

**OPTIMA HEALTH COMMUNITY CARE
AND
OPTIMA FAMILY CARE
(MEDICAID)**

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 1-844-723-2094.** 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 or authorization 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

(continued on next page)

- 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

- 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 #: _____