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 1-844-723-2094**. 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: Yescarta™ (tisagenlecleucel) **IV (J9999/Q2041) (Medical)**

DRUG INFORMATON: Complete information below or authorization process will be delayed.

Drug Form/Strength/Quantity: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code**: _____

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

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

- **1 infusion of Yescarta™ only**

NDC: Yescarta™ suspension for intravenous infusion: 1 infusion bag (68mL): 71287-0119-xx

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

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

Coverage is provided in the following conditions:

- ❑ Patient does **not** have a clinically significant active systemic infection or inflammatory disorder; **AND**
- ❑ Patient has not received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy, during Yescarta treatment, and will **not** receive live vaccines until immune recovery following treatment;

  AND
- ❑ Patient 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 Yescarta™ REMS and training has been given to providers on the management of cytokine release syndrome (CRS) and neurological toxicities; AND
- ❑ Patient does not have primary central nervous system lymphoma; **AND**
- ❑ Patient did not receive prior allogeneic hematopoietic stem cell transplantation (HSCT); **AND**

Diagnosis: Large B-Cell Lymphoma †

- ❑ Patient aged 18 years or greater; **AND**
- ❑ Patient has CD19-positive disease; **AND**
- ❑ Used as single agent therapy (not applicable to lymphodepleting or additional chemotherapy while awaiting manufacture); **AND**

(continued on next page)

- ❑ Patient has one of the follow aggressive B-Cell non-Hodgkin lymphomas:
  - ❑ Diffuse large B-cell lymphoma (DLBCL) not otherwise specified; **OR**
  - ❑ Primary mediastinal large B-cell lymphoma (PMBCL); **OR**
  - ❑ High grade B-cell lymphoma; **OR**
  - ❑ DLBCL arising from follicular lymphoma (TFL); **AND**
- ❑ Patient's disease is relapsed or refractory defined as one of the following:
  - ❑ Relapse within 1 year after autologous hematopoietic stem cell transplantation; **OR**
  - ❑ Refractory disease to the most therapy; **AND**
- ❑ Patient **must** have received two or more prior lines of systemic therapy which **must** have included an anthracycline as well as an anti-CD20 monoclonal antibody (unless tumor is CD20-negative); **AND**
- ❑ Patient has an ECOG performance status of 0-1; **AND**
- ❑ Patient has not received prior CAR-T therapy

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

Renewal Criteria – Coverage cannot be renewed

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:** 8/16/2018;
REVISED/UPDATED: 12/30/2018