

# Eligibility assessment for Axicel (Yescarta) CAR-T therapy: 3<sup>rd</sup> line LBCL

Age 18+ *or* post-pubescent (off licence)



## Diagnosis:

- DLBCL
- PMBL
- Transformed FL/MZL/CLL/NLPHL **to DLBCL**
- PTLD, DLBCL type (EBV neg or pos)
- FL grade 3B

AND  
Previously treated with at least three cycles of a full-dose anthracycline containing regimen (e.g. CHOP) *or* at least three cycles on MARIETTA protocol (e.g. 3xMATRIX)

AND  
Previously treated with at least one anti-CD20 antibody (e.g. ritux/obinu) unless demonstrated to have CD20 negative disease

AND  
If previously treated with CD19 directed therapy, is demonstrated to still have CD19 positive disease at the point of referral for CAR-T

AND  
Has not previously been treated with genetically modified T-cell therapy, except in an abandoned dosing cohort in a first in human dose-escalation phase I clinical trial

## Biopsy:

- Re-biopsy at first relapse confirmed DLBCL or PMBCL and the patient has progressive disease at the same site *or*
- Re-biopsy at second relapse has confirmed DLBL or PMBCL *or*
- Re-biopsy at first or second relapse was/is unsafe plus there is progressive disease at previously documented sites of active disease and the previous histology was DLBCL or PMBCL *or*
- Re-biopsy at second relapse has again confirmed transformed lymphoma (TFL, MZL, CLL, NLPHL) to DLBCL *or*
- Re-biopsy at second relapse has again confirmed PTLD of DLBCL type *or*
- Re-biopsy at second relapse has again confirmed FL grade 3B



## Clinical Scenario:

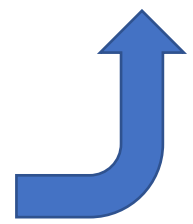
- Has DLBCL and received 2 or more lines of systemic therapy and relapsed after or was refractory to the last line of systemic therapy *or*
- Had DLBCL with CNS involvement at first diagnosis and treated with first line systemic therapy (eg Marietta protocol) **followed by stem cell transplantation** as part of first line therapy and has relapsed after or was refractory to this first line of systemic therapy *or*
- Has PMBCL and received 2 or more lines of systemic therapy and relapsed after or was refractory to the last line of systemic therapy *or*
- Has transformed lymphoma to DLBCL (TFL, MZL, CLL, NLPHL) and received 2 or more lines of systemic therapy since diagnosis of transformation and relapsed after or was refractory to the last line of systemic therapy *or*
- Has transformed lymphoma to DLBCL (TFL, MZL, NLPHL), received an anthracycline-containing regimen before transformation, and after transformation then received 1 or more lines of systemic therapy and relapsed after or was refractory to the last line of systemic therapy *or*
- Has PTLD of DLBCL type and received 2 or more lines of systemic therapy since diagnosis of PTLD of DLBCL type and relapsed after or was refractory to the last line of systemic therapy *or*
- Has FL grade 3B and received 2 or more lines of systemic therapy and relapsed after or was refractory to the last line of systemic therapy



## CNS disease:

- Has no known CNS involvement *or*
- Has both CNS and systemic disease

Note: patients with current **isolated** CNS involvement are not eligible



Apheresis

NCCP

UHS Lymphoma MDT

## Performance status and organ function

- Has ECOG performance status of 0 or 1, accounting for pre-existing or disease-related neurodisability.
- Has sufficient end organ function to tolerate treatment with CAR-T cell therapy

- *Refractory disease is defined as either progressive disease as the best response to the last line of systemic therapy or stable disease as the best response after **at least 2 cycles** of the last line of therapy with stable disease duration lasting no longer than 6 months from the last dose of the last line of systemic therapy.*
- *Relapsed disease is defined as disease that responded partially or completely to the last line of therapy and has since progressed.*
- *Progressive disease should be defined radiologically as per RECIST version 1.1 and be based on CT or MR scans and aided if necessary, after discussion at the NCCP, with the use of Lugano lymphoma response criteria.*
- *Second line treatment regimens which are appropriate include: R-GDP, R-GemOx, R-GemCarbo, R-ESHAP, R-ICE, R-IVE, R-IVAC, R-BendaPola and the Marietta protocol (e.g. 3xMATRIX).*
- *Neither radiotherapy nor steroids can be counted as a line of therapy*

Eligibility assessment based on Cancer Drugs Fund List, as online 2<sup>nd</sup> February 2023.  
<https://www.england.nhs.uk/publication/national-cancer-drugs-fund-list/>