

Acute Lymphoblastic Leukemia (ALL) CAR-T Eligibility Criteria

<p>Treatment History & Prognosis</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Patient has CD19+ B-cell acute lymphoblastic leukemia (ALL) and is one of the following: <ul style="list-style-type: none"> a. refractory b. has relapsed after allogeneic stem cell transplant (<i>CAR-T infusion must be at least 4 months from time of SCT</i>) c. has experienced second or later relapse d. Ineligible for allogeneic SCT because of: <ul style="list-style-type: none"> • Comorbid disease • Other contraindications to allogeneic SCT conditioning regimen • Lack of suitable donor • Prior SCT • Declines allogeneic SCT as a therapeutic option after documented discussion about the role of SCT with a BMT physician not part of the study team <input type="checkbox"/> Patient is 18 to 25 years inclusive <input type="checkbox"/> Patient is clinically stable and expected to remain so through to the planned CAR T-cell infusion date. Patient is expected to tolerate the therapy based on organ function criteria summarized below. <input type="checkbox"/> Karnofsky Performance Score (KPS) \geq 50% <input type="checkbox"/> Patients with Ph+ ALL are eligible if they are intolerant to or have failed two lines of TKI therapy, or if TKI therapy is contraindicated
<p>*Organ Function</p>	<p>Patients must have adequate organ function and sufficient T cells to allow a successful apheresis. The ranges below are a guide for your patient to qualify for CAR-T*. Patients not fulfilling specific criteria can still be considered on a case-by-case basis. Please discuss with transplant team.</p> <p>Renal function:</p> <ul style="list-style-type: none"> • A serum creatinine \leq 150.31 $\mu\text{mol/L}$ • ALT \leq 5 times the ULN for age <p>Liver function:</p> <ul style="list-style-type: none"> • Bilirubin $<$ 2.0 mg/dl <p>Pulmonary function:</p> <ul style="list-style-type: none"> • Pulse oxygenation $>$ 91% on room air <p>Cardiac function:</p> <ul style="list-style-type: none"> • LVSF \geq 28% confirmed by echocardiogram • Left ventricle ejection fraction (LVEF) \geq 45% confirmed by echocardiogram or Multigated Radionuclide Angiography (MUGA) <p>Lymphocyte count:</p> <ul style="list-style-type: none"> • 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 $0.1 \times 10^9/\text{L}$



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**Exclusion
Criteria**

There are no formal contraindications to the product.

Possible exclusion criteria:

- Active CNS involvement, defined as CNS-3 per NCCN guidelines. Note: Patients with history of CNS disease that has been effectively treated will be eligible.
- Active uncontrolled Hepatitis B, Hepatitis C or HIV infection
- Active uncontrolled GVHD with need for ongoing immunosuppression
- Prior treatment with genetically engineered T cell product