Commissioning Guidance to Support the Implementation of *Chimeric Antigen Receptor T Cell (CAR-T) Therapy (all indications, all ages) Service Specification*

12 November 2025, Version 3

1. Service Specification:	
Section 1a: Service Name	**Chimeric Antigen Receptor T Cell (CAR-T) Therapy**
Section 1b: Service Specification number	**2101**
Section 1c: Short summary of the specification	In 2018, service specifications were developed for Axicabtagene ciloleucel and Tisagenlecleucel to align with guidance from the National Institute for Health and Care Excellence (NICE). These products were the first in their drug class to be approved by NICE. As the NHS has gained more operational knowledge since the initial introduction of CAR T-cell therapy, the interim specification has been updated to reflect the increased understanding and experience in delivering this therapy (see appendix one).
To be completed for amended specifications only:	
Section 1d: Summary of proposed changes to published service specification:	The amendments to the specification are to: Combine all licensed CAR-T products into one service specification, rather than many individual service specifications. A full list of current commissioned CAR-T products and their associated National Institute for Health and Care Excellence (NICE) guidance is also included. • Update the content to reflect current clinical practice and patient pathways. This gives further autonomy to clinicians on how best to manage their patients. Future proof the service for the potential emergence of CAR-T products that are not solely for haematological

	conditions but may include solid malignant tumours also. Refresh of terminology and references and moving to the new specification template. There is no expectation of changes to the provider landscape, service provision, nor patient numbers because of this revision to the service specification.
Section 1e: Brief explanation of why the specification has been amended	Two draft interim service specifications were developed and published in 2019 to cover the inception of CAR-T as a treatment option in the NHS and for clinical teams to use as a guide. Since the creation of the Innovative Treatments Team, the original interim service specifications have been edited and combined to reflect more up to date clinical practice and patient pathways, and to include the newer CAR-T therapies that have since been launched. This version is intended to be published as one CAR-T service specification rather than needing to publish multiple specifications to accommodate new NICE recommended products normally covered under this service. Combining the service specifications will allow for a more streamlined approach; the delivery of the service has not changed as a result. The process is now clearer, and wording changes now give clinicians more autonomy on how patients are managed. Over the last 7 years since the introduction of CAR-T into the NHS a lot of clinical experience has been gained, and it is reasonable to enable the clinical community to use their expertise and clinical judgement in certain elements of the CAR-T patient management. An example of this is for example at which point a patient may need ITU referral. No significant / more material changes have been made.
Section 1e: Related service specifications and status	Chemotherapy - B15/S/a Cancer: Chemotherapy (Adult) B (england.nhs.uk) Adult Critical Care 170118S - Adult Critical Care https://www.england.nhs.uk/wp-content/uploads/2019/05/Adult-Critical-Care-Service-Specification-FINAL.pdf
NICE guidance	Brexucabtagene autoleucel for treating relapsed or refractory mantle cell lymphoma (TA677)

	Published: 24 February 2021 Axicabtagene ciloleucel for treating diffuse large B-cell lymphoma and primary mediastinal large B-cell lymphoma after 2 or more systemic therapies (TA872) Published: 28 February 2023 Brexucabtagene autoleucel for treating relapsed or refractory B-cell acute lymphoblastic leukaemia in people 26 years and over (TA893) Published: 07 June 2023 Axicabtagene ciloleucel for treating relapsed or refractory diffuse large B-cell lymphoma after first-line chemoimmunotherapy (TA895) Published: 07 June 2023 Tisagenlecleucel for treating relapsed or refractory B-cell acute lymphoblastic leukaemia in people 25 years and under (TA975) Published: 15 May 2024 Lisocabtagene maraleucel for treating relapsed or refractory large B-cell lymphoma after first-line chemoimmunotherapy when a stem cell transplant is suitable (TA1048) Published: 26 March 2025 Obecabtagene autoleucel for treating relapsed or refractory B-cell precursor acute lymphoblastic leukaemia (TA1116) Published: 11 December 2025

Capacity requirements and future service development needs	All commissioned treatments can be delivered within existing commissioned centres. As new commissioned indications become available, NHS England will monitor their uptake and engage directly with the relevant providers to determine if there are any capacity concerns. If capacity concerns were flagged, NHS England would explore potential expansion of CAR-T providers to include autologous stem cell transplant centres (for adults) and more paediatric allogeneic stem cell transplant centres for paediatric indications.

Executive Summary

This service specification outlines the commissioning framework for the delivery of Chimeric Antigen Receptor T Cell (CAR-T) therapy across England for all licensed indications and age groups. NHS England remains the accountable commissioner, ensuring equitable access, safety, and quality in the delivery of this advanced therapy. CAR-T is currently envisaged to continue as a retained commissioning responsibility.

The population covered by this service specification includes children, teenagers, young adults (TYA), and adults ordinarily resident in England or otherwise under NHS England's commissioning responsibility. Eligibility for treatment commencement is determined by NICE Technology Appraisals (TAs) and Highly Specialised Technology (HST) guidance, and commissioning includes cross-border commissioning rules (e.g., Welsh residents registered with English GPs).

The service aims and outcomes are to ensure national access to CAR-T therapy and to promote best practice in clinical delivery, safety, and follow-up. Through implementation of this specification clinical dependencies will become more streamlined and quality measures improved through alignment with NHS Outcomes Framework Domains 1–5 (e.g., reducing premature mortality, enhancing quality of life, patient safety).

Commissioned providers must hold JACIE accreditation for immune effector cell therapy and allogeneic transplantation and demonstrate SOPs and risk management for CAR-T delivery and toxicity management. In addition, providers need to comply with MHRA GMP/GDP standards and manufacturer accreditation which ensure capability of delivering all NICE-approved CAR-T products with appropriate training. Each commissioned centre is responsible for ensuring access to a certified clinical setting with age-appropriate critical care, pharmacy oversight for product handling and supportive care drugs (e.g., tocilizumab, immunoglobulin), access to diagnostics (e.g., EEG), neurology, and ITU as well as ambulatory care and rapid re-admission pathways. Commissioned centres are listed on NHS England's CAR-T therapy webpage.

As well as engagement with Cancer Alliances and clinical networks, it is expected that local MDTs assess and refer eligible patients to National Clinical CAR-T Panels where treatment options will be decided and approved. Treatment includes leukapheresis, lymphodepletion, CAR-T infusion, and intensive monitoring. Due to the intensity of the treatment, follow up includes 28-day, 100-day, and long-term toxicity monitoring, with data submission to relevant registries. Patient centred care is paramount and informed consent essential, this will mean access to counselling, plain language information and support for travel and accommodation. Any transition from a children's centre to an adult centre must be done with the patient's best interests in mind and careful planning.

PART ONE – Commissioning Plan

1. Key dates

Clinical Priorities Advisory Group recommendation:	November 2025
National Commissioning Group consideration:	November 2025
Rare Diseases Advisory Group consideration	August 2025
Highly Specialised Services Oversight Group consideration	August 2024
Development or update of tools to support identification of specialised activity	Not applicable
Date SSQD will be updated and reporting against metrics will commence	December 2025
Date service specification published:	[November 2025]
Planned implementation from:	[November 2025]

2. Delegated Commissioning Status

Delegated Commissioning Status	***Notes***
Retained Service	*All parts of this service will be retained*

3. Demand/activity

3.1 Number of patients currently eligible for the service according to the proposed service specification commissioning criteria.	Unknown due to the range of diseases treated by CAR-T therapy.			
3.2 How is the population currently distributed geographically?	North West	12%	South West	9%
	North East & Yorkshire	13%	Midlands	16%

	London 37% East of England 7% South East 5% *Data covers in which regions patients were treated with CAR-T YTD from 17/18 to 25/26 Months 1-5. The geographical location of patients' homes is uncertain and would need to be investigated.*
3.2. Is there expected to be annual growth in the eligible patient population?	NHS England is required under the NICE regulations 2013 to implement new CAR-T products which have had a positive recommendation post NICE appraisal; therefore, new incidence and prevalent populations will become relevant throughout the lifetime of the specification, for example, if there was expansion of CAR-T into multiple myeloma and solid tumour areas. Otherwise, the eligible patient population is expected to remain stable.
3.5. What is the annual activity associated with the existing pathway?	Annual activity has varied from when the first CAR-T product was recommended by NICE for use in the NHS in England, however recent data collection show the following numbers treated: Total CAR-T treatments CDF & Baseline — 23/24 YTD 490 — 24/25 YTD 390

4. Quality and compliance

Compliance with this service specification will be assessed via the quality surveillance assurance process as part of the Specialised Commissioning Quality Assurance & Improvement Framework;

Standard formal reporting processes will commence with new quality metrics from publication of the service specification and include quarterly submission of SSQD data. Commissioned providers will be expected to demonstrate an effective service through reporting these quality dashboards, in a complete and timely manner.

The service specification sets a standard CAR-T service delivery for all patients, irrespective of their protected characteristic or socio-economic status. Commissioned providers should ensure that their services are accessible and attractive to all patients and delivered in a manner that is free from judgement and welcoming to all.

5. Coding, finance and contracting

5.1 Financial and commercial considerations:

The information set out in this service specification is intended to clarify the service requirements associated with CAR-T but is not designed to directly influence the cost of commissioning this service for NHS England. A separate exercise was undertaken during 2023 to reassess the reimbursement arrangements for the CAR-T service for patients aged 19 and over. In September 2023, this work concluded with following agreed outcomes for the reimbursement arrangements for 2024/25 onwards:

- All activity from 2024/25 onwards will be reimbursed at a new variable rate of £62,414 plus Market Forces Factor (MFF). This revised variable rate tariff will be updated in future years in line with national uplift assumptions.
- In addition, providers will receive a supplementary transitional payment for any activity up to their 2023/24 baseline activity level. The calculation of this payment will be equivalent to the difference between the new variable tariff and the 2023/24 tariff.
- These arrangements will remain in place until there is a material change in the landscape of commissioned CAR-T activity. A material change would be defined as any change to the commissioned indications published by NICE after August 2023 where the steady state impact of the decision (existing activity for decommissioning of existing indications, or year 3 impact of new indications as set out in the budget impact test used in NICE decision making) is expected to have a greater than 20% net impact on the total commissioned activity undertaken in 2023/24. The overhead rate recommended for 2024/25 and beyond is not considered to set a precedent for the recommendations of any future reviews
- A specific timetable for a tariff review will be determined when a trigger point is reached. The base planning assumption is that a review of the tariff for a material change will commence once 12 months of data is available following the change trigger on which to base future financial modelling. This will apply unless circumstances surrounding the trigger point would particularly signal the need for an earlier review.
- That additional support will be provided to new service providers to ensure their first 12 months of activity is reimbursed in line with existing tariffs. The activity level during this period will then be used to inform the establishment of the baseline for transitional funding for the second year of service onwards which recognises an agreed estimation of a full year of steady state activity. Any change in activity against the calculated baseline will be reimbursed in line with the approach for established providers.

A separate exercise was undertaken to assess reimbursement for patients aged 18 and under. This work was finalised in December 2023 with the following outcomes:

- The tariff for reimbursing trusts for patients aged 18 and under should remain at the current rate of £138,456 plus MFF for the financial year 2024/25 onwards. This value will be uplifted in line with national cost uplift and efficiency factors.
- From 1 April 2024 the eligibility requirements for the payment of the paediatric tariff are clarified so that the higher rate is only paid where the patient:

    - Has been treated with an indication which is specifically recommended for the treatment of children, teenagers, and young adults (currently only applies to Tisagenlecleucel for ALL), AND
    - Is aged 18 and under, AND
    - Has been treated at a treatment centre commissioned to treat a patient of their age.
- These arrangements will remain in place until there is a material change in the landscape of commissioned CAR-T activity. A material change would be defined as any change to the commissioned indications published by NICE after August 2023 where the steady state impact of the decision (existing activity for decommissioning of existing indications, or year 3 impact of new indications as set out in the budget impact test used in NICE decision making) is expected to have a greater than 20% net impact on the total commissioned activity undertaken for patients aged 18 and under undertaken in 2023/24. The overhead rate recommended here for 2024/25 and beyond is not considered to set a precedent for the recommendations of any future reviews.
- A specific timetable for a tariff review will be determined when a trigger point is reached. The base planning assumption is that a review of the tariff for a material change will commence once 12 months of data is available following the change trigger on which to base future financial modelling. This will apply unless circumstances surrounding the trigger point would particularly signal the need for an earlier review.

To October 2025, the implementation of national uplift and efficiency assumptions has increased the values above to £66,949 plus MFF for patients aged 19 and over, and £148,517 plus MFF for patients ages 18 and under. There have not yet been any material changes in the commissioned indications to meet the trigger point for a further review of the tariff.

Feedback gathered as part of these tariff reviews has been considered in developing the proposed service specification, with the intention that this creates the opportunity for providers to identify potential efficiencies in their delivery approach. It was not anticipated that these observations would increase the costs associated with service delivery.

Coding	
5.1 Specify the datasets used to record the patient pathway activity. *expected to be populated for all commissioned activity	*Select all that apply:* Aggregate Contract Monitoring * ☐ Patient level contract monitoring ☒ Patient level drugs dataset ☒ Patient level devices dataset ☐ Devices supply chain reconciliation dataset ☐ Secondary Usage Service (SUS+) ☐ Mental Health Services DataSet (MHSDS) ☐

	National Return** ☒ Clinical Database** ☐ Other** ☐ **If National Return, Clinical database or other selected, please specify: Blueteq data collection
5.2 Specify how the activity related to the patient pathway will be identified.	*Select all that apply:* OPCS v4.8 ☐ ICD10 ☐ Service function code ☐ Main Speciality code ☐ HRG ☐ SNOMED ☐ Clinical coding / terming methodology used by clinical profession ☐
5.3 **Identification Rules for Devices:** How are device costs captured?	**Not applicable**
5.4 **Identification Rules for Activity:** How are activity costs captured?	Blueteq data provides NHS England with the information to support central activity payments by the national team. Providers code tariff reimbursement to NCBPS02C ADVANCED THERAPY MEDICINAL PRODUCTS (ATMPS)
Contracts	
5.5 **Contracts** Specify any new or revised data flow or data collection requirements, needed for inclusion in the NHS Standard Contract Information Schedule. Please identify any excluded drugs or devices relevant to the service and their current status with regard to NHS England	**None** There are no new requirements because of this service specification amendment. However, local commissioners may wish to review capacity, and access to local services. There are no new data flows anticipated because of this specification. *High-cost tariff excluded drugs relating to this service would include* *Drugs used to manage Acute Lymphoblastic Leukaemia* *Drugs used to manage B-Cell Lymphoma* *Drugs used to manage Mantle Cell Lymphoma*

specialised services commissioning.	*Drugs used to manage non-Hodgkin Lymphoma* *Drugs used to manage B-Cell acute Lymphoblastic Leukaemia*
5.6 **Contract monitoring** Is this part of routine contract monitoring?	**Yes** This service specification should form part of the standard NHS contract for specialised services in providers listed in the Provider Eligibility List.
Tariff/Pricing	
5.7 **How is the service contracted and/or charged?** Only specify for the relevant section of the patient pathway	*Select all that apply:* **Drugs** Not separately charged – part of local or national tariffs ☐ Excluded from tariff – cost & volume ☒ Excluded from tariff - block ☐ **Devices** Not separately charged – part of local or national tariffs ☐ Reimbursed via pass through ☐ Reimbursed via VCM ☐ Covered entirely by National Tariffs ☒ Covered entirely by Local Tariffs ☐ Partially covered by National Tariffs ☐ Partially covered by Local Tariffs ☐ **Activity** Part/fully covered under a Block arrangement ☐ Part/fully covered under Pass-Through arrangements ☐ Part/fully covered under other arrangements ☐
Average Cost per Patient	
5.12 What is the estimated cost per patient to NHS England, in years 1-5, including follow-up where required?	Please see background on the tariff for CAR-T therapy and service cost per patient in section 5.1. The tariff covers the whole pathway from the point at which CAR-T has been identified as the next appropriate step in the patient's pathway to 100 days post infusion. Any supportive chemotherapy or other tariff excluded drugs required in addition to the CAR-T product, and any associated

(1 cost per patient over the course of 5 years)	admissions to intensive care wards are reimbursed separately. In addition, there is the cost of the drug. This varies by product. The list prices for these products are: Axicabtagene ciloleucel: £316,118 Tisagenlecleucel: £280,451 Brexucabtagene autoleucel (also known as KTE-X19): £379,342 Lisocabtagene maraleucel £297,000 Obecabtagene autoleucel £372,00 All products are one-time infusions charged at a total set price per patient. Commercial arrangements are in place for all these products which adjust the actual price paid by the NHS, but details of these arrangements cannot be disclosed here due to commercial confidentiality. As noted below, these costs are already being reimbursed in line with the existing service specifications. The updates being proposed in the combined specification do not change these reimbursement arrangements.
Overall Cost Impact of this Service specification	
5.13 Specify the budget impact of the proposal for specialised services in relation to the relevant pathway.	**Cost neutral** There are no additional costs expected as a result of this specification - patient eligibility criteria are instead determined by relevance NICE guidance.
5.14 Specify the budget impact of the proposal on other parts of the NHS.	Budget impact for ICBs: **No impact on ICBs** Budget impact for provider: **No impact on providers**
5.15 Where a cost pressure is indicated? Who is funding (ICBs or NHS England?) and how is it being funded?	**N/a – no cost pressure has been identified**

6. Provider Landscape and Provider Selection

6.1 What is the current number of contracted providers for the eligible population by region?	North West 4 North East & Yorkshire 3 London 7 South East 2 South West 2 Midlands 3 East of England 1 *Please see list of providers in appendix 1*
6.2 Is there likely to be either an increase or decrease in the number of commissioned providers? If yes, specify the current and estimated number of providers required in each region	No nationally planned change in the provider landscape, although regional commissioners may wish to undertake their own compliance exercise and review whether commissioned services are delivering a specialised level of care.
6.3 Is provider selection required to support implementation of the service specification?	No
6.4 If provider selection is required, please describe plan including indicative timescales	Not applicable.

7. Other Actions Required

National Innovative Treatments Team

The national team is currently considering the opportunities that may be afforded by undertaking a nationally led programme to focus on potential health inequalities in the delivery of Advanced Therapies and if there is variation in the patients that are then able to access such services.

NHS England Regional Specialised Commissioning Team

Regional Specialised Commissioning Teams to continue to support CAR-T commissioned centres in onboarding for new treatments. To highlight to the national team should capacity or other service-related issues arise.

Integrated Care Boards

None to note.

PART TWO – FURTHER INFORMATION

Paediatric care:

The NHS in England has three commissioned treatment centres who are commissioned to deliver CAR-T services to patients aged 18 years and under, or patients who are not classed as post pubescent by the medicine for children policy in line with the NICE TA recommendation for the products, these sites are:

1. Great Ormond Street Hospital,
2. Royal Manchester Children's Hospital,
3. Newcastle University Hospitals NHS Trust

Adult CAR-T centre aligning with the teenager and young adult cancer service specification, other than those providers directly commissioned by NHS England to provide paediatric CART services, can potentially treat patients under 18; but only where the patient is assessed as being post-pubescent and therefore suitable for being treated in an adult setting following the usual treatment pathway for adult patients. In these cases, centres will be reimbursed in line with Adult CAR-T tariff for these patients.

Document completed by: Kiran Moyo, National Senior Manager, Innovative Treatments
Date: 2nd October 2025

Financial Review by: Michelle Thayre, Senior Finance lead, Innovative Treatments
Date: 2nd October 2025

Reviewed by: Ben Doak, Head of Innovative Treatments
Date: 6th October 2025

National Innovative Treatments Team
Email address: england.innovativetreatments@nhs.net

Appendix 1 (as referred to in section 6.1)

Providers of Chimeric Antigen Receptor T Cell (CAR-T) Therapy Service Specification

1. Barts Health NHS Trust
2. Cambridge University Hospitals NHS Foundation Trust
3. Imperial College Healthcare NHS Trust
4. King's College Hospital
5. Leeds Teaching Hospitals NHS Trust
6. Manchester University Hospital NHS Trust (adults and paediatrics)
7. The Newcastle Upon Tyne Hospitals NHS Foundation Trusts (adults and paediatrics)
8. Nottingham University Hospitals NHS Trust
9. Oxford University Hospitals NHS Trust
10. Royal Marsden Hospital NHS Foundation Trust
11. Sheffield Teaching Hospital NHS Foundation Trust
12. St George's University Hospitals NHS Foundation Trust
13. The Christie NHS Foundation Trust
14. The Clatterbridge Cancer Centre
15. University College London Hospital
16. University Hospitals of Leicester NHS Trust
17. University Hospitals Plymouth NHS Trust
18. University Hospital Southampton NHS Foundation Trust
19. University Hospitals Birmingham NHS Foundation Trust
20. University Hospitals Bristol and Weston NHS Trust
21. Great Ormond Street Hospital (paediatric only)