
Medical Assessment of CAR-T Patients

Lead Organisation: iMATCH

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Medical Assessment of CAR-T Patients

Patient addressograph:		Height cms:	Weight kgs:
Name:	Number:	Date:	
Address:	DOB:		
		PO number LYM number: NCCP: Date to panel:	

MEDICAL ASSESSMENT:					
Review of Systems: Please tick Yes/No where appropriate					
	Yes	No		Yes	No
Fever/sweats			Fits / Faints / Falls / Paresthesia		
Chest pain/palpitations			Back pain / joint pain		
SOB/Cough / Wheeze / Sputum / Haemoptysis			Hyperviscosity/ hyperleucostasis		
Adbo pain / N+V / Hematemesis			Bleeding / bruising		
Change in bowel habit / Malaena			Smoker/day		
Urinary symptoms?			Alcoholunit/week		
Headache/visual problems					
Pre Cart biopsy date:			Pre CART PET scan date :		
Details					
Disease History:					
Diagnosis, treatment and remission status:					
Previous History: if yes provide details					
	Yes	No		Yes	No
Cardiac or circulatory disease			General Anaesthetic		
Respiratory disease			Hepatitis, HIV, syphilis		
Diabetes Mellitus			Piercing / Tattoos last 3 months		
Acupuncture (past 3 months non-UK or by an unqualified practitioner)			Travel outside of Europe in the last year		
Any implantable medical devices			Malaria risk		
Jaundice					

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Document Name: Medical Assessment for CAR-T Patients		Version: 11
Index Number: APH-65		Author:
Effective Date: December 2024	Review Date: See Q Pulse	Page: 1 of 4



Details:				
Medication:				
			Allergies:	
			Previous G-CSF/cytokine?	
Patient Acknowledgement:				
The information documented on this medical assessment is true and complete to the best of my knowledge.				
Full name.....Signature.....Date.....				
General Examination:				
Pulse:	Temp:	BP:	RR:	SaO ₂ :
CVS:	RS:	Abdo:		
CNS:	Musculoskeletal:	Liver/spleen:		

Washout criteria guidance			
3 days	since since short acting cytotoxic therapy	<input type="checkbox"/> Yes	<input type="checkbox"/> No
5 days	Since short acting growth	<input type="checkbox"/> Yes	<input type="checkbox"/> No
7 days	Since steroids? IT Methotrexate or lenolidamide	<input type="checkbox"/> Yes	<input type="checkbox"/> No
14 days	Since systemic chemotherapy GVHD therapies Long-acting growth factors TKI therapy Blinatumomab, Immune modulatory therapy including checkpoint inhibitors Radiotherapy	<input type="checkbox"/> Yes	<input type="checkbox"/> No
4 weeks	Since Peg asparaginase Donor Lymphocytes Antibody therapy including CD20 specific treatments (rituximab, inotuzumab)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
8 weeks	Since clofarabine T cell Lytic agents (Alemtuzumb)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
12 weeks	Has the patient received Fludarabine Allogeneic transplant?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Other	Bendamustine treatment > 12 weeks Alemtuzumab + ATG >6 months	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Other	Tecartus only: Stop systemic therapies 2 weeks or 5 half-lives (whichever is shorter)	<input type="checkbox"/> Yes	<input type="checkbox"/> No

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Document Name: Medical Assessment for CAR-T Patients		Version: 11
Index Number: APH-65		Author:
Effective Date: December 2024	Review Date: See Q Pulse	Page: 2 of 4



Clinician to tick to confirm results have been reviewed as stated above:		
FBC	Yes <input type="checkbox"/>	
Urine dipstick analysis if indicated	Yes <input type="checkbox"/>	N/A <input type="checkbox"/>
Blood film (only if indicated)	Yes <input type="checkbox"/>	N/A <input type="checkbox"/>
Clotting screen	Yes <input type="checkbox"/>	
Christie Profile	Yes <input type="checkbox"/>	
Glucose	Yes <input type="checkbox"/>	
Blood group and antibody screen	Yes <input type="checkbox"/>	
Pre-harvest viral serology	Yes <input type="checkbox"/>	
Other serological testing as indicated	Yes <input type="checkbox"/>	N/A <input type="checkbox"/>
ECG	Yes <input type="checkbox"/>	
PA chest X-ray (if indicated)	Yes <input type="checkbox"/>	N/A <input type="checkbox"/>
MRSA screen and eradication (if for BM harvest or femoral line)	Yes <input type="checkbox"/>	N/A <input type="checkbox"/>
Other investigations (viscosity, cardiac, renal etc if indicated):		

Peripheral Venous Access:			
LEFT	GOOD / POOR/femoral	RIGHT	GOOD / POOR/femoral

Medically fit to donate? : Yes No	Signature: _____	Name: _____
	Date: _____	Time: _____
Written and verbal information given regarding the risks of HPC donation? : Yes No		

FINAL ASSESSMENT: (to be conducted by collection facility medical director or designee)

Passed final assessment?: Yes No	Signature: _____	Name: _____
Reason for Failure:	Date: _____	Time: _____

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Document Name: Medical Assessment for CAR-T Patients	Version: 11
Index Number: APH-65	Author:
Effective Date: December 2024	Review Date: See Q Pulse
	Page: 3 of 4



Cellular Therapy collection prescription and request for product processing – to be completed by the clinician and sent with product

Please arrange collection for _____

Patient likely to require central venous catheter?: Yes No

Product

- Kymriah (NOVARTIS) Tecartus (GILEAD)
- Yescarta (GILEAD) Other (please state):
- Trial (please specify)

Specific product requirements if stated

Number of collections allowed: 1 2

TBV to be processed *if stated*

Maximum or minimum collect volume *if stated*

Concurrent plasma to be collected: Standard Into product Not required

Cells to be transported: Fresh Cryopreserved

Target collection Dose *if stated*: CD3+____ TNC:____ MNC:____

FOR Kymriah/ tisagenlecleucel collect requirements

Optimal collect range of 1.5 - 4 x10⁹ CD3 cells but ideally greater than 2 and minimum for acceptance of 1
Greater than or equal to 2 x10⁹ TNC
At least 3% of TNC being CD3+ cells

Any other specific collection requirements:

Clinicians Signature: _____	Name: _____	Date: _____
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Document Name: Medical Assessment for CAR-T Patients	Version: 11
Index Number: APH-65	Author:
Effective Date: December 2024	Review Date: See Q Pulse
	Page: 4 of 4