

# OPTIMA HEALTH PLAN

## PHARMACY 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 1-844-348-3720. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. Incomplete form will delay authorization process.

**Drug Requested:**                      **Kymriah™** (tisagenlecleucel) (J9999/Q2040)                      **(Medical)**

**DRUG INFORMATION:** Complete information below. If incomplete, authorization process will be delayed.

Drug Form/Strength/Quantity: \_\_\_\_\_

Dosing Schedule: \_\_\_\_\_ Length of Therapy: \_\_\_\_\_

Diagnosis: \_\_\_\_\_ ICD Code: \_\_\_\_\_

**RECOMMENDED DOSAGE:**

- NDC: I infusion bag (10-50mL) 00078-0846-xx
- Coverage will be provided for one treatment course (approval for 1 dose of Kymriah only) and may not be renewed.
- 1 infusion (up to 250 million CAR-positive viable T-cells) of Kymriah only
- **Exclusion Criteria** (attach supportive documentation):
  - No active infection or inflammatory disorder
  - Within 2 weeks no live vaccines were administered prior to start of lymphodepleting chemotherapy and will not receive live vaccines until immune recovery following Kymriah

**CLINICAL CRITERIA:** All boxes that apply must be checked. Incomplete information will delay the authorization process. Documentation **MUST** be attached to this request form.

**Initial Approval Criteria (ALL of the following criteria MUST be met):**

- The healthcare facility providing treatment is enrolled in the Kymriah™ REMS program and training has been given to providers on the management of cytokine release syndrome (CRS) and neurological toxicities

**AND**

- Member has a diagnosis of B-cell precursor Acute Lymphoblastic Leukemia

**AND**

- Member is aged 3 to 25 years of age

**AND**

- Member has CD19-positive disease (***MUST attach labs/documentation***)

**AND**

- Kymriah™ is being used as single-agent therapy (not applicable to lymphodepleting or bridging chemotherapy)

**AND**

- Member's disease is refractory or in second or later relapse defined as **ONE** of the following (***documentation MUST be submitted***):
  - Member has history of second or greater bone marrow (BM) relapse
  - Member has history of BM relapse after allogeneic stem cell transplantation (SCT)
  - Member 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)
  - Member has Philadelphia chromosome (Ph) positive disease and a contraindication, intolerance to, or failure of two prior lines of tyrosine kinase inhibitor (TKI) therapies (e.g., imatinib, dasatinib, ponatinib, etc.)

**AND** *(continued on next page)*

- Member is not eligible for allogeneic SCT (*must* send supporting documentation; Complete Remission Minimal Residual Disease negative < 10e-2)

**AND**

- Member has a life expectancy > 12 weeks

**AND**

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

**AND**

- Member has not received prior CAR-T therapy

**Medication being provided by (check applicable box below):**

- Location/site of drug administration: \_\_\_\_\_

NPI or DEA # of administering location: \_\_\_\_\_

**OR**

- Specialty Pharmacy - PropriumRx

**\*\*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.\***

Patient Name: \_\_\_\_\_

Member Optima #: \_\_\_\_\_ Date of Birth: \_\_\_\_\_

Prescriber Name: \_\_\_\_\_

Prescriber Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Office Contact Name: \_\_\_\_\_

Phone Number: \_\_\_\_\_ Fax Number: \_\_\_\_\_

DEA OR NPI #: \_\_\_\_\_

\*Approved by Pharmacy and Therapeutics Committee: 11/16/2017  
REVISED/UPDATED: 3/28/2018; 5/25/2018