

Field Name	Field Description
Prior Authorization Group Description	<b>Anti-CD19 CAR-T Immunotherapies</b>
Drugs	Kymriah (tisagenlecleucel), Yescarta (axicabtagene ciloleucel), Tecartus (brexucabtagene autoleucel), Breyanzi (lisocabtagene maraleucel)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Patients with primary central nervous system lymphoma
Required Medical Information	See “Other Criteria”
Age Restrictions	See “Other Criteria”
Prescriber Restrictions	Prescriber must be an oncologist, hematologist or <del>other prescribers who specialize in the treatment of lymphoma.</del> <b><u>other appropriate specialist</u></b>
Coverage Duration	If all the criteria are met, the initial request will be approved for a one – time infusion per lifetime.
Other Criteria	<p><b><u>**Drug is being requested through the member’s medical benefit**</u></b></p> <p><b><u>Initial authorization:</u></b></p> <ul style="list-style-type: none"> <li>• Patient must not have received prior anti-CD19 CAR-T therapy.</li> <li>• Patient will be screened for HBV, HCV, and HIV in accordance with clinical guidelines.</li> <li>• Patient does not have an active infection or inflammatory disorder.</li> <li>• Patient has a life expectancy &gt;12 weeks.</li> <li>• Patient will not receive live virus vaccines for at least 6 weeks prior to the start of lymphodepleting chemotherapy and until immune recovery following treatment.</li> <li>• <b><u>Use is supported by a labeled indication or NCCN guidelines</u></b></li> </ul> <p><b><u>Leukemia</u></b></p> <p><b>B-cell precursor Acute Lymphoblastic Leukemia (ALL):</b></p> <ul style="list-style-type: none"> <li>• If the request is for Kymriah <ul style="list-style-type: none"> <li>○ Patient is 25 years of age or younger</li> <li>⊖ ALL that is refractory or in second or later relapse defined by: <ul style="list-style-type: none"> <li>⊖ <del>Second or greater bone marrow (BM) relapse or</del></li> </ul> </li> </ul> </li> </ul>

- ⊖ Any BM relapse after allogeneic stem cell transplant (alloSCT) and greater than or equal to 6 months from SCT at the time of tisagenlecleucel infusion or
- ⊖ Primary refractory, defined as not achieving complete remission (CR) after 2 cycles of a standard chemotherapy regimen, or chemorefractory, defined as not achieving CR after 1 cycle of standard chemotherapy for relapsed leukemia or
- ⊖ Philadelphia chromosome positive ALL intolerant of or with 2 failed lines of tyrosine kinase inhibitor (TKI) therapy or if TKI therapy is contraindicated or
- ⊖ Ineligible for alloSCT due to comorbid disease, contraindications to alloSCT conditioning regimen, lack of a suitable donor, prior SCT, or declined alloSCT after documented discussion about the role of SCT with a physician
- If the request is for Tecartus
  - Patient is 18 years of age or older
  - ALL that is relapsed or refractory
    - Primary refractory disease or
    - First relapse if first remission  $\leq$  12 months or
    - Relapsed or refractory disease after 2 or more lines of systemic therapy or
    - Relapsed or refractory disease after alloSCT, provided patient is at least 100 days from SCT at the time of brexucabtagene infusion

#### **Chronic Lymphocytic Leukemia (CLL):**

- **If the request is for Breyanzi**
  - **Patient is 18 years of age or older**
  - **Patient has relapsed/refractory disease defined as failure of two or more lines of therapy, including a Bruton tyrosine kinase (BTK) inhibitor AND a B-cell lymphoma 2 (BCL-2) inhibitor**

#### **Non-Hodgkin's Lymphoma (NHL)**

##### **Follicular Lymphoma (FL):**

- **If the request is for Breyanzi, Kymriah, or Yescarta:**
  - **Patient is 18 years of age or older**
  - **Patient has relapsed/refractory disease defined as failure of two or more lines of systemic therapy**

Revision/Review  
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**Large B-cell Lymphoma (LBCL), Diffuse Large B-cell Lymphoma (DLBCL) not otherwise specified, primary mediastinal high grade B-cell lymphoma, follicular lymphoma grade 3B, and DLBCL arising from follicular lymphoma:**

- **If the request is for Breyanzi, Kymriah, or Yescarta**
  - **Patient is 18 years of age or older**
  - **For Breyanzi ONE of the following:**
    - **Patient is refractory to first-line chemoimmunotherapy or relapsed within 12 months of first-line chemoimmunotherapy**
    - **Patient is refractory to first-line chemoimmunotherapy or relapsed after first-line chemoimmunotherapy and is not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age**
    - **Patient has failed two or more lines of systemic therapy**
  - **For Kymriah: Patient has relapsed/refractory disease defined as failure of two or more lines of systemic therapy**
  - **For Yescarta ONE of the following:**
    - **Patient is refractory to first-line chemoimmunotherapy or relapses within 12 months of first-line chemoimmunotherapy or**
    - **Patient has failed two or more lines of systemic therapy**

**Mantle Cell Lymphoma (MCL):**

- **If the request is for Tecartus:**
  - Patient is 18 years of age or older
  - Patient has relapsed/refractory disease defined as failure of BOTH the following lines of therapy:
    - Chemoimmunotherapy such as an anti-CD20 monoclonal antibody (e.g. Rituxan) + any chemotherapeutic agent
    - Bruton Tyrosine Kinase (BTK) Inhibitor (e.g. Calquence, Imbruvica, Brukinsa)

**Small Lymphocytic Lymphoma (SLL):**

- **If the request is for Breyanzi**
  - **Patient is 18 years of age or older**

- **Patient has received at least 2 prior lines of therapy including, a Bruton tyrosine kinase (BTK) inhibitor and a B-cell lymphoma 2 (BCL-2) inhibitor**

**Other forms of NHL:**

- If the request is for Breyanzi (lisocabtagene maraleucel), Kymriah (tisagenlecleucel), Yescarta (axicabtagene ciloleucel)
  - Use is supported by a labeled indication or NCCN guidelines
  - Patient is 18 years of age or older
  - For Breyanzi: One of the following:
    - Patient is refractory to first line chemoimmunotherapy or relapses within 12 months of first line chemoimmunotherapy
    - Patient is refractory to first line chemoimmunotherapy or relapses after first line chemoimmunotherapy and is not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age
    - Patient has failed two or more lines of systemic therapy
  - For Kymriah: Patient has relapsed/refractory disease defined as failure of two or more lines of systemic therapy
  - For Yescarta: Patient refractory to first line chemoimmunotherapy or relapses within 12 months of first line chemoimmunotherapy OR has failed two or more lines of systemic therapy

**Re-authorization:**

- Treatment exceeding 1 dose per lifetime will not be authorized.

**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**