1. This registration of electively discontinued treatment with nivolumab has been made by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy. | No | TA384 & TA400 | 18-Feb-16 & 27-Jul-16 | 18-May-16 (Blueteq approval required from 01-Feb-19) |
| | | | 2. The patient is in a stable disease or a response state in relation to treatment with nivolumab for his/her melanoma.<br>Please indicate the nature of the response to nivolumab and if in a complete or partial response, please enter the date that this response was achieved:<br>- complete response and date of complete response (dd/mm/yyyy) **or**<br>- partial response and date of partial response (dd/mm/yyyy) **or**<br>- stable disease | | | | |
| | | | 3. The patient has either received 2 or more years of nivolumab ( including any doses given with ipilimumab) or the patient was randomised to the 1 year discontinuation arm in the DANTE trial.<br>Please state which of these 2 reasons apply for discontinuation of therapy:<br>- Completed 2 or more years of nivolumab **or**<br>- Drew 1 year treatment arm in DANTE trial<br>Please also state the duration of treatment with nivolumab (i.e. the time between treatment commencement and discontinuation) | | | | |
| | | | 4. The patient has chosen this option of discontinuing therapy after an informed consenting process which has fully described the advantages and disadvantages of the options of either continuing on nivolumab or electively discontinuing nivolumab with the option of re-starting nivolumab if the disease progresses but only with nivolumab directly as the next systemic therapy following previous discontinuation of nivolumab | | | | |
| NIV8c | **Nivolumab** | Nivolumab for treating unresectable or advanced malignant melanoma **(form c)**: RE-START OF NIVOLUMAB MONOTHERAPY<br><br>The third part of the form which must use the same unique Blueteq identifier is for those patients registered as having electively and previously stopped nivolumab and in whom there is disease progression for which the clinician wishes to re-commence nivolumab as the next systemic treatment. | 1. This application to re-start nivolumab monotherapy has been made by and the first cycle of systemic anti -cancer therapy with nivolumab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy. | No | TA384 & TA400 | 18-Feb-16 & 27-Jul-16 | 18-May-16 (Blueteq approval required from 01-Feb-19) |
| | | | 2. The patient has progressive non-resectable or metastatic melanoma.<br>Please state the duration of time off treatment (i.e. the time between previous nivolumab discontinuation and decision to re-start nivolumab) | | | | |
| | | | 3. The patient has received no other systemic therapy in the time between the date of elective discontinuation of nivolumab and this application to re-start nivolumab | | | | |
| | | | 4. The prescribing clinician is fully aware of the management of and the treatment modifications that may be required for immune-related adverse reactions due to anti-PD-L1 treatments including pneumonitis, colitis, nephritis, endocrinopathies and hepatitis. | | | | |
| | | | 5. The present intention is that the patient will be treated with nivolumab monotherapy until there is progressive disease or unacceptable toxicity or if the patient declines further therapy. | | | | |
| | | | 6. The patient has a sufficient performance status (PS) to be fit to receive treatment with immunotherapy. | | | | |
| | | | 7. Nivolumab will be administered as monotherapy.<br>A re-start of treatment with the combination of nivolumab plus ipilimumab is not commissioned. | | | | |
| | | | 8. The licensed dose and frequency of nivolumab will be used (i.e. either 240mg every 2 weeks or 480mg every 4 weeks) | | | | |
| | | | 9. A formal medical review to assess the tolerability of treatment with nivolumab will be scheduled to occur at least by the start of the 3rd month of treatment and thereafter on a regular basis. | | | | |
| | | | 10. Treatment breaks of up to 12 weeks beyond the expected cycle length are allowed but solely to allow any toxicities to settle | | | | |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| NIV9 | **Nivolumab in combination with ipilimumab** | For the 1st line treatment of intermediate or poor risk advanced renal cell carcinoma where the following criteria are met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with the combination of nivolumab and ipilimumab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br><br>2. The patient has unresectable locally advanced or metastatic renal cell carcinoma (RCC) which has either a clear cell component or is one of the types of RCC as indicated below.<br>Please indicate below which RCC histology applies to this patient:<br>- RCC with a clear cell component or<br>- Papillary RCC or<br>- Chromophobe RCC or<br>- Collecting duct RCC (Bellini collecting duct RCC) or<br>- Medullary RCC or<br>- Mucinous tubular and spindle cell RCC or<br>- Multilocular cystic RCC or<br>- XP11 translocation RCC or<br>- Unclassified RCC<br><br>3. The patient has **intermediate or poor risk** advanced renal cell carcinoma as assessed by the International Metastatic RCC Database Consortium (IMDC) system which scores 1 point for each of the following 6 factors – a score of 0 indicates good risk disease, a score of 1-2 indicates intermediate risk and a score of 3-6 denotes poor risk:<br>The IMDC factors are:<br>- less than 1 year from time of initial diagnosis of RCC to now<br>- a Karnofsky performance status of <80% (see below for description of Karnofsky scale of performance status)<br>- the haemoglobin level is less than the lower limit of normal<br>- the corrected calcium level is >2.5mmol/L<br>- the platelet count is greater than the upper limit of normal<br>- the absolute neutrophil count is greater than the upper limit of normal.<br>Please indicate below whether the patient is in the intermediate or poor risk prognostic group.<br>- intermediate risk disease (IMDC score of 1 or 2) **or**<br>- poor risk disease (IMDC score of 3-6)<br>Note: IMDC favourable risk disease (IMDC score of 0) did worse with the combination of nivolumab and ipilimumab versus sunitinib in the Checkmate 214 study and thus the use of nivolumab plus ipilimumab is not licensed in the IMDC favourable risk population.<br><br>4. The patient is either completely treatment naïve for systemic immune-modulatory therapy for RCC or if the patient has received prior systemic immune-modulatory therapy in the context of adjuvant/neoadjuvant therapy, then such treatment was completed 12 or more months previously and the patient meets all other criteria listed here.<br>Please mark below whether or not previous systemic immune-modulatory therapy has been received in the adjuvant/neoadjuvant setting:<br>- no previous adjuvant/neoadjuvant systemic immune-modulatory therapy of any kind and the patient is treatment naïve for the locally advanced/metastatic RCC indication or<br>- prior adjuvant/neoadjuvant therapy with immune-modulatory therapies for RCC anti-Programmed Death receptor-1 (PD-1), anti-Programmed Death-1 ligand-1 (PD-L1), anti-PD L2, anti-CD137 or anti-cytotoxic T lymphocyte associated antigen-4 (anti-CTLA-4) antibodies and last dose received by the patient was 12 or more months prior to this application and the patient is treatment-naïve for the locally advanced/metastatic RCC indication<br>Please mark in the box the time since end of treatment with adjuvant/neoadjuvant immune-modulatory therapy:<br>_____<br><br>5. The patient has a Karnofsky performance status of at least 70%.<br><br>The relevant part of the Karnofsky performance status scale is as follows:<br><br>100% Normal, no complaints. No signs or symptoms of disease.<br>90% Able to carry on normal activities. Minor signs or symptoms of disease.<br>80% Normal activity with effort. Some signs or symptoms of disease.<br>70% Cares for self. Unable to carry on normal activity or to do active work.<br>60% Requires occasional assistance, but is able to care for most personal needs.<br>50% Requires considerable assistance and frequent medical care.<br><br>6. The patient has no symptomatic brain metastases or leptomeningeal metastases currently requiring steroids for symptom control.<br><br>7. The patient is to be treated until loss of clinical benefit or excessive toxicity or patient choice, whichever is the sooner.<br>Note: there is no stopping rule as to the maximum treatment duration of nivolumab in this indication.<br><br>8. Ipilimumab will be used at the RCC ipilimumab dose of 1mg/Kg every 3 or 12 weeks for a maximum of four cycles. Combination treatment can be given as four 3-weekly cycles or as four 12-weekly cycles in accordance with the PRISM trial data (JCO 2023 **42** 312-325). In this situation maintenance single agent nivolumab can be commenced between extended dosing combination treatment as IV or SC dosing. All combination treatments must use appropriate dose **IV** nivolumab.<br><br>Patients participating on the REFINE trial cannot be treated on extended interval combination dosing.<br><br>9. Nivolumab will be used at a dose of 3mg/Kg IV every 3 weeks for the first 4 cycles (i.e. when in combination with ipilimumab) and then as subsequent monotherapy at the licensed dose, frequency, and route for this indication, as shown below<br>• **Subcutaneously** – at a dose of 600mg every 2 weeks, or 1200mg every 4 weeks<br>• **Intravenously** – at a dose of 240mg every 2 weeks, or 480mg every 4 weeks<br>• 480mg IV every 8 weeks, **ONLY** if the patient is participating in the REFINE trial (NIHR CPMS ID 50169).<br>• 1200mg SC every 8 weeks **ONLY** if the patient is participating in the REFINE trial (NIHR CPMS ID 50169).<br><br>10. Nivolumab and ipilimumab will be prescribed and administered as outlined in their respective Summary of Product Characteristics (SPCs) for this indication.<br><br>11. When a treatment break of more than 12 weeks beyond the expected 2-, 3-, or 4-weekly cycle length is needed, I will complete a treatment break approval form requesting a restart of treatment. This **must** be approved before ipilimumab and/or nivolumab are re-commenced<br><br>12. If the disease progresses on the nivolumab plus ipilimumab combination the next set of treatment options are those drugs which are routinely commissioned as first to be used VEGF- or VEGFR-targeting drugs ie one choice of the following: cabozantinib or pazopanib or tivozanib or sunitinib. | No | TA780 | 23-Mar-22 | 21-Jun-22 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| NIV10 | **Nivolumab and ipilimumab** | For patients with microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR) metastatic or locally advanced and inoperable colorectal cancer after prior fluoropyrimidine-based chemotherapy for metastatic disease where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with nivolumab plus ipilimumab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has either metastatic or locally advanced and inoperable colorectal carcinoma.<br>3. The patient's tumour has a documented presence of microsatellite instability-high (MSI-H) or DNA mismatch repair deficiency (dMMR) confirmed by validated testing.<br>4. The patient's tumour has been determined to have wild type or mutant RAS status and the result is recorded below:<br>5. The patient's tumour has been determined to have wild type or mutant BRAF status and the result is recorded below:<br>- wild type BRAF status<br>- mutant BRAF status2.<br>6. The patient has received previous systemic fluoropyrimidine-based therapy for metastatic colorectal cancer unless the fluoropyrimidine part of chemotherapy was contra-indicated on account of documented DPD deficiency.<br>Please mark below which clinical scenario applies to this patient:<br>- previous systemic therapy for metastatic colorectal cancer with fluoropyrimidine-based chemotherapy<br>7. The patient has an ECOG performance status (PS) of 0 or 1.<br>8. The patient has no symptomatic brain or leptomeningeal metastases.<br>9. The patient has not received prior treatment with an anti-PD-1, anti-PD-L2, anti-CD137, or anti-Cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) antibody unless the patient was enrolled in the NEOPRISM-CRC clinical trial (NIHR CPMS ID 52000) and did not have radiologically-assessed evidence of progressive disease at the end of neoadjuvant pembrolizumab therapy.<br>Please mark below which clinical scenario applies to this patient:<br>- the patient has not received any previous anti-PD-1, anti-PD-L2, anti-CD137, or anti-Cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) antibody therapy for metastatic colorectal cancer<br>- the patient was enrolled in the NEOPRISM-CRC clinical trial ((NIHR CPMS ID:52000) and did not have clear evidence of radiologically assessed progressive disease at the end of neoadjuvant pembrolizumab therapy<br>Note: this combination of nivolumab plus ipilimumab is **not** funded after previous treatment with pembrolizumab for MSI-H or dMMR metastatic colorectal cancer.<br>10. Nivolumab will be administered in combination with ipilimumab as follows: nivolumab **IV** 3mg/Kg and ipilimumab 1mg/Kg are given in combination for a maximum of 4 cycles every 3 weeks and then nivolumab is continued as monotherapy at the licensed dose, frequency, and route for this indication, as shown below<br>•**Subcutaneously** – at a dose of 600mg every 2 weeks, or 1200mg every 4 weeks<br>•**Intravenously** – at a dose of 240mg every 2 weeks, or 480mg every 4 weeks<br>11. Nivolumab will be stopped on disease progression or unacceptable toxicity or withdrawal of patient consent, whichever occurs first.<br>Note: there is no stopping rule for nivolumab in this metastatic colorectal cancer indication and hence patients continuing to benefit from nivolumab after 2 years of treatment can continue if the patient and clinician agree.<br>Note: once nivolumab is stopped for disease progression or unacceptable toxicity or withdrawal of patient consent, nivolumab cannot be re-started.<br>12. When a treatment break of more than 12 weeks beyond the expected 2-, 3-, or 4-weekly cycle length is needed, I will complete a treatment break approval form requesting a restart of treatment. This **must** be approved before ipilimumab and/or nivolumab are re-commenced<br>13. Nivolumab and ipilimumab will be otherwise used as set out in their respective Summaries of Product Characteristics (SPCs). | No | TA716 | 28-Jul-21 | 26-Oct-21 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| NIV15 | **Nivolumab** | For the treatment of adult patients with unresectable locally advanced or recurrent or metastatic squamous cell carcinoma of the oesophagus previously treated with a fluoropyrimidine and platinum-based combination chemotherapy where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with nivolumab monotherapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br><br>2. The patient has a histologically confirmed diagnosis of squamous cell oesophageal carcinoma or adenosquamous oesophageal carcinoma.<br>Please enter below which type of oesophageal cancer the patient has:<br>- squamous cell carcinoma of the oesophagus<br>- adenosquamous carcinoma of the oesophagus<br><br>3. The patient has unresectable locally advanced or recurrent or metastatic disease.<br><br>4. The patient has been treated with a fluoropyrimidine- and platinum-based combination chemotherapy for his/her squamous cell carcinoma of the oesophagus and has progressed during or following such treatment or was intolerant of such therapy.<br><br>Please enter below at what stage in the treatment pathway the previous fluoropyrimidine- and platinum-based combination chemotherapy was given:<br>- as neoadjuvant chemotherapy prior to surgery<br>- as part of concurrent chemo-radiotherapy<br>- as adjuvant chemotherapy<br>- as treatment of recurrent or metastatic disease<br><br>5. The patient has an ECOG performance status score of 0 or 1.<br><br>6. The patient will receive the licensed* dose, frequency, and route of nivolumab for this indication, as shown below<br>• **Subcutaneously** – at a dose of 600mg every 2 weeks, or 1200mg every 4 weeks<br>• **Intravenously** – at a dose of 240mg every 2 weeks, or 480mg every 4 weeks (*4 weekly IV dosing is unlicensed)<br><br>7. Treatment with nivolumab monotherapy will continue as long as clinical benefit is observed or until the development of unacceptable toxicity or withdrawal of patient consent, whichever occurs first.<br>Note: there is no 2-year stopping rule for the use of nivolumab in this indication.<br><br>8. The patient has no symptomatically active brain metastases or leptomeningeal metastases.<br><br>9. The patient has not received prior treatment with any antibody which targets PD-1 or PD-L1 or PD-L2 or CD137 or OX40 or anti-cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) unless the patient discontinued or completed checkpoint inhibitor immunotherapy as part of adjuvant therapy without disease progression and at least 6 months has elapsed between the date of the last immunotherapy treatment and the date of first diagnosis of relapse with recurrent or metastatic disease<br><br>Please mark below which scenario applies to this patient:<br>- this patient has not received any previous immunotherapy for squamous cell or adenosquamous cell carcinoma of the oesophagus<br>- this patient was previously treated with neoadjuvant platinum-based chemoradiotherapy for squamous cell or adenosquamous carcinoma of the oesophagus and underwent surgery followed by adjuvant nivolumab (NICE TA713) then discontinued or completed treatment with adjuvant nivolumab without disease progression and it has been at least 6 months prior to the first diagnosis of relapse. Please document in the box below the time gap in months between completion of previous adjuvant nivolumab immunotherapy and first diagnosis of disease relapse<br>_____<br>Note: the mandatory interval between the last date of administration of any prior adjuvant immunotherapy and first relapse is **at least 6 months.** For patients suffering a first relapse within 6-12 months of previous immunotherapy, clinicians should bear in mind the long elimination half-lives of immunotherapies and make individual assessments of the overall benefit/risk ratio of re-treatment with immunotherapy.<br><br>10. When a treatment break of more than 12 weeks beyond the expected 2- or 4-weekly cycle length is needed, I will complete a treatment break approval form requesting a restart of treatment. This **must** be approved before nivolumab is re-commenced<br><br>11. Nivolumab will be otherwise used as set out in its Summary of Product Characteristics (SPC). | No | TA707 | 15-Jun-21 | 13-Sep-21 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| NIV17 | **Nivolumab**<br>as adjuvant monotherapy | For patients with completely resected oesophageal or gastro-oesophageal carcinoma who have residual pathological disease at surgery following prior neoadjuvant chemoradiotherapy where the following criteria has been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with nivolumab monotherapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a histologically confirmed diagnosis of oesophageal cancer (squamous or adenocarcinoma) or adenocarcinoma of the gastro-oesophageal junction.<br>Please mark below which histology applies to this patient:<br>- squamous cell carcinoma of the oesophagus<br>- adenocarcinoma of the oesophagus<br>- adenocarcinoma of the gastro-oesophageal junction<br>3. In this patient the primary treatment intent at the outset of therapy was to treat with the sequence of chemoradiotherapy followed by surgical resection.<br><br>NB The marketing authorisation of nivolumab stipulates the use of prior neoadjuvant chemoradiotherapy followed by surgery and thus NICE's considerations and recommendations are aligned to this. Patients treated with neoadjuvant chemotherapy without radiotherapy are not eligible for adjuvant nivolumab. Patients who are treated with primary chemoradiotherapy and who then progress locally and have salvage surgery are not eligible for adjuvant nivolumab.<br>4. The patient has been treated with neoadjuvant chemoradiotherapy and that the concurrent chemotherapy used with the radiotherapy was platinum-based.<br>Please document the number of weeks since the end of the chemoradiotherapy: _____<br>5. The patient has undergone surgery for M0 disease and that the tumour has been completely resected i.e. the patient has had a R0 resection for M0 disease.<br>6. The patient's resected specimen contained residual pathological disease i.e. that the pathological stage of the tumour was at least ypN1 or ypT1.<br>Please document below the pathological T and N stages in the resected specimen for this patient using the (latest) AJCC/UICC 8th edition:<br>Pathological T stage of resected tumour:<br>Pathological N stage of resected tumour:<br>7. This application for adjuvant nivolumab is less than 16 weeks since surgical resection of the tumour.<br>Please document the number of weeks since surgery:<br>8. The patient has had appropriate imaging within the last 4 weeks to check that the patient still has M0 disease i.e. that it is still suitable for the patient to proceed with adjuvant nivolumab therapy<br>9. The patient has not received prior treatment with any antibody which targets PD-1 or PD-L1 or PD-L2 or CD137 or OX40 or anti-cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4).<br>10. The patient has an ECOG performance status (PS) of 0 or 1.<br>11. The patient will receive the licensed dose, frequency, and route of nivolumab for this indication, as shown below<br>•**Subcutaneously** – at a dose of 600mg every 2 weeks, or 1200mg every 4 weeks<br>•**Intravenously** – at a dose of 240mg every 2 weeks, or 480mg every 4 weeks<br>12. Nivolumab will be stopped at whichever of the following events occurs first: disease progression or unacceptable toxicity or withdrawal of patient consent or after 1 year in total duration of nivolumab treatment (i.e. after a maximum of 13 x 4-weekly cycles or its equivalent if 2-weekly dosing is used).<br>13. When a treatment break of more than 12 weeks beyond the expected 2- or 4-weekly cycle length is needed, I will complete a treatment break approval form requesting a restart of treatment. This **must** be approved before nivolumab is re-commenced<br>14. Nivolumab will otherwise be used as set out in its Summary of Product Characteristics (SPC) | No | TA746 | 17-Nov-21 | 15-Feb-22 |
| NIV18 | **Nivolumab and ipilimumab** | Nivolumab in combination with ipilimumab for treating advanced melanoma | 1. I confirm that this application has been made by and the first cycle of systemic anti-cancer therapy with the combination of ipilimumab and nivolumab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has unresectable stage III or stage IV histologically confirmed melanoma.<br>3. The patient has not received previous treatment for this indication of unresectable or metastatic melanoma with any of the following: anti-Programmed Death receptor-1 (PD-1), anti-Programmed Death-1 ligand-1 (PD-L1), anti-PD-<br>4. The patient is completely treatment naïve for systemic therapy for melanoma or has only received allowed prior systemic therapy*.<br>* Allowed prior therapies are:<br>1) prior adjuvant therapy with nivolumab or pembrolizumab or<br>2) prior immune checkpoint inhibitors when given as part of a clinical trial either as monotherapy or in combination with ipilimumab and/or<br>3) BRAF/MEK inhibitor targeted therapies when given for adjuvant indication<br>4) BRAF/MEK inhibitor targeted therapies when given for advanced disease indication<br>5) First line tebentafusp, which has had to be stopped due to disease progression, or lack of tolerance, in patients with uveal melanoma<br>Please mark below previous systemic therapies received:<br>- no previous systemic therapy of any kind; or<br>- prior adjuvant therapy with nivolumab or pembrolizumab<br>- or prior immune checkpoint inhibitors when given as part of a clinical trial either as monotherapy or in combination with ipilimumab<br>- or BRAF/MEK inhibitor targeted therapies when given for adjuvant indication<br>- or BRAF/MEK inhibitor targeted therapies when given for advanced disease<br>- or a combination of the above allowed treatment options<br>- or First line tebentafusp, which has had to be stopped due to disease progression, or lack of tolerance, in patients with uveal melanoma<br>5. The patient is of ECOG performance status (PS) 0 or 1.<br>6. The patient has no symptomatic brain metastases or leptomeningeal metastases currently requiring steroids for symptom control.<br>7. Nivolumab will be used at a dose of 1mg/Kg **IV** every 3 weeks for the first 4 cycles (i.e. when in combination with ipilimumab) and then as subsequent monotherapy at the licensed dose, frequency, and route for this indication, as shown below<br>•**Subcutaneously** – at a dose of 600mg every 2 weeks, or 1200mg every 4 weeks<br>•**Intravenously** – at a dose of 240mg every 2 weeks, or 480mg every 4 weeks<br>or 480mg IV every 8 weeks if the patient is participating in the REFINE trial (NIHR SPMS 50169).<br>* For patients entered into the NIHR clinical trial reference number CANC44182, it is acceptable to continue to use nivolumab monotherapy with the mg/kg dosing schedule.<br>** For patients entered into the SCIB1-002 study (NIHR clinical trial ID 40068) nivolumab plus ipilimumab and then nivolumab monotherapy may be administered with the SCIB1 or iSCBI1+ vaccines (the trial's Investigational Medicinal Products)<br>8. When a treatment break of more than 12 weeks beyond the expected 2-, 3-, or 4-weekly cycle length is needed, I will complete a treatment break approval form requesting a restart of treatment. This **must** be approved before ipilimumab and/or nivolumab are re-commenced<br>9. Nivolumab and ipilimumab will be prescribed and administered as outlined in their respective Summary of Product Characteristics (SPCs) for this indication. | No | TA400 | 27-Jul-16 | 25-Oct-16 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| NIV19 | **Nivolumab** | Nivolumab monotherapy for adjuvant treatment after complete tumour resection in adult patients with high risk muscle invasive urothelial cancer with tumour cell PD-L1 expression of ≥1% and in whom adjuvant treatment with platinum-based chemotherapy is unsuitable where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with adjuvant nivolumab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a histologically documented diagnosis of muscle invasive urothelial cancer of the bladder, ureter or renal pelvis.<br>Please mark below the site of origin of the urothelial cancer:<br>- bladder<br>- ureter<br>- renal pelvis<br>3. The patient's urothelial cancer has been documented as exhibiting **PD-L1 expression on ≥1% of tumour cells** as determined by an approved and validated PD-L1 assay.<br>Please document below the actual PD-L1 expression on tumour cells (e.g. if 50%, please type just the number 50):<br>PD-L1 expression in this patient's tumour cells: _____<br>4. The patient was treated with neoadjuvant chemotherapy or not: please mark below as appropriate:<br>- yes, the patient was treated with neoadjuvant chemotherapy<br>- no, the patient did not receive neoadjuvant chemotherapy<br>5. The patient had M0 disease prior to surgery and has undergone a complete resection of the muscle invasive urothelial cancer with all surgical margins negative for tumour i.e. a R0 resection has taken place.<br>6. The pathological TNM stage determined on this patient's surgical urothelial cancer specimen represents high risk disease as defined by the following:<br>- if there has been prior neoadjuvant chemotherapy, the pathological stage of the resected tumour must be ypT2-ypT4a or any ypN+ stage<br>- or if there has not been any neoadjuvant chemotherapy, the pathological stage of the resected tumour must be pT3 or pT4a or any pN+ stage.<br>Please mark below which option applies to this patient:<br>- following neoadjuvant chemotherapy, the high risk criterion has been met by having ypT2-ypT4a ypN0 disease<br>- following neoadjuvant chemotherapy, the high risk criterion has been met by having ypN+ disease<br>- in the absence of neoadjuvant chemotherapy, the high risk criterion has been met by having pT3-pT4a pN0 disease<br>- in the absence of neoadjuvant chemotherapy, the high risk criterion has been met by having pN+ disease<br>7. The patient has not been treated with any adjuvant chemotherapy following resection of the urothelial tumour.<br>8. The patient has had an informed consent discussion as to the options of adjuvant systemic therapies and the conclusion is that adjuvant platinum-based chemotherapy is unsuitable.<br>Please mark below the reason as to why adjuvant chemotherapy is unsuitable in this patient:<br>- the patient had neoadjuvant chemotherapy<br>- the lack of robust RCT data in bladder cancer for the benefit of adjuvant chemotherapy<br>- the toxicity profile of adjuvant platinum-based chemotherapy<br>- the refusal by the patient to have adjuvant platinum-based chemotherapy<br>9. The patient underwent radical surgery less than 4 months prior to the expected date for the start of adjuvant nivolumab therapy.<br>10. The patient has been radiologically re-staged after surgery such that the patient remains disease-free within 1 month of the expected date for the start of adjuvant nivolumab therapy.<br>11. The patient has not received prior treatment with an anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CD137, or anti-Cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) antibody.<br>12. The patient has an ECOG performance status (PS) of 0 or 1.<br>13. The patient will receive the licensed dose, frequency, and route of nivolumab for this indication, as shown below<br>• **Subcutaneously** – at a dose of 600mg every 2 weeks, or 1200mg every 4 weeks<br>• **Intravenously** – at a dose of 240mg every 2 weeks, or 480mg every 4 weeks<br>14. Nivolumab will be stopped at whichever of the following events occurs first: disease progression or unacceptable toxicity or withdrawal of patient consent or on completion of 1 year in total duration of treatment with nivolumab (i.e. after a maximum of 13 x 4-weekly cycles).<br>15. When a treatment break of more than 12 weeks beyond the expected 2- or 4-weekly cycle length is needed, I will complete a treatment break approval form requesting a restart of treatment. This **must** be approved before nivolumab is re-commenced<br>16. Nivolumab will be otherwise used as set out in its Summary of Product Characteristics (SPC). | No | TA817 | 10-Aug-22 | 08-Nov-22 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| NIV20 | **Nivolumab** in combination with ipilimumab | For treatment of unresectable malignant mesothelioma previously untreated with systemic therapy where the following criteria have been met: | 1. This application for nivolumab in combination with ipilimumab is being made by and the first cycle of systemic anti-cancer therapy with nivolumab in combination with ipilimumab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The prescribing clinician is fully aware of the management of and the treatment modifications that may be required for immune-related adverse reactions due to anti-PD-L1 treatments including pneumonitis, colitis, nephritis, endocrinopathies, hepatitis and skin toxicity.<br>3. The patient has a histologically or cytologically confirmed diagnosis of mesothelioma.<br>4. The mesothelioma is of pleural or non-pleural origin.<br>Please indicate below the site of origin of the mesothelioma in this patient:<br>- the pleura **or**<br>- the peritoneum **or**<br>- the pericardium **or**<br>- the tunica vaginalis in the testis<br>5. The histological subtype of mesothelioma as to whether the mesothelioma in this patient is of epithelioid type or non-epithelioid type (sarcomatoid or mixed [biphasic] histological types) or the type cannot be determined.<br>Please indicate below the histological subtype of mesothelioma in this patient:<br>- the mesothelioma is of epithelioid type or<br>- the mesothelioma is of non-epithelioid (sarcomatoid or biphasic) type or<br>- the mesothelioma type cannot be determined<br>6. The patient has unresectable disease.<br>7. The patient has not previously received any systemic therapy for mesothelioma (neither cytotoxic chemotherapy nor immunotherapy) unless the patient was started on treatment with nivolumab and ipilumumab via the EAMS scheme and all other treatment criteria on this form are fulfilled.<br>Please mark below which of these 2 clinical scenarios applies to this patient:<br>- The patient has not received prior systemic treatment for mesothelioma including chemotherapy, anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CD137, or anti-cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) antibodies.<br>- Received prior treatment with nivolumab and ipilumumab via EAMS scheme and all other treatment criteria on this form are fulfilled<br>Note: patients previously treated with cytotoxic chemotherapy for mesothelioma or with immunotherapy for mesothelioma are not eligible to receive nivolumab plus ipilimumab.<br>8. The patient has an ECOG performance status of 0 or 1.<br>9. The patient either has no known brain metastases or if the patient has brain metastases, the patient is symptomatically stable prior to starting nivolumab in combination with ipilimumab.<br>10. Nivolumab and ipilimumab will not be combined with any other systemic anti-cancer therapy.<br>11. Nivolumab will be administered at a flat dose of 360mg every 3 weeks.<br>Note: if nivolumab is discontinued because of toxicity, ipilimumab must also be stopped.<br>12. Ipilimumab will be administered at a dose of 1mg/Kg every 6 weeks.<br>Note: if ipilimumab is discontinued because of toxicity, nivolumab can be continued as monotherapy.<br>13. The patient will be treated until loss of clinical benefit or excessive toxicity or patient choice to discontinue treatment or completion of 2 years of treatment (a maximum of 35 cycles of nivolumab and a maximum of 17 cycles of ipilimumab), whichever is the sooner.<br>Note: the registration trial for this indication (Checkmate743) had a 2 year stopping rule in the trial design and NICE's assessment of clinical and cost effectiveness was based on a treatment duration of nivolumab plus ipilimumab that reflected the 2 year stopping rule in Checkmate743.<br>14. A first formal medical review as to whether treatment with nivolumab in combination with ipilimumab should continue or not will be scheduled to occur at least by the end of the first 6 weeks of treatment.<br>15. When a treatment break of more than 12 weeks beyond the expected 6-weekly cycle length is needed, a treatment break approval form will be completed to restart treatment, including as appropriate if the patient had an extended break on account of Covid-19.<br>16. The next appropriate line of therapy would be platinum-based chemotherapy in combination with pemetrexed if the patient is fit enough to receive such treatment.<br>17. Nivolumab and ipilimumab will be used as set out in their respective Summary of Product Characteristics (SPCs). | No | TA818 | 17-Aug-22 | 16-Sep-22 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| NIV21 | **Nivolumab** in combination with platinum and fluoropyrimidine-based chemotherapy | For previously untreated unresectable advanced or recurrent or metastatic squamous cell carcinoma of the oesophagus with a tumour cell PD-L1 expression of 1% or more and a PD-L1 combined positive score of <10 where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with nivolumab in combination with chemotherapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a histologically- or cytologically-confirmed diagnosis of squamous cell carcinoma of the oesophagus or adenosquamous carcinoma of the oesophagus.<br>Please mark below which histology applies to this patient:<br>3. The patient has locally advanced unresectable or recurrent or metastatic disease.<br>4. The patient has not received any previous systemic therapy for locally advanced unresectable or recurrent or metastatic disease ie I confirm that nivolumab plus chemotherapy will be 1st line systemic therapy for locally advanced unresectable or recurrent or metastatic disease.<br>5. An approved and validated test has demonstrated that the **tumour cell PD-L1 expression is 1% or more.**<br>Please document the actual tumour cell PD-L1 expression result below:<br>Tumour cell PD-L1 expression %: _____<br>6. An approved and validated test has demonstrated that the tumour has a PD-L1 expression with a combined positive score (CPS) of <10.<br>Please document the actual PD-L1 combined positive score (CPS) below:<br>PD-L1 CPS: _____<br>7. The patient has not received prior treatment with any antibody which targets PD-1 or PD-L1 or PD-L2 or CD137 or OX40 or anti-cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) unless the patient discontinued or completed checkpoint inhibitor immunotherapy as part of adjuvant therapy without disease progression and at least 6 months has elapsed between the date of the last immunotherapy treatment and the date of first diagnosis of relapse with recurrent or metastatic disease.<br>8. The chemotherapy used in combination with nivolumab will be both platinum and fluoropyrimidine-based.<br>9. Nivolumab will be administered at the licensed doses shown below<br>• **Subcutaneously** – at a dose of 600mg every 2 weeks, or 1200mg every 4 weeks<br>• **Intravenously** – at a dose of 240mg every 2 weeks, or 480mg every 4 weeks<br>Note: Nivolumab at a dose of 360mg, 3-weekly, when given in combination with 3-weekly based chemotherapy is permitted, but this is off-label dosing, so trust procedures for off-label prescribing must be adhered to.<br>10. The patient has an ECOG performance status (PS) of 0 or 1 and is fit for platinum and fluoropyrimidine-based chemotherapy in combination with nivolumab.<br>11. The patient has no symptomatically active brain metastases or leptomeningeal metastases.<br>12. Nivolumab will be stopped at whichever of the following events occurs first: disease progression or unacceptable toxicity or withdrawal of patient consent or after **2 calendar years of treatment regardless of any treatment breaks.**<br>Note: the 2 year stopping rule for nivolumab in this indication is in the marketing authorisation and its measurement as a 2 calendar year stopping rule was part of the company submission to NICE for the clinical and cost effectiveness<br>13. When a treatment break of more than 12 weeks beyond the expected 2- or 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment.<br>14. Nivolumab will otherwise be used as set out in its Summary of Product Characteristics (SPC). | No | TA865 | 08-Feb-23 | 09-May-23 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| NIV22 | **Nivolumab** in combination with platinum and fluoropyrimidine-based chemotherapy | For previously untreated advanced or metastatic HER-2 negative adenocarcinomas of the stomach, gastro-oesophageal junction or oesophagus which express PD-L1 with a combined positive score of 5 or more where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with nivolumab in combination with fluoropyrimidine-based chemotherapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a histologically- or cytologically-confirmed diagnosis of HER-2 negative adenocarcinoma of the stomach or gastro-oesophageal junction or oesophagus.<br>Please mark below which site of disease applies to this patient:<br>- HER-2 negative adenocarcinoma of the stomach<br>- HER-2 negative adenocarcinoma of the gastro-oesophageal junction<br>- HER-2 negative adenocarcinoma of the oesophagus<br>3. The patient has locally advanced unresectable or metastatic disease.<br>4. An approved and validated test has demonstrated that the tumour has a PD-L1 expression with a combined positive score (CPS) of 5 or more.<br>Please document the actual PD-L1 combined positive score (CPS) below:<br>PD-L1 CPS: _____<br>5. The has not received any previous systemic therapy for locally advanced unresectable or metastatic disease i.e. that nivolumab plus chemotherapy will be 1st line systemic therapy for locally advanced unresectable or metastatic disease.<br><br>In addition, please mark below whether the patient has/has not previously received any systemic therapy for earlier stage disease:<br>- this patient has not received any previous systemic therapy for HER-2 negative adenocarcinoma of the stomach or gastro-oesophageal junction or oesophagus<br>- this patient was previously treated with neoadjuvant chemotherapy for HER-2 negative adenocarcinoma of the oesophagus or gastro-oesophageal junction or stomach and underwent surgery and has since had disease progression<br>- this patient was previously treated with adjuvant chemotherapy for HER-2 negative adenocarcinoma of the oesophagus or gastro-oesophageal junction or stomach and has since had disease progression<br>- this patient was previously treated with concurrent chemo-radiotherapy for HER-2 negative adenocarcinoma of the oesophagus or gastro-oesophageal junction and has since had disease progression<br>6. The patient has not received prior treatment with any antibody which targets PD-1 or PD-L1 or PD-L2 or CD137 or OX40 or anti-cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) unless the patient discontinued or completed checkpoint inhibitor immunotherapy as part of adjuvant therapy without disease progression and at least 6 months has elapsed between the date of the last immunotherapy treatment and the date of first diagnosis of relapse with recurrent or metastatic disease:<br>- this patient has not received any previous immunotherapy for adenocarcinoma of the oesophagus/gastro-oesophageal junction/stomach<br>- this patient was previously treated with neoadjuvant platinum-based chemoradiotherapy for HER-2 negative adenocarcinoma of the oesophagus or gastro-oesophageal junction and underwent surgery followed by adjuvant nivolumab (NICE TA746) and then discontinued or completed treatment with adjuvant nivolumab without disease progression at least 6 months prior to the first diagnosis of relapse. Please document in the box below the time gap in months between completion of previous adjuvant nivolumab immunotherapy and first diagnosis of disease relapse:<br>_____<br>Note: the mandatory interval between the last date of administration of any prior adjuvant immunotherapy and first relapse is at least 6 months. For patients suffering a first relapse within 6-12 months of previous immunotherapy, clinicians should bear in mind the long elimination half-lives of immunotherapies and make individual assessments of the overall benefit/risk ratio of re-treatment with immunotherapy.<br>7. The patient has an ECOG performance status (PS) of 0 or 1 and is fit for platinum and fluoropyrimidine-based chemotherapy in combination with nivolumab.<br>8. The patient has no symptomatically active brain metastases or leptomeningeal metastases.<br>9. Nivolumab will be administered at a dose of either 240mg **IV** 2-weekly or 360mg **IV** 3-weekly when in combination with platinum and fluoropyrimidine-based chemotherapy.<br>Then subsequently, as monotherapy, given at the licensed dose, frequency, and route, for this indication, as shown below<br>• **Subcutaneously** – at a dose of 600mg every 2 weeks, or 1200mg every 4 weeks<br>• **Intravenously** – at a dose of 240mg every 2 weeks, or 480mg every 4 weeks<br><br>Note: nivolumab monotherapy can be continued after discontinuation of chemotherapy in the absence of disease progression.<br>10. The chemotherapy used in combination with nivolumab will be both platinum and fluoropyrimidine-based.<br>Please mark below which chemotherapy regimen is being used in this patient:<br>- oxaliplatin plus capecitabine<br>- oxaliplatin plus modified de Gramont regimen<br>- cisplatin plus capecitabine<br>- cisplatin plus infused 5-fluorouracil<br>- another regimen<br>11. Nivolumab will be stopped at whichever of the following events occurs first: disease progression or unacceptable toxicity or withdrawal of patient consent **or after 2 calendar years of treatment regardless of any treatment breaks**.<br>Note: the 2 year stopping rule for nivolumab in this indication is in the marketing authorisation and its measurement as 2 calendar year stopping rule was part of the company submission to NICE as to the clinical and cost effectiveness of nivolumab in this indication.<br>Note: once nivolumab is stopped after 2 years of treatment, it cannot be re-started.<br>12. When a treatment break of more than 12 weeks beyond the expected 2-, 3-, or 4-weekly cycle length is needed, I will complete a treatment break approval form requesting a restart of treatment. This **must** be approved before nivolumab is re-commenced<br>13. Nivolumab will otherwise be used as set out in its Summary of Product Characteristics (SPC). | No | TA857 | 11-Jan-23 | 11-Apr-23 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| NIV23 | **Nivolumab** plus chemotherapy | For the neoadjuvant treatment of adults with previously untreated UICC/AJCC 8th edition stage IIA or IIB or IIIA or N2 only IIIB non-small cell lung cancer and who are candidates for potentially curative surgery where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with neoadjuvant nivolumab in combination with chemotherapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The prescribing clinician is fully aware of the management of and the treatment modifications that may be required for immune-related adverse reactions due to anti-PD-L1 treatments including pneumonitis, colitis, nephritis, endocrinopathies, hepatitis and skin toxicity.<br>3. The patient has a histologically documented diagnosis of non-small cell lung cancer (NSCLC).<br>Please mark below which histology applies to this patient:<br>- squamous NSCLC<br>- non-squamous NSCLC<br>4. The patient **either** has been documented as NOT having a NSCLC which harbours an EGFR 19 or 21 mutation or an ALK gene fusion or the patient has a squamous cell carcinoma and a decision to not test for an EGFR 19 or 21 mutation or an ALK gene fusion and proceed with nivolumab has been made following discussion at the Lung Cancer MDT and consideration of the relevant patient characteristics (including age and smoking status).<br>Please mark below which option applies to this patient:<br>- Documented as NOT having a NSCLC which harbours an EGFR 19 or 21 mutation or an ALK gene fusion.<br>- Patient has squamous NSCLC and a decision to not test for an EGFR 19 or 21 mutation or an ALK gene fusion and proceed with nivolumab has been made following discussion at the Lung Cancer MDT.<br>5. The clinical TNM staging has been agreed at the appropriate Lung Cancer MDT meeting to be stage IIA or IIB or IIIA or N2 only IIIB tumour according to the UICC/AJCC TNM 8th edition.<br>Please mark below which stage applies to this patient:<br>- stage IIA disease (T2b N0)<br>- stage IIB disease (T1a N1 or T1b N1 or T1c N1 or T2a N1 or T2b N1 or T3 N0)<br>- stage IIIA disease (T1a N2 or T1b N2 or T1c N2 or T2a N2 or T2b N2 or T3 N1 or T4 N0 or T4 N1)<br>- N2 only stage IIIB disease (T3 N2 or T4 N2)<br>Note: the trial included patients staged using the UICC/AJCC TNM 7th edition and hence the marketing authorisation uses the 7th edition staging system. As NSCLC clinical staging is now reported using the UICC/AJCC TNM 8th edition, the corresponding 7th edition stages included in the marketing authorisation have been translated into those of the 8th edition.<br>6. The patient has been staged as having M0 disease.<br>7. The patient has been assessed by the thoracic surgical team to be eligible for a potentially curative resection and that the patient has the necessary fitness to undergo such surgery.<br>8. The patient will be treated with a maximum of **3** cycles of neoadjuvant therapy with the combination of nivolumab 360mg and platinum-based chemotherapy, each cycle planned to be given every 3 weeks.<br>9. The chemotherapy partner to this neoadjuvant combination will be a 2-drug platinum-based combination with the platinum component being either cisplatin or carboplatin given at a dose of at least AUC of 5mg/ml/min.<br>Please mark below which will be the platinum-based component of the 2-drug combination:<br>- cisplatin<br>- carboplatin given with a drug dose of at least AUC 5mg/ml/min<br>Note: the partner cytotoxic drugs to cisplatin/carboplatin can be pemetrexed or paclitaxel or gemcitabine or vinorelbine.<br>10. The intent is for the patient to potentially undergo resection within 6 weeks of completing the final 3-week cycle of neoadjuvant nivolumab plus chemotherapy.<br>11. The patient has not received any previous anticancer therapy for this NSCLC or any prior treatment with an anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CD137, or anti-Cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) antibody.<br>12. The patient has an ECOG performance status (PS) of 0 or 1.<br>13. Nivolumab will be stopped at whichever of the following events occurs first: disease progression or unacceptable toxicity or withdrawal of patient consent **or on completion of 3 cycles of treatment with nivolumab**.<br>14. A formal medical review as to how nivolumab plus chemotherapy is being tolerated and whether treatment with nivolumab plus chemotherapy should be completed or not will be scheduled to occur at least by the end of the<br>15. When a treatment break of more than 3 months beyond the expected 3-weekly cycle length is needed, a treatment break approval form will be completed to restart treatment, including indicating as appropriate if the patient had an extended break because of Covid-19.<br>16. The prescribing clinician is aware of the following issues which relate to the subsequent management of this patient following neoadjuvant nivolumab plus chemotherapy:<br>17. Nivolumab will be otherwise used as set out in its Summary of Product Characteristics (SPC). | No | TA876 | 22-Mar-23 | 20-Jun-23 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| NIV24 | **Nivolumab** with ipilimumab | Nivolumab plus ipilimumab for previously untreated patients with microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR) metastatic or locally advanced and inoperable colorectal cancer where the following criteria have been met: | 1. This application for nivolumab plus ipilimumab is being made by and the first cycle of systemic anti-cancer therapy with nivolumab plus ipilimumab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has either metastatic or locally advanced and inoperable colorectal carcinoma and has not received any previous systemic therapy for this indication.<br>Note: patients may have received neoadjuvant systemic therapy for non-metastatic disease and/or adjuvant chemotherapy after surgery.<br>3. The patient's tumour has a documented presence of microsatellite instability-high (MSI-H) or DNA mismatch repair deficiency (dMMR) confirmed by validated testing.<br>4. The patient's tumour has been determined to have wild type or mutant RAS status and the result is recorded below:<br>5. The patient's tumour has been determined to have wild type or mutant BRAF status and the result is recorded below:<br>- wild type BRAF status<br>- mutant BRAF status<br>- BRAF test result not yet reported and the decision to proceed without knowing BRAF status has been discussed with the patient during the consenting process<br>6. The patient has an ECOG performance status (PS) of 0 or 1.<br>7. The patient has no symptomatic brain or leptomeningeal metastases.<br>8. The patient has not received prior treatment with an anti-PD-1, anti-PD-L2, anti-CD137, or anti-Cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) antibody unless the patient was enrolled in the NEOPRISM-CRC clinical trial (NIHR CPMS ID:52000) and did not have clear evidence of radiologically-assessed progressive disease at the end of neoadjuvant pembrolizumab therapy.<br><br>Please mark below which clinical scenario applies to this patient:<br>- the patient has not received any previous anti-PD-1, anti-PD-L2, anti-CD137, or anti-Cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) antibody therapy for metastatic colorectal cancer or<br>- the patient was enrolled in the NEOPRISM-CRC clinical trial (NIHR CPMS ID:52000) and did not have clear evidence of radiologically-assessed progressive disease at the end of neoadjuvant pembrolizumab therapy<br><br>Note: this combination of nivolumab plus ipilimumab is not funded after previous treatment with pembrolizumab for MSI-H or dMMR metastatic or locally advanced and inoperable colorectal cancer.<br>9. Nivolumab will be administered in combination with ipilimumab as follows: nivolumab 240mg and ipilimumab 1mg/Kg are given intravenously in combination for a maximum of 4 cycles every 3 weeks, and then nivolumab is continued as monotherapy at the licensed dose, frequency, and route for this indication, as shown below<br><br>• **Subcutaneously** – at a dose of 600mg every 2 weeks, or 1200mg every 4 weeks<br>• **Intravenously** – at a dose of 240mg every 2 weeks, or 480mg every 4 weeks<br>10. Nivolumab will be stopped on disease progression or unacceptable toxicity or withdrawal of patient consent or **completion of 2 calendar years of treatment with nivolumab**, whichever occurs first.<br>11. When a treatment break of more than 12 weeks beyond the expected 2, 3 or 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment. This MUST be approved before treatment is re-started.<br>12. Nivolumab and ipilimumab will be otherwise used as set out in their respective Summaries of Product Characteristics (SPCs). | No | TA1065 | 28-May-25 | 27-Aug-25 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| NIV25 | **Nivolumab** | Nivolumab plus chemotherapy for neoadjuvant treatment and then continued as adjuvant monotherapy in adults with previously untreated UICC/AJCC 8th edition stage IIA or IIB or IIIA or N2 only IIIB non-small cell lung cancer AND who are candidates for potentially curative surgery where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with neoadjuvant nivolumab in combination with chemotherapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a histologically documented diagnosis of non-small cell lung cancer (NSCLC).<br>Please mark below which histology applies to this patient:<br>- squamous NSCLC<br>- non-squamous NSCLC<br>3. **Either** the patient has been documented as NOT having a NSCLC which harbours an EGFR 19 or 21 mutation or an ALK gene fusion or the patient has a squamous cell carcinoma and a decision to not test for an EGFR 19 or 21 mutation or an ALK gene fusion and proceed with nivolumab has been made following discussion at the Lung Cancer MDT and consideration of the relevant patient characteristics (including age and smoking status).<br>Please mark below which option applies to this patient:<br>- Documented as NOT having a NSCLC which harbours an EGFR 19 or 21 mutation or an ALK gene fusion<br>- Patient has squamous NSCLC and a decision to not test for an EGFR 19 or 21 mutation or an ALK gene fusion and proceed with nivolumab has been made following discussion at the Lung Cancer MDT<br>4. The clinical TNM staging has been agreed at the appropriate Lung Cancer MDT meeting to be stage IIA or IIB or IIIA or N2 only IIIB tumour according to the UICC/AJCC TNM 8th edition.<br>Please mark below which stage applies to this patient:<br>- stage IIA disease (T2b N0)<br>- stage IIB disease (T1a N1 or T1b N1 or T1c N1 or T2a N1 or T2b N1 or T3 N0)<br>- stage IIIA disease (T1a N2 or T1b N2 or T1c N2 or T2a N2 or T2b N2 or T3 N1 or T4 N0 or T4 N1)<br>- N2 only stage IIIB disease (T3 N2 or T4 N2)<br>5. The patient has been staged as having M0 disease and has been assessed by the thoracic surgical team to be eligible and fit for a potentially curative resection.<br>6. The intent is to treat the patient with a maximum of 4 cycles of 3-weekly neoadjuvant platinum-based chemotherapy in combination with 3 weekly **intravenous** nivolumab at a dose of 360mg.<br><br>**Note**: Subcutaneous nivolumab at a dose of 900mg every three weeks is **NOT** commissioned by NHS England in the neoadjuvant phase, in this indication.<br>7. The chemotherapy partner to this neoadjuvant combination will be a 2-drug platinum-based combination with the platinum component being either cisplatin or carboplatin given at a dose of at least AUC of 5mg/ml/min.<br>Please mark below which will be the platinum-based component of the 2-drug combination:<br>- cisplatin<br>- carboplatin given with a drug dose of at least AUC 5mg/ml/min<br><br>Note: the partner cytotoxic drugs to cisplatin/carboplatin can be pemetrexed or paclitaxel or gemcitabine or vinorelbine.<br>8. The intent is for the patient to potentially undergo resection within 20 weeks of the 1st dose of neoadjuvant therapy.<br>9. The intent is for the patient to commence adjuvant nivolumab monotherapy no later than 12 weeks after surgery, with nivolumab administered at one of the licensed doses as shown below.<br>• 1200mg every 4 weeks if given via **subcutaneous** injection<br>• 480mg every 4 weeks if given via **intravenous** infusion<br><br>Adjuvant nivolumab monotherapy can be given for a maximum of 13 x 4 weekly cycles, and then it MUST be discontinued.<br>10. The intent for any patient requiring any form of post-operative radiotherapy is for this to start no later than 8 weeks after surgery and for adjuvant nivolumab to commence no later than 4 weeks after completion of radiotherapy.<br>11. The patient has not received any previous anticancer therapy for this NSCLC or any prior treatment with an anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CD137, or anti-Cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) antibody.<br>12. The patient has an ECOG performance status (PS) of 0 or 1.<br>13. Nivolumab will be stopped at whichever of the following events occurs first: any local or distant disease progression at any time in the neoadjuvant, peri-operative and adjuvant phases of treatment or unacceptable toxicity or withdrawal of patient consent or on completion of the maximum allowed duration of treatment with adjuvant nivolumab as outlined above.<br>14. When a treatment break of more than 12 weeks beyond the expected 3-weekly or 4-weekly cycle length (as appropriate) is needed, the prescribing clinician will complete a treatment break approval form to restart treatment, which MUST be approved before treatment is recommenced.<br>15. The prescribing clinician is aware of the following issues which relate to the subsequent management of this patient following neoadjuvant nivolumab plus chemotherapy:<br>i) if the patient has a resection, then post-operative radiotherapy or chemoradiotherapy can be given if indicated and in the absence of any progressive disease, the patient can proceed to adjuvant nivolumab<br>ii) if the patient does not have a resection, then radiotherapy or chemoradiotherapy can be given if indicated and in the absence of any progressive disease, the patient can proceed to adjuvant nivolumab<br>iii) if the patient does not have surgery or radiotherapy or chemoradiotherapy, no adjuvant nivolumab can be given<br>iv) if there is disease progression during neoadjuvant or adjuvant nivolumab, no further anti-PD1 or anti-PDL1 immunotherapy is funded in any indication<br>16. Nivolumab will be otherwise used as set out in its Summary of Product Characteristics (SPC). | No | TA1127 | 04-Feb-26 | 06-Mar-26 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| NIVREL1 | **Nivolumab** in combination with relatlimab (Opdualag ®) | As first immunotherapy for treating unresectable or metastatic melanoma in patients aged 12 years or more where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with the combination of nivolumab plus relatlimab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The prescribing clinician is fully aware of the management of and the treatment modifications that may be required for immune-related adverse reactions due to checkpoint inhibitor treatments including pneumonitis, colitis, nephritis, endocrinopathies, hepatitis, myocarditis and skin toxicities.<br>3. The patient has unresectable stage III or stage IV histologically confirmed melanoma.<br>4. The patient is aged 12 years or older.<br>5. The patient has not received previous treatment **for this indication of unresectable or metastatic melanoma with any of the following:** anti-Programmed Death receptor-1 (PD-1), anti-Programmed Death-1 ligand-1 (PD-L1), anti-PD-L2, or anti-cytotoxic T lymphocyte associated antigen-4 (anti-CTLA-4) antibodies.<br>Note: treatment with nivolumab plus relatlimab is not funded for any patients with unresectable or metastatic melanoma who have already started treatment with pembrolizumab monotherapy or nivolumab monotherapy or nivolumab plus ipilimumab.<br>6. The patient is completely treatment naïve for systemic therapy for melanoma or has only received specifically allowed prior systemic therapy*.<br><br>* Allowed prior therapies are:<br>1) prior adjuvant therapy with adjuvant nivolumab or pembrolizumab or<br>2) prior immune checkpoint inhibitors for the advanced disease indication only when given as part of a clinical trial either as monotherapy or in combination with ipilimumab or<br>3) BRAF/MEK inhibitor targeted therapies when given for the adjuvant indication or<br>4) BRAF/MEK inhibitor targeted therapies when given as 1st line treatment for the advanced disease indication.<br><br>Please mark below previous systemic therapies received:<br>- no previous systemic therapy of any kind for melanoma or<br>- prior adjuvant therapy with adjuvant nivolumab or pembrolizumab monotherapies or<br>- prior immune checkpoint inhibitors for the advanced disease indication only when given as part of a clinical trial either as monotherapy or in combination with ipilimumab or<br>- BRAF/MEK inhibitor targeted therapies when given for the adjuvant indication or<br>- BRAF/MEK inhibitor targeted therapies when given as 1st line treatment for the advanced disease indication or<br>7. The patient is of ECOG performance status (PS) 0 or 1 or if aged 12-17 years is of Lansky performance score of 80% or more.<br>8. The patient has no symptomatic brain metastases or leptomeningeal metastases currently requiring steroids for symptom control.<br>9. Nivolumab 480mg with relatlimab 160mg in a combined formulation (Opdualag®) will be used every 4 weeks.<br>Note: this dose is established for adolescent patients weighing at least 30Kg.<br>10. Nivolumab plus relatlimab will be given until whichever of the following occurs first: progressive disease or loss of clinical benefit or unacceptable toxicity or withdrawal of patient consent or **two calendar years have passed since the date of first treatment with nivolumab plus relatlimab.**<br>Note: NICE's recommendation as to the clinical and cost effectiveness of nivolumab plus relatlimab was based on a 2 calendar year stopping rule in the company's NICE submission. There is therefore no funding for nivolumab and relatlimab after 2 calendar years have passed since the date of first treatment.<br>Note: in patients who discontinued nivolumab plus relatlimab after 2 calendar years have passed since the date of first treatment and who subsequently relapse, a re-start of further treatment with nivolumab plus relatlimab is not funded.<br>11. During the consenting process to start treatment with nivolumab plus relatlimab the patient has been informed of the maximum treatment duration of 2 calendar years as measured from the date of first treatment.<br>12. A formal medical review to assess the tolerability of treatment with nivolumab plus relatlimab will be scheduled to occur by the start of the 3rd 4-weekly cycle of treatment and thereafter on a regular basis.<br>13. When a treatment break of more than 12 weeks beyond the expected cycle length is needed, a treatment break approval form will be completed to restart treatment.<br>14. Nivolumab plus relatlimab will be otherwise prescribed and administered as outlined in Opdualag's® Summary of Product Characteristics (SPC) for this indication. | No | TA950 | 07-Feb-24 | 07-May-24 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| OBE01a | **Obecabtagene autoleucel** | Obecabtagene autoleucel (obecel) CAR-T cells for treating relapsed/refractory Philadelphia negative or positive B cell precursor acute lymphoblastic leukaemia in patients aged 26 years and older where the following criteria have been met:<br><br>This form is for the approval of leucapheresis and manufacture of CAR-T cells. There is a second part to this form which relates to the subsequent infusion of CAR-T cells and this will be available after submission of the first part. The second part of the form (OBE01b) can only be completed as a continuation of this first part of the form (OBE01a) and OBE01b must be completed on infusion of CAR-T cells otherwise the treating Trust will not be reimbursed for the cost of obecabtagene autoleucel (obecel).<br><br>Note: the second part of the form (OBE01b) will only appear after the above first part of the form (OBE01a) has been fully completed and submitted. To complete the second part of the form, the user will have to complete a continuation request for the OBE1a application. | 1. This application is being made by and that leucapheresis for and treatment with obecabtagene autoleucel (obecel) will be initiated by a consultant haematologist specifically trained and accredited in the use of systemic anti-cancer therapy and working in an accredited CAR-T cell treatment centre and who is a member of the National CAR-T Clinical Panel for adult acute lymphoblastic leukaemia and a member of the treating Trust's adult acute lymphoblastic leukaemia and CAR-T cell multidisciplinary teams.<br><br>2. The patient has CD19 positive relapsed or refractory B lineage acute lymphoblastic leukaemia (ALL).<br>Please tick appropriate box as to which type of ALL the patient has:<br>- Philadelphia chromosome negative ALL or<br>- Philadelphia chromosome positive ALL previously treated with at least 1 tyrosine kinase inhibitor (TKI) or the patient is unsuitable for or intolerant of TKI therapy.<br>Note: patients with Burkitt leukaemia/lymphoma or with chronic myeloid leukaemia lymphoid blast crisis are not eligible for treatment with obecabtagene autoleucel (obecel).<br><br>3. The patient fulfils one of the following clinical scenarios relating to the definition of relapsed or refractory ALL.<br>Please tick the most appropriate box as to which applies to this patient:<br>- the patient has primary refractory disease i.e. did not achieve a complete remission after 2 cycles of combination systemic anti-cancer therapy for newly diagnosed ALL or<br>- the patient has a bone marrow relapse after allogeneic stem cell transplantation in 1st remission and is at least 3 months since allogeneic SCT with no active Graft versus Host Disease (GVHD) requiring systemic therapy or<br>- the patient has a bone marrow relapse after allogeneic stem cell transplantation in 2nd remission or beyond, and is at least 3 months since allogeneic SCT with no GvHD requiring systemic therapy or<br>- the patient is in 1st bone marrow relapse following a remission lasting 12 months or less (not had SCT) or<br>- the patient is refractory to or has relapsed after 2nd or more lines of systemic anti-cancer therapy (not had SCT) or<br>- relapsed disease and ineligible for allogeneic SCT due to comorbid disease (but still fit enough for CAR-T cell therapy with obecabtagene autoleucel (obecel)) or contraindicated to allogeneic SCT conditioning or lack of a suitable donor<br><br>4. Having fulfilled, and ticked one of the criteria in box 3 above, the patient at the time of demonstration of such refractory/relapsed disease and thus consideration for potential treatment with obecabtagene autoleucel (obecel) has a bone marrow with CD19+ B-ALL demonstrable by flow cytometry.<br>Measurable residual disease by molecular methods is insufficient to comply with access to obecabtagene autoleucel (obecel).<br><br>5. The patient does not have an isolated extramedullary ALL relapse i.e. if the patient has extramedullary disease, then the patient must also have bone marrow disease as set out above in criterion 4.<br><br>6. At the time of this application for treatment with obecabtagene autoleucel (obecel) the patient does not have active CNS involvement by ALL whether this be CNS2 with neurological changes or CNS3.<br><br>7. The patient has either been previously treated with blinatumomab or not. If there has been previous therapy with blinatumomab, there must be CD19 expression on the lymphoblasts (bone marrow or blood) after the most recent line of treatment.<br>Please tick appropriate box as to whether the patient has received blinatumomab or not:<br>- No previous treatment with blinatumomab or<br>- Yes, previous treatment with blinatumomab<br><br>8. The patient has been previously treated with inotuzumab or not.<br>Please tick appropriate box as to whether patient has received inotuzumab or not:<br>- No previous treatment with inotuzumab or<br>- Yes, previous treatment with inotuzumab<br><br>9. The patient has either had no previous therapy with any genetically modified autologous or allogeneic T cell immunotherapy or the patient has been treated with doses of genetically modified autologous or allogeneic T cell immunotherapy within an abandoned dosing cohort in a first in human dose-escalation phase I clinical trial.<br>Please tick appropriate box as to which type of previous treatment the patient has had:<br>- No previous therapy with any genetically modified autologous or allogeneic T cell immunotherapy or<br>- Previously treated with doses of genetically modified autologous or allogeneic T cell immunotherapy within an abandoned dosing cohort in a first in human dose-escalation phase I clinical trial.<br><br>10. The patient has an ECOG performance status of 0 or 1.<br>Please mark in the box below the current performance status:<br>- PS 0 or<br>- PS 1<br><br>11. The patient has sufficient end organ function to tolerate treatment with obecabtagene autoleucel (obecel).<br><br>12. The patient is aged 26 years or more on the date of approval for obecabtagene autoleucel (obecel) by the National CAR-T Adult ALL Clinical Panel.<br><br>13. The current intent is for the patient to receive bridging therapy prior to the conditioning chemotherapy before CAR-T infusion.<br>Please mark in the box below:<br>- no, there is no current intent for the patient to undergo bridging systemic anti-cancer therapy or<br>- yes, there is an intent for the patient to undergo bridging systemic anti-cancer therapy<br><br>14. Obecabtagene autoleucel (obecel) will be used as set out in its Summary of Product Characteristics (SPC).<br><br>15. Approval for the use of obecabtagene autoleucel (obecel) has been formally given by the National adult acute lymphoblastic leukaemia CAR-T cell Clinical Panel.<br>Please state date of approval:<br>_____<br><br>16. Following national approval for use of obecabtagene autoleucel (obecel) there has been local CAR-T cell multidisciplinary team agreement that this patient continues to have the necessary fitness for treatment and fulfils all the treatment criteria listed here. | No | TA1116 | 11-Dec-25 | 11-Mar-26 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| OBE01b | **Obecabtagene autoleucel** | Obecabtagene autoleucel (obecel) for treating relapsed/refractory Philadelphia negative and positive B cell acute lymphoblastic leukaemia in patients aged 26 years and older where the following criteria have been met:<br><br>This second form is to document the date of infusion of CAR T cell therapy and for registration of this infusion with NHS England so that the treating Trust is reimbursed for the cost of obecabtagene autoleucel (obecel). There is a first form for the approval of leucapheresis and manufacture of CAR T cells. This second form must use the same unique Blueteq identifier number generated when this patient was registered for leucapheresis and CAR T cell manufacture using the first form. | 1. This application is being made by and treatment with obecabtagene autoleucel (obecel) will be initiated by a consultant haematologist specifically trained and accredited in the use of systemic anti-cancer therapy and working in an accredited CAR-T cell treatment centre and who is a member of the National CAR T Clinical Panel for adult acute lymphoblastic leukaemia and a member of the treating Trust's adult acute lymphoblastic leukaemia and CAR-T cell multidisciplinary teams.<br>2. The patient was either treated with bridging therapy in between leucapheresis and CAR-T cell infusion or not. Please indicate what type(s) of bridging therapy have been required by ticking the most appropriate option below:<br>- no bridging therapy at all or<br>- Corticosteroids only or<br>- TKI therapy with or without steroids or<br>- systemic cytotoxic chemotherapy with or without steroids or<br>- systemic cytotoxic chemotherapy plus TKI with or without steroids or<br>- inotuzumab with or without steroids or<br>- other<br>3. The patient has an ECOG performance status of 0 or 1.<br>Please mark in the box below the current performance status:<br>- PS 0 or<br>- PS 1<br>4. The patient has sufficient end organ function to tolerate treatment with obecabtagene autoleucel (obecel).<br>5. Obecabtagene autoleucel (obecel) will be used as set out in its Summary of Product Characteristics (SPC).<br>6. Following national approval for use of obecabtagene autoleucel (obecel) there has been local CAR T cell multidisciplinary team agreement that this patient continues to have the necessary fitness for treatment and fulfils all the treatment criteria listed here. | No | TA1116 | 11-Dec-25 | 11-Mar-26 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| OBI2 | **Obinutuzumab** | Obinutuzumab in combination with chlorambucil for untreated chronic lymphocytic leukaemia where the following criteria have been met: | 1. This application is being made by and the 1st cycle of systemic anti cancer therapy with obinutuzumab plus chlorambucil will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a confirmed pathological diagnosis of chronic lymphocytic leukaemia.<br>3. The patient has documented CD20+ chronic lymphocytic leukaemia<br>4. The patient has NOT been previously treated for chronic lymphocytic leukaemia and has comorbidities that make full-dose fludarabine-based therapy and bendamustine-based therapy unsuitable for them, e.g. people who have comorbidities such as impaired renal function, hypertension or diabetes<br>5. A maximum of 6 cycles of the combination of obinutuzumab plus chlorambucil should be used<br>6. The patient has a performance status (PS) of 0 - 2.<br>7. No planned treatment breaks of more than 6 weeks beyond the expected cycle length are allowed (to allow any toxicity of current therapy to settle or intercurrent comorbidities to improve).*<br>*Requests for continuation of treatment after unplanned treatment breaks over this duration should be made via the treatment break approval process.<br>8. The licensed doses and frequencies of obinutuzumab and chlorambucil will be used. | No | TA343 | 02-Jun-15 | 31-Aug-15 |
| OBIBEN1 | **Obinutuzumab with bendamustine** | The treatment of follicular lymphoma refractory to rituximab where the following criteria apply: | 1. An application has been made by and the first cycle of systemic anti -cancer therapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a confirmed histological diagnosis of follicular lymphoma.<br>3. The patient has been previously treated for follicular lymphoma with rituximab-containing chemotherapy (i.e. with induction rituximab-containing chemotherapy followed if appropriate by maintenance rituximab therapy) and that the patient has either progressed during rituximab-containing induction chemotherapy or progressed during or within 6 months of completing maintenance rituximabmonotherapy.<br><br>Please indicate below whether the patient progressed during rituximab-containing induction chemotherapy or during or within 6 months of completing maintenance rituximab monotherapy:<br>- The patient has either failed to respond to or progressed during rituximab-containing combination induction chemotherapy **or**<br>- The patient has progressed during or within 6 months of completing maintenance single agent rituximab.<br><br>If the patient progressed during or within 6 months of completing maintenance single agent rituximab, please indicate how many months since completion of previous induction rituximab-containing combination chemotherapy progression occurred:<br>Please also indicate below whether the patient was originally treated with 1st line obinutuzumab-containing chemotherapy or not:<br>- The patient was previously treated with 1st line obinutuzumab-containing chemotherapy **or**<br>- The patient was not previously treated with 1st line obinituzumab-containing chemotherapy.<br>4. The patient has not previously received treatment with bendamustine unless completed more than 2 years previously.<br>5. A maximum of 6 cycles of the combination of obinutuzumab plus bendamustine should be used and followed in responding patients or in those with stable disease with maintenance single agent obinutuzumab once every 2 months for a maximum of 2 years or until disease progression (whichever occurs first).<br>6. The patient has an ECOG performance status (PS) of 0 - 2.<br>7. No planned treatment breaks of more than 6 weeks beyond the expected cycle length are allowed (to allow any toxicity of current therapy to settle or intercurrent comorbidities to improve).<br>8. The licensed doses and frequencies of obinutuzumab and bendamustine will be used. | No | TA629 | 13-May-20 | 11-Aug-20 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| OBI1 | **Obinutuzumab** | The treatment of untreated advanced follicular lymphoma where all the following crtieria are met: | 1. This application is made by and the first cycle of obinituzumab in combination with chemotherapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy<br>2. The patient has a confirmed histological diagnosis of grade 1-3a CD20-positive follicular lymphoma<br>3. The patient has not previously received any of the following for treatment of lymphoma: chemotherapy alone, immunotherapy alone (rituximab, obinutuzumab) or chemotherapy in combination with immunotherapy (rituximab, obinutuzumab).<br>4. The patient has been assessed according to the Follicular Lymphoma International Prognostic Index (FLIPI) and has scored a value of at least 2. Please indicate FLIPI score:<br>Follicular Lymphoma International prognostic Index (FLIPI) scoring system<br>1. Age: if < 60 years, score 0; if ≥ 60 years, score 1<br>2. Serum LDH: if in normal range, score 0; if raised above normal range, score 1<br>3. Haemoglobin level: if ≥ 120g/L, score 0; if < 120g/L, score 1<br>4. Ann Arbor stage: if stage I or II, score 0; if stage III or IV, score 1<br>5. Number of involved nodal areas: if ≤ 4, score 0; if ≥ 5, score 1. Each of the following is considered a single nodal area: left cervical, right cervical, left axillary, right axillary, mediastinal (includes hilar, paratracheal and retrocrural areas), mesenteric (includes coeliac, splenic and portal areas), para-aortic (includes common iliac and external iliac areas), left inguinal (includes left femoral area), right inguinal (includes right femoral area), other (eg epitrochlear, popliteal areas)<br>5. The patient has bulky stage II disease (>7cm) or stage III disease or stage IV disease. Patients with stage I disease or non-bulky stage II disease are not eligible for obinutuzumab<br>6. I confirm that obinutuzumab is to be given in combination with induction combination chemotherapy as either:<br>OPTION 1 - A maximum of 6 cycles if given with bendamustine.<br>OPTION 2 - A maximum of 6 cycles if given with CHOP (then give obinutuzumab alone for cycles 7 and 8)<br>OPTION 3 - A maximum of 8 cycles if given with CVP.<br>7. On completion of induction chemotherapy in combination with obinutuzumab, only patients having at least a documented partial response to treatment will commence maintenance therapy with single agent* obinutuzumab once every 2 months for a maximum of 2 years or until disease progression (whichever occurs first)<br>*Note patients entered into the PETReA** clinical trial may receive lenalidomide alongside obinutuzumab maintenance therapy as per the trial protocol.<br>**PETReA Phase 3 evaluation of PET-guided, Response-Adapted therapy in patients with previously untreated, high tumour burden follicular lymphoma<br>8. The patient has an ECOG performance status of 0, 1 or 2<br>9. A formal medical review as to whether treatment with obinutuzumab in combination with chemotherapy should continue or not will be scheduled to occur at least by the end of the third cycle of treatment<br>10. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment, including as appropriate if the patient had an extended break on account of Covid-19.<br>11. Obinutuzumab is to be otherwise used as set out in its Summary of Product Characteristics | No | TA513 | 21-Mar-18 | 19-Jun-18 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| OLAP1a | **Olaparib**<br>in its tablet formation | For the maintenance treatment in patients with high grade epithelial stage III or IV ovarian, fallopian tube or primary peritoneal carcinoma who are in response following platinum-based FIRST line chemotherapy AND who have a deleterious or suspected deleterious germline and/or somatic BRCA mutation where the following criteria have been met:<br><br>THIS FORM IS FOR INITIATION OF MAINTENANCE OLAPARIB AS A SINGLE AGENT ONLY.<br><br>THIS FORM IS FOR INITIATION OF MAINTENANCE OLAPARIB TABLETS IN THIS INDICATION. A separate CDF form OLAP1b is only for those patients with stable residual disease for whom it is appropriate to continue maintenance olaparib tablets after completion of 2 years of maintenance olaparib therapy. OLAP1b must be completed in such patients for funding of olaparib tablets to continue beyond 2 years<br><br>A separate form (**OLAP4**) is to be used for olaparib in combination with bevacizumab as maintenance treatment in this 1st line indication. | 1. This application is made by and the first cycle of systemic anti-cancer therapy with olaparib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy. | Yes | TA962 | 28-Mar-24 | 26-Jun-24 |
| | | | 2. This patient has a proven histological diagnosis of predominantly high grade serous or high grade endometrioid or high grade clear cell ovarian, fallopian tube or primary peritoneal carcinoma.<br>Please enter below as to which is the predominant histology in this patient:<br>- high grade serous adenocarcinoma **or**<br>- high grade endometrioid adenocarcinoma **or**<br>- high grade clear cell carcinoma | | | | |
| | | | 3. This patient has had germline and/or somatic (tumour) BRCA testing.<br>Please enter below the type of tissue on which BRCA mutation testing results are known at the time of this application:<br>- proven germline BRCA mutation **or**<br>- proven somatic BRCA mutation only i.e. somatic BRCA mutation positive and germline BRCA mutation negative **or**<br>- somatic BRCA mutation positive and germline BRCA mutation test not yet known | | | | |
| | | | 4. This patient HAS a documented deleterious or suspected deleterious BRCA 1 or BRCA 2 mutation(s).<br>Please enter below as to which deleterious or suspected deleterious BRCA mutation(s) the patient has:<br>- BRCA 1 mutation **or**<br>- BRCA 2 mutation **or**<br>- both BRCA1 and BRCA 2 mutations | | | | |
| | | | 5. The patient has recently diagnosed FIGO stage III or IV ovarian, fallopian tube or primary peritoneal carcinoma.<br>Note: maintenance olaparib in this indication is not funded for patients with recently diagnosed and treated stage 1-IIC disease or for patients relapsing after previous treatment. | | | | |
| | | | 6. One of the following scenarios applies to the surgical management of the patient in relation to the stage of the disease:<br>- the patient has stage III disease and had an upfront attempt at optimal cytoreductive surgery **or**<br>- the patient has stage III disease and had an interval attempt at optimal cytoreductive surgery **or**<br>- the patient has stage III disease and has had a biopsy only with no upfront or interval attempt at cytoreductive surgery **or**<br>- the patient has stage IV disease and had an upfront attempt at optimal cytoreductive surgery **or**<br>- the patient has stage IV disease and had an interval attempt at optimal cytoreductive surgery **or**<br>- the patient has stage IV disease and has had a biopsy only with no upfront or interval attempt at cytoreductive surgery | | | | |
| | | | 7. The patient has been treated with platinum-based 1st line chemotherapy and has received a minimum of 4 cycles of platinum-based treatment. | | | | |
| | | | 8. The patient is currently less than 8 weeks from the date of the last infusion of the last cycle of 1st line chemotherapy unless or the patient has been receiving niraparib maintenance after 1st line chemotherapy and all the other treatment criteria on this from are fulfilled.<br>Please indicate below which scenario applies to this patient:<br>- less than 8 weeks since date of last infusion in last cycle of 1st line chemotherapy i.e. the patient is olaparib naïve **or**<br>- previously received niraparib monotherapy as 1st line maintenance therapy and this has had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression | | | | |
| | | | 9. This patient has responded to the recently completed 1st line chemotherapy and has achieved a partial or complete response to treatment according to the definitions given below and with no evidence of progressive disease on the post-treatment scan or a rising CA125 level. Please enter below as to which response assessment applies to this patient:<br>- achieved a complete response at the end of 1st line chemotherapy i.e. has no measurable or non-measurable disease on the post-chemotherapy scan and the CA125 is normal or<br>- achieved a partial response at the end of 1st line chemotherapy i.e. has had at least a 30% reduction in measurable or non-measurable disease from the start of to the completion of 1st line chemotherapy or the patient has a complete remission on the post-chemotherapy CT scan but the CA125 has not decreased to within the normal range. | Yes | TA962 | 28-Mar-24 | 26-Jun-24 |
| | | | 10. The patient has not previously received any PARP inhibitor unless 1st line maintenance niraparib monotherapy has had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression. Please mark below which scenario applies to this patient:<br>- the patient has never previously received a PARP inhibitor **or**<br>- the patient has previously received niraparib monotherapy as 1st line maintenance therapy and this has had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression | | | | |
| | | | 11. Olaparib will be used as monotherapy. | | | | |
| | | | 12. Maintenance olaparib is not being administered concurrently with maintenance bevacizumab.<br>Please indicate below whether bevacizumab was used in combination with the 1st line chemotherapy<br>- bevacizumab 7.5mg/Kg given in combination with platinum-based chemotherapy **or**<br>- bevacizumab 15mg/Kg given in combination with platinum-based chemotherapy **or**<br>- no bevacizumab used in combination with chemotherapy | | | | |
| | | | 13. The patient has an ECOG performance status of either 0 or 1.<br>Note: a patient with a performance status of 2 or more is not eligible for olaparib | | | | |
| | | | 14. Olaparib is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment or **for a total treatment duration of 2 years if the patient is in complete remission at the end of the 2 year treatment period**.<br>For those patients with stable residual disease after completing 2 years of treatment, treatment with maintenance olaparib can continue if the treating clinician considers that the patient will derive further benefit. If treatment beyond 2 years is to occur, form OLAP1b must be completed prior to continuation otherwise olaparib will not be funded. | | | | |
| | | | 15. A formal medical review as to whether maintenance treatment with olaparib should continue or not will be scheduled to occur at least by the start of the third cycle of treatment | | | | |
| | | | 16. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, the prescribing clinician will complete a treatment break approval form to restart treatment. | | | | |
| | | | 17. Olaparib in its tablet formulation is to be otherwise used as set out in its Summary of Product Characteristics | | | | |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| OLAP1b | **Olaparib** in its tablet formation | For the maintenance treatment in patients with high grade epithelial BRCA mutation positive stage III or IV ovarian, fallopian tube or primary peritoneal carcinoma who responded to platinum-based FIRST line chemotherapy AND who still have stable residual disease after 2 years of olaparib maintenance therapy and who are planned to continue with maintenance olaparib where the following criteria have been met:<br><br>THIS FORM IS FOR CONTINUATION OF MAINTENANCE OLAPARIB AFTER COMPLETION OF 2 YEARS OF TREATMENT. A separate form OLAP1a is used for initiating maintenance olaparib shortly after completion of 1st line chemotherapy. | 1. This application is made by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy. | Yes | TA962 | 28-Mar-24 | 26-Jun-24 |
| | | | 2. This patient has just completed 2 years of maintenance therapy with olaparib following a response to platinum-based 1st line chemotherapy for BRCA mutation positive high grade serous or endometrioid ovarian, fallopian tube or primary peritoneal carcinoma. | | | | |
| | | | 3. The patient has had a scan after completing 2 years of maintenance olaparib and this scan confirms the presence of stable residual disease and serial CA125 measurements also show no evidence of disease relapse.<br>Note: if the patient is in complete remission after 2 years of maintenance olaparib, maintenance olaparib should be discontinued as per the marketing authorisation of olaparib and the NICE guidance. | | | | |
| | | | 4. The prescribing clinician considers that the patient is likely to benefit from continuing on maintenance olaparib. | | | | |
| | | | 5. The patient continues to have a sufficiently good ECOG performance to continue on olaparib maintenance therapy. | | | | |
| | | | 6. Olaparib is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment. | | | | |
| | | | 7. Olaparib will continue to be used as monotherapy. | | | | |
| | | | 8. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, the prescribing clinician will complete a treatment break approval form to restart treatment. | | | | |
| | | | 9. Olaparib in its tablet formulation is to be otherwise used as set out in its Summary of Product Characteristics | | | | |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| OLAP2 | **Olaparib**<br>in its tablet formation | For the maintenance treatment in patients with high grade epithelial ovarian, fallopian tube or primary peritoneal carcinoma who HAVE a deleterious or suspected deleterious germline and/or somatic BRCA mutation and who have a recent FIRST RELAPSE of platinum-sensitive disease and who are now in response following a SECOND platinum-based chemotherapy where the following criteria have been met:<br><br>There is a separate form OLAP1 for olaparib in its tablet formulation as maintenance treatment in patients with high grade epithelial stage III or IV ovarian, fallopian tube or primary peritoneal carcinoma who have a deleterious or suspected deleterious germline and/or somatic BRCA mutation who are in response following platinum-based FIRST line chemotherapy.<br><br>There is also a separate form OLAP3 for olaparib in its tablet formulation as maintenance treatment in patients with high grade epithelial stage III or IV ovarian, fallopian tube or primary peritoneal carcinoma who have a deleterious or suspected deleterious germline and/or somatic BRCA mutation who are in response following platinum-based THIRD or subsequent line chemotherapy. | 1. This application is made by and the first cycle of systemic anti-cancer therapy with olaparib tablets will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br><br>2. This patient has a proven histological diagnosis of predominantly high grade serous or high grade endometrioid or high grade clear cell ovarian, fallopian tube or primary peritoneal carcinoma.<br>Please enter below as to which is the predominant histology in this patient:<br>- high grade serous adenocarcinoma **or**<br>- high grade endometrioid adenocarcinoma **or**<br>- high grade clear cell carcinoma<br><br>3. This patient has had germline and/or somatic (tumour) BRCA testing.<br><br>4. This patient HAS a documented deleterious or suspected deleterious BRCA mutation(s) in the germline or in the tumour or in both. Please enter below the type of testing done in this patient to determine the presence of deleterious or suspected deleterious BRCA mutation(s):<br>- in the germline only **or**<br>- in the tumour (somatic tissue) only **or**<br>- in both germline and somatic tissue.<br><br>5. This patient HAS a documented deleterious or suspected deleterious BRCA 1 or BRCA 2 mutation(s). Please enter below as to which deleterious or suspected deleterious BRCA mutation(s) the patient has:<br>- BRCA 1 mutation **or**<br>- BRCA 2 mutation **or**<br>- both BRCA1 and BRCA 2 mutations<br>Note: Patients without a deleterious or suspected deleterious BRCA mutation are not eligible to receive olaparib but they are potentially eligible to receive niraparib (form NIR2) or rucaparib (form RUC2).<br><br>6. The patient had disease which was sensitive to initial (first line) platinum-based chemotherapy i.e. the recent FIRST relapse has occurred after a response to initial (first line) platinum-based chemotherapy.<br><br>7. The patient has recently completed a SECOND platinum-based chemotherapy and has received a minimum of 4 cycles of platinum-based treatment.<br><br>8. This patient has responded to the recently completed SECOND platinum-based chemotherapy and has achieved a partial or complete response to treatment according to the definitions given below and there is no evidence of progressive disease on the post-treatment scan or a rising CA125 level. Please enter below as to which response assessment applies to this patient:<br>- achieved a complete response at the end of the 2nd platinum-based chemotherapy i.e. has no measurable or non-measurable disease on the post-chemotherapy scan and the CA125 is normal **or**<br>- achieved a partial response at the end of the 2nd platinum-based chemotherapy i.e. has had a ≥30% reduction in measurable or non-measurable disease from the start of to the completion of the 2nd platinum-based chemotherapy or the patient has a complete remission on the post-chemotherapy CT scan but the CA125 has not decreased to within the normal range.<br><br>9. The patient is currently less than 8 weeks from the date of the last infusion of the last cycle of the 2nd platinum-based chemotherapy.<br><br>10. The patient has not previously received any PARP inhibitor unless either niraparib or rucaparib via the CDF has had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression or olaparib tablets have been received as part of an early access scheme and the patient meets all the other criteria listed here. Please mark below which of the four scenarios applies to this patient:<br>- the patient has never previously received a PARP inhibitor **or**<br>- the patient has previously received niraparib via the CDF and this has had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression **or**<br>- the patient has previously received rucaparib via the CDF and this has had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression **or**<br>- the patient has previously received olaparib tablets via an early access scheme and the patient meets all the other criteria listed here.<br><br>11. Olaparib tablets will be used as monotherapy.<br><br>12. The patient has an ECOG performance status of either 0 or 1. Please enter below as to which ECOG performance status applies to this patient:<br>- ECOG PS 0 **or**<br>- ECOG PS 1.<br>Note: a patient with a performance status of 2 or more is not eligible for olaparib.<br><br>13. Olaparib is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment.<br><br>14. A formal medical review as to whether maintenance treatment with olaparib should continue or not will be scheduled to occur at least by the start of the third cycle of treatment.<br><br>15. No treatment breaks of more than 6 weeks beyond the expected cycle length are allowed (to allow any toxicity of current therapy to settle or intercurrent comorbidities to improve).<br><br>16. Olaparib in its tablet formulation is to be otherwise used as set out in its Summary of Product Characteristics. | No | TA908 | 05-Jul-23 | 03-Oct-23 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| OLAP3 | **Olaparib**<br>in its tablet formation | For maintenance treatment in patients with high grade epithelial ovarian, fallopian tube or primary peritoneal carcinoma who have a deleterious or suspected deleterious germline and/or somatic BRCA mutation and who have a recent SECOND OR SUBSEQUENT relapse of platinum-sensitive disease and who are now in response following a THIRD OR SUBSEQUENT platinum-based chemotherapy where the following criteria have been met:<br><br>This OLAP3 form should also be used for patients transitioning from olaparib capsules to olaparib tablets in this particular indication for maintenance therapy after 3rd or subsequent platinum-based chemotherapy.<br><br>There is a separate form OLAP1 for olaparib in its tablet formulation as maintenance treatment in patients with high grade epithelial stage III or IV ovarian, fallopian tube or primary peritoneal carcinoma who have a deleterious or suspected deleterious germline and/or somatic BRCA mutation who are in response following platinum-based FIRST line chemotherapy.<br><br>There is also a separate form OLAP2 for olaparib in its tablet formulation as maintenance treatment in patients with high grade epithelial stage III or IV ovarian, fallopian tube or primary peritoneal carcinoma who have a deleterious or suspected deleterious germline and/or somatic BRCA mutation who are in response following platinum-based SECOND line chemotherapy. | 1. This application is made by and the first cycle of systemic anti-cancer therapy with olaparib tablets will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy. | No | TA620 | 15-Jan-20 | 14-Apr-20 |
| | | | 2. This patient has a proven histological diagnosis of predominantly high grade serous or endometrioid ovarian, fallopian tube or primary peritoneal carcinoma. | | | | |
| | | | 3. This patient has had germline and/or somatic (tumour) BRCA testing. | | | | |
| | | | 4. This patient HAS a documented deleterious or suspected deleterious BRCA mutation(s) in the germline or in the tumour or in both. Please enter the type of testing done in this patient to determine the presence of deleterious or suspected deleterious BRCA mutation(s):<br>- in the germline only **or**<br>- in the tumour (somatic tissue) only **or**<br>- in both germline and somatic tissue. | | | | |
| | | | 5. This patient HAS a documented deleterious or suspected deleterious BRCA 1 or BRCA 2 mutation(s). Please enter below as to which deleterious or suspected deleterious BRCA mutation(s) the patient has::<br>- BRCA 1 mutation **or**<br>- BRCA 2 mutation **or**<br>- both BRCA1 and BRCA 2 mutations. | | | | |
| | | | 6. The patient had disease which was sensitive to the penultimate line of platinum-based chemotherapy (ie the disease responded to the line of platinum-based chemotherapy preceding the most recent line of platinum-based chemotherapy). | | | | |
| | | | 7. The patient has recently completed a further line of platinum-based chemotherapy and has received a minimum of 4 cycles of platinum-based treatment. Please enter below which line of platinum-based treatment was the most recent line of platinum-based treatment. This must be 3rd line or 4th line or greater:<br>- 3rd line **or**<br>- 4th line or greater. | | | | |
| | | | 8. This patient has responded to the recently completed THIRD or subsequent line platinum-based chemotherapy and has achieved a partial or complete response to treatment according to the definitions given below and there is no evidence of progressive disease on the post-treatment scan or a rising CA125 level. Please enter below as to which response assessment applies to this patient:<br>- achieved a complete response at the end of the recent 3rd or subsequent line of platinum-based chemotherapy ie has no measurable or non-measurable disease on the post-chemotherapy scan and the CA125 is normal **or**<br>- achieved a partial response at the end of the recent 3rd or subsequent line of platinum-based chemotherapy ie has had a ≥30% reduction in measurable or non-measurable disease from the start of to the completion of the 2nd platinum-based chemotherapy or the patient has a complete remission on the post-chemotherapy CT scan but the CA125 has not decreased to within the normal range. | | | | |
| | | | 9. The patient is currently less than 8 weeks from the date of the last infusion of the last cycle of the 3rd or subsequent line of platinum-based chemotherapy. | | | | |
| | | | 10. The patient has not previously received any PARP inhibitor unless either switching from olaparib capsules and this is being done in the clear absence of disease progression or rucaparib via the CDF has had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression. Please mark below which of these three scenarios applies to this patient:<br>- the patient has never previously received a PARP inhibitor **or**<br>- the patient has previously received olaparib capsules and is switching to olaparib tablets and in the clear absence of disease progression. The recommended dosing algorithm for switching from capsules to tablets can be found in the following paper: Practical considerations for clinicians for transitioning patients on maintenance therapy with olaparib capsules to the tablet formulation of olaparib. Friedlander et al Asia Pac J Clin Oncol 2018 14 459-464. Available at https://onlinelibrary.wiley.com/doi/full/10.1111/ajco.13104 **or**<br>- the patient has previously received rucaparib via the CDF and has had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression. | | | | |
| | | | 11. Olaparib tablets will be used as monotherapy. | | | | |
| | | | 12. The patient has an ECOG performance status of either 0 or 1.<br>Note: a patient with a performance status of 2 or more is not eligible for olaparib | | | | |
| | | | 13. Olaparib in its tablet formulation is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment. | | | | |
| | | | 14. A formal medical review as to whether maintenance treatment with olaparib tablets should continue or not will be scheduled to occur at least by the start of the third cycle of treatment. | | | | |
| | | | 15. No treatment breaks of more than 6 weeks beyond the expected cycle length are allowed (to allow any toxicity of current therapy to settle or intercurrent comorbidities to improve) | | | | |
| | | | 16. Olaparib in its tablet formulation is to be otherwise used as set out in its Summary of Product Characteristics | | | | |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| OLAP4_v1.1 | **Olaparib** in combination with bevacizumab | As maintenance treatment in patients with high grade epithelial stage III or IV ovarian, fallopian tube or primary peritoneal carcinoma who are in response following platinum-based FIRST line chemotherapy AND whose cancer has a positive status for homologous recombination deficiency as defined by the presence of either a deleterious or suspected deleterious BRCA 1/2 germline and/or somatic mutation or genomic instability where the following criteria have been met:<br><br>There is a separate form **OLAP1a** for use of **olaparib monotherapy** as maintenance treatment in patients with high grade epithelial stage III or IV ovarian, fallopian tube or primary peritoneal carcinoma who are in response following platinum-based FIRST line chemotherapy AND whose cancer has the presence of a deleterious or suspected deleterious BRCA 1/2 germline and/or somatic mutation | 1. This application for maintenance olaparib in combination with bevacizumab is being made by and the first cycle of systemic anti-cancer therapy with olaparib in combination with bevacizumab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. This patient has a proven histological diagnosis of predominantly high grade serous or high grade endometrioid or high grade clear cell ovarian, fallopian tube or primary peritoneal carcinoma.<br>Please enter below as to which is the predominant histology in this patient:<br>- high grade serous adenocarcinoma<br>- high grade endometrioid adenocarcinoma<br>- high grade clear cell carcinoma<br>3. This patient has had germline and/or somatic BRCA testing and if appropriate has also had a validated homologous recombination deficiency (HRD) test for genomic instability.<br>4. This patient or this patient's cancer **HAS** documented evidence of a positive status for homologous recombination deficiency (HRD) defined by the presence of **either** deleterious/suspected deleterious BRCA 1 and/or BRCA 2 mutation(s) **or** genomic instability as defined by a score of ≥42 by the Myriad HRD test or the validated equivalent as tested and confirmed by an NHS Genomic Laboratory Hub.<br>Please enter below the basis for the patient having positive status for HRD:<br>- germline positive for BRCA 1 mutation<br>- germline positive for BRCA 2 mutation<br>- germline positive for both BRCA1 and BRCA 2 mutations<br>- somatic positive for BRCA 1 mutation<br>- somatic positive for BRCA 2 mutation<br>- somatic positive for both BRCA1 and BRCA 2 mutations<br>- negative tests for both BRCA1 and BRCA 2 mutations but either the Myriad HRD test is positive with a genomic instability score of ≥42 or there is a validated equivalent as tested and confirmed by an NHS Genomic Laboratory Hub<br><br>Note: there is no access to the maintenance combination of olaparib plus bevacizumab unless the patient has documented evidence of homologous recombination deficiency.<br>5. The patient has recently diagnosed FIGO stage III or IV ovarian, fallopian tube or primary peritoneal carcinoma.<br>Note: maintenance olaparib plus bevacizumab in this indication is not funded for patients with recently diagnosed and treated stage I-IIC disease.<br>6. One of the following scenarios applies to the surgical management of the patient in relation to the stage of the disease:<br>- the patient has stage III disease and had an upfront attempt at optimal cytoreductive surgery and had no visible residual disease at the end of surgery or<br>- the patient has stage III disease and had an upfront attempt at optimal cytoreductive surgery and had visible residual disease at the end of surgery or<br>- the patient has stage III disease and had an interval attempt at optimal cytoreductive surgery and had no visible disease at the end of surgery or<br>- the patient has stage III disease and had an interval attempt at optimal cytoreductive surgery and had visible disease at the end of surgery or<br>- the patient has stage III disease and has had a biopsy only with no upfront or interval attempt at cytoreductive surgery or<br>- the patient has stage IV disease and had an upfront attempt at optimal cytoreductive surgery and had no visible disease at the end of surgery or<br>- the patient has stage IV disease and had an upfront attempt at optimal cytoreductive surgery and had visible residual disease at the end of surgery or<br>- the patient has stage IV disease and had an interval attempt at optimal cytoreductive surgery and had no visible disease at the end of surgery or<br>- the patient has stage IV disease and had an interval attempt at optimal cytoreductive surgery and had visible disease at the end of surgery or<br>- the patient has stage IV disease and has had a biopsy only with no upfront or interval attempt at cytoreductive surgery<br>7. The patient has just completed 1st line platinum-based chemotherapy and has received a minimum of 4 cycles of platinum-based treatment.<br>8. The patient either received bevacizumab as part of 1st line platinum-based chemotherapy or not. Please indicate below whether bevacizumab was used in combination with the 1st line chemotherapy:<br>- bevacizumab given in combination with platinum-based chemotherapy at a 7.5mg/Kg dose<br>- bevacizumab given in combination with platinum-based chemotherapy at a 15mg/Kg dose<br>- no bevacizumab used in combination with chemotherapy<br>9. This patient is in response to the recently completed 1st line platinum-based chemotherapy and has achieved a partial or complete response to treatment according to the definitions given below and **has no evidence of progressive disease on the post-treatment scan or a rising CA125 level.**<br>Please confirm the category below:<br>- achieved a complete response at the end of 1st line platinum-based chemotherapy ie has no measurable or non-measurable disease on the post-chemotherapy scan and the CA-125 is normal<br>- achieved a complete response at the end of 1st line platinum-based chemotherapy ie has no measurable or non-measurable disease on the post-chemotherapy scan and the CA-125 has not decreased to within the normal range<br>- achieved a partial response at the end of 1st line platinum-based chemotherapy ie has had a ≥30% reduction in measurable or non-measurable disease from the start of to the completion of 1st line chemotherapy and the CA125 is normal<br>- achieved a partial response at the end of 1st line platinum-based chemotherapy ie has had a ≥30% reduction in measurable or non-measurable disease from the start of to the completion of 1st line chemotherapy and the CA125 has not decreased to within the normal range<br>10. The patient is currently no more than 9 weeks from the date of the last infusion of the last cycle of 1st line chemotherapy.<br>11. The patient has not previously received any PARP inhibitor.<br>12. Olaparib will be used in combination with bevacizumab.<br>13. Olaparib is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment or **for a maximum total treatment duration of 2 calendar years**, whichever is the sooner.<br>Note: There is a 2 calendar year stopping rule for the duration of treatment with olaparib as this was the basis of AstraZeneca's submission to NICE for consideration of cost effectiveness.<br>14. The maintenance dose of bevacizumab is **15mg/Kg** and that maintenance bevacizumab will be given until whichever is the sooner of: disease progression or unacceptable toxicity or patient choice to stop treatment or for a **maximum total bevacizumab treatment duration of 15 calendar months** (as measured from the start of bevacizumab-containing treatment, whether this was with chemotherapy or as maintenance therapy).<br>15. The patient has an ECOG performance status (PS) of either 0 or 1.<br>- PS 0<br>- PS 1<br>Note: a patient with a performance status of 2 or more is not eligible for olaparib in combination with bevacizumab.<br>16. A first formal medical review as to whether maintenance treatment with olaparib in combination with bevacizumab should continue or not will be scheduled to occur at least by the start of the third 3-weekly cycle of treatment<br>17. When a treatment break is needed of more than 6 weeks beyond the expected cycle length of 3-weekly treatment (when given with bevacizumab) or 4-weekly treatment (after completion of bevacizumab), the prescribing clinician will complete a treatment break approval form to restart treatment.<br>18. Olaparib in its tablet formulation is to be otherwise used as set out in its Summary of Product Characteristics.<br>19. Bevacizumab is to be otherwise used as set out in its Summary of Product Characteristics. | Yes | TA946 | 17-Jan-24 | 16-Apr-24 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| OLAP5 | **Olaparib** | Olaparib monotherapy as adjuvant treatment of high-risk TRIPLE NEGATIVE early breast cancer treated with neoadjuvant or adjuvant chemotherapy and definitive local therapy in patients with a deleterious or suspected deleterious germline BRCA mutation where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with olaparib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. This patient has a proven histological diagnosis of **triple negative** breast cancer (hormone receptor negative and HER 2 negative).<br>3. This patient has early breast cancer.<br>4. This patient **HAS** a documented **germline** deleterious or suspected deleterious BRCA 1 or BRCA 2 mutation(s).<br>Please enter below as to which deleterious or suspected deleterious BRCA mutation(s) the patient has:<br>- BRCA 1 mutation or<br>- BRCA 2 mutation or<br>- both BRCA1 and BRCA 2 mutations<br>5. The patient has recently completed either neoadjuvant chemotherapy or adjuvant chemotherapy.<br>Please enter below as to whether the patient was treated with a neoadjuvant cytotoxic chemotherapy-containing regimen or an adjuvant cytotoxic chemotherapy-containing chemotherapy regimen:<br>- the patient was treated with a neoadjuvant cytotoxic chemotherapy-containing regimen or<br>- the patient was treated with an adjuvant cytotoxic chemotherapy-containing regimen<br>Note: adjuvant olaparib without the use of prior neoadjuvant or adjuvant cytotoxic chemotherapy is not funded.<br>6. The patient was treated with at least 6 cycles of an anthracycline-containing regimen or at least 6 cycles of a taxane-containing regimen or at least a total of 6 cycles of anthracycline-containing and taxane-containing regimens.<br>Please mark below which option applies to this patient:<br>- the patient received at least 6 cycles of an anthracycline-containing regimen or<br>- the patient received at least 6 cycles of a taxane-containing regimen or<br>- the patient received at least a total of 6 cycles of anthracycline-containing and taxane-containing regimens<br>7. Whether the patient received pembrolizumab as part of neoadjuvant chemotherapy or not.<br>Please mark below which option applies to this patient as regards the receipt of neoadjuvant pembrolizumab as part of the neoadjuvant regimen:<br>- no pembrolizumab because the patient received adjuvant chemotherapy or<br>- no, the patient did not receive pembrolizumab as part of the neoadjuvant regimen or<br>- yes, the patient received pembrolizumab as part of the neoadjuvant treatment regimen<br>8. Which definition of high-risk early breast cancer applies to this patient noting that this depends on whether the patient had neoadjuvant or adjuvant chemotherapy.<br>Please mark below which of these 3 options applies to this patient:<br>- the patient received **neoadjuvant** chemotherapy as above **and** the post-surgical pathology revealed residual invasive breast carcinoma in the breast and/or resected lymph nodes<br>**Or**<br>- the patient received **adjuvant** chemotherapy as above with a pre-chemotherapy pathological demonstration of **axillary lymph node positive disease (at least pN1)** whatever the T stage<br>**Or**<br>- the patient received **adjuvant** chemotherapy as above with a pre-chemotherapy pathological demonstration of **axillary lymph node negative disease (pN0)** and an invasive primary tumour diameter of >2cm **(pT2 or greater)**<br>9. The patient has completed definitive local treatment for the breast cancer (this includes any radiotherapy).<br>10. The patient is ideally 8 weeks or less but no more than 12 weeks from the date of the last treatment (surgery, chemotherapy, radiotherapy).<br>Note: patients must be a minimum of 2 weeks after completion of radiotherapy and a minimum of 3 weeks since the last chemotherapy.<br>11. Adjuvant olaparib will be prescribed as monotherapy.<br>Note: Olaparib and pembrolizumab are not to be prescribed together in the adjuvant phase of treatment. If a patient is eligible for both of these adjuvant indications, the patient and the clinician can choose one of the options but not both.<br>12. The patient has not previously received any PARP inhibitor unless the patient has received olaparib as part of a company early access scheme for this adjuvant indication and the patient meets **all** the other criteria set out in this form, in particular the definition of high-risk disease in criterion 8.<br>NHS England will not fund the use of adjuvant olaparib in patients who have accessed olaparib via a company early access scheme unless ALL the treatment criteria on this form are fulfilled.<br>**Please mark below which scenario applies to this patient:**<br>- the patient has never previously received a PARP inhibitor or<br>- the patient has received olaparib as part of a company early access scheme for this adjuvant indication and all the other criteria set out in this form are fulfilled<br>13. The patient has an ECOG performance status of either 0 or 1.<br>14. Adjuvant olaparib is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment or for **a total treatment duration of 1 calendar year** as measured from the date of commencing adjuvant olaparib.<br>15. A formal medical review as to whether adjuvant olaparib should continue or not will be scheduled to occur at least by the start of the third 4-weekly cycle of treatment.<br>16. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, a treatment break approval form will be completed to restart treatment.<br>17. Olaparib is to be otherwise used as set out in its Summary of Product Characteristics. | No | TA886 | 10-May-23 | 08-Aug-23 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| OLAP6 | **Olaparib**<br>in combination with hormone therapy | As adjuvant treatment of high-risk HORMONE RECEPOR POSITIVE HER 2 NEGATIVE early breast cancer treated with neoadjuvant or adjuvant chemotherapy and definitive local therapy in patients with a deleterious or suspected deleterious germline BRCA mutation where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with olaparib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy. | No | TA886 | 10-May-23 | 08-Aug-23 |
| | | | 2. This patient has a proven histological diagnosis of **hormone receptor positive and HER 2 negative** breast cancer. | | | | |
| | | | 3. This patient has early breast cancer. | | | | |
| | | | 4. This patient **HAS** a documented **germline** deleterious or suspected deleterious BRCA 1 or BRCA 2 mutation(s).<br>Please enter below as to which deleterious or suspected deleterious BRCA mutation(s) the patient has:<br>- BRCA 1 mutation or<br>- BRCA 2 mutation or<br>- both BRCA1 and BRCA 2 mutations | | | | |
| | | | 5. The patient has recently completed either neoadjuvant chemotherapy or adjuvant chemotherapy.<br>Please enter below as to whether the patient was treated with a neoadjuvant cytotoxic chemotherapy-containing regimen or an adjuvant cytotoxic chemotherapy-containing chemotherapy regimen:<br>- the patient was treated with a neoadjuvant cytotoxic chemotherapy-containing regimen or<br>- the patient was treated with an adjuvant cytotoxic chemotherapy-containing regimen<br>Note: adjuvant olaparib without the use of prior neoadjuvant or adjuvant cytotoxic chemotherapy is not funded. | | | | |
| | | | 6. The patient was treated with at least 6 cycles of an anthracycline-containing regimen or at least 6 cycles of a taxane-containing regimen or at least a total of 6 cycles of anthracycline-containing and taxane-containing regimens.<br>Please mark below which option applies to this patient:<br>- the patient received at least 6 cycles of an anthracycline-containing regimen or<br>- the patient received at least 6 cycles of a taxane-containing regimen or<br>- the patient received at least a total of 6 cycles of anthracycline-containing and taxane-containing regimens | | | | |
| | | | 7. Which definition of **high-risk** early breast cancer applies to this patient noting that this depends on whether the patient had neoadjuvant or adjuvant chemotherapy.<br>Please mark below which of these 2 options applies to this patient:<br>- the patient received neoadjuvant chemotherapy as above and the post-surgical pathology revealed residual invasive breast carcinoma in the breast and/or resected lymph nodes and either diagnostic or surgical specimen confirmed high histological grade<br>- the patient received adjuvant chemotherapy as above with a pre-chemotherapy pathological demonstration of positive lymph node/s | | | | |
| | | | 8. The patient has completed definitive local treatment for the breast cancer (this includes any radiotherapy). | | | | |
| | | | 9. The patient is ideally 8 weeks or less but no more than 12 weeks from the date of the last treatment (surgery, chemotherapy, radiotherapy).<br>Note: patients must be a minimum of 2 weeks after completion of radiotherapy and a minimum of 3 weeks since the last chemotherapy. | | | | |
| | | | 10. Adjuvant olaparib will be prescribed in combination with adjuvant hormone therapy (an aromatase inhibitor or an anti-oestrogen or a LHRH agonist).<br>"Note: adjuvant olaparib, adjuvant abemaciclib (BT form ABEM3), and adjuvant ribociclib (BT form RIB3) are not to be prescribed concurrently **OR** sequentially. If a patient meets the criteria for more than one of these options, the patient and clinician must decide which **ONE** of the THREE options are to be used." | | | | |
| | | | 11. The patient has an ECOG performance status of either 0 or 1.<br>Note: a patient with a performance status of 2 or more is not eligible for Olaparib. | | | | |
| | | | 12. Adjuvant olaparib is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment or for **a total treatment duration of 1 calendar year** as measured from the date of commencing adjuvant olaparib. | | | | |
| | | | 13. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, a treatment break approval form will be completed to restart treatment. | | | | |
| | | | 14. Olaparib is to be otherwise used as set out in its Summary of Product Characteristics. | | | | |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| OLAP7 | **Olaparib** | Olaparib monotherapy for metastatic castration-resistant prostate cancer bearing germline and/or somatic BRCA 1 or 2 mutations in patients who have progressed following previous treatment with an androgen receptor targeted agent AND HAVE ALSO BEEN TREATED WITH DOCETAXEL where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with olaparib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. This patient either has a proven histological or cytological diagnosis of adenocarcinoma of the prostate or has presented with a clinical picture consistent with metastatic prostate cancer with both widespread bone metastases radiologically typical of prostate cancer and a serum PSA of at least 50ng/ml.<br>3. This patient **HAS** a documented **germline and/or somatic** deleterious or suspected deleterious BRCA 1 or BRCA 2 mutation(s).<br>Please enter below as to which deleterious or suspected deleterious BRCA mutation(s) the patient has<br>- BRCA 1 mutation or<br>- BRCA 2 mutation or<br>- both BRCA1 and BRCA 2 mutations<br>4. This patient has hormone-relapsed (castrate-resistant) metastatic prostate cancer.<br>5. The patient has been previously treated with an androgen receptor targeted agent (enzalutamide or apalutamide or darolutamide or abiraterone) and has progressed on such treatment.<br>6. The patient has been previously treated with docetaxel and has progressed after such treatment.<br>Note: there is a separate form OLAP8 for patients who have not been previously treated with docetaxel.<br>7. Olaparib will be prescribed as **monotherapy**.<br>Note: it is expected that treatment with LHRH agonists/antagonists will continue unless the patient has undergone surgical castration.<br>8. The patient has not received any previous treatment with a PARP inhibitor.<br>9. The patient has an ECOG performance status of 0 or 1 or 2.<br>Note: a patient with a performance status of 3 or more is not eligible for olaparib.<br>10. Olaparib is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment.<br>11. A formal medical review as to whether olaparib should continue or not will be scheduled to occur at least by the start of the third 4-weekly cycle of treatment.<br>12. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, a treatment break approval form will be completed to restart treatment.<br>13. Olaparib is to be otherwise used as set out in its Summary of Product Characteristics. | No | TA887 | 10-May-23 | 08-Aug-23 |
| OLAP8 | **Olaparib** | Olaparib monotherapy for metastatic castration-resistant prostate cancer bearing germline and/or somatic BRCA 1 or 2 mutations in patients who have progressed following previous treatment with an androgen receptor targeted agent AND HAVE NOT BEEN PREVIOUSLY TREATED WITH DOCETAXEL where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with olaparib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. This patient either has a proven histological or cytological diagnosis of adenocarcinoma of the prostate or has presented with a clinical picture consistent with metastatic prostate cancer with both widespread bone metastases radiologically typical of prostate cancer and a serum PSA of at least 50ng/ml.<br>3. This patient **HAS** a documented **germline and/or somatic** deleterious or suspected deleterious BRCA 1 or BRCA 2 mutation(s).<br>Please enter below as to which deleterious or suspected deleterious BRCA mutation(s) the patient has<br>- BRCA 1 mutation or<br>- BRCA 2 mutation or<br>- both BRCA1 and BRCA 2 mutations<br>4. This patient has hormone-relapsed (castrate-resistant) metastatic prostate cancer.<br>5. The patient has been previously treated with an androgen receptor targeted agent (enzalutamide or apalutamide or darolutamide or abiraterone) and has progressed on such treatment.<br>6. The patient has **NOT** been previously treated with docetaxel.<br>Note: there is a separate form OLAP7 for patients who have been previously treated with docetaxel.<br>7. Olaparib will be prescribed as **monotherapy**.<br>Note: it is expected that treatment with LHRH agonists/antagonists will continue unless the patient has undergone surgical castration.<br>8. The patient has not received any previous treatment with a PARP inhibitor.<br>9. The patient has an ECOG performance status of 0 or 1 or 2.<br>Note: a patient with a performance status of 3 or more is not eligible for olaparib.<br>10. Olaparib is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment.<br>11. A formal medical review as to whether olaparib should continue or not will be scheduled to occur at least by the start of the third 4-weekly cycle of treatment.<br>12. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, a treatment break approval form will be completed to restart treatment.<br>13. Olaparib is to be otherwise used as set out in its Summary of Product Characteristics. | No | TA887 | 10-May-23 | 08-Aug-23 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| OLAP9_v1.1 | **Olaparib** in combination with abiraterone | The treatment of metastatic hormone-relapsed (castrate-resistant) prostate cancer in patients who are treatment naïve to androgen receptor inhibitors and in whom chemotherapy is not yet clinically indicated or appropriate where the following criteria have been met: | 1. This application for olaparib plus abiraterone is being made by and the first cycle of systemic anti-cancer therapy with olaparib plus abiraterone will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient either has a proven histological or cytological diagnosis of adenocarcinoma of the prostate or has presented with a clinical picture consistent with metastatic prostate cancer with both widespread bone metastases typical of prostate cancer and a serum PSA of at least 50ng/ml.<br>3. The patient has progressive hormone-relapsed (castrate-resistant) disease.<br>4. The patient has not been treated with chemotherapy for the hormone-relapsed (castrate-resistant) indication and that for this same hormone-relapsed (castrate-resistant) indication chemotherapy is either not yet clinically indicated or is inappropriate (contraindicated or declined by the patient).<br><br>Note: chemotherapy given for hormone-sensitive disease earlier in the treatment pathway does not exclude patients from potential access to olaparib plus abiraterone.<br>5. The patient has not previously received any therapy with an androgen receptor inhibitor such as enzalutamide, abiraterone, apalutamide or darolutamide at any place in the prostate cancer treatment pathway except in the case of patients who received androgen receptor inhibitor therapy for hormone-sensitive disease and stopped this treatment more than 12 months prior to this application without PSA progression or evidence of clinical or radiological progressive disease at the time such androgen receptor inhibitor therapy was discontinued.<br>**OR**<br>the patient commenced enzalutamide (with talazoparib) in this same indication, and that combination had to be discontinued due to lack of tolerance (despite dose reductions being instigated) in the absence of any signs of disease progression<br>Please mark below which scenario applies to this patient:<br><br>- the patient has not previously received any therapy with an androgen receptor inhibitor such as enzalutamide, abiraterone, apalutamide or darolutamide at any place in the prostate cancer treatment pathway OR<br>- the patient received androgen receptor inhibitor therapy for hormone-sensitive disease and stopped this treatment more than 12 months prior to this application without PSA progression or evidence of clinical or radiological progressive disease at the time such androgen receptor inhibitor therapy was discontinued OR<br>the patient commenced enzalutamide (with talazoparib) in this same indication, and this combination had to be discontinued due to lack of tolerance (despite dose reductions being instigated) in the absence of any sign of disease progression<br><br>Note: patients previously treated with previous androgen receptor inhibitor therapy who do not fulfil the exceptions above are NOT eligible for treatment with olaparib plus abiraterone.<br>6. The patient has not received any previous PARP inhibitor therapy, unless the patient commenced talazoparib (with enzalutamide) in this same indication, and that combination had to be discontinued due to lack of tolerance (despite dose reductions being instigated) in the absence of any signs of disease progression.<br>7. The patient has an ECOG performance score of 0 or 1.<br>8. Olaparib is only to be given in combination with abiraterone plus prednisolone.<br><br>Note: olaparib cannot be given in combination with enzalutamide or any other androgen receptor inhibitor.<br><br>Note: it is expected that treatment with LHRH agonists/antagonists will continue unless the patient has undergone surgical castration.<br>9. Olaparib and abiraterone are to be continued until disease progression or the development of unacceptable toxicity or patient choice to discontinue treatment, whichever is the sooner.<br>10. When a treatment break of more than 6 weeks beyond the expected 4-week cycle length is needed, the prescribing clinician will complete a treatment break approval form to restart treatment, which MUST be approved before treatment is recommenced.<br>11. Olaparib and abiraterone will otherwise be used as set out in their respective Summaries of Product Characteristics (SPCs). | No | TA951 | 07-Feb-24 | 07-May-24 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| OLAP10 | **Olaparib** | Olaparib as monotherapy for treatment of adults with deleterious or suspected deleterious germline BRCA1 or 2 mutations who have HER-2 negative locally advanced or metastatic breast cancer previously treated with an anthracycline and a taxane in the adjuvant/neoadjuvant/advanced disease settings and also treated with prior endocrine-based therapy if the patient has hormone-receptor positive disease where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with olaparib monotherapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. This patient has a proven histological diagnosis of HER 2 negative breast cancer.<br>3. The patient has locally advanced or metastatic breast cancer.<br>4. This patient HAS a documented germline deleterious or suspected deleterious BRCA 1 or BRCA 2 mutation(s).<br><br>Please enter below as to which deleterious or suspected deleterious BRCA mutation(s) the patient has:<br>- BRCA 1 mutation or<br>- BRCA 2 mutation or<br>- both BRCA1 and BRCA 2 mutations<br>5. The patient has received prior chemotherapy with an anthracycline and a taxane in any of the adjuvant or neoadjuvant or advanced disease settings unless these chemotherapy agents were contraindicated<br><br>Please enter below as to which of the following scenarios applies to this patient:<br>- the patient has received treatment with both an anthracycline and a taxane in any of the adjuvant or neoadjuvant or advanced disease settings or<br>- chemotherapy with an anthracycline was contraindicated in the adjuvant or neoadjuvant or advanced disease settings and the patient has received a taxane in one of these indications<br>- chemotherapy with a taxane was contraindicated in the adjuvant or neoadjuvant or advanced disease settings and the patient has received an anthracycline in one of these indications<br>- chemotherapy with both an anthracycline and a taxane were contraindicated in the adjuvant or neoadjuvant or advanced disease settings<br>6. The patient either has triple negative disease or if the patient has hormone receptor positive disease then the patient has already been treated with appropriate endocrine-based therapy or such therapy was contraindicated.<br><br>Please mark below which option applies to this patient:<br>- the patient has triple negative disease or<br>- the patient has hormone receptor positive disease and received appropriate endocrine-based therapy or<br>- the patient has hormone receptor positive disease and use of appropriate endocrine-based therapy was contraindicated in this patient<br>7. Olaparib will be used as monotherapy and not in combination with any endocrine-based therapy<br>8. The patient has not received any previous treatment with a PARP inhibitor unless talazoparib for this same breast cancer indication has had to be stopped within 6 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression or the patient has received adjuvant olaparib and this was completed without disease progression during therapy or within 12 months of its completion or the patient has received olaparib via a company compassionate access scheme and all other treatment criteria in this form are fulfilled.<br><br>Please mark below which option applies to this patient:<br>- the patient has never received any PARP inhibitor therapy or<br>- talazoparib for this same advanced breast cancer indication has had to be stopped within 6 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression or<br>- the patient has received adjuvant olaparib and this was completed without disease progression during therapy or within 12 months of its completion<br>- the patient has received olaparib for this indication via a company compassionate access scheme and all other treatment criteria in this form are fulfilled<br>9. The patient has an ECOG performance status of either 0 or 1.<br>10. Any brain metastases or leptomeningeal metastases in this patient are symptomatically stable.<br>11. Olaparib is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment.<br>12. The prescribing clinician is aware of the dose reductions necessary for olaparib in patients with renal impairment as specified in the olaparib Summary of Product Characteristics (section 4.2).<br>13. The prescribing clinician is aware of the potential drug interactions which olaparib has with other medicines, as outlined in sections 4.2 and 4.5 of the olaparib Summary of Product Characteristics.<br>14. A formal medical review as to how olaparib is being tolerated and whether olaparib should continue or not will be scheduled to occur at least by the start of the third 4-weekly cycle of treatment.<br>15. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment.<br>16. Olaparib is to be otherwise used as set out in its Summary of Product Characteristics (SPC). | No | TA1040 | 12-Feb-25 | 14-Mar-25 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| OSI1 | **Osimertinib** | The the second-line treatment of locally advanced or metastatic epidermal growth factor receptor T790M mutation-positive non small cell lung cancer in adults where all the following criteria are met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with osimertinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has histological or cytological evidence of NSCLC that carries an EGFR T790M mutation based on a validated test **OR** there is documented agreement by the lung MDT that the radiological appearances are in keeping with locally advanced or metastatic NSCLC **AND** there is an informative circulating free DNA test result confirming the presence of an EGFR T790M mutation.<br>Please mark below on which basis the diagnosis of EGFR T790M mutation positive NSCLC has been made in this patient:<br>- Histological or cytological evidence.<br>- Documented agreement by the lung MDT that the radiological appearances are in keeping with locally advanced or metastatic NSCLC and there is an informative circulating free DNA test result confirming the presence of an EGFR T790M mutation<br>3. The patient has locally advanced or metastatic disease.<br>4. The patient's NSCLC has been documented as exhibiting an epidermal growth factor (EGFR) mutation.<br>5. The patient has been documented as exhibiting unequivocal evidence of a T790M mutation.<br>6. There is at least evidence of radiological disease progression on 1st line EGFR-targeted tyrosine kinase (TKI) therapy and there has been no further systemic anti-cancer treatment.<br>Please mark below on which TKI the patient has had progressive disease:<br>- erlotinib<br>- gefitinib<br>- afatinib<br>- dacomitinib<br>7. **Either** the patient has had no prior treatment with osimertinib **or** osimertinib has been received as adjuvant treatment for resected stages IB to N2 only IIIB NSCLC with either an EGFR exon 19 deletion or exon 21 substitution mutation and the patient did not progress whilst still receiving adjuvant osimertinib.<br>Please mark below which scenario applies to this patient:<br>- no prior treatment with osimertinib<br>- previously received adjuvant osimertinib for resected stages IB to N2 only IIIB NSCLC and did not progress whilst still receiving adjuvant osimertinib. Please state in box below how many months have elapsed since discontinuation of adjuvant osimertinib:<br>8. The patient has not received any previous cytotoxic chemotherapy or immunotherapy for the locally advanced/metastatic disease indication.<br>9. The patient has an ECOG performance status (PS) of 0 or 1.<br>10. The patient will be treated until loss of clinical benefit or excessive toxicity or patient choice to discontinue treatment, whichever is the sooner.<br>Note: treatment with osimertinib should be stopped if there is disease progression in the CNS and the CNS disease cannot be treated with surgery or stereotactic radiotherapy.<br>11. A formal medical review as to how osimertinib is being tolerated and whether treatment with osimertinib should continue or not will be scheduled to occur at least by the end of the second 4-weekly cycle of treatment.<br>12. Where a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment, including indicating as appropriate if the patient had an extended break because of COVID 19.<br>13. Osimertinib will be used as set out in its Summary of Product Characteristics (SPC). | No | TA653 | 14-Oct-20 | 12-Jan-21 |
| OSI2_v1.5 | **Osimertinib** | For the first line treatment of locally advanced or metastatic epidermal growth factor receptor mutation-positive non-small cell lung cancer in adults where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with osimertinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has histological or cytological evidence of NSCLC that carries a sensitising EGFR mutation based on a validated test **OR** there is documented agreement by the lung MDT that the radiological appearances are in keeping with locally advanced or metastatic NSCLC **AND** there is an informative circulating free DNA test result confirming the presence of a sensitising EGFR mutation.<br>Please mark below on which basis the diagnosis of EGFR mutation positive NSCLC has been made in this patient:<br>- Histological or cytological evidence.<br>- Documented agreement by the lung MDT that the radiological appearances are in keeping with locally advanced or metastatic NSCLC and there is an informative circulating free DNA test result confirming the presence of a sensitising EGFR mutation<br>3. The patient has locally advanced or metastatic disease, and that for this indication the patient has **not** received any previous cytotoxic chemotherapy or immunotherapy.<br>4. The patient has had no prior treatment with an EGFR inhibitor unless afatinib or dacomitinib or erlotinib or gefitinib has had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression or osimertinib has been received as adjuvant treatment for resected stages IB to N2 only IIIB NSCLC with either an EGFR exon 19 deletion or exon 21 substitution mutation and the patient did not progress whilst still receiving adjuvant osimertinib.<br>Please mark below which scenario applies to this patient:<br>- no prior treatment with an EGFR inhibitor<br>- previous treatment with a 1st line EGFR inhibitor but treatment has had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of progressive disease<br>- previously received adjuvant osimertinib for resected stages IB to N2 only IIIB NSCLC and did not progress whilst still receiving adjuvant osimertinib. Please state in box below how many months have elapsed since discontinuation of adjuvant osimertinib:<br>5. The patient has an ECOG performance status (PS) of 0 or 1.<br>6. The patient will be treated until loss of clinical benefit or excessive toxicity or patient choice to discontinue treatment, whichever is the sooner.<br>Note: treatment with osimertinib should be stopped if there is disease progression in the CNS and the CNS disease cannot be treated with surgery or stereotactic radiotherapy.<br>7. Where a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment, which MUST be approved before treatment is restarted.<br>8. Osimertinib will be used as set out in its Summary of Product Characteristics (SPC). | No | TA654 | 14-Oct-20 | 12-Jan-21 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| OSI3 | **Osimertinib** | Osimertinib for adjuvant treatment in adults after complete tumour resection in patients with UICC/AJCC 8th edition stage IB or stage IIA or stage IIB or stage IIIA or N2 only stage IIIB non-small cell lung cancer whose tumours have either an EGFR exon 19 deletion or an exon 21 (L858R) substitution mutation where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with adjuvant osimertinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy. | No | TA1043 | 26-Feb-25 | 27-May-25 |
| | | | 2. The patient has a histologically documented non-small cell lung cancer (NSCLC). | | | | |
| | | | 3. The patient has undergone a complete resection of the NSCLC with all surgical margins negative for tumour. | | | | |
| | | | 4. The pathological stage determined on this patient's surgical NSCLC specimen was a stage IB or IIA or IIB or IIIA or N2 only IIIB tumour according to the UICC/AJCC TNM 8th edition.<br>Please mark below which stage applies to this patient:<br>- stage IB disease (T2a N0)<br>- stage IIA disease (T2b N0)<br>- stage IIB disease (T1a N1 or T1b N1 or T1c N1 or T2a N1 or T2b N1 or T3 N0)<br>- stage IIIA disease (T1a N2 or T1b N2 or T1c N2 or T2a N2 or T2b N2 or T3 N1 or T4 N0 or T4 N1)<br>- N2 only stage IIIB disease (T3 N2 or T4 N2)<br>Note: the trial included patients using the UICC/AJCC 7th edition and hence the corresponding 7th edition stages have been translated into those of the 8th edition. | | | | |
| | | | 5. The patient's NSCLC has been documented **on the tumour specimen** (biopsy or surgical specimen) as exhibiting **either** an epidermal growth factor (EGFR) exon 19 deletion (Ex19del) **or** an exon 21 (L858R) substitution mutation, whether alone or in combination with other EGFR mutations<br>Please mark below which type of mutation applies to this patient:<br>- exon 19 deletion (EX19del) or<br>- exon 21 (L858R) substitution mutation | | | | |
| | | | 6. The patient did **not** receive any pre-operative systemic therapy (cytotoxic chemotherapy, immunotherapy, EGFR-targeted tyrosine kinase inhibitors) for the NSCLC. | | | | |
| | | | 7. The patient did not receive any pre-operative or post-operative radiation therapy for the NSCLC. | | | | |
| | | | 8. No more than 10 weeks have elapsed since surgery if the patient did not receive adjuvant chemotherapy or no more than 26 weeks have elapsed since surgery if the patient was treated with adjuvant cytotoxic chemotherapy after surgery for the NSCLC.<br>Please mark below which scenario applies to this patient:<br>- the patient has not received adjuvant chemotherapy after surgery and this application for adjuvant osimertinib is occurring at a time when no more than 10 weeks have elapsed since surgery or<br>- the patient has received and completed adjuvant chemotherapy after surgery and this application for adjuvant osimertinib is occurring at a time when no more than 26 weeks have elapsed since surgery | | | | |
| | | | 9. The patient has had no prior treatment with an EGFR inhibitor. | | | | |
| | | | 10. The patient has an ECOG performance status (PS) of 0 or 1. | | | | |
| | | | 11. The patient does not have brain metastases on CT or MR imaging of the brain done either before surgery or prior to this application. | | | | |
| | | | 12. The patient will be treated with osimertinib for whichever is the sooner of: disease progression or unacceptable toxicity or withdrawal of patient consent **or** for a total treatment duration of 3 calendar years. | | | | |
| | | | 13. A formal medical review as to how osimertinib is being tolerated and whether treatment with osimertinib should continue or not will be scheduled to occur at least by the end of the second 4-weekly cycle of treatment. | | | | |
| | | | 14. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment, including indicating as appropriate if the patient had an extended break because of COVID 19. | | | | |
| | | | 15. Osimertinib will be used as set out in its Summary of Product Characteristics (SPC). | | | | |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| OSI4 | **Osimertinib** in combination with pemetrexed and platinum-based chemotherapy | Osimertinib in combination with pemetrexed and platinum-based chemotherapy for the first line treatment of adult patients with recurrent or locally advanced or metastatic non-small cell lung cancer exhibiting epidermal growth factor receptor exon 19 deletions or exon 21 (L858R) substitution mutations where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with osimertinib plus pemetrexed and platinum-based chemotherapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a histologically or cytologically documented non-small cell lung cancer (NSCLC) that has been shown to exhibit an epidermal growth factor (EGFR) exon 19 deletion or exon 21 (L858R) substitution mutation OR there is documented agreement by the lung MDT that the radiological appearances are in keeping with recurrent/locally advanced/metastatic NSCLC AND there is an informative circulating free DNA test result confirming the presence of an exon 19 deletion or exon 21 (L858R) substitution mutation.<br><br>Please mark below on which basis the exon 19 deletion or exon 21 substitution mutation positive NSCLC has been made in this patient:<br>- histological or cytological evidence and tissue/ctDNA testing or<br>- there is documented agreement by the lung MDT that the radiological appearances are in keeping with recurrent/locally advanced/metastatic NSCLC AND there is an informative circulating free DNA test result confirming the presence of an exon 19 deletion or exon 21 (L858R) substitution mutation.<br>3. The patient has recurrent or locally advanced or metastatic disease.<br>4. For the recurrent/locally advanced/metastatic disease indication, the patient has not received any previous cytotoxic chemotherapy or immunotherapy<br>5. The patient has had no prior treatment with an EGFR inhibitor unless osimertinib has been received as adjuvant treatment for resected stages IB to N2 only IIIB NSCLC with either an EGFR exon 19 deletion or exon 21 substitution mutation and the patient did not progress whilst still receiving adjuvant osimertinib.<br><br>Please mark below which scenario applies to this patient:<br>- no prior treatment with an EGFR inhibitor<br>- previously received adjuvant osimertinib for resected stages IB to N2 only IIIB NSCLC and did not progress whilst still receiving adjuvant osimertinib<br><br>Please state in the box below how many months have elapsed since discontinuation of adjuvant osimertinib (or enter 'n/a' if not applicable): _____<br>6. Osimertinib will be given in combination with a maximum of 4 cycles of a pemetrexed and platinum-based chemotherapy regimen and then with maintenance pemetrexed monotherapy as appropriate.<br><br>Note: NHS England recognises that there may be an urgent clinical need to commence osimertinib prior to cytotoxic chemotherapy. This is permitted, but the maximum supply of osimertinib before chemotherapy commences is 30 days (1 original pack of osimertinib tablets) and there must be no undue delay in the commencement of cytotoxic chemotherapy.<br>7. Osimertinib will be commenced at the recommended maximum dose of 80 mg once daily.<br><br>Note: the use of osimertinib doses higher than 80mg per day are not commissioned.<br>8. The patient has known CNS spread or not and that if CNS spread is present the patient is either asymptomatic and not requiring regular steroids or has a stable neurological status for at least 2 weeks after completion of definitive therapy.<br><br>Please mark below which scenario applies to this patient:<br>- no known CNS metastases or<br>- CNS spread has been documented and the patient is either asymptomatic and not requiring regular steroids or has a stable neurological status for at least 2 weeks after completion of definitive therapy<br>9. The patient has an ECOG performance status (PS) of 0 or 1.<br>10. The patient will be treated with osimertinib until loss of clinical benefit or excessive toxicity or patient choice to discontinue treatment, whichever is the sooner.<br><br>Note: the use of osimertinib should be stopped if there is disease progression in the CNS that cannot be treated with surgery or stereotactic radiotherapy.<br>11. A formal medical review as to how osimertinib plus chemotherapy is being tolerated and whether treatment with such treatment should continue or not will be scheduled to occur at least by the end of the second 3-weekly cycle of treatment.<br>12. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment.<br>13. Osimertinib will be otherwise used as set out in its Summary of Product Characteristics (SPC). | No | TA1060 | 08-May-25 | 05-Aug-25 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| PAL1 | **Palbociclib** (in combination with an aromatase inhibitor) | The treatment of previously untreated, hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer | 1. This application for palbociclib in combination with an aromatase inhibitor is made by and the first cycle of systemic anti-cancer therapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy<br>2. The patient has histologically or cytologically documented oestrogen receptor positive and her-2 negative breast cancer<br>3. The patient has had no prior treatment with a CDK 4/6 inhibitor unless either ribociclib or abemaciclib has had to be stopped within 6 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression or a CDK 4/6 inhibitor has been previously received as adjuvant therapy and treatment was completed without disease progression at least **12** months prior to the first diagnosis of recurrent or metastatic disease.<br><br>Please mark below which one of these 4 scenarios applies to this patient:<br>- no prior treatment with a CDK 4/6 inhibitor or<br>- previous treatment with the 1st line CDK4/6 inhibitor abemaciclib but treatment has had to be stopped within 6 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of progressive disease or<br>- previous treatment with the 1st line CDK4/6 inhibitor ribociclib but treatment has had to be stopped within 6 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of progressive disease or<br>- previously received a CDK4/6 inhibitor with endocrine therapy in the adjuvant setting for high risk early breast cancer either via NHS England commissioned care or via a clinical trial and treatment with the CDK 4/6 inhibitor was completed without disease progression at least 12 months prior to the first diagnosis of recurrent or metastatic disease<br>4. The patient has metastatic breast cancer or locally advanced breast cancer which is not amenable to curative treatment<br>5. The patient is male or is female and if female is either post-menopausal or if pre- or peri-menopausal has undergone ovarian ablation or suppression with LHRH agonist treatment<br>6. The patient has had no previous hormone therapy for locally advanced or metastatic disease i.e. is hormone therapy naïve for locally advanced/metastatic breast cancer.<br><br>**Note: previous hormone therapy with anastrazole or letrozole whether as adjuvant therapy or as neoadjuvant treatment is allowed as long as the patient has had a disease-free interval of 12 months or more since completing treatment with anastrazole or letrozole.**<br>7. Palbociclib will only be given in combination with an aromatase inhibitor<br>8. The patient has an ECOG performance status of 0 or 1 or 2<br>9. Treatment will continue until there is progressive disease or excessive toxicity or until the patient chooses to discontinue treatment, whichever is the sooner<br>10. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, the prescribing clinician will complete a treatment break approval form to restart treatment.<br>11. Palbociclib will be otherwise used as set out in its Summary of Product Characteristics (SPC) | Yes | TA495 | 20-Dec-17 | 20-Mar-18 |
| PAL2 | **Palbociclib** in combination with fulvestrant | For hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer where the following criteria are met: | 1. This application for palbociclib in combination with fulvestrant is being made by and the first cycle of palbociclib plus fulvestrant will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has histologically or cytologically documented oestrogen receptor positive and HER-2 negative breast cancer.<br>3. The patient has metastatic breast cancer or locally advanced breast cancer which is not amenable to curative treatment.<br>4. The patient is male or is female and if female is either post-menopausal or if pre- or peri-menopausal has undergone ovarian ablation or suppression with LHRH agonist treatment.<br>5. The patient has an ECOG performance status of 0 or 1 or 2.<br>6. The patient has received previous endocrine therapy according to one of the three populations as set out below as these are the groups on which the NICE Technology Appraisal for palbociclib plus fulvestrant focused. Please record which population the patient falls into:<br>- has progressive disease whilst still receiving adjuvant or neoadjuvant endocrine therapy for early breast cancer with no subsequent endocrine therapy received following disease progression or<br>- has progressive disease within 12 or less months of completing adjuvant endocrine therapy for early breast cancer with no subsequent endocrine therapy received following disease progression or<br>- has progressive disease on 1st line endocrine therapy for advanced/metastatic breast cancer with no subsequent endocrine therapy received following disease progression.<br>7. The patient has had no prior treatment with a CDK 4/6 inhibitor unless either abemaciclib (in combination with fulvestrant) or ribociclib (in combination with fulvestrant) has had to be stopped within 6 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression or a CDK 4/6 inhibitor has been previously received as adjuvant therapy and treatment was completed without disease progression at least **12** months prior to the first diagnosis of recurrent or metastatic disease.<br><br>Please mark below which one of these 4 scenarios applies to this patient:<br>- no prior treatment with a CDK 4/6 inhibitor or<br>- previous treatment with the CDK4/6 inhibitor abemaciclib in combination with fulvestrant but treatment has had to be stopped within 6 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of progressive disease or<br>- previous treatment with the CDK4/6 inhibitor ribociclib in combination with fulvestrant but treatment has had to be stopped within 6 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of progressive disease or<br>- previously received a CDK4/6 inhibitor with endocrine therapy in the adjuvant setting for high risk early breast cancer either via NHS England commissioned care or via a clinical trial and treatment with the CDK 4/6 inhibitor was completed without disease progression at least 12 months prior to the first diagnosis of recurrent or metastatic disease<br>8. The patient has had no prior treatment with fulvestrant.<br>9. The patient has had no prior treatment with everolimus.<br>10. Palbociclib will only be given in combination with a fulvestrant.<br>11. Treatment will continue until there is progressive disease or excessive toxicity or until the patient chooses to discontinue treatment, whichever is the sooner<br>12. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, the prescribing clinician will complete a treatment break approval form to restart treatment.<br>13. Palbociclib and fulvestrant will be otherwise used as set out in their Summaries of Product Characteristics (SmPC). | Yes | TA836 | 26-Oct-22 | 24-Jan-23 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| PAN3 | **Panitumumab** in combination with FOLFIRINOX or FOLFOXIRI (5-fluorouracil, irinotecan and oxaliplatin) chemotherapy | For chemotherapy-naive untreated metastatic or locally advanced and inoperable colorectal cancer where the following criteria have been met: | 1. This application is being made by and the first cycle of panitumumab in combination with FOLFIRINOX/FOLFOXIRI chemotherapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. This patient has RAS wild-type metastatic or locally advanced and inoperable colorectal cancer.<br>3. This patient has not received previous cytotoxic chemotherapy for metastatic disease unless there has been use of previous neoadjuvant combination cytotoxic chemotherapy for potentially resectable metastatic colorectal cancer.<br>Please mark below whether the patient has had neoadjuvant chemotherapy or not:<br>- the patient has not had previous neoadjuvant cytotoxic chemotherapy for metastatic colorectal cancer **or**<br>- the patient has been treated with previous neoadjuvant cytotoxic chemotherapy for potentially resectable metastatic colorectal cancer<br>4. Panitumumab in this FOLFIRINOX/ FOLFOXIRI combination is being used as either 1st line treatment for metastatic colorectal cancer or as 2nd line treatment if treated with 1st line pembrolizumab for MSI-H/dMMR disease.<br>Please mark below in which line of therapy the patient is having panitumumab plus FOLFIRINOX/ FOLFOXIRI chemotherapy:<br>- panitumumab + FOLFIRINOX/ FOLFOXIRI is being used as 1st line treatment for metastatic colorectal cancer **or**<br>- panitumumab + FOLFIRINOX/ FOLFOXIRI is being used as 2nd line treatment for metastatic colorectal cancer as the patient has MSI-H/dMMR disease and has been treated with 1st line pembrolizumab or 1st line nivolumab which was previously available as an Interim COVID option<br>5. The patient has not received prior treatment with cetuximab or panitumumab unless this was received as part of combination neoadjuvant chemotherapy for potentially resectable metastatic disease.<br>Patients with potentially resectable metastatic disease who have received a neoadjuvant cetuximab/panitumumab-containing combination chemotherapy with the intention of resection if the metastases become resectable, and who do not progress while on treatment with cetuximab/panitumumab but who then become unsuitable for surgery or have unsuccessful surgery, may continue treatment with the same cetuximab/panitumumab-containing combination chemotherapy.<br><br>Patients who have successful resection(s) after neoadjuvant cetuximab/panitumumab-containing combination chemotherapy for metastatic disease and who did not progress on such chemotherapy may receive cetuximab/panitumumab with subsequent first-line combination chemotherapy if they present later with progression of metastatic disease.<br><br>Please mark below the patient's treatment status in respect of previous cetuximab/panitumumab-containing neoadjuvant chemotherapy:<br>- the patient has not been treated with previous chemotherapy with either cetuximab or panitumumab-containing combination chemotherapy for metastatic disease **or**<br>- the only previous cetuximab/panitumumab-containing chemotherapy was with neoadjuvant treatment for potentially resectable disease which resulted in a lack of disease progression and the patient was then unable to proceed to surgery or had unsuccessful surgery **or**<br>- the only previous cetuximab/panitumumab-containing chemotherapy was with neoadjuvant treatment for potentially resectable disease which resulted in a lack of disease progression and the patient was then able to proceed to surgery but has since relapsed<br>6. The prescribing clinician is aware that if this patient has BRAF V600 mutation-positive disease, the patient will be ineligible for encorafenib plus cetuximab as a subsequent line of therapy if they receive a cetuximab/panitumumab-containing regimen now as first-line therapy.<br>7. The prescribing clinician is aware that from 1st December 2020 an NHS England Best Value framework is in operation for cetuximab and panitumumab in first line colorectal cancer. The choice of this panitumumab -containing regimen is therefore in line with the local application of the Best Value framework for these drugs within my organisation.<br>8. Panitumumab will be given in combination FOLFIRINOX/ FOLFOXIRI (5-fluorouracil, irinotecan and oxaliplatin in combination) chemotherapy.<br>9. Panitumumab in combination with FOLFIRINOX/ FOLFOXIRI chemotherapy will be given until disease progression on this regimen and that panitumumab will be discontinued when this disease progression occurs.<br>If the patient experiences excessive toxicity with irinotecan and/or oxaliplatin, panitumumab can be subsequently continued in combination a fluoropyrimidine without irinotecan and/or oxaliplatin until disease progression and then will be discontinued.<br><br>Note: continued use of panitumumab beyond 1st line therapy is not commissioned once disease progression has occurred with 1st line treatment.<br>10. Where a treatment break of more than 6 weeks beyond the expected cycle length is needed, I will complete a treatment break form to restart treatment, including an indication as appropriate if the patient had an extended break because of COVID 19<br>11. The use of panitumumab will be as per the Summary of Product Characteristics (SPC). | Yes | TA439 | 29-Mar-17 | 27-Jun-17 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| PAN1_v1.3 | **Panitumumab** in combination with irinotecan-based chemotherapy | For chemotherapy-naive metastatic or locally advanced and inoperable colorectal cancer where the following criteria are met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with panitumumab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. This patient has RAS wild-type metastatic or locally advanced and inoperable colorectal cancer.<br>3. This patient has not received previous cytotoxic treatment for metastatic disease unless there has been use of previous neoadjuvant combination cytotoxic chemotherapy for potentially resectable metastatic colorectal cancer.<br>Please mark below whether the patient has had neoadjuvant cytotoxic chemotherapy or not:<br>- the patient has not had previous neoadjuvant cytotoxic chemotherapy for metastatic colorectal cancer **or**<br>- the patient has been treated with previous neoadjuvant cytotoxic chemotherapy for potentially resectable metastatic colorectal cancer<br>4. Panitumumab in this irinotecan-based combination is being used as either 1st line treatment for metastatic colorectal cancer or as 2nd line treatment if treated with 1st line pembrolizumab for MSI-H/dMMR disease.<br>Please mark below in which line of therapy the patient is having panitumumab plus an irinotecan-based combination chemotherapy:<br>- panitumumab + irinotecan-based chemotherapy is being used as 1st line treatment for metastatic colorectal cancer **or**<br>- panitumumab + irinotecan-based chemotherapy is being used as 2nd line treatment for metastatic colorectal cancer as the patient has MSI-H/dMMR disease and has been treated with 1st line pembrolizumab or 1st line nivolumab which was previously available as an Interim COVID option<br>5. The patient has not received prior treatment with cetuximab or panitumumab unless this was received as part of combination neoadjuvant chemotherapy for potentially resectable metastatic disease.<br>Patients with potentially resectable metastatic disease who have received a neoadjuvant cetuximab/panitumumab-containing combination chemotherapy with the intention of resection if the metastases become resectable, and who do not progress while on treatment with cetuximab/panitumumab but who then become unsuitable for surgery or have unsuccessful surgery, may continue treatment with the same cetuximab/panitumumab-containing combination chemotherapy.<br><br>Patients who have successful resection(s) after neoadjuvant cetuximab/panitumumab-containing combination chemotherapy for metastatic disease and who did not progress on such chemotherapy may receive cetuximab/panitumumab with subsequent first-line combination chemotherapy if they present later with progression of metastatic disease.<br><br>Please mark below the patient's treatment status in respect of previous cetuximab/panitumumab-containing neoadjuvant chemotherapy:<br>- the patient has not been treated with previous chemotherapy with either cetuximab or panitumumab-containing combination chemotherapy for metastatic disease **or**<br>- the only previous cetuximab/panitumumab-containing chemotherapy was with neoadjuvant treatment for potentially resectable disease which resulted in a lack of disease progression and the patient was then unable to proceed to surgery or had unsuccessful surgery **or**<br>- the only previous cetuximab/panitumumab-containing chemotherapy was with neoadjuvant treatment for potentially resectable disease which resulted in a lack of disease progression and the patient was then able to proceed to surgery but has since relapsed<br>6. The prescribing clinician is aware that if this patient has BRAF V600 mutation-positive disease, the patient will be ineligible for encorafenib plus cetuximab as a subsequent line of therapy if they receive a cetuximab/panitumumab-containing regimen now as first-line therapy.<br>7. The prescribing clinician is aware that from 1st December 2020 an NHS England Best Value framework is in operation for cetuximab and panitumumab in first line colorectal cancer. The choice of this panitumumab -containing regimen is therefore in line with the local application of the Best Value framework for these drugs within my organisation.<br>8. Panitumumab will be given in combination with irinotecan-based combination chemotherapy.<br>9. Panitumumab in combination with irinotecan-based chemotherapy will be given until disease progression on this regimen and that panitumumab will be discontinued when this disease progression occurs.<br>If the patient experiences excessive toxicity with irinotecan, panitumumab can be subsequently continued in combination with a fluoropyrimidine alone until disease progression and then will be discontinued.<br><br>Note: continued use of panitumumab beyond 1st line therapy is not commissioned once disease progression has occurred with 1st line treatment.<br>10. Where a treatment break of more than 6 weeks beyond the expected cycle length is needed, I will complete a treatment break form to restart treatment, including an indication as appropriate if the patient had an extended break because of COVID 19<br>11. The use of panitumumab will be as per the Summary of Product Characteristics (SPC). | Yes | TA439 | 29-Mar-17 | 27-Jun-17 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| PAN2_v1.2 | **Panitumumab** in combination with oxaliplatin-based chemotherapy | For chemotherapy-naive metastatic or locally advanced and inoperable colorectal cancer where the following criteria are met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with panitumumab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br><br>2. This patient has RAS wild-type metastatic or locally advanced and inoperable colorectal cancer.<br><br>3. This patient has not received previous cytotoxic treatment for metastatic disease unless there has been use of previous neoadjuvant combination cytotoxic chemotherapy for potentially resectable metastatic colorectal cancer.<br>Please mark below whether the patient has had neoadjuvant chemotherapy or not:<br>- the patient has not had previous neoadjuvant cytotoxic chemotherapy for metastatic colorectal cancer **or**<br>- the patient has been treated with previous neoadjuvant cytotoxic chemotherapy for potentially resectable metastatic colorectal cancer<br><br>4. Panitumumab in this oxaliplatin-based combination is being used as either 1st line treatment for metastatic colorectal cancer or as 2nd line treatment if treated with 1st line pembrolizumab for MSI-H/dMMR disease.<br>Please mark below in which line of therapy the patient is having panitumumab plus an oxaliplatin-based combination chemotherapy:<br>- panitumumab + oxaliplatin-based chemotherapy is being used as 1st line treatment for metastatic colorectal cancer **or**<br>- panitumumab + oxaliplatin-based chemotherapy is being used as 2nd line treatment for metastatic colorectal cancer as the patient has MSI-H/dMMR disease and has been treated with 1st line pembrolizumab or 1st line nivolumab which was previously available as an Interim COVID option<br><br>5. The patient has not received prior treatment with cetuximab or panitumumab unless this was received as part of combination neoadjuvant chemotherapy for potentially resectable metastatic disease.<br>Patients with potentially resectable metastatic disease who have received a neoadjuvant cetuximab/panitumumab-containing combination chemotherapy with the intention of resection if the metastases become resectable, and who do not progress while on treatment with cetuximab/panitumumab but who then become unsuitable for surgery or have unsuccessful surgery, may continue treatment with the same cetuximab/panitumumab-containing combination chemotherapy.<br><br>Patients who have successful resection(s) after neoadjuvant cetuximab/panitumumab-containing combination chemotherapy for metastatic disease and who did not progress on such chemotherapy may receive cetuximab/panitumumab with subsequent first-line combination chemotherapy if they present later with progression of metastatic disease.<br><br>Please mark below the patient's treatment status in respect of previous cetuximab/panitumumab-containing neoadjuvant chemotherapy:<br>- the patient has not been treated with previous chemotherapy with either cetuximab or panitumumab-containing combination chemotherapy for metastatic disease **or**<br>- the only previous cetuximab/panitumumab-containing chemotherapy was with neoadjuvant treatment for potentially resectable disease which resulted in a lack of disease progression and the patient was then unable to proceed to surgery or had unsuccessful surgery **or**<br>- the only previous cetuximab/panitumumab-containing chemotherapy was with neoadjuvant treatment for potentially resectable disease which resulted in a lack of disease progression and the patient was then able to proceed to surgery but has since relapsed<br><br>6. The prescribing clinician is aware that if this patient has BRAF V600 mutation-positive disease, the patient will be ineligible for encorafenib plus cetuximab as a subsequent line of therapy if they receive a cetuximab/panitumumab-containing regimen now as first-line therapy.<br><br>7. The prescribing clinician is aware that from 1st December 2020 an NHS England Best Value framework is in operation for cetuximab and panitumumab in first line colorectal cancer. The choice of this panitumumab -containing regimen is therefore in line with the local application of the Best Value framework for these drugs within my organisation.<br><br>8. Panitumumab will be given in combination with oxaliplatin-based combination chemotherapy.<br><br>9. Panitumumab in combination with oxaliplatin-based chemotherapy will be given until disease progression on this regimen and that panitumumab will be discontinued when this disease progression occurs.<br>If the patient experiences excessive toxicity with oxaliplatin, panitumumab can be subsequently continued in combination with a fluoropyrimidine alone until disease progression and then will be discontinued.<br><br>Note: continued use of panitumumab beyond 1st line therapy is not commissioned once disease progression has occurred with 1st line treatment.<br><br>10. Where a treatment break of more than 6 weeks beyond the expected cycle length is needed, I will complete a treatment break form to restart treatment, including an indication as appropriate if the patient had an extended break because of COVID 19<br><br>11. The use of panitumumab will be as per the Summary of Product Characteristics (SPC). | Yes | TA439 | 29-Mar-17 | 27-Jun-17 |
| PANO1 | **Panobinostat** | Panobinostat for treating multiple myeloma after at least 2 previous treatments | nca | No | TA380 | 27-Jan-16 | 26-Apr-16 |
| PDL1 | **Pegylated Liposomal Doxorubicin** | The treatment of sarcomas where all the following criteria are met: | 1. An application has been made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy<br><br>2. a) Sarcoma in patients with cardiac impairment requiring an anthracycline, 1st line indication **or**<br>b) Sarcoma in patients with cardiac impairment requiring an anthracycline, 2nd line indication<br><br>3. To be used within the treating Trust's governance framework, as Pegylated Liposomal Doxorubicin is not licensed in these indications | Yes | n/a - NHS England clinical policy | - | 01-Apr-21 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| PEMB1 | **Pembrolizumab** | Pembrolizumab monotherapy for the treatment of PD-L1 positive locally advanced or metastatic non-small cell lung cancer after chemotherapy where the following criteria are met: | 1. An application has been made by and the first cycle of systemic anti -cancer therapy is to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The prescribing clinician is fully aware of the management of and the treatment modifications that may be required for immune-related adverse reactions due to anti-PD-L1 treatments including pneumonitis, colitis, nephritis, endocrinopathies, hepatitis and skin toxicities.<br>3. The patient has a histologically- or cytologically-confirmed diagnosis of stage IIIB or stage IIIC or stage IV non-small cell lung cancer (squamous or non-squamous).<br>4. The patient has stage IIIB or IIIC or IV NSCLC or had disease that recurred after previous potentially curative local management of NSCLC with surgery/chemoradiotherapy/radiotherapy.<br>5. An approved and validated test has shown that the patient's tumour expresses PD-L1 with a positive tumour proportion score [TPS] of **at least 1%**.<br>6. The patient has progressed **either** after treatment with at least two cycles of platinum-based doublet chemotherapy for stage IIIB or IIIC or IV or recurrent NSCLC after previous potentially curative local management **or** has progressed within 6 months of completing platinum-based adjuvant or neoadjuvant therapy or chemoradiation and if appropriate that the patient has had all appropriate targeted treatments if the patient has a tumour which is positive for an actionable genomic change in relation to EGFR or ALK or ROS1 or MET exon 14 or KRAS G12C or RET or BRAF V600 status.<br>7. The patient has not received prior treatment with an anti PD-1, anti-PD-L1, anti-PD-L2, anti-CD137 or anti-cytotoxic T-lymphocyte-associated antigen-4 (CTL-4) antibody unless the patient discontinued or completed checkpoint inhibitor immunotherapy as part of adjuvant/neoadjuvant/maintenance therapy **without disease progression and at least 6 months elapsed between the date of the last immunotherapy treatment and the date of first diagnosis of relapse with recurrent or metastatic disease**.<br>Note: NHS England does not commission re-treatment with checkpoint inhibitor therapy for patients who have discontinued or completed previous checkpoint inhibitor therapy for the locally advanced/metastatic indication.<br><br>Please mark below if the patient received previous checkpoint inhibitor therapy and in which setting:<br>the patient has never received any immunotherapy for NSCLC. If so, please type 'n/a' in the 'Time gap' box below or<br>the patient has previously been treated with adjuvant immunotherapy for NSCLC and discontinued immunotherapy without disease progression and at least 6 months prior to the first diagnosis of relapse. Please document in the box below the time gap in months between completion of previous adjuvant immunotherapy and first diagnosis of disease relapse or<br>the patient has previously been treated with neoadjuvant immunotherapy for NSCLC and discontinued immunotherapy without disease progression and at least 6 months prior to the first diagnosis of relapse. Please document in the box below the time gap in months between completion of previous neoadjuvant immunotherapy and first diagnosis of disease relapse or<br>the patient has previously been treated with maintenance immunotherapy post chemoradiotherapy for NSCLC and discontinued immunotherapy without disease progression and at least 6 months prior to the first diagnosis of relapse. Please document in the box below the time gap in months between completion of previous maintenance immunotherapy and first diagnosis of disease relapse<br><br>Time gap in months after completion of previous adjuvant or neoadjuvant or maintenance checkpoint inhibitor immunotherapy and first diagnosis of disease relapse:_____<br>Note: the mandatory interval between the last date of administration of any prior adjuvant/neoadjuvant/maintenance immunotherapy and the date of first relapse is **at least 6 months**. For patients suffering a first relapse within 6-12 months of previous immunotherapy, clinicians should bear in mind the long elimination half-lives of immunotherapies and make individual assessments of the overall benefit/risk ratio of re-treatment with immunotherapy.<br>8. Treatment with pembrolizumab will continue for a total of 2 years* or until disease progression or unacceptable toxicity or withdrawal of patient consent, whichever occurs first.<br>*2 years treatment is defined as a maximum of 35 x 3-weekly cycles or the equivalent numbers of cycles if 6-weekly dosing is used.<br>9. Pembrolizumab will be used as monotherapy.<br>10. The patient has an ECOG performance status of 0 or 1.<br>11. The patient has no symptomatically active brain metastases or leptomeningeal metastases.<br>12. A formal medical review as to whether treatment with pembrolizumab should continue or not will occur at least by the end of the first 6 weeks of treatment.<br>13. When a treatment break of more than 12 weeks beyond the expected cycle length is needed, I will complete a treatment break approval form to restart treatment, including as appropriate if the patient had an extended break on account of COVID 19.<br>14. Pembrolizumab will be otherwise used as set out in its Summary of Product Characteristics. | No | TA428 | 11-Jan-17 | 11-Feb-17 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| PEMB2 | **Pembrolizumab** | Pembrolizumab monotherapy for the first line treatment of locally advanced or metastatic non-small cell lung cancer which expresses PD-L1 with a tumour proportion score of at least 50% where all the following criteria are met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with pembrolizumab monotherapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a histologically- or cytologically-confirmed diagnosis of non-small cell lung cancer (squamous or non-squamous).<br>Please mark below which histology applies to this patient:<br>- squamous NSCLC<br>- non-squamous NSCLC<br>3. The patient has stage IIIB or IIIC or IV NSCLC or has disease that has recurred after previous potentially curative local management of NSCLC with surgery/chemoradiotherapy/radiotherapy.<br>4. An approved and validated test has demonstrated that there is PD-L1 expression of **at least 50%** of tumour cells (the PD-L1 tumour proportion score).<br>Please document the actual PD-L1 expression below:<br>PD-L1 tumour proportion score_____<br>5. Either the patient has been documented as NOT having a NSCLC which harbours an EGFR 19 or 21 mutation or an ALK gene fusion or the patient has a squamous cell carcinoma and a decision to not test for an EGFR 19 or 21 mutation or an ALK gene fusion and proceed with pembrolizumab has been discussed with the patient during the consenting process, i.e. the patient has consented to be treated with an unknown EGFR/ ALK status.<br>Please mark below which option applies to this patient:<br>- Documented as NOT having a NSCLC which harbours an EGFR 19 or 21 mutation or an ALK gene fusion<br>- Patient has squamous NSCLC and a decision to not test for an EGFR 19 or 21 mutation or an ALK gene fusion and proceed with pembrolizumab has been discussed with the patient during the consenting process.<br>6. **Either** the patient has not received any previous systemic therapy for NSCLC **or** the patient **completed the last treatment** with chemotherapy or chemoradiotherapy or checkpoint inhibitor immunotherapy as part of adjuvant/neoadjuvant/maintenance therapy at least **6** months prior to the first diagnosis of locally recurrent or metastatic disease **or** the patient has a BRAFV600 mutation, or MET alteration, and has received 1st line therapy with a suitable targeted agent, and has now progressed on, or was unable to tolerate, the targeted agent.<br><br>Please indicate below whether the patient has received any previous systemic therapy for NSCLC:<br>- the patient has not been previously treated with any adjuvant or neoadjuvant or maintenance systemic therapy for NSCLC or<br>- the patient has been previously treated with adjuvant systemic therapy for NSCLC and this was completed more than 6 months before first diagnosis of recurrent or metastatic disease or<br>- the patient has been previously treated with neoadjuvant systemic therapy for NSCLC and this was completed more than 6 months before first diagnosis of recurrent or metastatic or<br>- the patient has been previously treated with maintenance systemic therapy for NSCLC and this was completed more than 6 months before first diagnosis of recurrent or metastatic disease<br>- the patient has a BRAFV600 mutation, or MET alteration, and has received 1st line therapy with a suitable targeted agent, and has now progressed on, or was unable to tolerate, the targeted agent.<br>7. The patient has not received prior treatment with an anti PD-1, anti-PD-L1, anti-PD-L2, anti-CD137 or anti-cytotoxic T-lymphocyte-associated antigen-4 (CTL-4) antibody unless the patient discontinued/completed treatment with checkpoint inhibitor immunotherapy as part of adjuvant/neoadjuvant/maintenance therapy **without disease progression and at least 6 months elapsed between the date of last immunotherapy treatment and the date of first diagnosis of relapse with recurrent or metastatic disease.**<br>Note: NHS England does not commission any re-treatment with checkpoint inhibitor therapy for patients who have discontinued or completed previous checkpoint inhibitor therapy for the locally advanced/metastatic indication.<br><br>Please mark below if the patient has received previous checkpoint inhibitor therapy and in which setting:<br>- the patient has never received any immunotherapy for NSCLC. If so, please type 'n/a' in the 'Time Gap' box below or<br>- the patient has previously been treated with adjuvant immunotherapy for NSCLC and discontinued immunotherapy without disease progression and at least 6 months prior to the first diagnosis of relapse. Please document in the box below the time gap in months between completion of previous adjuvant immunotherapy and first diagnosis of disease relapse or<br>- the patient has previously been treated with neoadjuvant treatment containing immunotherapy for NSCLC and discontinued immunotherapy without disease progression and at least 6 months prior to the first diagnosis of disease relapse. Please document in the box below the time gap in months between completion of previous neoadjuvant immunotherapy and first diagnosis of disease relapse or<br>- the patient has previously been treated with maintenance treatment containing immunotherapy for NSCLC and discontinued immunotherapy without disease progression and at least 6 months prior to the first diagnosis of disease relapse. Please document in the box below the time gap in months between completion of previous maintenance immunotherapy and first diagnosis of disease relapse<br><br>Time gap in months after completion of previous adjuvant or neoadjuvant or maintenance checkpoint inhibitor immunotherapy and first diagnosis of disease relapse:_____<br>Note: the mandatory interval between the last date of administration of any prior adjuvant/neoadjuvant/maintenance immunotherapy and first relapse is at least 6 months. For patients suffering a first relapse within 6-12 months of previous immunotherapy, clinicians should bear in mind the long elimination half-lives of immunotherapies and make individual assessments of the overall benefit/risk ratio of re-treatment with immunotherapy.<br>8. Pembrolizumab will be administered as 3-weekly or 6-weekly cycles or will be administered according to the extended dosing schedule to which the patient has been randomised as per the protocol in the NIHR-approved REFINE-Lung trial (Reference NIHR133011).<br>9. In the absence of disease progression pembrolizumab will continue for a total treatment duration of 2 years* of treatment or until disease progression or unacceptable toxicity or withdrawal of patient consent or unacceptable toxicity, whichever occurs first.<br>*2 years treatment is defined as a maximum of 35 x 3-weekly cycles or the equivalent numbers of cycles if 6-weekly dosing is used or is defined by the extended dosing schedule to which the patient has been randomised as per the protocol in the NIHR-approved REFINE-Lung trial (Reference NIHR133011).<br>10. The patient has an ECOG performance status of 0 or 1.<br>11. The patient has no symptomatically active brain metastases or leptomeningeal metastases.<br>12. When a treatment break of more than 12 weeks beyond the expected 3- or 6- weekly cycle length is needed, I will complete a treatment break approval form which must be approved **BEFORE** treatment with pembrolizumab is re-started<br>13. Pembrolizumab will otherwise be used as set out in its Summary of Product Characteristics. | No | TA531 | 18-Jul-18 | 16-Oct-18 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| PEMB5 | **Pembrolizumab** | The treatment of relapsed or refractory classical Hodgkin lymphoma in ADULTS who are stem cell transplant-ineligible and have failed brentuximab vedotin where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with pembrolizumab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The prescribing clinician I am fully aware of the management of and the treatment modifications that may be required for immune-related adverse reactions due to anti-PD-L1 treatments including pneumonitis, colitis, nephritis, endocrinopathies, hepatitis and skin toxicities.<br>3. The patient is an ADULT and has histologically documented classical Hodgkin lymphoma<br>**Note:** there is a separate Blueteq form to be used for pembrolizumab in this indication in children.<br>4. The patient has failed at least 2 lines of chemotherapy and also failed treatment with brentuximab vedotin.<br>5. The patient has not received stem cell transplantation of any kind.<br>6. The patient is currently ineligible for stem cell transplantation.<br>7. The patient is EITHER potentially a candidate for future stem cell transplantation or not. Please mark appropriately in one of the boxes below:<br>- The patient is a candidate for future stem cell transplantation if there is sufficient benefit of treatment with pembrolizumab or<br>- The patient is not a candidate for stem cell transplantation however good the response to pembrolizumab may be<br>8. The patient has an ECOG performance status (PS) of 0 or 1.<br>9. The patient has not received prior treatment with an anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CD137, or anti-cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) antibody.<br>10. Pembrolizumab is being given as monotherapy and will commence at a fixed dose of either 3-weekly cycles of pembrolizumab monotherapy 200mg or 6-weekly cycles of pembrolizumab monotherapy 400mg.<br>11. A formal medical review as to whether treatment with pembrolizumab should continue or not will be scheduled to occur at least by the end of the third cycle of treatment if 3-weekly administration of pembrolizumab or by the end of the second cycle if 6-weekly administration is used.<br>12. The patient will be treated until stem cell transplantation occurs or loss of clinical benefit or excessive toxicity or patient choice to discontinue treatment or completion of 2 years of treatment with pembrolizumab, whichever is the sooner.<br>13. The patient will receive a maximum treatment duration with pembrolizumab of 2 years (or 35 x 3-weekly cycles of pembrolizumab or its equivalent if 6-weekly pembrolizumab dosing is used).<br>14. When a treatment break of more than 12 weeks beyond the expected 3- or 6-weekly cycle length is needed, a treatment break approval form to re-start treatment will be completed.<br>15. Pembrolizumab will otherwise be used as set out in its Summary of Product Characteristics (SPC). | Yes | TA967 | 01-May-24 | 30-Jul-24 |
| PEMB6 | **Pembrolizumab** | The treatment of relapsed or refractory classical Hodgkin lymphoma in CHILDREN who are stem cell transplant-ineligible and have failed brentuximab vedotin where the following criteria have been met | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with pembrolizumab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The prescribing clinician is fully aware of the management of and the treatment modifications that may be required for immune-related adverse reactions due to anti-PD-L1 treatments including pneumonitis, colitis, nephritis, endocrinopathies, hepatitis and skin toxicities.<br>3. The patient is a CHILD aged 3 years and older and has histologically documented classical Hodgkin lymphoma.<br>**Note:** there is a separate Blueteq form to be used for pembrolizumab in this indication in adults.<br>4. The patient has failed at least 2 lines of chemotherapy and also failed treatment with brentuximab vedotin.<br>5. The patient has not received stem cell transplantation of any kind.<br>6. The patient is currently ineligible for stem cell transplantation.<br>7. The patient is EITHER potentially a candidate for future stem cell transplantation or not. Please mark appropriately in one of the boxes below:<br>- The patient is a candidate for future stem cell transplantation if there is sufficient benefit of treatment with pembrolizumab or<br>- The patient is not a candidate for stem cell transplantation however good the response to pembrolizumab may be<br>8. The patient has an ECOG performance status (PS) of 0 or 1 or its equivalent Lansky score.<br>9. The patient has not received prior treatment with an anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CD137, or anti-cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) antibody.<br>10. Pembrolizumab is being given as monotherapy and will commence at a dose of 2mg/kg bodyweight up to a maximum of 200mg in 3-weekly cycles of pembrolizumab monotherapy.<br>11. A formal medical review as to whether treatment with pembrolizumab should continue or not will be scheduled to occur at least by the end of the third cycle of treatment with 3-weekly administration of pembrolizumab.<br>12. The patient will be treated until stem cell transplantation occurs or loss of clinical benefit or excessive toxicity or patient choice to discontinue treatment or completion of 2 years of treatment with pembrolizumab, whichever is the sooner.<br>13. The patient will receive a maximum treatment duration with pembrolizumab of 2 years (or 35 x 3-weekly cycles of pembrolizumab).<br>14. When a treatment break of more than 12 weeks beyond the expected 3-weekly cycle length is needed, a treatment break approval form to re-start treatment will be completed.<br>15. Pembrolizumab will otherwise be used as set out in its Summary of Product Characteristics (SPC). | Yes | TA967 | 01-May-24 | 30-Jul-24 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| PEMB7 | **Pembrolizumab** | Pembrolizumab for adjuvant treatment of melanoma with high risk of recurrence where the following criteria have been met: | 1. This application is made by and the first cycle of systemic anti-cancer therapy with pembrolizumab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy<br><br>2. This patient has a confirmed histological diagnosis of malignant melanoma<br>Please indicate whether the melanoma is BRAF V600 mutation positive or not:<br>- BRAF V600 mutation positive **or**<br>- BRAFV600 mutation negative<br><br>3. The patient has melanoma which has been staged as stage III disease according to the AJCC 8th edition.<br>Please state which stage disease the patient has:<br>Stage IIIA disease **or**<br>Stage IIIB disease **or**<br>Stage IIIC disease **or**<br>Stage IIID disease<br><br>4. Complete resection has taken place for stage III disease and this has been done with either a sentinel lymph node biopsy ('sentinel lymphadenectomy') or when indicated with a completion lymph node dissection.<br><br>5. The patient is treatment naïve to any systemic therapy for malignant melanoma and in particular has not previously received any immunotherapy with any check point inhibitors or BRAF V600 inhibitors or MEK inhibitors.<br><br>Note: NHS England does not commission any adjuvant immunotherapy with checkpoint inhibitors for stage III disease in patients who have previously received adjuvant immunotherapy for stage IIB or IIC disease.<br><br>6. The prescribing clinician has discussed with the patient the benefits and toxicities of adjuvant pembrolizumab in stage III disease and has used the expected median figures below in relation to the risk of disease relapse if a routine surveillance policy is followed:<br>- for stage IIIA disease, the 5 and 10 year melanoma-specific survival probabilities with routine surveillance are 93% and 88%, respectively<br>- for stage IIIB disease, the 5 and 10 year figures are 83% and 77%, respectively<br>- for stage IIIC disease, the 5 and 10 year figures are 69% and 60%, respectively<br>- for stage IIID disease, the 5 and 10 year figures are 32% and 24%, respectively<br><br>7. The patient has an ECOG performance status of either 0 or 1<br><br>8. Adjuvant pembrolizumab will commence no more than 3 months after the date of surgery which documented the complete resection of stage III melanoma.<br><br>9. Treatment with pembrolizumab monotherapy will be continued for a maximum of 12 months from the start of treatment (or a maximum of 9 cycles if given 6-weekly) in the absence of disease recurrence, unacceptable toxicity or withdrawal of patient consent.<br><br>10. When a treatment break of more than 12 weeks beyond the expected 3-weekly, or 6-weekly cycle length is needed, I will complete a treatment break approval form, which MUST be approved before treatment is recommenced.<br><br>11. Pembrolizumab is to be otherwise used as set out in its Summary of Product Characteristics | No | TA766 | 02-Feb-22 | 03-May-22 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| PEMB8 | **Pembrolizumab** | Pembrolizumab in combination with pemetrexed- and platinum-based chemotherapy for the first line treatment of PD-L1 positive or negative locally advanced or metastatic non-squamous non-small cell lung cancer where all the following criteria are met: | 1. This application has been made by and the first cycle of systemic anti-cancer therapy with pembrolizumab in combination with pemetrexed- and platinum-based combination chemotherapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a histologically- or cytologically-confirmed diagnosis of non-squamous non-small cell lung cancer (NSCLC).<br>3. The patient has stage IIIB or IIIC or IV NSCLC or has disease that has recurred after potentially curative treatment with local management of NSCLC with surgery/chemoradiotherapy/radiotherapy.<br>4. EGFR and ALK mutation testing have been done and both are negative.<br>5. PD-L1 testing with an approved and validated test to determine the Tumour Proportion Score (TPS) has been attempted prior to this application and the result is set out below.<br>Note: for fully informed patient consent of all the potential 1st line treatment options, PD-L1 testing must still be attempted and recorded here.<br>Please document the actual TPS below (if negative, record '0') or enter 'n/a' if the TPS cannot be documented and the reason why:<br>TPS_____<br>If n/a, please indicate below the reason why the actual TPS cannot be documented:<br>- the TPS result was unquantifiable OR<br>- PD-L1 testing was not possible as the pathologist has documented that there is insufficient tissue for PD-L1 analysis<br>6. Either the patient has not received any previous systemic therapy for NSCLC or the patient **completed the last treatment** with chemotherapy or chemoradiotherapy or checkpoint inhibitor immunotherapy as part of adjuvant/neoadjuvant/maintenance therapy at least **6** months prior to the first diagnosis of locally recurrent or metastatic disease.<br>Please indicate below whether the patient has received any previous adjuvant or neoadjuvant or maintenance systemic therapy for NSCLC:<br>- the patient has not been previously treated with any adjuvant or neoadjuvant or maintenance systemic therapy for NSCLC or<br>- the patient has been previously treated with **adjuvant** systemic therapy for NSCLC and this was completed more than 6 months before first diagnosis of recurrent or metastatic disease or<br>- the patient has been previously treated with **neoadjuvant** systemic therapy for NSCLC and this was completed more than 6 months before first diagnosis of recurrent or metastatic disease or<br>- the patient has been previously treated with **maintenance** systemic therapy for NSCLC and this was completed more than 6 months before first diagnosis of recurrent or metastatic disease<br>7. The patient has not received prior treatment with an anti PD-1, anti-PD-L1, anti-PD-L2, anti-CD137 or anti-cytotoxic T-lymphocyte-associated antigen-4 (CTL-4) antibody unless the patient completed or discontinued checkpoint inhibitor immunotherapy as part of adjuvant/neoadjuvant/maintenance therapy **without disease progression on treatment and at least 6 months elapsed between the date of last immunotherapy treatment and the date of first diagnosis of relapse with recurrent or metastatic disease**.<br>Note: NHS England does not commission any re-treatment with checkpoint inhibitor therapy for patients who have discontinued or completed previous checkpoint inhibitor therapy for the locally advanced/metastatic indication.<br>Please mark below if the patient has received previous checkpoint inhibitor therapy and in which setting:<br>- the patient has never received any immunotherapy for NSCLC. If so, please type 'n/a' in the 'Time gap' box below or<br>- the patient has previously been treated with adjuvant immunotherapy for NSCLC and discontinued immunotherapy without disease progression and at least 6 months prior to the first diagnosis of disease relapse. Please document in the box below the time gap in months between completion of previous adjuvant immunotherapy and first diagnosis of disease relapse or<br>- the patient has previously been treated with neoadjuvant treatment containing immunotherapy for NSCLC and discontinued immunotherapy without disease progression and at least 6 months prior to the first diagnosis of disease relapse. Please document in the box below the time gap in months between completion of previous neoadjuvant immunotherapy and first diagnosis of disease relapse or<br>- the patient has previously been treated with maintenance immunotherapy post chemoradiotherapy for NSCLC and discontinued immunotherapy without disease progression and at least 6 months prior to the first diagnosis of disease relapse. Please document in the box below the time gap in months between completion of previous maintenance immunotherapy and first diagnosis of disease relapse<br>Time gap in months after completion of previous adjuvant or neoadjuvant or maintenance checkpoint inhibitor immunotherapy and first diagnosis of disease relapse:_____<br>Note: the mandatory interval between the last date of administration of any prior adjuvant/neoadjuvant/maintenance immunotherapy and the date of first relapse is **at least 6 months**. For patients suffering a first relapse within 6-12 months of previous immunotherapy, clinicians should bear in mind the long elimination half-lives of immunotherapies and make an individual assessment of the overall benefit/risk ratio of re-treatment with immunotherapy.<br>8. The patient will be treated with a maximum of 4 cycles of pembrolizumab plus pemetrexed- and platinum-based combination chemotherapy with either cisplatin or carboplatin (AUC 5).<br>Please indicate below whether the pemetrexed will be given in combination with:<br>- cisplatin OR<br>- carboplatin (AUC 5)<br>9. On completion of 4 cycles of pembrolizumab plus pemetrexed with carboplatin or cisplatin based chemotherapy, pembrolizumab will be administered as 3-weekly or 6-weekly cycles or pembrolizumab will be administered according to the extended dosing schedule to which the patient has been randomised as per the protocol in the NIHR-approved REFINE-Lung trial (Reference NIHR133011).<br>10. On completion of 4 cycles of pembrolizumab plus pemetrexed-based chemotherapy in combination with cisplatin or carboplatin and in the absence of disease progression, treatment with pembrolizumab will continue for a total treatment duration of 2 years* or until disease progression or unacceptable toxicity or withdrawal of patient consent, whichever occurs first.<br>*2 years treatment is defined as a maximum of 35 x 3-weekly cycles or the equivalent numbers of cycles if either 6-weekly dosing is used or is defined by the extended dosing schedule to which the patient has been randomised as per the protocol in the NIHR-approved REFINE-Lung trial (Reference NIHR133011).<br>11. The patient has a performance status (PS) of 0 or 1 and is fit for pemetrexed- and platinum-based chemotherapy in combination with pembrolizumab.<br>12. The patient has no symptomatically active brain metastases or leptomeningeal metastases.<br>13. Where a treatment break of more than 12 weeks beyond the expected cycle length is needed, a treatment break form will be completed to restart treatment, which MUST be approved, before treatment is re-commenced.<br>14. Pembrolizumab will be otherwise used as set out in its Summary of Product Characteristics. | No | TA683 | 10-Mar-21 | 08-Jun-21 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| PEMB9a | **Pembrolizumab** | Pembrolizumab monotherapy for treating unresectable or advanced malignant melanoma **(form a)**: REGISTRATION OF START OF PEMBROLIZUMAB MONOTHERAPY OR OF PREVIOUSLY COMMENCED AND CURRENTLY CONTINUED PEMBROLIZUMAB MONOTHERAPY<br><br>This form comes in 3 parts.<br>1. The first part is for patients who are either scheduled to commence pembrolizumab monotherapy or who commenced and continue to receive pembrolizumab monotherapy.<br>2. The second part of the form which must use the same unique Blueteq identifier is for those benefitting patients who choose to electively discontinue pembrolizumab after 2 or more years of treatment; this second part (patient details will be automatically entered) will only appear once the first part of the form is approved and should be completed at the time of elective discontinuation of pembrolizumab.<br>3. The third part of the form which must use the same unique Blueteq identifier is for those patients registered as having electively and previously stopped pembrolizumab and in whom there is disease progression for which the clinician wishes to re-commence pembrolizumab; this third part of the form (patient details will be automatically entered) will only appear once the second part of the form has been approved. | 1. This application has been made by and the first cycle of systemic anti -cancer therapy with pembrolizumab will be/was prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br><br>Note: if treatment with pembrolizumab has already commenced, it is vital that the treatment start date has been entered in the box above.<br>2. The patient has a histologically- or cytologically-confirmed diagnosis of malignant melanoma.<br>3. The patient has unresectable or advanced melanoma.<br>4. In respect of his/her treatment for unresectable/advanced disease and at the time of starting pembrolizumab, the patient is/was treatment-naïve to systemic therapy, or<br>• Has/had previously only received BRAF/MEK-targeted therapy, or ipilimumab monotherapy or both BRAF/MEK-targeted treatment and ipilimumab monotherapy.<br>• Has a diagnosis of uveal melanoma, and has received treatment with tebentafusp in the first line setting, and has stopped this therapy due to disease progression, or lack of tolerance<br>5. At the time of commencing pembrolizumab the patient has/had not received prior treatment with any of the following: anti-PD-1, anti-PD-L1, anti-PD-L2 and anti-CD137 treatments unless the patient has received adjuvant immunotherapy with nivolumab or pembrolizumab in which case the patient must have relapsed after the discontinuation of such adjuvant immunotherapy.<br><br>Please tick appropriate box:<br>- No prior immunotherapy with anti-PD-1, anti-PD-L1, anti-PD-L2 or anti-CD137 treatments or<br>- Prior adjuvant immunotherapy with nivolumab or pembrolizumab.<br>6. There is the future opportunity for patients continuing in a stable disease or a response disease state after 2 or more years of planned treatment to choose to discontinue pembrolizumab and then to re-start pembrolizumab on disease progression as the next systemic therapy and should this option be chosen that both the date of discontinuation must be registered on the second part of this form and the application to re-start pembrolizumab be made on the third part of this form.<br>7. The patient has a sufficient performance status (PS) to be fit to receive treatment with immunotherapy.<br>8. Pembrolizumab will be administered as monotherapy unless being administered in the SCIB1-002 study in which case it may be given with SCIB1 (the trial's Investigational Medicinal Product)<br>9. the licensed dose and frequency of pembrolizumab will be used as shown below<br>• 395mg every 3 weeks, or 790mg every 6 weeks if given via **subcutaneous** injection<br>• 200mg every 3 weeks, or 400mg every 6 weeks if given via **intravenous** infusion<br><br>(400mg every 12 weeks may be used if the patient is participating in the REFINE trial (NIHR SPMS 50169))<br>10. When a treatment break of more than 12 weeks beyond the expected 3- or 6-weekly cycle length is needed, I will complete a treatment break approval form requesting a restart of treatment. This must be approved before pembrolizumab is re-commenced. | No | TA366 | 25-Nov-15 | 23-Feb-2016 (Blueteq approval required from 01-Feb-19) |
| PEMB9b | **Pembrolizumab** | Pembrolizumab monotherapy for treating unresectable or advanced malignant melanoma **(form b)**: REGISTRATION OF DISCONTINUATION OF PEMBROLIZUMAB<br><br>This second part of the form which must use the same unique Blueteq identifier is for those patients in stable or response remission who have chosen to electively discontinue pembrolizumab; this second part must be completed at the time of discontinuation of pembrolizumab. The third part of the form which must use the same unique Blueteq identifier is for those patients registered as having electively and previously stopped pembrolizumab and in whom there is disease progression for which the clinician wishes to re-commence pembrolizumab; this third part of the form (patient details will be automatically entered) will only appear once the second part of the form has been approved. | 1. This registration of electively discontinued treatment with pembrolizumab has been made by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient is in a stable disease or a response state in relation to treatment with pembrolizumab for his/her melanoma.<br>Please indicate the nature of the response to pembrolizumab and if in a complete or partial response, please enter the date that this response was achieved:<br>- complete response and date of complete response (dd/mm/yyyy) **or**<br>- partial response and date of partial response (dd/mm/yyyy) **or**<br>- stable disease<br>3. The patient has either received 2 or more years of pembrolizumab (including any doses given with ipilimumab) or the patient was randomised to the 1-year discontinuation arm in the DANTE trial.<br>Please state which of these 2 reasons apply for discontinuation of therapy:<br>- Completed 2 or more years of pembrolizumab **or**<br>- Drew 1-year treatment arm in DANTE trial<br>Please also state the duration of treatment with pembrolizumab (i.e. the time between treatment commencement and discontinuation)<br>4. The patient has chosen this option of discontinuing therapy after an informed consenting process which has fully described the advantages and disadvantages of the options of either continuing on pembrolizumab or electively discontinuing pembrolizumab with the option of re-starting pembrolizumab if the disease progresses but only with pembrolizumab directly as the next systemic therapy following previous discontinuation of pembrolizumab<br><br>***Form C is shown on the next page*** | No | TA366 | 25-Nov-15 | 23-Feb-2016 (Blueteq approval required from 01-Feb-19) |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| PEMB9c | **Pembrolizumab** | Pembrolizumab monotherapy for treating unresectable or advanced malignant melanoma **(form c)**: RE-START OF PEMBROLIZUMAB MONOTHERAPY<br><br>The third part of the form which must use the same unique Blueteq identifier is for those patients registered as having electively and previously stopped pembrolizumab and in whom there is disease progression for which the clinician wishes to re-commence pembrolizumab as the next systemic treatment. | 1. This application to re-start pembrolizumab has been made by and the first cycle of systemic anti -cancer therapy with pembrolizumab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy. | No | TA366 | 25-Nov-15 | 23-Feb-2016 (Blueteq approval required from 01-Feb-19) |
| | | | 2. The patient has progressive non-resectable or metastatic melanoma.<br><br>Please state the duration of time off treatment (i.e. the time between previous pembrolizumab discontinuation and decision to re-start pembrolizumab) | | | | |
| | | | 3. The patient has received no other systemic therapy in the time between the date of elective discontinuation of pembrolizumab and this application to re-start pembrolizumab | | | | |
| | | | 4. The prescribing clinician is fully aware of the management of and the treatment modifications that may be required for immune-related adverse reactions due to anti-PD-L1 treatments including pneumonitis, colitis, nephritis, endocrinopathies and hepatitis. | | | | |
| | | | 5. The present intention is that the patient will be treated with pembrolizumab until there is progressive disease or unacceptable toxicity or if the patient declines further therapy. | | | | |
| | | | 5. The present intention is that the patient will be treated with pembrolizumab until there is progressive disease or unacceptable toxicity or if the patient declines further therapy. | | | | |
| | | | 7. Pembrolizumab will be administered as monotherapy | | | | |
| | | | 8. The licensed dose and frequency of pembrolizumab will be used. *Can use either 3-weekly cycles of pembrolizumab monotherapy 200mg (or if the patient is stable and well, 6-weekly cycles of pembrolizumab monotherapy 400mg) | | | | |
| | | | 9. A formal medical review to assess the tolerability of treatment with pembrolizumab will be scheduled to occur by the start of the 3rd 3-weekly cycle of treatment (or equivalent if having 6 weekly dosing) and thereafter on a regular basis | | | | |
| | | | 10. Treatment breaks of up to 12 weeks beyond the expected cycle length are allowed but solely to allow any toxicities to settle | | | | |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| PEMB10 | **Pembrolizumab** in combination with carboplatin and paclitaxel | For the first line treatment of PD-L1 positive or negative locally advanced or metastatic squamous non-small cell lung cancer where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with the combination of pembrolizumab, carboplatin and paclitaxel will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a histologically- or cytologically confirmed diagnosis of squamous non-small cell lung cancer (NSCLC) which is stage IIIB or IIIC or IV **or** has disease that has recurred after previous potentially curative local management.<br>3. PD-L1 testing with an approved and validated test to determine the Tumour Proportion Score (TPS) has been attempted prior to this application and the result is set out below.<br>Note: for fully informed consent of all the potential 1st line treatment options, PD-L1 testing must still be attempted and recorded here.<br>Please document the actual TPS below (if negative, record '0') or enter 'n/a' if the TPS cannot be documented and the reason why:<br>TPS_____<br>If n/a, please indicate below the reason why the actual TPS cannot be documented:<br>- the TPS result was unquantifiable OR<br>- PD-L1 testing was not possible as the pathologist has documented that there is insufficient tissue for PD-L1 analysis<br>Note: The NICE appraisal committee has made a specific comment in those patients with a TPS of 50-100% about the need for a detailed discussion to take place between oncologist and patient as to the relative merits of pembrolizumab monotherapy versus the combination of pembrolizumab, carboplatin and paclitaxel (see criterion 6). Hence PD-L1 testing and knowledge of the numeric result remain mandatory in all patients accessing this indication.<br>4. The patient's NSCLC had a TPS that could not be documented or has a PD-L1 TPS of 0-49% or has a PD-L1 TPS of 50-100% and requires an urgent clinical response (e.g. impending major airway obstruction) so as to justify the use of the combination of pembrolizumab, carboplatin and paclitaxel rather than pembrolizumab monotherapy and this issue has been fully discussed with the patient.<br>Please mark below which of these two scenarios applies to this patient:<br>- the PD-L1 TPS could not be documented (see criterion 5) or<br>- PD-L1 TPS of 0-49% or<br>- PD-L1 TPS of 50-100% and requires an urgent clinical response (e.g. impending major airway obstruction) to justify the use of the combination of pembrolizumab, carboplatin and paclitaxel rather than pembrolizumab monotherapy and this issue has been fully discussed with the patient<br>5. Either the patient has not received any previous systemic therapy for NSCLC or the patient **completed the last treatment** with chemotherapy or chemoradiotherapy or checkpoint inhibitor immunotherapy as part of adjuvant/neoadjuvant/maintenance therapy at least **6** months prior to the first diagnosis of locally recurrent or metastatic disease.<br>Please indicate below whether the patient has received any previous adjuvant or neoadjuvant or maintenance systemic therapy for NSCLC:<br>- the patient has not been previously treated with any adjuvant or neoadjuvant or maintenance systemic therapy for NSCLC or<br>- the patient has been previously treated with adjuvant systemic therapy for NSCLC and this was completed more than 6 months before first diagnosis of recurrent or metastatic disease or<br>- the patient has been previously treated with neoadjuvant systemic therapy for NSCLC and this was completed more than 6 months before first diagnosis of recurrent or metastatic disease or<br>- the patient has been previously treated with maintenance systemic therapy for NSCLC and this was completed more than 6 months before first diagnosis of recurrent or metastatic disease<br>6. The patient has not received prior treatment with an anti PD-1, anti-PD-L1, anti-PD-L2, anti-CD137 or anti-cytotoxic T-lymphocyte-associated antigen-4 (CTL-4) antibody unless the patient discontinued/completed treatment with checkpoint inhibitor immunotherapy as part of adjuvant/neoadjuvant/maintenance therapy **without disease progression and at least 6 months elapsed between the date of last immunotherapy treatment and the date of the first diagnosis of relapse with recurrent or metastatic disease.**<br>Note: NHS England does not commission any re-treatment with checkpoint inhibitor therapy for patients who have discontinued or completed previous checkpoint inhibitor therapy for the locally advanced/metastatic indication.<br>Please mark below if the patient has received previous checkpoint inhibitor therapy and in which setting:<br>- the patient has never received any immunotherapy for NSCLC. If so, please type 'n/a' in the 'Time Gap' box below or<br>- the patient has previously been treated with adjuvant immunotherapy for NSCLC and discontinued immunotherapy without disease progression and at least 6 months prior to the first diagnosis of relapse with recurrent or metastatic disease. Please document in the box below the time gap in months between completion of previous adjuvant immunotherapy and first diagnosis of disease relapse or<br>- the patient has previously been treated with neoadjuvant treatment containing immunotherapy for NSCLC and discontinued immunotherapy without disease progression and at least 6 months prior to the first diagnosis of relapse with recurrent or metastatic disease. Please document in the box below the time gap in months between completion of previous neoadjuvant immunotherapy and first diagnosis of disease relapse or<br>- the patient has previously been treated with maintenance immunotherapy post chemoradiotherapy for NSCLC and discontinued immunotherapy without disease progression and at least 6 months prior to the first diagnosis of relapse with recurrent or metastatic disease. Please document in the box below the time gap in months between completion of previous maintenance immunotherapy and first diagnosis of disease relapse<br><br>Time gap in months after completion of previous adjuvant or neoadjuvant or maintenance checkpoint inhibitor immunotherapy and first diagnosis of disease relapse:_____<br>Note: the mandatory interval between the last date of administration of any prior adjuvant/neoadjuvant/maintenance immunotherapy and first relapse is **at least 6 months**. For patients suffering a first relapse within 6-12 months of previous immunotherapy, clinicians should bear in mind the long elimination half-lives of immunotherapies and make individual assessments of the overall benefit/risk ratio of re-treatment with immunotherapy.<br>7. The patient is fit for the combination of pembrolizumab, carboplatin and paclitaxel and that a maximum of 4 cycles of chemotherapy will be given.<br><br>Note: the use of the combination of pembrolizumab, carboplatin and nab-paclitaxel in this indication was not submitted to NICE for appraisal by MSD and hence nab-paclitaxel is not commissioned in this indication.<br>8. On completion of the combination phase of pembrolizumab plus carboplatin and paclitaxel, pembrolizumab will be administered as monotherapy as 3-weekly or 6-weekly cycles or pembrolizumab will be administered according to the extended dosing schedule to which the patient has been randomised as per the protocol in the NIHR-approved REFINE-Lung trial (Reference NIHR133011).<br>9. After completion of the combination of pembrolizumab plus carboplatin and paclitaxel and in the absence of disease progression, treatment with pembrolizumab will continue for a total treatment duration of 2 years* or until disease progression or unacceptable toxicity or withdrawal of patient consent, whichever occurs first.<br>*2 years treatment is defined as a maximum of 35 x 3-weekly cycles or the equivalent numbers of cycles if 6-weekly dosing is used or is defined by the extended dosing schedule to which the patient has been randomised as per the protocol in the NIHR-approved REFINE-Lung trial (Reference NIHR133011).<br>10. The patient has an ECOG performance status (PS) of 0 or 1.<br>11. The patient has no symptomatically active brain metastases or leptomeningeal metastases.<br>12. Where a treatment break of more than 12 weeks beyond the expected cycle length is needed, I will complete a treatment break form to restart treatment, which MUST be approved before treatment is restarted.<br>13. Pembrolizumab will be otherwise used as set out in its Summary of Product Characteristics. | No | TA770 | 09-Feb-22 | 10-May-22 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| PEMB12 | **Pembrolizumab** | For previously untreated metastatic or unresectable recurrent PD-L1 positive head and neck squamous cell carcinoma (HNSCC) where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with pembrolizumab monotherapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a documented histological diagnosis of squamous cell carcinoma of the head and neck.<br>3. The patient has either metastatic head and neck cancer or locally advanced/unresectable recurrent head and neck cancer that is not amenable to curative intent with local therapy (surgery and/or radiation therapy with or without chemotherapy).<br>4. PD-L1 testing with an approved and validated test to determine the Combined Positive Score (CPS) has been done prior to this application and the CPS is ≥1% and the result is set out below.<br>Please document the actual CPS below<br>Note: pembrolizumab is not funded in this indication for patients with tumours without a documented ≥1% positive PD-L1 CPS score.<br>5. The patient has an ECOG performance status of 0 or 1 and would otherwise be potentially fit for 1st line combination chemotherapy.<br>6. The patient has not received prior treatment with an anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CD137, or anti-Cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) antibody for this metastatic or unresectable recurrent head and neck squamous cell carcinoma indication.<br>8. Pembrolizumab will be administered as **monotherapy** following the licensed dose schedules shown below<br>• 395mg every 3 weeks, or 790mg every 6 weeks if given via **subcutaneous** injection<br>• 200mg every 3 weeks, or 400mg every 6 weeks if given via **intravenous** infusion<br>8. The patient has no symptomatically active brain metastases or leptomeningeal metastases.<br>9. The patient will receive a maximum treatment duration of 2 years of uninterrupted treatment (or 35 x 3-weekly cycles of pembrolizumab or its equivalent if 6-weekly pembrolizumab monotherapy dosing is used) or on disease progression or unacceptable toxicity, whichever occurs first.<br>10. Where a treatment break of more than 12 weeks beyond the expected 3 or 6-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment, which MUST be approved before treatment with pembrolizumab is recommenced.<br>11. Pembrolizumab will otherwise be used as set out in its Summary of Product Characteristics (SPC) | No | TA661 | 25-Nov-20 | 23-Feb-21 |
| PEMB14_v1.2 | **Pembrolizumab** | For the 1st line treatment of patients with either metastatic or locally advanced and inoperable colorectal cancer exhibiting microsatellite instability-high (MSI-H) or mismatch repair deficiency (dMMR) where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with pembrolizumab monotherapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has either metastatic or locally advanced and inoperable colorectal carcinoma.<br>3. The patient's tumour has a documented presence of microsatellite instability-high (MSI-H) or DNA mismatch repair deficiency (dMMR) confirmed by validated testing.<br>4. Wild type or mutant RAS status has been determined on this patient's tumour and the result is recorded below:<br>- wild type RAS status<br>- mutant RAS status<br>- Test result not yet reported and the decision to proceed without knowing RAS status has been discussed with the patient during consenting process.<br>5. Wild type or mutant BRAF status has been determined on this patient's tumour and the result is recorded below:<br>- wild type BRAF status<br>- mutant BRAF status<br>- Test result not yet reported and the decision to proceed without knowing BRAF status has been discussed with the patient during consenting process.<br>6. The patient has not received previous systemic therapy for **metastatic** colorectal cancer unless this was given with neoadjuvant intent.<br>Please mark below which clinical scenario applies to this patient:<br>- no previous systemic therapy for **metastatic** colorectal cancer and no previous neoadjuvant chemotherapy for metastatic disease<br>- previous systemic therapy for **metastatic** colorectal cancer has been solely with neoadjuvant intent for the metastatic indication<br>Note: patients may of course have previously received neoadjuvant systemic therapy for non-metastatic disease and/or adjuvant chemotherapy after surgery.<br>7. The patient has an ECOG performance status (PS) of 0 or 1.<br>8. The patient has no symptomatic brain or leptomeningeal metastases.<br>9. The patient has not received prior treatment with an anti-PD-1, anti-PD-L2, anti-CD137, or anti-Cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) antibody unless the patient was enrolled in the NEOPRISM-CRC clinical trial (NIHR CPMS ID:52000) and did not have radiologically-assessed evidence of progressive disease at the end of neoadjuvant pembrolizumab therapy.<br>Please mark below which clinical scenario applies to this patient:<br>- the patient has not received any previous anti-PD-1, anti-PD-L2, anti-CD137, or anti-Cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) antibody therapy for metastatic colorectal cancer<br>- the patient was enrolled in the NEOPRISM-CRC clinical trial ((NIHR CPMS ID:52000) and did not have clear evidence of radiologically-assessed progressive disease at the end of neoadjuvant pembrolizumab therapy<br>10. Pembrolizumab will be administered as **monotherapy** following the licenced dosing schedules shown below<br>• 395mg every 3 weeks, or 790mg every 6 weeks if given via **subcutaneous** injection<br>• 200mg every 3 weeks, or 400mg every 6 weeks if given via **intravenous** infusion<br>11. Pembrolizumab will be stopped on disease progression or unacceptable toxicity or withdrawal of patient consent or after a total treatment duration of 2 years (or a maximum of 35 3-weekly cycles or the equivalent number of 6-weekly cycles to result in a total treatment duration of 2 years), whichever of these events occurs first.<br>12. Where a treatment break of more than 12 weeks beyond the expected 3 or 6-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment, which MUST be approved before treatment with pembrolizumab is recommenced.<br>13. Pembrolizumab will be otherwise used as set out in its Summary of Product Characteristics (SPC). | No | TA709 | 23-Jun-21 | 21-Sep-21 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| PEMB15 | **Pembrolizumab** in combination with platinum and fluoropyrimidine-based chemotherapy | For previously untreated advanced oesophageal carcinoma which expresses PD-L1 with a combined positive score of 10 or more where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with pembrolizumab in combination with chemotherapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a histologically- or cytologically-confirmed diagnosis of oesophageal cancer (squamous cell or adenosquamous or adenocarcinoma).<br><br>Please mark below which histology applies to this patient:<br>- squamous cell carcinoma of the oesophagus<br>- adenosquamous cell carcinoma of the oesophagus<br>- adenocarcinoma of the oesophagus<br>3. The patient has locally advanced unresectable or metastatic disease.<br>4. An approved and validated test has demonstrated that the tumour has a PD-L1 expression with a combined positive score (CPS) of 10 or more.<br><br>Please document the actual PD-L1 combined positive score (CPS) below: PD-L1 CPS: _____<br>5. The patient has not received any previous systemic therapy for locally advanced unresectable or metastatic disease i.e. that pembrolizumab plus chemotherapy will be 1st line systemic therapy for locally advanced unresectable or metastatic disease.<br><br>In addition, please mark below whether the patient has/has not previously received any systemic therapy for earlier stage disease:<br>- this patient has not received any previous systemic therapy for oesophageal cancer<br>- this patient was previously treated with neoadjuvant chemotherapy for oesophageal cancer and underwent surgery and has since had disease progression<br>- this patient was previously treated with adjuvant chemotherapy for oesophageal cancer and has since had disease progression<br>- this patient was previously treated with concurrent chemo-radiotherapy for oesophageal cancer with or without surgery and has since had disease progression<br>6. The patient has not received prior treatment with any antibody which targets PD-1 or PD-L1 or PD-L2 or CD137 or OX40 or anti-cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) **unless** the patient discontinued or completed checkpoint inhibitor immunotherapy as part of adjuvant therapy without disease progression and at least 6 months has elapsed between the date of the last immunotherapy treatment and the date of first diagnosis of relapse with recurrent or metastatic disease.<br><br>Please mark the appropriate scenario below for this patient:<br>this patient has not received any previous immunotherapy for squamous cell or adenosquamous carcinoma or adenocarcinoma of the oesophagus<br>this patient was previously treated with neoadjuvant platinum-based chemoradiotherapy for squamous cell or adenosquamous or adenocarcinoma of the oesophagus and underwent surgery followed by adjuvant nivolumab (NICE TA 713) and then discontinued or completed treatment with adjuvant nivolumab without disease progression and this was at least 6 months prior to the first diagnosis of relapse. Please document in the box below the time gap in months between completion of previous adjuvant nivolumab immunotherapy and first diagnosis of disease relapse:<br>_____<br>Note: the mandatory interval between the last date of administration of any prior adjuvant immunotherapy and first relapse is **at least 6 months.** For patients suffering a first relapse within 6-12 months of previous immunotherapy, clinicians should bear in mind the long elimination half-lives of immunotherapies and make individual assessments of the overall benefit/risk ratio of re-treatment with immunotherapy.<br>7. The patient has an ECOG performance status (PS) of 0 or 1 and is fit for platinum and fluoropyrimidine-based chemotherapy in combination with pembrolizumab.<br>8. The patient has no symptomatically active brain metastases or leptomeningeal metastases.<br>9. Pembrolizumab will be administered at one of the licensed doses shown below, initially in combination with platinum and fluoropyrimidine-based chemotherapy and subsequently as monotherapy.<br>• 395mg every 3 weeks, or 790mg every 6 weeks if given via **subcutaneous** injection<br>• 200mg every 3 weeks, or 400mg every 6 weeks if given via **intravenous** infusion<br>10. The chemotherapy used in combination with pembrolizumab will be both platinum and fluoropyrimidine-based.<br><br>Please mark below which chemotherapy regimen is being used in this patient:<br>- oxaliplatin plus capecitabine<br>- oxaliplatin plus modified de Gramont<br>- cisplatin plus capecitabine<br>- cisplatin plus infused 5-fluorouracil<br>- another regimen<br>11. Pembrolizumab will be stopped at whichever of the following events occurs first: disease progression or unacceptable toxicity or withdrawal of patient consent or after 2 years of treatment (or after 35 x 3-weekly cycles or its equivalent if 6-weekly dosing is used).<br><br>Note: the 2 year stopping rule for pembrolizumab in this indication was a key part of the company submission to NICE of the clinical and cost effectiveness of pembrolizumab in this indication.<br><br>Note: once pembrolizumab is stopped after 2 years of treatment, it cannot be re-started.<br>12. When a treatment break of more than 3 months beyond the expected 3- or 6-weekly cycle length is needed, I will complete a treatment break approval form which MUST be approved before treatment is recommenced.<br>13. Pembrolizumab will otherwise be used as set out in its Summary of Product Characteristics (SPC) with the exception of criterion 12. | No | TA737 | 20-Oct-21 | 18-Jan-22 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| PEMB16 | **Pembrolizumab** | For relapsed/refractory classical Hodgkin lymphoma in patients aged 3 years and older who have been treated with stem cell transplantation but never previously received brentuximab vedotin where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with pembrolizumab monotherapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The prescribing clinician is fully aware of the management of and the treatment modifications that may be required for immune-related adverse reactions due to anti-PD-1 or anti-PD-L1 treatments including pneumonitis, colitis, nephritis, endocrinopathies, hepatitis and skin toxicity.<br>3. The patient has a histologically confirmed diagnosis of classical Hodgkin lymphoma.<br>4. The patient is aged 3 years and older.<br>5. The patient has relapsed or refractory Hodgkin lymphoma following stem cell transplantation.<br>Please mark below whether the patient had autologous and/or allogeneic stem cell transplantation:<br>- autologous transplantation only<br>- allogeneic transplantation only<br>- both autologous and allogeneic transplantation<br>6. The patient has never previously been treated with brentuximab vedotin.<br>7. The patient has not received prior treatment with any antibody which targets PD-1 or PD-L1 or PD-L2 or CD137 or OX40 or anti-cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4).<br>8. The patient has an ECOG performance status (PS) of 0 or 1 and is fit for treatment with pembrolizumab.<br>9. Pembrolizumab will be administered as monotherapy:<br>•For adult patients (aged 18 years and older), at a dose of either 200mg 3-weekly or 400mg 6-weekly.<br>•For paediatric patients (aged between 3 and 17 years), pembrolizumab will commence at a dose of 2mg/kg bodyweight up to a maximum of 200mg 3-weekly.<br>10. Pembrolizumab will be stopped at whichever of the following events occurs first: disease progression or unacceptable toxicity or withdrawal of patient consent or after 2 years of treatment (or after 35 x 3-weekly cycles or its equivalent if 6-weekly dosing is used).<br>Note: the 2 year stopping rule for pembrolizumab in this indication was a key part of the company submission to NICE of the clinical and cost effectiveness of pembrolizumab in this indication.<br>Note: once pembrolizumab is stopped after 2 years of treatment, it cannot be re-started.<br>11. A formal medical review as to how pembrolizumab monotherapy is being tolerated and whether pembrolizumab should continue or not will be scheduled to occur at least by the end of the second 3-weekly cycle of treatment.<br>12. When a treatment break of more than 12 weeks beyond the expected 3- or 6-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment.<br>13. Pembrolizumab will otherwise be used as set out in its Summary of Product Characteristics (SPC) with the exception of criterion 10. | No | TA772 | 23-Feb-22 | 24-May-22 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| PEMB17 | **Pembrolizumab** | Pembrolizumab monotherapy for relapsed/refractory classical Hodgkin lymphoma in patients aged 3 years and older who have NOT been previously treated with stem cell transplantation or brentuximab vedotin | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with pembrolizumab monotherapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. Tthe prescribing clinician is fully aware of the management of and the treatment modifications that may be required for immune-related adverse reactions due to anti-PD-1 or anti-PD-L1 treatments including pneumonitis, colitis, nephritis, endocrinopathies, hepatitis and skin toxicity.<br>3. The patient has a histologically confirmed diagnosis of classical Hodgkin lymphoma.<br>4. The patient is aged 3 years and older.<br>Please mark below whether the patient is aged 3-17 years or 18 years and older:<br>- the patient is aged between 3 and 17 years or<br>- the patient is aged 18 years and older<br>5. The patient has relapsed or refractory Hodgkin lymphoma following 2 prior lines of cytotoxic chemotherapy.<br>6. The patient has never previously been treated with brentuximab vedotin.<br>7. The patient has not been previously treated with stem cell transplantation of any kind.<br>8. The patient is currently ineligible for stem cell transplantation.<br>9. The patient is EITHER a candidate for future stem cell transplantation if there is sufficient benefit of treatment with pembrolizumab OR is not a candidate for stem cell transplantation however good the response to pembrolizumab may be.<br>Please mark below the patient status as regards future autologous/allogeneic stem cell transplantation:<br>- the patient is a candidate for future stem cell transplantation if there is sufficient benefit of treatment with pembrolizumab<br>- the patient is not a candidate for stem cell transplantation however good the response to treatment with pembrolizumab may be<br>10. The patient has not received prior treatment with any antibody which targets PD-1 or PD-L1 or PD-L2 or CD137 or OX40 or anti-cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4).<br>11. The patient has an ECOG performance status (PS) of 0 or 1 and is fit for treatment with pembrolizumab.<br>12. Pembrolizumab will be administered as monotherapy:<br>•For adult patients (aged 18 years and older), at a dose of either 200mg 3-weekly or 400mg 6-weekly.<br>•For paediatric patients (aged between 3 and 17 years), pembrolizumab will commence at a dose of 2mg/kg bodyweight up to a maximum of 200mg 3-weekly.<br>13. Pembrolizumab will be stopped at whichever of the following events occurs first: stem cell transplantation or disease progression or unacceptable toxicity or withdrawal of patient consent or after 2 years of treatment (or after 35 x 3-weekly cycles or its equivalent if 6-weekly dosing is used).<br>Note: the 2 year stopping rule for pembrolizumab in this indication was a key part of the company submission to NICE of the clinical and cost effectiveness of pembrolizumab in this indication.<br>Note: once pembrolizumab is stopped for any of the above reasons, it cannot be re-started.<br>14. A formal medical review as to how pembrolizumab monotherapy is being tolerated and whether pembrolizumab should continue or not will be scheduled to occur at least by the end of the second 3-weekly cycle of treatment.<br>15. When a treatment break of more than 12 weeks beyond the expected 3- or 6-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment.<br>16. Pembrolizumab will otherwise be used as set out in its Summary of Product Characteristics (SPC) with the exception of criterion 13. | No | TA772 | 23-Feb-22 | 24-May-22 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| PEMB18_v1.2 | **Pembrolizumab** in combination with paclitaxel or nab-paclitaxel | The treatment of previously untreated locally advanced unresectable or metastatic triple negative breast cancer in patients with PD-L1 expression test results of immune cell (IC) <1% and a combined positive score (CPS) of 10 or more where the following criteria have been met: | 1. An application has been made by and the first cycle of systemic anti-cancer therapy with pembrolizumab in combination with paclitaxel or nab-paclitaxel will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The prescribing clinician is fully aware of the management of and the treatment modifications that may be required for immune-related adverse reactions due to anti-PD-L1 treatments including pneumonitis, colitis, nephritis, endocrinopathies, hepatitis and skin toxicity.<br>3. The patient has a histologically- or cytologically-confirmed diagnosis of breast cancer.<br>4. The patient has either locally advanced unresectable or metastatic breast cancer.<br>5. The patient's breast cancer has had receptor analysis performed and this is negative for **all** of the following: the HER2 receptor, oestrogen receptor and progesterone receptor i.e. the patient has **triple negative disease**.<br>6. The patient's tumour has been tested by an approved and validated test for PD-L1 expression as measured by the **immune cell (IC) test** and the result is **<1%**.<br>Note: if the PD-L1 immune cell (IC) result is 1% or more, the patient must not be treated with pembrolizumab and should be treated with atezolizumab.<br>7. The patient's tumour has been tested by an approved and validated test for PD-L1 expression as measured by the combined positive score (CPS) test and the result is 10 or more.<br>Please document the actual PD-L1 expression below with the CPS result:<br>PD-L1 expression with the CPS test: _____<br><br>Note two separate tests for PD-L1 expression are required as the manufacturer of pembrolizumab, MSD, only sought a recommendation from NICE for patients who were ineligible for atezolizumab and had a PD-L1 expression test result as measured by the combined positive score (CPS) test of 10 or more.<br>8. The patient has had no prior systemic therapy for the locally advanced unresectable or metastatic disease indication.<br>9. **Either** the patient has never had any prior treatment with anti-PD-L1/PD-1 therapy for the breast cancer or the only previous anti-PD-1/PD-L1 treatment that the patient has received was with prior neoadjuvant and adjuvant therapy **and** there was no disease progression during such treatment and for at least 12 months after completion of anti-PD-1/PD-L1 therapy.<br><br>Please mark below which of these clinical scenarios applies to this patient:<br>- the patient has never had any prior treatment with anti-PD-1/PD-L1 therapy for the breast cancer or<br>- the only previous anti-PD-1/PD-L1 treatment that the patient has received was prior neoadjuvant and adjuvant therapy **and** there was no disease progression during such treatment and for at least 12 months after completion of anti-PD-1/PD-L1 therapy<br><br>Please document in the box below the time gap in months between completion of the previous neoadjuvant and adjuvant anti-PD-1/PD-L1immunotherapy and the first diagnosis of disease relapse. If the patient has never had such immunotherapy, please type 'n/a'.<br>Time gap in months after the completion of previous neoadjuvant and adjuvant anti-PD-1/PD-L1 immunotherapy and the first diagnosis of disease relapse: _____<br>10. The patient will be treated with a fixed dose pembrolizumab of either 200mg every 3 weeks or 400mg every 6 weeks.<br>Note: Pembrolizumab may be continued as a single agent if paclitaxel/nab-paclitaxel has to be discontinued due to toxicity.<br>11. Treatment with pembrolizumab will be stopped at whichever of the following events occurs first: disease progression or unacceptable toxicity or withdrawal of patient consent **or after 2 years of treatment** (or after 35 x 3-weekly cycles or its equivalent if 6-weekly pembrolizumab is used).<br>12. The patient will be treated with either paclitaxel at an initial dose of 90mg/$m^2$ on days 1, 8 and 15 of a 28 day treatment cycle or nab-paclitaxel at an initial dose of 100mg/$m^2$ on days 1, 8 and 15 of a 28 day treatment cycle, both of these chemotherapies having no maximum number of cycles as long as there is no disease progression, unacceptable toxicity or withdrawal of patient consent.<br>Note: this dose and schedule of nab-paclitaxel is not currently the licensed dose and schedule in metastatic breast cancer.<br>Note: pembrolizumab is only recommended by NICE in combination with paclitaxel or nab-paclitaxel. The use of pembrolizumab in combination with carboplatin and gemcitabine (which was an option in the registration trial) is not funded as the company did not make a case to NICE for the clinical and cost effectiveness for pembrolizumab in combination with carboplatin and gemcitabine.<br>13. The patient has an ECOG performance status (PS) of 0 or 1.<br>14. The patient has no symptomatically active brain metastases or leptomeningeal metastases.<br>15. A formal medical review as to how pembrolizumab and paclitaxel/nab-paclitaxel are being tolerated and whether treatment with the combination of pembrolizumab and paclitaxel/nab-paclitaxel should continue or not will be scheduled to occur at least by the end of the first 8 weeks of treatment.<br>16. When a treatment break of more than 12 weeks beyond the expected 3 or 6 weekly cycle length is needed, a treatment break approval form will be completed to restart treatment.<br>17. Pembrolizumab and paclitaxel/nab-paclitaxel will be otherwise used as set out in their respective Summary of Product Characteristics (SPCs). | No | TA801 | 29-Jun-22 | 27-Sep-22 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| PEMB19_v1.1 | **Pembrolizumab** | Pembrolizumab monotherapy for adjuvant treatment after complete tumour resection of renal cell carcinoma in adult patients at increased risk of recurrence following nephrectomy or following nephrectomy and resection of all metastatic disease where the following criteria have been met: | 1. An application has been made by and the first cycle of systemic anti-cancer therapy with adjuvant pembrolizumab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy. | No | TA830 | 19-Oct-22 | 17-Jan-23 |
| | | | 2. The patient has a histologically documented diagnosis of renal cell carcinoma (RCC).<br>Please indicate below which RCC histology applies to this patient:<br>- RCC with a clear cell component or<br>- Papillary RCC or<br>- Chromophobe RCC or<br>- Collecting duct RCC (Bellini collecting duct RCC) or<br>- Medullary RCC<br>- Mucinous tubular and spindle cell RCC or<br>- Multilocular cystic RCC or<br>- XP11 translocation RCC or<br>- Unclassified RCC | | | | |
| | | | 3. At the time of first presentation with RCC, the patient had either loco-regional disease only or had both loco-regional and distant metastatic (M1) disease.<br>Please mark below which pattern of disease at the time of first presentation with RCC applies to this patient:<br>- loco-regional disease only (M0 disease) or<br>- loco-regional disease and M1 disease | | | | |
| | | | 4. The patient has undergone a partial nephro-protective or radical nephrectomy and complete resection of all known metastatic disease if present with **all** surgical excision margins being negative i.e. a R0 resection(s) has/have taken place.<br>Please indicate the type of surgery undergone:<br>- nephrectomy (partial or radical) for M0 disease or<br>- nephrectomy (partial or radical) **and** metastasectomy/ metastasectomies in which case the M1 disease must have been completely resected at the time of nephrectomy or within 1 year of nephrectomy | | | | |
| | | | 5. The patient has an increased risk of recurrence of RCC after surgery as defined in the 3 categories of 'intermediate-high' risk, 'high' risk and 'M1 with no evidence of disease' as used in the Keynote-564 clinical trial and in pembrolizumab's marketing authorisation.<br>Please mark below which stage applies to this patient:<br>- pT2 N0 M0 disease with either Fuhrman grade 4 or sarcomatoid histology (intermediate-high risk) or<br>- pT3 N0 M0 with any histological grade (intermediate-high risk) or<br>- pT4 N0 M0 with any histological grade (high risk) or<br>- any pT N1 M0 with any histological grade (high risk) or<br>- any pT any N M1 with no evidence of disease after complete resection of both loco-regional disease and all metastatic lesion(s) | | | | |
| | | | 6. The patient has been radiologically re-staged after completion of surgery and has no evidence of residual or metastatic disease. | | | | |
| | | | 7. No more than 12 weeks have elapsed since the date of nephrectomy or metastasectomy. | | | | |
| | | | 8. The patient has not received prior treatment with an anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CD137, or anti-Cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) antibody or with any other systemic therapy for RCC. | | | | |
| | | | 9. The patient has an ECOG performance status (PS) of 0 or 1. | | | | |
| | | | 10. Pembrolizumab will be stopped at whichever of the following events occurs first: disease progression or unacceptable toxicity or withdrawal of patient consent **or on completion of 1 year in total duration of treatment with pembrolizumab** (i.e. after a maximum of 17 x 3-weekly cycles or 9 x 6-weekly cycles of pembrolizumab). | | | | |
| | | | 11. When a treatment break of more than 12 weeks beyond the expected 3 or 6 weekly cycle length is needed, a treatment break approval form will be completed, which MUST be approved before treatment with pembrolizumab is recommenced. | | | | |
| | | | 12. Pembrolizumab will be otherwise used as set out in its Summary of Product Characteristics (SPC). | | | | |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| PEMB20_v1.0 | **Pembrolizumab** | Pembrolizumab for the adjuvant treatment of newly diagnosed and completely resected stage IIB or stage IIC malignant melanoma where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with adjuvant pembrolizumab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. This patient has a documented histological diagnosis of malignant melanoma.<br>Please indicate whether the melanoma is BRAF V600 mutation positive or not:<br>- BRAF V600 mutation positive or<br>- BRAFV600 mutation negative<br>3. The patient has melanoma which has been staged as stage IIB or stage IIC disease according to the AJCC 8th edition.<br>Please state which stage disease the patient has:<br>- Stage IIB disease or<br>- Stage IIC disease<br>4. Complete resection has taken place for stage II disease.<br>5. The patient is treatment naïve to any systemic therapy for malignant melanoma and in particular has not previously received any immunotherapy with any check point inhibitors or BRAF V600 inhibitors or MEK inhibitors.<br>Note: NHS England does not commission any adjuvant immunotherapy with checkpoint inhibitors for stage III disease in patients who have previously received adjuvant immunotherapy for stage IIB or IIC disease.<br>6. The prescribing clinician has discussed with the patient the benefits and toxicities of adjuvant pembrolizumab in stage IIB/IIC disease and has used the expected median figures below for melanoma-specific survival in relation to the risk of disease relapse if a routine surveillance policy is followed:<br>- for stage IIB disease, the 5 and 10 year figures for melanoma-specific survival probabilities with routine surveillance are 87% and 82%, respectively<br>- for stage IIC disease, the 5 and 10 year figures are 82% and 75%, respectively<br>7. The patient has an ECOG performance status of either 0 or 1.<br>8. Adjuvant pembrolizumab will commence no more than 3 months after the date of surgery which documented the complete resection of stage II melanoma.<br>9. Treatment with pembrolizumab monotherapy will be continued for a maximum of 12 months from the start of treatment (or a maximum of 9 cycles if given 6-weekly) in the absence of disease recurrence, unacceptable toxicity or withdrawal of patient consent.<br>10. When a treatment break of more than 12 weeks beyond the expected 3-weekly, or 6-weekly cycle length is needed, I will complete a treatment break approval form which MUST be approved before treatment with pembrolizumab is recommenced.<br>11. Pembrolizumab will be otherwise used as set out in its Summary of Product Characteristics (SPC). | No | TA837 | 26-Oct-22 | 24-Jan-23 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| PEMB21 | **Pembrolizumab** | Pembrolizumab in combination with chemotherapy as neoadjuvant treatment and then continued as adjuvant monotherapy after definitive surgery for patients with previously untreated locally advanced or early stage triple negative breast cancer at high risk of recurrence where the following criteria have been met: | 1. This application is being made by and the first cycle of neoadjuvant systemic anti-cancer therapy with pembrolizumab in combination with carboplatin and paclitaxel will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a histologically- or cytologically-confirmed diagnosis of breast cancer.<br>3. The patient's breast cancer has had receptor analysis performed and this is negative for all the following: the HER2 receptor, oestrogen receptor and progesterone receptor i.e. the patient has **triple negative disease**.<br>4. The patient has newly diagnosed and previously untreated breast cancer.<br>5. There is no clinical/radiological evidence to suggest that the patient has metastatic disease ie **the patient has M0 disease**.<br>6. The patient is defined as being at high risk of recurrence as defined by having T1c N1-2 or T2-4 N0-2 disease.<br>Please indicate below the staging of the breast cancer in this patient:<br>- T1c N1-2 disease or<br>- T2 N0 disease or<br>- T2 N1-2 disease or<br>- T3 N0 disease or<br>- T3 N1-2 disease or<br>- T4 N0 disease or<br>- T4 N1-2 disease<br>7. The intent of the neoadjuvant part of therapy is to treat this patient with the sequential combinations of both carboplatin plus paclitaxel and then an anthracycline plus cyclophosphamide in combination with pembrolizumab.<br>8. The patient will commence the first phase of neoadjuvant treatment with pembrolizumab in combination with carboplatin (AUC 5 mg/ml/min if given 3-weekly) and paclitaxel and the intent is to give 4 cycles of chemotherapy with this pembrolizumab, carboplatin and paclitaxel regimen (i.e. a planned 12 weeks of treatment).<br>9. After completing the first phase of neoadjuvant chemotherapy, the intent in the second phase of neoadjuvant treatment is to treat with pembrolizumab in combination with an anthracycline and cyclophosphamide for 4 cycles (i.e. a planned 12 weeks of treatment).<br>10. During the neoadjuvant phases of treatment the patient will be treated with a fixed dose of pembrolizumab of either:<br>• 395mg every 3 weeks, or 790mg every 6 weeks if given via **subcutaneous** injection<br>• 200mg every 3 weeks, or 400mg every 6 weeks if given via **intravenous** infusion Such that the patient will receive a maximum of 4 cycles of 6-weekly pembrolizumab or 8 cycles of its 3-weekly equivalent ie there is a maximum of a 24 week pembrolizumab treatment duration in the neoadjuvant phases of treatment.<br>11. If the patient has progressive disease despite neoadjuvant treatment and/or does not have definitive surgery then the patient will **NOT** proceed to adjuvant pembrolizumab therapy.<br>12. If the patient proceeds to adjuvant pembrolizumab after definitive surgery the intent is to commence adjuvant pembrolizumab within 2 months of that surgery.<br>13. During the adjuvant phase of treatment the patient will be treated with a fixed dose of pembrolizumab monotherapy of either<br>• 395mg every 3 weeks, or 790mg every 6 weeks if given via **subcutaneous** injection<br>• 200mg every 3 weeks, or 400mg every 6 weeks if given via **intravenous** infusion<br>Such that the patient will receive a maximum of 5 cycles of 6-weekly pembrolizumab or 9 cycles of 3-weekly pembrolizumab.<br>14. Treatment with pembrolizumab will be stopped at whichever of the following events occurs first: disease progression during neoadjuvant chemotherapy such that all neoadjuvant chemotherapy is discontinued or disease progression at the end of neoadjuvant chemotherapy or unacceptable toxicity or withdrawal of patient consent **or after a maximum total of 9 x 6-weekly cycles of pembrolizumab treatment in both neoadjuvant and adjuvant phases of treatment** (or after a maximum total of 17 x 3-weekly cycles).<br>15. The patient has not received prior treatment with an anti-PD-1, anti-PD-L2, anti-CD137, or anti-Cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) antibody for this neoadjuvant/adjuvant breast cancer indication.<br>16. The patient has an ECOG performance status (PS) of 0 or 1.<br>17. When a treatment break of more than 12 weeks beyond the expected 3 or 6 weekly cycle length is needed, a treatment break approval form will be completed, which MUST be approved before treatment is recommenced.<br>18. Pembrolizumab and the neoadjuvant cytotoxic chemotherapies will be otherwise used as set out in their respective Summary of Product Characteristics (SPCs). | No | TA851 | 14-Dec-22 | 14-Mar-23 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| PEMB22 | **Pembrolizumab** in combination with chemotherapy with or without bevacizumab | For the treatment of persistent, recurrent or metastatic cervical cancer in patients whose tumour PD-L1 expression test results have a combined positive score (CPS) of 1 or more where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with pembrolizumab in combination with chemotherapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a histologically- or cytologically confirmed diagnosis of cervical carcinoma.<br>Please mark below which histology applies to this patient:<br>- squamous carcinoma<br>- adeno-squamous carcinoma<br>- adenocarcinoma<br>3. The patient's tumour has been tested by an approved and validated test for PD-L1 expression as measured by the combined positive score (CPS) test and the result is 1 or more.<br>Please document the actual CPS test result for PD-L1 expression below:<br>PD-L1 expression with the CPS test: _____<br>Note: patients with tumours with a CPS test result of <1 or who have not had a CPS test are not eligible for treatment with pembrolizumab.<br>4. The current disease status as to whether the patient has persistent locoregional disease with or without distant metastases or recurrent locoregional disease with or without distant metastases or has presented with distant metastatic spread.<br>Please mark below which scenario applies to this patient:<br>- persistent locoregional disease without distant metastatic spread<br>- persistent locoregional disease with distant metastatic spread<br>- recurrent locoregional disease without distant metastatic spread<br>- recurrent locoregional disease with distant metastatic spread<br>- first presentation with distant metastatic spread<br>5. The patient's disease is currently not amenable to curative treatment (such as with surgery or radiotherapy or chemoradiotherapy).<br>6. The type of treatment previously received by this patient for the cervical cancer:<br>Please mark below the type of treatment received by this patient:<br>- chemoradiotherapy and surgery<br>- radiotherapy and surgery<br>- chemoradiotherapy only<br>- neoadjuvant chemotherapy followed by chemoradiotherapy<br>- radiotherapy only<br>- surgery only<br>- none<br>7. I confirm that the patient has either not been previously treated with any systemic chemotherapy or has only received chemotherapy whether specifically used as a radio-sensitising agent or received neoadjuvant chemotherapy prior to chemoradiotherapy.<br>8. The cytotoxic chemotherapy partner with the pembrolizumab is a combination chemotherapy with either paclitaxel plus cisplatin or paclitaxel plus carboplatin (AUC 5mg/mL/min).<br>Note: a maximum of 6 cycles of cytotoxic chemotherapy is to be administered.<br>9. Whether or not bevacizumab is also to be given in combination with chemotherapy and pembrolizumab:<br>Please mark below whether bevacizumab is also to be given:<br>- yes, bevacizumab is also being given<br>- no, bevacizumab is not being administered<br>Note: bevacizumab can be continued in combination with pembrolizumab beyond completion of chemotherapy if the patient is benefiting from treatment.<br>Note: if after completing the course of pembrolizumab (see criterion 13) and the patient is still benefitting from treatment, the patient and the clinician have the option to continue with the bevacizumab as monotherapy until disease progression.<br>Note: if bevacizumab is to be given with pembrolizumab and chemotherapy, there is no need to complete a separate blueteq form for the use of bevacizumab in cervical cancer.<br>10. The patient has not received any prior antibody treatment which targets PD-1 or PD-L1 or PD-L2 or CD137 or OX40 or anti-cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) for this cervical cancer indication.<br>11. The patient will be treated with a fixed dose of pembrolizumab following the licenced dosing schedules as shown below<br>• 395mg every 3 weeks, or 790mg every 6 weeks if given via **subcutaneous** injection<br>• 200mg every 3 weeks, or 400mg every 6 weeks if given via **intravenous** infusion<br>12. Treatment with pembrolizumab will be stopped at whichever of the following events occurs first: disease progression or unacceptable toxicity or withdrawal of patient consent or **after 2 years of treatment (or after 35 x 3-weekly cycles or its equivalent if 6-weekly pembrolizumab is used).**<br>13. The patient has an ECOG performance status (PS) of 0 or 1.<br>14. The patient has no symptomatically active brain metastases or leptomeningeal metastases.<br>15. Where a treatment break of more than 12 weeks beyond the expected 3 or 6 weekly cycle length is needed, a treatment break approval form will be completed, which MUST be approved before treatment with pembrolizumab is recommenced.<br>16. Pembrolizumab will be otherwise used as set out in its Summary of Product Characteristics (SPC). | No | TA939 | 13-Dec-23 | 12-Mar-24 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| PEMB23 | **Pembrolizumab** in combination with lenvatinib | For the treatment of patients with endometrial carcinoma who have progressive disease during or following prior platinum-containing therapy given in any setting for advanced or recurrent or metastatic disease and who are not candidates for potentially curative surgery or radiotherapy or chemoradiotherapy where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with pembrolizumab in combination with lenvatinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a histologically- or cytologically confirmed diagnosis of endometrial carcinoma.<br>Note: patients with endometrial sarcoma of any kind or with carcinosarcoma (Mixed Mullerian tumour) are NOT eligible for pembrolizumab plus lenvatinib.<br>3. The mismatch repair status of the endometrial carcinoma if known at present:<br>- mismatch repair deficient<br>- mismatch repair proficient<br>- mismatch repair status not known at present<br>4. The patient has advanced or recurrent or metastatic endometrial carcinoma and is not a candidate for any potentially curative treatment with surgery or radiotherapy or chemoradiotherapy.<br>5. The patient has received at least 1 prior platinum-containing chemotherapy given in any setting whether this was as neoadjuvant chemotherapy or as adjuvant therapy or as chemoradiotherapy or for recurrent disease or for metastatic disease or for more than one of these settings.<br>6. The patient has progressive disease during or following the most recent platinum-containing chemotherapy.<br>7. Pembrolizumab will be given in combination with lenvatinib.<br>Note: neither pembrolizumab nor lenvatinib are to be used with any other systemic anti-cancer treatments in this indication.<br>8. The patient has not received any prior vascular endothelial receptor-targeted agent for this endometrial carcinoma diagnosis.<br>9. The patient has not received any prior antibody treatment which targets PD-1 or PD-L1 or PD-L2 or CD137 or OX40 or anti-cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) for this endometrial carcinoma diagnosis.<br>10. Lenvatinib will be stopped at whichever of the following events occurs first: disease progression or loss of clinical benefit or unacceptable toxicity or withdrawal of patient consent.<br>Note: lenvatinib can be continued in responding patients after pembrolizumab has been discontinued (see criterion 12).<br>11. The patient will be treated with a fixed dose of pembrolizumab as shown below<br>• 395mg every 3 weeks, or 790mg every 6 weeks if given via **subcutaneous** injection<br>• 200mg every 3 weeks, or 400mg every 6 weeks if given via **intravenous** infusion<br>12. Treatment with pembrolizumab will be stopped at whichever of the following events occurs first: disease progression or loss of clinical benefit or unacceptable toxicity or withdrawal of patient consent or after 2 years of treatment (or after 35 x 3-weekly cycles or its equivalent if 6-weekly pembrolizumab is used).<br>Note: provided that the above maximum treatment duration of pembrolizumab has not been and will not be exceeded, pembrolizumab can be continued in responding patients if treatment with lenvatinib has to be stopped.<br>13. The patient has an ECOG performance status (PS) of 0 or 1.<br>14. The patient has no symptomatically active brain metastases or leptomeningeal metastases.<br>15. When a treatment break of more than 12 weeks beyond the expected 3 or 6 weekly cycle length is needed, a treatment break approval form will be completed which MUST be approved before treatment is restarted.<br>16. Pembrolizumab and lenvatinib will be otherwise used as set out in their respective Summary of Product Characteristics (SPCs). | No | TA904 | 21-Jun-23 | 19-Sep-23 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| PEMB24 | **Pembrolizumab monotherapy** | For the subsequent treatment of patients with previously treated unresectable or metastatic **COLORECTAL** cancer exhibiting microsatellite instability-high (MSI-H) or mismatch repair deficiency (dMMR) where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with pembrolizumab monotherapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The prescribing clinician is fully aware of the management of and the treatment modifications that may be required for immune-related adverse reactions due to anti-PD-L1 treatments including pneumonitis, colitis, nephritis, endocrinopathies, hepatitis and skin toxicity.<br>3. The patient has unresectable or metastatic colorectal carcinoma.<br>4. The patient's tumour has a documented presence of microsatellite instability-high (MSI-H) or DNA mismatch repair deficiency (dMMR) confirmed by validated testing.<br>5. Wild type or mutant RAS status has been determined on this patient's tumour and the result is recorded below:<br>- wild type RAS status<br>- mutant RAS status<br>6. Wild type or mutant BRAF status has been determined on this patient's tumour and the result is recorded below:<br>- wild type BRAF status<br>- mutant BRAF status<br>7. The patient has received previous fluoropyrimidine-based combination therapy for unresectable or metastatic colorectal cancer unless the fluoropyrimidine part of the chemotherapy was contraindicated on account of documented DPD deficiency.<br>Please mark below which clinical scenario applies to this patient:<br>- previous combination therapy for unresectable or metastatic colorectal cancer with fluoropyrimidine-based combination chemotherapy (with oxaliplatin or irinotecan or both)<br>- previous combination therapy for unresectable or metastatic colorectal cancer (with oxaliplatin and irinotecan or both) but not with fluoropyrimidine-based combination chemotherapy on account of documented DPD deficiency contraindicating the use of fluoropyrimidine-based chemotherapy<br>8. The patient has progressive disease during or following the most recent chemotherapy.<br>9. The patient has an ECOG performance status (PS) of 0 or 1.<br>Note: NHS England does not fund this treatment in patients of ECOG PS 2.<br>10. The patient is unsuitable for treatment with the combination of nivolumab plus ipilimumab.<br>Note: the NICE guidance restricts the use of pembrolizumab in this indication to those patients for whom treatment with the combination of nivolumab plus ipilimumab is unsuitable.<br>11. The patient has no symptomatic brain or leptomeningeal metastases.<br>12. The patient has **NOT received prior treatment with an anti-PD-1, anti-PD-L2, anti-CD137, or anti-Cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) antibody** unless the patient was enrolled in the NEOPRISM-CRC clinical trial (NIHR CPMS ID:52000) and did not have radiologically-assessed evidence of progressive disease at the end of neoadjuvant pembrolizumab therapy.<br>Please mark below which clinical scenario applies to this patient:<br>- the patient has not received any previous anti-PD-1, anti-PD-L2, anti-CD137, or anti-cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) antibody therapy for metastatic colorectal cancer<br>- the patient was enrolled in the NEOPRISM-CRC clinical trial (NIHR CPMS ID:52000) and did not have clear evidence of radiologically-assessed progressive disease at the end of neoadjuvant pembrolizumab therapy<br>13. Pembrolizumab will be administered as monotherapy at a dose of 200mg every 3 weeks or a dose of 400mg every 6 weeks.<br>Note: NHS England recommends the use of 6-weekly pembrolizumab whenever appropriate.<br>14. Pembrolizumab will be stopped at whichever of the following events occurs first: progressive disease or loss of clinical benefit or unacceptable toxicity or withdrawal of patient consent or after a total treatment duration of 2 years (or a maximum of 35 3-weekly cycles or the equivalent number of 6-weekly cycles to result in a total treatment duration of 2 years).<br>15. A formal medical review as to whether treatment with pembrolizumab should continue will occur at least by the end of the 2nd month of treatment.<br>16. When a treatment break of more than 12 weeks beyond the expected 3 or 6-weekly cycle length is needed, a treatment break approval form will be completed to restart treatment.<br>17. Pembrolizumab will be otherwise used as set out in its Summary of Product Characteristics (SPC). | No | TA914 | 20-Sep-23 | 19-Dec-23 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| PEMB25 | **Pembrolizumab monotherapy** | For the treatment of patients with **ENDOMETRIAL** carcinoma exhibiting microsatellite instability (MSI-H) or deficient mismatch repair (dMMR) and who have progressive disease during or following prior platinum-containing therapy given in any setting for advanced or recurrent or metastatic disease and who are not candidates for potentially curative surgery or radiotherapy or chemoradiotherapy where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with pembrolizumab monotherapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy. | No | TA914 | 20-Sep-23 | 19-Dec-23 |
| | | | 2. The prescribing clinician is fully aware of the management of and the treatment modifications that may be required for immune-related adverse reactions due to anti-PD-L1 treatments including pneumonitis, colitis, nephritis, endocrinopathies, hepatitis and skin toxicity. | | | | |
| | | | 3. The patient has a histologically- or cytologically confirmed diagnosis of endometrial carcinoma.<br>Note: patients with endometrial sarcoma of any kind or with carcinosarcoma (Mixed Mullerian tumour) are NOT eligible for pembrolizumab monotherapy. | | | | |
| | | | 4. The patient's endometrial carcinoma has documented presence of microsatellite instability (MSI-H) or deficient mismatch repair (dMMR) confirmed by validated testing. | | | | |
| | | | 5. The patient has advanced or recurrent or metastatic endometrial carcinoma and is not a candidate for any potentially curative treatment with surgery or radiotherapy or chemoradiotherapy. | | | | |
| | | | 6. The patient has received at least 1 prior platinum-containing chemotherapy given in any setting whether this was as neoadjuvant chemotherapy or as adjuvant therapy or as chemoradiotherapy or for recurrent disease or for metastatic disease or for more than one of these settings. | | | | |
| | | | 7. The patient has progressive disease during or following the most recent platinum-containing chemotherapy. | | | | |
| | | | 8. Pembrolizumab will be given as monotherapy.<br>Note: pembrolizumab is not to be used with any other systemic anti-cancer treatments in this indication. | | | | |
| | | | 9. The patient has **NOT received any prior antibody treatment which targets PD-1 or PD-L1 or PD-L2 or CD137 or OX40 or anti-cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4).** | | | | |
| | | | 10. The patient will be treated with a fixed dose of pembrolizumab of either 200mg every 3 weeks or 400mg every 6 weeks.<br>Note: NHS England recommends the use of 6-weekly pembrolizumab whenever appropriate. | | | | |
| | | | 11. Treatment with pembrolizumab will be stopped at whichever of the following events occurs first: disease progression or loss of clinical benefit or unacceptable toxicity or withdrawal of patient consent **or after 2 years of treatment (or after 35 x 3-weekly cycles or its equivalent if 6-weekly pembrolizumab is used).** | | | | |
| | | | 12. The patient has an ECOG performance status (PS) of 0 or 1.<br>Note: NHS England does not fund this treatment in patients of ECOG PS 2. | | | | |
| | | | 13. The patient has no symptomatically active brain metastases or leptomeningeal metastases. | | | | |
| | | | 14. A formal medical review as to how pembrolizumab is being tolerated and whether treatment should continue or not will be scheduled to occur at least by the end of the second month of treatment. | | | | |
| | | | 15. When a treatment break of more than 12 weeks beyond the expected 3 or 6 weekly cycle length is needed, a treatment break approval form will be completed to restart treatment. | | | | |
| | | | 16. Pembrolizumab will be otherwise used as set out in its Summary of Product Characteristics (SPC). | | | | |
| PEMB26 | **Pembrolizumab monotherapy** | For the subsequent treatment of patients with previously treated unresectable or metastatic **GASTRIC** cancer exhibiting microsatellite instability-high (MSI-H) or mismatch repair deficiency (dMMR) where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with pembrolizumab monotherapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy. | No | TA914 | 20-Sep-23 | 19-Dec-23 |
| | | | 2. The prescribing clinician is fully aware of the management of and the treatment modifications that may be required for immune-related adverse reactions due to anti-PD-L1 treatments including pneumonitis, colitis, nephritis, endocrinopathies, hepatitis and skin toxicity. | | | | |
| | | | 3. The patient has unresectable or metastatic gastric carcinoma. | | | | |
| | | | 4. The patient's tumour has a documented presence of microsatellite instability-high (MSI-H) or DNA mismatch repair deficiency (dMMR) confirmed by validated testing. | | | | |
| | | | 5. The patient has received previous chemotherapy for unresectable or metastatic gastric cancer. | | | | |
| | | | 6. The patient has progressive disease during or following the most recent chemotherapy. | | | | |
| | | | 7. The patient has an ECOG performance status (PS) of 0 or 1.<br>Note: NHS England does not fund this treatment in patients of ECOG PS 2. | | | | |
| | | | 8. The patient has no symptomatically active brain metastases or leptomeningeal metastases. | | | | |
| | | | 9. The patient has **NOT received prior treatment with an anti-PD-1, anti-PD-L2, anti-CD137, or anti-Cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) antibody.** | | | | |
| | | | 10. Pembrolizumab will be administered as monotherapy at a dose of 200mg every 3 weeks or a dose of 400mg every 6 weeks.<br>Note: NHS England recommends the use of 6-weekly pembrolizumab whenever appropriate. | | | | |
| | | | 11. Pembrolizumab will be stopped at whichever of the following events occurs first: disease progression or loss of clinical benefit or unacceptable toxicity or withdrawal of patient consent or **after a total treatment duration of 2 years (or a maximum of 35 3-weekly cycles or the equivalent number of 6-weekly cycles to result in a total treatment duration of 2 years).** | | | | |
| | | | 12. A formal medical review as to whether treatment with pembrolizumab should continue will occur at least by the end of the 2nd month of treatment. | | | | |
| | | | 13. When a treatment break of more than 12 weeks beyond the expected 3 or 6-weekly cycle length is needed, a treatment break approval form will be completed to restart treatment. | | | | |
| | | | 14. Pembrolizumab will be otherwise used as set out in its Summary of Product Characteristics (SPC). | | | | |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| PEMB27 | **Pembrolizumab monotherapy** | For the subsequent treatment of patients with previously treated unresectable or metastatic **SMALL INTESTINA**L carcinoma exhibiting microsatellite instability-high (MSI-H) or mismatch repair deficiency (dMMR) where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with pembrolizumab monotherapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy. | No | TA914 | 20-Sep-23 | 19-Dec-23 |
| | | | 2. The prescribing clinician is fully aware of the management of and the treatment modifications that may be required for immune-related adverse reactions due to anti-PD-L1 treatments including pneumonitis, colitis, nephritis, endocrinopathies, hepatitis and skin toxicity. | | | | |
| | | | 3. The patient has unresectable or metastatic small intestinal carcinoma. | | | | |
| | | | 4. The patient's tumour has a documented presence of microsatellite instability-high (MSI-H) or DNA mismatch repair deficiency (dMMR) confirmed by validated testing. | | | | |
| | | | 5. The patient has received previous treatment for unresectable or metastatic small intestinal cancer. | | | | |
| | | | 6. The patient has progressive disease during or following the most recent chemotherapy. | | | | |
| | | | 7. The patient has an ECOG performance status (PS) of 0 or 1.<br>Note: NHS England does not fund this treatment in patients of ECOG PS 2. | | | | |
| | | | 8. The patient has no symptomatically active brain metastases or leptomeningeal metastases. | | | | |
| | | | 9. The patient has **NOT received prior treatment with an anti-PD-1, anti-PD-L2, anti-CD137, or anti-Cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) antibody.** | | | | |
| | | | 10. Pembrolizumab will be administered as monotherapy at a dose of 200mg every 3 weeks or a dose of 400mg every 6 weeks.<br>Note: NHS England recommends the use of 6-weekly pembrolizumab whenever appropriate. | | | | |
| | | | 11. Pembrolizumab will be stopped at whichever of the following events occurs first: disease progression or loss of clinical benefit or unacceptable toxicity or withdrawal of patient consent or **after a total treatment duration of 2 years (or a maximum of 35 3-weekly cycles or the equivalent number of 6-weekly cycles to result in a total treatment duration of 2 years).** | | | | |
| | | | 12. A formal medical review as to whether treatment with pembrolizumab should continue will occur at least by the end of the 2nd month of treatment. | | | | |
| | | | 13. When a treatment break of more than 12 weeks beyond the expected 3 or 6-weekly cycle length is needed, a treatment break approval form will be completed to restart treatment. | | | | |
| | | | 14. Pembrolizumab will be otherwise used as set out in its Summary of Product Characteristics (SPC). | | | | |
| PEMB28 | **Pembrolizumab monotherapy** | For the subsequent treatment of patients with previously treated unresectable or metastatic **BILIARY TRACT** cancer exhibiting microsatellite instability-high (MSI-H) or mismatch repair deficiency (dMMR) where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with pembrolizumab monotherapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy. | No | TA914 | 20-Sep-23 | 19-Dec-23 |
| | | | 2. The prescribing clinician is fully aware of the management of and the treatment modifications that may be required for immune-related adverse reactions due to anti-PD-L1 treatments including pneumonitis, colitis, nephritis, endocrinopathies, hepatitis and skin toxicity. | | | | |
| | | | 3. The patient has unresectable or metastatic biliary tract carcinoma. | | | | |
| | | | 4. The patient's tumour has a documented presence of microsatellite instability-high (MSI-H) or DNA mismatch repair deficiency (dMMR) confirmed by validated testing. | | | | |
| | | | 5. The patient has received previous chemotherapy for unresectable or metastatic biliary tract cancer. | | | | |
| | | | 6. The patient has progressive disease during or following the most recent chemotherapy. | | | | |
| | | | 7. The patient has an ECOG performance status (PS) of 0 or 1.<br>Note: NHS England does not fund this treatment in patients of ECOG PS 2. | | | | |
| | | | 8. The patient has no symptomatically active brain metastases or leptomeningeal metastases. | | | | |
| | | | 9. The patient has **NOT received prior treatment with an anti-PD-1, anti-PD-L2, anti-CD137, or anti-Cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) antibody.** | | | | |
| | | | 10. Pembrolizumab will be administered as monotherapy at a dose of 200mg every 3 weeks or a dose of 400mg every 6 weeks.<br>Note: NHS England recommends the use of 6-weekly pembrolizumab whenever appropriate. | | | | |
| | | | 11. Pembrolizumab will be stopped at whichever of the following events occurs first: disease progression or loss of clinical benefit or unacceptable toxicity or withdrawal of patient consent or **after a total treatment duration of 2 years (or a maximum of 35 3-weekly cycles or the equivalent number of 6-weekly cycles to result in a total treatment duration of 2 years).** | | | | |
| | | | 12. A formal medical review as to whether treatment with pembrolizumab should continue will occur at least by the end of the 2nd month of treatment. | | | | |
| | | | 13. When a treatment break of more than 12 weeks beyond the expected 3 or 6-weekly cycle length is needed, a treatment break approval form will be completed to restart treatment. | | | | |
| | | | 14. Pembrolizumab will be otherwise used as set out in its Summary of Product Characteristics (SPC). | | | | |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| PEMB29 | **Pembrolizumab** | Pembrolizumab in combination with platinum and fluoropyrimidine-based chemotherapy for previously untreated advanced HER-2 negative gastric or gastro-oesophageal junction adenocarcinoma either of which expresses PD-L1 with a combined positive score of 1 or more where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with pembrolizumab plus chemotherapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The prescribing clinician is fully aware of the management of and the treatment modifications that may be required for immune-related adverse reactions due to anti-PD-1 or anti-PD-L1 treatments including pneumonitis, colitis, nephritis, endocrinopathies, hepatitis and skin toxicity.<br>3. The patient has a histologically- or cytologically-confirmed diagnosis of HER-2 negative adenocarcinoma of the gastro-oesophageal junction or stomach.<br>Please mark below which site of the primary tumour applies to this patient:<br>- HER-2 negative adenocarcinoma of the gastro-oesophageal junction<br>- HER-2 negative adenocarcinoma of the stomach<br>4. The patient has locally advanced unresectable or metastatic disease.<br>5. An approved and validated test has demonstrated that the tumour has a PD-L1 expression with a combined positive score (CPS) of ≥1.<br><br>Please document the actual PD-L1 combined positive score (CPS) below:<br>PD-L1 CPS: _____<br>6. The patient has not received any previous systemic therapy for locally advanced unresectable or metastatic disease i.e. that pembrolizumab plus chemotherapy will be 1st line systemic therapy for locally advanced unresectable or metastatic disease.<br><br>In addition, please mark below whether the patient has/has not previously received any systemic therapy for earlier stage disease:<br>- this patient has not received any previous systemic therapy for adenocarcinoma of the gastro-oesophageal junction or stomach<br>- this patient was previously treated with neoadjuvant chemotherapy for HER-2 negative adenocarcinoma of the gastro-oesophageal junction or stomach and underwent surgery and has since had disease progression<br>- this patient was previously treated with adjuvant chemotherapy for HER-2 negative adenocarcinoma of the gastro-oesophageal junction or stomach and has since had disease progression<br>- this patient was previously treated with concurrent chemo-radiotherapy for HER-2 negative adenocarcinoma of the gastro-oesophageal junction with or without surgery and has since had disease progression<br>7. The patient has not received prior treatment with any antibody which targets PD-1 or PD-L1 or PD-L2 or CD137 or OX40 or anti-cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) unless the patient discontinued or completed checkpoint inhibitor immunotherapy as part of adjuvant therapy without disease progression and at least 6 months has elapsed between the date of the last immunotherapy treatment and the date of first diagnosis of relapse with recurrent or metastatic disease.<br><br>Please mark below the appropriate scenario for this patient<br>- this patient has not received any previous immunotherapy for adenocarcinoma of the gastro-oesophageal junction or stomach<br>- this patient was previously treated with neoadjuvant platinum-based chemoradiotherapy for adenocarcinoma of the gastro-oesophageal junction and underwent surgery followed by adjuvant nivolumab (NICE TA 713) then discontinued or completed treatment with adjuvant nivolumab without disease progression and this was at least 6 months prior to the first diagnosis of relapse. Please document in the box below the time gap in months between completion of previous adjuvant nivolumab immunotherapy and first diagnosis of disease relapse:<br>_____<br><br>Note: the mandatory interval between the last date of administration of any prior adjuvant immunotherapy and first relapse is **at least 6 months.** For patients suffering a first relapse within 6-12 months of previous immunotherapy, clinicians should bear in mind the long elimination half-lives of immunotherapies and make individual assessments of the overall benefit/risk ratio of re-treatment with immunotherapy.<br>8. The patient has an ECOG performance status (PS) of 0 or 1 and is fit for platinum and fluoropyrimidine-based chemotherapy in combination with pembrolizumab.<br>9. The patient has no symptomatically active brain metastases or leptomeningeal metastases.<br>10. Pembrolizumab will be administered at a dose of either 200mg 3-weekly or 400mg 6-weekly initially in combination with platinum and fluoropyrimidine-based chemotherapy and subsequently as monotherapy.<br>11. The chemotherapy used in combination with pembrolizumab will be both platinum and fluoropyrimidine-based.<br><br>Please mark below which chemotherapy regimen is being used in this patient:<br>- oxaliplatin plus capecitabine<br>- oxaliplatin plus modified de Gramont regimen<br>- cisplatin plus capecitabine<br>- cisplatin plus infused 5-fluorouracil<br>- another regimen<br>12. Pembrolizumab will be stopped at whichever of the following events occurs first: disease progression or unacceptable toxicity or withdrawal of patient consent or after 2 years of treatment (or after 35 x 3-weekly cycles or its equivalent if 6-weekly dosing is used).<br>Note: the 2 year stopping rule for pembrolizumab in this indication was a key part of the company submission to NICE of the clinical and cost effectiveness of pembrolizumab in this indication.<br>Note: once pembrolizumab is stopped after 2 years of treatment, it cannot be re-started.<br>13. A formal medical review as to how pembrolizumab plus chemotherapy is being tolerated and whether pembrolizumab should continue or not will be scheduled to occur at least by the end of the second 3-weekly cycle of treatment.<br>14. When a treatment break of more than 3 months beyond the expected 3- or 6-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment.<br>15. Pembrolizumab will otherwise be used as set out in its Summary of Product Characteristics (SPC) with the exception of criterion 12. | No | TA997 | 29-Aug-24 | 27-Nov-24 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| PEMB30_v1.1 | **Pembrolizumab** in combination with chemotherapy | Pembrolizumab in combination with chemotherapy for neoadjuvant treatment and then continued as adjuvant monotherapy in adults with previously untreated UICC/AJCC 8th edition stage IIA or IIB or IIIA or N2 only IIIB non-small cell lung cancer AND who are candidates for potentially curative surgery where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with neoadjuvant pembrolizumab in combination with chemotherapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a histologically documented diagnosis of non-small cell lung cancer (NSCLC).<br><br>Please mark below which histology applies to this patient:<br>- squamous NSCLC<br>- non-squamous NSCLC<br>3. The patient either has been documented as NOT having a NSCLC which harbours an EGFR 19 or 21 mutation or an ALK gene fusion or the patient has a squamous cell carcinoma and a decision to not test for an EGFR 19 or 21 mutation or an ALK gene fusion and proceed with pembrolizumab has been made following discussion at the Lung Cancer MDT and consideration of the relevant patient characteristics (including age and smoking status).<br><br>Please mark below which option applies to this patient:<br>- Documented as NOT having a NSCLC which harbours an EGFR 19 or 21 mutation or an ALK gene fusion<br>- Patient has squamous NSCLC and a decision to not test for an EGFR 19 or 21 mutation or an ALK gene fusion and proceed with pembrolizumab has been made following discussion at the Lung Cancer MDT<br>4. The clinical TNM staging has been agreed at the appropriate Lung Cancer MDT meeting to be stage IIA or IIB or IIIA or N2 only IIIB tumour according to the UICC/AJCC TNM 8th edition.<br><br>Please mark below which stage applies to this patient:<br>- stage IIA disease (T2b N0)<br>- stage IIB disease (T1a N1 or T1b N1 or T1c N1 or T2a N1 or T2b N1 or T3 N0)<br>- stage IIIA disease (T1a N2 or T1b N2 or T1c N2 or T2a N2 or T2b N2 or T3 N1 or T4 N0 or T4 N1)<br>- N2 only stage IIIB disease (T3 N2 or T4 N2)<br>5. The patient has been staged as having M0 disease and has been assessed by the thoracic surgical team to be eligible and fit for a potentially curative resection<br>6. The intent is to treat the patient with a maximum of 4 cycles of 3-weekly neoadjuvant platinum-based chemotherapy in combination with 3- or 6-weekly pembrolizumab.<br>7. The chemotherapy partner to this neoadjuvant combination will be a 2-drug platinum-based combination with the platinum component being either cisplatin or carboplatin given at a dose of at least AUC of 5mg/ml/min.<br><br>Please mark below which will be the platinum-based component of the 2-drug combination:<br>- cisplatin<br>- carboplatin given with a drug dose of at least AUC 5mg/ml/min<br><br>Note: the partner cytotoxic drugs to cisplatin/carboplatin can be pemetrexed or paclitaxel or gemcitabine or vinorelbine.<br>8. The intent is for the patient to potentially undergo resection within 20 weeks of the 1st dose of neoadjuvant therapy.<br>9. The intent is for the patient to commence adjuvant pembrolizumab monotherapy no later than 12 weeks after surgery for a maximum of either 13 x 3-weekly cycles or 7 x 6-weekly cycles and then discontinue treatment with pembrolizumab. Dosing of pembrolizumab can be as below<br>• 395mg every 3 weeks, or 790mg every 6 weeks if given via **subcutaneous** injection<br>• 200mg every 3 weeks, or 400mg every 6 weeks if given via **intravenous** infusion<br>10. The intent for any patient requiring any form of post-operative radiotherapy is for this to start no later than 8 weeks after surgery and for adjuvant pembrolizumab to commence no later than 4 weeks after completion of radiotherapy.<br>11. The patient has not received any previous anticancer therapy for this NSCLC or any prior treatment with an anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CD137, or anti-Cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) antibody.<br>12. The patient has an ECOG performance status (PS) of 0 or 1.<br>13. Pembrolizumab will be stopped at whichever of the following events occurs first: any local or distant disease progression at any time in the neoadjuvant, peri-operative and adjuvant phases of treatment or unacceptable toxicity or withdrawal of patient consent or on completion of the maximum allowed duration of treatment with adjuvant pembrolizumab as outlined above.<br>14. When a treatment break of more than 12 weeks beyond the expected 3-weekly or 6-weekly cycle length (as appropriate) is needed, I will complete a treatment break approval form to restart treatment, which MUST be approved before treatment is recommenced.<br>15. The prescribing clinician is aware of the following issues which relate to the subsequent management of this patient following neoadjuvant pembrolizumab plus chemotherapy:<br><br>i) if the patient has a resection, then post-operative radiotherapy or chemoradiotherapy can be given if indicated and in the absence of any progressive disease, the patient can proceed to adjuvant pembrolizumab<br>ii) the patient does not have a resection, then radiotherapy or chemoradiotherapy can be given if indicated and in the absence of any progressive disease, the patient can proceed to adjuvant pembrolizumab<br>iii) if the patient does not have surgery or radiotherapy or chemoradiotherapy, no adjuvant pembrolizumab can be given<br>iv) if there is disease progression during neoadjuvant or adjuvant pembrolizumab, no further anti-PD1 or anti-PDL1 immunotherapy is funded in any indication<br>16. Pembrolizumab will be otherwise used as set out in its Summary of Product Characteristics (SPC). | Yes | TA1017 | 20-Nov-24 | 19-Feb-25 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| PEMB31 | **Pembrolizumab** monotherapy | Pembrolizumab monotherapy for adjuvant treatment after complete tumour resection in adult patients with UICC/AJCC 8th edition stage IIA or IIB or IIIA or N2 only IIIB non-small cell lung cancer and whose disease has not progressed on recently completed adjuvant platinum-based chemotherapy where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with adjuvant pembrolizumab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The prescribing clinician is fully aware of the management of and the treatment modifications that may be required for immune-related adverse reactions due to anti-PD-L1 treatments including pneumonitis, colitis, nephritis, endocrinopathies, hepatitis and skin toxicity.<br>3. The patient has a histologically documented diagnosis of non-small cell lung cancer (NSCLC).<br><br>Please mark below which histology applies to this patient:<br>- squamous NSCLC<br>- non-squamous NSCLC<br>4. The result of this patient's NSCLC testing for PD-L1 expression on tumour cells is shown below:<br><br>Please document below the actual PD-L1 expression on tumour cells (e.g. if 80%, please type just the number 80; if not known, please write 'NK'):<br>PD-L1 expression in this patient's tumour cells: _____<br>5. The patient's NSCLC genomic status either has been documented for an EGFR 19 or 21 mutation and an ALK gene fusion or the patient has a squamous cell carcinoma and a decision to not test for an EGFR 19 or 21 mutation or an ALK gene fusion and proceed with adjuvant pembrolizumab has been made following discussion at the Lung Cancer MDT and consideration of the relevant patient characteristics (including age and smoking status).<br><br>Please mark below which option applies to this patient:<br>- the EGFR 19 or 21 mutation test and ALK gene fusion tests are all negative<br>- the EGFR 19 or 21 mutation test is positive<br>- the ALK gene fusion test is positive<br>- Patient has squamous NSCLC and a decision to not test for an EGFR 19 or 21 mutation or an ALK gene fusion and proceed with adjuvant pembrolizumab has been made following discussion at the Lung Cancer MDT<br>6. The patient has been documented as having any other actionable NSCLC mutation or not: ROS1, RET, KRAS G12C, MET14 or BRAF.<br><br>Please mark in the box below whether such an actionable mutation has been found or not:<br>- genomic testing has not been done for all the other genomic alterations listed below and any results so far have been negative<br>- genomic testing has been done for all the other genomic alterations listed below and results are all negative<br>- the patient's NSCLC is positive for a ROS1 gene rearrangement<br>- the patient's NSCLC is positive for a RET gene fusion<br>- the patient's NSCLC is positive for a KRAS G12C mutation<br>- the patient's NSCLC is positive for a MET exon 14 skipping mutation<br>- the patient's NSCLC is positive for a BRAF mutation<br>7. The patient had M0 disease prior to surgery and has undergone a complete resection of the primary NSCLC with all surgical margins negative for tumour i.e. a R0 resection has taken place.<br>8. The pathological TNM stage determined on this patient's surgical NSCLC specimen was a stage IIA or IIB or IIIA or N2 only IIIB tumour according to the UICC/AJCC TNM 8th edition.<br><br>Please mark below which stage applies to this patient:<br>- stage IIA disease (T2b N0)<br>- stage IIB disease (T1a N1 or T1b N1 or T1c N1 or T2a N1 or T2b N1 or T3 N0)<br>- stage IIIA disease (T1a N2 or T1b N2 or T1c N2 or T2a N2 or T2b N2 or T3 N1 or T4 N0 or T4 N1)<br>- N2 only stage IIIB disease (T3 N2 or T4 N2)<br><br>Note: the trial included patients staged using the UICC/AJCC TNM 7th edition and hence the marketing authorisation uses the 7th edition staging system. As NSCLC surgical resection specimens are now reported using the UICC/AJCC TNM 8th edition, the corresponding 7th edition stages included in the marketing authorisation have been translated into those of the 8th edition.<br>9. The patient commenced adjuvant platinum-based chemotherapy within 12 weeks of resection of the NSCLC.<br><br>NB The marketing authorisation and NICE recommendation of pembrolizumab in this adjuvant NSCLC indication stipulates that patients must have received adjuvant chemotherapy prior to commencing adjuvant pembrolizumab.<br>10. The patient has received a maximum of 4 cycles of adjuvant platinum-based chemotherapy.<br><br>Please mark below how many cycles of adjuvant chemotherapy were received by this patient<br>- 1 cycle of adjuvant chemotherapy<br>- 2 cycles of adjuvant chemotherapy<br>- 3 cycles of adjuvant chemotherapy<br>- 4 cycles of adjuvant chemotherapy<br>11. The patient has been radiologically re-staged after completion of adjuvant chemotherapy and continues to have no evidence of residual or metastatic disease.<br>12. No more than 12 weeks have elapsed since the start of the last cycle of adjuvant platinum-based chemotherapy.<br>**(continues on next page)** | No | TA1037 | 05-Feb-25 | 06-May-25 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| PEMB31 | **Pembrolizumab** monotherapy | Pembrolizumab monotherapy for adjuvant treatment after complete tumour resection in adult patients with UICC/AJCC 8th edition stage IIA or IIB or IIIA or N2 only IIIB non-small cell lung cancer and whose disease has not progressed on recently completed adjuvant platinum-based chemotherapy where the following criteria have been met: | 13. The patient has not received prior treatment with an anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CD137, or anti-Cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) antibody.<br>14. The patient has not received any neoadjuvant chemotherapy for this NSCLC or any prior or planned adjuvant radiotherapy.<br>15. The patient has an ECOG performance status (PS) of 0 or 1.<br>16. Pembrolizumab will be stopped at whichever of the following events occurs first: disease progression or unacceptable toxicity or withdrawal of patient consent **or on completion of 1 year in total duration of treatment with pembrolizumab** (i.e. after a maximum of 18 x 3-weekly or 9 x 6-weekly cycles).<br>17. Pembrolizumab will be administered as monotherapy.<br>18. A formal medical review as to how pembrolizumab is being tolerated and whether treatment with pembrolizumab should continue or not will be scheduled to occur at least by the end of the second month of treatment.<br>19. When a treatment break of more than 3 months beyond the expected 3- or 6-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment.<br>20. Pembrolizumab will be otherwise used as set out in its Summary of Product Characteristics (SPC). | No | TA1037 | 05-Feb-25 | 06-May-25 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| PEMB32 | **Pembrolizumab** in combination with platinum-containing chemotherapy (carboplatin and paclitaxel) | Pembrolizumab in combination with platinum-containing chemotherapy (carboplatin and paclitaxel) for the 1st line treatment of mismatch repair deficient (dMMR) or microsatellite instability-high endometrial carcinoma in adult patients who have recurrent or primary advanced disease and who are not candidates for potentially curative surgery or radiotherapy or chemoradiotherapy but are eligible for systemic therapy where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with pembrolizumab in combination with carboplatin and paclitaxel will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a histologically- or cytologically confirmed diagnosis of endometrial carcinoma (including clear cell and serous histologies).<br><br>Note: patients with carcinosarcoma (Mixed Mullerian tumour) are eligible, but otherwise uterine sarcomas of any kind are **NOT** eligible for pembrolizumab in this indication.<br>3. The patient's tumour has a documented presence of mismatch repair deficiency (dMMR) or microsatellite instability (MSI-H) confirmed by validated testing.<br>4. The patient **either** has a 1st recurrence of endometrial carcinoma after surgery or radiotherapy or chemoradiotherapy **or** has presented with primary locally advanced or metastatic endometrial carcinoma **and** in whichever scenario is **not** a candidate for any potentially curative treatment with surgery or radiotherapy or chemoradiotherapy.<br><br>Please mark below which scenario applies to this patient:<br>- 1st recurrence after previous surgery, radiotherapy or chemoradiotherapy or<br>- presented with primary stage IIIA disease and has received no systemic therapy or<br>- presented with primary stage IIIB disease and has received no systemic therapy or<br>- presented with primary stage IIIC1 disease and has received no systemic therapy or<br>- presented with primary stage IIIC2 disease and has received no systemic therapy or<br>- presented with primary stage IV disease and has received no systemic therapy<br>5. The patient **either** has not previously received any systemic chemotherapy for the endometrial carcinoma, or the only systemic therapy has been as neoadjuvant or adjuvant chemotherapy or chemoradiotherapy and the patient has progressed or recurred at least 6 months since the completion of such chemotherapy.<br><br>Please mark below which scenario applies to this patient:<br>- the patient is treatment-naïve to chemotherapy for the endometrial cancer or<br>- the only systemic therapy has been as neoadjuvant or adjuvant chemotherapy or chemoradiotherapy and the patient has progressed or recurred at least 6 months since the completion of such chemotherapy<br>6. Pembrolizumab will be given in combination with carboplatin and paclitaxel unless there is a clear contraindication to the use of one or both cytotoxic agents.<br><br>Please mark below which scenario applies to this patient:<br>- the intent is to use the combination of carboplatin and paclitaxel as the chemotherapy partner to pembrolizumab or<br>- the patient has a clear contraindication to the use of carboplatin and/or paclitaxel and hence an alternative platinum-based combination therapy must be used as the chemotherapy partner to pembrolizumab<br><br>Note: in patients who suffer a severe allergic reaction to paclitaxel or carboplatin which necessitates discontinuation of the drug causing the severe allergy, use of pembrolizumab can continue with carboplatin or paclitaxel in combination with whichever agent is considered appropriate by the clinician.<br>7. Unless the patient is contraindicated from starting with carboplatin and paclitaxel, the patient will commence combination chemotherapy with carboplatin at a dose of AUC 5mg/ml/min and paclitaxel at 175mg/m$^2$, planned to be given 3-weekly and for a maximum of 6 cycles of chemotherapy.<br>8. The patient has not received any prior antibody treatment which targets PD-1 or PD-L1 or PD-L2 or CD137 or OX40 or anti-cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) unless the patient has already received pembrolizumab for the same indication via a company sponsored early access scheme<br><br>Please mark below which scenario applies to this patient:<br>- the patient has not received any prior antibody treatment which targets PD-1 or PD-L1 or PD-L2 or CD137 or OX40 or anti-cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) or<br>- the patient has received pembrolizumab for the same indication via a company sponsored early access scheme and meets all other criteria on this form<br>9. Treatment with pembrolizumab will be stopped at whichever of the following events occurs first: disease progression or loss of clinical benefit or unacceptable toxicity or withdrawal of patient consent or **after a maximum of 2 years of treatment (or after 35 x 3-weekly cycles or its equivalent if 6-weekly dosing is used)**.<br>10. The patient has an ECOG performance status (PS) of 0 or 1 or 2.<br>11. The patient has no symptomatically active brain metastases or leptomeningeal metastases.<br>12. When a treatment break of more than 12 weeks beyond the expected 3- or 6-weekly cycle length is needed, Ithe prescribing clinician will complete a treatment break approval form to restart treatment.<br>13. Pembrolizumab will be otherwise used as set out in its Summary of Product Characteristics (SPC). | No | TA1092 | 27-Aug-25 | 25-Nov-25 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| PEMB33 | **Pembrolizumab** in combination with platinum-containing chemotherapy (carboplatin and paclitaxel) | Pembrolizumab in combination with platinum-containing chemotherapy (carboplatin and paclitaxel) for the 1st line treatment of mismatch repair proficient (pMMR) or microsatellite stable endometrial carcinoma in adult patients who have recurrent or primary advanced disease and who are not candidates for potentially curative surgery or radiotherapy or chemoradiotherapy but are eligible for systemic therapy where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with pembrolizumab in combination with carboplatin and paclitaxel will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a histologically- or cytologically confirmed diagnosis of endometrial carcinoma (including clear cell and serous histologies).<br><br>Note: patients with carcinosarcoma (Mixed Mullerian tumour) are eligible but otherwise uterine sarcomas of any kind are **NOT** eligible for pembrolizumab in this indication.<br>3. The patient's tumour has a documented presence of mismatch repair proficiency (pMMR) or microsatellite stability confirmed by validated testing.<br>4. The patient **either** has a 1st recurrence of endometrial carcinoma after surgery or radiotherapy or chemoradiotherapy or has presented with primary locally advanced or metastatic endometrial carcinoma and in whichever scenario is not a candidate for any potentially curative treatment with surgery or radiotherapy or chemoradiotherapy.<br><br>Please mark below which scenario applies to this patient:<br>- 1st recurrence after previous surgery, radiotherapy or chemoradiotherapy or<br>- presented with primary stage IIIA disease and has received no systemic therapy or<br>- presented with primary stage IIIB disease and has received no systemic therapy or<br>- presented with primary stage IIIC1 disease and has received no systemic therapy or<br>- presented with primary stage IIIC2 disease and has received no systemic therapy or<br>- presented with primary stage IV disease and has received no systemic therapy<br>5. The patient **either** has not previously received any systemic chemotherapy for the endometrial carcinoma, or the only systemic therapy has been as neoadjuvant or adjuvant chemotherapy or chemoradiotherapy and the patient has progressed or recurred at least 6 months since the completion of such chemotherapy.<br><br>Please mark below which scenario applies to this patient:<br>- the patient is treatment-naïve to chemotherapy for the endometrial cancer or<br>- the only systemic therapy has been as neoadjuvant or adjuvant chemotherapy or chemoradiotherapy and the patient has progressed or recurred at least 6 months since the completion of such chemotherapy<br>6. Pembrolizumab will be given in combination with carboplatin and paclitaxel unless there is a clear contraindication to the use of one or both cytotoxic agents.<br><br>Please mark below which scenario applies to this patient:<br>- the intent is to use the combination of carboplatin and paclitaxel as the chemotherapy partner to pembrolizumab or<br>- the patient has a clear contraindication to the use of carboplatin and/or paclitaxel and hence an alternative platinum-based combination therapy must be used as the chemotherapy partner to pembrolizumab<br><br>Note: in patients who suffer a severe allergic reaction to paclitaxel or carboplatin which necessitates discontinuation of the drug causing the severe allergy, use of pembrolizumab can continue with carboplatin or paclitaxel in combination with whichever agent is considered appropriate by the clinician.<br>7. Unless the patient is contraindicated from starting with carboplatin and paclitaxel, the patient will commence combination chemotherapy with carboplatin at a dose of AUC 5mg/ml/min and paclitaxel at 175mg/m², planned to be given 3-weekly and for a maximum of 6 cycles of chemotherapy.<br>8. The patient has not received any prior antibody treatment which targets PD-1 or PD-L1 or PD-L2 or CD137 or OX40 or anti-cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) unless the patient has already received pembrolizumab for the same indication via a company sponsored early access scheme<br><br>Please mark below which scenario applies to this patient:<br>- the patient has not received any prior antibody treatment which targets PD-1 or PD-L1 or PD-L2 or CD137 or OX40 or anti-cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) or<br>- the patient has received pembrolizumab for the same indication via a company sponsored early access scheme and meets all other criteria on this form<br>9. Treatment with pembrolizumab will be stopped at whichever of the following events occurs first: disease progression or loss of clinical benefit or unacceptable toxicity or withdrawal of patient consent or **after a maximum of 2 years of treatment (or after 35 x 3-weekly cycles or its equivalent if 6-weekly dosing is used)**.<br>10. The patient has an ECOG performance status (PS) of 0 or 1 or 2.<br>11. The patient has no symptomatically active brain metastases or leptomeningeal metastases.<br>12. When a treatment break of more than 12 weeks beyond the expected 3- or 6-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment.<br>13. Pembrolizumab will be otherwise used as set out in its Summary of Product Characteristics (SPC). | No | TA1092 | 27-Aug-25 | 25-Nov-25 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| PEMIG1 | **Pemigatinib** | For locally advanced or metastatic cholangiocarcinoma which has a fibroblast growth factor receptor 2 gene fusion/rearrangement in patients with disease progression during or after previous systemic therapy where the following criteria have been met: | 1. This application for pemigatinib is being made by and the first cycle of systemic anti-cancer therapy with pemigatinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a histologically or cytologically confirmed diagnosis of cholangiocarcinoma.<br>Please also indicate below whether the cholangiocarcinoma is of intrahepatic or extrahepatic origin:<br>- the cholangiocarcinoma is of intra-hepatic origin or<br>- the cholangiocarcinoma is of extrahepatic origin<br>3. The cholangiocarcinoma has been tested for fibroblast growth factor receptor 2 (FGFR2) gene fusion or rearrangement with a validated test and the result is positive.<br>4. The patient has unresectable locally advanced or metastatic disease.<br>5. The patient has been previously treated with systemic therapy for cholangiocarcinoma and the disease has progressed during or after such therapy.<br>Please also indicate whether the patient has received 1 or ≥2 lines of systemic therapy:<br>- the patient has been previously treated with 1 line of systemic therapy for cholangiocarcinoma or<br>- the patient has been previously treated with ≥2 lines of systemic therapy for cholangiocarcinoma<br>6. The patient has not previously received any specifically FGFR2-targeted therapy unless futibatinib monotherapy has had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of progressive disease.<br><br>Please mark below which scenario applies to this patient:<br>- the patient has not been previously treated with a FGFR2-targeted therapy Or<br>- futibatinib monotherapy has had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of progressive disease<br>7. The patient has an ECOG performance status of 0 or 1 or 2.<br>8. The patient either has no known brain metastases or if the patient has brain metastases, the patient is symptomatically stable prior to starting treatment with pemigatinib.<br>9. Pemigatinib will be used as monotherapy.<br>10. The patient will be treated until loss of clinical benefit or excessive toxicity or patient choice to discontinue treatment, whichever is the sooner.<br>11. The prescribing clinician understands that pemigatinib can cause serous retinal detachment and therefore opthalmological examination (including optical coherence tomography) has been arranged prior to initiation of pemigatinib and then whilst on therapy (every 2 months for the first 6 months and every 3 months thereafter).<br>12. The prescribing clinician is aware of the risk of the patient developing hyper-phosphataemia during treatment with pemigatinib and understand all of the following: the requirement for monitoring of phosphate levels, the role of<br>13. The prescribing clinician is aware of the important drug interactions which can occur between pemigatinib and CYP3A/P-gp inhibitors and inducers as outlined in sections 4.2 and 4.5 of the pemigatinib SPC.<br>14. The prescribing clinician is aware that the use of proton pump inhibitors should be avoided in patients receiving pemigatinib.<br>15. A first formal medical review as to whether treatment with pemigatinib should continue or not will be scheduled to occur at least by the end of the first 8 weeks of treatment.<br>16. When a treatment break of more than 6 weeks beyond the expected 3-weekly cycle length is needed, the prescribing clinician will complete a treatment break approval form to restart treatment.<br>17. Pemigatinib will be otherwise used as set out in its Summary of Product Characteristics (SPC). | No | TA722 | 25-Aug-21 | 24-Sep-21 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| PER2a | **Pertuzumab** | Neoadjuvant pertuzumab plus trastuzumab in NODE POSITIVE patients for the neoadjuvant treatment of locally advanced, inflammatory or early breast cancer at high risk of recurrence (**PER2a**) where the following criteria have been met<br><br>This form (introduced in November 2019) is for patients known to be pathologically node positive prior to commencing neo-adjuvant therapy. On commencing adjuvant treatment with pertuzumab, form PER4a (for node positive patients) must be completed.<br><br>For patients with locally advanced, inflammatory or early breast cancer who are node negative or of unknown nodal status when commencing neo-adjuvant pertuzumab, form PER2b must be used for the neoadjuvant part of treatment followed by form PER4b for the adjuvant part of treatment only if the histology post-surgery is node +ve. | 1. This application has been made by and the first cycle of systemic anti -cancer therapy with pertuzumab (in combination with chemotherapy and trastuzumab) will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>**NOTE: This application should be made immediately prior to commencing pertuzumab plus trastuzumab when given with single agent docetaxel/paclitaxel chemotherapy as part of sequential anthracycline/taxane regimen and not at the start of the anthracycline based component.** | No | TA424 | 21-Dec-16 | 21-Mar-17 |
| | | | 2. Treatment is being initiated with neoadjuvant intent | | | | |
| | | | 3. The patient has newly diagnosed locally advanced, inflammatory or early breast cancer at high risk of recurrence (i.e must have stage T2-T4b and M0 disease) and has pathologically-proven node positive disease | | | | |
| | | | 4. The patient has HER2 3+ by IHC or FISH/CISH positive disease | | | | |
| | | | 5. The patient has a baseline LVEF greater than or equal to 55% % or if anthracyclines were given that the LVEF was greater than or equal to 50% after completion of the anthracycline component of the neo-adjuvant chemotherapy. | | | | |
| | | | 6. The patient has received no prior treatment with chemotherapy or HER2 therapy for this breast cancer | | | | |
| | | | 7. Pertuzumab plus trastuzumab will be given in combination with docetaxel/paclitaxel-containing chemotherapy. The exceptions to this are for patients enrolled in the NIHR-approved ROSCO trial (UKCRN Study ID:19069 where neoadjuvant pertuzumab can be given with chemotherapy in either arm of the study) or potential participants in the NIHR-approved HER2 RADiCAL trial (UKCRN Study ID131362 where paclitaxel/nab-paclitaxel/docetaxel may be used).<br>Please indicate below if the patient is enrolled in the NIHR-approved ROSCO neoadjuvant trial:<br>- Patient NOT enrolled/eligible for either of the ROSCO or HER2 RADiCAL trials<br>- Patient enrolled in the ROSCO neoadjuvant trial<br>- Patient is a potential participant in the HER2 RADiCAL trial of tailored treatment for HER2 +ve early breast cancer | | | | |
| | | | 8. The patient will receive a maximum of 4 cycles of pertuzumab plus trastuzumab if given with single agent docetaxel chemotherapy as part of sequential anthracycline/docetaxel regimen OR 4 cycles of pertuzumab plus trastuzumab if given with weekly paclitaxel chemotherapy as part of sequential anthracycline-paclitaxel regimen OR a maximum of 6 cycles of pertuzumab plus trastuzumab only if given with combination of docetaxel and carboplatin chemotherapy OR a maximum of 4 cycles of pertuzumab plus trastuzumab if given with the first 4 cycles of chemotherapy in either arm of the NIHR-approved ROSCO neoadjuvant trial OR a maximum of 6 cycles (minimum of 4) of pertuzumab plus trastuzumab with non-anthracycline taxane containing chemotherapy as part of the NIHR-approved HER2 RADiCAL trial of tailored treatment for HER2 positive early breast cancer.<br>Please indicate below the maximum number of cycles of pertuzumab it is planned for the patient to receive:<br>- 4 cycles OR<br>- 6 cycles OR<br>- Patient enrolled on the ROSCO neoadjuvant trial (4 cycles) OR<br>- Patient is a potential participant in on the HER2 RADICAL neoadjuvant trial (4-6 cycles)<br>It is acknowledged that in patients who are node positive and whose blood counts have not recovered post neoadjuvant chemotherapy and there is a consequent delay to surgery, such patients may receive additional cycles of pertuzumab plus trastuzumab pre-surgery in order to ensure there is no break in anti-HER2 therapy. It is also acknowledged that such patients may continue with pertuzumab plus trastuzumab after surgery pending determination of status as to pathological complete remission or not. | | | | |
| | | | 9. Treatment will be given using either intravenous pertuzumab and intravenous biosimilar trastuzumab or using the PHESGO® brand combination pertuzumab and trastuzumab subcutaneous injection.<br>Please mark as to which mode of administration is to be used:<br>- Intravenous pertuzumab and intravenous best value biosimilar trastuzumab or<br>- PHESGO® subcutaneous pertuzumab and trastuzumab combination injection | | | | |
| | | | 9. The prescribing clinician understands the differing dosages to be used for the different formulations of pertuzumab and trastuzumab in relation to the first (loading) cycle and then in subsequent cycles:<br>•**Intravenous** pertuzumab is given at an initial loading dose 840mg followed every 3 weeks thereafter by a maintenance dose of 420mg.<br>•**Intravenous** trastuzumab is given as an initial loading dose of 8 mg/kg body weight followed every 3 weeks thereafter by a maintenance dose of 6 mg/kg body weight<br>•**Subcutaneous** PHESGO® is given at an initial loading dose of 1,200mg pertuzumab and 600mg trastuzumab in 15 mL of solution in a single-dose vial followed every 3 weeks thereafter by a maintenance dose of 600mg pertuzumab and 600mg trastuzumab in a 10 mL of solution in a single-dose vial. | | | | |
| | | | 11. Pertuzumab or PHESGO® will be otherwise used as set out in their respective Summary of Product Characteristics (SPCs). | | | | |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| PER2b | **Pertuzumab** | Neoadjuvant pertuzumab plus trastuzumab in patients who are NODE NEGATIVE or of UNKNOWN NODAL STATUS for the neoadjuvant treatment of locally advanced, inflammatory or early breast cancer at high risk of recurrence (**PER2b**) where the following criteria have been met:<br><br>This form (introduced November 2019) is for patients who are node negative or of unknown nodal status prior to commencing neo-adjuvant therapy. If a biopsy post-surgery shows that the patients are found to be node positive, then for them to commence adjuvant treatment with pertuzumab and trastuzumab, form PER4b must be completed.<br><br>For patients with locally advanced, inflammatory or early breast cancer who are node positive when commencing neo-adjuvant chemotherapy in combination with pertuzumab and trastuzumab, form PER2a must be used followed by form PER4b when commencing adjuvant treatment with pertuzumab and trastuzumab | 1. An application has been made by and the first cycle of systemic anti -cancer therapy with pertuzumab (in combination with chemotherapy and trastuzumab) will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>**NOTE: This application should be made immediately prior to commencing pertuzumab plus trastuzumab when given with single agent docetaxel/paclitaxel chemotherapy as part of sequential anthracycline/taxane regimen and not at the start of the anthracycline based component.**<br><br>2. Treatment is being initiated with neoadjuvant intent<br><br>3. The patient has newly diagnosed locally advanced, inflammatory or early breast cancer at high risk of recurrence (i.e. must have stage T2-T4b and M0 disease) and is either node negative or is of unknown nodal status prior to surgery.<br><br>4. The patient has HER2 3+ by IHC or FISH/CISH positive disease<br><br>5. The patient has a baseline LVEF greater than or equal to 55% or if anthracyclines were given that the LVEF was greater than or equal to 50% after completion of the anthracycline component of the neo-adjuvant chemotherapy.<br><br>6. The patient has received no prior treatment with chemotherapy or HER2 therapy for this breast cancer<br><br>7. Pertuzumab plus trastuzumab will be given in combination with docetaxel/paclitaxel-containing chemotherapy. The exceptions to this are for patients enrolled in the NIHR-approved ROSCO trial (UKCRN Study ID:19069 where neoadjuvant pertuzumab can be given with chemotherapy in either arm of the study) or potential participants in the NIHR-approved HER2 RADiCAL trial (UKCRN Study ID131362 where paclitaxel/nab-paclitaxel/docetaxel may be used).<br>Please indicate below if the patient is enrolled in the NIHR-approved ROSCO neoadjuvant trial:<br>- Patient NOT enrolled/eligible for either of the ROSCO or HER2 RADiCAL trials<br>- Patient enrolled in the ROSCO neoadjuvant trial<br>- Patient is a potential participant in the HER2 RADiCAL trial of tailored treatment for HER2 +ve early breast cancer<br><br>8. The patient will receive a maximum of 4 cycles of pertuzumab plus trastuzumab if given with single agent docetaxel chemotherapy as part of sequential anthracycline/docetaxel regimen OR 4 cycles of pertuzumab plus trastuzumab if given with weekly paclitaxel chemotherapy as part of sequential anthracycline-paclitaxel regimen OR a maximum of 6 cycles of pertuzumab plus trastuzumab only if given with combination of docetaxel and carboplatin chemotherapy OR a maximum of 4 cycles of pertuzumab plus trastuzumab if given with the first 4 cycles of chemotherapy in either arm of the NIHR-approved ROSCO neoadjuvant trial OR a maximum of 6 cycles (minimum of 4) of pertuzumab plus trastuzumab with non-anthracycline taxane containing chemotherapy as part of the NIHR-approved HER2 RADiCAL trial of tailored treatment for HER2 positive early breast cancer.<br>Please indicate below the maximum number of cycles of pertuzumab it is planned for the patient to receive:<br>- 4 cycles OR<br>- 6 cycles OR<br>- Patient enrolled on the ROSCO neoadjuvant trial (4 cycles) OR<br>- Patient is a potential participant in on the HER2 RADICAL neoadjuvant trial (4-6 cycles)<br><br>It is acknowledged that in patients whose blood counts have not recovered post neoadjuvant chemotherapy and there is a consequent delay to surgery, such patients may receive additional cycles of pertuzumab plus trastuzumab pre-surgery in order to ensure there is no break in anti-HER2 therapy. It is also acknowledged that such patients may continue with pertuzumab plus trastuzumab after surgery pending determination of status as to axillary nodal involvement or not and pathological complete remission or not.<br><br>9. Treatment will be given using either intravenous pertuzumab and intravenous biosimilar trastuzumab or using the PHESGO® brand combination pertuzumab and trastuzumab subcutaneous injection.<br>Please mark as to which mode of administration is to be used:<br>- Intravenous pertuzumab and intravenous best value biosimilar trastuzumab **or**<br>- PHESGO® subcutaneous pertuzumab and trastuzumab combination injection<br><br>10. The prescribing clinician understands the differing dosages to be used for the different formulations of pertuzumab and trastuzumab in relation to the first (loading) cycle and then in subsequent cycles:<br>•**Intravenous** pertuzumab is given at an initial loading dose 840mg followed every 3 weeks thereafter by a maintenance dose of 420mg.<br>•**Intravenous** trastuzumab is given as an initial loading dose of 8 mg/kg body weight followed every 3 weeks thereafter by a maintenance dose of 6 mg/kg body weight<br>•**Subcutaneous** PHESGO® is given at an initial loading dose of 1,200mg pertuzumab and 600mg trastuzumab in 15 mL of solution in a single-dose vial followed every 3 weeks thereafter by a maintenance dose of 600mg pertuzumab and 600mg trastuzumab in a 10 mL of solution in a single-dose vial.<br><br>11. Pertuzumab or PHESGO® will be otherwise used as set out in their respective Summary of Product Characteristics (SPC) | No | TA424 | 21-Dec-16 | 21-Mar-17 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| PER1 | **Pertuzumab** (in combination with trastuzumab and a taxane or capecitabine) | The first line treatment of locally advanced or metastatic breast cancer where all the following criteria are met: | 1. This application for pertuzumab in combination with trastuzumab and a taxane or capecitabine is being made by and the first cycle will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has histologically documented breast cancer which is HER2 3+ by immunohistochemistry and/or has a HER2 ratio of ≥2.0 by in situ hybridisation.<br>3. The patient has been diagnosed with locally advanced or metastatic breast cancer.<br>4. The patient has an ECOG performance status of 0 or 1.<br>5. The patient has a baseline LVEF of greater than or equal to 50%.<br>6. Any adjuvant HER2 therapy was completed more than 12 months prior to the diagnosis of locally advanced or metastatic disease.<br>7. The patient has had no prior treatment with chemotherapy or HER2 therapy for locally advanced or metastatic disease.<br>8. The patient will receive pertuzumab and trastuzumab as first line treatment in combination with a taxane or capecitabine.<br>9. The prescribing clinican understands that pertuzumab and trastuzumab are not to be used beyond first disease progression outside the CNS.<br>Note: Treatment with pertuzumab and trastuzumab can continue if there is disease progression solely within the CNS.<br>10. Treatment will be given using either intravenous pertuzumab and intravenous biosimilar trastuzumab or using the PHESGO® brand combination pertuzumab and trastuzumab subcutaneous injection.<br>Please mark as to which mode of administration is to be used:<br>- Intravenous pertuzumab and intravenous best value biosimilar trastuzumab **or**<br>- PHESGO® subcutaneous pertuzumab and trastuzumab combination injection<br>11. The prescribing clinician understands the differing dosages to be used for the different formulations of pertuzumab and trastuzumab in relation to the first (loading) cycle and then in subsequent cycles:<br>- **Intravenous** pertuzumab is given at an initial loading dose of 840mg followed every 3 weeks thereafter by a maintenance dose of 420mg.<br>- **Intravenous** trastuzumab is given as an initial loading dose of 8 mg/kg body weight followed every 3 weeks thereafter by a maintenance dose of 6 mg/kg body weight<br>- **Subcutaneous** PHESGO® is given at an initial loading dose of 1,200mg pertuzumab and 600mg trastuzumab in 15 mL of solution in a single-dose vial followed every 3 weeks thereafter by a maintenance dose of 600mg pertuzumab and 600mg trastuzumab in a 10 mL of solution in a single-dose vial.<br>12. When a treatment break of more than 6 weeks beyond the expected cycle length is needed, I will complete a treatment break form to restart treatment.<br>13. Pertuzumab or PHESGO® will be otherwise used as set out in their respective Summary of Product Characteristics (SPC) | Yes | TA509 | 07-Mar-18 | 05-Jun-18 |
| PER3 | **Pertuzumab** | Pertuzumab in combination with trastuzumab and chemotherapy as adjuvant therapy for axillary node positive HER2-positive early breast cancer and with NO preceding neoadjuvant chemotherapy in combination with pertuzumab and trastuzumab (**PER3**) where the following criteria have been met:<br>Note: there is a separate form PER4a for adjuvant pertuzumab for node positive patients who received neoadjuvant chemotherapy in combination with pertuzumab and trastuzumab and who continue on to adjuvant treatment after surgery.<br>For patients who were node negative or of unknown nodal status when commencing neo-adjuvant chemotherapy in combination with pertuzumab and trastuzumab and in whom surgery has demonstrated node positive disease, form PER4b must be used for adjuvant pertuzumab. | 1. This application for pertuzumab in combination with trastuzumab as part of adjuvant systemic therapy is made by and the first cycle of adjuvant pertuzumab and trastuzumab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has histologically documented breast cancer which is HER2 3+ by immunohistochemistry and/or has a ratio of ≥2.0 by in situ hybridisation.<br>3. The patient has been diagnosed with early breast cancer and this has been adequately excised.<br>4. The patient has pathologically confirmed axillary lymph node involvement.<br>Pertuzumab in combination with trastuzumab as adjuvant treatment is only NICE-recommended and commissioned in patients with pathologically documented axillary lymph node involvement.<br>5. The patient is due to commence adjuvant chemotherapy in combination with pertuzumab and trastuzumab and will receive one of the standard adjuvant anthracycline- and/or taxane-based chemotherapy regimens as set out in section 4.2 and 5.1 of pertuzumab's Summary of Product Characteristics. Please mark as to which regimen is to be used:<br>- 3-4 cycles of FEC or FAC followed by 3-4 cycles of docetaxel or 12 cycles of weekly paclitaxel or<br>- 3-4 cycles of AC or EC followed by 3-4 cycles of docetaxel or 12 cycles of weekly paclitaxel or<br>- 6 cycles of docetaxel and carboplatin<br>Pertuzumab and trastuzumab should start following completion of the entire anthracycline regimen if given. Pertuzumab and trastuzumab should commence with the first taxane cycle. Pertuzumab and trastuzumab are not commissioned in combination with other adjuvant chemotherapy regimens.<br>If a patient has a severe allergic reaction to the docetaxel part of the treatment combination, the patient can be switched to a trial of weekly paclitaxel.<br>6. A maximum of 18 cycles of pertuzumab plus trastuzumab will be administered as adjuvant treatment.<br>7. Treatment will be given using either intravenous pertuzumab and intravenous biosimilar trastuzumab or using the PHESGO® brand combination pertuzumab and trastuzumab subcutaneous injection.<br>Please mark as to which mode of administration is to be used:<br>- Intravenous pertuzumab and intravenous best value biosimilar trastuzumab **or**<br>- PHESGO® subcutaneous pertuzumab and trastuzumab combination injection<br>8. The prescribing clinician understands the differing dosages to be used for the different formulations of pertuzumab and trastuzumab in relation to the first (loading) cycle and then in subsequent cycles:<br>- **Intravenous** pertuzumab is given at an initial loading dose of 840mg followed every 3 weeks thereafter by a maintenance dose of 420mg.<br>- **Intravenous** trastuzumab is given as an initial loading dose of 8 mg/kg body weight followed every 3 weeks thereafter by a maintenance dose of 6 mg/kg body weight<br>- **Subcutaneous** PHESGO® is given at an initial loading dose of 1,200mg pertuzumab and 600mg trastuzumab in 15 mL of solution in a single-dose vial followed every 3 weeks thereafter by a maintenance dose of 600mg pertuzumab and 600mg trastuzumab in a 10 mL of solution in a single-dose vial.<br>9. The patient has an ECOG performance status of 0 or 1.<br>10. The pre-treatment left ventricular ejection fraction was ≥55% and if anthracyclines were given that the LVEF was ≥50% after completion of the anthracycline component of the adjuvant chemotherapy.<br>11. When a treatment break of more than 6 weeks beyond the expected cycle length is needed, I will complete a treatment break form to restart treatment, including an indication as appropriate if the patient had an extended break because of COVID 19.<br>12. Pertuzumab or PHESGO® will be otherwise used as set out in their respective Summary of Product Characteristics (SPC) | No | TA569 | 20-Mar-19 | 18-Jun-19 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| PER4a | **Pertuzumab** | Pertuzumab in combination with trastuzumab as adjuvant therapy for patients with HER2-positive early breast cancer which was diagnosed as being NODE POSITIVE prior to neoadjuvant treatment and has now completed neoadjuvant pertuzumab in combination with trastuzumab and chemotherapy and surgery (**PER4a**) where the following criteria have been met:<br><br>These patients must have had form PER2a completed for the neoadjuvant portion of their therapy.<br><br>For patients who were node negative or of unknown nodal status prior to commencing neo-adjuvant therapy, form PER2b (neoadjuvant portion) should have been completed and form PER4b is for adjuvant pertuzumab in such PER2b patients who are found to be node positive after surgery.<br><br>For node positive patients who did not receive neo-adjuvant chemotherapy with pertuzumab, form PER3 should be used for adjuvant treatment of pertuzumab + trastuzumab. | 1. This application for pertuzumab in combination with trastuzumab as part of adjuvant chemotherapy is made by and the first cycle of adjuvant pertuzumab and trastuzumab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has histologically documented breast cancer which is HER2 3+ by immunohistochemistry and/or has a ratio of ≥2.0 by in situ hybridisation.<br>3. The patient has been diagnosed with early breast cancer and this has been adequately excised.<br>4. The patient has received neoadjuvant chemotherapy in combination with pertuzumab and trastuzumab and has not had disease progression. Please indicate below whether or not the patient achieved a pathological complete response in terms of the invasive carcinoma to neoadjuvant chemotherapy in combination with pertuzumab and trastuzumab:<br>- pathological complete response in breast and axillary nodes after neoadjuvant chemotherapy in combination with pertuzumab and trastuzumab or<br>- residual invasive disease remaining in breast and/or axillary nodes after neoadjuvant chemotherapy in combination with pertuzumab and trastuzumab<br>- unknown (patient started on adjuvant pertuzumab plus trastuzumab post-surgery as they were known to be node positive before the pathology results were available to confirm the status as to pathological complete remission)<br>5. The patient had confirmed node positive disease prior to neo-adjuvant treatment and surgery<br>6. A maximum of 18 cycles of pertuzumab plus trastuzumab will be administered during the whole treatment period of neoadjuvant and adjuvant treatments added together e.g. if 4 cycles of neoadjuvant pertuzumab and trastuzumab are given in combination with neoadjuvant chemotherapy, then a maximum of 14 cycles of adjuvant pertuzumab and trastuzumab will be subsequently administered.<br><br>It is acknowledged that patients may be started on adjuvant pertuzumab plus trastuzumab post-surgery as they were known to be node positive and before the pathology results have confirmed the status as to pathological complete remission.<br>A maximum of 18 cycles of HER2-directed therapy (neoadjuvant plus adjuvant) are funded provided all other criteria are met.<br>7. Treatment will be given using either intravenous pertuzumab and intravenous biosimilar trastuzumab or using the PHESGO® brand combination pertuzumab and trastuzumab subcutaneous injection.<br>Please mark as to which mode of administration is to be used:<br>- Intravenous pertuzumab and intravenous best value biosimilar trastuzumab **or**<br>- PHESGO® subcutaneous pertuzumab and trastuzumab combination injection<br>8. The prescribing clinician understands the differing dosages to be used for the different formulations of pertuzumab and trastuzumab in relation to the first (loading) cycle and then in subsequent cycles:<br>- **Intravenous** pertuzumab is given at an initial loading dose of 840mg followed every 3 weeks thereafter by a maintenance dose of 420mg.<br>- **Intravenous** trastuzumab is given as an initial loading dose of 8 mg/kg body weight followed every 3 weeks thereafter by a maintenance dose of 6 mg/kg body weight<br>- **Subcutaneous** PHESGO® is given at an initial loading dose of 1,200mg pertuzumab and 600mg trastuzumab in 15 mL of solution in a single-dose vial followed every 3 weeks thereafter by a maintenance dose of 600mg pertuzumab and 600mg trastuzumab in a 10 mL of solution in a single-dose vial.<br>9. The patient has an ECOG performance status of 0 or 1.<br>10. The left ventricular ejection fraction prior to commencing adjuvant cycles of pertuzumab plus trastuzumab remains ≥50%.<br>11. When a treatment break of more than 6 weeks beyond the expected cycle length is needed, I will complete a treatment break form to restart treatment, including an indication as appropriate if the patient had an extended break because of COVID 19.<br>12. Pertuzumab or PHESGO® will be otherwise used as set out in their respective Summary of Product Characteristics (SPC) | No | TA569 | 20-Mar-19 | 18-Jun-19 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| PER4b | **Pertuzumab** | Pertuzumab in combination with trastuzumab as adjuvant therapy for HER2-positive early breast cancer patients thought to be node negative or of unknown nodal status prior to neoadjuvant chemotherapy and found to be axillary node positive AFTER completion of neoadjuvant pertuzumab/trastuzumab and surgery (**PER4b**) where the following criteria have been met:<br><br>These patients must have completed form PER2b for the neoadjuvant portion of their therapy.<br><br>PER2b patients (node negative or of unknown nodal status prior to neoadjuvant chemotherapy) who are node negative after surgery cannot have adjuvant pertuzumab as NICE has only recommended adjuvant pertuzumab in patients who are node positive.<br><br>For patients known to be node positive prior to commencing neoadjuvant therapy, forms PER2a (neoadjuvant portion of treatment) and PER4a (adjuvant portion of treatment) must be used.<br><br>For node positive patients who did not receive neoadjuvant chemotherapy, applications for adjuvant pertuzumab should proceed directly to adjuvant treatment in combination with pertuzumab and trastuzumab (form PER3). | 1. This application for pertuzumab in combination with trastuzumab as part of adjuvant chemotherapy is made by and the first cycle of adjuvant pertuzumab and trastzumab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has histologically documented breast cancer which is HER2 3+ by immunohistochemistry and/or has a ratio of ≥2.0 by in situ hybridisation.<br>3. The patient has been diagnosed with early breast cancer and this has been adequately excised.<br>4. The patient has received neoadjuvant chemotherapy in combination with pertuzumab and trastuzumab and has not had disease progression. Please confirm below the pathological status after neoadjuvant chemotherapy in combination with pertuzumab and trastuzumab:<br>- pathological complete response in breast and axillary nodes after neoadjuvant chemotherapy in combination with pertuzumab and trastuzumab or<br>- pathological complete response in the breast but not in the axillary nodes after neoadjuvant chemotherapy in combination with pertuzumab and trastuzumab or<br>- residual invasive disease remaining in both breast and axillary nodes after neoadjuvant chemotherapy in combination with pertuzumab and trastuzumab<br>5. One of the following scenarios applies to this patient in order to conclude that the patient had documented axillary lymph node involvement and is now eligible to receive pertuzumab in addition to trastuzumab.<br>- the patient was concluded to be node negative or of unknown nodal status prior to neoadjuvant treatment and definitive surgery has since found residual invasive carcinoma in the axillary node(s) **or**<br>- was concluded to be node negative or of unknown nodal status prior to neoadjuvant treatment and definitive surgery has since found an absence of invasive carcinoma in the axillary nodes but there are histological changes (such as fibrosis) which the pathologist has interpreted as representing previous axillary nodal involvement<br>6. A maximum of 18 cycles of pertuzumab plus trastuzumab will be administered during the whole treatment period of neoadjuvant and adjuvant treatments added together e.g. if 4 cycles of neoadjuvant pertuzumab and trastuzumab are given in combination with neoadjuvant chemotherapy, then a maximum of 14 cycles of adjuvant pertuzumab and trastuzumab will be subsequently administered.<br><br>It is acknowledged that patients may have received an additonal cycle of adjuvant pertuzumab and trastuzumab post-surgery (see form PER2b, question 8).<br>A maximum of 18 cycles of HER2-directed therapy (neoadjuvant plus adjuvant) are funded provided all other criteria are met.<br>7. Treatment will be given using either intravenous pertuzumab and intravenous biosimilar trastuzumab or using the PHESGO® brand combination pertuzumab and trastuzumab subcutaneous injection.<br>Please mark as to which mode of administration is to be used:<br>- Intravenous pertuzumab and intravenous best value biosimilar trastuzumab **or**<br>- PHESGO® subcutaneous pertuzumab and trastuzumab combination injection<br>8. The prescribing clinician understands the differing dosages to be used for the different formulations of pertuzumab and trastuzumab in relation to the first (loading) cycle and then in subsequent cycles:<br>- **Intravenous** pertuzumab is given at an initial loading dose of 840mg followed every 3 weeks thereafter by a maintenance dose of 420mg.<br>- **Intravenous** trastuzumab is given as an initial loading dose of 8 mg/kg body weight followed every 3 weeks thereafter by a maintenance dose of 6 mg/kg body weight<br>- **Subcutaneous** PHESGO® is given at an initial loading dose of 1,200mg pertuzumab and 600mg trastuzumab in 15 mL of solution in a single-dose vial followed every 3 weeks thereafter by a maintenance dose of 600mg pertuzumab and 600mg trastuzumab in a 10 mL of solution in a single-dose vial.<br>9. The patient has an ECOG performance status of 0 or 1.<br>10. The left ventricular ejection fraction prior to commencing adjuvant cycles of pertuzumab plus trastuzumab remains ≥50%.<br>11. When a treatment break of more than 6 weeks beyond the expected cycle length is needed, I will complete a treatment break form to restart treatment, including an indication as appropriate if the patient had an extended break because of COVID 19.<br>12. Pertuzumab or PHESGO® will be otherwise used as set out in their respective Summary of Product Characteristics (SPC) | No | TA569 | 20-Mar-19 | 18-Jun-19 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| POL1 | **Polatuzumab vedotin** in combination with bendamustine and rituximab | For previously treated patients with relapsed or refractory diffuse large B-cell lymphoma and who are not candidates for haematopoietic stem cell transplantation where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with polatuzumab vedotin in combination with bendamustine and rituximab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient is either an adult (age >=18 years) or a post-pubescent child (age <18 years).<br>Please mark below whether the patient is an adult or a post-pubescent child:<br>- the patient is an adult OR<br>- the patient is a post-pubescent child*<br>*Please note the use of polatuzumab vedotin in combination with bendamustine and rituximab is unlicensed in under 18 year old patients so the Trust policy regarding the use of unlicensed medicines should be followed.<br>3. The patient has a histologically confirmed diagnosis of diffuse large B cell lymphoma (DLBCL). This includes the following:<br>- DLBCL not otherwise specified (NOS) (including germinal centre B-cell (GCB)and activated B-cell (ABC) subtypes)<br>- primary mediastinal large B cell lymphoma<br>- T cell rich B cell lymphoma<br>- Epstein-Barr virus (EBV) positive DLBCL<br>- intravascular large B cell lymphoma<br>- double hit and triple hit high grade B cell lymphoma.<br>Note: Primary CNS lymphoma, Burkitt lymphoma and plasmablastic lymphoma are NOT included for treatment with polatuzumab.<br>4. The patient has DLBCL which has either relapsed following or is refractory to standard routinely commissioned DLBCL chemotherapies. Please record in the box below which of the following best applies to this patient now:<br>- has only received 1st line DLBCL chemotherapy (R-CHOP or similar), responded to it but has now relapsed OR<br>- has only received 1st line DLBCL chemotherapy (R-CHOP or similar) and is refractory to it OR<br>- has received 2nd (or greater) line of chemotherapy (e.g. R-ICE, R-IVE, R-IGEV, R-GDP, R-GDCarbo, R-ESHAP, R- DHAP or R-GemOx), responded to it but has now relapsed OR<br>- has received 2nd (or greater) line of chemotherapy (e.g. R-ICE, R-IVE, R-IGEV, R-GDP, R-GDCarbo, R-ESHAP, R- DHAP or R-GemOx) and is either refractory to it or had insufficient response to merit consideration of stem cell transplantation (SCT) OR<br>- has relapsed/refractory disease after a previous autologous SCT OR<br>- has relapsed/refractory disease after a previous allogeneic SCT OR<br>- has relapsed/refractory disease after a previous CAR-T therapy<br>- has relapsed/refractory disease and the patient has been formally accepted by the National CAR-T cell Clinical Panel for CAR-T therapy and polatuzumab combination therapy is being used as bridging therapy before CAR-T treatment<br>5. The patient is not a candidate for future haemopoietic stem cell transplantation either as set out in formal local/regional lymphoma network guidelines or after discussion at a lymphoma multidisciplinary meeting which incorporates SCT centre representation. Please record in the box below which of the following best applies to this patient:<br>- not a candidate for SCT on account of fitness OR<br>- not a candidate for SCT on account of comorbidities OR<br>- not a candidate for SCT on account of inadequate response to salvage chemotherapy OR<br>- has relapsed after SCT<br>Note: it is expected that patients with relapsed/refractory disease after standard chemotherapy and who are fit for SCT will proceed to standard salvage chemotherapy and consideration of SCT<br>6. The patient has not been previously treated with polatuzumab vedotin or the patient has been previously treated with polatuzumab vedotin in which case the patient responded to polatuzumab vedotin as a bridging therapy to CAR-T cell therapy and has relapsed following CAR-T cell therapy or if continuing previous treatment with polatuzumab vedotin, this was either within the polatuzumab EAMS scheme and all other criteria in this form are fulfilled or within the Interim SACT treatment options allowed for polatuzumab as bridging therapy to CAR-T therapy during the Covid-19 pandemic and all other criteria in this form are fulfilled.<br>Please record in the box below which of the following applies to this patient:<br>- no previous treatment with polatuzumab vedotin OR<br>- the patient received and responded to bridging treatment with polatuzumab prior to CAR-T therapy, received the CAR-T cell therapy and has relapsed following the CAR-T therapy OR<br>- continuation of previous treatment with polatuzumab within the EAMS scheme for the use of the combination of polatuzumab, bendamustine and rituximab OR<br>- continuation of previous treatment with polatuzumab within the interim SACT change options allowed for polatuzumab as bridging treatment prior to CAR-T therapy during the Covid-19 pandemic<br>7. Treatment with polatuzumab vedotin will be used in combination only with bendamustine and the intravenous formulation of rituximab.<br>8. Either the patient has not been previously treated with bendamustine for DLBCL or if the patient has been treated previously with bendamustine for DLBCL, this application is to continue a previous registration for the polatuzumab EAMS scheme or the interim polatuzumab Covid-19 access or the patient received bendamustine as part of combination treatment with polatuzumab for bridging therapy to CAR-T cell treatment or if treated with bendamustine outside either of these three options, then the response duration to that course of treatment with bendamustine for DLBCL exceeded 1 year.<br>9. The patient has an ECOG performance status score of 0 or 1 or 2.<br>10. The patient will be treated with a maximum of six 3-weekly cycles of polatuzumab vedotin in combination with bendamustine and rituximab.<br>11. The prescribing clinician understands that the use of bendamustine in this DLBCL indication is unlicensed and that Trust policy regarding the use unlicensed treatments has been followed.<br>12. The prescribing clinician is fully aware of the MHRA warning in July 2017 that increased mortality has been observed in recent clinical studies in off-label use of bendamustine and that patients need to be monitored for opportunistic infection and hepatitis B reactivation.<br>13. A formal medical review as to whether treatment with polatuzumab in combination with bendamustine plus rituximab should continue or not will be scheduled to occur at least by the end of the first 6 weeks of treatment.<br>14. When a treatment break of more than 6 weeks beyond the expected 3-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment, including as appropriate if the patient had an extended break on account of Covid-19.<br>15. Polatuzumab vedotin, bendamustine and rituximab will otherwise be used as set out in their respective Summary of Product Characteristics SPCs). | No | TA649 | 23-Sep-20 | 23-Oct-20 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| POL2_v1.2 | **Polatuzumab vedotin** in combination with rituximab, cyclophosphamide, doxorubicin and prednisolone | For people with previously untreated diffuse large B-cell lymphoma where the following criteria have been met: | 1. This application is being made by and also the first cycle of systemic anti-cancer therapy with polatuzumab vedotin in combination with rituximab, cyclophosphamide, doxorubicin and prednisolone will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br><br>2. The patient is either an adult (age 18 years or over) or a post-pubescent child (age <18 years).<br>Please mark below whether the patient is an adult or a post-pubescent child:<br>- the patient is an adult OR<br>- the patient is a post-pubescent child*<br>***Please note that the use of polatuzumab vedotin in combination with rituximab, cyclophosphamide, doxorubicin and prednisolone is unlicensed in patients who are under 18 years old and so the Trust policy regarding the use of unlicensed medicines should be followed.**<br><br>3. The patient has a histologically confirmed diagnosis of CD20 positive diffuse large B cell lymphoma (DLBCL) or CD20 positive follicular lymphoma grade 3B.<br><br>Please mark below which of the two options applies:<br>- the patient has CD20 positive DLBCL (which includes the types listed below) OR<br>- the patient has CD20 positive follicular lymphoma grade 3B and as polatuzumab is unlicensed in this subtype of lymphoma, I confirm that the Trust policy regarding the use of unlicensed medicines will be followed<br><br>Types of DLBCL:<br>- DLBCL not otherwise specified (NOS) [including germinal centre B-cell (GCB) and activated B-cell (ABC) subtypes]<br>- T cell rich B cell lymphoma<br>- Epstein-Barr virus (EBV) positive DLBCL<br>- intravascular large B cell lymphoma<br>- double hit and triple hit high grade B cell lymphoma<br>- ALK positive large B cell lymphoma<br>- HHV8 positive DLBCL<br>- transformation of CLL to DLBCL (Richter's transformation)<br>- transformation of follicular lymphoma to DLBCL<br>- transformation of marginal zone lymphoma to DLBCL<br>- transformation of nodular lymphocyte predominant Hodgkin lymphoma to DLBCL<br>- post transplant lymphoproliferative disorder of DLBCL type<br><br>Note: Primary CNS lymphoma, primary cutaneous DLBCL, primary effusion lymphoma, primary mediastinal B cell lymphoma, Burkitt lymphoma and plasmablastic lymphoma are NOT included for treatment with this first line polatuzumab combination.<br><br>4. The International Prognostic Index (IPI) score for this patient is between 2 and 5.<br>Please record in the box below the IPI score for this patient:<br>- 2<br>- 3<br>- 4<br>- 5<br>The IPI scores 1 for each of the following: Ann Arbor stage III or IV; age >60 years; LDH >1 x ULN; ECOG PS of 2 or more; extranodal involvement at 2 or more sites.<br>Note: the use of polatuzumab vedotin in patients with an IPI score of 1 is NOT allowed. This is because the NICE positive recommendation is only for patients with an IPI score of 2 or more.<br><br>5. This patient does not have any known CNS involvement by the lymphoma.<br><br>6. The patient has an ECOG performance status score of 0 or 1 or 2.<br><br>7. The patient has DLBCL or follicular lymphoma grade 3b either of which is previously untreated with any anthracycline-containing combination chemotherapy.<br><br>8. The patient has either not been previously treated with polatuzumab vedotin or the patient was treated with polatuzumab vedotin in combination with rituximab, cyclophosphamide, doxorubicin and prednisolone as 1st line therapy for DLBCL via a company early access scheme and all other criteria in this form are fulfilled.<br>Please record in the box below which of the following applies to this patient:<br>- no previous treatment with polatuzumab vedotin ***OR***<br>- continuation of previous treatment with polatuzumab within the company early access scheme for the use of the combination of polatuzumab, rituximab, cyclophosphamide and prednisolone for the 1st line treatment of DLBCL and all other criteria in this form are fulfilled<br><br>9. Treatment with polatuzumab vedotin will be used in combination only with rituximab, cyclophosphamide, doxorubicin and prednisolone and that the intent from the start of treatment is to use standard ('full') doses of all these agents.<br><br>10. The patient will be treated with a maximum of six 3-weekly cycles of polatuzumab vedotin in combination with rituximab, cyclophosphamide, doxorubicin and prednisolone.<br><br>11. A formal medical review as to whether treatment with polatuzumab in combination with rituximab, cyclophosphamide, doxorubicin and prednisolone should continue or not will be scheduled to occur at least by the end of the second cycle of treatment.<br><br>12. When a treatment break of more than 6 weeks beyond the expected 3-weekly cycle length is needed, a treatment break approval form will be completed to restart treatment.<br><br>13. Polatuzumab vedotin, rituximab, cyclophosphamide, doxorubicin and prednisolone will otherwise be used as set out in their respective Summary of Product Characteristics (SPCs). | No | TA874 | 01-Mar-23 | 30-May-23 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| POM1 | **Pomalidomide** | Pomalidomide for multiple myeloma previously treated with lenalidomide and bortezomib | 1. This application for pomalidomide has been made by and the first cycle of systemic anti-cancer therapy with pomalidomide will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy<br>2. The patient has multiple myeloma<br>3. The patient's performance status (PS) is 0-2<br>4. The patient has previously received 3 lines of treatment with adequate trials of at least all of the following options of therapy: a routinely commissioned or CDF-funded proteasome inhibitor (bortezomib/carfilzomib/ixazomib), lenalidomide and alkylating agents<br>5. The patient has refractory disease to the previous line of treatment<br>6. The patient has not received any prior treatment with pomalidomide either as monotherapy or within combination therapy<br>7. Pomalidomide will be used as outlined in the Summary of Product Characteristics (SPC) | No | TA427 | 11-Jan-17 | 11-Apr-17 |
| PON1 | **Ponatinib** | The treatment of Philadelphia chromosome positive acute lymphoblastic leukaemia where all the following criteria are met: | 1. An application has been made by and the first cycle of systemic anti-cancer therapy is to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy<br>2. The patient has Philadelphia chromosome positive acute lymphoblastic leukaemia<br>3. Imatinib is not clinically appropriate for the patient or the T315I gene mutation is present | Yes | TA451 | 13-Feb-17 | 26-Sep-17 |
| PON6 | **Ponatinib** | The treatment of chronic phase, accelerated phase or blast phase chronic myeloid leukaemia where all the following criteria are met: | 1. An application has been made by and the first cycle of systemic anti-cancer therapy is to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy<br>2. The patient has chronic phase, accelerated phase or blast phase chronic myeloid leukaemia<br>3. The disease is resistant to dasatinib or nilotinib, or the patient cannot have dasatinib nor nilotinib and imatinib is not clinically appropriate, or the T315I gene mutation is present | Yes | TA451 | 13-Feb-17 | 26-Sep-17 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| QUIZ1 | **Quizartinib** | For the treatment of adult patients for treating newly diagnosed FLT3-ITD mutation positive acute myeloid leukaemia where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with quizartinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. This patient is an adult and has a confirmed diagnosis of acute myeloid leukaemia.<br>3. The patient's AML FLT3-ITD mutation as determined by a validated test.<br><br>Note: quizartinib is not commissioned for use in patients with AML bearing a FLT3-TKD mutation.<br>4. The patient is newly diagnosed with FLT3-ITD positive acute myeloid leukaemia and either has not received any induction chemotherapy or has only received a single cycle of induction chemotherapy whilst awaiting FLT3 status.<br><br>Please record the status as to induction chemotherapy:<br>- the patient has not yet received any induction chemotherapy or<br>- the patient has received only a single cycle of induction chemotherapy whilst awaiting the FLT3 result<br>5. The patient is fit for intensive induction chemotherapy.<br>6. The patient will be treated with quizartinib only in combination with standard anthracycline and cytarabine induction chemotherapy and then in combination with high dose cytarabine consolidation chemotherapy.<br><br>Quizartinib is excluded from the NHS England Treatment Breaks Policy.<br>7. As maintenance monotherapy, quizartinib is to be only used in patients in complete remission of their AML.<br>8. In the maintenance monotherapy phase, a maximum of 36 x 28-day cycles of quizartinib will be used.<br>9. If the patient has undergone a stem cell transplant, maintenance quizartinib can be re-started subject to the maximum total maintenance treatment duration of 36 x 28 day cycles.<br>10. In view of the potential QT interval prolongation by quizartinib, the patient will have ECGs performed in accordance with the quizartinib SPC: pre-treatment, once weekly during induction and consolidation chemotherapy, once weekly during the 1st month of maintenance quizartinib and more frequently as required.<br>11. In prescribing the quizartinib dosaging as described in the quizartinib SPC, the potential drug interactions with CYP3A inhibitors and inducers have been taken into account, in particular the need for the quizartinib dose to be reduced when the patient is also receiving strong CYP3A inhibitors such as posoconazole and voriconazole (see sections of 4.2 and 4.5 and Table 3 of the SPC).<br>12. Quizartinib is to be otherwise used as set out in its Summary of Product Characteristics | No | TA1013 | 23-Oct-24 | 21-Jan-25 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| N/A | **Radium-223** | Radium-223 dichloride for treating hormone-relapsed prostate cancer with bone metastases | 1. This application has been made by and the first cycle of systemic anti-cancer therapy with radium-223 will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy<br>2. ONE of the following applies to this patient:<br>- The patient has histologically or cytologically confirmed adenocarcinoma of the prostate and has castration-resistant disease with two or more symptomatic bone metastases detected on skeletal scintigraphy **OR**<br>- The patient had a high clinical suspicion of prostate cancer with a high PSA value (>100ng/ml) at diagnosis and has castration-resistant disease with two or more symptomatic bone metastases detected on skeletal scintigraphy<br>3. The patient has symptomatic bone metastases with either regular use of analgesic medication or treatment with external-beam radiation therapy required for cancer related bone pain within the previous 12 weeks<br>4. The patient has no known visceral metastases and no previous history of visceral spread.<br>5. The patient has no malignant lymphadenopathy that is more than 3cm in diameter<br>6. The patient's Performance Status is 0-2<br>7. The patient has no imminent or established spinal cord compression<br>8. The patient has had no previous hemibody external radiotherapy or systemic radiotherapy with radioisotopes within the previous 24 weeks<br>9. ONE of the following applies to this patient as the amended marketing authorisation for radium-223 now requires patients to be in disease progression after at least 2 prior lines of systemic therapy (other than LHRH analogues) for metastatic castration-resistant prostate cancer or who are ineligible for available systemic therapy options:<br>- The patient has already had prior docetaxel AND either abiraterone or enzalutamide and has disease progression<br>- The patient has already had prior docetaxel and cabazitaxel and has disease progression<br>- Docetaxel is contraindicated or the patient is not suitable for docetaxel AND the patient has already had either abiraterone or enzalutamide and has disease progression<br>- Docetaxel is contra indicated or the patient is not suitable for docetaxel AND both abiraterone and enzalutamide are contraindicated or the patient is not suitable for both abiraterone and enzalutanide<br>- Due to COVID19 the patient is not suitable for docetaxel AND the patient has already had either abiraterone or enzalutamide and has disease progression<br>10. Radium-223 will be used as monotherapy or in combination only with LHRH analogues.<br>Radium-223 must not be taken in combination with abiraterone or enzalutamide or any other systemic therapies except those that maintain reduced levels of male hormones<br>11. Radium-223 will otherwise be used as set out in its Summary of Product Characteristics (SPC)<br>12. No treatment breaks of more than 6 weeks beyond the expected 4-weekly cycle length are allowed (to allow any toxicity of current therapy to settle or intercurrent comorbidities to improve)*<br>*Requests for continuation of treatment after unplanned treatment breaks over this duration should be made via the treatment break approval process | Yes | TA412 | 28-Sep-16 | 28-Dec-16 |
| REG1 | **Regorafenib** | The treatment of previously treated unresectable or metastatic gastrointestinal stromal tumours where all the following criteria are met: | 1. An application has been made by and the first cycle of systemic anti-cancer therapy is to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy<br>2. Patient has histologically confirmed, metastatic or unresectable GIST<br>3. Patient has ECOG performance status (PS) 0-1<br>4. Patient has had disease progression on or intolerance to previous imatinib<br>5. Patient has had disease progression on or intolerance to previous sunitinib<br>6. No treatment breaks of more than 6 weeks beyond the expected cycle length are allowed (to allow any toxicity of current therapy to settle or intercurrent comorbidities to improve)<br>7. Regorafenib to be otherwise used as set out in its Summary of Product Characteristics | Yes | TA488 | 15-Nov-17 | 14-Feb-18 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| REG2_v1.1 | **Regorafenib** | The second line of tyrosine kinase inhibitor systemic therapy of Child-Pugh A locally advanced or metastatic hepatocellular carcinoma previously treated with sorafenib where the following criteria are met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with regorafenib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has been previously treated with sorafenib for locally advanced or metastatic hepatocellular carcinoma.<br>3. The patient currently has Child-Pugh liver function class A.<br>**Note**: NICE has not recommended regorafenib for patients with Child-Pugh liver function class B.<br>4. The prescribing clinician is aware that there is no efficacy and toxicity data for regorafenib in patients previously treated with sorafenib who had to either discontinue sorafenib on account of toxicity or were unable to tolerate total daily doses of sorafenib of 400mg or more.<br>5. The patient has an ECOG performance status of 0 or 1.<br>**Note**: NICE has not recommended regorafenib in patients with an ECOG performance status of ≥2.<br>6. The only other TKI with which the patient has been previously treated is sorafenib unless cabozantinib has had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression.<br>7. The patient has not been previously treated with regorafenib.<br>8. Regorafenib is to be used only as monotherapy.<br>9. Regorafenib is to be continued until loss of clinical benefit or unacceptable toxicity or patient choice to stop treatment, whichever is the sooner.<br>10. A formal medical review as to whether treatment with regorafenib should continue or not will be scheduled to occur no later than by the end of the 2nd month of therapy.<br>11. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, a treatment break form will be completed to restart treatment, including an indication as appropriate if the patient had an extended break because of COVID 19.<br>12. Regorafenib will be otherwise used as set out in its Summary of Product Characteristics. | No | TA555 | 09-Jan-19 | 09-Apr-19 |
| REG3 | **Regorafenib** | For patients with either metastatic or locally advanced and inoperable colorectal cancer who have been previously treated with, or are not considered candidates for, available therapies including fluoropyrimidine-based chemotherapy and anti-EGFR-based treatment where the following criteria have been met: | 1. This application is both being made by and the first cycle of systemic anti-cancer therapy with regorafenib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a histologically confirmed diagnosis of adenocarcinoma of the colon or rectum.<br>3. The patient has metastatic or locally advanced and inoperable disease.<br>4. The patient has been previously treated for metastatic disease with, or is not considered a candidate for, fluoropyrimidine-containing chemotherapies which include 5-fluorouracil and/or capecitabine and/or tegafur but not necessarily trifluridine (plus tipiracil).<br>5. The patient has been previously treated with, or is not considered a candidate for, anti-EGFR-containing chemotherapy.<br>6. If the patient has previously been treated with trifluridine plus tipiracil (with or without bevacizumab) or not.<br>Please tick which option applies to this patient:<br>- yes, the patient has been previously treated with trifluridine plus tipiracil or<br>- no, the patient has not been previously treated with trifluridine plus tipiracil<br>7. If the patient has been previously treated with fruquintinib or not.<br>Please tick which option applies to this patient:<br>- yes, the patient has been previously treated with fruquintinib or<br>- no, the patient has not been previously treated with fruquintinib<br>8. The patient has an ECOG performance status of 0 or 1.<br>9. The patient has not been previously treated with regorafenib.<br>10. Regorafenib is not to be used in combination with any other systemic anti-cancer therapy.<br>11. The prescribing clinician understands that concomitant use of regorafenib with strong CYP3A4 inhibitors and inducers should be avoided and that close monitoring of patients is required of patients on concomitant use of regorafenib and drugs which are BRCP substrates (see section 4.5 of the regorafenib SPC).<br>12. Regorafenib is to be continued until loss of clinical benefit or unacceptable toxicity or patient choice to stop treatment, whichever is the sooner.<br>13. A formal medical review as to whether treatment with regorafenib should continue or not will be scheduled to occur no later than by the end of the 2nd (28-day) cycle of therapy.<br>14. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, the prescribing clinician will complete a treatment break form to restart treatment.<br>15. Regorafenib will be otherwise used as set out in its Summary of Product Characteristics. | No | TA866 | 08-Feb-23 | 09-May-23 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| RIB1_v1.4 | **Ribociclib** (in combination with an aromatase inhibitor) | The treatment of previously untreated, hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer | 1. This application for ribociclib in combination with an aromatase inhibitor is made by and the first cycle of systemic anti-cancer therapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy<br>2. The patient has histologically or cytologically documented oestrogen receptor positive and her-2 negative breast cancer<br>3. The patient has had no prior treatment with a CDK 4/6 inhibitor unless either palbociclib or abemaciclib has had to be stopped within 6 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression or a CDK 4/6 inhibitor has been previously received as adjuvant therapy and treatment was completed without disease progression at least 12 months prior to the first diagnosis of recurrent or metastatic disease.<br><br>Please mark below which one of these 4 scenarios applies to this patient:<br>- no prior treatment with a CDK 4/6 inhibitor or<br>- previous treatment with the 1st line CDK4/6 inhibitor palbociclib but treatment has had to be stopped within 6 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of progressive disease or<br>- previous treatment with the 1st line CDK4/6 inhibitor abemaciclib but treatment has had to be stopped within 6 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of progressive disease or<br>- previously received a CDK4/6 inhibitor with endocrine therapy in the adjuvant setting for high risk early breast cancer either via NHS England commissioned care or via a clinical trial and treatment with the CDK 4/6 inhibitor was completed without disease progression at least 12 months prior to the first diagnosis of recurrent or metastatic disease<br>4. The patient has metastatic breast cancer or locally advanced breast cancer which is not amenable to curative treatment<br>5. The patient is male or is female and if female is either post-menopausal or if pre- or peri-menopausal has undergone ovarian ablation or suppression with LHRH agonist treatment<br>6. The patient has had no previous hormone therapy for locally advanced or metastatic disease i.e. is hormone therapy naïve for locally advanced/metastatic breast cancer.<br><br>**Note:** previous hormone therapy with anastrazole or letrozole whether as adjuvant therapy or as neoadjuvant treatment is allowed as long as the patient has had a disease-free interval of 12 months or more since completing treatment with neoadjuvant or adjuvant anastrazole or letrozole.<br>7. Ribociclib will only be given in combination with an aromatase inhibitor<br>8. The patient has an ECOG performance status of 0 or 1 or 2<br>9. Treatment will continue until there is progressive disease or excessive toxicity or until the patient chooses to discontinue treatment, whichever is the sooner<br>10. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, the prescribing clinician will complete a treatment break approval form to restart treatment.<br>11. Ribociclib will be otherwise used as set out in its Summary of Product Characteristics (SPC) | No | TA496 | 20-Dec-17 | 20-Mar-18 |
| RIB2 | **Ribociclib** in combination with fulvestrant | The treatment of hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer where the following criteria have been met: | 1. This application for ribociclib in combination with fulvestrant is being made by and the first cycle of ribociclib plus fulvestrant will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has histologically or cytologically documented oestrogen receptor positive and HER-2 negative breast cancer.<br>3. The patient has metastatic breast cancer or locally advanced breast cancer which is not amenable to curative treatment.<br>4. The patient is male or is female and if female is either post-menopausal or if pre- or peri-menopausal has undergone ovarian ablation or suppression with LHRH agonist treatment.<br>5. The patient has an ECOG performance status of 0 or 1 or 2.<br>6. The patient has received previous endocrine therapy according to one of the three populations as set out below as these are the groups on which the NICE Technology Appraisal for ribociclib plus fulvestrant focused. Please record which population the patient falls into:<br>- has progressive disease whilst still receiving adjuvant or neoadjuvant endocrine therapy for early breast cancer with no subsequent endocrine therapy received following disease progression or<br>- has progressive disease within 12 or less months of completing adjuvant endocrine therapy for early breast cancer with no subsequent endocrine therapy received following disease progression or<br>- has progressive disease on 1st line endocrine therapy for advanced/metastatic breast cancer with no subsequent endocrine therapy received following disease progression.<br>7. The patient has had no prior treatment with a CDK 4/6 inhibitor unless either abemaciclib (in combination with fulvestrant) or palbociclib (in combination with fulvestrant) has had to be stopped within 6 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression or a CDK 4/6 inhibitor has been previously received as adjuvant therapy and treatment was completed without disease progression at least **12** months prior to the first diagnosis of recurrent or metastatic disease.<br><br>Please mark below which one of these 4 scenarios applies to this patient:<br>- no prior treatment with a CDK 4/6 inhibitor or<br>- previous treatment with the CDK4/6 inhibitor abemaciclib in combination with fulvestrant but treatment has had to be stopped within 6 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of progressive disease or<br>- previous treatment with the CDK4/6 inhibitor palbociclib in combination with fulvestrant but treatment has had to be stopped within 6 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of progressive disease or<br>- previously received a CDK4/6 inhibitor with endocrine therapy in the adjuvant setting for high risk early breast cancer either via NHS England commissioned care or via a clinical trial and treatment with the CDK 4/6 inhibitor was completed without disease progression at least 12 months prior to the first diagnosis of recurrent or metastatic disease<br>8. The patient has had no prior treatment with fulvestrant<br>9. The patient has had no prior treatment with everolimus.<br>10. Ribociclib will only be given in combination with a fulvestrant.<br>11. Treatment will continue until there is progressive disease or excessive toxicity or until the patient chooses to discontinue treatment, whichever is the sooner<br>12. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, the prescribing clinician will complete a treatment break approval form to restart treatment.<br>13. Ribociclib and fulvestrant will be otherwise used as set out in their Summaries of Product Characteristics (SPC) including the need for ECGs to be performed prior to treatment, after 2 weeks of treatment and after 4 weeks of therapy. | No | TA687 | 31-Mar-21 | 29-Jun-21 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| RIB3 | **Ribociclib** in combination with an aromatase inhibitor | Ribociclib in combination with an aromatase inhibitor as adjuvant treatment for high risk hormone receptor-positive and HER2-negative early breast cancer where the following criteria have been met: | 1. This application for ribociclib in combination with an aromatase inhibitor is being made by and the first cycle of ribociclib plus an aromatase inhibitor will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has early breast cancer.<br>3. The patient has histologically or cytologically documented hormone receptor-positive and HER-2 negative breast cancer.<br>4. The patient has high-risk early breast cancer as defined by having one of the following combinations of T and N stage, number of involved axillary nodes, histological grade, Ki67 index or gene signature.<br><br>Please mark in the box below which category describes the disease staging of this patient's breast cancer:<br>- T0 N1 grade 1 or grade 2 disease with 1-3 positive axillary nodes or<br>- T1 N1 grade 1 or grade 2 disease with 1-3 positive axillary nodes or<br>- T2 N0 grade 3 disease or<br>- T2 N0 grade 2 disease which has one of the following: a Ki67 score of ≥20% or an Oncotype DX RS score of ≥26 or a Prosigna PAM50 high risk classification or a MammaPrint high risk classification or an EndoPredict high risk classification or<br>- T2 N1 grade 1 or grade 2 disease with 1-3 positive axillary nodes or<br>- T3 N0 disease of any grade or<br>- T4 N0 disease of any grade or<br>- ≥4 positive axillary lymph nodes or<br>- 1-3 positive axillary lymph nodes and a primary tumour size ≥5cm or<br>- 1-3 positive axillary lymph nodes and histological grade 3 disease or<br>- 1-3 positive axillary lymph nodes and a primary tumour size ≥5cm and histological grade 3 disease<br>5. The patient has completed definitive locoregional therapy (surgery with or without radiotherapy).<br>6. The patient has completed any adjuvant or neoadjuvant chemotherapy.<br><br>Please mark in the box below the relevant treatment that the patient did or did not receive:<br>- the patient did not receive any adjuvant or neoadjuvant chemotherapy or<br>- the patient received adjuvant chemotherapy only or<br>- the patient received neoadjuvant chemotherapy<br>7. The patient has currently received no more than 12 months of adjuvant or neoadjuvant endocrine therapy.<br>8. If the patient is a pre- or peri-menopausal female then the patient has undergone ovarian ablation or suppression with LHRH agonist treatment or if the patient is male then the patient has undergone treatment with LHRH agonist treatment.<br><br>Please mark in the box below which category applies to this patient:<br>- post-menopausal female on adjuvant aromatase inhibitor therapy or<br>- pre- or peri-menopausal female on adjuvant aromatase inhibitor therapy and LHRH agonist treatment/ovarian ablation or<br>- male on LHRH agonist treatment<br>9. The patient has an ECOG performance status of 0 or 1.<br>10. Ribociclib is being given only in combination with an aromatase inhibitor.<br>11. The patient has had no prior treatment with a CDK 4/6 inhibitor unless either the patient is transferring from a company early access scheme for adjuvant ribociclib AND meets all the criteria on this form or the patient has suffered unacceptable toxicity on adjuvant abemaciclib plus endocrine therapy without any evidence of disease progression and is transferring to treatment with adjuvant ribociclib plus an aromatase inhibitor. If the latter, the treatment plan should be for a maximum CDK4/6 inhibitor treatment duration of 3 calendar years in all (time on abemaciclib plus that on ribociclib).<br><br>Please mark in the box below which scenario applies to this patient:<br>- the patient has never received any prior therapy with any CDK4/6 inhibitor or<br>- the patient is transferring from a company early access scheme for adjuvant ribociclib AND meets all the criteria on this form or<br>- the patient has suffered unacceptable toxicity on abemaciclib plus endocrine therapy without any evidence of disease progression and is transferring to treatment with adjuvant ribociclib plus an aromatase inhibitor with a treatment plan for a maximum CDK4/6 inhibitor treatment duration of 3 calendar years in all<br>12. Treatment with ribociclib will continue until there is progressive disease or excessive toxicity or until the patient chooses to discontinue treatment or for a maximum of 3 calendar years, whichever is the sooner.<br><br>For patients switching from abemaciclib, the maximum total CDK4/6 inhibitor treatment duration is for 3 calendar years (time on abemaciclib plus time on ribociclib).<br>13. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, the prescribing clinician will complete a treatment break approval form to restart treatment.<br>14. Ribociclib will be otherwise used as set out in its Summary of Product Characteristics (SPC). | Yes | TA1086 | 06-Aug-25 | 04-Nov-25 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| RUC1 | **Rucaparib** | As maintenance treatment in patients with high grade epithelial ovarian, fallopian tube or primary peritoneal carcinoma who have a deleterious or suspected deleterious germline and/or somatic BRCA mutation and who have a recent FIRST OR SUBSEQUENT relapse of platinum-sensitive disease and who are now in response following a SECOND OR SUBSEQUENT platinum-based chemotherapy where the following criteria have been met:<br><br>There is a separate form (RUC2) for rucaparib as maintenance treatment in patients with high grade epithelial ovarian, fallopian tube or primary peritoneal carcinoma who do NOT have a deleterious or suspected deleterious germline and/or somatic BRCA mutation and who are in response following platinum-based SECOND or subsequent line chemotherapy | 1. This application is made by and the first cycle of systemic anti-cancer therapy with rucaparib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br><br>2. This patient has a proven histological diagnosis of predominantly high grade serous or high grade endometrioid or high grade clear cell ovarian, fallopian tube or primary peritoneal carcinoma.<br>Please enter below as to which is the predominant histology in this patient:<br>- high grade serous adenocarcinoma or<br>- high grade endometrioid adenocarcinoma or<br>- high grade clear cell carcinoma<br><br>3. This patient has had germline and/or somatic (tumour) BRCA testing.<br><br>4. This patient HAS a documented deleterious or suspected deleterious BRCA mutation(s) in the germline or in the tumour or in both. Please enter below the type of testing done in this patient to determine the presence of deleterious or suspected deleterious BRCA mutation(s):<br>- in the germline only or<br>- in the tumour (somatic tissue) only or<br>- in both germline and somatic tissue.<br><br>5. This patient HAS a documented deleterious or suspected deleterious BRCA 1 or BRCA 2 mutation(s). Please enter below as to which deleterious or suspected deleterious BRCA mutation(s) the patient has:<br>- BRCA 1 mutation or<br>- BRCA 2 mutation or<br>- both BRCA1 and BRCA 2 mutations<br><br>6. The patient had disease which was sensitive to the penultimate line of platinum-based chemotherapy (ie the disease responded to the line of platinum-based chemotherapy preceding the most recent line of platinum-based chemotherapy).<br><br>7. The patient has recently completed a further line of platinum-based chemotherapy and has received a minimum of 4 cycles of platinum-based treatment. Please enter below what line of platinum-based treatment was the most recent line of treatment:<br>- 2nd line or<br>- 3rd line or<br>- 4th line or greater<br><br>8. This patient has responded to the recently completed SECOND or subsequent line platinum-based chemotherapy and has achieved a partial or complete response to treatment according to the definitions given below and there is no evidence of progressive disease on the post-treatment scan or a rising CA125 level.<br>Please enter below as to which response assessment applies to this patient:<br>- achieved a complete response at the end of the recent 2nd or subsequent line of platinum-based chemotherapy i.e. has no measurable or non-measurable disease on the post-chemotherapy scan and the CA125 is normal<br>- achieved a partial response at the end of the recent 2nd or subsequent line of platinum-based chemotherapy i.e. has had at least a 30% reduction in measurable or non-measurable disease from the start of to the completion of the 2nd platinum-based chemotherapy or the patient has a complete remission on the post-chemotherapy CT scan but the CA125 has not decreased to within the normal range.<br><br>9. The patient is currently less than 8 weeks from the date of the last infusion of the last cycle of the 2nd or subsequent line of platinum-based chemotherapy.<br><br>10. The patient has not previously received any PARP inhibitor unless olaparib or niraparib via the CDF has had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression. Please mark below which of the four scenarios applies to this patient:<br>- the patient has never previously received a PARP inhibitor or<br>- the patient has previously received olaparib via the CDF and this has had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression<br>- the patient has previously received niraparib via the CDF and this has had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression or<br>- the patient has previously received rucaparib via an early access scheme and the patient meets all the other criteria listed here.<br><br>11. Rucaparib will be used as monotherapy.<br><br>12. The patient has an ECOG performance status of either 0 or 1. Please enter below as to which ECOG performance status applies to this patient:<br>- ECOG PS 0 or<br>- ECOG PS 1<br>Note: a patient with a performance status of 2 or more is not eligible for niraparib<br><br>13. Rucaparib is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment.<br><br>14. A formal medical review as to whether maintenance treatment with rucaparib should continue or not will be scheduled to occur at least by the start of the third cycle of treatment.<br><br>15. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment, including as appropriate if the patient needed an extended break on account of Covid-19.<br><br>16. Rucaparib is to be otherwise used as set out in its Summary of Product Characteristics | Yes | TA1007 | 17-Sep-24 | 17-Oct-24 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| RUC2 | **Rucaparib** | As maintenance treatment in patients with high grade epithelial ovarian, fallopian tube or primary peritoneal carcinoma who do NOT have a deleterious or suspected deleterious germline and/or somatic BRCA mutation and who have a recent FIRST OR SUBSEQUENT relapse of platinum-sensitive disease and who are now in response following a SECOND OR SUBSEQUENT line platinum-based chemotherapy where the following criteria have been met:<br><br>There is a separate form RUC1 for rucaparib as maintenance treatment in patients with high grade epithelial stage III or IV ovarian, fallopian tube or primary peritoneal carcinoma who have a deleterious or suspected deleterious germline and/or somatic BRCA mutation and who are in response following a platinum-based SECOND OR SUBSEQUENT line chemotherapy | 1. This application is made by and the first cycle of systemic anti-cancer therapy with rucaparib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br><br>2. I confirm that this patient has a proven histological diagnosis of predominantly high grade serous or high grade endometrioid or high grade clear cell ovarian, fallopian tube or primary peritoneal carcinoma.<br>Please enter below as to which is the predominant histology in this patient:<br>- high grade serous adenocarcinoma or<br>- high grade endometrioid adenocarcinoma or<br>- high grade clear cell carcinoma<br><br>3. This patient has had germline and/or somatic (tumour) BRCA testing.<br><br>4. This patient DOES NOT HAVE a documented deleterious or suspected deleterious BRCA mutation(s) in the germline or in the tumour.<br><br>5. The patient had disease which was sensitive to the penultimate line of platinum-based chemotherapy (i.e. the disease responded to the line of platinum-based chemotherapy preceding the most recent line of platinum-based chemotherapy).<br><br>6. The patient has recently completed a further line of platinum-based chemotherapy and has received a minimum of 4 cycles of platinum-based treatment. Please enter below what line of platinum-based treatment was the most recent line of treatment:<br><br>7. This patient has responded to the recently completed SECOND or subsequent line platinum-based chemotherapy and has achieved a partial or complete response to treatment according to the definitions given below and there is no evidence of progressive disease on the post-treatment scan or a rising CA125 level.<br>Please enter below as to which response assessment applies to this patient:<br>- achieved a complete response at the end of the 2nd or subsequent line of platinum-based chemotherapy i.e. has no measurable or non-measurable disease on the post-chemotherapy scan and the CA125 is normal<br>- achieved a partial response at the end of the 2nd or subsequent line of platinum-based chemotherapy i.e. has had at least a 30% reduction in measurable or non-measurable disease from the start of to the completion of the 2nd platinum-based chemotherapy or the patient has a complete remission on the post-chemotherapy CT scan but the CA125 has not decreased to within the normal range.<br><br>8. The patient is currently less than 8 weeks from the date of the last infusion of the last cycle of the recent 2nd or subsequent line platinum-based chemotherapy.<br><br>9. The patient has not previously received any PARP inhibitor unless either niraparib via the CDF has had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression or the patient has received rucaparib via an early access scheme and the patient meets all the other criteria listed here. Please mark below which of the three scenarios applies to this patient:<br>- the patient has never previously received a PARP inhibitor or<br>- the patient has previously received niraparib via the CDF and this has had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression or<br>- the patient has previously received rucaparib via an early access scheme and the patient meets all the other criteria listed here.<br><br>10. Rucaparib will be used as monotherapy.<br><br>11. The patient has an ECOG performance status of either 0 or 1.<br>Please enter below as to which ECOG performance status applies to this patient:<br>- ECOG PS 0 or<br>- ECOG PS 1.<br>Note: a patient with a performance status of 2 or more is not eligible for rucaparib<br><br>12. Rucaparib is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment.<br><br>13. A formal medical review as to whether maintenance treatment with rucaparib should continue or not will be scheduled to occur at least by the start of the third cycle of treatment.<br><br>14. When a treatment break of more than 6 weeks beyond the expected 4-weekly is needed, I will complete a treatment break approval form to restart treatment, including as appropriate if the patient had an extended break on account of Covid-19.<br><br>15. Rucaparib is to be otherwise used as set out in its Summary of Product Characteristics | Yes | TA1007 | 17-Sep-24 | 17-Oct-24 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| RUC3 | **Rucaparib** | As maintenance treatment in patients with high grade epithelial stage III or IV ovarian, fallopian tube or primary peritoneal carcinoma who are in response following platinum-based FIRST line chemotherapy AND who DO NOT HAVE a deleterious or suspected deleterious BRCA germline and/or somatic BRCA mutation BUT DO HAVE a positive status for homologous recombination deficiency as defined by the presence of genomic instability where the following criteria have been met: | 1. This application for maintenance rucaparib is being made by and the first cycle of systemic anticancer therapy with rucaparib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. This patient has a proven histological diagnosis of predominantly high grade serous or high grade endometrioid or high grade clear cell ovarian, fallopian tube or primary peritoneal carcinoma.<br>Please enter below as to which is the predominant histology in this patient:<br>- high grade serous adenocarcinoma or<br>- high grade endometrioid adenocarcinoma or<br>- high grade clear cell carcinoma<br>3. This patient has had germline and/or somatic (tumour) BRCA testing.<br>Please enter below the type of tissue on which BRCA mutation testing has been done:<br>- negative germline BRCA mutation test with somatic BRCA mutation test not done or<br>- negative somatic BRCA mutation test<br>4. This patient DOES NOT HAVE a documented deleterious or suspected deleterious BRCA 1 or BRCA 2 mutation(s).<br>Note: The company did not seek a NICE recommendation in patients with deleterious or suspected BRCA mutations.<br>5. The patient has documented evidence for a positive status for homologous recombinant deficiency as determined by genomic instability and defined by a positive Myriad HRD test or the validated equivalent as tested and confirmed by an NHS Genomic Laboratory Hub.<br>Note: patients with a negative or unknown genomic instability status are ineligible for rucaparib.<br>6. The patient has recently diagnosed FIGO stage III or IV ovarian, fallopian tube or primary peritoneal carcinoma and has just completed 1st line platinum-based chemotherapy.<br>Note: maintenance rucaparib in this 1st line maintenance indication is not funded for patients with recently diagnosed and treated stage I-IIC disease.<br>7. One of the following scenarios applies to the surgical management of the patient in relation to the stage of the disease:<br>- the patient has stage III disease and had an upfront attempt at optimal cytoreductive surgery and had no visible residual disease at the end of surgery or<br>- the patient has stage III disease and had an upfront attempt at optimal cytoreductive surgery and had visible residual disease at the end of surgery or<br>- the patient has stage III disease and had an interval attempt at optimal cytoreductive surgery and had no visible disease at the end of surgery or<br>- the patient has stage III disease and had an interval attempt at optimal cytoreductive surgery and had visible disease at the end of surgery or<br>- the patient has stage III disease and has had a biopsy only with no upfront or interval attempt at cytoreductive surgery or<br>- the patient has stage IV disease and had an upfront attempt at optimal cytoreductive surgery and had no visible disease at the end of surgery or<br>- the patient has stage IV disease and had an upfront attempt at optimal cytoreductive surgery and had visible residual disease at the end of surgery or<br>- the patient has stage IV disease and had an interval attempt at optimal cytoreductive surgery and had no visible disease at the end of surgery or<br>- the patient has stage IV disease and had an interval attempt at optimal cytoreductive surgery and had visible disease at the end of surgery or<br>- the patient has stage IV disease and has had a biopsy only with no upfront or interval attempt at cytoreductive surgery<br>8. The patient has been treated with platinum-based 1st line chemotherapy and has received a minimum of 4 cycles of platinum-based treatment.<br>9. Whether the patient received bevacizumab as part of 1st line platinum-based treatment or not:<br>Please indicate below whether bevacizumab was used in combination with the 1st line chemotherapy:<br>- bevacizumab 7.5mg per Kg given in combination with platinum-based chemotherapy or<br>- bevacizumab 15mg per Kg given in combination with platinum-based chemotherapy or<br>- no bevacizumab used in combination with chemotherapy<br>10. This patient is in response to the recently completed 1st line platinum-based chemotherapy and has achieved a partial or complete response to treatment according to the definitions given below and has no evidence of progressive disease on the post-treatment scan or a rising CA125 level.<br>Please enter below as to which response assessment applies to this patient:<br>- achieved a complete response at the end of 1st line platinum-based chemotherapy i.e. has no measurable or non-measurable disease on the post-chemotherapy scan and the CA125 is normal or<br>- achieved a complete response at the end of 1st line platinum-based chemotherapy i.e. has no measurable or non-measurable disease on the post-chemotherapy scan and the CA125 has not decreased to within the normal range or<br>- achieved a partial response at the end of 1st line platinum-based chemotherapy i.e. has had a =30% reduction in measurable or non-measurable disease from the start of to the completion of 1st line chemotherapy and the CA125 is normal or<br>- achieved a partial response at the end of 1st line platinum-based chemotherapy i.e. has had a =30% reduction in measurable or non-measurable disease from the start of to the completion of 1st line chemotherapy and the CA125 has not decreased to within the normal range.<br>11. The patient will commence maintenance rucaparib monotherapy within 8 weeks from the date of the first day of the last cycle of 1st line chemotherapy unless the patient was previously entered into the company's early access scheme for maintenance rucaparib after 1st line chemotherapy and all the other treatment criteria set out in this form are fulfilled.<br>12. The patient has not previously received any PARP inhibitor unless either the patient has received rucaparib as part of a company early access scheme for this 1st line maintenance indication and the patient meets all the other criteria set out in this form or 1st line maintenance niraparib monotherapy has had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression. Such patients must have a positive status for HRD and a negative status for a BRCA mutation.<br><br>Please mark below which scenario applies to this patient:<br>- the patient has never previously received a PARP inhibitor or<br>- the patient has received rucaparib as part of a company early access scheme for this 1st line maintenance indication and all the other criteria set out in this form are fulfilled<br>- the patient has previously received niraparib monotherapy as 1st line maintenance therapy and this has had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression and all the other criteria on this form are fulfilled. By ticking this box, you are confirming that the patient has HRD-positive and BRCA-negative disease.<br><br>**(continued on next page)** | Yes | TA1055 | 16-Apr-25 | 15-Jul-25 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| RUC3 (CONT) | **Rucaparib** | As maintenance treatment in patients with high grade epithelial stage III or IV ovarian, fallopian tube or primary peritoneal carcinoma who are in response following platinum-based FIRST line chemotherapy AND who DO NOT HAVE a deleterious or suspected deleterious BRCA germline and/or somatic BRCA mutation BUT DO HAVE a positive status for homologous recombination deficiency as defined by the presence of genomic instability where the following criteria have been met: | 13. Rucaparib will be used as monotherapy. | Yes | TA1055 | 16-Apr-25 | 15-Jul-25 |
| | | | 14. Maintenance rucaparib is not being administered concurrently with maintenance bevacizumab. | | | | |
| | | | 15. The patient either has a contraindication to bevacizumab or the prescribing clinician has discussed with the patient that rucaparib in this indication is less effective than olaparib plus bevacizumab but less costly.<br>Please mark below which scenario applies to this patient:<br>- the patient has a contraindication to bevacizumab or<br>- the prescribing clinician has discussed with the patient that rucaparib in this indication is less effective than olaparib plus bevacizumab but less costly | | | | |
| | | | 16. The patient has an ECOG performance status of either 0 or 1.<br>Note: a patient with a performance status of 2 or more is not eligible for rucaparib. | | | | |
| | | | 17. Rucaparib is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment or completion of 2 years of treatment, whichever is the sooner.<br>Note: NICE's decision as regards the clinical and cost effectiveness of rucaparib in this indication was based on the application of a 2 year calendar year for stopping treatment, i.e. treatment is stopped 2 calendar years after starting, irrespective of treatment breaks. | | | | |
| | | | 18. A first formal medical review as to whether maintenance treatment with rucaparib should continue or not will be scheduled to occur at least by the start of the third 4-weekly cycle of treatment. | | | | |
| | | | 19. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, the prescribing clinician will complete a treatment break approval form to restart treatment. | | | | |
| | | | 20. Rucaparib is to be otherwise used as set out in its Summary of Product Characteristics. | | | | |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| RUC4 | **Rucaparib** | As maintenance treatment in patients with high grade epithelial stage III or IV ovarian, fallopian tube or primary peritoneal carcinoma who are in response following platinum-based FIRST line chemotherapy for a tumour which has a NEGATIVE status for a deleterious or suspected deleterious BRCA germline and/or somatic BRCA mutation AND a NEGATIVE or UNKNOWN status for homologous recombination deficiency as defined by the presence of genomic instability where the following criteria have been met: | 1. This application for maintenance rucaparib is being made by and the first cycle of systemic anticancer therapy with rucaparib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. This patient has a proven histological diagnosis of predominantly high grade serous or high grade endometrioid or high grade clear cell ovarian, fallopian tube or primary peritoneal carcinoma.<br>Please enter below as to which is the predominant histology in this patient<br>- high grade serous adenocarcinoma or<br>- high grade endometrioid adenocarcinoma or<br>- high grade clear cell carcinoma<br>3. This patient has had germline and/or somatic (tumour) BRCA testing done and the result is negative.<br>Please enter below the type of tissue on which BRCA mutation testing has been done:<br>- negative germline BRCA mutation test with somatic BRCA mutation test not done or<br>- negative somatic BRCA mutation test<br>4. This patient's tumour has either documented evidence of a negative status for homologous recombinant deficiency as determined by genomic instability testing by a NHS Genomic Laboratory Hub or the HRD test result is unknown.<br>Please enter below the current status of HRD testing:<br>- negative HRD status<br>- unknown HRD status<br>5. The patient has recently diagnosed FIGO stage III or IV ovarian, fallopian tube or primary peritoneal carcinoma and has just completed 1st line platinum-based chemotherapy.<br>Note: maintenance rucaparib in this 1st line maintenance indication is not funded for patients with recently diagnosed and treated stage I-IIC disease.<br>6. One of the following scenarios applies to the surgical management of the patient in relation to the stage of the disease:<br>- the patient has stage III disease and had an upfront attempt at optimal cytoreductive surgery and had no visible residual disease at the end of surgery or<br>- the patient has stage III disease and had an upfront attempt at optimal cytoreductive surgery and had visible residual disease at the end of surgery or<br>- the patient has stage III disease and had an interval attempt at optimal cytoreductive surgery and had no visible disease at the end of surgery or<br>- the patient has stage III disease and had an interval attempt at optimal cytoreductive surgery and had visible disease at the end of surgery or<br>- the patient has stage III disease and has had a biopsy only with no upfront or interval attempt at cytoreductive surgery or<br>- the patient has stage IV disease and had an upfront attempt at optimal cytoreductive surgery and had no visible disease at the end of surgery or<br>- the patient has stage IV disease and had an upfront attempt at optimal cytoreductive surgery and had visible residual disease at the end of surgery or<br>- the patient has stage IV disease and had an interval attempt at optimal cytoreductive surgery and had no visible disease at the end of surgery or<br>- the patient has stage IV disease and had an interval attempt at optimal cytoreductive surgery and had visible disease at the end of surgery or<br>- the patient has stage IV disease and has had a biopsy only with no upfront or interval attempt at cytoreductive surgery<br>7. The patient has been treated with platinum-based 1st line chemotherapy and has received a minimum of 4 cycles of platinum-based treatment.<br>8. Whether the patient received induction bevacizumab as part of 1st line platinum-based treatment or not:<br><br>Please indicate below whether induction bevacizumab was used in combination with the 1st line chemotherapy<br>- bevacizumab 7.5mg per Kg given in combination with platinum-based chemotherapy or<br>- bevacizumab 15mg per Kg given in combination with platinum-based chemotherapy or<br>- no bevacizumab used in combination with chemotherapy<br>9. The patient is in response to the recently completed 1st line platinum-based chemotherapy and has achieved a partial or complete response to treatment according to the definitions given below and has no evidence of progressive disease on the post-treatment scan or a rising CA125 level.<br><br>Please enter below as to which response assessment applies to this patient:<br>- achieved a complete response at the end of 1st line platinum-based chemotherapy i.e. has no measurable or non-measurable disease on the post-chemotherapy scan and the CA125 is normal or<br>- achieved a complete response at the end of 1st line platinum-based chemotherapy i.e. has no measurable or non-measurable disease on the post-chemotherapy scan and the CA125 has not decreased to within the normal range or<br>- achieved a partial response at the end of 1st line platinum-based chemotherapy i.e. has had a =30% reduction in measurable or non-measurable disease from the start of to the completion of 1st line chemotherapy and the CA125 is normal or<br>- achieved a partial response at the end of 1st line platinum-based chemotherapy i.e. has had a =30% reduction in measurable or non-measurable disease from the start of to the completion of 1st line chemotherapy and the CA125 has not decreased to within the normal range.<br><br>**(continued on next page)** | Yes | TA1055 | 16-Apr-25 | 15-Jul-25 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| RUC4 (CONT) | **Rucaparib** | As maintenance treatment in patients with high grade epithelial stage III or IV ovarian, fallopian tube or primary peritoneal carcinoma who are in response following platinum-based FIRST line chemotherapy for a tumour which has a NEGATIVE status for a deleterious or suspected deleterious BRCA germline and/or somatic BRCA mutation AND a NEGATIVE or UNKNOWN status for homologous recombination deficiency as defined by the presence of genomic instability where the following criteria have been met: | 10. Maintenance bevacizumab is NOT a treatment option because the patient is not eligible for maintenance bevacizumab monotherapy as set out in form BEV10 or the use of bevacizumab is contraindicated or the maintenance bevacizumab has had to be discontinued within 3 months of its start on account of unacceptable toxicity and in the clear absence of disease progression and all the other criteria on this form are fulfilled.<br><br>11. The patient will commence maintenance rucaparib monotherapy within 8 weeks from the date of the first day of the last cycle of 1st line chemotherapy unless the patient was previously entered into the company's early access scheme for maintenance rucaparib after 1st line chemotherapy and all the other treatment criteria set out in this form are fulfilled.<br><br>12. The patient has not previously received any PARP inhibitor unless either the patient has received rucaparib as part of a company early access scheme for this 1st line maintenance indication and the patient meets all the other criteria set out in this form or 1st line maintenance niraparib monotherapy has had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression and all the other criteria on this form are fulfilled.<br><br>13. Rucaparib will be used as monotherapy.<br><br>14. Maintenance rucaparib is not being administered concurrently with maintenance bevacizumab.<br><br>15. The patient has an ECOG performance status of either 0 or 1.<br><br>Note: a patient with a performance status of 2 or more is not eligible for rucaparib.<br><br>16. Rucaparib is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment or completion of 2 years of treatment, whichever is the sooner.<br><br>Note: NICE's decision as regards the clinical and cost effectiveness of rucaparib in this indication was based on the application of a 2 year calendar year for stopping treatment, i.e. treatment is stopped 2 calendar years after starting, irrespective of treatment breaks.<br><br>17. A first formal medical review as to whether maintenance treatment with rucaparib should continue or not will be scheduled to occur at least by the start of the third 4-weekly cycle of treatment.<br><br>18. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment.<br><br>19. Rucaparib is to be otherwise used as set out in its Summary of Product Characteristics | Yes | TA1055 | 16-Apr-25 | 15-Jul-25 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| RUX1_v2.1 | **Ruxolitinib** | Ruxolitinib for treating disease-related splenomegaly or symptoms in adults with intermediate-2 or high-risk myelofibrosis where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with ruxolitinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has primary myelofibrosis (also known as chronic idiopathic myelofibrosis) or post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis.<br>Please mark below which of these 3 diagnoses applies to this patient:<br>- primary myelofibrosis (also known as chronic idiopathic myelofibrosis) **or**<br>- post polycythaemia vera myelofibrosis **or**<br>- post essential thrombocythaemia myelofibrosis<br>3. The risk category of myelofibrosis applied to this patient is either intermediate-2 or high-risk disease.<br>Please mark below which of these risk categories applies to this patient:<br>- the patient has intermediate-2 risk myelofibrosis **or**<br>- the patient has high-risk myelofibrosis<br>Note: ruxolitinib is not funded for patients with the intermediate-1 risk category of myelofibrosis.<br>4. The patient has symptomatic disease-related splenomegaly and/or constitutional symptoms of myelofibrosis.<br>5. Treatment with ruxolitinib will be continued provided that the benefit-risk ratio for treatment remains positive.<br>6. Treatment will be discontinued after 6 months if there has been no reduction in spleen size or improvement in symptoms since initiation of therapy.<br>7. For patients who have previously demonstrated some degree of clinical improvement but have since sustained an increase in their spleen length of 40% compared with their baseline size (roughly equivalent to a 25% increase in splenic volume), ruxolitinib therapy will be discontinued.<br>8. The patient has never received any therapy with a JAK inhibitor or has been previously treated only with momelotinib or received previous ruxolitinib before subsequently being treated with momelotinib and has failed or was intolerant of momelotinib and a re-start of ruxolitinb is being requested.<br>Please mark which option applies to this patient:<br>- the patient has not received any previous therapy with a JAK inhibitor or<br>- the only JAK inhibitor received by the patient has been momelotinib or<br>- the patient was previously treated with ruxolitinib before subsequently being treated with momelotinib and has failed or was intolerant of momelotinib and a re-start of ruxolitinib is being requested<br>9. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, a treatment break form will be completed to restart treatment.<br>10. Ruxolitinib will otherwise be used as set out its Summary of Product Characteristics. | Yes | TA386 | 23-Mar-16 | 21-Jun-16 |
| RUX2 | **Ruxolitinib** | For the treatment of polycythaemia vera for adult patients who are resistant to treatment with hydroxycarbamide or who cannot tolerate treatment with hydroxycarbamide where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with ruxolitinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a confirmed diagnosis of polycythaemia vera (PV).<br>3. The patient has high risk polycythaemia vera as defined by any one of the following criteria applying to this patient:<br>• age >60 years<br>• previous documented thrombosis (including transient ischaemic attack) or erythromelalgia or migraine (severe, recurrent, requiring medication and considered to be secondary to the PV) either after diagnosis of the PV or within the 10 years before diagnosis and regarded as being disease-related<br>• significant or symptomatic splenomegaly<br>• a platelet count exceeding 1000 x $10^9$/L at any point during the patient's disease<br>• diabetes or hypertension requiring pharmacological treatment for more than 6 months<br>4. The patient has been previously treated with hydroxycarbamide (HC) and is resistant to it or cannot tolerate treatment with it or is both resistant to it and intolerant of it.<br>Note: the definitions of intolerance and resistance are those used by the European LeukaemiaNet (ELN) consensus.<br>Please mark below which one of these scenarios applies to this patient:<br>- the patient is resistant to HC or<br>- the patient cannot tolerate treatment with HC or<br>- the patient is both resistant to HC and intolerant of it<br>5. The patient has either not been previously treated with ruxolitinib or has received previous ruxolitinib within the MAJIC-PV trial or via a company compassionate access scheme and all the other criteria on this form are fulfilled.<br>Please mark below which one of these scenarios applies to this patient:<br>- the patient has not been previously treated with ruxolitinib or<br>- the patient has received previous ruxolitinib within the MAJIC-PV trial and the benefit-risk ratio for continuing treatment remains positive and all the other criteria on this from are fulfilled or<br>- the patient has received previous ruxolitinib within a company compassionate access scheme and the benefit-risk ratio for continuing treatment remains positive and all the other criteria on this from are fulfilled<br>6. Treatment will be continued unless there is progression to myelofibrosis or myelodysplastic syndrome or acute myeloid leukaemia or the development of unacceptable toxicity or withdrawal of patient consent, whichever is the sooner.<br>Note: this continuation rule was the one accepted by NICE in its assessment of clinical and cost effectiveness for ruxolitinib in this indication and is not the continuation rule for polycythaemia vera as set out in ruxolitinib's Summary of Product Characteristics (SPC).<br>7. The patient has an ECOG performance score of 0 or 1 or 2.<br>NHS England does not fund the use of ruxolitinib in patients of ECOG performance score of 3.<br>8. The prescribing clinician is aware of the potential drug interactions that may occur with ruxolitinib as set out in ruxolitinib's Summary of Product Characteristics.<br>9. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, a treatment break form to restart treatment will be completed.<br>10. Ruxolitinib will otherwise be used as set out in its Summary of Product Characteristics. | Yes | TA921 | 18-Oct-23 | 16-Jan-24 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| SAC1_v1.1 | **Sacituzumab govitecan** | For the treatment of patients with previously treated unresectable locally advanced or metastatic triple negative breast cancer where the following criteria have been met: | 1. This application for sacituzumab govitecan is being made by and the first cycle of systemic anti-cancer therapy with sacituzumab govitecan will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a histologically or cytologically-confirmed diagnosis of breast cancer.<br>3. The patient has unresectable locally advanced or metastatic breast cancer.<br>4. The patient's breast cancer has had receptor analysis performed and this is negative for **all** of the following: the HER2 receptor, oestrogen receptor and progesterone receptor i.e. the patient has **triple negative disease**.<br>5. ***Either*** this patient has had 2 or more prior lines of systemic therapy specifically for the unresectable locally advanced or metastatic breast cancer indication ***or*** the patient has only had 1 line of systemic therapy specifically for the unresectable locally advanced or metastatic breast cancer indication and has also previously received adjuvant or neoadjuvant systemic therapy.<br><br>Please mark below which of these 2 clinical scenarios applies to this patient:<br>- this patient has had 2 or more prior lines of systemic therapy specifically for the unresectable locally advanced or metastatic breast cancer indication<br>- this patient has only had 1 line of systemic therapy specifically for the unresectable locally advanced or metastatic breast cancer indication and has also previously received adjuvant or neoadjuvant systemic therapy<br>6. Whether the patient's breast cancer has known positive PD-L1 expression or not has been confirmed and that if positive and according to NICE recommendations, either the patient has been treated with 1st line atezolizumab or pembrolizumab or the patient was technically eligible for 1st line atezolizumab or pembrolizumab but use of immunotherapy was contraindicated.<br><br>Please mark below which of these 4 clinical scenarios applies to this patient:<br>- Insufficient PD-L1 expression according to NICE recommendations for the patient to be eligible for 1st line atezolizumab or pembrolizumab<br>- Sufficient PD-L1 expression according to NICE recommendations and the patient was treated with 1st line atezolizumab or pembrolizumab<br>- Sufficient PD-L1 expression according to NICE recommendations to be eligible for 1st line atezolizumab or pembrolizumab but use of immunotherapy was contraindicated<br>- PD-L1 expression unknown and the patient has already had non-immunotherapy as 1st line treatment and hence ineligible for consideration of 1st line atezolizumab or pembrolizumab<br><br>Note: immunotherapy is only licensed and recommended by NICE as 1st line treatment for locally advanced or metastatic disease and sacituzumab govitecan is only licensed and recommended by NICE as 2nd or 3rd or further line treatment for locally advanced or metastatic disease as outlined in criterion 5 above. Thus, the use of sacituzumab govitecan can only be after any previous immunotherapy for locally advanced or metastatic disease.<br>7. The patient has been previously treated with taxane chemotherapy in the adjuvant or neoadjuvant or advanced disease settings unless the patient has a clear and documented contraindication to chemotherapy with a taxane.<br>8. The patient has had no prior treatment with sacituzumab govitecan for locally advanced or metastatic disease unless this was received for this indication via the Gilead early access scheme and all other treatment criteria on this form are fulfilled.<br><br>Please mark below which of these 2 scenarios applies to this patient:<br>- No prior treatment with sacituzumab govitecan<br>- Received prior treatment with sacituzumab govitecan via the Gilead early access scheme and all other treatment criteria are fulfilled<br>9. The patient will continue to be treated with sacituzumab govitecan until disease progression or unacceptable toxicity or withdrawal of patient consent, whichever occurs first.<br>10. The patient has an ECOG performance status (PS) of 0 or 1.<br>11. The patient has no symptomatically active brain metastases or leptomeningeal metastases.<br>12. The prescribing clinician is aware of the following:<br>- sacituzumab govitecan can cause severe diarrhoea and life-threatening neutropenia<br>- patients known to be homozygous for uridine diphosphate-glucuronosyl transferase 1A1 (UGT1A1) 28 allele are at risk of increased toxicity<br>- sacituzumab govitecan has drug interactions with UGT1A1 inhibitors and inducers as outlined in its Summary of Product Characteristics<br>13. A formal medical review as to how sacituzumab govitecan is being tolerated and whether treatment with sacituzumab govitecan should continue or not will be scheduled to occur at least by the end of the first 6 weeks of treatment.<br>14. When a treatment break of more than 12 weeks beyond the expected 3 weekly cycle length is needed, a treatment break approval form will be completed to restart treatment, including indicating as appropriate if the patient had an extended break because of COVID 19.<br>15. Sacituzumab govitecan will be otherwise used as set out in its Summary of Product Characteristics (SPC). | Yes | TA819 | 17-Aug-22 | 15-Nov-22 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| SELIN1_v1.1 | **Selinexor**<br>in combination with bortezomib and dexamethasone | For the treatment of multiple myeloma in transplant ineligible patients who have had only 1 prior line of systemic therapy where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with selinexor in combination with bortezomib and dexamethasone will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a diagnosis of multiple myeloma.<br>3. The prescribing clinician understands that the combination of selinexor plus bortezomib and dexamethasone is not funded for amyloidosis patients (with the exception of patients who have a proven diagnosis of myeloma with an associated diagnosis of amyloidosis) and that NHS funding for selinexor plus bortezomib and dexamethasone is only for the specific 2nd line multiple myeloma indication recommended by NICE.<br><br>Please tick box below:<br>- this patient does not have a diagnosis of primary amyloidosis<br>- this patient has a proven diagnosis of progressive myeloma with an associated diagnosis of amyloidosis and the combination of selinexor plus bortezomib and dexamethasone is being prescribed for the myeloma<br>4. The patient has received 1 and no more than 1 prior line of systemic treatment and that the numbering of a line of treatment is in accordance with the International Myeloma Workshop Consensus recommendations for the uniform reporting of clinical trials (http://doi.org/10.1182/blood-2010-10-299487). A line of therapy is defined as one or more cycles of a planned treatment program. This may consist of one or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner (ie induction chemotherapy/chemotherapies when followed by stem cell transplantation is considered to be 1 line of therapy). A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse or toxicity, the exception to this being the need to attain a sufficient response for stem cell transplantation to proceed. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease.<br><br>Please verify that the patient has only received 1 prior line of systemic therapy by ticking the box below:<br>- this patient has received 1 and no more than 1 prior line of systemic treatment and this patient is therefore receiving selinexor plus bortezomib and dexamethasone as 2nd line therapy<br><br>Note: The use of the combination of selinexor plus bortezomib and dexamethasone in the 1-prior treatment setting was one of the places in the treatment pathway chosen by Menarini Stemline for its submission to NICE for the appraisal of clinical and cost effectiveness of this combination and the 1-prior treatment setting is the only place in the treatment pathway that currently has a positive NICE recommendation for this combination.<br>5. The patient has demonstrated disease progression whilst receiving or after receiving 1st line combination therapy which contained **both an anti-CD38 targeted antibody and lenalidomide**.<br><br>Note: the need for patients to have myeloma which was or has become refractory to a 1st line combination therapy containing both an anti-CD38 targeted antibody and lenalidomide is the basis of the 1-prior subgroup chosen by Menarini Stemline for its submission to NICE for the appraisal of clinical and cost effectiveness of this combination of selinexor plus bortezomib and dexamethasone as 2nd line systemic therapy.<br>6. The patient is ineligible for high dose chemotherapy and stem cell transplantation.<br>7. The patient is of ECOG performance status 0 or 1 or 2.<br><br>Please tick one of the boxes below:<br>- performance status 0 or<br>- performance status 1 or<br>- performance status 2<br>8. Selinexor is only to be used in combination with bortezomib and dexamethasone and that it is not to be used in combination with any other agents.<br>9. The combination of selinexor plus bortezomib and dexamethasone is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment<br>10. A formal medical review as to whether treatment with selinexor in combination with bortezomib and dexamethasone continues or not will be scheduled to occur at least by the end of the second 5-week cycle of treatment, which MUST be approved before Selinexor is restarted.<br>11. Selinexor will be otherwise used as set out in its Summary of Product Characteristics. | No | TA974 | 15-May-24 | 13-Aug-24 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| SELIN2 | **Selinexor** in combination with dexamethasone | For the treatment of multiple myeloma in patients who have had at least 4 prior lines of systemic therapy and whose disease is refractory to at least 2 proteasome inhibitors, 2 immunomodulatory agents and an anti-CD38 monoclonal antibody and which has also demonstrated disease progression on the last therapy where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with selinexor plus dexamethasone will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy. | No | TA970 | 08-May-24 | 06-Aug-24 |
| | | | 2. The patient has a diagnosis of multiple myeloma. | | | | |
| | | | 3. The prescribing clinician understands that the combination of selinexor plus dexamethasone is not funded for amyloidosis patients (with the exception of patients who have a proven diagnosis of myeloma with an associated diagnosis of amyloidosis) and that NHS funding for selinexor plus dexamethasone is only for the specific 5th or more line multiple myeloma indication recommended by NICE.<br><br>Please tick box below:<br>- this patient does not have a diagnosis of primary amyloidosis<br>- this patient has a proven diagnosis of progressive myeloma with an associated diagnosis of amyloidosis and the combination of selinexor plus dexamethasone is being prescribed for the myeloma | | | | |
| | | | 4. The patient has received at **least 4 prior lines of systemic treatment** and that the numbering of a line of treatment is in accordance with the International Myeloma Workshop Consensus recommendations for the uniform reporting of clinical trials (http://doi.org/10.1182/blood-2010-10-299487). A line of therapy is defined as one or more cycles of a planned treatment program. This may consist of one or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner (ie induction chemotherapy/chemotherapies when followed by stem cell transplantation is considered to be 1 line of therapy). A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse or toxicity, the exception to this being the need to attain a sufficient response for stem cell transplantation to proceed. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease.<br><br>Please state the number of lines of systemic therapy received by the patient by ticking the appropriate box below:<br>- this patient has received 4 prior lines of systemic treatment and this patient is therefore receiving selinexor plus dexamethasone as 5th line therapy<br>- this patient has received 5 prior lines of systemic treatment and this patient is therefore receiving selinexor plus dexamethasone as 6th line therapy<br>- this patient has received 6 or more prior lines of systemic treatment and this patient is therefore receiving selinexor plus dexamethasone as 7th or more line therapy | | | | |
| | | | 5. The patient's myeloma is **refractory to at least 2 proteasome inhibitors.**<br><br>NB Refractory myeloma is disease that is non-responsive to therapy or disease that progresses within 60 days of the last line of therapy. | | | | |
| | | | 6. The patient's myeloma is **refractory to at least 2 immunomodulatory agents.**<br><br>NB Refractory myeloma is disease that is non-responsive to therapy or disease that progresses within 60 days of the last line of therapy. | | | | |
| | | | 7. The patient's myeloma is **refractory to an anti-CD38 monoclonal antibody.**<br><br>NB Refractory myeloma is disease that is non-responsive to therapy or disease that progresses within 60 days of the last line of therapy. | | | | |
| | | | 8. The patient's myeloma has demonstrated disease progression whilst receiving or after receiving the last line of therapy. | | | | |
| | | | 9. The patient has not been previously treated with selinexor plus dexamethasone unless the patient was receiving selinexor plus dexamethasone as 5th or more line of therapy via a company compassionate access scheme and all other criteria on this form are fulfilled.<br><br>Please enter below as to which scenario applies to this patient:<br>- no previous treatment with selinexor plus dexamethasone or<br>- previous treatment with selinexor plus dexamethasone as 5th or more line of therapy via a company compassionate access scheme and all other criteria on this form are fulfilled. | | | | |
| | | | 10. The patient is of ECOG performance status 0 or 1 or 2.<br><br>Please tick one of the boxes below:<br>- performance status 0 or<br>- performance status 1 or<br>- performance status 2 | | | | |
| | | | 11. Selinexor is only to be used in combination with dexamethasone and that it is not to be used in combination with any other agents. | | | | |
| | | | 12. The administration schedule of selinexor is as a twice-weekly treatment given in a weekly cycle. | | | | |
| | | | 13. The combination of selinexor plus dexamethasone is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment. | | | | |
| | | | 14. A formal medical review as to whether treatment with selinexor plus dexamethasone continues or not will be scheduled to occur at least by the end of the second month of treatment. | | | | |
| | | | 15. When a treatment break of more than 6 weeks beyond the expected weekly cycle length is needed, a treatment break approval form will be completed to restart treatment. | | | | |
| | | | 16. Selinexor will be otherwise used as set out in its Summary of Product Characteristics. | | | | |

# National Cancer Drugs Fund (CDF) List

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| SELIN3 | **Selinexor** in combination with bortezomib and dexamethasone | For the treatment of multiple myeloma in transplant ineligible patients who have had only 2 prior lines of systemic therapy and who are refractory to lenalidomide where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with selinexor in combination with bortezomib and dexamethasone will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a diagnosis of multiple myeloma.<br>3. The prescribing clinician understands that the combination of selinexor plus bortezomib and dexamethasone is not funded for amyloidosis patients (with the exception of patients who have a proven diagnosis of myeloma with an associated diagnosis of amyloidosis) and that NHS funding for selinexor plus bortezomib and dexamethasone is only for the specific 3rd line multiple myeloma indication recommended by NICE.<br><br>Please tick box below:<br>- this patient does not have a diagnosis of primary amyloidosis<br>- this patient has a proven diagnosis of progressive myeloma with an associated diagnosis of amyloidosis and the combination of selinexor plus bortezomib and dexamethasone is being prescribed for the myeloma<br>4. The patient has received **2 and no more than 2 prior lines of systemic treatment** and that the numbering of a line of treatment is in accordance with the International Myeloma Workshop Consensus recommendations for the uniform reporting of clinical trials (http://doi.org/10.1182/blood-2010-10-299487). A line of therapy is defined as one or more cycles of a planned treatment program. This may consist of one or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner (ie induction chemotherapy/chemotherapies when followed by stem cell transplantation is considered to be 1 line of therapy). A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse or toxicity, the exception to this being the need to attain a sufficient response for stem cell transplantation to proceed. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease.<br><br>Please verify that the patient has only received 2 prior lines of systemic therapy by ticking the box below:<br>- this patient has received 2 and no more than 2 prior lines of systemic treatment and this patient is therefore receiving selinexor plus bortezomib and dexamethasone as 3rd line therapy<br><br>Note: The use of the combination of selinexor plus bortezomib and dexamethasone in the 2-prior treatment setting was one of the places in the treatment pathway chosen by Menarini Stemline for its submission to NICE for the appraisal of clinical and cost effectiveness of this combination.<br>5. The patient has demonstrated disease progression whilst receiving or within 60 days of completion of 1st or 2nd line combination therapy which contained lenalidomide.<br><br>Note: the need for patients to have myeloma which was or has become refractory to a 1st or 2nd line therapy containing lenalidomide is the basis of the NICE recommendation as this combination of selinexor plus bortezomib and dexamethasone was not cost effective in patients eligible to receive lenalidomide as part of 3rd line systemic therapy. For example, selinexor plus bortezomib and dexamethasone was not cost effective when compared with ixazomib plus lenalidomide and dexamethasone.<br>6. The patient has not been previously treated with selinexor plus bortezomib and dexamethasone unless the patient was receiving selinexor plus bortezomib and dexamethasone as 3rd line therapy via a company compassionate access scheme and all other criteria on this form are fulfilled.<br><br>Please enter below as to which scenario applies to this patient:<br>- no previous treatment with selinexor plus bortezomib and dexamethasone or<br>- previous treatment with selinexor plus bortezomib and dexamethasone as 3rd line therapy via a company compassionate access scheme and all other criteria on this form are fulfilled.<br>7. The patient is ineligible for high dose chemotherapy and stem cell transplantation.<br>8. The patient is of ECOG performance status 0 or 1 or 2.<br><br>Please tick one of the boxes below:<br>- performance status 0 or<br>- performance status 1 or<br>- performance status 2<br>9. Selinexor is only to be used in combination with bortezomib and dexamethasone and that it is not to be used in combination with any other agents.<br>10. The dosage schedule of selinexor is as a once-weekly treatment given in weeks 1-5 of each 5-week cycle.<br>11. The combination of selinexor plus bortezomib and dexamethasone is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment.<br>12. A formal medical review as to whether treatment with selinexor in combination with bortezomib and dexamethasone continues or not will be scheduled to occur at least by the end of the second 5-week cycle of treatment.<br>13. When a treatment break of more than 6 weeks beyond the expected 5-week cycle length is needed, a treatment break approval form will be completed to restart treatment.<br>14. Selinexor will be otherwise used as set out in its Summary of Product Characteristics. | No | TA974 | 15-May-24 | 13-Aug-24 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| SEL1 | **Selpercatinib** | For the treatment of adults or adolescents aged 12 years and older with previously treated RET fusion positive non-medullary thyroid cancer where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with selpercatinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy. | No | TA1038 | 12-Feb-25 | 13-May-25 |
| | | | 2. This patient has a proven histological or cytological diagnosis of non-medullary thyroid cancer (there is a separate form SEL02 for selpercatinib in medullary thyroid cancer).<br>Please enter below as to which type of thyroid cancer this patient has:<br>- papillary thyroid cancer or<br>- follicular thyroid cancer or<br>- Hurtle cell thyroid cancer or<br>- anaplastic thyroid cancer | | | | |
| | | | 3. This patient's thyroid cancer has been documented as having a RET fusion as determined by a validated genomic test.<br>Please enter below as to which is the RET fusion partner in this patient's thyroid cancer:<br>- CCDC6 or<br>- NCOA4 or<br>- another fusion partner | | | | |
| | | | 4. The patient is either an adult or an adolescent aged 12 years and older.<br>Please indicate which applies:<br>- the patient is an adult or<br>- the patient is an adolescent<br>Note: if the patient is an adolescent, open growth plates should be monitored. | | | | |
| | | | 5. Either the patient's disease is refractory to radioactive iodine or that treatment with radioactive iodine is inappropriate. | | | | |
| | | | 6. Either the patient has differentiated thyroid cancer (papillary/follicular/Hurtle cell) and has therefore been treated with lenvatinib or sorafenib or the patient has anaplastic thyroid cancer in which case no previous TKI treatment requirement is necessary.<br>Please enter below as to the previous TKI therapy that the patient has received:<br>- lenvatinib for differentiated thyroid cancer or<br>- sorafenib for differentiated thyroid cancer or<br>- has anaplastic thyroid cancer and hence no previous TKI therapy | | | | |
| | | | 7. The patient has an ECOG performance status (PS) of 0 or 1 or 2. | | | | |
| | | | 8. Selpercatinib is being given as monotherapy. | | | | |
| | | | 9. The patient has not previously received selpercatinib or any other TKI which targets the RET receptor unless the patient has received selpercatinib via a company early access scheme and the patient meets all the other criteria listed here. | | | | |
| | | | 10. Selpercatinib is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment. | | | | |
| | | | 11. The prescribing clinician is aware of the following issues as regards the administration of selpercatinib as detailed in its Summary of Product Characteristics (SPC):<br>- the dosage of selpercatinib is according to body weight<br>- selpercatinib has reduced solubility at a higher pH and hence precautions are necessary with the co-administration of proton pump inhibitors or H2 antagonists<br>- selpercatinib has clinically important interactions with CYP3A inhibitors or CYP3A inducers | | | | |
| | | | 12. A formal medical review as to how selpercatinib is being tolerated and whether treatment with selpercatinib should continue or not will be scheduled to occur at least by the start of the third 4-weekly cycle of treatment. | | | | |
| | | | 13. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, a treatment break approval form will be completed to restart treatment. | | | | |
| | | | 14. Selpercatinib is to be otherwise used as set out in its Summary of Product Characteristics. | | | | |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| SEL2 | **Selpercatinib** | For the treatment of adults or adolescents aged 12 years and older with previously treated RET mutant medullary thyroid cancer where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with selpercatinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. This patient is an adult or an adolescent aged 12 years and older with a proven histological or cytological diagnosis of medullary thyroid cancer (there is a separate form SEL01 for selpercatinib in non-medullary thyroid cancer).<br>Please enter below as to whether the patient is an adult or adolescent aged 12 years or older:<br>- the patient is an adult or<br>- the patient is an adolescent aged 12 years or older<br>Note: if the patients is an adolescent, open growth plates should be monitored.<br>3. This patient's thyroid cancer has been documented as having a RET mutation as determined by a validated genomic test.<br>Please enter below as to which RET mutation is present in this patient's thyroid cancer:<br>- M918T mutation or<br>- an extracellular cysteine mutation or<br>- V804M/L mutation or<br>- another mutation<br>4. The patient has been previously treated with cabozantinib or vandetanib.<br>Please enter below as to the previous TKI therapy that the patient has received:<br>- cabozantinib or<br>- vandetanib<br>5. The patient has an ECOG performance status (PS) of 0 or 1 or 2.<br>6. Selpercatinib is being given as monotherapy.<br>7. The patient has not previously received selpercatinib or any other TKI which targets the RET receptor unless the patient has received selpercatinib via a company early access scheme and the patient meets all the other criteria listed here.<br>8. Selpercatinib is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment.<br>9. The prescribing clinician is aware of the following issues as regards the administration of selpercatinib as detailed in its Summary of Product Characteristics (SPC):<br>- the dosage of selpercatinib is according to body weight<br>- selpercatinib has reduced solubility at a higher pH and hence precautions are necessary with the co-administration of proton pump inhibitors or H2 antagonists<br>- selpercatinib has clinically important interactions with CYP3A inhibitors or CYP3A inducers<br>10. A formal medical review as to how selpercatinib is being tolerated and whether treatment with selpercatinib should continue or not will be scheduled to occur at least by the start of the third 4-weekly cycle of treatment.<br>11. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, a treatment break approval form will be completed to restart treatment.<br>12. Selpercatinib is to be otherwise used as set out in its Summary of Product Characteristics. | No | TA1038 | 12-Feb-25 | 13-May-25 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| SEL3 | **Selpercatinib** | Selpercatinib as monotherapy for the treatment of adult patients with advanced non-small cell lung cancer (NSCLC) exhibiting a RET gene fusion and who have previously received immunotherapy and/or platinum-based chemotherapy where the following criteria have been met: | 1. This application for selpercatinib is being made by and the first cycle of systemic anti-cancer therapy with selpercatinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has locally advanced or metastatic non-small cell lung cancer.<br>3. The patient has a histologically or cytologically confirmed diagnosis of non-small cell lung cancer.<br>Please mark which type of NSCLC applies to this patient:<br>- non-squamous NSCLC or<br>- squamous NSCLC<br>4. This patient's NSCLC has been shown to harbour a RET gene fusion as determined on a tumour tissue biopsy or a plasma specimen (liquid biopsy) or both.<br>Please mark which type of specimen was positive for the presence of the RET gene fusion:<br>- tumour tissue biopsy or<br>- plasma specimen (liquid biopsy) or<br>- both tumour tissue and plasma specimen<br>5. This patient's RET fusion partner has been determined to be in one of the categories as set out below:<br>- KIF5B<br>- CCDC6<br>- NCOA4<br>- RELCH<br>- another fusion partner<br>- unknown fusion partner<br>6. This patient has previously received immunotherapy and/or platinum-based chemotherapy for this locally advanced or metastatic NSCLC indication.<br>Please mark below which of these 5 scenarios applies to this patient:<br>- the only treatment that the patient has received is platinum-based cytotoxic chemotherapy for locally advanced or metastatic NSCLC with or without 2nd line cytotoxic chemotherapy or<br>- the only treatment that the patient has received is 1st line immunotherapy monotherapy for locally advanced or metastatic NSCLC or<br>- the patient has received 1st line combination treatment of platinum-based chemotherapy with immunotherapy for locally advanced or metastatic NSCLC with or without 2nd line cytotoxic chemotherapy or<br>- the patient has received 1st line immunotherapy monotherapy for locally advanced or metastatic NSCLC followed by 2nd line cytotoxic chemotherapy with or without further cytotoxic chemotherapy or<br>- the patient has received 1st line platinum-based cytotoxic chemotherapy for locally advanced or metastatic NSCLC followed by 2nd line immunotherapy with or without further cytotoxic chemotherapy<br>7. The patient has not previously received selpercatinib or any other TKI which targets the RET receptor unless the patient has received selpercatinib via a company early access scheme and the patient meets all the other criteria listed here.<br>8. The patient has an ECOG performance status (PS) score of 0 or 1 or 2.<br>Please mark below the performance status of the patient:<br>- ECOG PS 0<br>- ECOG PS 1<br>- ECOG PS 2<br>9. The patient either has no known brain/CNS metastases or if the patient does have brain/CNS metastases then the patient is symptomatically stable before starting selpercatinib.<br>Please mark below the status with respect to known brain/CNS metastases:<br>- the patient has never had known brain/CNS metastases<br>- the patient has had brain/CNS metastases treated before with surgery/radiotherapy and is currently symptomatically stable<br>- the patient has brain secondaries which have not been treated with surgery/radiotherapy and is currently symptomatically stable<br>10. Selpercatinib will be used as monotherapy.<br>11. The prescribing clinician is aware of the following issues as regards the administration of selpercatinib as detailed in its Summary of Product Characteristics (SPC):<br>- the dosage of selpercatinib is according to body weight<br>- selpercatinib has reduced solubility at a higher pH and hence precautions are necessary with the co-administration of proton pump inhibitors or H2 antagonists<br>- selpercatinib has clinically important interactions with CYP3A inhibitors or CYP3A inducers<br>12. The patient will be treated until loss of clinical benefit or excessive toxicity or patient choice to discontinue treatment whichever is the sooner.<br>13. A formal medical review as to how selpercatinib is being tolerated and whether treatment with selpercatinib should continue or not will be scheduled to occur at least by the start of the third 4-weekly cycle of treatment.<br>14. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment, including as appropriate if the patient has had an extended break on account of Covid-19.<br>15. Selpercatinib is to be otherwise used as set out in its Summary of Product Characteristics (SPC). | No | TA1042 | 19-Feb-25 | 20-May-25 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| SEL5 | **Selpercatinib** | For the treatment of adults and adolescents aged 12 years and older with RET fusion positive non-medullary thyroid cancer previously UNTREATED with any kinase inhibitor therapy where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with selpercatinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy. | No | TA1039 | 12-Feb-25 | 13-May-25 |
| | | | 2. This patient has a proven histological or cytological diagnosis of non-medullary thyroid cancer (there is a separate form SEL6 for selpercatinib in medullary thyroid cancer previously untreated with any kinase inhibitor therapy).<br>Please enter below as to which type of thyroid cancer this patient has:<br>- papillary thyroid cancer or<br>- follicular thyroid cancer or<br>- Hurtle cell thyroid cancer or<br>- anaplastic thyroid cancer | | | | |
| | | | 3. This patient's thyroid cancer has been documented as having a RET fusion as determined by a validated genomic test.<br>Please enter below as to which is the RET fusion partner in this patient's thyroid cancer:<br>- CCDC6 or<br>- NCOA4 or<br>- another fusion partner | | | | |
| | | | 4. The patient is either an adult or an adolescent aged 12 years and older.<br>Please enter below as to which applies to this patient:<br>- the patient is an adult or<br>- the patient is an adolescent aged 12 years and older<br>Note: if the patient is an adolescent, open growth plates should be monitored. | | | | |
| | | | 5. The patient's disease is either refractory to radioactive iodine or that treatment with radioactive iodine is inappropriate. | | | | |
| | | | 6. The patient is previously untreated with any kinase inhibitor unless the patient has received selpercatinib via a company early access scheme and the patient meets all the treatment criteria on this form. | | | | |
| | | | 7. The patient has an ECOG performance status (PS) of 0 or 1 or 2. | | | | |
| | | | 8. Selpercatinib is being given as monotherapy. | | | | |
| | | | 9. Selpercatinib is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment. | | | | |
| | | | 10. The prescribing clinician is aware of the following issues as regards the administration of selpercatinib as detailed in its Summary of Product Characteristics (SPC): | | | | |
| | | | 11. A formal medical review as to how selpercatinib is being tolerated and whether treatment with selpercatinib should continue or not will be scheduled to occur at least by the start of the third 4-weekly cycle of treatment. | | | | |
| | | | 12. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, the prescribing clinician will complete a treatment break approval form to restart treatment. | | | | |
| | | | 13. Selpercatinib is to be otherwise used as set out in its Summary of Product Characteristics. | | | | |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| SEL6 | **Selpercatinib** | For the treatment of adults or adolescents aged 12 years and older with RET mutant medullary thyroid cancer previously UNTREATED with any kinase inhibitor therapy where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with selpercatinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy. | No | TA1039 | 12-Feb-25 | 13-May-25 |
| | | | 2. This patient is an adult or an adolescent aged 12 years and older with a proven histological or cytological diagnosis of medullary thyroid cancer (there is a separate form SEL5 for selpercatinib in non-medullary thyroid cancer previously untreated with any kinase inhibitor therapy).<br>Please enter below as to which applies to this patient:<br>- the patient is an adult or<br>- the patient is an adolescent aged 12 years and older<br>Note: if the patient is an adolescent, open growth plates should be monitored. | | | | |
| | | | 3. This patient's thyroid cancer has been documented as having a RET mutation as determined by a validated genomic test.<br>Please enter below as to which RET mutation is present in this patient's thyroid cancer:<br>- M918T mutation or<br>- an extracellular cysteine mutation or<br>- V804M/L mutation or<br>- another mutation | | | | |
| | | | 4. The patient is **previously untreated with any kinase inhibitor** unless the patient has received selpercatinib via a company early access scheme and the patient meets all the treatment criteria on this form. | | | | |
| | | | 5. The patient has an ECOG performance status (PS) of 0 or 1 or 2. | | | | |
| | | | 6. Selpercatinib is being given as monotherapy. | | | | |
| | | | 7. Selpercatinib is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment. | | | | |
| | | | 8. The prescribing clinician is aware of the following issues as regards the administration of selpercatinib as detailed in its Summary of Product Characteristics (SPC):<br>- the dosage of selpercatinib is according to body weight<br>- selpercatinib has reduced solubility at a higher pH and hence precautions are necessary with the co-administration of proton pump inhibitors or H2 antagonists<br>- selpercatinib has clinically important interactions with CYP3A inhibitors or CYP3A inducers | | | | |
| | | | 9. A formal medical review as to how selpercatinib is being tolerated and whether treatment with selpercatinib should continue or not will be scheduled to occur at least by the start of the third 4-weekly cycle of treatment. | | | | |
| | | | 10. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, the prescribing clinician will complete a treatment break approval form to restart treatment. | | | | |
| | | | 11. Selpercatinib is to be otherwise used as set out in its Summary of Product Characteristics. | | | | |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| SOR2 | **Sorafenib** | The treatment of differentiated thyroid cancer after radioactive iodine where the following criteria are met: | 1. This application is made by and the first cycle of systemic anti-cancer therapy with sorafenib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy<br>2. This patient has a confirmed histological diagnosis of differentiated thyroid carcinoma (papillary or follicular or Hurtle cell type)<br>3.The patient has either metastatic disease or inoperable locally advanced disease<br>4. The disease is refractory to radioactive iodine<br>5. The disease is progressive and is either symptomatic or imminently likely to become symptomatic<br>6. The patient is treatment naïve to both lenvatinib and sorafenib unless the patient has had to discontinue lenvatinib within 3 months of starting lenvatinib because of toxicity (ie there is lenvatinib toxicity which cannot be managed by dose delay or dose modification) and there has been no disease progression whilst on lenvatinib.<br>Note: Sequential use of sorafenib and then lenvatinib is only funded if the patient has to discontinue sorafenib because of intolerance within 3 months of its start and if the disease has not progressed whilst the patient is on sorafenib. The use of sorafenib after disease progression on or after lenvatinib is not funded and vice versa.<br>7. The patient has an ECOG performance status of 0 or 1 or 2.<br>8. Sorafenib is to be continued as long as clinical benefit is observed or until there is unacceptable toxicity or patient choice to stop treatment.<br>9. A formal medical review as to whether treatment with sorafenib should continue or not will be scheduled to occur at least by the end of the first 8 weeks of treatment<br>10. No treatment breaks of more than 6 weeks beyond the expected cycle length are allowed (to allow any toxicity of current therapy to settle or intercurrent comorbidities to improve)<br>11. Sorafenib is to be otherwise used as set out in its Summary of Product Characteristics | Yes | TA535 | 08-Aug-18 | 06-Nov-18 |
| SOR3 | **Sorafenib monotherapy** | Treatment of Child-Pugh A locally advanced or metastatic hepatocellular carcinoma where the following criteria are met: | 1. An application has been made by and the first cycle of systemic anti-cancer therapy is to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy<br>2. ONE of the following applies to the patient: the patient has a confirmed histological diagnosis of hepatocellular carcinoma **or** a biopsy is deemed to be very high risk or technically not feasible in the patient AND the criteria below are met:<br>a. The decision not to biopsy has been made and documented by a specialist HCC MDM<br>b. The tumour meets the non-invasive diagnostic criteria of hepatocellular carcinoma*<br>c. Data is submitted as part of the ongoing Sorafenib Audit 2.<br>It is expected that OPTION 2 will only apply in exceptional circumstances and it should be noted that responses will be reviewed regularly to ensure that this is the case.<br>*EASL–EORTC Clinical Practice Guidelines: Management, Journal of Hepatology 2012 vol. 56 p 908–943. Non-invasive criteria can only be applied to cirrhotic patients and are based on imaging techniques obtained by 4-phase multidetector CT scan or dynamic contrast-enhanced MRI. Diagnosis should be based on the identification of the typical hallmark of HCC (hypervascular in the arterial phase with washout in the portal venous or delayed phases). While one imaging technique is required for nodules beyond 1 cm in diameter a more conservative approach with 2 techniques is recommended in suboptimal settings.<br>3. Patient must have either metastatic disease or locally advanced disease that is ineligible for or failed surgical or locoregional therapies<br>4. Either:<br>- the patient has not received any previous systemic therapy for hepatocellular carcinoma (option 1) **or**<br>- the patient has had to discontinue lenvatinib within 3 months of starting lenvatinib and solely because of toxicity (i.e. there was lenvatinib toxicity which could not be managed by dose delay or dose modification) and there has been no disease progression whilst on lenvatinib (option 2) **or**<br>- if the patient has received atezolizumab+bevacizumab or durvalumab/tremelimumab as 1st line treatment (option 3)<br>5. Patient must have Child-Pugh liver function class A<br>6. Patient has a performance status of 0-2<br>7. Sorafenib is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment<br>8. No treatment breaks of more than 6 weeks beyond the expected cycle length of four weeks are allowed (to allow any toxicity of current therapy to settle or intercurrent comorbidities to improve).<br>9. Sorafenib to be otherwise used as set out in its Summary of Product Characteristics | Yes | TA474 | 06-Sep-17 | 05-Dec-17 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| SOR5 | **Sorafenib** | Sorafenib maintenance for the treatment of FLT3-Internal Tandem Duplication (FLT3-ITD) acute myeloid leukaemia (AML) post allogeneic haematopoietic stem cell transplantation (allo-HSCT) **IN ADULTS** where the following criteria are met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with sorafenib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a diagnosis of FLT3-Internal Tandem Duplication (FLT3-ITD) mutation acute myeloid leukaemia (AML).<br>3. The patient is aged 18 and over.<br>4. Sorafenib is not licensed for FLT3-ITD mutation AML maintenance therapy post allogeneic haematopoietic stem cell transplantation (allo-HSCT) and therefore Trust policy regarding unlicensed medicines has been followed.<br>5. The patient has been discussed by a relevant specialist MDT and it has been agreed that sorafenib is the most appropriate therapy.<br>6. Sorafenib in this indication is to be used as monotherapy and not combined with any other maintenance therapy and that the patient will receive the recommended dosing of sorafenib as outlined in the NHS England Clinical Commissioning Policy and the product's Summary of Product Characteristics.<br>7. The patient meets all of the following eligibility criteria:<br>o has undergone allogeneic haematopoietic stem cell transplantation **AND**<br>o Exhibits adequate engraftment (absolute neutrophil count of at least 1.0 x $10^9$/L and a non-transfused platelet count of at least 30 x $10^9$/L) at the time of sorafenib initiation.<br>8. The patient does not meet any one of the following exclusion criteria:<br>o Individuals with contraindications to sorafenib, as outlined in the summary of product characteristics (SPC) OR<br>o Uncontrolled graft versus host disease (GvHD) OR<br>o Persistent liver dysfunction (total bilirubin twice or more the upper limit of normal [ULN] or alanine aminotransferase or aspartate aminotransferase twice or more the ULN) OR<br>o Persistent renal dysfunction (creatinine twice or more the ULN or creatinine clearance <30mL/min) OR<br>o Individuals with severe concomitant conditions for whom the MDT determines that sorafenib maintenance cannot be delivered safely.<br>9. The patient has not been previously treated with sorafenib unless the patient received sorafenib via the Bayer compassionate access scheme in which case all other treatment criteria on this form must be fulfilled.<br>10. Treatment with sorafenib maintenance therapy will commence no later than 4 months after the date of allo-HSCT and continue for up to a maximum of 24-months post allo-HSCT.<br>**Note:** the 24 months duration is fixed and starts from the date of the allo-HSCT regardless of the actual start date of sorafenib or the need for any treatment breaks. Ticking this criterion is also confirming that the patient has been consented to future discontinuation of sorafenib no later than 24 months after the date of allo-HSCT.<br>11. Treatment with sorafenib maintenance therapy will be stopped at whichever of the following events occurs first; completion of 24-month duration after the date of allo-HSCT, grade 3 or grade 4 GvHD, disease progression or withdrawal of patient consent, whichever is the sooner.<br>12. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, the prescribing clinician will complete a treatment break approval form to restart treatment.<br>13. Sorafenib will otherwise be used as set out in its Summary of Product Characteristics (SPC). | No | NHSE Policy: URN2262 | N/A | 06-Nov-23 |
| SOR6 | **Sorafenib** | Sorafenib maintenance for the treatment of FLT3-Internal Tandem Duplication (FLT3-ITD) acute myeloid leukaemia (AML) post allogeneic haematopoietic stem cell transplantation (allo-HSCT) **IN POST-PUBESCENT CHILDREN** where the following criteria are met: | 1. An application has being made by and the first cycle of systemic anti-cancer therapy with sorafenib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a diagnosis of FLT3-Internal Tandem Duplication (FLT3-ITD) mutation acute myeloid leukaemia (AML).<br>3. The patient is a post-pubescent child receiving access under the Medicines for Children policy.<br>4. Sorafenib is not licensed for FLT3-ITD mutation AML maintenance therapy post allogeneic haematopoietic stem cell transplantation (allo-HSCT) and therefore Trust policy regarding unlicensed medicines has been followed.<br>5. The patient has been discussed by a relevant specialist MDT and it has been agreed that sorafenib is the most appropriate therapy. This MDT must include at least two consultants with experience in the treatment of FLT3-ITD AML of whom at least one must be a consultant paediatrician. The MDT should also include a paediatric pharmacist and other professional groups appropriate to the disease area.<br>6. I confirm that sorafenib in this indication is to be used as monotherapy and not combined with any other maintenance therapy and that the patient will receive the recommended dosing of sorafenib as outlined in the NHS England Clinical Commissioning Policy and the product's Summary of Product Characteristics.<br>7. The patient meets all of the following eligibility criteria:<br>o has undergone allogeneic haematopoietic stem cell transplantation **AND**<br>o Exhibits adequate engraftment (absolute neutrophil count of at least 1.0 x $10^9$/L and a non-transfused platelet count of at least 30 x $10^9$/L) at the time of sorafenib initiation.<br>8. The patient does not meet any one of the following exclusion criteria:<br>o Individuals with contraindications to sorafenib, as outlined in the summary of product characteristics (SPC) OR<br>o Uncontrolled graft versus host disease (GvHD) OR<br>o Persistent liver dysfunction (total bilirubin twice or more the upper limit of normal [ULN] or alanine aminotransferase or aspartate aminotransferase twice or more the ULN) OR<br>o Persistent renal dysfunction (creatinine twice or more the ULN or creatinine clearance <30mL/min) OR<br>o Individuals with severe concomitant conditions for whom the MDT determines that sorafenib maintenance cannot be delivered safely.<br>9. The patient has not been previously treated with sorafenib unless the patient received sorafenib via the Bayer compassionate access scheme in which case all other treatment criteria on this form must be fulfilled.<br>10. Treatment with sorafenib maintenance therapy will commence no later than 4 months after the date of allo-HSCT and continue for up to a maximum of 24-months post allo-HSCT.<br>**Note:** the 24 months duration is fixed and starts from the date of the allo-HSCT regardless of the actual start date of sorafenib or the need for any treatment breaks. Ticking this criterion is also confirming that the patient and/or carer have been informed and consented (as appropriate) to future discontinuation of sorafenib no later than 24 months after the date of allo-HSCT.<br>11. Treatment with sorafenib maintenance therapy will be stopped at whichever of the following events occurs first; completion of 24-month duration after the date of allo-HSCT, grade 3 or grade 4 GvHD, disease progression or withdrawal of patient consent, whichever is the sooner.<br>12. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, the prescribing clinician will complete a treatment break approval form to restart treatment.<br>13. Sorafenib will otherwise be used as set out in its Summary of Product Characteristics (SPC). | No | NHSE Policy: URN2262 | N/A | 06-Dec-23 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| SUN1 | **Sunitinib** | The treatment of unresectable or metastatic neuroendocrine tumours of pancreatic origin with disease progression where all the following criteria are met: | 1. An application has been made by and the first cycle of systemic anti-cancer therapy is to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy<br>2. The patient has histopathologically proven well differentiated neuroendocrine tumour of pancreatic origin<br>3. The patient has unresectable or metastatic disease<br>4. The patient has exhibited disease progression in past 12 months<br>5. The patient has a performance status of 0-1<br>6. The patient has had no previous treatment with a tyrosine kinase inhibitor.<br>7. No planned treatment breaks of more than 6 weeks beyond the expected cycle length are allowed (to allow any toxicity of current therapy to settle or intercurrent comorbidities to improve).*<br>*Requests for continuation of treatment after unplanned treatment breaks over this duration should be made via the treatment break approval process<br>8. Sunitinib will otherwise be used as set out in its Summary of Product Characteristics (SPC). | Yes | TA449 | 13-May-17 | 26-Sep-17 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| TAL1 | **Talazoparib monotherapy** | Talazoparib as monotherapy for treatment of adults with deleterious or suspected deleterious germline BRCA1 or 2 mutations who have HER-2 negative locally advanced or metastatic breast cancer previously treated with an anthracycline and/or taxane in the adjuvant/neoadjuvant/advanced disease settings and also treated with prior endocrine-based therapy if the patient has hormone-receptor positive disease where the following criteria have been met: | 1. This application is both being made by and the first cycle of systemic anti-cancer therapy with talazoparib monotherapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy<br>2. This patient has a proven histological diagnosis of **HER 2 negative** breast cancer.<br>3. This patient has locally advanced or metastatic breast cancer.<br><br>Note: talazoparib for the treatment of early breast cancer is not funded.<br>4. This patient **HAS** a documented **germline** deleterious or suspected deleterious BRCA 1 or BRCA 2 mutation(s).<br><br>Please enter below as to which deleterious or suspected deleterious BRCA mutation(s) the patient has:<br>- BRCA 1 mutation or<br>- BRCA 2 mutation or<br>- both BRCA1 and BRCA 2 mutations<br>5. The patient has received prior chemotherapy with an anthracycline and/or a taxane in any of the adjuvant or neoadjuvant or advanced disease settings unless these chemotherapy agents were contraindicated.<br><br>Please enter below as to which of the following scenarios applies to this patient:<br>- the patient has received treatment with an anthracycline and/or a taxane in any of the adjuvant or neoadjuvant or advanced disease settings or<br>- chemotherapy with an anthracycline and/or a taxane was contraindicated in the adjuvant or neoadjuvant or advanced disease settings<br>6. The patient either has triple negative disease or if the patient has hormone receptor positive disease then the patient has already been treated with appropriate endocrine-based therapy or such therapy was contraindicated.<br><br>Please mark below which option applies to this patient:<br>- the patient has triple negative disease or<br>- the patient has hormone receptor positive disease and received appropriate endocrine-based therapy or<br>- the patient has hormone receptor positive disease and use of appropriate endocrine-based therapy was contraindicated in this patient<br>7. Talazoparib will be used as monotherapy and not in combination with any endocrine-based therapy.<br>8. The patient has not received any previous treatment with a PARP inhibitor unless olaparib for this same advanced breast cancer indication has had to be stopped within 6 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression or the patient has received adjuvant olaparib and this was completed without disease progression during therapy or within 12 months of its completion.<br><br>Please mark below which option applies to this patient:<br>- the patient has never received any PARP inhibitor therapy<br>- olaparib for this same advanced breast cancer indication has had to be stopped within 6 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression<br>- the patient has received adjuvant olaparib and this was completed without disease progression during therapy or within 12 months of its completion<br>9. The patient has an ECOG performance status of either 0 or 1 or 2.<br>10. Any brain metastases or leptomeningeal metastases in this patient are symptomatically stable<br>11. Talazoparib is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment.<br>12. The prescribing clinician is aware of the dose reductions necessary for talazoparib in patients with renal impairment as specified in the talazoparib Summary of Product Characteristics (section 4.2).<br>13. The prescribing clinician is aware of the potential drug interactions which talazoparib has with other medicines, as outlined in sections 4.2 and 4.5 of the talazoparib Summary of Product Characteristics.<br>14. A formal medical review as to how talazoparib is being tolerated and whether talazoparib should continue or not will be scheduled to occur at least by the start of the third 4-weekly cycle of treatment.<br>15. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, the prescribing clinician will complete a treatment break approval form to restart treatment.<br>16. Talazoparib is to be otherwise used as set out in its Summary of Product Characteristics (SPC). | No | TA952 | 21-Feb-24 | 21-May-24 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| TAL2 | **Talazoparib** plus enzalutamide | For the treatment of metastatic hormone-relapsed (castrate-resistant) prostate cancer in patients who are treatment naïve to androgen receptor inhibitors and in whom chemotherapy is not yet clinically indicated or appropriate where the following criteria have been met: | 1. This application for talazoparib plus enzalutamide is being made by and the first cycle of systemic anti-cancer therapy with talazoparib plus enzalutamide will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient either has a proven histological or cytological diagnosis of adenocarcinoma of the prostate or has presented with a clinical picture consistent with metastatic prostate cancer with both widespread bone metastases typical of prostate cancer and a serum PSA of at least 50ng/ml.<br>3. The patient has progressive hormone-relapsed (castrate-resistant) disease.<br>4. The patient has not been treated with chemotherapy for the hormone-relapsed (castrate-resistant) indication and that for this same hormone-relapsed (castrate-resistant) indication chemotherapy is either not yet clinically indicated or is inappropriate (contraindicated or declined by the patient).<br><br>Note: chemotherapy given for hormone-sensitive disease earlier in the treatment pathway does not exclude patients from potential access to talazoparib plus enzalutamide.<br>5. The patient has pre existing clinical conditions that preclude the use of abiraterone plus prednisolone (given with olaparib) **OR** the patient commenced abiraterone (with olaparib) in this same indication, and that combination had to be discontinued due to lack of tolerance (despite dose reductions being instigated) in the absence of any signs of disease progression.<br><br>Please mark below which scenario applies to this patient:<br>- the patient has pre existing clinical conditions that preclude the use of abiraterone plus prednisolone (given with olaparib) **OR**<br>- the patient commenced abiraterone (with olaparib) in this same indication, and that combination had to be discontinued due to lack of tolerance (despite dose reductions being instigated) in the absence of any signs of disease progression.<br>6. The patient has not previously received any therapy with an androgen receptor inhibitor such as enzalutamide, abiraterone, apalutamide or darolutamide at any place in the prostate cancer treatment pathway except in the case of patients who received androgen receptor inhibitor therapy for hormone-sensitive disease and stopped this treatment more than 12 months prior to this application without PSA progression or evidence of clinical or radiological progressive disease at the time such androgen receptor inhibitor therapy was discontinued<br>**OR**<br>the patient commenced abiraterone (with olaparib) in this same indication, and that combination had to be discontinued due to lack of tolerance (despite dose reductions being instigated) in the absence of any signs of disease progression<br><br>Please mark below which scenario applies to this patient:<br>- the patient has not previously received any therapy with an androgen receptor inhibitor such as enzalutamide, abiraterone, apalutamide or darolutamide at any place in the prostate cancer treatment pathway OR<br>- the patient received androgen receptor inhibitor therapy for hormone-sensitive disease and stopped this treatment more than 12 months prior to this application without PSA progression or evidence of clinical or radiological progressive disease at the time such androgen receptor inhibitor therapy was discontinued OR<br>- the patient commenced abiraterone (with olaparib) in this same indication, and this combination had to be discontinued due to lack of tolerance (despite dose reductions being instigated) in the absence of any sign of disease progression<br><br>Note: patients previously treated with previous androgen receptor inhibitor therapy who do not fulfil the exceptions above are NOT eligible for treatment with olaparib plus abiraterone.<br>7. The patient has not received any previous PARP inhibitor therapy, unless the patient commenced olaparib (with abiraterone) in this same indication, and that combination had to be discontinued due to lack of tolerance (despite dose reductions being instigated) in the absence of any signs of disease progression.<br>8. The patient has an ECOG performance score of 0 or 1.<br>9. Talazoparib is only to be given in combination with enzalutamide.<br><br>Note: talazoparib cannot be given in combination with abiraterone or any other androgen receptor inhibitor.<br><br>Note: it is expected that treatment with LHRH agonists/antagonists will continue unless the patient has undergone surgical castration.<br>10. Talazoparib and enzalutamide are to be continued until disease progression or the development of unacceptable toxicity or patient choice to discontinue treatment, whichever is the sooner.<br>11. When a treatment break of more than 6 weeks beyond the expected 4-week cycle length is needed, the prescribing clinician will complete a treatment break approval form to restart treatment, which MUST be approved before treatment is recommenced.<br>12. Talazoparib and enzalutamide will otherwise be used as set out in their respective Summaries of Product Characteristics (SPCs). | No | TA1130 | 11-Feb-26 | 13-Mar-26 |

# National Cancer Drugs Fund (CDF) List

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| TALI1 | **Talimogene Laherparepvec** | Talimogene laherparepvec for treating unresectable metastatic melanoma | 1. I confirm that an application has been made and the first treatment will be prescribed and administered by a consultant specialist experienced in the treatment of melanoma<br>2. I confirm this treatment will be given by a specialist trained to give intra-lesional injections of talimogene.<br>3. I confirm the patient has cutaneous, subcutaneous or nodal deposit(s) of melanoma which is/are suitable for direct injection but is/are not surgically resectable.<br>4. I confirm the patient has stage IIIb, stage IIIc or stage IVM1a disease according to the AJCC stage criteria of 2009 7th edition and if stage IVM1a disease (ie metastases to the skin, subcutaneous tissues or distant lymph nodes) has a normal serum LDH.<br>5. I confirm the patient has no bone, brain, lung or any other visceral secondaries and if stage IVM1a disease, the serum LDH is not elevated.<br>6. I confirm talimogene has been sanctioned by a specialist melanoma multidisciplinary team which includes an oncologist and a surgeon with expertise in the management of metastatic and locally advanced melanoma, respectively.<br>7. I confirm that talimogene is appropriate for this patient as systemically administered immunotherapies or approved targeted therapies are not considered the best option by the specialist melanoma multidisciplinary team meeting which includes an oncologist and a surgeon with expertise in the management of metastatic and locally advanced melanoma, respectively.<br>8. I confirm that talimogene will only be administered as a single agent and not in combination with systemic therapies eg chemotherapy, targeted agents or immunotherapy unless this is within the context of a Health Research Authority clinical trial.<br>9. I confirm the patient will receive the licensed dose and frequency of talimogene laherparepvec | No | TA410 | 28-Sep-16 | 28-Dec-16 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| TALQ1 | **Talquetamab monotherapy** | For treating relapsed or refractory multiple myeloma after 3 or more treatments where the following criteria have been met: | 1. This application is being made by, and drugs prescribed by, a consultant or senior resident doctor specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient is an adult with proven relapsed or refractory multiple myeloma.<br><br>Note: patients with amyloidosis or POEMS syndrome are not eligible for talquetamab.<br>3. The patient has had 3 or more lines of treatment, according to the definition below, which must include:<br><br>- an immunomodulatory drug<br>- a proteasome inhibitor and<br>- an anti-CD38 antibody<br><br>The numbering of a line of treatment is in accordance with the International Myeloma Workshop Consensus recommendations for the uniform reporting of clinical trials (http://doi.org/10.1182/blood-2010-10-299487). A line of therapy is defined as one or more cycles of a planned treatment program. This may consist of one or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner (ie induction chemotherapy/chemotherapies when followed by stem cell transplantation is considered to be 1 line of therapy). A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse or toxicity, the exception to this being the need to attain a sufficient response for stem cell transplantation to proceed. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease.<br><br>Please record at which line of therapy talquetamab is being given:<br><br>- as 4th line of therapy<br>- as 5th line of therapy<br>- as 6th or subsequent line of therapy<br>4. This patient has been previously treated with **at least one immunomodulatory agent**.<br><br>Please confirm how many immunomodulatory agents have been used to treat this patient's myeloma:<br>- 1 immunomodulatory agent<br>- 2 or more different immunomodulatory agents<br>5. This patient has been previously treated with **at least one proteasome inhibitor**.<br><br>Please confirm how many different proteasome inhibitors have been used to treat this patient's myeloma:<br>- 1 proteasome inhibitor<br>- 2 or more different proteasome inhibitors<br>6. This patient has been previously treated with **at least one anti-CD38 antibody**.<br><br>Please confirm how many anti-CD38 antibodies have been used to treat this patient's myeloma:<br>- 1 anti-CD38 antibody<br>- 2 or more different anti-CD38 antibodies<br>7. The patient has either previously received a **pomalidomide-containing regime**n or not.<br>- no, the patient has not been treated with a pomalidomide containing regimen<br>- yes, the patient has been treated with a pomalidomide-containing regimen<br>8. The patient has either previously received a **bispecific antibody** or not.<br>- the patient has been treated with teclistamab<br>- the patient has been treated with elranatamab<br>- the patient has been treated with belantamab<br>- no treatment with a bispecific antibody has been given<br>9. Myeloma has progressed on the last treatment.<br>10. The patient has an ECOG performance status of 0, 1 or 2.<br><br>Please record below the ECOG performance status:<br>- PS 0<br>- PS 1<br>- PS 2<br>11. The patient will be treated with talquetamab until loss of clinical benefit or the occurrence of excessive toxicity or the withdrawal of patient consent, whichever is the sooner.<br><br>Note: once talquetamab is electively stopped (ie for reasons other than temporary toxicity), it cannot be re-started.<br>12. When a treatment break of more than 6 weeks beyond the expected weekly or 2-weekly cycle length (as appropriate) is needed, a treatment break approval form will be completed to restart treatment.<br>13. Talquetamab will be used as set out in its Summary of Product Characteristics (SPC). | No | TA1114 | 03-Dec-25 | 03-Mar-26 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| TEB1 | **Tebentafusp** | Tebentafusp as monotherapy for adult patients with human leukocyte antigen HLA-A*02:01 positive unresectable or metastatic uveal melanoma where the following criteria have been met: | 1. This application for tebentafusp monotherapy is both being made by and the first cycle of systemic anti-cancer therapy with tebentafusp will be prescribed by a consultant melanoma specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient is an adult with a histologically proven diagnosis of uveal melanoma.<br>3. The patient's uveal melanoma has been tested for human leukocyte antigen (HLA) and the result is positive for the subtype HLA-A*02:01.<br>4. The patient has unresectable or metastatic uveal melanoma.<br>5. The patient does not have symptomatic or untreated brain metastases.<br>6. The patient has either been previously treated with any prior systemic therapy or not including if the patient has received tebentafusp via a company early access scheme and all other treatment criteria on this form apply.<br><br>Please mark below which clinical scenario applies to this patient:<br>- the patient has not been treated with any prior systemic therapy or tebentafusp<br>- the patient has been treated with prior checkpoint inhibitor systemic therapy and has not received prior tebentafusp<br>- the patient has been treated with prior tebentafusp via a company early access scheme and both continues to benefit from tebentafusp and all other treatment criteria on this form apply<br>7. The patient has an ECOG performance score of 0 or 1.<br>8. Tebentafusp will be used as monotherapy only.<br><br>Note: tebentafusp is not to be used in combination with any other agent.<br>9. The treating hospital has facilities (including those for resuscitation) to manage severe reactions to tebentafusp including cytokine release syndrome (CRS).<br>10. The prescribing clinician and the treating team are aware of the risks and grading of cytokine release syndrome (CRS),<br><br>its monitoring and management as illustrated in Table 1 of section 4.2 of the tebentafusp Summary of Product Characteristics and both I and the treating team have all undergone training in these clinical issues.<br>11. Clear arrangements have been made for the patient to be monitored as an inpatient for signs and symptoms of toxicities including CRS for 16 hours after administration of the first 3 x weekly doses of tebentafusp.<br>12. The prescribing clinician and the treating team are aware that if any grade 3 or 4 hypotension occurs during any of the first 3 infusions, the patient will be monitored every hour for the next 4 hours in an outpatient setting for the<br>13. There is immediate access to treatment with tocilizumab if required to manage CRS.<br>14. The patient will be treated with tebentafusp until there is clear evidence of progressive disease or the occurrence of excessive toxicity or the withdrawal of patient consent, whichever is the sooner.<br>15. A formal medical review as to how tebentafusp is being tolerated and whether treatment with tebentafusp should continue or not will be scheduled to occur at least by the end of the first 4 weeks of treatment.<br>16. When a treatment break of more than 6 weeks beyond the expected weekly cycle length is needed, a treatment break approval form will be completed to restart treatment.<br>17. Tebentafusp will be otherwise used as set out in its Summary of Product Characteristics (SPC). | No | TA1027 | 09-Jan-25 | 09-Apr-25 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| TEC1 | **Teclistamab** | For the treatment of relapsed or refractory myeloma in adult patients who have relapsed or are refractory to their last anti-myeloma regimen AND have received at least 3 prior lines of systemic therapies which must have included at least one proteasome inhibitor, at least one immune-modulatory agent and at least one anti-CD38 antibody and where the following criteria have been met: | 1. This application for teclistamab monotherapy is both being made by and the first cycle of systemic anti-cancer therapy with teclistamab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient is an adult with a proven diagnosis of multiple myeloma.<br>Note: patients with amyloidosis or POEMS syndrome are not eligible for teclistamab.<br>3. The prescribing clinician understands that teclistamab is not funded for amyloidosis patients (with the exception of patients who have a proven diagnosis of myeloma with an associated diagnosis of amyloidosis) and that NHS funding for teclistamab is only for the relapsed or refractory myeloma indication in the specific indication recommended by NICE.<br><br>Please tick the relevant box below:<br>- this patient does not have a diagnosis of primary amyloidosis or<br>- this patient has a proven diagnosis of progressive myeloma with an associated diagnosis of amyloidosis and teclistamab is being prescribed for the myeloma (and all other treatment criteria on this form apply)<br>4. The patient patient has been previously treated with at least one proteasome inhibitor.<br><br>Please confirm how many different proteasome inhibitors have been used to treat this patient's myeloma:<br>- 1 proteasome inhibitor or<br>- 2 or more different proteasome inhibitors<br>5. This patient has been previously treated with at least one immunomodulatory agent.<br><br>Please confirm how many different immunomodulatory agents have been used to treat this patient's myeloma:<br>- 1 immunomodulatory agent or<br>- 2 or more different immunomodulatory agents<br>6. The patient has previously received a pomalidomide-containing regimen or not.<br>- no, the patient has not been treated with a pomalidomide-containing regimen<br>- yes, the patient has been treated with a pomalidomide-containing regimen<br>7. The patient has been previously been treated with at least one anti-CD38 antibody.<br><br>Please confirm how many anti-CD38 antibodies have been used to treat this patient's myeloma:<br>- 1 anti-CD38 antibody or<br>- 2 or more different anti-CD38 antibodies<br>8. The patient **has received at least 3 lines of treatment according to the definition below** and also set out below which line of myeloma therapy teclistamab is being used for.<br>The prescribing clinician confirms that numbering of a line of treatment is in accordance with the International Myeloma Workshop Consensus recommendations for the uniform reporting of clinical trials (http://doi.org/10.1182/blood-2010-10-299487). A line of therapy is defined as one or more cycles of a planned treatment program. This may consist of one or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner (ie induction chemotherapy/chemotherapies when followed by stem cell transplantation is considered to be 1 line of therapy). A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse or toxicity, the exception to this being the need to attain a sufficient response for stem cell transplantation to proceed. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease.<br><br>Please record at which line of therapy teclistamab is being given:<br>- as 4th line of therapy or<br>- as 5th line of therapy or<br>- as 6th or subsequent line of therapy<br>9. The has **NOT** been previously treated with any bispecific antibody targeting both BCMA and CD3 unless teclistamab needs to be continued following access to teclistamab via a company compassionate access scheme AND all treatment criteria on this form are fulfilled.<br><br>Please confirm which situation applies to this patient:<br>- this patient has not been previously treated with a bispecific antibody targeting both BCMA and CD3 or<br>- this patient needs to continue teclistamab following access to teclistamab via a company compassionate access scheme AND all treatment criteria on this form are fulfilled.<br><br>Note: patients previously treated with any bispecific antibody targeting BCMA and CD3 (e.g. elranatamab) are not eligible for teclistamab.<br>10. The patient has ever been treated with a CAR-T therapy such as idecabtagene vicleucel or ciltacabtagene autoleucel.<br><br>Please confirm which situation applies to this patient:<br>- this patient has not been previously treated with a CAR-T therapy or<br>- this patient has received prior CAR-T treatment (eg idecabtagene, ciltacabtagne).<br>**(continued on next page)** | No | TA1015 | 13-Nov-24 | 11-Feb-25 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| TEC1 | **Teclistamab** | For the treatment of relapsed or refractory myeloma in adult patients who have relapsed or are refractory to their last anti-myeloma regimen AND have received at least 3 prior lines of systemic therapies which must have included at least one proteasome inhibitor, at least one immune-modulatory agent and at least one anti-CD38 antibody and where the following criteria have been met: | 11. The patient has been treated with a BCMA-targeted antibody drug conjugate (such as belantamab mafodotin).<br><br>Please confirm which situation applies to this patient:<br>- this patient has not been previously treated with a BCMA-targeted antibody drug conjugate or<br>- this patient has been treated with a BCMA-targeted antibody drug conjugate. | No | TA1015 | 13-Nov-24 | 11-Feb-25 |
| | | | 12. The patient has had progressive disease during or following the last received line of systemic anti-myeloma therapy. | | | | |
| | | | 13. The patient has an ECOG performance status of 0 or 1.<br><br>Please record below the ECOG performance status<br>- PS 0 or<br>- PS 1 | | | | |
| | | | 14. Teclistamab will be used as monotherapy only.<br><br>Note: teclistamab is not to be used in combination with any other anti-myeloma agent. | | | | |
| | | | 15. The prescribing clinician is aware of a) the 2 step up doses of teclistamab for the cycle 1 day 1 and cycle 1 day 3 treatments with teclistamab before the patient is then treated with the recommended full teclistamab dose on cycle 1 day 5 and from then on the maintenance weekly dosing schedule<br>and b) the need for patients to switch to 2-weekly teclistamab dosing **only if they have had a complete response or better for a minimum of 6 months.** | | | | |
| | | | 16. The treating hospital has facilities to manage severe reactions to teclistamab including cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS). | | | | |
| | | | 17. The prescribing clinician and the treating team are aware of the risks and grading of both cytokine release syndrome and immune effector cell-associated neurotoxicity syndrome, their monitoring and management as illustrated in Table 3 of section 4.2 and Table 4 of section 4.4 of the teclistamab Summary of Product Characteristics and both I and the treating team have all undergone training in these clinical issues. | | | | |
| | | | 18. Clear arrangements have been made for the patient to be monitored for signs and symptoms of toxicities including CRS and ICANS for 48 hours after administration of the 2 step up doses and 1st maintenance full dose in week 1 of teclistamab treatment and the patient has been instructed to remain within close proximity of a healthcare facility for these 48 hour periods following treatment on all of the week 1 day 1, week 1 day 3 and week 1 day 5 treatments. | | | | |
| | | | 19. 1 dose of tocilizumab is immediately available should tocilizumab be required for the treatment of cytokine release syndrome and access to an additional dose of tocilizumab within 8 hours of the previous tocilizumab dose must be ensured. | | | | |
| | | | 20. The prescribing clinician is aware that serum immunoglobulin levels require monitoring and treatment with SC or IV immunoglobulin should be considered according to NHS England's Clinical Commissioning Policy 2024 version 2.0. | | | | |
| | | | 21. The prescribing clinician is aware of the risk of infections in patients treated with teclistamab and that prophylactic antimicrobials and antivirals should be administered according to local institutional guidelines, as stated in sections 4.2 and 4.4 of teclistamab's Summary of Product Characteristics. | | | | |
| | | | 22. The patient will be treated with teclistamab until loss of clinical benefit or the occurrence of excessive toxicity or the withdrawal of patient consent, whichever is the sooner.<br><br>Note: once teclistamab is electively stopped (ie for reasons other than temporary toxicity), it cannot be re-started. | | | | |
| | | | 23. A formal medical review as to how teclistamab is being tolerated and whether treatment with teclistamab should continue or not will be scheduled to occur at least by the end of the first 6 weeks of treatment. | | | | |
| | | | 24. When a treatment break of more than 6 weeks beyond the expected weekly or 2-weekly cycle length (as appropriate) is needed, a treatment break approval form will be completed to restart treatment. | | | | |
| | | | 25. Teclistamab will be otherwise used as set out in its Summary of Product Characteristics (SPC). | | | | |

# National Cancer Drugs Fund (CDF) List

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| TEP1 | **Tepotinib** | Tepotinib as monotherapy for the treatment of adult patients with untreated advanced/metastatic non-small cell lung cancer (NSCLC) harbouring mesenchymal-epithelial transition (MET) exon 14 skipping alterations where the following criteria are met: | 1. This application for tepotinib is being made by and the first cycle of systemic anti-cancer therapy with tepotinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has locally advanced or metastatic non-small cell lung cancer.<br>Please indicate below whether the patient has non-squamous or squamous NSCLC:<br>- non-squamous NSCLC or<br>- squamous NSCLC<br>3. The patient has histological or cytological evidence of NSCLC that carries a MET exon 14 skipping alteration based on a validated test **OR** there is documented agreement by the lung MDT that the radiological appearances are in keeping with locally advanced or metastatic NSCLC **AND** there is an informative circulating free DNA test result confirming the presence of a MET exon 14 skipping alteration.<br>Please mark below on which basis the diagnosis of a MET exon 14 skipping alteration positive NSCLC has been made in this patient:<br>- Histological or cytological evidence.<br>- Documented agreement by the lung MDT that the radiological appearances are in keeping with locally advanced or metastatic NSCLC and there is an informative circulating free DNA test result confirming the presence of a MET exon 14 skipping alteration<br>4. The patient's lung cancer is of EGFR wild type and is also negative for both ALK and ROS1 gene rearrangements.<br>5. This patient is **treatment-naïve as regards to systemic therapy** for the locally advanced or metastatic NSCLC indication.<br>6. The patient has not been previously treated with a drug specifically targeting a MET exon 14 skipping alteration unless the patient received tepotinib via the EAMS program and the patient meets all the other treatment criteria on this form.<br>7. The patient has an ECOG performance status (PS) score of 0 or 1.<br>8. The patient either has no known brain metastases or if the patient does have brain metastases then the patient is symptomatically stable before staring tepotinib.<br>Please mark below the status with respect to known brain/CNS metastases:<br>- the patient has never had known brain/CNS metastases<br>- the patient has had brain/CNS metastases treated before with surgery/radiotherapy and is currently symptomatically stable<br>- the patient has brain secondaries which have not been treated with surgery/radiotherapy and is currently symptomatically stable<br>9. Tepotinib will be used as **monotherapy**.<br>10. The prescribing clinician is aware of the side-effects of tepotinib including the risk of developing oedema, interstitial lung disease and hepatotoxicity.<br>11. The prescribing clinician is aware of the potential drug interactions that may occur with tepotinib as set out in tepotinib's Summary of Product Characteristics (SPC) including the potential interaction with metformin.<br>12. The patient will be treated until loss of clinical benefit or excessive toxicity or patient choice to discontinue treatment whichever is the sooner.<br>13. A formal medical review as to how tepotinib is being tolerated will be done before the start of the second month of treatment and the next review to determine whether treatment with tepotinib should continue or not will be scheduled to occur at least by the end of the second month of therapy.<br>14. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment, including as appropriate if the patient has had an extended break on account of Covid-19.<br>15. Tepotinib will otherwise be used as set out in its Summary of Product Characteristics (SPC). | No | TA789 | 18-May-22 | 17-Jun-22 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| TEP2 | **Tepotinib** | Tepotinib as monotherapy for the treatment of adult patients with previously treated advanced/metastatic non-small cell lung cancer (NSCLC) harbouring mesenchymal-epithelial transition (MET) exon 14 skipping alterations where the following criteria are met: | 1. This application for tepotinib is being made by and the first cycle of systemic anti-cancer therapy with tepotinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has locally advanced or metastatic non-small cell lung cancer.<br>Please indicate below whether the patient has non-squamous or squamous NSCLC:<br>- non-squamous NSCLC or<br>- squamous NSCLC<br>3. The patient has histological or cytological evidence of NSCLC that carries a MET exon 14 skipping alteration based on a validated test **OR** there is documented agreement by the lung MDT that the radiological appearances are in keeping with locally advanced or metastatic NSCLC **AND** there is an informative circulating free DNA test result confirming the presence of a MET exon 14 skipping alteration.<br>Please mark below on which basis the diagnosis of a MET exon 14 skipping alteration NSCLC has been made in this patient:<br>- Histological or cytological evidence.<br>- Documented agreement by the lung MDT that the radiological appearances are in keeping with locally advanced or metastatic NSCLC and there is an informative circulating free DNA test result confirming the presence of a MET exon 14 skipping alteration<br>4. The patient's lung cancer is of EGFR wild type and is also negative for both ALK and ROS1 gene rearrangements.<br>5. This patient has **previously received systemic therapy** for the locally advanced or metastatic NSCLC indication:<br>As regards the previous treatment received by the patient, please mark which of these 5 scenarios below applies to this patient:<br>- the only treatment that the patient has received is platinum-based cytotoxic chemotherapy for locally advanced or metastatic NSCLC with or without 2nd line cytotoxic chemotherapy or<br>- the only treatment that the patient has received is 1st line immunotherapy monotherapy for the locally advanced or metastatic NSCLC indication or<br>- the patient has received the 1st line combination treatment of platinum doublet chemotherapy plus immunotherapy for the locally advanced or metastatic NSCLC indication with or without 2nd line cytotoxic chemotherapy or<br>- the patient has received 1st line immunotherapy monotherapy for the locally advanced or metastatic NSCLC indication followed by 2nd line cytotoxic chemotherapy or<br>- the patient has received 1st line platinum-based cytotoxic chemotherapy for locally advanced or metastatic NSCLC followed by 2nd line immunotherapy with or without further cytotoxic chemotherapy<br>6. The patient has not been previously treated with a drug specifically targeting a MET exon 14 skipping alteration unless the patient received tepotinib via the EAMS program and the patient meets all the other treatment criteria on this form.<br>7. The patient has an ECOG performance status (PS) score of 0 or 1.<br>8. The patient either has no known brain metastases or if the patient does have brain metastases then the patient is symptomatically stable before staring tepotinib.<br>Please mark below the status with respect to known brain/CNS metastases:<br>- the patient has never had known brain/CNS metastases<br>- the patient has had brain/CNS metastases treated before with surgery/radiotherapy and is currently symptomatically stable<br>- the patient has brain secondaries which have not been treated with surgery/radiotherapy and is currently symptomatically stable<br>9. Tepotinib will be used as **monotherapy**.<br>10. The prescribing clinician is aware of the side-effects of tepotinib including the risk of developing oedema, interstitial lung disease and hepatotoxicity.<br>11. The prescribing clinician is aware of the potential drug interactions that may occur with tepotinib as set out in tepotinib's Summary of Product Characteristics (SPC) including the potential interaction with metformin.<br>12. The patient will be treated until loss of clinical benefit or excessive toxicity or patient choice to discontinue treatment whichever is the sooner.<br>13. A formal medical review as to how tepotinib is being tolerated will be done before the start of the second month of treatment and the next review to determine whether treatment with tepotinib should continue or not will be scheduled to occur at least by the end of the second month of therapy.<br>14. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment, including as appropriate if the patient has had an extended break on account of Covid-19.<br>15. Tepotinib will otherwise be used as set out in its Summary of Product Characteristics (SPC). | No | TA789 | 18-May-22 | 17-Jun-22 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| TIS01a | **Tisagenlecleucel** | Tisagenlecleucel-modified CAR-T cells for treating relapsed/refractory Philadelphia negative and positive B cell acute lymphoblastic leukaemia in patients aged 25 years and under where the following criteria are met:<br><br>Note: This form is for the approval of leucapheresis and manufacture of CAR-T cells. There is a second part to this form which relates to the subsequent infusion of CAR-T cells and this will be available after submission of the first part. The second part of the form (TIS01b) can only be completed as a continuation of this first part of the form (TIS01a) and must be completed on infusion of CAR-T cells otherwise the treating Trust will not be reimbursed for the cost of tisagenlecleucel | 1. This application is being made by and that leucapheresis for and treatment with tisagenlecleucel-modified CAR T cells will be initiated by a consultant haematologist specifically trained and accredited in the use of systemic anti-cancer therapy and working in an accredited CAR T cell treatment centre and who is a member of the National CAR T Clinical Panel for acute lymphoblastic leukaemia and a member of the treating Trust's acute lymphoblastic leukaemia and CAR T cell multidisciplinary teams. | Yes | TA975 | 15-May-24 | 13-Aug-24 |
| | | | 2. The patient has relapsed or refractory B lineage acute lymphoblastic leukaemia (ALL).<br>Please tick appropriate box as to which type of ALL the patient has:<br>- Philadelphia chromosome negative ALL or<br>- Philadelphia chromosome positive ALL | | | | |
| | | | 3. The patient fulfils one of the following clinical scenarios relating to the definition of relapsed or refractory ALL:<br>- 2nd or more bone marrow relapse following conventional doses of chemotherapy/monoclonal antibody therapy OR<br>- any bone marrow relapse after allogeneic stem cell transplantation (SCT) and if so, a period of 4 months must have passed since time of transplant to planned time of CAR-T cell infusion OR<br>- primary refractory disease ie not achieving a complete remission after 2 cycles of standard chemotherapy for newly diagnosed ALL OR<br>- secondary refractory disease ie not achieving a complete remission after at least 1 cycle of standard chemotherapy for relapsed disease OR<br>- the patient has Philadelphia positive ALL that is refractory to primary chemotherapy or has relapsed post transplant or is in 2nd or greater relapse despite treatment with standard chemotherapy plus TKI therapy OR<br>- relapsed disease and ineligible for allogeneic SCT due to comorbid disease (but still fit enough for CAR T cell therapy with tisagenlecleucel) or contraindicated to allogeneic SCT conditioning or lack of a suitable donor<br>- isolated CNS relapse as manifestation of 2nd disease relapse or after allogeneic stem cell transplantation | | | | |
| | | | 4. Having fulfilled and ticked one of the criteria in box 3 above, the patient at the time of demonstration of such refractory/relapsed disease and thus consideration for potential treatment with tisagenlecleucel either had a bone marrow with both flow cytometry detectable ALL and CD19 ALL positivity in the bone marrow or in the case of an isolated CNS relapse had both flow cytometry detectable ALL and CD19 ALL positivity in the cerebrospinal fluid. Molecularly detectable minimal residual disease is not sufficient to comply with access to tisagenlecleucel. | | | | |
| | | | 5. The patient does not have an isolated extramedullary ALL relapse other than an isolated CNS relapse ie if the patient has non-CNS extramedullary disease, then the patient must also have bone marrow disease as set out above in criterion 4. | | | | |
| | | | 6. At the time of this application for treatment with tisagenlecleucel the patient does not have active CNS involvement by ALL (CNS3). | | | | |
| | | | 7. The patient's status as to previous treatment with blinatumomab or not.<br><br>Please tick appropriate box as to whether patient has received blinatumomab or not:<br>No previous treatment with blinatumomab or<br>Previous treatment with blinatumomab | | | | |
| | | | 8. The patient is aged less than 26 years on the date of approval for tisagenlecleucel by the National CAR-T Clinical Panel. | | | | |
| | | | 9. The patient has a Karnofsky (age =16 years) or a Lansky (<16 years) performance status of at least 50% | | | | |
| | | | 10. The patient has sufficient end organ function to tolerate treatment with tisagenlecleucel. | | | | |
| | | | 11. The patient has either had no previous therapy with any genetically modified autologous or allogeneic T cell immunotherapy or the patient has been treated with doses of genetically modified autologous or allogeneic T cell immunotherapy within an abandoned dosing cohort in a first in human dose-escalation phase I clinical trial.<br>Please tick appropriate box as to which type of previous treatment the patient has had:<br>- No previous therapy with any genetically modified autologous or allogeneic T cell immunotherapy or<br>- Previously treated with doses of genetically modified autologous or allogeneic T cell immunotherapy within an abandoned dosing cohort in a first in human dose-escalation phase I clinical trial | | | | |
| | | | 12. Prior to infusion 2 doses of tocilizumab are available for use in this patient in the event of the development of cytokine release syndrome. | | | | |
| | | | 13. Tisagenlecleucel-modified CAR T cells will otherwise be used as set out in its Summary of Product Characteristics (SPC). | | | | |
| | | | 14. Approval for the use of tisagenlecleucel has been formally given by the National acute lymphoblastic leukaemia CAR-T cell Clinical Panel.<br>Please state date of approval: | | | | |
| | | | 15. Following national approval for use of tisagenlecleucel there has been local CAR T cell multidisciplinary team agreement that this patient continues to have the necessary fitness for treatment and fulfils all of the treatment criteria listed here. | | | | |
| TIS01b | **Tisagenlecleucel** | Tisagenlecleucel for treating relapsed/refractory Philadelphia negative and positive B cell acute lymphoblastic leukaemia in patients aged 25 years and under where the following criteria are met:<br><br>Note: This second part of the form is to document the date of infusion of CAR-T cell therapy and for registration of this infusion with NHS England so that the treating Trust is reimbursed for the cost of tisagenlecleucel. There is a first part of the form for the approval of leucapheresis and manufacture of CAR-T cells which has already been completed (TIS01a). This second part of the form (TIS01b) should only be completed as a continuation form once the date of CAR T cell infusion is known. | 1. This application for continuation is being made by and treatment with tisagenlecleucel-modified CAR T cells will be initiated by a consultant haematologist specifically trained and accredited in the use of systemic anti-cancer therapy and working in an accredited CAR T cell treatment centre and who is a member of the National CAR T Clinical Panel for acute lymphoblastic leukaemia and a member of the treating Trust's acute lymphoblastic leukaemia and CAR T cell multidisciplinary teams. | Yes | TA975 | 15-May-24 | 13-Aug-24 |
| | | | 2. The patient has a performance score of at least 50% as assessed by the Karnofsky scale (age 16 years or over) or the Lansky scale (<16 years). | | | | |
| | | | 3. The patient has sufficient end organ function to tolerate treatment with tisagenlecleucel-modified CAR T cells. | | | | |
| | | | 4. Prior to infusion 2 doses of tocilizumab are available for use in this patient in the event of the development of cytokine release syndrome. | | | | |
| | | | 5. Tisagenlecleucel-modified CAR T cell therapy will otherwise be used as set out in its Summary of Product Characteristics (SPC). | | | | |
| | | | 6. Following national approval for use of tisagenlecleucel there has been local CAR T cell multidisciplinary team agreement that this patient continues to have the necessary fitness for infusion and fulfils all of the treatment criteria listed here. | | | | |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| TIV1 | **Tivozanib** | The treatment of advanced renal cell carcinoma where all the following criteria are met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with tivozanib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br><br>2. This patient has a histologically- or cytologically-proven diagnosis of renal cell carcinoma (RCC) which either has a clear cell component or is one of the types of RCC as indicated below.<br><br>Please indicate below which RCC histology applies to this patient:<br>- RCC with a clear cell component or<br>- papillary RCC or<br>- chromophobe RCC or<br>- collecting duct RCC (Bellini collecting duct RCC) or<br>- medullary RCC or<br>- mucinous tubular and spindle cell RCC or<br>- multilocular cystic RCC or<br>- XP11 translocation RCC or<br>- unclassified RCC<br><br>3.The patient has either metastatic disease or inoperable locally advanced disease<br><br>4. Tivozanib is either being used as 1st line treatment for renal carcinoma or as 2nd line treatment in patients previously treated with 1st line nivolumab plus ipilimumab or pembrolizumab plus lenvatinib or nivolumab plus cabozantinib or avelumab plus axitinib.<br><br>Please mark below in which setting tivozanib is being used in this patient:<br>- 1st line treatment or<br>- 2nd line treatment after 1st line therapy with nivolumab plus ipilimumab or pembrolizumab plus lenvatinib or nivolumab plus cabozantinib or avelumab plus axitinib<br><br>5.The patient has not previously received any vascular endothelial growth factor (VEGF)-targeted systemic monotherapy unless the patient commenced 1st line treatment with whichever of pazopanib or sunitinib or cabozantinib as the immediate prior therapy and this had to be stopped within 3 months of its start solely because of dose-limiting toxicity and in the clear absence of disease progression.<br><br>Please mark which of these 2 scenarios below applies to this patient:<br>- the patient has not previously received any vascular endothelial growth factor (VEGF)-targeted systemic monotherapy or<br>- the patient has only previously received treatment with 1st line pazopanib or sunitinib or cabozantinib as the immediate prior therapy and which had to be stopped within 3 months of its start solely because of dose-limiting toxicity and in the clear absence of disease progression<br><br>6. If the patient has brain metastases, then these have been treated and are stable<br><br>7. The patient has an ECOG performance status of either 0 or 1. A patient with a performance status of 2 is not eligible for tivozanib<br><br>8. Tivozanib is to be continued until loss of clinical benefit or unacceptable toxicity or patient choice to stop treatment or tivozanib can be stopped with a planned treatment break following the protocol used in the STAR trial.<br><br>Note: following 24 weeks of continuous tivozanib therapy, and if there is no evidence of disease progression on therapy, patients and clinicians may choose to stop treatment for a planned drug free interval/treatment break and then restart tivozanib on disease progression as per the STAR trial design.<br><br>Note: all patients who undergo planned treatment breaks must have regular clinical and radiological assessments and then have the option of restarting tivozanib on disease progression.<br><br>Note: if the patient benefits from restarting after the first planned treatment break, they can take further planned treatments breaks following the same strategy, i.e. after a further 24 weeks on treatment.<br>Ref for the STAR trial: Brown JE, Royle KA, Gregory W, Ralph C, Maraveyas A, Din O et al. 'Temporary treatment cessation versus continuation of first-line tyrosine kinase inhibitor in patients with advanced clear cell renal cell carcinoma (STAR): an open-label, non-inferiority, randomised, controlled, phase 2/3 trial.' The Lancet Oncology,2023, February 13 https://doi.org/10.1016/S1470-2045(22)00793-8.<br><br>9. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle is needed, a treatment break approval form will be completed to restart treatment unless the patient is following a planned intermittent treatment schedule as evidenced by the STAR trial and described above. | No | TA512 | 21-Mar-18 | 19-Jun-18 |

# National Cancer Drugs Fund (CDF) List

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| TRADAB1 | **Trametinib and Dabrafenib** | Trametinib in combination with dabrafenib for treating unresectable or metastatic melanoma where the following criteria have been met: | 1. This application is made by and the first cycle of systemic anti-cancer therapy with trametinib in combination with dabrafenib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy<br>2. This patient has a confirmed histological diagnosis of malignant melanoma which is BRAF V600 mutation positive<br>3. The patient has unresectable stage III or stage IV disease that has been staged according to the AJCC 8th edition<br>4. The patient is treatment naïve to BRAF V600 and MEK inhibitors for malignant melanoma unless either the patient has previously received adjuvant dabrafenib and trametinib and did not progress during such therapy or has received a sufficient trial of encorafenib plus binimetinib for advanced disease and this has had to be stopped solely as a consequence of persistent dose-limiting toxicity and in the documented absence of disease progression.<br>Note: sequential treatment is not commissioned with encorafenib plus binimetinib and then on disease progression with dabrafenib plus trametinib.<br>5. The patient has sufficient ECOG performance status to tolerate treatment with the combination of trametinib plus dabrafenib<br>6. Treatment with trametinib in combination with dabrafenib will be continued until loss of clinical benefit or unacceptable toxicity or withdrawal of patient consent.<br>The only exception to this is for patients enrolled in the NIHR-approved INTERIM trial in which intermittent treatment is allowed and can be given in the experimental arm<br>7. A formal medical review as to whether treatment with trametinib in combination with dabrafenib should continue or not will be scheduled to occur at least by the end of the first 8 weeks of treatment<br>8. No treatment breaks of more than 6 weeks beyond the expected 4-weekly cycle length are allowed (to allow any toxicity of current therapy to settle or intercurrent comorbidities to improve)*<br>*Requests for continuation of treatment after unplanned treatment breaks over this duration should be made via the treatment break approval process.<br>9. Trametinib in combination with dabrafenib is to be otherwise used as set out in their respective Summaries of Product Characteristics | No | TA396 | 22-Jun-16 | 20-Sep-16 |
| TRADAB2 | **Trametinib and Dabrafenib** | Dabrafenib in combination with trametinib for the adjuvant treatment of completely resected stage III BRAF V600 positive malignant melanoma where the following criteria are met: | 1. This application is made by and the first cycle of systemic anti-cancer therapy with dabrafenib in combination with trametinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy<br>2. This patient has a confirmed histological diagnosis of malignant melanoma which is BRAF V600 mutation positive<br>3. The patient has disease that has been staged as stage III disease according to the AJCC 8th edition<br>4. This stage III disease has been completely resected either via sentinel lymph node biopsy ('sentinel lymphadenectomy') or when indicated via completion lymph node dissection and/or there has been complete resection of intransit metastases.<br>5. The patient is treatment naïve to systemic therapy for malignant melanoma and in particular has not previously received any BRAF V600 inhibitors or MEK inhibitors or immunotherapy with any check point inhibitors<br>6. The prescribing clinician has discussed with the patient the benefits and toxicities of adjuvant trametinib and dabrafenib in stage III disease and has used the expected median figures below in relation to the risk of disease relapse if a routine surveillance policy is followed:<br>- for stage IIIA disease, the 5 and 10 year melanoma-specific survival probabilities with routine surveillance are 93% and 88%, respectively<br>- for stage IIIB disease, the 5 and 10 year figures are 83% and 77%, respectively<br>- for stage IIIC disease, the 5 and 10 year figures are 69% and 60%, respectively<br>- for stage IIID disease, the 5 and 10 year figures are 32% and 24%, respectively.<br>7. The patient has an ECOG performance status of either 0 or 1<br>8. Treatment with dabrafenib in combination with trametinib will be continued for a maximum of 12 months from the start of treatment in the absence of disease recurrence, unacceptable toxicity or withdrawal of patient consent<br>9. A formal medical review as to whether treatment with dabrafenib in combination with trametinib should continue or not will be scheduled to occur at least by the end of the first 8 weeks of treatment<br>10. No treatment breaks of more than 6 weeks beyond the expected 4-weekly cycle length are allowed (to allow any toxicity of current therapy to settle or intercurrent comorbidities to improve)*<br>*Requests for continuation of treatment after unplanned treatment breaks over this duration should be made via the treatment break approval process.<br>11. Dabrafenib in combination with trametinib is to be otherwise used as set out in their respective Summaries of Product Characteristics. | No | TA544 | 17-Oct-18 | 15-Jan-19 |
| TRADAB3 | **Trametinib and Dabrafenib** | Dabrafenib in combination with trametinib for BRAF V600-mutated anaplastic thyroid cancer (ATC) for **ADULT** patients where the following criteria have been met: | 1. This application for dabrafenib and trametinib for BRAF V600-mutated anaplastic thyroid cancer (ATC) is being made by and the first cycle of dabrafenib and trametinib for BRAF V600-mutated ATC will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anticancer therapy.<br>2. The patient has been diagnosed with locally advanced inoperable anaplastic thyroid cancer.<br>3. The patient has been tested for and has a confirmed BRAF V600 mutation.<br>4. The patient has a performance status of 0 or 1 or 2.<br>5. Dabrafenib and trametinib for BRAF V600-mutated anaplastic thyroid cancer are to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment.<br>6. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, a treatment break approval form will be completed to restart treatment.<br>7. Dabrafenib and trametinib will be otherwise used as set out in their respective Summary of Product Characteristics (SPCs).<br>8. Trust policy regarding the use of unlicensed (off-label) treatments has been followed as these drugs in this treatment are not licensed in this indication. | No | NHSE Policy: 221006P | N/A | 21-Oct-22 |

# National Cancer Drugs Fund (CDF) List

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| TRA2 | **Trastuzumab emtansine MONOTHERAPY** | As adjuvant therapy for patients with HER2-positive early breast cancer who have residual invasive disease following the combination of taxane-based and HER2-targeted neoadjuvant systemic therapy and surgery where the following criteria have been met: | 1. This application for trastuzumab emtansine as adjuvant chemotherapy is being made by and the first cycle of adjuvant trastuzumab emtansine will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has histologically documented breast cancer which is HER2 3+ by immunohistochemistry and/or has a ratio of ≥2.0 by in situ hybridisation.<br>3. The patient has been diagnosed with early breast cancer and this has been adequately excised.<br>4. Prior to neoadjuvant chemotherapy the patient had clinical stage T1-T4, nodal stage N0-3 and metastasis stage M0 disease.<br>5. The patient has been previously treated with at least 16 weeks of neoadjuvant cytotoxic chemotherapy which incorporated a minimum of at least 9 weeks of taxane-based chemotherapy and 9 weeks of HER2-targeted therapy unless entered into the ROSCO trial , or was entered into the 3 Pillars trial, or was considered potentially eligible for the HER2 RADiCAL trial.<br>Please tick below which option applies:<br>- At least 16 weeks of neoadjuvant cytotoxic chemotherapy which incorporated a minimum of at least 9 weeks of taxane-based chemotherapy and at least 9 weeks of HER2-targeted therapy or<br>- The patient was enrolled into the ROSCO trial (UKCRN Study ID19069) and was treated with 4 cycles of neoadjuvant chemotherapy plus trastuzumab with or without pertuzumab but did not achieve a pathological complete response and has therefore received 4 cycles of adjuvant chemotherapy with trastuzumab with or without pertuzumab or<br>- The patient was enrolled into the 3 Pillars clinical trial and was treated with palbociclib, tucatinib and trastuzumab in the neoadjuvant setting, completing at least 18 weeks of treatment prior to surgery, therefore having received at least 6 doses of subcutaneous trastuzumab or<br>- The patient was potentially eligible for the HER2 RADiCAL trial (UKCRN Study ID131362) and was treated with at least 12 weeks of taxane-based chemotherapy with trastuzumab and pertuzumab but did not achieve a pathological complete response and has therefore received at least 9 weeks of anthracycline-based adjuvant treatment<br>6. The patient has documented residual disease after neoadjuvant chemotherapy and HER2-directed treatment and that one of the following scenarios applies to this patient as to the documented residual invasive disease after completion of neoadjuvant therapy and surgery:<br>- the patient had residual invasive disease in the breast only or<br>- the patient had residual invasive disease in the lymph nodes only or<br>- the patient had residual invasive disease in both the breast and lymph nodes.<br>Note: trastuzumab emtansine as adjuvant treatment is only NICE-recommended and NHS England-commissioned in patients with documented residual disease invasive disease after completion of neoadjuvant chemotherapy and surgery.<br>7. Trastuzumab emtansine is the only HER2-directed therapy to be given after surgery i.e. no adjuvant trastuzumab/pertuzumab has been administered since surgery with the exception of patients enrolled in the ROSCO clinical trial. It is acknowledged that post-surgery patients may have received one cycle of adjuvant pertuzumab and trastuzumab whilst awaiting the pathology results to confirm the status of axillary lymph node involvement and any residual disease<br>8. A maximum of 14 cycles of trastuzumab emtansine will be administered as adjuvant therapy unless there is evidence of progressive disease or unacceptable toxicity or withdrawal of patient consent.<br>If trastuzumab emtansine has to be discontinued early, and without disease progression, completion of the intended adjuvant treatment duration up to 14 cycles of adjuvant HER2-directed therapy can be done with trastuzumab (if lymph node negative) or trastuzumab plus pertuzumab (if lymph node positive).<br>Note: A maximum of 18 cycles of HER2-directed therapy (neoadjuvant plus adjuvant) are funded provided all other criteria are met.<br>9. The patient has an ECOG performance status of 0 or 1.<br>10. Where a treatment break of more than 6 weeks beyond the expected cycle length is needed, a treatment break approval form will be completed to restart treatment, which MUST be approved before treatment is recommenced.<br>11. Trastuzumab emtansine will be otherwise used as set out in its Summary of Product Characteristics (SPC). | No | TA632 | 10-Jun-20 | 08-Sep-20 |
| TRA1 | **Trastuzumab Emtansine** | The treatment of HER2-positive locally advanced/ unresectable or metastatic (Stage IV) breast cancer where all the following criteria are met: | 1. An application has been made by and the first cycle of systemic anti-cancer therapy is to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy<br>2. Progression of her-2 positive locally advanced or metastatic breast cancer<br>3. Progression during or after the most recent treatment for advanced stage disease or within 6 months of completing treatment for early stage disease<br>4. Previous treatment with a taxane OR capecitabine.<br>5. Previous treatment with trastuzumab<br>6. Perfomance statau of 0, 1 or 2<br>7. Left ventricular ejection fraction of 50% or more<br>8. NOTE: not to be used beyond first disease progression outside the CNS. Do not discontinue if disease progression is within the CNS alone<br>9. No planned treatment breaks of more than 6 weeks beyond the expected cycle length are allowed (to allow any toxicity of current therapy to settle or intercurrent comorbidities to improve).<br>10. will otherwise be used as set out in its Summary of Product Characteristics (SPC).<br>Note: To minimise the risk of errors due to the similarity of the product name Trastuzumab Emtansine (Kadcyla) with that of Trastuzumab the recommendations in the Risk Minimisation Plan educational material from the manufacturer should be followed when prescribing, dispensing and administering the product | Yes | TA458 (formerly TA371) | 19-Jul-17 | 17-Oct-17 |
| TRAM1 | **Trametinib** | For serous low grade ovarian or peritoneal cancer for disease which has recurred or progressed following at least one platinum-based chemotherapy regimen where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with trametinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient was initially diagnosed with either:<br>- a serous ovarian or peritoneal carcinoma that has recurred with low grade serous histology (invasive micropapillary serous carcinoma or invasive grade 1 serous carcinoma)<br>- or started with a serous borderline ovarian or peritoneal carcinoma which has recurred as low-grade serous carcinoma (invasive micropapillary serous carcinoma or invasive grade 1 carcinoma)<br>3. The patient has or had disease which has progressed following at least 1 previous platinum-based chemotherapy regimen.<br>4. The patient has not previously received any MEK inhibitors.<br>5. Trametinib will be used as monotherapy at a dose of 2 mg daily as part of a 28 day cycle.<br>6. The patient has an ECOG performance status of either 0 or 1.<br>7. Trametinib is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment.<br>8. A formal medical review as to how trametinib is being tolerated and whether treatment with trametinib should continue or not will be scheduled to occur at least by the end of the first 8 weeks of treatment.<br>9. Trust policy regarding the use of unlicensed treatments has been followed as this treatment is not licensed in this indication.<br>10. Where a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, the prescribing clinician will complete a treatment break approval form to restart treatment.<br>11. Trametinib is to be otherwise used as set out in its Summary of Product Characteristics. | No | NHSE Policy: URN2253 | N/A | 08-Nov-23 |

# National Cancer Drugs Fund (CDF) List

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| TRE1 | **Treosulfan (Trecondi®)** in combination with fludarabine | Treosulfan (Trecondi®) in combination with fludarabine for part of conditioning treatment prior to allogeneic haemopoietic stem cell transplantation for malignant disease in ADULTS for whom a reduced intensity conditioning regimen (such as low dose busulfan with fludarabine) would otherwise be suitable where the following criteria have been met:<br><br>There is a separate form TRE2 for treosulfan in combination with fludarabine for part of conditioning treatment prior to allogeneic haemopoietic stem cell transplantation for malignant disease in PAEDATRIC PATIENTS OLDER THAN 1 MONTH AND YOUNGER THAN 18 YEARS for whom a reduced intensity conditioning regimen (such as low dose busulfan with fludarabine) would | 1. This application for treosulfan (as Trecondi®) in combination with fludarabine is being made by and will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy and who has specific expertise in the allogeneic stem cell transplantation of malignant disease. | No | TA640 | 05-Aug-20 | 03-Nov-20 |
| | | | 2. The patient is an adult and the allogeneic stem cell transplantation is for the treatment of malignant disease. | | | | |
| | | | 3. This patient is ineligible for high intensity myeloablative therapy and as a consequence a reduced intensity conditioning regimen (such as low dose busulfan plus fludarabine or low dose melphalan plus fludarabine) as treatment prior to allogeneic stem cell transplantation would otherwise be suitable. | | | | |
| | | | 4. Treosulfan (as Trecondi®) plus fludarabine will be used as part of the reduced intensity conditioning treatment prior to the allogeneic stem cell transplantation.<br><br>Note: Trecondi® is the only licensed formulation of tresosulfan for use in this indication. | | | | |
| | | | 5. Treosulfan (as Trecondi®) and fludarabine (including their doses and schedules of administration) will be otherwise used as set out in their respective Summaries of Product Characteristics (SmPCs). | | | | |
| TRE2 | **Treosulfan (Trecondi®)** in combination with fludarabine | Treosulfan (as Trecondi®) in combination with fludarabine for part of conditioning treatment prior to allogeneic haemopoietic stem cell transplantation for malignant disease in PAEDIATRIC PATIENTS OLDER THAN 1 MONTH AND YOUNGER THAN 18 YEARS for whom a reduced intensity conditioning regimen (such as low dose busulfan with fludarabine) would otherwise be suitable where the following criteria have been met:<br><br>There is a separate form TRE1 for treosulfan in combination with fludarabine for part of conditioning treatment prior to allogeneic haemopoietic stem cell transplantation for malignant disease in ADULTS for whom a reduced intensity conditioning regimen (such as low dose busulfan with fludarabine) would otherwise be suitable. | 1. This application for treosulfan (as Trecondi®) in combination with fludarabine is being made by and will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy and who has specific expertise in the allogeneic stem cell transplantation of malignant disease. | No | TA640 | 05-Aug-20 | 09-May-24 |
| | | | 2. The patient is older than 1 month and younger than 18 years patient.<br><br>Note: this access to Trecondi® in this indication is a Medicines for Children Policy extension of TA640.<br><br>Note: there is a separate application form TRE1 to be used for this indication in adults. | | | | |
| | | | 3. Allogeneic stem cell transplantation is for the treatment of malignant disease. | | | | |
| | | | 4. This patient is ineligible for high intensity myeloablative therapy and as a consequence a reduced intensity conditioning regimen (such as low dose busulfan plus fludarabine or low dose melphalan plus fludarabine) as treatment prior to allogeneic stem cell transplantation would otherwise be suitable. | | | | |
| | | | 5. Treosulfan (as Trecondi®) plus fludarabine will be used as part of the reduced intensity conditioning treatment prior to the allogeneic stem cell transplantation.<br><br>Note: Trecondi® is the only licensed formulation of tresosulfan for use in this indication. | | | | |
| | | | 6. The use of treosulfan (as Trecondi®) in combination with fludarabine as a reduced intensity conditioning regimen prior to allogeneic stem cell transplantation has been discussed at a multidisciplinary team (MDT) meeting which must include at least 2 consultants in the subspecialty with active and credible expertise in the relevant field of whom at least one must be a consultant paediatrician. The MDT should include a paediatric pharmacist and other professional groups appropriate to the disease. | | | | |
| | | | 7. Treosulfan (as Trecondi®) and fludarabine (including their doses and schedules of administration in this indication) will be otherwise used as set out in their respective Summaries of Product Characteristics (SPCs). | | | | |

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| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| TRI1_v1.2 | **Trifluridine plus tipiracil** | For patients with either metastatic or locally advanced and inoperable colorectal cancer who have been previously treated with, or are not considered candidates for, available therapies including fluoropyrimidine-based chemotherapy and anti-EGFR-based treatment where the following criteria have been met: | 1. This application is both being made by and the first cycle of systemic anti-cancer therapy with trifluridine plus tipiracil will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a histologically confirmed diagnosis of adenocarcinoma of the colon or rectum.<br>3. The patient has either metastatic or locally advanced and inoperable disease.<br>4. The patient has been previously treated for metastatic disease with, or is not considered a candidate for, fluoropyrimidine-containing chemotherapies which include 5-fluorouracil and/or capecitabine and/or tegafur but not trifluridine (plus tipiracil).<br>5. The patient has been previously treated with, or is not considered a candidate for, anti-EGFR-containing chemotherapy.<br>6. The patient has previously been treated with regorafenib or not.<br>Please tick which option applies to this patient:<br>- yes, the patient has been previously treated with regorafenib or<br>- no, the patient has not been previously treated with regorafenib<br>7. The patient has an ECOG performance status of 0 or 1.<br>8. The patient has not been previously treated with trifluridine plus tipiracil.<br>9. Trifluridine plus tipiracil is not to be used in combination with any other systemic anti-cancer therapy.<br>10. Trifluridine plus tipiracil is to be continued until loss of clinical benefit or unacceptable toxicity or patient choice to stop treatment, whichever is the sooner.<br>11. A formal medical review as to whether treatment with trifluridine plus tipiracil should continue or not will be scheduled to occur no later than by the end of the 2nd (28-day) cycle of therapy.<br>12. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, a treatment break approval form will be completed to restart treatment.<br>13. Trifluridine plus tipiracil will be otherwise used as set out in its Summary of Product Characteristics. | No | TA405 | 24-Aug-16 | 22-Nov-16 |
| TRI2_v1.1 | **Trifluridine plus tipiracil** | For the third or more line of systemic therapy for locally advanced or metastatic adenocarcinoma of the stomach or gastro-oesophageal junction where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with trifluridine plus tipiracil will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a histologically confirmed diagnosis of adenocarcinoma of the stomach or gastro-oesophageal junction.<br>3. The patient has been treated with 2 or more systemic therapy regimens for locally advanced or metastatic disease.<br>4. The patient has an ECOG performance status of 0 or 1.<br>5. The patient has not been previously treated with trifluridine plus tipiracil.<br>6. Trifluridine plus tipiracil is not to be used in combination with any other systemic anti-cancer therapy.<br>7. Trifluridine plus tipiracil is to be continued until loss of clinical benefit or unacceptable toxicity or patient choice to stop treatment, whichever is the sooner.<br>8. A formal medical review as to whether treatment with trifluridine plus tipiracil should continue or not will be scheduled to occur no later than by the end of the 2nd (28-day) cycle of therapy.<br>9. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, a treatment break form will be completed to restart treatment.<br>10. Trifluridine plus tipiracil will be otherwise used as set out in its Summary of Product Characteristics. | No | TA852 | 14-Dec-22 | 14-Mar-23 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| TRI3 | **Trifluridine plus tipiracil** in combination with bevacizumab | For patients with either metastatic or locally advanced and inoperable colorectal cancer who have received 2 or more prior anticancer treatment regimens including fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapies with or without anti-VEGF agents and/or anti-EGFR-based agents where the following criteria have been met: | 1. This application is both being made by and the first cycle of systemic anti-cancer therapy with trifluridine plus tipiracil in combination with bevacizumab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a histologically confirmed diagnosis of adenocarcinoma of the colon or rectum.<br>3. The patient has either metastatic disease or locally advanced and inoperable disease.<br>4. The patient has been previously treated for metastatic or locally advanced and inoperable disease with 2 or more prior anticancer regimens including fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapies. If disease has recurred during or within 6 months after the last administration of neoadjuvant or adjuvant therapy, this can be counted as a prior line of treatment for metastatic or locally advanced and inoperable disease.<br>Note: the regimens of either FOLFIRINOX or FOLFOXIRI can be counted as 2 chemotherapy regimens.<br>5. The patient has either been previously treated with anti-EGFR-containing chemotherapy or not.<br>Please tick which option applies to this patient:<br>- yes, the patient has been previously treated with anti-EGFR-containing chemotherapy or<br>- no, the patient has not been previously treated with anti-EGFR-containing chemotherapy<br>6. The patient has either been previously treated with an anti-VEGF-containing chemotherapy or not.<br>Please tick which option applies to this patient:<br>- yes, the patient has been previously treated with an anti-VEGF-containing chemotherapy or<br>- no, the patient has not been previously treated with an anti-VEGF-containing chemotherapy<br>7. The patient has either been previously treated with regorafenib or not.<br>Please tick which option applies to this patient:<br>- yes, the patient has been previously treated with regorafenib or<br>- no, the patient has not been previously treated with regorafenib<br>8. The patient has an ECOG performance status of 0 or 1.<br>9. The patient has not been previously treated with trifluridine plus tipiracil.<br>10. The bevacizumab will be commenced at the same time as trifluridine plus tipiracil and at a dose of 5mg/Kg administered at 2-weekly intervals.<br>11. Trifluridine plus tipiracil in combination with bevacizumab is to be continued until loss of clinical benefit or unacceptable toxicity or patient choice to stop treatment, whichever is the sooner.<br>12. If the trifluridine plus tipiracil has to be permanently discontinued then the bevacizumab will also be stopped at the same time.<br>13. A formal medical review as to whether treatment with trifluridine plus tipiracil in combination with bevacizumab should continue or not will be scheduled to occur no later than by the end of the 2nd (28-day) cycle of therapy.<br>14. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, a treatment break approval form will be completed to restart treatment.<br>15. Both trifluridine plus tipiracil and bevacizumab will be otherwise used as set out in their respective Summaries of Product Characteristics (SPCs). | No | TA1008 | 25-Sep-24 | 24-Dec-24 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| TUC1 | **Tucatinib** in combination with trastuzumab and capecitabine | For treating over-expressed HER2 positive unresectable locally advanced or metastatic breast cancer after 2 or more anti-HER2 treatment regimens where the following criteria have been met: | 1. This application for tucatinib in combination with trastuzumab and capecitabine for the treatment of unresectable locally advanced or metastatic breast cancer is being made by and the first cycle of this tucatinib combination will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has unresectable locally advanced or metastatic breast cancer.<br>3. The patient has histologically documented breast cancer which is HER2 3+ by immunohistochemistry and/or has a HER2 amplification ratio of ≥2.0 by in situ hybridisation.<br>4. Confirmation of whether this patient received a HER2-targeted neoadjuvant regimen and if so its nature.<br>Please tick which option applies to this patient:<br>- the patient was not treated with a HER2-targeted neoadjuvant regimen<br>- the patient was treated with a HER2-targeted neoadjuvant regimen which contained both pertuzumab and trastuzumab<br>- the patient was treated with a HER2-targeted neoadjuvant regimen which contained trastuzumab as the sole HER2-targeted agent<br>5. Confirmation of whether the patient received a HER2-targeted adjuvant regimen and if so its nature.<br>Please tick which option applies to this patient:<br>- the patient was not treated with a HER2-targeted adjuvant regimen<br>- the patient was treated with a HER2-targeted adjuvant regimen which contained both pertuzumab and trastuzumab<br>- the patient was treated with a HER2-targeted adjuvant regimen which contained trastuzumab as the sole HER2-targeted agent<br>- the patient was treated with a HER2-targeted adjuvant regimen which contained trastuzumab emtansine<br>6. Confirmation of whether the patient received a HER2-targeted regimen for locally advanced/metastatic disease which included both pertuzumab and trastuzumab.<br>Please tick which option applies to this patient:<br>- the patient was not treated with a HER2-targeted regimen for locally advanced/metastatic disease which included both pertuzumab and trastuzumab<br>- the patient was treated with a HER2-targeted regimen for locally advanced/metastatic disease which included both pertuzumab and trastuzumab<br>7. Confirmation of whether the patient received a HER2-containing regimen for locally advanced/metastatic disease which included trastuzumab as the sole HER2-targeted agent.<br>Please tick which option applies to this patient:<br>- the patient was not treated with a HER2-targeted regimen for locally advanced/metastatic disease which contained trastuzumab as the sole HER2-targeted agent<br>- the patient was treated with a HER2-targeted regimen for locally advanced/metastatic disease which contained trastuzumab as the sole HER2-targeted agent<br>8. The patient has previously been treated with an anti-HER-2 antibody drug conjugate (ADC) and is now either resistant or refractory to this ADC, or had to discontinue the drug due to intolerance/toxicity which was not able to be managed by dose reductions as outlined in the relevant summary of product characteristics.<br>9. The treatment status as to whether the patient has been treated with trastuzumab deruxtecan or not for locally advanced/metastatic breast cancer:<br>- the patient has been treated with trastuzumab deruxtecan<br>- the patient has not been treated with trastuzumab deruxtecan<br>10. The patient has received two or more anti-HER2 treatment regimens which must have included a trastuzumab-containing regimen and an anti-HER-2 antibody drug conjugate (ADC).<br><br>Please tick below how many anti-HER2 therapies this patient has received in all clinical settings (neoadjuvant, adjuvant and locally advanced/metastatic indications; eg a treatment pathway of neoadjuvant pertuzumab plus trastuzumab regimen followed by adjuvant trastuzumab and then a 1st relapse treated with a pertuzumab plus trastuzumab regimen and a 2nd relapse treated with trastuzumab emtansine counts as 4 anti-HER2 therapies):<br>- 2 anti-HER2 therapies<br>- 3 anti-HER2 therapies<br>- 4 anti-HER2 therapies<br>- 5 or more anti-HER2 therapies<br>11. The patient has not been previously treated with capecitabine in the locally advanced/metastatic disease setting.<br>12. The status as to the presence of brain metastases/leptomeningeal spread and its symptomatic and treatment status:<br>- the patient has never had any known brain metastases or leptomeningeal spread<br>- the patient has active brain metastases/leptomeningeal spread and has not received any active treatment for this CNS spread<br>- the patient has been previously treated with CNS radiotherapy/stereotactic radiosurgery/intrathecal chemotherapy and the metastatic CNS disease is stable<br>- the patient has been previously treated with CNS radiotherapy/stereotactic radiosurgery/intrathecal chemotherapy and the metastatic CNS disease is progressing<br>13. The patient has an ECOG performance status of 0 or 1.<br>14. Tucatinib will be given until disease progression or unacceptable toxicity or patient choice to stop treatment.<br>15. When a treatment break of more than 6 weeks beyond the expected 3-weekly cycle length is needed, I confirm that I will complete a treatment break approval form to restart treatment, which MUST be approved before treatment is re-commenced<br>16. Tucatinib, trastuzumab and capecitabine will be otherwise used as set out in their respective Summaries of Product Characteristics (SmPCs). | No | TA786 | 27-Apr-22 | 26-Jul-22 |
| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |

# National Cancer Drugs Fund (CDF) List

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| VEN1_v1.1 | **Venetoclax monotherapy** | Treatment of chronic lymphatic leukaemia in the ABSENCE of 17p deletion (and absence of TP53 mutation if tested) where the following criteria have been met: | 1. This application for venetoclax plus rituximab is being made by and the first cycle of this systemic anti -cancer therapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has been diagnosed with chronic lymphatic leukaemia or small lymphocytic lymphoma that requires treatment.<br>3. The patient has been tested for 17p deletion and the result is negative. If TP53 mutation has been tested, then it must be negative too.<br>4. The prescribing clinician can confirm whether the patient was previously treated with chemoimmunotherapy and if so, then the patient must have had progressive disease.<br>Please mark below which applies to this patient:<br>- the patient has never received chemoimmunotherapy<br>- the patient has previously been treated with chemoimmunotherapy and had progressive disease on/after such treatment<br>5. The patient had progressive disease on or after treatment with a B cell receptor pathway inhibitor: a Bruton's tyrosine kinase inhibitor (BTKi e.g. ibrutinib, acalabrutinib) and/or a PI3K inhibitor (PI3Ki e.g. idelalisib) or has a contraindication to receiving both a BTKi and a PI3Ki. Please indicate which:<br>- relapse on/after a BTKi<br>-relapse on/after a PI3Ki<br>- relapse on/after both a BTKi and a PI3Ki<br>- there is a contraindication to both a BTKi and a PI3Ki<br>6. The number of previous lines of therapy that the patient has received:<br>- 1 previous line of treatment<br>- 2 previous lines of treatment<br>- 3 previous lines of treatment<br>- 4 or more lines of previous treatment<br>7. The patient has never received venetoclax before or has been previously treated with the combination of venetoclax with an anti-CD20 antibody (obinutuzumab or rituximab) or the combination of ibrutinib plus venetoclax in which case the patient must not have progressed during such treatment with venetoclax.<br>Please mark below whether patient has received previous venetoclax:<br>- no previous treatment ever with venetoclax or<br>- previous treatment with the combination of venetoclax and obinutuzumab and there was no disease progression whilst on venetoclax<br>- previous treatment with the combination of venetoclax and rituximab and there was no disease progression whilst on venetoclax<br>- previous treatment with the combination of ibrutinib plus venetoclax and there was no disease progression whilst on venetoclax<br>8. The patient has an ECOG performance status of 0-2<br>9. All of the following for the prevention and treatment of tumour lysis syndrome:<br>- that the patient has been prospectively assessed for the risk of the development of tumour lysis syndrome (TLS) with venetoclax<br>- that appropriate TLS risk mitigation strategies have been put in place as outlined in the updated venetoclax Summary of Product Characteristics<br>- that there is a robust system in place for measuring appropriate blood chemistries both at the specified timings of blood chemistries according to TLS risk status and at the venetoclax dose levels described in Section 4.2 Table 3 of the Summary of Product Characteristics. See https://www.medicines.org.uk/emc/medicine/32650 or https://products.mhra.gov.uk/substance/?substance=VENETOCLAX<br>- that there is a robust system in place for ensuring the rapid review in real time of these blood chemistry results by a senior clinician with experience in the management of TLS<br>- that there is a robust system in place for the withholding of the next days dose of each scheduled dose escalation until the blood chemistry results have been confirmed as being satisfactory by a senior clinician<br>10. The patient has been assessed specifically for potential drug interactions with venetoclax.<br>11. Venetoclax is to be used **as a single agent**.<br>12. Venetoclax is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment.<br>13. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, a treatment break approval form will be completed to restart treatment.<br>14. Venetoclax to be otherwise used as set out in its Summary of Product Characteristics. | No | TA796 | 15-Jun-22 | 15-Jul-22 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| VEN2_v1.1 | **Venetoclax monotherapy** | The treatment of previously treated chronic lymphatic leukaemia in the PRESENCE of 17p deletion or TP53 mutation where the following criteria have been met: | 1. This application for venetoclax plus rituximab is being made by and the first cycle of this systemic anti -cancer therapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has been diagnosed with chronic lymphatic leukaemia or small lymphocytic lymphoma that requires treatment.<br>3. The patient has been tested for 17p deletion and/or TP53 mutation and the result is positive.<br>4. The prescribing clinician can confirm whether the patient was previously treated with chemoimmunotherapy and if so, then the patient must have had progressive disease.<br>Please mark below which applies to this patient:<br>- the patient has never received chemoimmunotherapy<br>- the patient has previously been treated with chemoimmunotherapy and had progressive disease on/after such treatment<br>5. The patient had progressive disease on or after treatment with a B cell receptor pathway inhibitor: a Bruton's tyrosine kinase inhibitor (BTKi e.g. ibrutinib, acalabrutinib) and/or a PI3K inhibitor (PI3Ki e.g. idelalisib) or has a contraindication to receiving both a BTKi and a PI3Ki. Please indicate which:<br>- relapse on/after a BTKi<br>-relapse on/after a PI3Ki<br>- relapse on/after both a BTKi and a PI3Ki<br>- there is a contraindication to both a BTKi and a PI3Ki<br>6. The number of previous lines of therapy that the patient has received:<br>- 1 previous line of treatment<br>- 2 previous lines of treatment<br>- 3 previous lines of treatment<br>- 4 or more lines of previous treatment<br>7. The patient has never received venetoclax before or has been previously treated with the combination of venetoclax with an anti-CD20 antibody (obinutuzumab or rituximab) or the combination of ibrutinib plus venetoclax in which case the patient must not have progressed during such treatment with venetoclax.<br>Please mark below whether patient has received previous venetoclax:<br>- no previous treatment ever with venetoclax or<br>- previous treatment with the combination of venetoclax and obinutuzumab and there was no disease progression whilst on venetoclax<br>- previous treatment with the combination of venetoclax and rituximab and there was no disease progression whilst on venetoclax<br>- previous treatment with the combination of ibrutinib plus venetoclax and there was no disease progression whilst on venetoclax<br>8. The patient has an ECOG performance status of 0-2<br>9. All of the following for the prevention and treatment of tumour lysis syndrome:<br>- that the patient has been prospectively assessed for the risk of the development of tumour lysis syndrome (TLS) with venetoclax<br>- that appropriate TLS risk mitigation strategies have been put in place as outlined in the updated venetoclax Summary of Product Characteristics<br>- that there is a robust system in place for measuring appropriate blood chemistries both at the specified timings of blood chemistries according to TLS risk status and at the venetoclax dose levels described in Section 4.2 Table 3 of the Summary of Product Characteristics. See https://www.medicines.org.uk/emc/medicine/32650 or https://products.mhra.gov.uk/substance/?substance=VENETOCLAX<br>- that there is a robust system in place for ensuring the rapid review in real time of these blood chemistry results by a senior clinician with experience in the management of TLS<br>- that there is a robust system in place for the withholding of the next days dose of each scheduled dose escalation until the blood chemistry results have been confirmed as being satisfactory by a senior clinician<br>10. The patient has been assessed specifically for potential drug interactions with venetoclax.<br>11. Venetoclax is to be used **as a single agent**.<br>12. Venetoclax is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment.<br>13. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, a treatment break approval form will be completed to restart treatment.<br>14. Venetoclax to be otherwise used as set out in its Summary of Product Characteristics. | No | TA796 | 15-Jun-22 | 15-Jul-22 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| VEN3_v1.7 | **Venetoclax** (in combination with rituximab) | The treatment of previously treated chronic lymphatic leukaemia | 1. This application for venetoclax plus rituximab is being made by and the first cycle of this systemic anti -cancer therapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has been diagnosed with chronic lymphatic leukaemia or small lymphocytic lymphoma.<br>3. The patient has been tested for 17p deletion. Please indicate the result of this test below:<br>- Negative for 17p deletion **or**<br>- Positive for 17p deletion<br>4. The patient has been tested for TP53 mutation or has not been tested for TP53 mutation. Please indicate the result of this test below:<br>- Negative for TP53 mutation **or**<br>- Positive for TP53 mutation **or**<br>- TP53 mutation status not tested<br>5. The patient has symptomatic disease which requires systemic therapy.<br>6. The patient has been previously treated with systemic therapy for CLL/SLL.<br>Please indicate the previous treatment that the patient has received:<br>- anti-CD20-containing chemoimmunotherapy alone<br>- a B cell receptor pathway inhibitor alone<br>- both anti-CD20-containing chemoimmunotherapy and a B cell receptor pathway inhibitor<br>- previous treatment with a venetoclax-containing combination with obinutuzumab/rituximab with or without other previous systemic therapies as well. Note: the patient must not have had progressive disease during venetoclax and obinutuzumab/rituximab<br>- previous treatment with ibrutinib plus venetoclax during which the patient did not have progressive disease<br>- several of the above<br>7. The previous treatment status as to whether the patient has or has not received a B cell receptor pathway inhibitor or inhibitors. Please indicate previous treatment below:<br>- previous treatment with a Bruton's TKI (e.g. ibrutinib, acalabrutinib)<br>- previous treatment with a PI3Ki (e.g. idelalisib)<br>- previous treatment with both a BTKI and a PI3Ki<br>- no previous treatment with a BTKI or a PI3Ki<br>8. The number of previous lines of therapy that the patient has received:<br>- 1 previous line of treatment **or**<br>- 2 previous lines of treatment **or**<br>- 3 previous lines of treatment **or**<br>- 4 or more lines of previous treatment<br>9. The patient has a performance status of 0 or 1 or 2.<br>10. The patient has either not previously received venetoclax whether as monotherapy or in combination with obinutuzumab/rituximab or has been previously treated with venetoclax in combination with obinutuzumab/rituximab or the combination of ibrutinib plus venetoclax in which case the patient must not have progressed during such treatment with venetoclax.<br>Please indicate previous treatment below:<br>- no previous treatment with venetoclax whether as monotherapy or in combination with obinutuzumab/rituximab<br>- previous treatment with venetoclax plus obinutuzumab during which the patient did not have progressive disease<br>- previous treatment with venetoclax plus rituximab during which the patient did not have progressive disease<br>- previous treatment with the combination of ibrutinib plus venetoclax during which the patient did not have progressive disease<br>11. Venetoclax will be given in combination with rituximab and that the rituximab will only be commenced after the patient has completed the venetoclax dose titration schedule.<br>12. All of the following for the prevention and treatment of tumour lysis syndrome:<br>- that the patient has been prospectively assessed for the risk of the development of tumour lysis syndrome (TLS) with venetoclax<br>- that appropriate TLS risk mitigation strategies have been put in place as outlined in the updated venetoclax Summary of Product Characteristics<br>- that there is a robust system in place for measuring appropriate blood chemistries both at the specified timings of blood chemistries according to TLS risk status and at the venetoclax dose levels described in Section 4.2 Table 3 of the Summary of Product Characteristics. See https://www.medicines.org.uk/emc/medicine/32650 or https://products.mhra.gov.uk/substance/?substance=VENETOCLAX<br>- that there is a robust system in place for ensuring the rapid review in real time of these blood chemistry results by a senior clinician with experience in the management of TLS<br>- that there is a robust system in place for the withholding of the next days dose of each scheduled dose escalation until the blood chemistry results have been confirmed as being satisfactory by a senior clinician<br>13. The patient has been assessed specifically for potential drug interactions with venetoclax.<br>14. The maximum treatment duration of venetoclax in this indication is for a maximum of 2 years (as measured from cycle 1 day 1 of rituximab administration)<br>15. The maximum treatment duration of rituximab will be for 6 cycles of rituximab<br>16. Venetoclax is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment or for the maximum treatment duration of 2 years (as measured from the cycle 1 day 1 administration of rituximab), whichever of these events is the sooner.<br>17. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, a treatment break approval form will be completed to restart treatment.<br>18. Venetoclax will be otherwise used as set out in its Summary of Product Characteristics. | No | TA561 | 27-Feb-19 | 28-May-19 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| VEN5 | **Venetoclax** in combination with obinutuzumab | For the treatment of patients with previously untreated chronic lymphatic leukaemia which has a 17p deletion or TP53 mutation where the following criteria have been met: | 1. This application for venetoclax plus obinutuzumab is being made by and the first cycle of this systemic anti-cancer therapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has been diagnosed with chronic lymphatic leukaemia (CLL) or small lymphocytic lymphoma (SLL).<br>3. The patient has been tested for 17p deletion and for TP53 mutation and the results are positive for 17p deletion or TP53 mutation or both.<br>Please indicate the result of these tests below:<br>- Positive for 17p deletion and negative for TP53 mutation or<br>- Negative for 17 deletion and positive for TP53 mutation or<br>- Positive for both 17p deletion and TP53 mutation.<br>4. The patient has symptomatic disease which requires systemic therapy.<br>5. The patient has not received any previous systemic therapy for CLL/SLL.<br>6. The patient has a performance status of 0 or 1 or 2.<br>7. Venetoclax will be given in combination with obinutuzumab and that the venetoclax dose titration schedule will only be commenced after the patient has received the first 3 doses of obinutuzumab in cycle 1 (on days 1±2, 8 and 15) i.e. the venetoclax dose titration schedule is planned to commence on cycle 1 day 22 and be completed on cycle 2 day 28.<br>8. All of the following for the prevention and treatment of tumour lysis syndrome:<br>- that the patient has been prospectively assessed for the risk of the development of tumour lysis syndrome (TLS) with venetoclax<br>- that appropriate TLS risk mitigation strategies have been put in place as outlined in the updated venetoclax Summary of Product Characteristics<br>- that there is a robust system in place for measuring appropriate blood chemistries both at the specified timings of blood chemistries according to TLS risk status and at the venetoclax dose levels described in Section 4.2 Table 3 of the Summary of Product Characteristics. See https://www.medicines.org.uk/emc/medicine/32650 or https://products.mhra.gov.uk/substance/?substance=VENETOCLAX<br>- that there is a robust system in place for ensuring the rapid review in real time of these blood chemistry results by a senior clinician with experience in the management of TLS<br>- that there is a robust system in place for the withholding of the next days dose of each scheduled dose escalation until the blood chemistry results have been confirmed as being satisfactory by a senior clinician<br>9. The patient has been assessed specifically for potential drug interactions with venetoclax.<br>10. The maximum treatment duration of venetoclax in this indication is until day 28 of the 12th cycle of treatment i.e. the maximum duration of venetoclax treatment is for 45 weeks, consisting of 1 week from cycle 1 day 22 followed by 11 cycles of 4-weekly cycles of venetoclax in cycles 2-12.<br>11. The treatment duration of obinutuzumab is for a maximum of 6 cycles of obinutuzumab.<br>12. Venetoclax is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment or for the maximum treatment duration of 12 cycles (as measured above), whichever of these events is the sooner.<br>13. A formal medical review as to whether treatment with venetoclax in combination with obinutuzumab should continue or not will be scheduled to occur at least by the end of the first 8 weeks of treatment.<br>14. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment, including as appropriate if the patient had an extended break on account of Covid-19.<br>15. Venetoclax and obinutuzumab will be otherwise used as set out in their respective Summary of Product Characteristics (SPCs). | No | TA663 | 09-Dec-20 | 09-Mar-21 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| VEN6 | **Venetoclax** in combination with obinutuzumab | For the treatment of patients with previously untreated chronic lymphatic leukaemia in whom chemotherapy with the combinations of either FCR or BR would otherwise have been UNSUITABLE where the following criteria have been met: | 1. This application for venetoclax plus obinutuzumab is being made by and the first cycle of this systemic anti-cancer therapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has been diagnosed with chronic lymphatic leukaemia (CLL) or small lymphocytic lymphoma (SLL).<br>3. The patient has been tested for 17p deletion and the result is negative.<br>4. The patient has been tested for TP53 mutation and the result is negative.<br>5. The patient has symptomatic disease which requires systemic therapy.<br>6. The patient has not received any previous systemic therapy for CLL/SLL.<br>7. The patient has a performance status of 0 or 1 or 2.<br>8. In the absence of this venetoclax plus obinutuzumab treatment option, the patient would otherwise have been considered to have been **UNSUITABLE** for treatment with the combination of fludarabine, cyclophosphamide and rituximab (FCR) or the combination of bendamustine and rituximab (BR).<br>9. Venetoclax will be given in combination with obinutuzumab and that the venetoclax dose titration schedule will only be commenced after the patient has received the first 3 doses of obinutuzumab in cycle 1 (on days 1±2, 8 and 15) i.e. the venetoclax dose titration schedule is planned to commence on cycle 1 day 22 and be completed on cycle 2 day 28.<br>10. All of the following for the prevention and treatment of tumour lysis syndrome:<br>- that the patient has been prospectively assessed for the risk of the development of tumour lysis syndrome (TLS) with venetoclax<br>- that appropriate TLS risk mitigation strategies have been put in place as outlined in the updated venetoclax Summary of Product Characteristics<br>- that there is a robust system in place for measuring appropriate blood chemistries both at the specified timings of blood chemistries according to TLS risk status and at the venetoclax dose levels described in Section 4.2 Table 3 of the Summary of Product Characteristics. See https://www.medicines.org.uk/emc/medicine/32650 or https://products.mhra.gov.uk/substance/?substance=VENETOCLAX<br>- that there is a robust system in place for ensuring the rapid review in real time of these blood chemistry results by a senior clinician with experience in the management of TLS<br>- that there is a robust system in place for the withholding of the next days dose of each scheduled dose escalation until the blood chemistry results have been confirmed as being satisfactory by a senior clinician<br>11. The patient has been assessed specifically for potential drug interactions with venetoclax.<br>12. The maximum treatment duration of venetoclax in this indication is until day 28 of the 12th cycle of treatment i.e. the maximum duration of venetoclax treatment is for 45 weeks, consisting of 1 week from cycle 1 day 22 followed by 11 cycles of 4-weekly cycles of venetoclax in cycles 2-12.<br>13. The treatment duration of obinutuzumab is for a maximum of 6 cycles of obinutuzumab.<br>14. Venetoclax is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment or for the maximum treatment duration of 12 cycles (as measured above), whichever of these events is the sooner.<br>15. A formal medical review as to whether treatment with venetoclax in combination with obinutuzumab should continue or not will be scheduled to occur at least by the end of the first 8 weeks of treatment.<br>16. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment, including as appropriate if the patient had an extended break on account of Covid-19.<br>17. Venetoclax and obinutuzumab will be otherwise used as set out in their respective Summary of Product Characteristics (SPCs). | No | TA663 | 09-Dec-21 | 09-Mar-21 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| VEN8 | **Venetoclax** in combination with azacitidine | For untreated adult acute myeloid leukaemia in patients unsuitable for intensive chemotherapy where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with venetoclax plus azacitidine will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has newly diagnosed acute myeloid leukaemia (AML).<br>3. The patient has had/is having molecular analysis performed.<br>Please mark below the somatic mutation found:<br>- no analysis is being performed<br>- not yet available<br>- IDH1 or IDH2<br>- FLT3 ITD or TKD<br>- NPM1<br>- TP53<br>- another mutation<br>4. The patient has previously untreated de novo AML or previously untreated secondary AML.<br>- de novo AML<br>- secondary AML<br>5. The most recent bone marrow blast count is:<br>- 20% to <30% blasts<br>- 30% to <50% blasts<br>- 50% or more blasts<br>6. Standard intensive chemotherapy is unsuitable for this patient.<br>Please mark below the dominant reason as to why this patient is unsuitable for intensive chemotherapy:<br>- age<br>- fitness<br>- significant comorbidity or comorbidities1.<br>7. The patient is fit for treatment with venetoclax plus azacitidine and has an ECOG performance status (PS) of 0-3.<br>8. The patient has been prospectively assessed for the risk of the development of tumour lysis syndrome with venetoclax and that appropriate risk mitigation strategies have been put in place.<br>9. The patient has been assessed specifically for potential drug interactions with venetoclax as set out in sections 4.2 and 4.5 of venetoclax's Summary of Product Characteristics.<br>10. Antifungal prophylaxis with posaconazole or voriconazole is to be given to this patient (unless there is intolerance of such antifungal prophylaxis) and thus the dosing of venetoclax has taken this drug interaction into account with the maximum venetoclax daily dose prescribed of 100mg as set out in Table 7 in section 4.2 of the Summary of Product Characteristics for venetoclax.<br><br>Note: if the patient develops toxicities to posaconazole and voriconazole such that these anti-fungal agents are discontinued, venetoclax dosing at a maximum daily dose of 400mg is funded.<br><br>Note: for patients in the BioDrive AFS trial (NIHR trial ID 132674) who are randomised to the intervention biomarker arm, the requirement for antifungal prophylaxis with posaconazole or voriconazole is waived and venetoclax dosing at a maximum daily dose of 400mg is funded.<br>11. Venetoclax will be given in combination with azacitidine.<br>12. The prescribing clinician has given consideration to the dosing schedule of venetoclax in cycle 2 onwards being for 14 days of each 28 day cycle as this was the clinical expert submission to NICE that venetoclax treatment schedule durations would usually be for 14 days from cycle 2 onwards and thus this level of dose intensity was incorporated into the economic modelling (see section 3.8 of the NICE venetoclax FAD ID1564).<br>13. Venetoclax will be continued until disease progression or unacceptable toxicity or withdrawal of patient consent or an elective decision to discontinue treatment consequent to a sustained complete remission to therapy.<br>Note: if venetoclax is stopped for any of the above reasons, no further venetoclax can be prescribed.<br>14. A formal medical review as to whether treatment with venetoclax should continue will occur at least by the end of the second cycle of treatment.<br>15. Where a treatment break of more than 10 weeks beyond the expected cycle length is needed, I will complete a treatment break approval form to restart treatment, including indicating as appropriate if the patient had an extended break because of COVID 19.<br>16. Venetoclax will be otherwise used as set out in their respective Summaries of Product Characteristics (SPC). | No | TA765 | 02-Feb-22 | 03-May-22 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| VEN9 | **Venetoclax** in combination with low dose cytarabine | For previously untreated adult acute myeloid leukaemia in patients unsuitable for intensive chemotherapy and who have a bone marrow blast count >30% where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with venetoclax plus low dose cytarabine will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has newly diagnosed acute myeloid leukaemia (AML).<br>3. The patient has had/is having molecular analysis performed.<br>Please mark below the somatic mutation found:<br>- no analysis is being performed<br>- not yet available<br>- IDH1 or IDH2<br>- FLT3 ITD or TKD<br>- NPM1<br>- TP53<br>- another mutation<br>4. The patient has previously untreated de novo AML or previously untreated secondary AML:<br>- de novo AML<br>- secondary AML<br>5. The most recent bone marrow blast count shows >30% blasts.<br>Please indicate whether the bone marrow shows >30 to <50% blasts or 50% or more blasts:<br>- >30% to <50% blasts<br>- 50% or more blasts<br>Note: the company did not present any evidence to NICE of venetoclax plus low dose cytarabine in the 20-30% blast group and hence venetoclax plus low dose cytarabine is not commissioned in this population.<br>6. Standard intensive chemotherapy is unsuitable for this patient.<br>Please mark below the dominant reason as to why this patient is unsuitable for intensive chemotherapy:<br>- age<br>- fitness<br>- significant comorbidity or comorbidities.<br>7. The patient is fit for treatment with venetoclax plus low dose cytarabine and has an ECOG performance status (PS) of 0-3.<br>8. The patient has been prospectively assessed for the risk of the development of tumour lysis syndrome with venetoclax and that appropriate risk mitigation strategies have been put in place.<br>9. The patient has been assessed specifically for potential drug interactions with venetoclax as set out in sections 4.2 and 4.5 of venetoclax's Summary of Product Characteristics.<br>10. Antifungal prophylaxis with posaconazole or voriconazole is to be given to this patient (unless there is intolerance of such antifungal prophylaxis) and thus the dosing of venetoclax has taken this drug interaction into account with the maximum venetoclax daily dose prescribed of 100mg as set out in Table 7 in section 4.2 of the Summary of Product Characteristics for venetoclax.<br><br>Note: if the patient develops toxicities to posaconazole and voriconazole such that these anti-fungal agents are discontinued, venetoclax dosing at a maximum daily dose of 600mg is funded.<br><br>Note: for patients in the BioDrive AFS trial (NIHR trial ID 132674) who are randomised to the intervention biomarker arm, the requirement for antifungal prophylaxis with posaconazole or voriconazole is waived and venetoclax dosing at a maximum daily dose of 400mg is funded.<br>11. Venetoclax will be given in combination with low dose cytarabine.<br>12. The prescribing clinician has given consideration to the dosing schedule of venetoclax in cycle 2 onwards being for 14 days of each 28 day cycle as this was the clinical expert submission to NICE that venetoclax treatment schedule durations would usually be for 14 days from cycle 2 onwards and thus this level of dose intensity was incorporated into NICE's economic modelling (see section 3.9 of the NICE venetoclax plus low dose cytarabine FAD ID4071).<br>13. Venetoclax will be continued until disease progression or unacceptable toxicity or withdrawal of patient consent or an elective decision to discontinue treatment consequent to a sustained complete remission to therapy.<br>Note: if venetoclax is stopped for any of the above reasons, no further venetoclax can be prescribed.<br>14. A formal medical review as to whether treatment with venetoclax should continue will occur at least by the end of the second cycle of treatment.<br>15. Where a treatment break of more than 10 weeks beyond the expected cycle length is needed, I will complete a treatment break approval form to restart treatment, including indicating as appropriate if the patient had an extended break because of COVID 19.<br>16. Venetoclax will be otherwise used as set out in the Summary of Product Characteristics (SPC). | No | TA787 | 27-Apr-22 | 26-Jul-22 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
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| VIS2 | **Vismodegib** | For patients with multiple basal cell carcinomas (BCC) in adults where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with vismodegib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy<br>2. The patient has either (tick as appropriate):<br>- Gorlin syndrome with non-locally advanced, non-metastatic multiple basal cell carcinomas (BCC) (≥6) clinically evident at the point of decision to treat BCCs of which 3 are at least 5mm or<br>- Non-locally advanced, non-metastatic multiple BCC (≥6) clinically evident at the point of decision to treat BCCs of which 3 are at least 5mm AND are appropriate for surgery i.e. surgically eligible tumours.<br>3. The patient has at least 6 operable clinically evident non-locally advanced, non-metastatic BCC with surgically eligible tumours of 3 lesions of at least 5mm diameter, of which at least 1 is histopathologically confirmed.<br>4. The patient is suitable for surgical intervention, but surgical intervention alone has the potential for substantial disfigurement.<br>5. The patient has been assessed and vismodegib recommended by a specialised skin cancer or head and neck multidisciplinary team.<br>6. The patient has an ECOG performance status of 0, 1 or 2<br>7. The stopping criteria have been explained and agreed with the patient before the treatment is started.<br>8. Vismodegib will be prescribed at a dose of 150mg daily taken once daily OR on an intermittent schedule, until disease progression or adverse effects which necessitate stopping.<br>Please note which treatment schedule will be used (tick box):<br>- Continuous therapy or<br>- A 72 week period of: vismodegib 12 weeks; off treatment 8 weeks; vismodegib 12 weeks; off treatment 8 weeks; vismodegib 12 weeks; off treatment 8 weeks; vismodegib 12 weeks* or<br>- A 72 week period of: vismodegib 24 weeks; off treatment 8 weeks; vismodegib 8 weeks; off treatment 8 weeks; vismodegib 8 weeks; off treatment 8 weeks; vismodegib 8 weeks*<br>*Reference: Dreno, B., Kunstfeld, R., Hauschild, A., Fosko, S., Zloty, D., Labeille, B., Grob, J-J. et al. (2017) Two intermittent vismodegib dosing regimens in patients with multiple basal-cell carcinomas (MIKIE): a randomised regimen-controlled, double-blind, phase 2 trial. The Lancet Oncology 18:404-12.<br>9. The patient is either male or female<br>10. The prescibing clinician understands that vismodegib must not be used during pregnancy and female and male patients will be counselled as describe below.<br>*Counselling for female patients:*<br>The patient has been counselled about the adverse use of vismodegib in pregnancy AND,<br>if a woman of child-bearing potential, has been advised that she should use two forms of contraception (including one highly effective method and one barrier) during vismodegib therapy and for 24 months after the final dose, AND has had a negative medically supervised pregnancy test within the past seven days.<br>*Counselling for male patients* :<br>The patient has been counselled about the adverse use of vismodegib in relation to pregnancy and has been advised that he should always use a condom (with spermicide if available), during vismodegib therapy and for 2 months after the final dose.<br>11. This application is for an adult patients and vismodegib will not be used in children and adolescents aged below 18 years.<br>12. Trust policy regarding the use of unlicensed treatments has been followed as vismodegib and the recommended intermittent schedules are not licensed in this indication.<br>13. Where a treatment break of more than 6 weeks beyond the expected 4-week cycle length is needed, I will complete a treatment break approval form to restart treatment, including indicating as appropriate if the patient had an extended break because of COVID 19.<br>14. Vismodegib will otherwise be used as set out its Summary of Product Characteristics | No | NHSE Policy: 210504P | n/a | 14-Jul-21 |

# National Cancer Drugs Fund (CDF) List

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| ZAN1 | **Zanubrutinib** | Zanubrutinib monotherapy for the treatment of patients with previously treated Waldenstrom's macroglobulinaemia and who would otherwise be next treated with bendamustine plus rituximab where the following criteria have been met: | 1. This application is being made by and the first cycle of this systemic anti-cancer therapy with zanubrutinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has been previously diagnosed with Waldenstrom's macroglobulinaemia.<br>3. The patient has symptomatic disease which requires systemic therapy.<br>4. The patient has been previously treated with at least 1 prior systemic therapy for Waldenstrom's macroglobulinaemia.<br>Note: NICE could not recommend the use of zanubrutinib in treatment-naïve patients in whom chemo-immunotherapy is unsuitable as the company did not submit evidence for the clinical and cost effectiveness of zanubrutinib in this patient group.<br>5. In the absence of this access to zanubrutinib, the patient would otherwise be next treated with the combination of bendamustine and rituximab.<br>Note: the only previously treated patient group for which NICE concluded that zanubrutinib was clinically and cost effective was in those patients who would otherwise be next treated with bendamustine plus rituximab. NICE did not recommend zanubrutinib in patients who would otherwise be next treated with the combination of dexamethasone, rituximab and cyclophosphamide or any other therapies.<br>6. The patient is treatment naïve to a Bruton's kinase inhibitor **or** the patient has been commenced on zanubrutinib via the manufacturer's (BeiGene) early access scheme for previously treated Waldesntrom's macroglobulinaemia and all other treatment criteria on this from are fulfilled **or** the patient has been previously commenced on ibrutinib for previously treated Waldenstrom's macroglobulinaemia and the ibrutinib has had to be discontinued solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression.<br>Please mark which of the 3 scenarios below applies to this patient:<br>- the patient has not received any previous therapy for Waldenstrom's macroglobulinaemia with a Bruton's kinase inhibitor **or**<br>- the patient previously commenced zanubrutinib via the manufacturer's (BeiGene) early access scheme for previously treated Waldenstrom's macroglobulinaemia and all other treatment criteria on this form are fulfilled **or**<br>- the patient previously commenced ibrutinib for relapsed/refractory Waldenstrom's macroglobulinaemia and the ibrutinib has had to be stopped solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression<br>7. The patient has an ECOG performance status of 0 or 1 or 2.<br>8. The use of zanubrutinib in this indication will be as **monotherapy**.<br>9. The prescribing clinician is aware that zanubrutinib has clinically significant drug interactions with CYP3A inhibitors and inducers as described in zanubrutinib's Summary of Product Characteristics.<br>10. Zanubrutinib is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment, whichever is the sooner.<br>11. A formal medical review as to whether treatment with zanubrutinib should continue or not will be scheduled to occur at least by the end of the first 8 weeks of treatment.<br>12. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, a treatment break approval form will be completed to restart treatment, including as appropriate if the patient had an extended break on account of Covid-19.<br>13. Zanubrutinib will be otherwise used as set out in its Summary of Product Characteristics (SPC). | No | TA833 | 19-Oct-22 | 17-Jan-23 |
| ZAN2_v1.0 | **Zanubrutinib** monotherapy | For the treatment of patients with previously untreated chronic lymphatic leukaemia which has a 17p deletion or TP53 mutation where the following criteria have been met: | 1. This application for zanubrutinib is being made by and the first cycle of this systemic anti-cancer therapy with zanubrutinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has been diagnosed with chronic lymphatic leukaemia (CLL) or small lymphocytic lymphoma (SLL).<br>3. The patient has been tested for 17p deletion and for TP53 mutation and the results are positive for 17p deletion or TP53 mutation or both.<br>Please indicate the result of these tests below:<br>- positive for 17p deletion and negative for TP53 mutation or<br>- negative for 17 deletion and positive for TP53 mutation or<br>positive for both 17p deletion and TP53 mutation.<br>4. The patient has symptomatic disease which requires systemic therapy.<br>5. The patient has not received any previous systemic therapy for CLL/SLL unless 1st line zanubrutinib was previously commenced via a BeiGene early access scheme or 1st line acalabrutinib or 1st line ibrutinib has had to be stopped due to dose-limiting toxicity and in the clear absence of disease progression.<br>Please mark which of the 4 scenarios below applies to this patient:<br>- the patient has not received any systemic therapy for CLL/SLL i.e. is completely treatment-naive or<br>- the patient previously commenced 1st line zanubrutinib via a BeiGene early access scheme and all other treatment criteria on this form are fulfilled or<br>- the patient previously commenced 1st line acalabrutinib and the acalabrutinib has had to be stopped solely due to dose-limiting toxicity and in the clear absence of disease progression<br>- the patient previously commenced 1st line ibrutinib and the ibrutinib has had to be stopped solely due to dose-limiting toxicity and in the clear absence of disease progression<br>6. The patient has an ECOG performance status of 0 or 1 or 2.<br>7. Use of zanubrutinib in this indication will be as monotherapy.<br>Note: Zanubrutinib is not licensed in CLL in combination with any other agent.<br>8. The prescribing clinician is aware that zanubrutinib has clinically significant interactions with cytochrome P450 enzyme 3A (CYP3A) inhibitors and inducers as described in zanubrutinib's Summary of Product Characteristics.<br>9. Zanubrutinib is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment, whichever is the sooner.<br>10. A formal medical review as to whether treatment with zanubrutinib should continue or not will be scheduled to occur at least by the end of the first 8 weeks of treatment.<br>11. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, a treatment break approval form will be completed to restart treatment.<br>12. Zanubrutinib will be otherwise used as set out in its Summary of Product Characteristics (SPC). | No | TA931 | 22-Nov-23 | 20-Feb-24 |

# National Cancer Drugs Fund (CDF) List

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| ZAN3_v1.0 | **Zanubrutinib** monotherapy | For the treatment of patients with previously untreated chronic lymphatic leukaemia which does not have a 17p deletion or a TP53 mutation and in whom chemotherapy with FCR or BR is unsuitable where the following criteria have been met: | 1. This application for zanubrutinib is being made by and the first cycle of this systemic anti-cancer therapy with zanubrutinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has been diagnosed with chronic lymphatic leukaemia (CLL) or small lymphocytic lymphoma (SLL).<br>3. The patient has been tested for 17p deletion and the result is negative.<br>4. The patient has been tested for TP53 mutation and the result is negative.<br>5. The patient has symptomatic disease which requires systemic therapy.<br>6. In the absence of this zanubrutinib treatment option, the patient would otherwise have been considered as UNSUITABLE for treatment with the combination of fludarabine, cyclophosphamide and rituximab (FCR) or the combination of bendamustine and rituximab (BR).<br>Note: NICE's assessment of the clinical and cost effectiveness of 1st line zanubrutinib resulted in a positive recommendation for zanubrutinib to be an option in those places in the treatment pathway which have current recommendations for use of a BTK inhibitor as monotherapy.<br>7.The patient has not received any previous systemic therapy for CLL/SLL unless 1st line zanubrutinib was previously commenced via a BeiGene early access scheme or 1st line acalabrutinib has had to be stopped solely due to dose-limiting toxicity and in the clear absence of disease progression.<br>Please mark which of the 3 scenarios below applies to this patient:<br>- the patient has not received any systemic therapy for CLL/SLL i.e. is completely treatment-naive or<br>- the patient previously commenced 1st line zanubrutinib via a BeiGene early access scheme and all other treatment criteria on this form are fulfilled.<br>- the patient previously commenced 1st line acalabrutinib and the acalabrutinib has had to be stopped solely due to dose-limiting toxicity and in the clear absence of disease progression<br>8. The patient has an ECOG performance status of 0 or 1 or 2.<br>9. Use of zanubrutinib in this indication will be as monotherapy.<br>10. The prescribing clinician is aware that zanubrutinib has clinically significant interactions with cytochrome P450 enzyme 3A (CYP3A) inhibitors and inducers as described in zanubrutinib's Summary of Product Characteristics.<br>11. Zanubrutinib is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment, whichever is the sooner.<br>12. A formal medical review as to whether treatment with zanubrutinib should continue or not will be scheduled to occur at least by the end of the first 8 weeks of treatment.<br>13. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, a treatment break approval form will be completed to restart treatment.<br>14. Zanubrutinib will be otherwise used as set out in its Summary of Product Characteristics (SPC). | No | TA931 | 22-Nov-23 | 20-Feb-24 |
| ZAN4_v1.0 | **Zanubrutinib** monotherapy | For the treatment of patients with previously treated chronic lymphatic leukaemia where the following criteria have been met: | 1. This application for zanubrutinib is being made by and the first cycle of this systemic anti-cancer therapy with zanubrutinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has been previously diagnosed with chronic lymphatic leukaemia (CLL) or small lymphocytic lymphoma (SLL).<br>3. The patient has been tested for 17p deletion and for TP53 mutation and the results are as shown below:<br>- negative for both 17p deletion and TP53 mutation<br>- positive for 17p deletion and negative for TP53 mutation or<br>- negative for 17p deletion and positive for TP53 mutation or<br>- positive for both 17p deletion and TP53 mutation<br>4. The patient has symptomatic disease which requires systemic therapy.<br>5. The patient has been previously treated with systemic therapy for CLL/SLL.<br>6. The patient is treatment naïve to a Bruton's kinase inhibitor or the patient has been previously commenced on ibrutinib or acalabrutinib monotherapy for previously treated CLL/SLL and the ibrutinib or acalabrutinib has had to be discontinued solely due to dose-limiting toxicity and in the clear absence of disease progression or the patient has previously been treated with the 1st line combination of ibrutinib plus venetoclax and was still in response on completion of treatment but has since relapsed and this application will be the first use of a BTK inhibitor since the 1st line combination of ibrutinib plus venetoclax.<br>Please mark which of the 4 scenarios below applies to this patient:<br>- the patient has not received any previous therapy for CLL/SLL with a Bruton's kinase inhibitor or<br>- the patient previously commenced acalabrutinib for relapsed/refractory CLL/SLL and acalabrutinib has had to be stopped solely due to dose-limiting toxicity and in the clear absence of disease progression or<br>- the patient previously commenced ibrutinib for relapsed/refractory CLL/SLL and ibrutinib has had to be stopped solely due to dose-limiting toxicity and in the clear absence of disease progression or<br>- the patient has previously been treated with the 1st line combination of ibrutinib plus venetoclax and was still in response on completion of treatment but has since relapsed and this application will be the first use of a BTK inhibitor since the 1st line combination of ibrutinib plus venetoclax<br>7. The patient has an ECOG performance status of 0 or 1 or 2.<br>8. Use of zanubrutinib in this indication will be as **monotherapy**.<br>Note: zanubrutinib is not licensed in CLL to be used in combination with any other agent.<br>9. The prescribing clinician is aware that zanubrutinib has clinically significant interactions with cytochrome P450 enzyme 3A (CYP3A) inhibitors and inducers as described in zanubrutinib's Summary of Product Characteristics.<br>10. Zanubrutinib is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment, whichever is the sooner.<br>11. A formal medical review as to whether treatment with zanubrutinib should continue or not will be scheduled to occur at least by the end of the first 12 weeks of treatment.<br>12. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, a treatment break approval form will be completed to restart treatment.<br>13. Zanubrutinib will be otherwise used as set out in its Summary of Product Characteristics (SPC). | No | TA931 | 22-Nov-23 | 20-Feb-24 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| ZAN5 | **Zanubrutinib** | Zanubrutinib monotherapy for the treatment of patients with marginal zone lymphoma treated with at least 1 prior anti-CD20-based therapy where the following criteria have been met: | 1. This application for zanubrutinib is being made by and the first cycle of this systemic anti-cancer therapy with zanubrutinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a confirmed histological diagnosis of marginal zone lymphoma (MZL).<br>3. The patient has been previously treated with at least 1 prior anti-CD20- based regimen for MZL.<br><br>Please mark below how many lines of systemic therapy the patient has received:<br>- the patient has had 1 prior line of systemic therapy and this contained an anti-CD20 agent or<br>- the patient has had 2 prior lines of systemic therapy of which at least one line of treatment contained an anti-CD20 agent or<br>- the patient has had 3 prior lines of systemic therapy of which at least one line of treatment contained an anti-CD20 agent or<br>- the patient has had 4 or more prior lines of systemic therapy of which at least one line of treatment contained an anti-CD20 agent<br>4. The patient's disease has failed to respond to or has progressed following the last line of systemic therapy.<br>5. The patient is either treatment naïve to therapy with a Bruton's kinase inhibitor or has been treated with zanubrutinib for previously treated MZL via a company compassionate access scheme and all other treatment criteria on this<br>6. The patient has an ECOG performance status of 0 or 1 or 2.<br>7. Use of zanubrutinib in this indication will be as monotherapy.<br><br>Note: zanubrutinib is not licensed in MZL to be used in combination with any other agent.<br>8. The prescribing clinician is aware that zanubrutinib has clinically significant interactions with cytochrome P450 enzyme 3A (CYP3A) and other inhibitors and inducers as described in zanubrutinib's Summary of Product Characteristics (sections 4.2 and 4.5).<br>9. Zanubrutinib is to be continued until disease progression or unacceptable toxicity or patient choice to stop treatment, whichever is the sooner.<br>10. A formal medical review as to whether treatment with zanubrutinib should continue or not will be scheduled to occur at least by the end of the first 8 weeks of treatment.<br>11. When a treatment break of more than 6 weeks beyond the expected 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment.<br>12. Zanubrutinib will be otherwise used as set out in its Summary of Product Characteristics (SPC). | No | TA1001 | 04-Sep-24 | 03-Dec-24 |

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | NICE Approved Indication | Blueteq Approval Criteria | Previous CDF drug/ indication | TA | Date of Final NICE Guidance | Date baseline funding started |
|---|---|---|---|---|---|---|---|
| ZAN6 | **Zanubrutinib** | For the treatment of patients with relapsed/refractory mantle cell lymphoma in patients who have received only 1 prior line of systemic therapy where the following criteria have been met: | 1. This application is being made by and the first cycle of systemic anti-cancer therapy with zanubrutinib will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>2. The patient has a confirmed histopathological diagnosis of mantle cell lymphoma.<br>3. The patient has previously been treated with one and only one prior line of rituximab-containing chemotherapy.<br><br>**Note: Patients treated with more than 1 line of prior therapy are not eligible for treatment with zanubrutinib.**<br>4. The presence of relapsed/refractory mantle cell lymphoma with documented progression of disease during or following rituximab-containing 1st line systemic therapy.<br>5. The patient has never received any prior therapy with a BTK inhibitor (ibrutinib or zanubrutinib or another BTK inhibitor) unless the patient has either received zanubrutinib via a company early access scheme and all other treatment criteria on this form apply or the patient has suffered unacceptable toxicity on therapy with ibrutinib without any evidence of disease progression and is transferring to treatment with zanubrutinib.<br><br>Please enter below which of these scenarios applies to this patient:<br>- the patient is treatment-naïve to a BTK inhibitor or<br>- the patient has received zanubrutinib via a company early access scheme and all other treatment criteria on this form apply or<br>- the patient has been receiving line therapy with ibrutinib but has suffered unacceptable toxicity without any evidence of disease progression and is transferring to treatment with zanubrutinib.<br>6. Zanubrutinib is to be used as a single agent.<br>7. Zanubrutinib is to be continued until disease progression, unacceptable toxicity or the patient's choice to stop treatment.<br>8. The patient's ECOG performance status is 0 or 1 or 2.<br>9. The patient is not on concurrent therapy with warfarin.<br>10. The prescribing clinician I am aware that zanubrutinib has clinically significant interactions with cytochrome P450 enzyme 3A (CYP3A) inhibitors and inducers as described in zanubrutinib's Summary of Product Characteristics.<br>11. When a treatment break of more than 6 weeks beyond the expected cycle length occurs, the prescribing clinician will complete a treatment break approval form to restart treatment.<br>12. Zanubrutinib will be otherwise used as set out in its Summary of Product Characteristics (SPC). | No | TA1081 | 10-Jul-25 | 09-Aug-25 |

# Section C. Interim Systemic Anti-Cancer Therapy (SACT) treatment change options introduced during the COVID-19 pandemic.

**To support the response to the COVID pandemic, NHS England and NICE published a guideline on the delivery of SACT (NICE NG161) and commissioned a list of 'COVID-friendly' interim cancer treatment options. These allowed clinicians to treat patients with less toxic therapies compared to standard treatment and could be given at home.**

**These arrangements maximised the safety of cancer patients due to start or on chemotherapy during the pandemic response, whilst also preserving efficacy, as well as making the best use of NHS resources (service capacity) and protecting staff from infection and lightening the burden on hospitals, critical during the pandemic response.**

**Funding for the Interim COVID treatments was provided from the start of the pandemic until the end of 2022/23. The number of Interim options available has decreased over time as indications were removed either because they had been superseded by NICE guidance or the need for the flexibility, they provided during the pandemic has reduced and clinicians have reverted to standard commissioned treatment options.**

**From 1st April 2023 four options have been retained until the agreed exit strategy for those indications is complete i.e., a decision from NICE which supersedes the COVID-friendly interim option or completion of assessment of a Clinical Policy application by the NHS England Specialised Services Clinical Panel. The options will be removed from this list when the final commissioning position is known or sooner if there is no longer a clinical need to retain these options.**

# National Cancer Drugs Fund (CDF) List

| Blueteq Form ref: | Drug | Indication | Criteria for use | Date form made available | NICE Guideline | Comment |
|---|---|---|---|---|---|---|
| NIV13CV_v1.1 | **Nivolumab** | As 2nd line or subsequent line treatment for malignant pleural and peritoneal mesothelioma which has progressed during/after 1st line chemotherapy with pemetrexed- and platinum-based chemotherapy where the following criteria have been met: | 1. This application is for an interim version of the usual treatment criteria for this drug/regimen as an option to reduce the risk to patients and alleviate the impact on service capacity during the COVID19 pandemic.<br>2. This application is being made by and the first cycle of systemic anti-cancer therapy with nivolumab monotherapy will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.<br>3. The prescribing clinician is fully aware of the management of and the treatment modifications that may be required for immune-related adverse reactions due to anti-PD-L1 treatments including pneumonitis, colitis, nephritis, endocrinopathies, hepatitis and skin toxicities.<br>4. The patient has a histologically or cytologically confirmed diagnosis of mesothelioma.<br>5. The mesothelioma is of pleural or non-pleural origin.<br>Please indicate below the site of origin of the mesothelioma in this patient:<br>- the pleura **Or**<br>- the peritoneum **Or**<br>- the pericardium **Or**<br>- the tunica vaginalis in the testis<br>6. The histological subtype of mesothelioma as to whether the mesothelioma in this patient is of epithelioid type or non-epithelioid type (sarcomatoid or mixed [biphasic] histological types) or the type cannot be determined.<br>Please indicate below the histological subtype of mesothelioma in this patient:<br>- the mesothelioma is of epithelioid type **Or**<br>- the mesothelioma is of non-epithelioid (sarcomatoid or biphasic) type **Or**<br>- the mesothelioma type cannot be determined<br>7. In terms of previous systemic therapy the patient has only been treated with cytotoxic chemotherapy (which has included first-line pemetrexed and platinum-based combination chemotherapy) and thus this application for nivolumab monotherapy is for second or a subsequently line of systemic treatment.<br>8. The patient started 1st line chemotherapy on or before **14th July 2022,** i.e. the date until which the only first line option available was chemotherapy.<br><br>Note: Patients who started 1st line treatment after 14th July 2022 had the option of first line nivolumab with ipilumumab or chemotherapy and are therefore **ineligible** for second or subsequent line immunotherapy with single agent nivolumab.<br>9. The patient has not received prior treatment with an anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CD137, or anti-Cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) antibody.<br>10. In the absence of this COVID19-related nivolumab treatment option, this patient would otherwise have been eligible for 2nd or subsequent line cytotoxic chemotherapy.<br>11. The patient has an ECOG performance status of 0 or 1.<br>12. The patient has no symptomatically active brain metastases or leptomeningeal metastases.<br>13. Nivolumab will be administered as monotherapy as either 2-weekly cycles of nivolumab at a dose of 240mg (or if the patient is stable and well, 4-weekly cycles of nivolumab monotherapy at a dose of 480mg).<br>Note: nivolumab is not funded in combination with ipilimumab for this indication.<br>14. Nivolumab will be continued until disease progression or unacceptable toxicity or withdrawal of patient consent, whichever occurs first.<br>15. A formal medical review as to how nivolumab monotherapy is being tolerated and whether treatment with nivolumab monotherapy should continue or not will be scheduled to occur at least by the end of the first 8 weeks of treatment.<br>16. Where a treatment break of more than 12 weeks beyond the expected cycle length is needed, a treatment break approval form will be completed to restart treatment, including indicating as appropriate if the patient had an extended break because of COVID 19.<br>17. The prescribing clinician has fully discussed with the patient as to the risks/benefits of giving this regimen including the discussion as to likely clinical benefit and toxicities of this treatment option compared with any cytotoxic chemotherapy regimen.<br>18. Trust policy regarding the use of unlicensed treatments has been followed as the drug, its dose (480mg) and frequency (every 4 weeks) are not licensed in this indication.<br>19. Nivolumab will otherwise be used as set out in its Summary of Product Characteristics (SPC). | 03-Aug-20 | NG161 | NICE approved nivolumab plus ipilimumab as a first line immunotherapy option in mesothelioma on 14 July 2022 (see NICE ID1609). Therefore, the option to give nivolumab monotherapy instead of second-line chemotherapy to reduce risk of immunosuppression only remains in place for patients who started first-line chemotherapy on or before 14 July 2022, when the only first-line option available was chemotherapy. |

# National Cancer Drugs Fund (CDF) List

## Version Control

| Version No. | Date published | Author(s) | Revision summary |
|---|---|---|---|
| 0.1 | n/a | D Thomson; P Clark | Initial draft of new CDF list, based on pre-existing national CDF list but updated for changes to the CDF, for review. |
| 1.0 | 29-Jul-16 | D Thomson; P Clark | Final version of new CDF list |
| 1.1 | 09-Aug-16 | P Clark | New addition to CDF list |
| 1.2 | 18-Aug-16 | D Thomson; P Clark | New addition to CDF list and revision of criteria for a number of existing drugs |
| 1.3 | 24-Aug-16 | D Thomson; P Clark | Removal of one drug/indication for baseline funding and date for baseline funding added for existing drugs. |
| 1.4 | 02-Sep-16 | D Thomson; P Clark | Update to Radium criteria and timeline following publication of NICE FAD |
| 1.5 | 20-Sep-16 | D Thomson; P Clark | Removal of two drugs/indications for baseline funding |
| 1.6 | 27-Sep-16 | D Thomson; P Clark | Removal of two drug indications |
| 1.7 | 04-Oct-16 | D Thomson; P Clark | Addition of new CDF drug and date for baseline funding added for existing drugs |
| 1.8 | 21-Oct-16 | D Thomson; P Clark | New addition to CDF list |
| 1.9 | 25-Oct-16 | D Thomson; P Clark | Removal of one drug/indication for baseline funding. |
| 1.10 | 03-Nov-16 | D Thomson; P Clark | Update to eribulin following publication of NICE FAD |
| 1.11 | 10-Nov-16 | D Thomson; P Clark | Update to everolimus following publication of NICE FAD; update to section B - "NICE approved and baseline funded drugs/indications from 1st April 2016" |
| 1.12 | 17-Nov-16 | D Thomson; P Clark | Two new addition to CDF list and update to dasatinib criteria following publication of NICE FAD |
| 1.13 | 23-Nov-16 | D Thomson; P Clark | New addition to CDF list, removal of two drugs/indications for baseline funding and update to Nivolumab timeline following publication of final guidance |
| 1.14 | 02-Dec-16 | D Thomson; P Clark | New addition to CDF list (PEMB1_v1.0); update to neoadjuvant pertuzumab (PER2) criteria. |
| 1.15 | 12-Dec-16 | D Thomson; P Clark | New addition to CDF list (IBR3_v1.0); update to ibrutinib in pretreated CLL (IBR1) criteria. |
| 1.16 | 21-Dec-16 | D Thomson; P Clark | Removal of two drugs/indications for baseline funding; update of five timelines following publication of final NICE guidance; update to pembrolizumab criteria. |
| 1.17 | 23-Dec-16 | D Thomson; P Clark | Removal of one drug/indication for baseline funding; update to pertuzumab criteria |
| 1.18 | 28-Dec-16 | D Thomson; P Clark | Removal of three drugs and indications for baseline funding; removal of pegaspargase. |
| 1.19 | 12-Jan-17 | D Thomson; P Clark | Update to everolimus (RCC) following publication of NICE FAD; update to two timelines following publication of final NICE guidance; update to radium 223 criteria in section B |
| 1.20 | 10-Feb-17 | D Thomson; P Clark | Update to section B - "NICE approved and baseline funded drugs/indications from 1st April 2016"; update of 2 timelines following publication of final NICE guidance; update to ponatinib following ACD |
| 1.21 | 02-Mar-17 | D Thomson; P Clark | Updates to section A - CET1, CET4, PAN3, PAN1. Updates to section B - Ipilimumab + Nivolumab, Dabrafenib + Trametinib |
| 1.22 | 21-Mar-17 | D Thomson; P Clark | Removal of 5 drugs/indications for routine funding and addition to section B. Update to Ipilimumab + Nivolumab criteria. |
| 1.23 | 11-Apr-17 | D Thomson; P Clark | Removal of 1 drugs/indications for routine funding . |
| 1.24 | 27-Apr-17 | D Thomson; P Clark | Removal of 2 drug/indications for routine funding and update to section B. Addition of two drug/indications following publication of FAD |
| 1.25 | 28-Apr-17 | D Thomson; P Clark | Following publication of ponatinib in CML FAD - incorporation of 2 previous separate sets of criteria into a single set |
| 1.26 | 02-May-17 | D Thomson; P Clark | Replacement of current criteria for brentuximab in HD with new criteria following publication of NICE FAD and update to blimautmomab in children criteria |
| 1.27 | 12-May-17 | D Thomson; P Clark | Addition of 2 CDF drug/indications and updated of 1 CDF drug/indication following publication of FAD |
| 1.28 | 31-May-17 | D Thomson; P Clark | Removal of 1 drug/indication for routine funding and 1 new drug/indication addition following publication of the FAD |
| 1.29 | 02-Jun-17 | D Thomson; P Clark | 2 new drug/indications following publication of FAD |
| 1.30 | 09-Jun-17 | D Thomson; P Clark | 3 new drug/indications following publication of 2 FADs; update to existing criteria |
| 1.31 | 15-Jun-17 | B Groves; P Clark | Revision to 1 drug/indication following publication of FAD |
| 1.32 | 30-Jun-17 | D Thomson; B Groves | Revision to 1 drug/indication in CDF / two drugs in 4 indications moved from CDF to routine commissioning |
| 1.33 | 10-Jul-17 | P Clark; B Groves | 1 new drug/indication following publication of FAD |
| 1.34 | 24-Jul-17 | P Clark; D Thomson; B Groves | 1 new drug/indication; two drugs entering baseline commissioning, update to OLA2_v1.1 interim funding status |
| 1.35 | 04-Aug-17 | P Clark; D Thomson; B Groves | 1 new drug/indication for interim funding before moving into routine commissioning |
| 1.36 | 08-Aug-17 | P Clark; D Thomson; B Groves | 1 drug/indication revised and 1 new drug indication added |
| 1.37 | 10-Aug-17 | P Clark; D Thomson; B Groves | 1 drug/indication revised and 1 new drug indication added; update to treatment break criteria throughout; update to 1 drug with date for transition to routine commissioning |
| 1.38 | 24-Aug-17 | P Clark; B Groves | 1 indication deleted and replaced with updated and separate child and adult treatment criteria; Removal of 1 drug/indication for routine funding and update to section B; 2 drugs 'available to new patients' status updated |
| 1.39 | 31-Aug-17 | D Thomson; B Groves | 1 indication moved into routine commissioning; 1 indication updated to reflect notice period for registering new patients |
| 1.40 | 06-Sep-17 | D Thomson; B Groves | 2 indications updated to reflect the date they move into routine commissioning; 1 indication updated to reflect notice period for registering new patients |
| 1.41 | 08-Sep-17 | P Clark; D Thomson; B Groves | 1 new drug in 2 indications added; 1 existing indication updated to reflect expected entry into routine commissioning |
| 1.42 | 26-Sep-17 | P Clark; D Thomson; B Groves | 11 indications moved from CDF to routine commissioning |
| 1.43 | 28-Sep-17 | P Clark; D Thomson; B Groves | 1 drug/indication added |
| 1.44 | 05-Oct-17 | P Clark; D Thomson; B Groves | 1 drug/indication removed; 2 new CDF indications added |
| 1.45 | 12-Oct-17 | P Clark; D Thomson | 1 drug/indication revised following interim funding |
| 1.46 | 13-Oct-17 | P Clark; D Thomson | 1 new drug/indication entering CDF |
| 1.47 | 17-Oct-17 | P Clark; D Thomson; B Groves | 2 drugs/indications moving from CDF to routine commissioning |
| 1.48 | 01-Nov-17 | P Clark; D Thomson; B Groves | 1 drug/indication criteria updated |
| 1.49 | 05-Nov-17 | P Clark; D Thomson; B Groves | 1 drug/indication criteria removed |
| 1.50 | 08-Nov-17 | P Clark; D Thomson; B Groves | 1 drug/indication moved from CDF into routine commissioning |

# National Cancer Drugs Fund (CDF) List

**Version Control(Cont)**

| Version No. | Date published | Author(s) | Revision summary |
|---|---|---|---|
| 1.51 | 16-Nov-17 | P Clark; D Thomson; B Groves | 2 new drug/indications added following publication of FAD |
| 1.52 | 22-Nov-17 | P Clark; D Thomson; B Groves | Notice of removal for 1 drug/indication; treatment criteria clarified for 1 drug/indication; 2 drug/indication titles amended |
| 1.53 | 05-Dec-17 | P Clark; D Thomson; B Groves | 2 drugs/indications moved into routine commissioning; |
| 1.54 | 07-Dec-17 | P Clark; D Thomson; B Groves | 1 drug/indication with interim funding |
| 1.55 | 08-Dec-17 | P Clark; D Thomson; B Groves | 1 drug/indication with interim funding |
| 1.56 | 14-Dec-17 | P Clark; D Thomson; B Groves | 1 drug/indication split into two indications; 2 drugs/indication updated with dates for expected entry into routine commissioning |
| 1.57 | 19-Dec-17 | P Clark; D Thomson; B Groves | 1 new CDF drug/indication; notice given for 2 drugs/indications attracting interim funding which will move into rountine commissioning in 90-days; 4 updates to criteria (1 CDF, 3 routine) |
| 1.58 | 02-Jan-18 | P Clark; D Thomson | 2 drug/indications moving from CDF to routine commissioning; 4 updates to criteria (1CDF, 3 routine); 1 update to IFA section |
| 1.59 | 17-Jan-18 | P Clark: B Groves | 1 drug/indication added to the CDF; 1 drug/indication updated |
| 1.60 | 18-Jan-18 | P Clark; D Thomson; B Groves | 1 drug/indication updated |
| 1.61 | 22-Jan-18 | B Groves | 1 drug/indication delisted |
| 1.62 | 01-Feb-18 | B Groves | 3 drugs for 4 indications upated following NICE final guidance |
| 1.63 | 09-Feb-18 | P Clark; D Thomson; B Groves | 1 drug/indication for routine commissioning |
| 1.64 | 12-Feb-18 | P Clark; D Thomson; B Groves | 1 drug/indication for routine commissioning |
| 1.65 | 15-Feb-18 | P Clark; D Thomson; B Groves | 3 drug/indication for routine commissioning which will receive interim CDF funding; 1 drug/indication moved into routine commissioning; 1 drug/indication with updated treatment criteria |
| 1.66 | 21-Feb-18 | B Groves | 2 drug/indications updated |
| 1.67 | 01-Mar-18 | P Clark; D Thomson; D Dwyer | 1 drug/indication added to the CDF; 1 drug/ indication for routine commissioning which will receive interim CDF funding; 3 drug/indications with updated treatment criteria |
| 1.68 | 07-Mar-18 | D Thomson; D Dwyer | 1 indication moved into routine commissioning |
| 1.69 | 16-Mar-18 | P Clark; D Thomson; D Dwyer | 1 drug/indication added to the CDF |
| 1.70 | 20-Mar-18 | D Thomson; D Dwyer | 2 drugs/indications moved into routine commissioning |
| 1.71 | 21-Mar-18 | D Thomson; D Dwyer | 2 drugs/indications updated to reflect the date they move into routine commissioning |
| 1.72 | 28-Mar-18 | D Thomson; D Dwyer | 1 drug/indication updated to reflect the date it moves into routine commissioning; 1 drug/indication moved into routine commissioning; 1 drug/indication with updated treatment criteria |
| 1.73 | 03-Apr-18 | P Clark; D Thomson; D Dwyer | 1 drug/indication removed |
| 1.74 | 09-Apr-18 | P Clark; D Thomson; D Dwyer | 1 drug/ indication for routine commissioning which will receive interim CDF funding |
| 1.75 | 11-Apr-18 | D Thomson; D Dwyer | 1 drug/indication updated to reflect the date it moves into routine commissioning |
| 1.76 | 19-Apr-18 | P Clark; D Thomson; D Dwyer | 1 drug/indication with updated treatment criteria |
| 1.77 | 24-Apr-18 | D Thomson; D Dwyer | 2 drugs/indications moved into routine commissioning |
| 1.78 | 25-Apr-18 | D Thomson; D Dwyer | 2 drugs/indications moved into routine commissioning |
| 1.79 | 27-Apr-18 | P Clark; D Thomson; D Dwyer | 1 drug/indication added to the CDF |
| 1.80 | 01-May-18 | D Thomson; D Dwyer | 1 drug/indication moved into routine commissioning |
| 1.81 | 04-May-18 | P Clark; D Thomson; D Dwyer | 5 drugs/indications which will receive interim CDF funding; 2 drugs/indications for routine commissioning |
| 1.82 | 16-May-18 | D Thomson; D Dwyer | 1 drug/indication updated to reflect the date it moves into routine commissioning |
| 1.83 | 17-May-18 | P Clark; D Thomson; D Dwyer | 1 drug/ indication for routine commissioning which will receive interim CDF funding |
| 1.84 | 25-May-18 | P Clark; D Thomson; D Dwyer | 1 drug/indication added to the CDF |
| 1.85 | 01-Jun-18 | P Clark; D Thomson; D Dwyer | 1 drug/indication added to the CDF |
| 1.86 | 05-Jun-18 | D Thomson; D Dwyer | 1 drug/indication moved into routine commissioning |
| 1.87 | 13-Jun-18 | P Clark; D Thomson; D Dwyer | 8 drugs/indications updated to reflect the date they move into routine commissioning; 2 drugs/indications updated to note EMA recommendation; 1 drug/indication with updated treatment criteria |
| 1.88 | 19-Jun-18 | D Thomson; D Dwyer | 2 drugs/indications moved into routine commissioning |
| 1.89 | 26-Jun-18 | D Thomson; D Dwyer | 1 drug/indication moved into routine commissioning |
| 1.90 | 28-Jun-18 | P Clark; D Thomson; D Dwyer | 1 drug/ indication for routine commissioning which will receive interim CDF funding; 1 drug/indication with updated treatment criteria |
| 1.91 | 05-Jul-18 | D Thomson; D Dwyer | 2 drugs/indications with updated treatment criteria |
| 1.92 | 10-Jul-18 | D Thomson; D Dwyer | 1 drug/indication moved into routine commissioning |
| 1.93 | 12-Jul-18 | P Clark; D Thomson; D Dwyer | 2 drugs/ indications for routine commissioning which will receive interim CDF funding; 3 drugs/indications moved into routine commissioning; 1 drug/indication with updated treatment criteria |
| 1.94 | 13-Jul-18 | D Thomson; D Dwyer | 1 drug/indication moved into routine commissioning; |
| 1.95 | 20-Jul-18 | P Clark; D Thomson; D Dwyer | 1 drug/indication updated to reflect the date it moves into routine commissioning; 1 drug/ indication for routine commissioning which will receive interim CDF funding; 1 drug/indication with updated treatment criteria |
| 1.96 | 25-Jul-18 | P Clark; D Thomson; B Groves | 1 drug in 2 indications entering a CDF managed access period |
| 1.97 | 03-Aug-18 | D Thomson; D Dwyer | 1 drug/indication with updated treatment criteria |
| 1.98 | 09-Aug-18 | P Clark; D Thomson; D Dwyer | 2 drugs/indications for routine commissioning which will receive interim CDF funding; 2 drugs/indications with updated treatment criteria; 3 drugs/indications updated to reflect the date they move into routine commissioning |
| 1.99 | 14-Aug-18 | B Groves; P Clark; D Thomson | 1 drug/indication moved into routine commissioning; 1 drug/indication moved back to the CDF list |
| 1.100 | 24-Aug-18 | P Clark; D Thomson; D Dwyer | 1 drug/indication for routine commissioning which will receive interim CDF funding; 3 drugs/indications with updated treatment criteria; 2 drugs/indications updated to reflect the date they move into routine commissioning |

# National Cancer Drugs Fund (CDF) List

**Version Control(Cont)**

| Version No. | Date published | Author(s) | Revision summary |
|---|---|---|---|
| 1.101 | 31-Aug-18 | P Clark; D Thomson; D Dwyer | 2 drugs/indications with updated treatment criteria; 1 drug/indication updated to reflect the date it moves into routine commissioning |
| 1.102 | 07-Sep-18 | P Clark; D Thomson; D Dwyer | 1 drug/indication moved into routine commissioning; 1 drugs/indications with updated treatment criteria |
| 1.103 | 11-Sep-18 | D Thomson; D Dwyer | 7 drugs/indications moved into routine commissioning |
| 1.104 | 17-Sep-18 | P Clark; D Thomson; D Dwyer | 1 drug/indication for routine commissioning which will receive interim CDF funding |
| 1.105 | 05-Oct-18 | P Clark; D Thomson; D Dwyer | 2 drugs/indications for routine commissioning which will receive interim CDF funding; 2 drugs/indications updated to reflect the date it moves into routine commissioning; 1 drug/indication with an updated form code; 2 drugs/ indications with updated treatment criteria |
| 1.106 | 16-Oct-18 | P Clark; D Thomson; D Dwyer | 1 drug/indication moved into routine commissioning; 18 drugs/indications with updated treatment criteria |
| 1.107 | 06-Nov-18 | P Clark; D Thomson; D Dwyer | 2 drugs/indications moved into routine commissioning |
| 1.108 | 08-Nov-18 | P Clark; D Thomson; D Dwyer | 2 drugs/ indications for routine commissioning which will receive interim CDF funding |
| 1.109 | 20-Nov-18 | P Clark; D Thomson; D Dwyer | 2 drugs/indication added to the CDF; 2 drugs/indications updated to reflect the date it moves into routine commissioning; 2 drugs/indications moved into routine commissioning |
| 1.110 | 22-Nov-18 | P Clark; D Thomson; D Dwyer | 1 drug/indication added to the CDF |
| 1.111 | 27-Nov-18 | D Thomson; D Dwyer | 1 drug/indication moved into routine commissioning |
| 1.112 | 30-Nov-18 | P Clark; D Thomson; D Dwyer | 1 drug/indication added to the CDF |
| 1.113 | 07-Dec-18 | P Clark; D Thomson; D Dwyer | 1 drug/indication added to the CDF; 1 drug/indication recommended for routine commissioning which will be available via a free of charge compassionate access scheme until 90 days after the date NICE publishes final guidance; 1 drug/indication updated to reflect the date it will be delisted; 1 drug/indication with updated treatment criteria |
| 1.114 | 12-Dec-18 | P Clark; D Thomson; D Dwyer | 1 drug/indication with updated treatment criteria |
| 1.115 | 17-Dec-18 | P Clark; D Thomson; D Dwyer | 3 drugs/indications with updated treatment criteria; 1 drug/indication updated to reflect the date it will be delisted |
| 1.116 | 19-Dec-18 | P Clark; D Thomson; D Dwyer | 2 drugs/indications moved into routine commissioning; 2 drugs/indications with updated treatment criteria; 2 drugs/indications updated to reflect the date it moves into routine commissioning |
| 1.117 | 21-Dec-18 | P Clark; D Thomson; D Dwyer | 3 drugs/indications with updated treatment criteria |
| 1.118 | 31-Dec-18 | P Clark; B Groves | 8 drugs/indications updated; 1 drug/indication moved to routine commissioning |
| 1.119 | 15-Jan-19 | P Clark; D Dwyer | 1 drug/indication moved to routine commissioning; 1 drug/indication removed from the CDF list; 1 drug/indication updated to reflect the date it moves into routine commissioning |
| 1.120 | 17-Jan-19 | P Clark; D Dwyer | 1 drug/ indication for routine commissioning which will receive interim CDF funding; 2 drugs/indications with updated treatment criteria |
| 1.121 | 18-Jan-19 | P Clark; S Williamson; D Dwyer | 2 drugs/ indications for routine commissioning which will receive interim CDF funding; 4 drugs/indications with updated treatment criteria |
| 1.122 | 23-Jan-19 | P Clark; S Williamson; D Dwyer | 2 drugs/indications with updated treatment criteria |
| 1.123 | 24-Jan-19 | P Clark; S Williamson; D Dwyer | 1 drug/indication with updated treatment criteria |
| 1.124 | 25-Jan-19 | P Clark; S Williamson; D Dwyer | 2 drugs/indications suspended from CDF funding for new patients |
| 1.125 | 01-Feb-19 | P Clark; S Williamson; D Dwyer | 1 drug/indication added to the CDF |
| 1.126 | 01-Feb-19 | P Clark; S Williamson; D Dwyer | 2 drug/indication added to list B |
| 1.127 | 15-Feb-19 | P Clark; S Williamson; D Dwyer | 1 drug/indication removed from the CDF; 2 drugs/indications moved to routine commissioning; 3 drugs/indications for routine commissioning which will receive CDF interim funding; 6 drugs/indications with updated treatment criteria |
| 1.128 | 12-Mar-19 | P Clark; S Williamson; D Dwyer | 1 drug/indication added to the CDF; 3 drugs/indications updated to reflect the date it moves into routine commissioning |
| 1.129 | 21-Mar-19 | P Clark; S Williamson; D Dwyer | 1 drug/ indication for routine commissioning which will receive interim CDF funding; 2 drugs/indications moved to rountine commissioning; 1 drug/indication with updated treatment criteria |
| 1.130 | 28-Mar-19 | P Clark; S Williamson; D Dwyer | 1 drug/indication added to the CDF |
| 1.131 | 02-Apr-19 | P Clark; S Williamson; D Dwyer | 1 drug/indication added to the CDF |
| 1.132 | 05-Apr-19 | P Clark; S Williamson; D Dwyer | 1 drug/indication added to the CDF |
| 1.133 | 09-Apr-19 | P Clark; S Williamson; D Dwyer | 1 drug/indication added to list B; 1 drug/indication with updated treatment criteria |
| 1.134 | 18-Apr-19 | P Clark; S Williamson; D Dwyer | 2 drugs/indications with updated treatment criteria; 3 drugs/indications updated to reflect the date it moves into routine commissioning |
| 1.135 | 02-May-19 | P Clark; S Williamson; D Dwyer | 2 drugs/ indications for routine commissioning which will receive interim CDF funding; 1 drug/indication updated to reflect the date it moves into routine commissioning |
| 1.136 | 17-May-19 | P Clark; S Williamson; D Dwyer | 2 drugs/ indications for routine commissioning which will receive interim CDF funding; 1 drug/indication with updated treatment criteria; 2 drugs/indications with new Blueteq forms created |
| 1.137 | 28-May-19 | P Clark; S Williamson; D Dwyer | 3 drugs/indications moved into routine commissioning |
| 1.138 | 18-Jun-19 | P Clark; S Williamson; D Dwyer | 3 drugs/indications moved into routine commissioning |
| 1.139 | 19-Jun-19 | P Clark; S Williamson; D Dwyer | 2 drugs/ indications for routine commissioning which will receive interim CDF funding; 9 drug/indication with updated treatment criteria |
| 1.140 | 02-Jul-19 | P Clark; S Williamson; D Dwyer | 1 drug/indication recommendation to the CDF |
| 1.141 | 05-Jul-19 | P Clark; S Williamson; D Dwyer | 1 drug/ indication for routine commissioning which will receive interim CDF funding; 1 drug/indication moved to routine commissioning |
| 1.142 | 17-Jul-19 | P Clark; S Williamson; D Dwyer | 1 drug/indication recommendation to the CDF; 4 drugs/indications with updated treatment criteria; 2 drugs/indications removed from the CDF |
| 1.143 | 23-Jul-19 | P Clark; S Williamson; D Dwyer | 2 drugs/indications moved into routine commissioning |
| 1.144 | 26-Jul-19 | P Clark; S Williamson; D Dwyer | 2 drugs/indications updated to reflect the date it moves into routine commissioning: 1 drug/indication recommeded to the CDF |
| 1.145 | 30-Jul-19 | P Clark; S Williamson; D Dwyer | 1 drug/indication updated to reflect the date supply became available |
| 1.146 | 02-Aug-19 | P Clark; S Williamson; D Dwyer | 3 drugs/indications with updated treatment criteria |
| 1.147 | 06-Aug-19 | P Clark; S Williamson; D Dwyer | 1 drug/ indication for routine commissioning which will receive interim CDF funding |
| 1.148 | 08-Aug-19 | P Clark; S Williamson; D Dwyer | 1 drug/indication added to the CDF |
| 1.149 | 03-Sep-19 | P Clark; S Williamson; D Dwyer | 1 drug/indication added to the CDF |

# National Cancer Drugs Fund (CDF) List

## Version Control(Cont)

| Version No. | Date published | Author(s) | Revision summary |
|---|---|---|---|
| 1.150 | 24-Sep-19 | P Clark; S Williamson; D Dwyer | 2 drug/indication added to list B |
| 1.151 | 03-Oct-19 | P Clark; S Williamson; D Dwyer | 1 drug/indication updated to reflect the date supply became available |
| 1.152 | 11-Oct-19 | P Clark; S Williamson; D Dwyer | 2 drugs/indications added to the CDF; 2 drugs/indications with updated treatment criteria |
| 1.153 | 22-Oct-19 | P Clark; S Williamson; D Dwyer | 2 drug/indication added to list B |
| 1.154 | 12-Nov-19 | P Clark; S Williamson; D Dwyer | 1 drug/indication added to list B; 7 drugs/indications with updated criteria; 1 drug/indication with treatment criteria added to list B |
| 1.155 | 28-Nov-19 | P Clark; S Williamson; D Dwyer | 1 drugs/indications added to the CDF; 2 drugs/indications with updated treatment criteria |
| 1.156 | 29-Nov-19 | P Clark; S Williamson; D Dwyer | 1 drugs/indications added to the CDF; 1 drug/ indication for routine commissioning which will receive interim CDF funding; 6 drugs/indications with updated treatment criteria |
| 1.157 | 04-Dec-19 | P Clark; S Williamson; D Dwyer | 4 drugs/indications with updated treatment criteria |
| 1.158 | 15-Jan-20 | P Clark; S Williamson; D Dwyer | 1 drug/indication for routine commissioning which will receive interim CDF funding; 4 drugs/indications with updated treatment criteria |
| 1.159 | 27-Feb-20 | P Clark; S Williamson; D Dwyer | 1 drug/indication added to list B; 1 drug/indication for routine commissioning which will receive interim CDF funding |
| 1.160 | 09-Mar-20 | P Clark; S Williamson; D Dwyer | 3 drugs/indications with updated treatment criteria |
| 1.161 | 03-Apr-20 | P Clark; S Williamson; D Dwyer | 1 drug/indication added to the CDF; 12 drugs/indications with updated treatment criteria |
| 1.162 | 17-Apr-20 | P Clark; S Williamson; D Dwyer | 1 drug/indication recommended for the CDF; 17 drug/indications added to list C; 1 drug/indication added to list B |
| 1.163 | 07-May-20 | P Clark; S Williamson; D Dwyer | 1 drug/indication for routine commissioning which will receive interim CDF funding; 17 drug/indications added to list C |
| 1.164 | 22-May-20 | P Clark; S Williamson; D Dwyer | 1 drug/indication for routine commissioning which will receive interim CDF funding; 1 drug/indications added to list C; 6 drugs/indications with updated treatment criteria |
| 1.165 | 27-May-20 | P Clark; S Williamson; D Dwyer | 1 drug/indication for routine commissioning which will receive interim CDF funding |
| 1.166 | 13-Jul-20 | P Clark; S Williamson; D Dwyer | 1 drug/indication for routine commissioning which will receive interim CDF funding; 2 drug/indications with updated treatment criteria; 1 drug/indication added to list B; 1 drug/indication with CDF exit date added |
| 1.167 | 31-Jul-20 | P Clark; S Williamson; D Dwyer | 1 drug/indication added to the CDF; 1 drug/indication for routine commissioning which will receive interim CDF funding; 2 drugs/indications added to list B; 1 drug/indication removed from list C |
| 1.168 | 20-Aug-20 | P Clark; S Williamson; D Dwyer | 1 drug/indication for routine commissioning which will receive interim CDF funding; 3 drugs/indications with published treatment criteria after marketing authorisation; 2 drugs/indications added to list B; 4 drugs/indications with date moving to routine commissioning updated |
| 1.169 | 11-Sep-20 | P Clark; S Williamson; D Dwyer | 2 drugs/indications for routine commissioning which will receive interim CDF funding; 6 indications added to list C; 1 drug/indication removed from list C; 5 drugs/indications with updated treatment criteria |
| 1.170 | 23-Oct-20 | P Clark; S Williamson; D Dwyer | 2 drugs/indications added to the CDF; 1 drugs/indications for routine commissioning which will receive interim CDF funding; 1 indications removed from list C; 2 drugs/indications with updated treatment criteria |
| 1.171 | 12-Nov-20 | P Clark; S Williamson; D Dwyer | 3 drugs/indications for routine commissioning which will receive interim CDF funding; 1 drugs/indications added to the CDF; 4 drugs/indications added to list B |
| 1.172 | 25-Nov-20 | P Clark; S Williamson; D Dwyer | 1 drug/indication for routine commissioning which will receive interim CDF funding; 1 drugs/indications removed from list C; 2 drugs/indications with date moving to routine commissioning updated |
| 1.173 | 15-Dec-20 | P Clark; S Williamson; D Dwyer | 3 drugs/indications for routine commissioning which will receive interim CDF funding; 5 drugs/indications with updated treatment criteria |
| 1.174 | 19-Jan-21 | P Clark; S Williamson; D Dwyer | 3 drugs/indications added to the CDF; 3 drugs/indications added to list B; 5 drugs/indications with updated treatment criteria |
| 1.175 | 27-Jan-21 | P Clark; S Williamson; D Dwyer | 1 drug/indication for routine commissioning which will receive interim CDF funding; 2 drugs/indications with updated treatment criteria |
| 1.176 | 18-Feb-21 | P Clark; S Williamson; D Dwyer | 13 drugs/indications with updated treatment criteria; 1 drug/indication with an updated form title; 1 drug/indication updated to reflect the date it leaves the CDF after terminated guidance |
| 1.177 | 19-Mar-21 | P Clark; S Williamson; D Dwyer | 2 drugs/indications for routine commissioning which will receive interim CDF funding; 1 drug/indication recommended for the CDF; 1 drug/indication added to list C; 14 durgs/indications with updated treatment criteria; 4 drugs/indications added to list B |
| 1.178 | 29-Mar-21 | P Clark; S Williamson; R Mishra | 9 drugs/indications removed from list C |
| 1.179 | 28-Apr-21 | P Clark; S Williamson; D Dwyer | 2 durgs/indications removed from the CDF; 1 drug/indication recommended for the CDF; 1 drug/indication for routine commissioning which will receive interim CDF funding; 2 drugs/indications added to list B; 6 drugs/indications with updated date moving to routine commissioning |
| 1.180 | 17-May-21 | P Clark; S Williamson; D Dwyer | 1 drug/indication added to list D; 2 drugs/indications recommended for routine commissioning; 1 drug/indication removed from list C; 7 drugs/indications with updated treatment criteria |
| 1.181 | 17-Jun-21 | P Clark; S Williamson; D Dwyer | 2 drugs/indications for routine commissioning which will receive interim CDF funding; 11 drugs/indications added to list B; 8 drugs/indications with updated treatment criteria; 1 durg/indication removed from list C; 1 drug/indication removed from the CDF |
| 1.182 | 25-Jun-21 | P Clark; S Williamson; D Dwyer | 1 drug/indication removed from list B; 5 drugs/indications with updated treatment criteria |
| 1.183 | 01-Jul-21 | P Clark; S Williamson; D Dwyer | 4 drugs/indications removed from list C; 1 drug/indication added to list B |
| 1.184 | 23-Jul-21 | P Clark; S Williamson; D Dwyer | 1 drugs/indications for routine commissioning which will receive interim CDF funding; 1 drug/indication added to list B; 7 drugs/indications with updated treatment criteria; 1 drug/indication removed from list C |
| 1.185 | 30-Jul-21 | P Clark; S Williamson; D Dwyer | 1 drugs/indications for routine commissioning which will receive interim CDF funding; 1 drug/indication added to list B; 1 drug/indication removed from list C |
| 1.186 | 21-Aug-21 | P Clark; S Williamson; D Dwyer | 1 drugs/indications for routine commissioning which will receive interim CDF funding; 1 drug/indication with updated treatment criteria |
| 1.187 | 10-Sep-21 | P Clark; S Williamson; D Dwyer | 2 drugs/indications for routine commissioning which will receive interim CDF funding; 2 drug/indication with updated treatment criteria |
| 1.188 | 17-Sep-21 | P Clark; S Williamson; D Dwyer | 1 drugs/indications for routine commissioning which will receive interim CDF funding; 1 drug/indication added to list B |
| 1.189 | 21-Sep-21 | P Clark; S Williamson; D Dwyer | 1 drugs/indications for routine commissioning which will receive interim CDF funding; 1 drug/indication added to list B; 4 drugs/indications with updated treatment criteria |
| 1.190 | 24-Sep-21 | P Clark; S Williamson; D Dwyer | 1 drug/indication added to list B; 1 drug/indication with updated date moving to routine commissioning |
| 1.191 | 01-Oct-21 | P Clark; S Williamson; D Dwyer | 2 drugs/indications recommended for the CDF; 1 drug/indication with updated treatment criteria |
| 1.192 | 08-Oct-21 | P Clark; S Williamson; D Dwyer | 2 drugs/indications added to list B; 1 drug/indication with an updated title |
| 1.193 | 15-Oct-21 | P Clark; S Williamson; D Dwyer | 1 drugs/indications for routine commissioning which will receive interim CDF funding; 2 drugs/indications with updated treatment criteria |
| 1.194 | 02-Nov-21 | P Clark; S Williamson; D Dwyer | 1 drug/indication added to list D; 1 drug/indication added to list B; 5 drugs/indications with updated date moving to routine commissioning |
| 1.195 | 11-Nov-21 | P Clark; S Williamson; D Dwyer | 2 drugs/indications for routine commissioning which will receive interim CDF funding |
| 1.196 | 17-Nov-21 | P Clark; S Williamson; D Dwyer | 1 drug/indication recommended for the CDF; 1 drug/indication with updated date moving to routine commissioning; 9 drugs/indications with updated treatment criteria |
| 1.197 | 30-Nov-21 | P Clark; S Williamson; D Dwyer | 2 drugs/indications recommended for the CDF; 2 drugs/indications with updated treatment criteria |
| 1.198 | 03-Dec-21 | P Clark; S Williamson; D Dwyer | 5 drugs/indications with updated treatment criteria |
| 1.199 | 16-Dec-21 | P Clark; S Williamson; D Dwyer | 1 drug/indication for routine commissioning which will receive interim CDF funding; 1 drug/indication with updated treatment criteria; 1 drug/indication added to list B; 1 drug/indication with updated date moving to routine commissioning |
| 1.200 | 22-Dec-21 | P Clark; S Williamson; D Dwyer | 1 drug/indication for routine commissioning which will receive interim CDF funding; 8 drugs/indications with updated treatment criteria; 1 drug/indication added to list B |
| 1.201 | 21-Jan-22 | P Clark; S Williamson; D Dwyer | 1 drug/indication for routine commissioning which will receive interim CDF funding; 2 drugs/indications added to list B |
| 1.202 | 26-Jan-22 | P Clark; S Williamson; D Dwyer | 3 drugs/indications added to list B |
| 1.203 | 02-Feb-22 | P Clark; S Williamson; D Dwyer | 1 drug/indication added to list D; 3 drugs/indications with updated date moving to routine commissioning |
| 1.204 | 08-Feb-22 | P Clark; S Williamson; D Dwyer | 1 drug/indication recommended for the CDF; 1 drug/indication removed from list C |
| 1.205 | 25-Feb-22 | P Clark; S Williamson; D Dwyer | 1 drug/indication recommended for the CDF; 1 drug/indication added to list B |
| 1.206 | 03-Mar-22 | P Clark; S Williamson; D Dwyer | 1 drug/indication recommended for the CDF; 2 drugs/indications added to list B |
| 1.207 | 24-Mar-22 | P Clark; S Williamson; D Dwyer | 1 drug/indication recommended for the CDF; 2 drugs/indications added to list B: 10 drugs/indications with updated treatment criteria |
| 1.208 | 01-Apr-22 | P Clark; S Williamson; D Dwyer | 7 drugs/indications removed from list C: 6 drugs/indications with updated treatment criteria |
| 1.209 | 07-Apr-22 | P Clark; S Williamson; D Dwyer | 1 drug/indication for routine commissioning which will receive interim CDF funding; 3 drugs/indications with updated treatment criteria |
| 1.210 | 14-Apr-22 | P Clark; S Williamson; Z Niwaz | 2 drugs/indications for routine commissioning which will receive interim CDF funding; 9 drugs/indications with updated treatment criteria |
| 1.211 | 05-May-22 | P Clark; S Williamson; D Dwyer | 1 drug/indication added to list D; 3 drugs/indications for routine commissioning which will receive interim CDF funding; 6 drugs/indications with updated treatment criteria |
| 1.212 | 17-May-22 | P Clark; S Williamson; D Dwyer | 1 drug/indication added to list B; 3 drugs/indications with updated treatment criteria; 10 drugs/indications with updated date moving to routine commissioning |
| 1.213 | 25-May-22 | P Clark; S Williamson; Z Niwaz | 2 drugs/indications for routine commissioning which will receive interim CDF funding; 2 drugs/indications added to list B; 1 drug/indication with updated treatment criteria |
| 1.214 | 06-Jun-22 | P Clark; S Williamson; Z Niwaz | 6 drugs/indications with updated treatment criteria |
| 1.215 | 17-Jun-22 | P Clark; S Williamson; D Dwyer | 1 drug/indication for routine commissioning which will receive interim CDF funding; 1 drug/indication moved into routine commissioning; 1 drug/indication removed from the CDF; 2 drugs/indications with updated treatment criteria; 2 drugs/indications with updated date moving to routine commissioning |
| 1.216 | 23-Jun-22 | P Clark; S Williamson; Z Niwaz | 1 drug/indication with updated date moving to routine commissioning; 3 drugs/indications moved into routine commissioning; 10 drugs/indications with updated treatment criteria |
| 1.217 | 29-Jun-22 | P Clark; S Williamson; Z Niwaz | 1 drug/indication for routine commissioning which will receive interim CDF funding; 2 drugs/indications with updated date moving to routine commissioning; 1 drug/indication with updated treatment criteria |
| 1.218 | 30-Jun-22 | P Clark; S Williamson; Z Niwaz | 1 drug/indication for routine commissioning which will receive interim CDF funding |
| 1.219 | 07-Jul-22 | P Clark; S Williamson; Z Niwaz | 1 drug/indication for routine commissioning which will receive interim CDF funding |
| 1.220 | 14-Jul-22 | P Clark; S Williamson; Z Niwaz | 3 drugs/indications for routine commissioning which will receive interim CDF funding; 1 drug/indication moved into routine commissioning; 3 drugs/indications with updated indication and treatment criteria |

# National Cancer Drugs Fund (CDF) List

## Version Control(Cont)

| Version No. | Date published | Author(s) | Revision summary |
|---|---|---|---|
| 1.221 | 18-Jul-22 | P Clark; S Williamson; Z Niwaz | 1 drug/indication updated to reflect the date supply became available and treatment criteria added; 1 drug/indication with updated treatment criteria |
| 1.222 | 20-Jul-22 | P Clark; S Williamson; Z Niwaz | 4 drugs/indications moved into routine commissioning; 1 drug/indication with updated date moving to routine commissioning; 2 drugs/indications with updated treatment criteria |
| 1.223 | 26-Jul-22 | P Clark; S Williamson; Z Niwaz | 2 drugs/indications moved into routine commissioning |
| 1.224 | 03-Aug-22 | P Clark; S Williamson; Z Niwaz | 1 drug/indication with updated date moving to routine commissioning |
| 1.225 | 10-Aug-22 | P Clark; S Williamson; Z Niwaz | 2 drugs/indications with updated date moving to routine commissioning; 1 drug/indication with updated treatment criteria: changes made to section C and front page |
| 1.226 | 18-Aug-22 | P Clark; S Williamson; Z Niwaz | 1 drug/indication for routine commissioning which will receive interim CDF funding; 1 drug/indication with updated date moving to routine commissioning; 1 drug/indication with updated treatment criteria |
| 1.227 | 23-Aug-22 | P Clark; S Williamson; Z Niwaz | 1 drug/indication recommended for the CDF, removed from list D, with updated treatment criteria |
| 1.228 | 02-Sep-22 | P Clark; S Williamson; Z Niwaz | 1 drug/indication for routine commissioning which will receive interim CDF funding; 1 drug/indication moved into routine commissioning; 1 drug/indication with updated date moving to routine commissioning |
| 1.229 | 07-Sep-22 | P Clark; S Williamson; Z Niwaz | 1 drug/indication updated to reflect availability |
| 1.230 | 16-Sep-22 | P Clark; S Williamson; Z Niwaz | 1 drug/indication for routine commissioning which will receive interim CDF funding; 1 drug/indication moved into routine commissioning; 10 drugs/indications with updated treatment criteria |
| 1.231 | 23-Sep-22 | P Clark; S Williamson; D Dwyer | 1 drug/indication for routine commissioning which will receive interim CDF funding; 1 drug/indication with updated treatment criteria; 1 drug/indication moved into routine commissioning |
| 1.232 | 07-Oct-22 | P Clark; S Williamson; Z Niwaz | 2 drugs/indications moved into routine commissioning; 1 drug/indication with updated date moving to routine commissioning; 1 drug/indication with updated treatment criteria |
| 1.233 | 11-Oct-22 | P Clark; S Williamson; Z Niwaz | 1 drug/indication for routine commissioning which will receive interim CDF funding |
| 1.234 | 13-Oct-22 | P Clark; S Williamson; Z Niwaz | 1 drug/indication updated to reflect the date supply became available |
| 1.235 | 19-Oct-22 | P Clark; S Williamson; Z Niwaz | 2 drugs/indications moved into routine commissioning; 2 drugs/indications with updated date moving to routine commissioning; 3 drugs/indications removed from list C; 13 drugs/indications assigned with Blueteq Form references |
| 1.236 | 26-Oct-22 | P Clark; S Williamson; Z Niwaz | 2 drugs/indications with updated date moving to routine commissioning |
| 1.237 | 08-Nov-22 | P Clark; S Williamson; Z Niwaz | 1 drug/indication for routine commissioning which will receive interim CDF funding; 2 drugs/indications moved into routine commissioning |
| 1.238 | 10-Nov-22 | P Clark; S Williamson; Z Niwaz | 2 drugs/indications for routine commissioning which will receive interim CDF funding; 2 drugs/indications with updated treatment criteria; 1 drug/indication with updated indication and treatment criteria |
| 1.239 | 16-Nov-22 | P Clark; S Williamson; Z Niwaz | 1 drug/indication recommended for the CDF, removed from list D, with updated treatment criteria; 1 drug/indication moved into routine commissioning |
| 1.240 | 24-Nov-22 | P Clark; S Williamson; Z Niwaz | 1 drug/indication for routine commissioning which will receive interim CDF funding |
| 1.241 | 25-Nov-22 | P Clark; S Williamson; Z Niwaz | 1 drug/indication added to list D |
| 1.242 | 14-Dec-22 | P Clark; S Williamson; Z Niwaz | 3 drugs/indications with updated date moving to routine commissioning |
| 1.243 | 20-Dec-22 | P Clark; S Williamson; Z Niwaz | 1 drug/indication recommended for the CDF; 1 drug/indication with updated indication and treatment criteria |
| 1.244 | 22-Dec-22 | P Clark; S Williamson; Z Niwaz | 1 drug/indication for routine commissioning which will receive interim CDF funding; 1 drug/indication assigned with a Blueteq Form reference; 1 drug/indication with updated indication; 2 drugs/indications with updated treatment criteria |
| 1.245 | 04-Jan-23 | P Clark; S Williamson; Z Niwaz | 1 drug/indication with updated date moving to routine commissioning |
| 1.246 | 12-Jan-23 | P Clark; S Williamson; Z Niwaz | 2 drugs/indications with updated date moving to routine commissioning |
| 1.247 | 18-Jan-23 | P Clark; S Williamson; Z Niwaz | 2 drugs/indications moved into routine commissioning; 1 drug/indication for routine commissioning which will receive interim CDF funding; 1 drug/indication with updated treatment criteria |
| 1.248 | 25-Jan-23 | P Clark; S Williamson; Z Niwaz | 1 drug/indication for routine commissioning which will receive interim CDF funding; 2 drugs/indications moved into routine commissioning; 2 drugs/indications with updated treatment criteria; 1 drug/indication with updated Blueteq Form reference |
| 1.249 | 26-Jan-23 | P Clark; S Williamson; Z Niwaz | 1 drug/indication for routine commissioning which will receive interim CDF funding; 1 drug/indication with updated treatment criteria |
| 1.250 | 09-Feb-23 | P Clark; S Williamson; Z Niwaz | 1 drug/indication with updated CDF managed access status; 2 drugs/indications with updated date moving to routine commissioning |
| 1.251 | 22-Feb-23 | P Clark; S Williamson; Z Niwaz | 1 drug/indication for routine commissioning which will receive interim CDF funding;1 drug/indication with updated CDF managed access status; 1 drug/indication with updated date moving to routine commissioning; 1 drug/indication with updated treatment criteria |
| 1.252 | 01-Mar-23 | P Clark; S Williamson; Z Niwaz | 2 drugs/indications with updated date moving to routine commissioning ; 2 drugs/indications with updated treatment criteria |
| 1.253 | 09-Mar-23 | P Clark; S Williamson; Z Niwaz | 2 drugs/indications added to routine commissioning; 20 drugs/indications with updated treatment criteria |
| 1.254 | 14-Mar-23 | P Clark; S Williamson; Z Niwaz | 3 drugs/indications moved into routine commissioning; 6 drugs/indications with updated treatment criteria |
| 1.255 | 22-Mar-23 | P Clark; S Williamson; Z Niwaz | 1 drug/indication with updated date moving to routine commissioning |
| 1.256 | 29-Mar-23 | P Clark; S Williamson; Z Niwaz | 1 drug/indication recommended for the CDF |
| 1.257 | 31-Mar-23 | P Clark; S Williamson; Z Niwaz | 4 drugs/indications removed from list C; 2 drugs/indications with updated treatment criteria |
| 1.258 | 06-Apr-23 | P Clark; S Williamson; Z Niwaz | 2 drugs/indications for routine commissioning which will receive interim CDF funding; 1 drug/indication moved into routine commissioning |
| 1.259 | 11-Apr-23 | P Clark; S Williamson; Z Niwaz | 2 drugs/indications moved into routine commissioning; 2 drugs/indications (4 forms) with updated treatment criteria |
| 1.260 | 21-Apr-23 | P Clark; S Williamson; Z Niwaz | 1 drug/indication for routine commissioning which will receive interim CDF funding; 1 drug/indication (2 forms) with updated treatment criteria |
| 1.261 | 24-Apr-23 | P Clark; S Williamson; Z Niwaz | 1 drug/indication for routine commissioning which will receive interim CDF funding; 1 drug/indication with updated indication and treatment criteria |
| 1.262 | 27-Apr-23 | P Clark; S Williamson; J Hill | 2 drugs/indications recommended for the CDF; 1 drug/indication (2 forms) with updated drug name and treatment criteria |
| 1.263 | 04-May-23 | P Clark; S Williamson; J Hill | 1 drug/indication with updated Blueteq form reference; 6 drugs/indications with updated drug column; 6 drugs/indications with updated treatment criteria |
| 1.264 | 11-May-23 | P Clark; S Williamson; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding, removed from list C; 2 drugs/indications moved into routine commissioning, with updated treatment criteria; 2 drugs/indications (4 forms) with updated date moving to routine commissioning |
| 1.265 | 18-May-23 | P Clark; S Williamson; J Hill | 2 drugs/indications for routine commissioning which will receive interim CDF funding; 1 drug/indication with updated treatment criteria |
| 1.266 | 02-Jun-23 | P Clark; R Nijjar; J Hill | 3 drugs/indications moved into routine commissioning; 1 drug/indication with updated date moving to routine commissioning; 2 drugs/indications with updated treatment criteria; 2 drugs/indications with updated Blueteq form reference; 1 drug/indication with updated drug column |
| 1.267 | 08-Jun-23 | R Nijjar; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding; 8 drugs/indications with updated Blueteq form reference |
| 1.268 | 14-Jun-23 | P Clark; S Williamson; J Hill | 1 drug/indication with updated date moving to routine commissioning |
| 1.269 | 22-Jun-23 | P Clark; S Williamson; Z Niwaz | 1 drug/indication recommended for the CDF; 1 drug/indication moved into routine commissioning; 2 drugs/indications with updated date moving to routine commissioning |
| 1.270 | 31-Jul-23 | P Clark; S Williamson; J Hill | 2 drugs/indications with updated treatment criteria |
| 1.271 | 08-Aug-23 | P Clark; S Williamson; J Hill | 2 drugs/indications (4 forms) moved into routine commissioning; 1 drug/indication with updated treatment criteria; 1 drug/indication with updated TA number, Date of final NICE guidance, Date baseline funding started |
| 1.272 | 17-Aug-23 | P Clark; S Williamson; J Hill | 1 drug/indication (5 forms) for routine commissioning which will receive interim CDF funding; 1 drug/indication removed from list C |
| 1.273 | 24-Aug-23 | P Clark; S Williamson; J Hill | 2 drugs/indications with updated treatment criteria |
| 1.274 | 07-Sep-23 | P Clark; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding; 2 drugs/indications moved into routine commissioning; 2 drugs/indications with updated Previous CDF drug/ indication column |
| 1.275 | 12-Sep-23 | P Clark; J Hill | 1 drugs/indications moved into routine commissioning |
| 1.276 | 14-Sep-23 | P Clark; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding |
| 1.277 | 22-Sep-23 | P Clark; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding; 2 drug/indications moved into routine commissioning; 11 drugs/indications with updated treatment criteria; 5 drugs/indications with updated date moving to routine commissioning |
| 1.278 | 19-Oct-23 | P Clark; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding; 1 drug/indication moved into routine commissioning; 2 drugs/indications with updated date moving to routine commissioning; 9 drugs/indications with updated treatment criteria; 1 drug/indication with updated 'Expected Entry into Baseline Commissioning' status |
| 1.279 | 01-Nov-23 | P Clark; J Hill | 1 drug/indication updated to reflect the date supply became available and treatment criteria added; 1 drug/indication with updated date moving to routine commissioning |
| 1.280 | 17-Nov-23 | P Clark; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding with updated treatment criteria; 1 drug/indication moved into routine commissioning; 1 drug/indication added to list B |
| 1.281 | 23-Nov-23 | P Clark; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding; 1 drug/indication (3 forms) with updated date moving to routine commissioning |
| 1.282 | 30-Nov-23 | P Clark; J Hill | 1 drug/indication removed from the CDF; 1 drug/indication added to list B; 1 drug/indication removed from list C; 8 drugs/indications with updated treatment criteria |
| 1.283 | 08-Dec-23 | P Clark; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding; 2 drugs/indications added to list B; 1 drug/indication with updated treatment criteria |

# National Cancer Drugs Fund (CDF) List

## Version Control(Cont)

| Version No. | Date published | Author(s) | Revision summary |
|---|---|---|---|
| 1.284 | 14-Dec-23 | P Clark; J Hill | 2 drugs/indications for routine commissioning which will receive interim CDF funding; 1 drug/indication with updated date moving to routine commissioning |
| 1.285 | 21-Dec-23 | P Clark; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding; 1 drug/indication (5 forms) moved into routine commissioning |
| 1.286 | 09-Jan-24 | P Clark; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding |
| 1.287 | 19-Jan-24 | P Clark; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding; 1 drug/indication moved into routine commissioning; 2 drugs/indications with updated date moving to routine commissioning; 1 drug/indication with updated treatment criteria |
| 1.288 | 26-Jan-24 | R Chauhan; J Hill | 1 drug/indication moved into routine commissioning |
| 1.289 | 01-Feb-24 | P Clark; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding, 2 drugs/indications with updated date moving to routine commissioning, 2 drugs/indications with updated treatment criteria |
| 1.290 | 02-Feb-24 | P Clark; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding |
| 1.291 | 08-Feb-24 | P Clark; J Hill | 2 drugs/indications with updated date moving to routine commissioning; 1 drug/indication withdrawn market authorisation notice |
| 1.292 | 15-Feb-24 | P Clark; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding; 1 drug/indication with updated treatment criteria |
| 1.293 | 20-Feb-24 | P Clark; J Hill | 1 drug/indication updated to reflect the date supply became available and treatment criteria added; 1 drug/indication (3 forms) moved into routine commissioning |
| 1.294 | 28-Feb-24 | P Clark; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding; 1 drug/indication with updated treatment criteria (2 forms); 1 drug/indication with updated date moving to routine commissioning |
| 1.295 | 05-Mar-24 | P Clark; Z Niwaz | 1 drug/indication recommended for the CDF; 1 drug/indication with updated treatment criteria |
| 1.296 | 07-Mar-24 | P Clark; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding; 1 drug/indication removed from list B |
| 1.297 | 13-Mar-24 | P Clark; J Hill | 1 drug/indication updated to reflect the date supply became available and treatment criteria added; 1 drug/indication moved into routine commissioning; 1 drug/indication with updated date moving to routine commissioning |
| 1.298 | 21-Mar-24 | P Clark; J Hill | 2 drugs/indications for routine commissioning which will receive interim CDF funding and with updated treatment criteria; 1 drug/indication with updated date moving to routine commissioning |
| 1.299 | 28-Mar-24 | P Clark; J Hill | 2 drugs/indications with updated date moving to routine commissioning (3 forms) |
| 1.300 | 09-Apr-24 | P Clark; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding; 1 drug/indication moved into routine commissioning |
| 1.301 | 11-Apr-24 | P Clark; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding and with updated treatment criteria (2 forms); 1 drug/indication with updated date moving to routine commissioning |
| 1.302 | 17-Apr-24 | P Clark; J Hill | 1 drug/indication moved into routine commissioning; 1 continuation form for 1 drug/indication removed from the CDF |
| 1.303 | 22-Apr-24 | P Clark; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding |
| 1.304 | 24-Apr-24 | P Clark; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding |
| 1.305 | 02-May-24 | P Clark; J Richardson; J Hill | 2 drugs/indications moved into routine commissioning; 1 drug/indication with updated date moving to routine commissioning (2 forms) |
| 1.306 | 10-May-24 | P Clark; J Richardson; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding; 1 drug/indication added to list B; 2 drugs/indications moved into routine commissioning; 2 drugs/indications with updated treatment criteria; 1 drug/indication with updated date moving to routine commissioning |
| 1.307 | 17-May-24 | P Clark; J Richardson; J Hill | 2 drugs/indications with updated date moving to routine commissioning (3 forms) |
| 1.308 | 21-May-24 | P Clark; J Richardson; J Hill | 1 drug/indication moved into routine commissioning; 15 drugs/indications formatting issues fixed |
| 1.309 | 31-May-24 | P Clark; J Richardson; J Hill | 5 drugs/indications with updated treatment criteria; 1 drug/indication with updated date moving to routine commissioning |
| 1.310 | 07-Jun-24 | P Clark; J Richardson; J Hill | 1 drug/indication moved into routine commissioning; 1 drug/indication with updated note in NICE approved indication column |
| 1.311 | 13-Jun-24 | P Clark; J Richardson; J Hill | 1 drug/indication updated to reflect the date supply became available and treatment criteria added; 1 drug/indication with updated note in NICE approved indication column |
| 1.312 | 21-Jun-24 | P Clark; J Richardson; J Hill | 1 drug/indication recommended for the CDF; 1 drug/indication moved into routine commissioning |
| 1.313 | 28-Jun-24 | P Clark; J Richardson; J Hill | 2 drugs/indications moved into routine commissioning (3 forms); 1 drug/indication with updated treatment criteria |
| 1.314 | 08-Jul-24 | P Clark; J Richardson; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding |
| 1.315 | 16-Jul-24 | P Clark; J Richardson; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding; 1 drug/indication moved into routine commissioning;1 drug/indication with updated treatment criterion |
| 1.316 | 26-Jul-24 | P Clark; J Richardson; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding; 5 drugs/indications with updated treatment criterion |
| 1.317 | 01-Aug-24 | P Clark; J Richardson; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding; 1 drug/indication moved into routine commissioning (2 forms) |
| 1.318 | 09-Aug-24 | P Clark; J Richardson; J Hill | 3 drugs/indications with updated treatment criterion |
| 1.319 | 20-Aug-24 | P Clark; J Richardson; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding; 3 drugs/indications (5 forms) moved into routine commissioning; 7 drugs/indications with updated treatment criterion |
| 1.320 | 23-Aug-24 | P Clark; J Richardson; J Hill | 1 drug/indication (2 forms) for routine commissioning which will receive interim CDF funding |
| 1.321 | 28-Aug-24 | P Clark; J Richardson; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding; 1 drug/indication moved into routine commissioning; 11 drugs/indications with updated/added treatment criteria; 10 drugs/indications with updated indication column |
| 1.322 | 05-Sep-24 | P Clark; J Richardson; Z Niwaz | 1 drug/indication (2 forms) recommended for the CDF; 1 drug/indication (2 forms) for routine commissioning which will receive interim CDF funding; 2 drugs/indications with updated date moving to routine commissioning; 2 drugs/indications with updated indication column; 4 drugs/indications with updated/added treatment criteria |
| 1.323 | 13-Sep-24 | P Clark; J Richardson; J Hill | 1 drug/indication moved into routine commissioning; 1 drug/indication with updated date moving to routine commissioning; 1 drug/indication with updated treatment criterion |
| 1.324 | 20-Sep-24 | P Clark; J Richardson; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding; 1 drug/indication (2 forms) with updated date moving to routine commissioning; 3 drugs/indications with updated indication column; 4 drugs/indications with updated/added treatment criteria |
| 1.325 | 27-Sep-24 | P Clark; J Richardson; J Hill | 1 drug/indication (2 forms) for routine commissioning which will receive interim CDF funding, 1 drug/indication with updated date moving to routine commissioning; 3 drugs/indications with updated treatment criterion |
| 1.326 | 04-Oct-24 | P Clark; J Richardson; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding, 1 drug/indication with updated treatment criteria |
| 1.327 | 10-Oct-24 | P Clark; J Richardson; J Hill | 1 drug/indication with updated date moving to routine commissioning; 1 drug/indication with updated indication column; 2 drugs/indications with updated treatment criteria |
| 1.328 | 16-Oct-24 | P Clark; J Richardson; J Hill | 2 drugs/indications for routine commissioning which will receive interim CDF funding; 1 drug/indication with updated indication column; 4 drugs/indications with updated treatment criteria |
| 1.329 | 18-Oct-24 | P Clark; J Richardson; J Hill | 1 drug/indication (2 forms) moved into routine commissioning; 2 drugs/indications with updated treatment criteria; 1 drug/indication with updated date moving to routine commissioning |
| 1.330 | 24-Oct-24 | P Clark; J Richardson; J Hill | 2 drugs/1 indication (4 forms) added to list b; 1 drug/indication with updated treatment criteria |
| 1.331 | 07-Nov-24 | P Clark; J Richardson; J Hill | 1 drug/indication with updated treatment criterion ; 3 drugs/indications with updated date moving to routine commissioning |
| 1.332 | 14-Nov-24 | P Clark; J Richardson; J Hill | 3 drugs/indications with updated treatment criterion; 2 drugs/indications with updated date moving to routine commissioning |
| 1.333 | 21-Nov-24 | P Clark; J Richardson; J Hill | 1 drug/indication (2 forms) with updated treatment criterion; 2 drugs/indications with updated date moving to routine commissioning |
| 1.334 | 29-Nov-24 | P Clark; J Richardson; J Hill | 1 drug/indication moved into routine commissioning; 2 drugs/indications with updated treatment criteria |
| 1.335 | 04-Dec-24 | P Clark; J Richardson; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding; 1 drug/indication moved into routine commissioning; 1 drug/indication with updated date moving to routine commissioning |
| 1.336 | 06-Dec-24 | P Clark; J Richardson; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding; 3 drugs/indications with updated treatment criterion |
| 1.337 | 12-Dec-24 | P Clark; J Richardson; J Hill | 1 drug/indication moved into routine commissiong - see entry for more information |
| 1.338 | 13-Dec-24 | P Clark; J Richardson; J Hill | 1 drug/indication added to list b |
| 1.339 | 19-Dec-24 | P Clark; J Richardson; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding; 1 drug/indication with updated title and treatment criterion; 2 drugs/indications with updated treatment criterion; 1 drug/indication (2 forms) with updated date moving to routine commissioning |
| 1.340 | 20-Dec-24 | P Clark; J Richardson; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding |
| 1.341 | 03-Jan-25 | P Clark; J Richardson; J Hill | 2 drugs/indications moved into routine commissiong; 5 drugs/indications with updated treatment criterion |
| 1.342 | 09-Jan-25 | P Clark; J Richardson; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding; 1 drug/indication with updated treatment criterion |
| 1.343 | 20-Jan-25 | P Clark; J Richardson; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding |
| 1.344 | 24-Jan-25 | P Clark; J Richardson; J Hill | 1 drug/indication with updated treatment criterion |
| 1.345 | 04-Feb-25 | P Clark; J Richardson; J Hill | 1 drug/indication moved into routine commissiong; 3 drugs/indications with updated treatment criterion |
| 1.346 | 07-Feb-25 | P Clark; J Richardson; J Hill | 1 drug/indication with updated treatment criterion; 3 drugs/indications with updated date moving to routine commissioning |
| 1.347 | 14-Feb-25 | P Clark; J Richardson; J Hill | 2 drugs/indications moved into routine commissiong; 2 drugs/indications (4 forms) with updated date moving to routine commissioning |
| 1.348 | 19-Feb-25 | P Clark; J Richardson; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding; 2 drugs/indications moved into routine commissiong; 1 drug/indication with updated treatment criterion; 2 drugs/indications with updated date moving to routine commissioning |
| 1.349 | 20-Feb-25 | P Clark; J Richardson; J Hill | 1 drug/indication (2 forms) for routine commissioning which will receive interim CDF funding; 2 drugs/indications with updated treatment criterion |
| 1.350 | 21-Feb-25 | P Clark; J Richardson; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding - see web list for more information |
| 1.351 | 26-Feb-25 | P Clark; J Richardson; J Hill | 1 drug/indication with updated date moving to routine commissioning ; 1 drug/indication with updated available to new patients column updated |
| 1.352 | 03-Mar-25 | P Clark; J Richardson; J Hill | 1 drug/indication with treatment criteria added; 1 drug/indication with updated treatment criterion |
| 1.353 | 07-Mar-25 | P Clark; J Richardson; J Hill | 1 drug/indication (2 forms) added to list b; 2 drugs/indications with updated treatment criteria |
| 1.354 | 14-Mar-25 | P Clark; J Richardson; J Hill | 1 drug/indication moved into routine commissiong; 1 drug/indication with updated treatment criterion; 1 drug/indication with updated date moving to routine commissioning |
| 1.355 | 20-Mar-25 | P Clark; J Richardson; J Hill | 1 drug/indication moved into routine commissiong; 1 drug/indication with updated treatment criterion; 1 drug/indication with updated date moving to routine commissioning |

# National Cancer Drugs Fund (CDF) List

## Version Control(Cont)

| Version No. | Date published | Author(s) | Revision summary |
|---|---|---|---|
| 1.356 | 26-Mar-25 | P Clark; J Richardson; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding; 2 drug/indications (3 forms) with updated date moving to routine commissioning |
| 1.357 | 02-Apr-25 | P Clark; J Richardson; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding; 2 drugs/indications with updated treatment criteria |
| 1.358 | 10-Apr-25 | P Clark; J Richardson; J Hill | 2 drugs/indications for routine commissioning which will receive interim CDF funding; 2 drugs/indications with updated treatment criterion |
| 1.359 | 11-Apr-25 | P Clark; J Richardson; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding |
| 1.360 | 25-Apr-25 | P Clark; J Richardson; J Hill | 2 drugs/indications for routine commissioning which will receive interim CDF funding; 2 drugs/indications moved into routine commissiong; 2 drugs/indications with updated treatment criteria |
| 1.361 | 02-May-25 | P Clark; J Richardson; J Hill | 8 drugs/indications with updated treatment criteria |
| 1.362 | 09-May-25 | P Clark; J Richardson; J Hill | 2 drugs/indications moved into routine commissiong; 2 drug/indications with updated date moving to routine commissioning |
| 1.363 | 16-May-25 | P Clark; J Richardson; J Hill | 2 drugs/indications (4 forms) moved into routine commissiong; 5 drugs/indications with updated treatment criteria; 1 drug/indication with updated title; 1 drug/indication with updated date moving to routine commissioning |
| 1.364 | 23-May-25 | P Clark; J Richardson; J Hill | 1 drug/indication moved into routine commissiong; 6 drugs/indications with updated treatment criteria; 1 drug/indication with updated TA column |
| 1.365 | 06-Jun-25 | P Clark; J Richardson; J Hill | 1 drug/indication moved into routine commissiong; 8 drugs/indications with updated treatment criteria; 1 drug/indication with updated date moving to routine commissioning |
| 1.366 | 12-Jun-25 | P Clark; J Richardson; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding |
| 1.367 | 27-Jun-25 | P Clark; J Richardson; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding; 1 drug/indication for routine commissioning which moved directly into section B; 2 drugs/indications moved into routine commissiong; 11 drugs/indications with updated treatment criteria; 1 drug/indication with updated date moving to routine commissioning |
| 1.368 | 03-Jul-25 | P Clark; J Richardson; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding; 2 drugs/indications with updated treatment criteria; 1 drug/indication with updated date moving to routine commissioning |
| 1.369 | 25-Jul-25 | J Richardson; J Hill | 2 drugs/indications (3 forms) moved into routine commissioning; 2 drugs/indications with updated treatment criteria; 3 drugs/indications with updated date moving to routine commissioning |
| 1.370 | 29-Jul-25 | J Richardson; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding; 1 drug/indication with updated treatment criteria |
| 1.371 | 06-Aug-25 | J Richardson; R Chauhan; J Hill | 1 drug/indication (2 forms) for routine commissioning which will receive interim CDF funding; 2 drugs/indications moved into routine commissioning |
| 1.372 | 21-Aug-25 | J Richardson; R Chauhan; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding; 2 drugs/indications moved into routine commissiong; 1 drug/indication with updated treatment criterion |
| 1.373 | 04-Sep-25 | J Richardson; R Chauhan; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding; 2 drugs/indications moved into routine commissiong; 1 drug/indication (2 forms) with updated date moving to routine commissioning |
| 1.374 | 16-Sep-25 | J Richardson; J Hill | 1 drug/indication with updated date moving to routine commissioning |
| 1.375 | 07-Oct-25 | J Richardson; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding; 1 drug/indication (4 forms) removed from CDF weblist, 1 drug/indication with updated treatment criterion; 4 drugs/indications with updated treatment criteria |
| 1.376 | 24-Oct-25 | J Richardson; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding; 6 drugs/indications with updated treatment criteria; 1 drug/indication moved into routine commissiong; 1 drug/indication with updated date moving to routine commissioning |
| 1.377 | 13-Nov-25 | S O'Brien; J Richardson; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding; 12 drugs/indications with updated treatment criteria; 1 drug/indication moved into routine commissiong; 1 drug/indication with updated date moving to routine commissioning |
| 1.378 | 18-Nov-25 | S O'Brien; J Richardson; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding; 1 drug/indication moved into routine commissiong |
| 1.379 | 26-Nov-25 | S O'Brien; R Hudson; Z Niwaz | 2 drugs/indications for routine commissioning which will receive interim CDF funding; 1 drug/indication (2 forms) moved into routine commissiong |
| 1.380 | 18-Dec-25 | R Plummer; R Chauhan; Z Niwaz; J Hill | 2 drugs/indications for routine commissioning which will receive interim CDF funding; 2 drugs/indications moved into routine commissiong; 3 drugs/indications with updated date moving to routine commissioning; 6 drugs/indications with updated treatment criteria |
| 1.381 | 24-Dec-25 | J Richardson; R Hudson; Z Niwaz; J Hill | 1 drug/indication (2 forms) for routine commissioning; 1 drug/indication moved into routine commissiong; 9 drugs/indications with updated treatment criteria |
| 1.382 | 08-Jan-26 | J Richardson; R Chauhan; Z Niwaz | 1 initiation form for 1 drug/indication removed from the CDF; 1 drug/indication with updated indication; 2 drugs/indications with updated treatment criteria; 1 drug/indication with updated CDF managed access status; 1 drug/indication with updated date moving to routine commissioning |
| 1.383 | 20-Jan-26 | J Richardson; R Hudson; Z Niwaz; J Hill | 1 drug/indication for routine commissioning which will receive interim CDF funding; 1 drug/indication for routine commissiong; 6 drugs/indications with updated treatment criteria; 1 drug/indication with updated TA column, date of final guidance and date baseline funding started |
| 1.384 | 23-Jan-26 | R Chauhan; Z Niwaz | 2 drugs/indications for routine commissioning which will receive interim CDF funding; 1 drug/indication with updated date moving to routine commissioning; 2 drugs/indications with updated treatment criteria |
| 1.385 | 26-Jan-26 | R Hudson; Z Niwaz | 1 drug/indication for routine commissioning which will receive interim CDF funding; 3 drugs/indications with updated treatment criteria |
| 1.386 | 11-Feb-26 | R Hudson; Z Niwaz | 1 drug/indication for routine commissioning which will receive interim CDF funding; 3 drugs/indications moved into routine commissiong; 4 drugs/indications with updated treatment criteria; 1 drug/indication with corrected spelling of drug name |
| 1.387 | 23-Feb-26 | J Richardson; R Hudson; Z Niwaz | 1 drug/indication for routine commissioning which will receive interim CDF funding; 10 drugs/indications with updated treatment criteria |
| 1.388 | 09-Mar-26 | R Chauhan; Z Niwaz | 3 drugs/indications moved into routine commissiong; 1 drug/indication with updated date moving to routine commissioning; 1 drug/indication (2 forms) with updated TA number and Date of final guidance; 4 drugs/indications with updated treatment criteria |
| 1.389 | 20-Mar-26 | J Richardson; J Hill | Correction of 1 drug/indication 'Nice Approved Indication' |
| 1.390 | 24-Mar-26 | R Hudson; Z Niwaz | 1 drug/indication for routine commissioning which will receive interim CDF funding; 5 drugs/indications (7 forms) moved into routine commissiong; 1 drug/indication with updated date moving to routine commissioning; 2 drugs/indications with updated treatment criteria; 1 drug/indication with updated drug column |
| 1.391 | 26-Mar-26 | J Richardson; Z Niwaz | Correction of 1 drug/indication 'Available to new patients' |

# National Cancer Drugs Fund (CDF) List

## Changes to recent versions

| General or criteria changed | Summary of changes |
|---|---|
| **Changes to version 1.391** | |
| PEMB34 | Correction of 'Available to new patients' |
| **Changes to version 1.390** | |
| PEMB34 | Recommended for routine commissioning, receiving CDF interim funding |
| BELA2 | Moved into routine commissioning - section B of list |
| DOS3 | Moved into routine commissioning - section B of list |
| NIR3<br>NIR4 | Moved into routine commissioning - section B of list |
| OBE01a<br>OBE01b | Moved into routine commissioning - section B of list |
| TAL2 | Moved into routine commissioning - section B of list |
| EPC2 | Date moving into routine commissioning updated |
| LNV1 | Treatment criterion (#10 and 11) updated; Treatment criteria (#10) removed |
| TRA2 | Drug column updated; Treatment criterion (#5 and 10) updated; Treatment criterion (#7 and 11) removed |
| **Changes to version 1.389** | |
| NIV25 | Correction of Nice Approved Indication |
| **Changes to version 1.388** | |
| GLO2 | Moved into routine commissioning - section B of list |
| TALQ1 | Moved into routine commissioning - section B of list |
| NIV25 | Moved into routine commissioning - section B of list; Treatment criteria (#9) updated |
| DUR8 | Date moving into routine commissioning updated |
| BEV11<br>BEV12 | 'TA' and 'Date of Final NICE Guidance' columns updated |
| NIV25 | Treatment criteria (#9) updated |
| PEMB9a | Treatment criteria (#9) updated |
| PEMB15 | Treatment criterion (#9, 10 and 12) updated; Treatment criterion (#2 and 13) removed |
| PEMB23 | Treatment criterion (#8, 9, 10, 11, 13 and 15) updated; Treatment criterion (#2, 10 and 17) removed |
| **Changes to version 1.387** | |
| EPC2 | Recommended for routine commissioning, receiving CDF interim funding |
| CAR2 | Treatment criterion (#6 and 13) updated; Treatment criteria (#13) removed |
| PEMB7 | Treatment criteria (#10) updated; Treatment criterion (#2 and 11) removed |
| PEMB8 | Treatment criteria (#13) updated; Treatment criterion (#2 and 14) removed |
| PEMB12 | Treatment criterion (#6, 7 and 10) updated; Treatment criteria (#2) removed |
| PEMB14 | Treatment criterion (#10 and 12) updated; Treatment criterion (#2, 13 and 15) removed |
| PEMB19 | Treatment criterion (#8, 10 and 11) updated; Treatment criterion (#2, 11 and 13) removed |
| PEMB20 | Treatment criteria (#10) updated; Treatment criterion (#2 and 11) removed |
| PEMB21 | Treatment criterion (#10, 13, 15 and 17) updated; Treatment criterion (#2 and 18) removed |
| PEMB22 | Treatment criterion (#10, 11, 15 and 16) updated; Treatment criterion (#2 and 16) removed |
| PEMB30 | Treatment criteria (#9) updated |
| **Changes to version 1.386** | |
| DUR8 | Recommended for routine commissioning, receiving CDF interim funding |
| AVE3 | Moved into routine commissioning - section B of list |
| DUR7 | Moved into routine commissioning - section B of list |
| LOR2 | Moved into routine commissioning - section B of list |
| NIV25 | Date moving into routine commissioning updated |
| ABI4 | Treatment criterion (#6) updated |
| BEV11 | Treatment criterion (#4) updated |
| NIV9 | Treatment criterion (#8) updated |
| POM1 | Treatment criterion (#6) updated |
| BELA1 | Spelling of drug name corrected to Belantamab mafodotin |
| BELA2 | Spelling of drug name corrected to Belantamab mafodotin |
| **Changes to version 1.385** | |
| NIR3<br>NIR4 | Recommended for routine commissioning, receiving CDF interim funding - column N updated |
| APA2 | Treatment criterion (#8) updated |
| DARO3 | Treatment criterion (#8) updated |
| ENZ3 | Treatment criterion (#7) updated |
| **Changes to version 1.384** | |
| BELA2 | Recommended for routine commissioning, receiving CDF interim funding |
| TAL2 | Recommended for routine commissioning, receiving CDF interim funding |
| AMI1 | Date moving into routine commissioning updated |
| BELA1 | Treatment criterion (#4 and 7) updated; Treatment criteria (#18) removed |
| OLAP9 | Treatment criterion (#5, 6 and 10) updated; Treatment criteria (#3 and 11) removed |
| **Changes to version 1.383** | |
| NIV25 | Recommended for routine commissioning, receiving CDF interim funding |
| ABI5 | Recommended for routine commissioning - straight into section B of the list |
| AVE4 | Treatment criteria (#2, 4 and 11) updated; 'TA' column updated, 'Date of NICE Final Guidance' column updated; 'Date Baseline Funding started' column updated |
| BEV10 | Treatment criteria (#2, 4 and 6) updated |
| OLAP6 | Treatment criterion (#7) updated |
| PEMB10 | Treatment criteria (#2, 7 and 12) updated |
| DUR3 | Treatment criterion (#5 and 14) updated; Treatment criteria (#2, 6 and 16) removed |
| PEMB30 | Treatment criterion (#5 and 14) updated; Treatment criteria (#2, 6, 8 and 17) removed |