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 1-844-202-5034. 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 INFORMATON: 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 was 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 chemotherapy0 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):

❑ **Physician's office** **OR** ❑ **Specialty Pharmacy**: **BriovaRx**

*****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