SENTARA COMMUNITY PLAN
(MEDICAID)

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 1-844-305-2331**. 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**.

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

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❑ Diagnosis: Follicular Lymphoma †‡

- ❑ Member is 18 years of age or older

AND

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

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 Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health'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.****