

Adult BMT/CAR-T

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

Delivered on the same ward

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	25		
Number of beds allocated / ring fenced for <u>CART patients only</u>	Not ring-fenced as such, but there are 25 beds on D703 where CAR-T pts are admitted – numbers permitted on the unit are discussed at the weekly planning meetings and will be dependent on several factors. This includes where the patient is on the inpatient pathway, acuity across the ward, staffing & conditioning regime		
Number of beds allocated / ring fenced for <u>BMT patients only</u>	As above for BMT	NA	
Nurse: patient ratio in your centre	BMT - 1:2 Haematology - 1:4 Oncology - 1:5 TYA - 1:2.5 (we have x5 TYA beds, looked after by x2 RNs) Across level 6 (TYA and D603) therefore, they		

	<p>effectively work to a 1:4 ratio.</p> <p>Of course, this is flexible. Sometimes patient acuity will mean that there can be more patients per nurse.</p> <p>CAR-T patients when they are pre-ITU will need 1:1 care for short periods (hence the need to maintain staffing levels to meet this need when it arises).</p>		
Average number of days per CAR-T patient	22	It is not possible to provide accurate numbers for this.	7
Average number of days per BMT patient	median 21, mean 25 (for BMTs January to mid-December 2022)	It is not possible to provide accurate numbers for this.	median 4, mean 11

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	0	14	16	41	32

year					
Number of leukapheresis procedures conducted for <u>CAR-T patients only</u> per year (if available)	*	12	22	38	33 (up to 21/12/2022)
Number of leukapheresis procedures conducted for <u>BMT patients only</u> per year (if available)	0	0	0	0	9
Number of hospital beds available for the administration of CAR-T and BMT patients in your centre.					
Number of patients that received a BMT over the period (allogeneic SCT)	49	43	57	49	39 (up to 21/12/22)
Number of patients that received a BMT over the period (autologous SCT)	43	54	33	35	39 (up to 21/12/22)
Number of patients that received a commercial CAR-T infusion over the period	0	9	14	27	26 (up to 21/12/22)

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	Total number of staff involved in CART therapy delivery	Total number of staff involved both in the delivery of BMT and	For staff involved across BMT and CART, what % time is only
--	--	---	--	---

	only	only	CART therapy	devoted to CART
Consultant Haematologist (including research staff and fellows)		0	3	This is not information it is possible to provide
Clinical Specialist Nurse	0	0	4	This is not information it is possible to provide
Ward nurses		0		This is not information it is possible to provide
Pharmacist	0	0	4	This is not information it is possible to provide
Apheresis nurse	Apheresis is provided by NHSBT	Apheresis is provided by NHSBT	Apheresis is provided by NHSBT	Apheresis is provided by NHSBT
Intensivist consultant		0		This is not information it is possible to provide
Stem cell lab consultant/specialist	Provided by NHSBT	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 Coordinators	0	0	3	This is not information it is possible to provide
BMT/CAR-T Data Manager	1	1	0	N/A
Quality Manager	0	0	1	This is not information it is possible to provide

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		6/7
Ward nurses	Refer to NHS salary band		5/6/7
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 Coordinators	Refer to NHS salary band		4
BMT/CAR-T Data Managers	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	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	Staff member and number of hours needed per CAR-T patient

	ICU)	ICU))	
Identification and Workup	Outpatient visits to hospital / virtual appointments	1 day initial consultation 1 day outpatient visit for work up	This is not information it is possible to provide
Leukapheresis	Apheresis unit at BHOC, provided by NHSBT	1 day	This is not information it is possible to provide
Pre-conditioning	Inpatient ward	5-6 days	This is not information it is possible to provide
Inpatient admission up to discharge	Inpatient ward	Approx 3-4 weeks	This is not information it is possible to provide
Early follow up close to treatment centre	Near hospital accommodation / outpatient clinics	Up to 28 days post CAR-T	This is not information it is possible to provide
Adverse events up to discharge	Acute assessment unit / outpatient clinics	Varied	This is not information it is possible to provide
Follow up post discharge	Outpatient visit / virtual appointments	Unable to quantify – follow-up required for 15 years	This is not information it is possible to provide

Steps involved in	Setting where the care is	Number of days / admission (if	Staff member and number of
-------------------	---------------------------	--------------------------------	----------------------------

BMT Delivery	delivered. If more than one setting (e.g. some days in a regular i/p bed and others in an ICU) please specify this)	applicable). Please specify if this is more than one setting (e.g., some days in a regular inpatient bed and others in an ICU))	hours needed per patient
Identification and Workup	Outpatient visits to hospital / virtual appointments	1 day initial consultation Up to 4-5 days for work up investigations	This is not information it is possible to provide
Leukapheresis	Apheresis unit at BHOC, provided by NHSBT	2 day (for autologous BMT patients or stem cell donors only)	This is not information it is possible to provide
Pre-conditioning	Inpatient ward	Up to 7 days	This is not information it is possible to provide
Inpatient admission	Inpatient ward	Approx 3-5 weeks	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	Near hospital accommodation / outpatient clinics	Up to 100 days post BMT	This is not information it is possible to provide
Adverse events up to discharge	Acute assessment unit / outpatient clinics	Varied	This is not information it is possible to provide
Follow up post discharge	Outpatient visit / virtual appointments	Unable to quantify, lifelong follow-up	This is not information it is possible to

		required	provide
--	--	----------	---------

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	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	Please see the attached	We do not hold this	

	SOP.	SOP.	information	
Follow up post discharge to day 100	Please see the attached SOP.	Please see the attached SOP.	We do not hold this information	
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 assessments per patient	Number of assessments needed per patient	Unit cost per assessment	Source/References
Per CAR-T 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	
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	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	50	363
Total number of patients needing inpatient care of 0 - 14 days	0	9
Total number of patients needing inpatient care of 15 - 30 days	45	293
Total number of patients needing inpatient care of >30 days	*	61
Minimum number of inpatient days recorded for any patient	18	14
Maximum number of inpatient days recorded for any patient	60	161

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).

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

Please note, the Trust does not hold the data in a format that would enable us to fully respond to your request to the level of detail required and a manual trawl for this information would significantly exceed the 18 hours limit set down by the FOI as the reasonable limit. Section 12 of the FOIA provides that we are not obliged to spend in excess of 18 hours in any sixty-day period locating, retrieving and identifying information in order to deal with a request for information and therefore we are withholding this information at this time.

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)			

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)			