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: Tecartus® (brexucabtagene autoleucel) **IV (Q2053) (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.

A. Quantity Limit (max daily dose) [NDC Unit]:

- 1 infusion of Tecartus® 200 million autologous anti-cd19 CAR -positive viable T cells only

B. Max Units (per dose and over time) [HCPCS Unit]:

- 1 infusion of Tecartus® 200 million autologous anti-cd19 CAR -positive viable T cells only

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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.

Authorization Criteria - Coverage cannot be renewed

- ❑ Member is 18 years of age or older

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 does **NOT** have a clinically significant active systemic infection or inflammatory disorder

AND

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

AND

- ❑ Member has **NOT** received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy, during brexucabtagene autoleucel 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

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

AND

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

AND

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

AND

- ❑ Provider attests to all applicable clinical criteria for at least **ONE** of the diagnoses below:

❑ Mantle Cell Lymphoma

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

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AND

- ❑ Member does **NOT** have central nervous system lymphoma, detectable cerebrospinal fluid malignant cells or brain metastases

AND

- ❑ Member has a confirmed diagnosis of Mantle Cell Lymphoma, determined to be relapsed or refractory

AND

- ❑ Member must have received previous systemic therapy which included at least **ONE** agent from **EACH** of the following categories:
  - ❑ Bruton tyrosine kinase (BTK) inhibitor (e.g., ibrutinib, acalabrutinib, zanubrutinib)
  - ❑ Anti-CD20 monoclonal antibody (e.g., rituximab)
  - ❑ Anthracycline- OR bendamustine-containing chemotherapy

❑ B-Cell Precursor Acute Lymphoblastic Leukemia

- ❑ Member has relapsed or refractory disease

AND

- ❑ **ONE** of the following must be met:
  - ❑ Member has **NOT** received prior anti-CD19 therapy (e.g., blinatumomab)
  - ❑ Member previously received anti-CD19 therapy and re-biopsy indicates CD-19 positive disease

AND

- ❑ Member does **NOT** have CNS-3 disease or CNS-2 disease with neurological changes

AND

- ❑ Member's current disease state satisfies **ONE** of the following:
  - ❑ Member has Philadelphia chromosome (Ph)-positive disease **[MUST be tyrosine kinase inhibitor (TKI) intolerant OR refractory to at least two (2) different TKIs]**
  - ❑ Member has Philadelphia chromosome (Ph)-negative disease

Reauthorization Criteria – Coverage cannot be renewed

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Medication being provided by: Please check applicable box below.

- ❑ **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**: 11/19/2020
REVISED/UPDATED/REFORMATTED: ~~3/15/2021; 2/23/2022; 6/15/2022;~~ **6/21/2022**;