

LARGE B-CELL LYMPHOMA: ELIGIBILITY CRITERIA FOR CAR T-CELL THERAPY (SECOND LINE)

PATIENT HAS THE FOLLOWING DIAGNOSIS:

- Diffuse large B-cell lymphoma (DLBCL)
- High grade B-cell lymphoma
- Large B-cell lymphoma arising from follicular lymphoma or other indolent non-Hodgkin lymphoma (*with the exception of CLL/SLL*)
- Primary mediastinal large B-cell lymphoma (PMBCL)
- Follicular large B-cell lymphoma (previously known as follicular lymphoma, Grade 3B)

Applications that do not satisfy all eligibility criteria are subject to additional review. This may extend the turnaround time to a funding decision.

PATIENT MUST MEET THE FOLLOWING CRITERIA: *Note: It is the referring physician's responsibility to ensure all criteria are met at the time of CAR T-cell therapy assessment.

- Patient must be ≥ 18 years of age
- Histological confirmation of diagnosis
- Patient must be eligible for autologous stem cell transplant
 - Patients <70 years of age must have an ECOG of 2 or less
 - Patients 70 years of age or older must have an ECOG of 0-1
- **Refractory to first line chemoimmunotherapy**
 - Progressive disease while on first line therapy, OR
 - Stable disease after 3 or more cycles of chemotherapy for aggressive lymphoma, OR
 - Partial response with biopsy proven residual disease as best response after at least 6 cycles of chemotherapy for aggressive lymphoma

OR

- **Relapsed disease within 12 months of completion of chemotherapy for aggressive lymphoma**
 - Relapse is defined as biopsy proven aggressive lymphoma within the stated timeframe
- Patient must be off PD1/PDL1 inhibitor treatment for at least 6 weeks prior to expected CAR T-cell therapy infusion
- Patient is sufficiently stable to travel out of province (if needed), to tolerate the wait between leukapheresis and CAR T-cell infusion, and to return to BC for bridging therapy if required.
- Patients must have adequate organ function. The ranges below are a guide for CAR T-cell therapy.
 - Creatinine ≤ 141.44 $\mu\text{mol/L}$ and estimated glomerular filtration rate (eGFR) $\geq 45\text{ml/min/1.73m}^2$
 - ALT or AST $\leq 3\text{x}$ upper limit of normal, Bilirubin $\leq 2\text{x}$ upper limit of normal
 - Left ventricle ejection fraction (LVEF) $\geq 40\%$ confirmed by echocardiogram or MUGA
 - No recent myocardial infarction or cardiac stenting within 6 months
 - Oxygen saturation $\geq 91\%$ on room air
 - Absolute lymphocyte count (ALC) $> 0.1 \times 10^9/\text{L}$ ($100/\text{mm}^3$). Note: If ALC is below $0.1 \times 10^9/\text{L}$, application can be considered; but for apheresis to proceed, ALC must be at least $0.1 \times 10^9/\text{L}$

Exclusion Criteria

- Prior treatment with CD19 CAR T-cell therapy
- Primary CNS lymphoma
- Pregnancy
- Acute life threatening bacterial, viral (active/uncontrolled Hepatitis B, C or HIV*) or fungal infection

**In the setting of controlled HIV, some CAR T-cell products may be considered on a case-by-case basis; certain CAR T-cell products remain contraindicated as per manufacturer's labeling.*

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