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: Tecelra® (afamitresgene autoleucel) **(C9399/J9999) (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:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

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

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

Weight (if applicable): _____ **Date weight obtained:** _____

❑ 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]:

- A single dose of Tecelra containing a minimum of 2.68×10^9 to a maximum of 10×10^9 of viable cells suspended in one or more patient-specific infusion bags

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

- A single dose of Tecelra containing a minimum of 2.68×10^9 to a maximum of 10×10^9 of viable cells suspended in one or more patient-specific infusion bags

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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.

- ❑ Member is 18 years of age or older
- ❑ Provider is an oncologist and the administrating healthcare facility is trained in the management of cytokine release syndrome (CRS) and neurological toxicities
- ❑ Member has **NOT** received prior CAR-T therapy
- ❑ Member has **NOT** received systemic corticosteroids for at least 14 days prior to leukapheresis and lymphodepletion
- ❑ Member has **NOT** received a prior allogeneic stem cell transplant (or has, but is without evidence of residual donor cells present), and is a candidate for autologous stem cell transplantation (e.g., adequate renal and hepatic function)
- ❑ Member has been screened and found to be negative for Epstein-Barr Virus (EBV), Cytomegalovirus (CMV), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), and any other infectious agents, if clinically indicated
- ❑ Member is HIV negative as confirmed by a HIV test prior to mobilization

  NOTE*:* Patients who have received Tecelra are likely to test false-positive on some commercial HIV nucleic acid tests for HIV due to the lentiviral vector used to make Tecelra having limited, short spans of genetic material which is identical to HIV
- ❑ Member does **NOT** have a left ventricular ejection fraction (LVEF) less than 50%
- ❑ Member does **NOT** have a history of hypersensitivity to dimethyl sulfoxide (DMSO)
- ❑ Member does **NOT** have a clinically significant active systemic infection
- ❑ Member does **NOT** does not have symptomatic brain metastases including leptomeningeal disease
- ❑ Provider will monitor for secondary malignancies periodically after treatment
- ❑ Member has a diagnosis of unresectable or metastatic synovial sarcoma confirmed by the presence of a translocation between SYT on the X chromosome and SSX1, SSX2, or SSX4 on chromosome 18 (may be presented in the pathology report as t (X; 18))
- ❑ Member's condition has been confirmed to express the MAGE-A4 tumor antigen as determined by FDA-approved or cleared companion diagnostic device
- ❑ Member's condition has been confirmed to show positive for the HLA-A*02:01P, HLA-A*02:02P, HLA-A*02:03P, and HLA-A*02:06P allele
- ❑ Member's condition does **NOT** have HLA-A*02:05P in either allele (i.e., heterozygous or homozygous)
- ❑ Member has received one prior line of therapy with an anthracycline (e.g., doxorubicin) or ifosfamide

  NOTE*:* Members who have a contraindication or are intolerant to both anthracycline and ifosfamide must have previously received at least one systemic therapy

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Reauthorization: Coverage cannot be renewed

Medication being provided by: Please check applicable box below.

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy – Proprium Rx**

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.*