

| Field Name | Field Description |
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| Prior Authorization Group Description | Anti-CD19 CAR-T Immunotherapies |
| Drugs | Kymriah (tisagenlecleucel), Yescarta (axicabtagene ciloleucel), Tecartus (brexucabtagene autoleucel), Breyanzi (lisocabtagene maraleucel), Aucatzyl (obecabtagene autoleucel) |
| 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 appropriate specialist . |
| Coverage Duration | <p>If all the criteria are met, the initial request will be approved for a single treatment regimen per lifetime.</p> <ul style="list-style-type: none"> • Kymriah, Yescarta, Tecartus, Breyanzi :a one-time infusion • Aucatzyl: a split-dose infusion administered on day 1 and day 10 (\pm 2 days) |
| 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. • Use is supported by a labeled indication or NCCN guidelines <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 or Aucatzyl <ul style="list-style-type: none"> ○ Patient is 18 years of age or older ○ ALL that is relapsed or refractory |

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

Large B-cell Lymphoma (LBCL), Diffuse Large B-cell Lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, follicular lymphoma grade 3B, and DLBCL arising from follicular lymphoma or indolent 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 relapsed or refractory disease after 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

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| <p>Revision/Review Date: 4/2025</p> | <p>Mantle Cell Lymphoma (MCL):</p> <ul style="list-style-type: none">• Patient is 18 years of age or older• If the request is for Tecartus:<ul style="list-style-type: none">○ Patient has relapsed/refractory disease defined as failure of BOTH the following:<ul style="list-style-type: none">▪ Chemoimmunotherapy such as an anti-CD20 monoclonal antibody (e.g. Rituxan) + any chemotherapeutic agent▪ Bruton Tyrosine Kinase (BTK) Inhibitor (e.g. Calquence, Imbruvica, Brukinsa)• If the request is for Breynazi:<ul style="list-style-type: none">○ Patient has relapsed or refractory disease who have received at least 2 prior lines of systemic therapy, including a BTK inhibitor <p>Small Lymphocytic Lymphoma (SLL):</p> <ul style="list-style-type: none">• If the request is for Breyanzi<ul style="list-style-type: none">○ 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 <p><u>Re-authorization:</u></p> <ul style="list-style-type: none">• Treatment exceeding 1 single treatment regimen per lifetime will not be authorized.<ul style="list-style-type: none">○ Kymriah, Yescarta, Tecartus, Breyanzi :a one-time infusion○ Aucatzyl: a split-dose infusion administered on day 1 and day 10 (± 2 days) <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p> |
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