

Paediatric BMT

1. Please can you confirm if there are separate units / beds allocated for delivery of CAR-T therapy and BMT or if both services are provided in the same unit / beds

Please note that we do not provide a paediatric CAR-T service.

2. Please can you provide details for the following units in your centre used to deliver CAR-T and BMT therapies, as of Dec 2022?

	Inpatient units	High dependency unit	Intensive care unit
Total number of beds in unit	17	6	18
Number of beds allocated / ring fenced for <u>CART patients only</u>	N/A	N/A	N/A
Number of beds allocated / ring fenced for <u>BMT patients only</u>	6	0	0
Nurse: patient ratio in your centre	1:2/1:3	1:2	1:1
Average number of days per CAR-T patient	N/A	N/A	N/A
Average number of days per BMT patient (for BMTs January – mid-December 2022)	median 58, mean 65	At times, HDU level patients may be treated on non-HDU designated wards, and non-HDU patients may be treated on HDU. We are unable to provide accurate response to this without an extensive audit of casenotes	0

3. Please provide the number of all patients that received a CAR-T therapy or bone marrow transplant (BMT) in the below periods in your centre.

	2018	2019	2020	2021	2022
Number of chairs available for leukapheresis We have 4 beds on the unit but none are specifically for leukapheresis, we allocate slots based on availability and patient need.					
Number of leukapheresis procedures conducted per year					
Number of leukapheresis procedures conducted for <u>CAR-T patients only</u> per year (if available)	0	0	0	0	0
Number of leukapheresis procedures conducted for <u>BMT patients only</u> per year (if available)	*	*	*	*	*
Number of hospital beds available for the administration of CAR-T and BMT patients in your centre.	6 BMT 0 CAR-T	6 BMT 0 CAR-T	6 BMT 0 CAR-T	6 BMT 0 CAR-T	6 BMT 0 CAR-T
Number of patients that received a BMT over the period (allogeneic SCT)	33	33	30	30	26 (up to 21/12/22)
Number of patients that received a BMT over the period (autologous SCT)	*	*	*	*	* (up to 21/12/22)
Number of patients that received a commercial CAR-T infusion over the period	0	0	0	0	0

Please note: Where the figures are between 1 and 5, this has been denoted by *. Due to the low numbers, we have considered that there is the potential for individuals to be identified from the information provided, when considered with other information that may also be in the public domain. In our view disclosure of these low figures would breach one of the Data Protection Principles set out in Schedule 1 of the Data Protection Act, namely Principle 1.

The Trust therefore finds that the Section 40(2) exemption contained within the Freedom of information Act 2000 is engaged. (Section 40 is the exemption for personal information).

4. Please provide information on the multidisciplinary team who are involved in any aspect of the treatment pathway for delivering BMT or CAR-T therapies. If the breakdown by type of professional is not available, please provide some aggregate data / ratios of the different members of the BMT and CAR-T team at your centre

	Total number of staff involved in BMT delivery only	Total number of staff involved in CART therapy delivery only	Total number of staff involved both in the delivery of BMT and CART therapy	For staff involved across BMT and CART, what % time is only devoted to CART
Consultant Haematologist (including research staff and fellows)	2 Paediatric BMT consultants (3 rd position vacant until March 2023) 1 Paediatric BMT Associate Specialist	0	0	N/A
Clinical Specialist Nurse	2	0	0	N/A
Ward nurses	Staffing Should be 8RCN's in the day and 6 RCN's at Night. For the whole paediatric Haem/Onc/BMT Ward.	0	0	N/A
Pharmacist	3 pharmacists covering Paediatric Haem/Onc BMT	0	0	N/A
Apheresis nurse	Apheresis is provided by	Apheresis is provided	Apheresis is provided	N/A

	NHSBT	by NHSBT	by NHSBT	
Intensivist consultant	0	0	0	N/A
Stem cell lab consultant/specialist	Provided by NHSBT	Provided by NHSBT	Provided by NHSBT	N/A
Any other roles essential for delivery of CART and/or BMT like administrators or quality managers (please list)				
BMT/CAR-T Admin Coordinators	1	0	0	N/A
BMT/CAR-T Data Manager	1	0	0	N/A
Quality Manager (covers adult CAR-T, Paed and Adult BMT, Paed Haematology and Oncology)	0	0	1	N/A

5. Please provide details of unit (per hour) costs for the above roles or NHS salary bands for each of the above roles. If there are specific codes for these roles already available within Personal Social Services Research Units (PSSRU) publications, please provide details of the cost codes that should be applied to these roles. If these resources are available / published already, please provide a link to the specific website or publication where these details can be found.

	Unit cost per hour	Any specific cost code for this role (either NHS or PSSRU)?	NHS Salary band
Consultant Haematologist (including research staff and			

fellows)			
Clinical Specialist Nurse	Refer to NHS salary band		7
Ward nurses	Refer to NHS salary band		5/6
Pharmacist	Refer to NHS salary band		7/8a/8b
Apheresis nurse	Apheresis is provided by NHSBT	Apheresis is provided by NHSBT	Apheresis is provided by NHSBT
Intensivist consultant			
Stem cell lab consultant/specialist	Provided by NHSBT	Provided by NHSBT	Provided by NHSBT
Any other roles essential for delivery of CART and/or BMT like administrators or quality managers (please list)			
BMT/CAR-T Admin Coordinator	Refer to NHS salary band		5
BMT/CAR-T Data Manager	Refer to NHS salary band		5
Quality Manager	Refer to NHS salary band		6

6. The below table lists seven resource categories included in the National CART tariff, as described by NHS England as part of ongoing NICE appraisal for axicabtagene ciloleucel (axi-cel) for treating relapsed or refractory diffuse large B-cell lymphoma after 1 systemic treatment [ID1684; [click here for link to NICE website](#)].

Please can you provide details of the types of setting in which the care would be administered, and the staff required (please refer back to roles listed under question 3) to deliver this service, and the average number of hours they will spend per patient receiving a CAR-T or a BMT, per treatment cycle.

Steps involved in CAR-T delivery	Setting where the care is delivered. Please specify if this is more than one setting (e.g., some days in a regular inpatient bed and others in an ICU)	Number of days / admission (if applicable). Please specify if this is more than one setting (e.g., some days in a regular inpatient bed and others in an ICU))	Staff member and number of hours needed per CAR-T patient
Identification and Workup	N/A	N/A	N/A
Leukapheresis	N/A	N/A	N/A
Pre-conditioning	N/A	N/A	N/A
Inpatient admission up to discharge	N/A	N/A	N/A
Early follow up close to treatment centre	N/A	N/A	N/A
Adverse events up to discharge	N/A	N/A	N/A
Follow up post discharge	N/A	N/A	N/A

Steps involved in BMT Delivery	Setting where the care is delivered. If more than one setting (e.g. some days in a regular i/p bed and others in an ICU) please specify this)	Number of days / admission (if applicable). Please specify if this is more than one setting (e.g., some days in a regular inpatient bed and others in an ICU))	Staff member and number of hours needed per patient
Identification and Workup	Outpatient visits to hospital / virtual appointments		This is not information it is possible to provide
Leukapheresis	Apheresis unit at BHOC, provided by NHSBT		This is not information it is possible to provide
Pre-conditioning			This is not information it is possible to provide
Inpatient admission	Inpatient ward		This is not information it is possible to provide
Early follow up close to treatment centre until they can be sent back home or to their local treating hospital	Charity accommodation		This is not information it is possible to provide
Adverse events up to discharge	Inpatient ward		This is not information it is possible to provide

Follow up post discharge			This is not information it is possible to provide
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7. For each of the seven Resource Categories included in the National CART tariff, please provide details of the number and types of planned laboratory tests, along with unit costs and references. Please provide these details per patient receiving either a CAR-T therapy or a BMT. If there is an existing protocol / SOP providing these details, please can you share the document

	Type of planned laboratory tests per patient	Number of tests needed per patient	Unit cost per test	Source/ References
Per CAR-T patient				
Identification and Workup	N/A	N/A	N/A	
Leukapheresis	N/A	N/A	N/A	
Pre-conditioning	N/A	N/A	N/A	
Inpatient admission	N/A	N/A	N/A	
Early follow up close to treatment centre until they can be sent back home or to their local treating hospital	N/A	N/A	N/A	
Adverse events up to discharge	N/A	N/A	N/A	
Follow up post discharge to day 100	N/A	N/A	N/A	

Per BMT patient				
Identification and Workup	Please see the attached SOP.	Please see the attached SOP.	We do not hold this information	
Leukapheresis	Please see the attached SOP.	Please see the attached SOP.	We do not hold this information	
Pre-conditioning	Please see the attached SOP.	Please see the attached SOP.	We do not hold this information	
Inpatient admission	Please see the attached SOP.	Please see the attached SOP.	We do not hold this information	
Early follow up close to treatment centre until they can be sent back home or to their local treating hospital	Please see the attached SOP.	Please see the attached SOP.	We do not hold this information	
Adverse events up to discharge	Please see the attached SOP.	Please see the attached SOP.	We do not hold this information	
Follow up post discharge to day 100	Please see the attached SOP.	Please see the attached SOP.	We do not hold this information	

8. Please provide details of the number and types of planned clinical or physical assessments, along with unit costs and references, included in the below Resource Categories. Please provide these details per patient receiving either a CAR-T therapy or a BMT. If there is an existing protocol / SOP providing these details, please can you share the document

	Types of planned	Number of assessments	Unit cost per	Source/
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	assessments per patient	needed per patient	assessment	References
Per CAR-T patient				
Identification and Workup	N/A	N/A	N/A	
Leukapheresis	N/A	N/A	N/A	
Pre- conditioning	N/A	N/A	N/A	
Inpatient admission	N/A	N/A	N/A	
Early follow up close to treatment centre until they can be sent back home or to their local treating hospital	N/A	N/A	N/A	
Adverse events up to discharge	N/A	N/A	N/A	
Follow up post discharge to day 100	N/A	N/A	N/A	
Per BMT patient				
Identification and Workup	Please see the attached SOP.	Please see the attached SOP.	We do not hold this information	
Leukapheresis	Please see the attached SOP.	Please see the attached SOP.	We do not hold this information	
Pre-	Please see the	Please see the	We do not	

conditioning	attached SOP.	attached SOP.	hold this information	
Inpatient admission	Please see the attached SOP.	Please see the attached SOP.	We do not hold this information	
Early follow up close to treatment centre until they can be sent back home or to their local treating hospital	Please see the attached SOP.	Please see the attached SOP.	We do not hold this information	
Adverse events up to discharge	Please see the attached SOP.	Please see the attached SOP.	We do not hold this information	
Follow up post discharge	Please see the attached SOP.	Please see the attached SOP.	We do not hold this information	

9. Please provide hospital episode data showing length of stay for all patients receiving a CAR-T therapy and BMT during the period Jan 2018 to Dec 2021. If hospital episode data is stored in any other format, please can you provide those details

	CAR-T therapies	BMT
Number of patients	N/A	140
Total number of patients needing inpatient care of 0 - 14 days	N/A	0
Total number of patients needing inpatient care of 15 - 30 days	N/A	10

Total number of patients needing inpatient care of >30 days	N/A	130
Minimum number of inpatient days recorded for any patient	N/A	18
Maximum number of inpatient days recorded for any patient	N/A	221

10. Please provide details of the number of patients that experienced an AE, the types of Adverse Events reported by 5% or more of all patients and the frequency of each AE, the grades and severity of each of these AEs, and the treatment strategies employed to treat each of these AEs. Please provide these data for all patients receiving a CAR-T therapy or BMT

AEs in patients receiving CAR-T	Number of patients that had a Grade 1 or 2 adverse event	Number of patients that had a Grade 3 or above adverse event	Treatment (please provide details of any drugs, procedures, assessments)
(please list AEs, add as many rows as needed)	N/A	N/A	N/A
	N/A	N/A	N/A
	N/A	N/A	N/A
	N/A	N/A	N/A

AEs in patients receiving BMT	Number of patients that had a Grade 1 or 2 adverse event	Number of patients that had a Grade 3 or above adverse event	Treatment (please provide details of any drugs, procedures, assessments)

(please list AEs, add as many rows as needed)	N/A	N/A	N/A
	N/A	N/A	N/A
	N/A	N/A	N/A
	N/A	N/A	N/A