

FOLLICULAR (& MARGINAL ZONE LYMPHOMA) CAR T-CELL THERAPY ELIGIBILITY CRITERIA

PATIENT HAS THE FOLLOWING DIAGNOSIS:

- Follicular lymphoma, Grade 1, 2 or 3a
- Marginal zone lymphoma (MZL)

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

Switching to CAR T-cell therapy in a third or subsequent line of therapy will not be funded if the patient is receiving, responding to (i.e. no disease progression) and tolerating the therapy.

THE 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
- Relapsed or refractory after two or more lines of systemic therapy with prior regimens that included an anti-CD20 monoclonal antibody combined with an alkylating agent-containing chemotherapy regimen (e.g. bendamustine-rituximab, R-CHOP).
- Histological confirmation of diagnosis
- Patient must be off PD1/PDL1 inhibitor treatment for at least 6 weeks prior to expected CAR T-cell therapy infusion
- ECOG performance status ≤ 2
- 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 $\leq 141.44 \mu\text{mol/L}$ and estimated glomerular filtration rate (eGFR) $\geq 45\text{ml/min/1.73m}^2$
- ALT and AST $\leq 3\text{x}$ upper limit of normal
- Total bilirubin $\leq 2\text{x}$ upper limit of normal
- Left ventricle ejection fraction (LVEF) $\geq 40\%$ confirmed by echocardiogram or MUGA
- 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 involvement
- Active graft versus host disease (following prior allogeneic stem cell transplant).
- Received autologous stem cell transplant within 6 weeks of planned axicabtagene ciloleucel infusion.
- 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.*