Large B-Cell Lymphoma (Second Line): CAR T-cell Therapy Eligibility Criteria

PATIENT HAS THE FOLLOWING DIAGNOSIS:

- Diffuse large B-cell lymphoma (DLBCL)
- High grade B-cell lymphoma (HGBL)
- 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)

Diagnoses NOT specifically included in the health Canada approved product monographs are not eligible for consideration.

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

- Eligible frontline chemotherapy regimens must contain a rituximab or equivalent and an anthracycline (or etoposide if an anthracycline is not appropriate)
- 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 µmol/L and estimated glomerular filtration rate (eGFR) ≥ 45ml/min/1.73m²
  - ALT or AST ≤ 3x upper limit of normal, Bilirubin ≤ 2x upper limit of normal

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- Left ventricle ejection fraction (LVEF) ≥ 40% confirmed by echocardiogram or MUGA
- No recent myocardial infarction or cardiac stenting within 6 months
- Oxygen saturation ≥ 91% on room air
- Absolute lymphocyte count (ALC) > 0.1 $x10^9$/L (100/mm^3). Note: If ALC is below 0.1 $x10^9$/L, application can be considered; but for apheresis to proceed, ALC must be at least 0.1 $x10^9$/L

EXCLUSION CRITERIA:

- Prior treatment with CD19 CAR T-cell therapy
- Primary CNS lymphoma, Richter's transformation, Burkitt lymphoma
- Pregnancy
- Acute life threatening bacterial, viral (active/uncontrolled Hepatitis B, C or HIV*) or fungal infection
- Graft versus host disease on systemic therapy
- Active malignancy other than lymphoma
- Uncontrolled/untreated CNS involvement

**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.*