Mantle Cell Lymphoma (≥ 18): CAR T-cell Therapy Eligibility Criteria

PATIENT HAS THE FOLLOWING DIAGNOSIS:

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

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 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.
- 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
    - SaO2 >91% on room air
    - Absolute lymphocyte count (ALC) > 0.1 x109/L (100/mm3). 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
- 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.*