

Field Name	Field Description
Prior Authorization Group Description	Anti-CD19 CAR-T Immunotherapies
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 other prescribers who specialize in the treatment of blood cancers.
Coverage Duration	If all the criteria are met, the initial request will be approved for a one – time infusion per lifetime.
Other Criteria	<p><u>Initial authorization:</u></p> <ul style="list-style-type: none"> • Patient must not have received prior anti-CD19 CAR-T therapy. • Patient will be screened for HBV, HCV, and HIV in accordance with clinical guidelines. • Patient does not have an active infection or inflammatory disorder. • 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. <p><u>Leukemia</u></p> <p>B-cell precursor Acute Lymphoblastic Leukemia (ALL):</p> <ul style="list-style-type: none"> • If the request is for Kymriah <ul style="list-style-type: none"> ○ Patient is 25 years of age or younger ○ ALL that is refractory or in second or later relapse • If the request is for Tecartus <ul style="list-style-type: none"> ○ Patient is 18 years of age or older ○ ALL that is relapsed or refractory <p><u>Non-Hodgkin’s Lymphoma (NHL)</u></p> <p>Mantle Cell Lymphoma (MCL):</p> <ul style="list-style-type: none"> • If the request is for Tecartus: <ul style="list-style-type: none"> ○ Patient is 18 years of age or older ○ Patient has relapsed/refractory disease defined as failure of BOTH the following lines of therapy:

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- Chemoimmunotherapy such as an anti-CD20 monoclonal antibody (e.g. Rituxan) + any chemotherapeutic agent
- Bruton Tyrosine Kinase (BTK) Inhibitor (e.g. Calquence, Imbruvica, Brukinsa)

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.