

SENTARA HEALTH PLANS

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request. All other information may be filled in by office staff; **fax to 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed.**

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Drug Requested: **Kymriah[®]** (tisagenlecleucel) (Q2040) (Medical)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ Length of Therapy: _____

Diagnosis: _____ ICD Code, if applicable: _____

Weight: _____ Date: _____

Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

A. Quantity Limit (max daily dose) – Pharmacy Benefit: N/A

B. Max Units (per dose and over time) – Medical Benefit:

B-Cell Precursor Acute Lymphoblastic Leukemia (ALL):

- 1 billable unit (1 infusion of up to 250 million car positive viable t-cells)

Large B-Cell Lymphoma:

- 3 billable units (1 infusion of up to 600 million car positive viable t-cells)
- NDC: I infusion bag (10-50mL) 00078-0846-xx

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CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Approval Criteria – Coverage cannot be renewed

- Member does **NOT** have an active infection or inflammatory disorder

AND

- Member has **NOT** received live vaccines within 2 weeks prior to the start of lymphodepleting chemotherapy and will not receive live vaccines until immune recovery following Kymriah treatment

AND

- Member has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to collection of cells (leukapheresis)

AND

- Prophylaxis for infection has been followed according to local guidelines

AND

- Healthcare facility has enrolled in the Kymriah REMS and training has been given to providers on the management of cytokine release syndrome (CRS) and neurological toxicities

AND

- Member has **NOT** received prior CAR-T therapy

AND

- Member has **NOT** received prior blinatumomab therapy

AND

- Member has CD19-positive disease

AND

- Medication will be used as single agent therapy (not applicable to lymphodepleting or bridging chemotherapy)

AND

- Member has a life expectancy > 12 weeks

Diagnosis: B-Cell Precursor Acute Lymphoblastic Leukemia (ALL) †‡

- Member is between the ages of 3 to 25 years old

AND

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- Member's disease is refractory or in second or later relapse as defined by **ONE** of the following:
 - Second or greater bone marrow (BM) relapse
 - Any BM relapse after allogeneic stem cell transplantation (SCT)
 - Member's disease is primary refractory (not achieving a complete response after 2 cycles of standard chemotherapy) or chemorefractory (not achieving a complete response after 1 cycle of standard chemotherapy for relapsed disease)
 - Members with Philadelphia chromosome (Ph)-positive disease have a contraindication, intolerance, or have failed two prior lines of tyrosine kinase inhibitor (TKI) therapy (e.g., imatinib, dasatinib, ponatinib)
 - Member is **NOT** eligible for allogeneic SCT

AND

- Member has a performance status (Karnofsky/Lansky) ≥ 50

Diagnosis: Large B-Cell Lymphoma †‡

- Member is 18 years of age or older

AND

- Member has **ONE** of the following aggressive B-cell non-Hodgkin lymphomas:
 - Diffuse large B-cell lymphoma (DLBCL) not otherwise specified
 - High grade B-cell lymphoma
 - DLBCL arising from follicular lymphoma (TFL)

AND

- Member's disease is relapsed or refractory, after two or more lines of systemic therapy, which included an anthracycline and an anti-CD20 monoclonal antibody (e.g., rituximab) [unless tumor is CD20-negative], and is defined as **ONE** of the following:
 - Relapse after autologous hematopoietic stem cell transplantation (HSCT)
 - Refractory disease to the most recent therapy

AND

- Member has an ECOG performance status of 0-1

AND

- Member does **NOT** have primary central nervous system lymphoma

Diagnosis: Follicular Lymphoma †‡

- Member is 18 years of age or older

AND

- Member has a diagnosis of Grade 1-2 follicular lymphoma

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AND

- Disease is relapsed, refractory, or progressive after two (2) or more prior lines of therapy

† FDA Approved Indication(s); ‡ Compendium Recommended Indication(s)

Reauthorization Criteria – Coverage cannot be renewed

Medication being provided by (check box below that applies):

- Location/site of drug administration: _____
NPI or DEA # of administering location: _____

OR

- Specialty Pharmacy - PropriumRx

For urgent reviews: Practitioner should call Sentara Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health Plan's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****