National Innovative Medicines Fund List

(Including live list of indications funded via the Innovative Medicines Fund with their commissioning criteria for use)

v1.6

20-Dec-24

National Innovative Medicines Fund (IMF) List

A. National IMF List

Notes: This list should be read in conjunction with all other available information found at: https://www.england.nhs.uk/medicines-2/innovative-medicines-fund/

Blueteq Form ref:	Drug	Indication	Criteria for use	Available to new patients		Eligible for Interim Funding	Interim Funding agreed by manufacturer	IMF Managed Access Scheme	Expected Entry into Baseline Commissioning (if known)
				Yes	Yes (but notice of removal served)				
ETR1a_v1.0	**Etranacogene dezaparvovec**	Initial Funding Application for treating moderately severe or severe haemophilia B (TA989) where the following criteria have been met:	1. The prescribing clinician confirms the patient is aged 18 years or older. 2. The prescribing clinician confirms the patient has moderately severe or severe haemophilia B 3. The prescribing clinician confirms the patient has a demonstrated absence of Factor IX inhibitors and no previous history of Factor IX inhibitors. 4. The prescribing clinician confirms a pre-existing neutralising antibody titre has been performed and that the patient does not have neutralising anti-AAV5 antibodies above a titre of 1:678 (7-point assay) or 1:898 (9-point assay). 5. The prescribing clinician confirms the patient's baseline hepatic function has been assessed. 6. The prescribing clinician confirms compliance with UKHCDO guideline, in particular the approval and pathway process and that treatment will be delivered by a commissioned haemophilia ATMP treatment hub. 7. The prescribing clinician confirms that use is in accordance with the SmPC and the managed access agreement, as detailed in NICE TA989.	From 27-June-24		Yes	Agreed	Yes	nca
ETR1b_v1.0	**Etranacogene dezaparvovec**	Post Infusion Funding Application for treating moderately severe or severe haemophilia B (TA989) where the following criteria have been met:	1.The prescribing clinician confirms that one of the following applies: - The patient remained eligible for treatment and was infused with etranacogene dezaparvovec - The patient was no longer eligible for treatment and the order was cancelled before acceptance of the product - The patient was no longer eligible for treatment and the order had to be cancelled after acceptance of the product - The product was destroyed following identification of a defect or latent defect (i.e. a fault occurring prior to receipt of product, regardless of when it was detected) - The product was destroyed following identification of other damage to the product Please enter the date of infusion with etranacogene dezaparvovec if option 1 applies, otherwise please enter '00/00/0000': _____ 2. The prescribing clinician confirms that etranacogene dezaparvovec was otherwise used as set out in the SmPC and the managed access agreement as detailed in NICE TA989	From 27-June-24		Yes	Agreed	Yes	nca

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EXA1a_v1.0	**Exagamglogene autotemcel**	Initial Funding Application (for each cell collection) – Exagamglogene autotemcel for treating transfusion-dependent beta-thalassaemia [TA1003] where the following criteria have been met:	1.The prescribing clinician confirms that one of the following applies: a. The prescribing clinician confirms the patient is 16 years and older, being treated in an adult service, and the centre is commissioned to deliver this treatment OR b. The prescribing clinician confirms the patient is 12-18 years old at the point of referral to the panel for approval, is being treated within a paediatric service, and the centre is commissioned to deliver treatment in this age group 2. The prescribing clinician confirms the patient has transfusion-dependent beta-thalassaemia (diagnosis confirmed by DNA technology) and is suitable for haematopoetic stem cell transplant but a human leukocyte antigen (HLA)- matched related haematopoietic stem cell donor is not available. 3. The prescribing clinician confirms that the patient has not received a prior allogeneic or autologous haematopoietic stem cell transplant. 4. The prescribing clinician confirms that approval for treatment has been obtained from the National Haemoglobinopathy Panel on: To enter date in the box as (00/00/0000) ---------- 5. The prescribing clinician confirms that one of the following applies 5a.The prescribing clinician confirms this is the patients first mobilisation cycle* OR 5b. The prescribing clinician confirms this is the patients second mobilisation cycle* OR 5c. The prescribing clinician confirms this is the patients third mobilisation cycle* OR 5d. The prescribing clinician confirms this is the patients fourth mobilisation cycle* OR 5e. The prescribing clinician confirms this is the patients fifth mobilisation cycle* *One mobilisation cycle is defined as mobilisation plus the completion of all collective attempts at apheresis that may occur from Day 5 to Day 7 (inclusive). 6. The prescribing clinician confirms that use is in accordance with the SmPC and the managed access agreement, as detailed in NICE TA1003 . 7. The prescribing clinician confirms the required data will be collected as per the managed access agreement.	From 08-August-24		Yes	Agreed	Yes	nca
EXA1b_v1.0	**Exagamglogene autotemcel**	Funding Application (treatment outcome)– Exagamglogene autotemcel for treating transfusion-dependent beta-thalassaemia [TA1003] where the following criteria have been met:	1. The prescribing clinician confirms that one of the following applies: The patient remained eligible for treatment and was infused with exagamglogene autotemcel. The patient was no longer eligible for treatment and the order was cancelled before acceptance of the product. The patient was no longer eligible for treatment and the order had to be cancelled after acceptance of the product. The product was destroyed following identification of a defect or latent defect (i.e. a fault occurring prior to receipt of product, regardless of when it was detected). The product was destroyed following identification of other damage to the product 2.If option 1a applies, I confirm that Exagamglogene autotemcel was otherwise used as set out in the SmPC and the managed access agreement as detailed in NICE TA 1003 and please enter the date of infusion with Exagamglogene autotemcel, otherwise please enter '00/00/0000':	From 08-August-24		Yes	Agreed	Yes	nca

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ELAF1_v1.0	**Elafibranor**	ELAF1 – National Innovative Medicines Fund Application Form - Elafibranor for treating primary biliary cholangitis [TA1016]	1. The prescribing clinician confirms the patient is an adult and has primary biliary cholangitis	From 22-October-24		Yes	Agreed	Yes	12-Feb-25
			2. The prescribing clinician confirms that ONE of the following applies to this patient OPTION 1 - The patient has taken ursodeoxycholic acid (UDCA) as monotherapy and had an inadequate response* and therefore elafibranor is to be taken in combination with ursodeoxycholic acid. OPTION 2 - The patient has taken ursodeoxycholic acid (UDCA) as monotherapy and has an intolerance to UDCA therefore elafibranor will be taken as monotherapy. Please choose correct option: Please Select Option 1 OR Option 2 *An inadequate response to UDCA as defined by the ELATIVE and POISE phase 3 trial is a serum alkaline phosphatase of >1.67x upper limit of normal (ULN) following 12 months of weight-appropriate UDCA OR A total bilirubin above the normal range but <2x ULN following 12 months of weight-appropriate UDCA.						
			3. The prescribing clinician confirms that the patient's treatment options have been considered by the relevant specialist MDT and it has been agreed that elafibranor is the most appropriate therapy.						
			4. The prescribing clinician confirms ONE of the following applies to this patient OPTION 1 - The patient is on the UK PBC registry. OPTION 2 - The patient is not on the UK PBC registry. Please choose correct option Please select: Option 1 OR Option 2						
			5. The prescribing clinician confirms that this course of treatment will be reviewed in 12 months' time.						
			6. The prescribing clinician confirms the patient will receive the licensed dose and frequency of elafibranor.						

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CRO1_v1.0	**Crovalimab**	CRO1-National Innovative Medicines Fund Application Form - Crovalimab for treating paroxysmal nocturnal haemoglobinuria in people 12 years and over [TA1019]	1. The prescribing clinician confirms the patient is over 12 years of age and weighs 40kg or more and has paroxysmal nocturnal haemoglobinuria (PNH). 2. The prescribing clinician confirms the patient has haemolysis with clinical symptoms indicating high disease activity. 3.The prescribing clinician confirms the patient is already clinically stable after having a complement component 5 (C5) inhibitor for at least the past 6 months and is suitable for switching to crovalimab monotherapy. 4. The prescribing clinician confirms that the decision to treat the patient has followed approval from the national PNH service (Leeds or London). 5.The prescribing clinician confirms that use is in line with the summary of product characteristics (SmPC).	From 20-November-24		Yes	Agreed	Yes	20-Dec-24

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UBL1_v1.0	**Ublituximab**	UBL1-National Innovative Medicines Fund Application Form – Initial Funding Application for Ublituximab for treating relapsing multiple sclerosis [ID6350]	1.The prescribing clinician confirms the patient has a diagnosis of relapsing–remitting multiple sclerosis defined as active by clinical or imaging features. 2. The prescribing clinician confirms the patient is aged 18 or over 3. The prescribing clinician confirms that the patient has received prior treatment with ONE or MORE of the following therapies. Please tick all that apply: - Beta interferon - Dimethyl fumarate - Diroximel fumarate - Fingolimod - Glatiramer acetate - Natalizumab - Teriflunomide - Cladribine - Ofatumumab - Ocrelizumab - Ponesimod - Alemtuzumab - No prior treatment 4. Please enter the patient's EDSS score. Please Select (use the following scores in the radio button : 0, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6, 6.5, 7) 5. The prescribing clinician confirms the stopping criteria have been explained and agreed with the patient before the treatment is started 6. The prescribing clinician confirms the use of the drug has been discussed at a multi-disciplinary team (MDT) meeting. 7. The prescribing clinician confirms the patient will receive the licensed dose and frequency of ublituximab	From 29-November-24		Yes	Agreed	Yes	18-Mar-25

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Version Control

Version No.	Date published	Author(s)	Revision summary
0.1	n/a	D Dwyer	Initial draft of new IMF list, based on pre-existing national IMF list but updated for changes to the IMF, for review.
1.0	03/07/2024	S Patel; R Gowa; P Ryan; S Ahmed	Final version of new IMF list
1.1	19/08/2024	R Gowa; S Ahmed	1 drug/indication recommended for the IMF, 2 drugs/indications removed from the list
1.2	06/09/2024	R Gowa; S Ahmed	1 drug/indication recommended for routine commissioning, receiving IMF interim funding
1.3	22/10/2024	R Gowa; S Ahmed	1 drug/indication recommended for the IMF
1.4	20/11/2024	R Gowa; S Ahmed	1 drug/indication recommended for the IMF
1.5	06/12/2024	R Gowa; S Ahmed	1 drug/indication recommended for the IMF, 1 drugs/indications removed from the list
1.6	20/12/2024	R Gowa; S Ahmed	0 drug/indication recommended for the IMF

Changes to recent versions

General or criteria changed	Summary of changes
Changes to version 1.0	
ETR1a_v1.0, ETR1b _v1.0	Recommended for the IMF
VOX1a_v1.0	Recommended for routine commissioning, receiving IMF interim funding
TAF1a _v1.0	Recommended for routine commissioning, receiving IMF interim funding
Changes to version 1.1	
EXA1a_v1.0 ,EXA1b_v1.0	Recommended for the IMF
VOX1a_v1.0 , TAF1a _v1.0	Removed from the list
Changes to version 1.2	
IPT1_v1.0	Recommended for routine commissioning, receiving IMF interim funding
Changes to version 1.3	
ELAF1_v1.0	Recommended for routine commissioning, receiving IMF interim funding
EXA1a_v1.0 ,EXA1b_v1.0	Updated EXA1a questions Q4 & Q5; EXA1b Question 2&3 combined
Changes to version 1.4	
CRO1_v1.0	Recommended for routine commissioning, receiving IMF interim funding
ETR1a_v1.0, ETR1b _v1.0,EXA1a_v1.0 ,EXA1b_v1.0,ELAF1_v1.0 and IPT1_v1.0	Updated IDs
Changes to version 1.5	
UBL1_v1.0	Recommended for routine commissioning, receiving IMF interim funding
IPT1_v1.0	Removed from the list
Changes to version 1.6	
CRO1_v1.1	Updated CRO1 question 2 & added a new question.