

## Mantle Cell Lymphoma (MCL) CAR T-cell Eligibility Criteria (≥ 18)

**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.**

Mantle cell lymphoma that is pathologically confirmed, with documentation of either overexpression of cyclin D1 or presence of t(11;14).

### **THE PATIENT MUST MEET THE FOLLOWING CRITERIA:**

**\*Note: It is the referring physician's responsibility to ensure all criteria is met at the time of CAR T-cell therapy assessment**

- Patient must be ≥ 18 years of age
- Relapsed or refractory disease, after 2 or more, and up to 5, prior regimens that included an anthracycline or bendamustine-containing chemotherapy, an antiCD20 monoclonal antibody therapy and a Bruton's tyrosine kinase (BTK) inhibitor.
- ECOG performance status ≤2
- 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, to tolerate the wait between leukapheresis and CAR T-cell infusion, and to return to BC for bridging therapy if required.
- Recommendation for CAR T-cell therapy obtained from the Provincial Lymphoma Conference.

Patients must have adequate organ function. The ranges below are a guide for CAR T-cell therapy.

- Serum creatinine ≤ 141.44 umol/L
- ALT and AST ≤ 3X ULN
- Total bilirubin ≤ 2X ULN
- Left ventricular ejection fraction (LVEF) >40% confirmed by echocardiogram or MUGA
- SaO<sub>2</sub> >91% on room air
- Absolute lymphocyte count (ALC) > 0.1 x10<sup>9</sup>/L (100/mm<sup>3</sup>). Note: If ALC is below 0.1 x10<sup>9</sup>/L, application can be considered; but for apheresis to proceed, ALC must be at least 0.1 x10<sup>9</sup>/L

### **Exclusion Criteria**

- Prior treatment with CD19 CAR T-cell therapy, adoptive T-cell immunotherapy or allogeneic stem cell transplant.
- Active CNS involvement
- 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.*