AvMed

MEDICAL 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 1-877-535-1391**. 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 can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Yescarta® (axicabtagene ciloleucel) IV (Q2041) (Medical)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

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

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

- ❑ 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.

Quantity Limit (max daily dose and over time):

- **Pharmacy Benefit**: N/A
- **Medical Benefit**: 1 infusion of Yescarta® 200 million autologous anti-cd19 CAR-positive viable T- cells only

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 may be denied. **(Trials will be verified using pharmacy claims and/or submitted chart notes.)**

Approval Criteria – Coverage cannot be renewed

(Continued on next page)

- ❑ 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)

AND

- ❑ Prophylaxis for infection has been followed according to local guidelines

AND

- ❑ Healthcare facility has enrolled in the YESCARTA & TECARTUS REMS and training has been given to providers on the management of cytokine release syndrome (CRS) and neurological toxicities

AND

- ❑ Member has **NOT** received prior CAR-T therapy

AND

- ❑ Medication will be used as single agent therapy (not applicable to lymphodepleting or additional chemotherapy while awaiting manufacture)

AND

- ❑ Member did **NOT** receive prior allogeneic hematopoietic stem cell transplantation (HSCT)

AND

- ❑ Member does **NOT** have primary central nervous system lymphoma

AND

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

AND

- ❑ Provider attests to all applicable clinical criteria in the diagnosis section below

❑ Diagnosis: B-Cell Lymphomas †

- ❑ Member is 18 years of age or older

AND

- ❑ Member must meet **ONE** of the following **diagnosis and previous therapy scenarios:**
  - **I.** ❑ Member has a diagnosis of large B-cell lymphoma (LBCL)

(Continued on next page)

AND

- ❑ Member has refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy (e.g., rituximab with dexamethasone, cytarabine, and cisplatin)

OR

- ❑ Member has documented previous therapy with two (2) or more prior lines of chemoimmunotherapy which must have included an anthracycline or anthracenedione-based regimen, unless contraindicated

II. ❑ Member has AIDS-related large B-cell lymphoma (e.g., diffuse large B-cell lymphoma, primary effusion lymphoma, and HHV8-positive diffuse large B-cell lymphoma, not otherwise specified), DLBCL, primary mediastinal large B-cell lymphoma (PMBCL), high grade B-cell lymphoma, or monomorphic posttransplant lymphoproliferative disorder (B-cell type)

AND

- ❑ Medication will be used as additional therapy for members with intention to proceed to transplant who have partial response following second-line therapy for relapsed or refractory disease

OR

- ❑ Medication will be used for treatment of disease that is in second or greater relapse

III. ❑ Member has a diagnosis of Grade 1-2 follicular lymphoma

AND

- ❑ Disease is relapsed, refractory, or progressive after two (2) or more prior lines of therapy

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

Reauthorization 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**

For urgent reviews: Practitioner should call AvMed Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. AvMed's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

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.

***Approved by Pharmacy and Therapeutics Committee:** 8/16/2018;
REVISED/UPDATED: 12/30/2018; (Reformatted) 4/27/2019; 7/8/2019; 9/25/2019; 1/12/2022; 2/23/2022; 3/23/2022; **8/7/2022**