NHS England

SCHEDULE 2 – THE SERVICES

A. Service Specifications

1. Service name	Service specification for the delivery of Chimeric Antigen Receptor T Cell (CAR-T) Therapy (all indications, all ages)
2. Service specification number	**2101**
3. Date published	14th April 2026
4. Accountable Commissioner	NHS England – Specialised Commissioning

5.	**Population and/or geography to be served**
5.1	**Population Covered** This specification (the 'Specification') relates to children, teenagers and young adults (TYA) and adult patients who are undergoing Chimeric Antigen Receptor T Cell (CAR-T) ordinarily resident in England or otherwise the commissioning responsibility of NHS England (as defined in 'Who Pays? Determining which NHS commissioner is responsible for making a payment to a provider' - https://www.england.nhs.uk/wp-content/uploads/2022/06/B1578_i_who-pays-framework-final.pdf). Note: for the purposes of commissioning health services, this excludes patients, who whilst resident in England, are registered with a GP Practice in Wales, but includes patient's resident in Wales who are registered with a GP Practice in England. Patient eligibility for individual products is in line with the licences and National Institute for Health and Care Excellence (NICE) Technology Appraisal (TA) or Highly Specialised Technology (HST) guidance recommendations for each of the individual CAR-T products. The need for CAR-T and its place in treatment will vary by indication, age group and product. Please see section 7.7.1 for the relevant NICE guidance. Demographic changes impacting the need for CAR-T will vary by indication, age group and product. Where the NICE TA is for a cancer topic, an adult CAR-T centre meeting the requirements of the teenager and young adult cancer service specification (as well as those providers directly

<table>
<tr><td></td><td>commissioned by NHS England to provide paediatric CAR-T services) can potentially treat patients under 18. This should only be the case 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 the adult CAR-T tariff for these patients.
Where the NICE TA align with a non-cancer topic area, the NICE TA will specify populations, and NHS England will provide further guidance on reimbursed approaches.</td></tr>
<tr><td>5.2</td><td>Minimum population size

Minimum population size for individual products is in line with the licences and NICE TA recommendations for each of the individual CAR-T products.</td></tr>
<tr><td>6.</td><td>Service aims and outcomes</td></tr>
<tr><td>6.1</td><td>Service aims

The aim of the service is to oversee the clinical delivery of CAR-T therapy to eligible patients.

The specification will ensure:

1) Patient access is secured at a national level.
2) Best practice for the safe and effective delivery of CAR-T therapy.
3) Clinical dependencies are addressed and secured.
4) Traceability, tracking, best practice for patient follow-up and data capture is secured.</td></tr>
<tr><td>6.2</td><td>Outcomes

<u>NHS Outcomes Framework Domains & Indicators</u>

<table>
<tr><td>Domain 1</td><td>Preventing people from dying prematurely</td><td>This domain captures how successful the NHS is in reducing the number of avoidable deaths.</td></tr>
<tr><td>Domain 2</td><td>Enhancing quality of life for people with long-term conditions</td><td>This domain captures how successful the NHS is in supporting people with long-term conditions to live as normal a life as possible.</td></tr>
</table>
</td></tr>
</table>

Domain 3	Helping people to recover from episodes of ill-health or following injury	This domain captures how successful the NHS is in supporting people with long-term conditions to live as normal a life as possible.
Domain 4	Ensuring people have a positive experience of care	This domain looks at the importance of providing a positive experience of care for patients, service users, and carers.
Domain 5	Treating and caring for people in safe environments and protecting them from avoidable harm	This domain explores patient safety and its importance in terms of quality of care to deliver better health outcomes.

Service defined outcomes / outputs.

Indicators include the following, as outlined below. In addition, CAR-T manufacturers will have indicator requirements as part of their regulatory arrangements, and all efforts will be taken to harmonise these to ensure key data is collected without duplication. Complete and timely data collection, reporting and submission will be a mandatory requirement for commissioned providers as well as agreements for data sharing. The indicators will be subject to further amendment based on regulatory requirements, the British Society of Blood and Marrow Transplantation and Cellular Therapy (BSBMTCT) registry and the European Society for Blood and Marrow transplantation (EBMT) registry.

Service defined outcomes.

Reference	Domain	Rationale	Indicator
CART01,02,03		It is important to understand the relationship between the treatment and the person's life in the days after treatment.	Proportion of patients who complete treatment and are alive 28 days, 1 year and 2 years after infusion

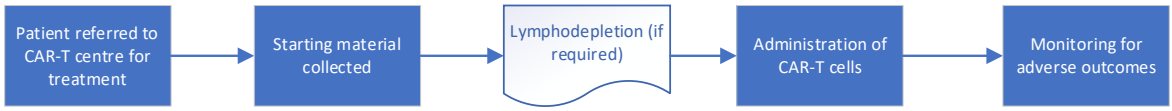
	CART10a		It is important to understand the impact the treatment has on the person's life in the days after treatment.	3-month mortality rate - due to treatment
	CART10b		It is important to understand the impact the treatment has on the person's life in the days after treatment.	3-month mortality rate - due to original disease

The service will complete/upload data for all listed quality outcomes and metrics to the national Specialised Services Quality Dashboard (SSQD), BSBMTCT registry and EBMT registry. The full definition of the quality outcomes and metrics and their descriptions including the numerators and denominators can be accessed at https://www.england.nhs.uk/commissioning/spec-services/npc-crg/spec-dashboards/

7.	**Service description**
7.1	**Service model**
7.1.1	**Prescribed Specialised Service** CAR-T is a medicinal product manufactured usually from the patient's own cells and re-infused to treat certain types of cancers and non-cancer indications. During the initiation of CAR-Ts into the NHS, allogeneic haematopoietic stem cell transplant (HSCT) centres were seen as best placed to deliver the CAR-T services. The rationale for this was to build on the requirements provided by these centres for allogeneic Blood and Marrow Transplantation (BMT). However, as expertise is developing in other clinical areas clinicians experienced in the delivery of CAR-T will be best placed to deliver the service. Clinical practice in CAR-T has developed in haematology and Stem Cell Transplant Units, which are certified by the Foundation for the Accreditation of Cellular Therapy (hereafter FACT)

	Joint Assurance Committee of the International Society for Cellular Therapy (ISCT) and the European Society for Blood and Marrow Transplantation (EBMT) (subsequently referred to in this document as 'FACT-JACIE') providing assurance and certification for cellular therapy practice. Clinical practice also draws on complex cancer services such as immunotherapy and on clinical trial and academic research activity. The specification relates to commissioned clinical care, treating with medicines holding marketing authorisations and within their licenced indication. This specification does not govern research or trial activity. This is a generic specification for services commissioned to deliver CAR-T therapies, the individual CAR-T products and indications which have been recommended by NICE and commissioned by NHS England are referenced in section 7.7.1.
7.1.2	**Commissioned provider requirements** Commissioned providers will be required to: 1) Evidence age-appropriate assurance to FACT-JACIE standards for all stages of the patient pathway: a) for immune effector cell (IEC) therapy (either integral to assurance of the broader programme or via a separate focussed inspection). b) as a collection, storage and clinical centre for allogeneic transplantation. c) with certified collection facilities (leukapheresis and/or bone marrow harvest procedures) on-site or via a FACT-JACIE standards compliant 3rd party sub-contracted arrangement. 2) Evidence effective implementation of standard operating procedures (SOP) and risk management arrangements for successfully providing CAR-T therapy and treating all complications including those that are severe and life-threatening. 3) Evidence experience of managing serious toxicities associated with cellular therapies such as CAR-T therapy e.g. allogeneic transplantation, complex immunotherapy. 4) Ensure the following 2 regulatory approvals (Medicines and Healthcare products Regulatory Agency [MHRA] licensing) are in place where either a third party is used to outsource receipt and storage of a CAR-T product or where a preparation step is required by the site after receipt and before issue: 1. MHRA Good Manufacturing Practice (GMP).

	2. MHRA Good Documentation Practice (GDP). 5) Ensure alignment with NHSE's Assurance of Aseptic processes NHS England » Assurance of aseptic preparation of medicines guidance where the preparation step is completed remotely from the site, but does not mandate that a site holds a GMP licence. Where this is the case, sites will provide assurance as a pre-requisite for commissioning of this service. 6) Complete CAR-T manufacturer site assurance. This is a pre-requisite for commissioning of this service and will be evidenced by a letter of site accreditation from each CAR-T manufacturer. 7) To demonstrate the provider's ability to meet quality standards relevant to CAR-T therapy and to satisfy on-going data collection requirements of the MHRA and in some situations NHSE and NICE for example for CAR-T products in managed accessed agreements. 8) Follow the manufactures requirements (which will be based on regulatory requirements) for the procurement, manufacture, storage and delivery of the product. In some cases, clinical and commissioning consensus regarding the clinical management of the patient prior, during and after treatment and in relation to the management of toxicities may be more stringent than those required by the manufacturer. These must be followed. 9) Deliver all relevant CAR-T therapy products which are licenced and approved by NICE. Providers will be commissioned on this expectation. For example, where CAR-T therapy products cover a similar patient group, providers will be expected to be able to deliver all products available for that age group. This will include completing training and accreditation by each individual manufacturer providing the relevant CAR-T therapy.
7.1.3	**How the service is differentiated from services falling within the responsibilities of other commissioners** CAR-Ts are used to treat cancer, and ICBs/local systems as well as NHS England commission elements of care along the cancer pathway. To date, NHS England has taken on the commissioning responsibility of CAR-T products and services which are linked to the delivery of BMT, which is a prescribed specialised service. BMT has been identified as a service ready for delegation to ICBs, nevertheless, CAR-T will remain the commissioning responsibility of NHS England.

	Advanced therapy medicinal products (ATMPs) are listed as a general exclusion to national tariff. Managed entry agreements may be developed with regard to the cost of the medicinal product. CAR-T tariffs for both adults and paediatric have been developed, these superseded, the interim CAR-T tariff. As experience with CAR-T continues to improve, the approach to reimbursement for service costs will be reviewed and aligned with the financial regime. Providers must note that this specification and the associated published NICE guidance set out the commissioned position for England. Treatments and interventions associated with CAR-T but not included in these documents will not be supported or funded.
7.2	**Pathways**
7.2.1	**Overall patient pathway** Figure 1 provides a high-level pathway for CAR-T treatment. Please see section 7.7.1 for links to the individual CAR-T products and indications covered by this specification. Figure 1: high-level CAR-T treatment pathway for blood cancers 
7.2.2	**Decision to Treat** If approved, clinicians currently treating patients with disease indicated in the CAR-T treatment marketing authorisation (MA) will consider their patient's eligibility for the specified CAR-T treatment. At this stage they will: 1) Identify eligible patients who might benefit from CAR-T therapy. 2) Confirm patient eligibility in line with the manufacturer's MA with regard to age, fitness, disease and treatment stage. 3) Confirm that patients have been informed and understand the potential benefits, risks and complications of treatment as part of shared decision-making. Ensure referral of such patients via the appropriate pathway. In line with agreed cancer care pathways, this may be to a disease-specific multi-disciplinary team (MDT), an allogeneic

transplant centre or direct to the CAR-T provider specialist MDTs. CAR-T provider MDTs will then refer to the relevant National Clinical CAR-T Panels (NCCPs) where these are in place.

If a National Clinical CAR-T Panel is in operation, it will meet and ensure that patients referred do meet the eligibility criteria, taking an overview of capacity planning and scheduling, and undertaking audit to ensure equity of access as well as outcomes.

The role of the CAR-T centre MDTs will be to:

1) Identify eligible patients from their own and neighbouring NHS Trusts who may benefit for CAR-T therapy in accordance with the agreed commissioning criteria. Referral to a National Clinical CAR-T Panel would occur at this point.

Once approved, the centre MDT would also do the following:

2) Provide confidence that the treating physician has confirmed that patients (and / or their carers) have been informed and understand the potential benefits, risks and complications of treatment as part of shared decision-making and psychological support is available.
3) Assess individual patients prior to treatment preparation and initiation.
4) Manage the treatment, post treatment management and follow up in line with the approved and accredited standard operating procedures.
5) Confirm to patients the named consultant responsible for their treatment.
6) Undertake reporting, data analysis and audit – this may include engagement with manufacturers as required.
7) Review cases 3 months after treatment from a learning perspective and feed results into audit/service evaluation and national learning processes.
8) Ensure appropriate patient monitoring post treatment.

CAR-T provider MDTs will demonstrate governance arrangements which meet the requirements for robust and effective quality management systems from a manufacturer accreditation, FACT-JACIE immune effector cell therapy certification and NICE Improving Outcomes Guidance perspective.

Current best practice recommendations of EBMT FACT-JACIE and the European Haematology Association (EHA) (https://www.ebmt.org/) provide support for the whole pathway including selection, treatment processes, administration, management of toxicities and medium- and long-term follow up and can be used by treatment centres and referral teams to inform shared care policies, procedures, other written materials and decision making.

7.2.2.1	**Initial Admission** The generic pathway is as follows: After starting material collection but before administration of CAR-T cells, patients are likely to require lymphodepleting chemotherapy as per the Summary of medicinal Product Characteristics (SmPC). This may be administered in ambulatory care or outpatient settings. Bridging chemotherapy may be required following leucapheresis as per the SmPC of the NICE recommended products (see section 7.7.1).
7.2.3.2	**CAR-T Administration** CAR-T therapy can only be administered in a certified clinical setting. Care provided will be in accordance with the standard operating procedures, accredited and certified under the FACT-JACIE standards. The product must be prepared and delivered, and patients monitored in line with the SmPC, referenced in section 7.7.2, and the manufacturer-specific requirements about which all authorised providers must complete training and follow specific instructions provided. Following infusion of the CAR-T therapy, patients should be monitored daily for the first 7-10 days, or in line with the products SmPC, which may include a combination of inpatient and ambulatory care. Following discharge from inpatient care, patients should then remain within approximately 2 hours' travel time of the administering unit for a minimum of 2 weeks post discharge, with the recommendation being 2-4 weeks at the discretion of the CAR-T centre, according to the local pathways established with their referral units. Frequent outpatient follow-up for late onset cytokine release syndrome (CRS) / immune effector cell-associated neurotoxicity (ICANS) is required until 28 days post infusion. For this period, principles of ambulatory care can be applied, as per the recommendations for ambulatory care for high intensity chemotherapy in the NICE Improving Outcomes Guidance for haematological cancer: https://www.nice.org.uk/guidance/ng47/chapter/Recommendations. The patient may be referred back to the referring team with clear written guidance on follow up and side effect monitoring, including late CRS/ICANS and other haematological, immunological, infective and other toxicity. Reassessment of medium-term treatment toxicity (day +28 to +100) and long-term sequelae (date of infusion + 100 days and onwards) should

	be reviewed at the appropriate centre. Long term follow up is required by regulatory bodies and there should be a nominated individual at the treatment centre with this responsibility. As adhering to these arrangements for safe clinical management can represent a significant burden for patients and their families, CAR-T providers must ensure that patients and families are supported to secure the most appropriate arrangements to meet this. This may include signposting to forms of support including charities and benefits. Staff should be familiar with the travel costs under the Healthcare Travel Costs Scheme (HTCS) and be able to advise families about accommodation in or near the hospital. Further information can be found here**:** **Healthcare Travel Costs Scheme (HTCS) - NHS** At the introduction of CAR-T cell therapy, treating centres need to follow consensus grading systems to assess side-effects and toxicities of treatment and to inform clinical management decision making including an admission into an age appropriate ITU facility (7.2.3.3).
7.2.3.3	**Management of Cytokine Release Syndrome (CRS) and immune effector cell-associated neurotoxicity (ICANS)** Cytokine Release Syndrome is a form of Systemic Inflammatory Response Syndrome and is characterised by elevated circulating levels of several cytokines, including interleukin (IL) 6. This is a potential side effect of all CAR-T products. CAR-Ts are associated with potentially significant and life-threatening toxicities which require specific infrastructure, staff and standard operating procedures for effective management. Frequent monitoring is required at commissioned CAR-T providers during the inpatient stay for signs of CRS and ICANS and for signs and symptoms of CRS and neurologic toxicities for 4 weeks after infusion. Patients and their carers should be counselled to seek immediate attention should the signs or symptoms occur. This should include who they can contact at any time. CAR-T centre MDTs require training in the clinical management of CRS, neurological and other sequelae in accordance with current FACT-JACIE or equivalent standards. Product licences generally require a grading system be used for assessment/description of CRS. A grading system is available from the American Society for Transplantation and Cellular Therapy (ASTCT) Consensus Grading for CRS and Neurologic Toxicity Associated with Immune Effector Cells - Biology of Blood and Marrow Transplantationhttps://www.tctjournal.org/article/S1083-8791(18)31691-4/fulltext.

7.2.3.4	**Supportive care drugs** Access to supportive treatments is required as set out in the product specific SmPC for each product. These will require pharmacy facilities, expertise and capacity. Provision of immunoglobulin can be required for the management of CAR-T complications. This is a commissioned indication and should be used in line with the eligibility criteria under secondary antibody deficiency in the NHS England Clinical Commissioning Policy for the use of therapeutic immunoglobulin (Ig) England (2024) https://www.england.nhs.uk/wp-content/uploads/2021/12/ccp-for-the-use-of-therapeutic-immunoglobulin-england-2025.pdf and will need prior approval by the Sub-Regional Immunoglobulin Assessment Panel (SRiAP). Generally, product SmPCs require that at least 1 dose of tocilizumab per patient must be available prior to infusion. The regulatory requirements for access to tocilizumab as part of CAR-T therapy will be specified by the manufacturer. These must be followed.
7.2.4	**Interdependence with other Services** All commissioned CAR-T providers must be able to demonstrate they have the required processes and protocols, clinical facilities, staffing, medical supervision and care, training and education, accreditation, certification and governance to address the following sections.
7.2.5	**Regulatory** The Human Tissue Authority (HTA) in the UK and Health Products Regulatory Authority (HPRA) in Ireland are the Competent Authorities responsible for regulating human tissue and organs and as such, responsible for regulation Tissue Establishment registration. The following is required of all CAR-T providers: 1) Compliance with HTA (for apheresis procurement), FACT-JACIE HSCT standards and any relevant MHRA standards. 2) Starting material procurement sites should hold HTA licenses for Human application covering the relevant activity and export if applicable when testing, processing, storage, distribution, and import/export of human and tissue cells relevant to CAR-T. 3) CAR-T cells contain genetically modified cells and must be handled and disposed of in accordance with Genetically Modified Organisms (Contained Use) Regulations 2014. 4) An accredited Quality Management System, standard operating procedures and Protocols and Risk Evaluation and Mitigation Strategy capable of demonstrating a high quality, safe

	treatment pathway capable of effectively managing all side effects including those that are life threatening.
7.2.5.1	**Pharmacy** As CAR-T therapy is an Advanced Therapy Medicinal Product (ATMP), its governance (via medicines management / clinical effectiveness committees) and operational management (i.e. receipt, storage, preparation, prescription and issue) is the responsibility of pharmacy. Pharmacy will need to collaborate with local experts e.g. stem cell laboratory colleagues to ensure that optimal arrangements are in place for the implementation site in line with the Specialist Pharmacy Service Gene Therapy Medicinal Products Governance and Preparation Requirements, version 3 (https://www.sps.nhs.uk/wp-content/uploads/2024/02/PAN-UK-PWG-for-ATMPs-Gene-Therapy-Guidance-V3.pdf) unless, subsequently published guidance suspends. Where the storage and preparation facility are part of a different organisation or hospital department, the local site pharmacy is responsible for ensuring appropriate supplier approval assurances and technical agreements detailing the roles of both parties and ongoing monitoring are in place. Clinical pharmacists and expertise for CAR-T adverse events management should be available and will also be required to ensure medicines management requirements for monitoring of high-cost medicines are complied with a prior approval form if applicable.
7.2.6	**Specialist MDT for clinical management by CAR-T providers** The core clinical MDT will be led by the haematologist or equivalent CAR-T specialist who meets FACT-JACIE standards for training and competency in immune effector cell therapy (including the ability to deal with safety issues such as CRS, TLS, and neurotoxicity), immunotherapy, disease specialist, critical care staff, nursing and a clinical pharmacist with ATMP knowledge. This MDT must have named members and clear agreements in place and operate in accordance with criteria in the MA licence and any other agreed criteria (e.g. Cancer Drugs Fund [CDF] or any National Clinical CAR-T Panel criteria) for the appropriate selection of patients and management of complications.

	The clinical team will be appropriately constituted in terms of seniority, skills and capacity to successfully negotiate and manage the significant logistical issues and interfaces involved in effective scheduling of cell procurement; product manufacture, storage and preparation; treatment delivery, close monitoring and clinical patient management. Services will require immediate access to specialised diagnostic services for assessment of potential complications as required. Electroencephalogram (EEG) must be available, with interpretation available during the working day of the working week. Patients with grade 2 immune effector cell associated neurotoxicity syndrome (ICANS) and above should be discussed with the critical care (adults or paediatrics) lead, as required, and have immediate access to an age-appropriate critical care as needed. Access to neurological assessment is required including use of regular standard EEG (up to daily) or other treatment as indicated. Co-location with neurosurgery is preferred but not a mandatory requirement. Close links with a regional neurosurgery centre will be required, with an evidenced referral pathway for where neurosurgical input is required. Infrastructure for ambulatory care and rapid re-admission supported by standard operating procedures must be in place as per NICE Improving Outcomes Guidance https://www.nice.org.uk/guidance/ng47/chapter/Recommendations to safeguard patients in the 3-4 weeks following discharge from inpatient care. As patients may not recognise the onset of encephalopathy on their own, 24-hour availability of a carer is mandatory during the post infusion 4-week monitoring period. Provision of appropriate patient and carer information is required.
7.2.6.1	**Management of toxicities and critical care** Summary of requirements: • On-site age-appropriate critical care • Capability to deliver the critical care needs of all CAR-T patients at all times including those with the most serious side effects (e.g. level 3) in accordance with required Risk Management Plans and standard operating procedure. • CAR-T cell centres will need immediate 24/7 access to a wide range of support specialists in intensive, renal, respiratory, cardiovascular / cardiological and neurological medicine.

	• The critical care facilities should be age-appropriate and should comply with either or both the relevant service specifications for adult and paediatric critical care as outlined below, 1. NHS commissioning » Paediatric critical care 2. 220502S-adult-critical-care-service-specification.pdf • The above information is not limited or exhaustive to the following guidelines and standards. ○ https://www.nice.org.uk/guidance/health-and-social-care-delivery/acute-and-critical-care/products?ProductType=Guidance&Status=Published ○ https://www.ics.ac.uk/ICS/ICS/GuidelinesAndStandards/GPICS_2nd_Edition.aspx ○ https://pccsociety.uk/wp-content/uploads/2016/05/PICS_standards_2015.pdf. • Critical care should have sufficient capacity to receive recipients of CAR-T therapy and be able to demonstrate how that capacity is maintained throughout the year including at times of any system and winter pressures.
7.2.7	**Out of Specification CAR-T products** Due to the unique cellular nature of CAR-T therapy, there are occasions (often but not always due to inherent biological variation of starting materials) when the manufactured medicines are not in full compliance with their release specification (as opposed to this service specification). It is recognised that due to the specialised nature of these medicines and depending on the nature and degree of non-compliance it may be that the administration of an out-of-specification (OOS) ATMP remains in the best interest of the patient and that administration is the correct course of action. A system to ensure appropriate governance of this process is recommended as detailed in https://www.sps.nhs.uk/articles/out-of-specification-advanced-therapy-medicinal-products-guidance-for-healthcare-organisations/. NHS England has established a subgroup of the National Clinical CAR-T Panel to assist with the governance requirements of this process. When out of specification products are provided, this will always need to be limited to commissioned providers in accordance with this service specification.
7.2.8	**Training**

	All training as outlined through this document should be completed for all staff as required by the regulators (e.g. the MHRA, NHS England), the manufacturer and FACT-JACIE.
7.2.9	**Patients, quality and information** The centre must enable the informed participation of the patient, carer and advocate at each step in the treatment pathway and be able to demonstrate this. Provision shall be made for patients with communication difficulties, reduced mental capacity, disabilities and those whose first language is not English. Patients and carers shall be given details of the names and responsibilities of the multidisciplinary team. Services will provide patients, their families and/or carers (as appropriate) with access to counselling services. Counselling services should be accessible, during working hours. Monitoring of patients access to counselling should be undertaken routinely. Good quality, plain language information should be made available to patients and their carers in a variety of accessible formats. Written information (which has been evaluated by patients) should be made available at the point of referral and should be used to reinforce clinical communication and to inform patients on all aspects of the condition and treatment and its effects on daily living. This shall include balanced information about the probability of improved survival and/or symptom reduction, together with risks and potential short and long-term adverse effects. Where appropriate, patients shall be given information on the reasons anticipated treatments/interventions are not being offered to them. A review of information shall be carried out annually. Covid 19, which was first described in 2019, has caused major toxicity in many patient groups and toxicity in patients receiving CAR-T has been significant. Vaccination programmes have identified this population as high risk which should be highlighted to patients: see the BSBMTCT Covid 19 vaccination schedule https://bsbmtct.org/bsbmtct-and-covid/.
7.2.9.1	**Patient / data registry** A written agreement is required to submit to or provide access for NHS England the long-term follow-up data required by safety registries and a clear outline for how they will ensure the accuracy and sustainability of this data collection.

	The Committee for Medicinal Products for Human Use (CHMP) issued a draft opinion in July 2018 stating it considers that the cellular therapy module of the European Blood Marrow Transplant registry, may be used as a data source for regulatory purposes in the context of CAR-T cell therapies authorised for haematological malignancies. The draft opinion goes on to stipulate in detail the scope of the studies that may be performed based on the registry. The European Blood Marrow Transplant already have forms and data collection covering cell therapy including CAR-T (Cell Therapy Minimal Essential Data-A). BMT services across England already subscribe data to European Blood Marrow Transplant via BSBMTCT for patients that have consented to this. Utilising an established and credible existing registry will ensure good quality data and access. There may be additional requirements to be added to Cell Therapy Minimal Essential Data-A depending on regulatory requirements.
7.2.10	**Transition** All healthcare services are required to deliver developmentally appropriate healthcare to patients and families. Children and young people with ongoing healthcare needs may present direct to adult services or may be required to transition into adult services from children's services. Transition is defined as a 'purposeful and planned process of supporting young people to move from children's to adults' services. Poor planning of transition and transfer can result in a loss in continuity of treatment, patients being lost to follow up, patient disengagement, poor self-management and inequitable health outcomes for young people. It is therefore crucial that adult and children's NHS services, in line with what they are responsible for, plan, organise and implement transition support and care (for example, holding joint annual review meetings with the child/young person, their family/carers, the children's and adult service). This should ensure that young people are equal partners in planning and decision making and that their preferences and wishes are central throughout transition and transfer. NICE guidelines recommend that planning for transition into adult services should start by age 13-14 at the latest, or as developmentally appropriate and continue until the young person is embedded in adult services.
7.3	**Clinical Networks** Cancer Alliances bring together clinical and managerial leaders from different hospital trusts and other health and social care organisations, to transform the diagnosis, treatment and care

	for cancer patients in their local area. These partnerships enable care to be more effectively planned across local cancer pathways. CAR-T centres are expected to engage with their local cancer alliance**.**
7.4	**Essential Staff Groups** Clinical decision making about individual patient treatment (assessment prior to treatment preparation, initiation and complications management) will be made by specialist MDTs operating at CAR-T providers (and where appropriate, with support from the relevant National Clinical CAR-T Panel where needed). MDTs must operate in line with NICE Improving Outcomes Guidance (IOG) for haematological cancer recommendations for MDTs https://www.nice.org.uk/guidance/ng47/chapter/Recommendations. The primary clinicians overseeing the planned CAR-T pathway will include transplant physicians / immunotherapy leads. Other named specialists for pharmacy, critical care, neurology support and nursing will be part of the MDT available 24/7 to manage the planned and unplanned needs of CAR-T patients. Psychology input into the MDT will also be required given the nature of the treatment, the need for high levels of patient awareness of symptoms and the side effects profile. A multidisciplinary collaborative approach to CAR-T therapy delivery is required, albeit the primary clinicians for the delivery of this CAR-T therapy (a cell infusion procedure) will be consultants (haematologists / haemato-oncologists) and their teams. Teams with appropriate training and competency in caring for the relevant age and disease group and providing cellular therapies according to quality managed policies and procedures are required. Support from the relevant disease-specific clinical teams will be essential. The core CAR-T Team will include expertise in allogeneic stem cell transplantation / haematology with disease specific expertise as required, immunotherapy / age appropriate ITU / nursing / psychology / pharmacy / laboratory. The extended team would also include expertise in neurology/neurophysiology, +/- neurosurgery, cardiology, renal, infectious disease etc as required. It is also advisable to have palliative care input into all cases as patients may require this before, during and after CAR-T infusion. Training, competencies, policies and procedures are defined as accredited and certified under the FACT-JACIE standards that were current and included the Immune Effector Cell therapy standards. Commissioned providers must maintain full active FACT-JACIE certification. FACT-

	JACIE recertification against the standards occurs every four years. Commissioners will seek evidence from both the Trust and JACIE to establish the circumstances of those awaiting recertification. The selected providers will need to demonstrate age-appropriate, disease-specific expertise and experience, training and competency in treating patients with the toxicities associated with the treatment (e.g. multi-organ failure managed in an age appropriate ITU) and immediate access to diagnostic and management interventions which are matched to the toxicity profile associated with CAR-T therapy. All children and young people receiving CAR-T therapy must be treated within designated Children and Young People (CYP) providers with full access to age-appropriate care as defined in the model of care for Teenage and Young Adults with cancer and the service specifications for cancer services for Children and for Teenagers and Young Adults. Commissioned providers for individual CAR-T therapies will ensure that CYP will have access to CAR-T therapies for which they are eligible within the licence.
7.5	**Essential equipment and/or facilities**
7.5.1	**Product manufacture and delivery** This and relevant commercially confidential information is included in the contract between the manufacturer and the commissioned provider.
7.5.2	**Service requirements for product receipt, storage, and preparation** Manufacturer responsibilities for delivery of the CAR-T product are set out in the relevant commercial agreement with the NHS Trust and / or NHS England. Receipt of the CAR-T product will be to the pharmacy or a pharmacy-approved location and recorded in line with regulatory requirements. The commissioned provider will follow the manufacturer's instructions for storage and preparation of the product, including any aseptic manipulation for infusion. The optimal location for storage would be established by each organisation. Preparation of the product should be undertaken in line with the current Specialist Pharmacy Service guidance and SmPC, 'Gene Therapy Medicinal Products Governance and Preparation

	Requirements' https://www.sps.nhs.uk/wp-content/uploads/2024/02/PAN-UK-PWG-for-ATMPs-Gene-Therapy-Guidance-V3.pdf. Where this is not a pharmacy, the procedures used should have pharmacy oversight. Where this is outsourced to a different legal organisation, a technical agreement should be in place. All staff involved in handling CAR-T products will be trained in the following areas and confirmation will be required from the manufacturer and provider: • Final product unpacking, storage, preparation, thawing and infusion • Monitoring the product temperature at the time of receipt • Traceability • Identification and reporting of product complaints
7.6	**Interdependent Service Components – Links with other NHS services** • Chemotherapy - B15/S/a Cancer: Chemotherapy (Adult) https://www.england.nhs.uk/wp-content/uploads/2013/06/b15-cancr-chemoth.pdf • Chemotherapy (children, teenagers and young adults) https://www.england.nhs.uk/wp-content/uploads/2018/08/Cancer-chemotherapy-child-teenager-and-young-adult.pdf • Adult Critical Care - 170118S - Adult Critical Care https://www.england.nhs.uk/wp-content/uploads/2019/05/Adult-Critical-Care-Service-Specification-FINAL.pdf • Haematopoietic stem cell transplantation (adult) https://www.england.nhs.uk/wp-content/uploads/2018/08/Haematopoietic-stem-cell-transplantation-adult.pdf • Haematopoietic stem cell transplantation (children) https://www.england.nhs.uk/wp-content/uploads/2018/08/Haematopoietic-stem-cell-transplantation-children.pdf • Children's and Teenager and Young Adults Cancer specifications https://www.england.nhs.uk/wp-content/uploads/2018/08/Cancer-services-for-teenager-and-young-adults-1.pdf
7.7	**Additional requirements**
7.7.1	**NICE guidance** NICE produces technology appraisal guidance which NHS England has a statutory requirement to fund. The following NICE guidance has been published on CAR-T therapies:

	• Axicabtagene ciloleucel for treating diffuse large B-cell lymphoma and primary mediastinal large B-cell lymphoma after 2 or more systemic therapies, published February 2023, **https://www.nice.org.uk/guidance/ta872** • Brexucabtagene autoleucel for treating relapsed or refractory mantle cell lymphoma, published February 2021, **https://www.nice.org.uk/guidance/ta677** • Brexucabtagene autoleucel for treating relapsed or refractory B-cell acute lymphoblastic leukaemia in people 26 years and over, published June 2023, **https://www.nice.org.uk/guidance/ta893** • Axicabtagene ciloleucel for treating relapsed or refractory follicular lymphoma, published June 2023, **https://www.nice.org.uk/guidance/ta894** • Axicabtagene ciloleucel for treating relapsed or refractory diffuse large B-cell lymphoma after first-line chemoimmunotherapy, published June 2023, **https://www.nice.org.uk/guidance/ta895** • Tisagenlecleucel for treating relapsed or refractory B-cell acute lymphoblastic leukaemia in people 25 years and under, published May 2024**,** **https://www.nice.org.uk/guidance/ta975** • Lisocabtagene maraleucel for treating relapsed or refractory large B-cell lymphoma after first-line chemoimmunotherapy when a stem cell transplant is suitable, published March 2025 **https://www.nice.org.uk/guidance/ta1048** • Obecabtagene autoleucel for treating relapsed or refractory B-cell precursor acute lymphoblastic leukaemia, published December 2025 **https://www.nice.org.uk/guidance/ta1116**
7.7.2	**Summary of medicinal product characteristics** The following list includes all licensed CAR-T products and signposts to their SmPC: • Tisagenlecleucel https://www.medicines.org.uk/emc/product/9456 • Axicabtagene ciloleucel https://www.medicines.org.uk/emc/product/9439 • Brexucabtagene autoleucel https://www.medicines.org.uk/emc/product/11987 • Lisocabtagene maraleucel https://www.medicines.org.uk/emc/product/100499/smpc • Obecabtagene autoleucel https://www.medicines.org.uk/emc/product/100818/smpc
7.7.3	**Applicable Obligatory National Standards**

	All commissioned providers must meet the standards and be FACT-JACIE certified for age-appropriate delivery of allogeneic HSCT, including standards covering immune effector cell therapy. Over the next 4 years, all cellular therapy providers are expected to complete recertification against the latest edition (or equivalent) of the standards. Commissioned providers for adult patients must meet the mandatory requirements set out in NHS England's draft service specifications for Adult Critical Care (ACC) and HSCT (Adult). CAR-T commissioned providers for children and young adult patients must meet the mandatory requirements set out in NHS England's service specifications for Paediatric Critical Care and HSCT (Children). All providers must hold HTA licenses as well as follow the current version of the FACT-JACIE International Standards for Haematopoietic Cellular Therapy Product Collection, Processing, and Administration. These can be found here: https://www.ebmt.org/jacie/jacie-standards
7.8	**Commissioned providers** A full list of centres commissioned to provide CAR-T are available at https://www.england.nhs.uk/commissioning/spec-services/advanced-therapy-medicinal-products/car-t-therapy/
7.9	**Links to other key documents** Please refer to the Prescribed Specialised Services Manual for information on how the services covered by this specification are commissioned and contracted for. Please refer to the Identification Rules tool for information on how the activity associated with the service is identified and paid for.