

OPTIMA HEALTH COMMUNITY CARE (MEDICAID)

MEDICAL/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. **If information provided is NOT complete, correct, or legible, authorization will be delayed.**

Drug Requested: Yescarta™ (tisagenlecleucel) IV (J9999/Q2041) (Medical)

URGENT REVIEW. In checking this box, prescriber attests to the fact that by applying the standard review timeframe may seriously jeopardize the member's life, health, or ability to regain maximum function.

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.

DRUG INFORMATION: Complete **all** information below or authorization will be delayed.

Drug Form/Strength/Quantity: _____

Dosing Schedule: _____ Length of Therapy: _____

Diagnosis: _____ ICD Code: _____

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

• **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: 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 will be denied.

Initial Approval Criteria

Coverage is provided in the following conditions:

Member does **not** have a clinically significant active systemic infection or inflammatory disorder;

AND

Member 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

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);

(Continued on next page)

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†

- Member aged 18 years or greater;

AND

- Member has CD19-positive disease;

AND

- Used as single agent therapy (not applicable to lymphodepleting or additional chemotherapy while awaiting manufacture);

AND

- Member 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;

(Continued on next page; signature **MUST** be attached with form)

(Signature page **MUST** be included with request)

AND

- Member **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

- Member has an ECOG performance status of 0-1;

AND

- Member 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 box below that applies):

- 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.

Member 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 (Reformatted) 4/27/2019; 5/10/2019; 7/26/2019