

## Acute Lymphoblastic Leukemia (ALL) CAR T-cell Eligibility Criteria - Pediatric/Young Adult (≤ 25 years)

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

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

### TREATMENT HISTORY

Patient has CD19+ B-cell acute lymphoblastic leukemia and is one of the following:

- refractory to therapy
- relapsed after allogeneic stem cell transplant (CAR-T infusion must be at least 4 months from time of SCT and 6 weeks post DLI)
- ineligible for SCT (comorbid disease, other contraindications, lack of suitable donor, prior SCT, declines SCT as a therapeutic option)
- has experienced second or later relapse
- Patient is up to and including 25 years of age
- Patient is sufficiently stable to travel out of province/country, to tolerate the wait between leukapheresis and CAR T-cell infusion therapy and to return to BC for bridging if required
- Karnofsky Performance Score  $\geq 50\%$  or ECOG  $\leq 2$

### ORGAN FUNCTION

Patients must have adequate organ function. The ranges below are a guide for your patient to qualify 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 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
- 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  $0.1 \times 10^9$

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### EXCLUSION CRITERIA

- Active CNS involvement is defined as CNS-3 per National Comprehensive Cancer Network (patients with history of CNS disease that has been effectively treated will be eligible).
- Pregnancy
- Active/uncontrolled Hepatitis B, C and HIV\*
- Active grade 2-4 GVHD
- Ongoing immunosuppression to treat GVHD
- Patients with concomitant genetic syndrome leading to bone marrow failure (i.e. Fanconi anemia, Kostmann syndrome, Shwachman or other known inherited bone marrow failure syndromes). Patients with Down Syndrome will not be excluded.
- Patients with Burkitt's lymphoma/leukemia (i.e. patients with mature B-cell ALL, leukemia with B-cell [slg positive and kappa or lambda restricted positivity] ALL, with FAB L3 morphology and/or a MYC translocation).
- Active malignancy other than B-cell ALL
- Treatment with any prior commercial CD19 directed CAR T-cell therapy (does not apply in select circumstances of re-infusion of a previously manufactured CAR T-cell product).

\*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