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: Kresladi™ (marnetegragene autotemcel) **(C9399/J3590) 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.

Dosing Limits:

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

- Kresladi is supplied in 1 to 2 infusion bags containing 0.34 to 6.1 × 10^6 cells/mL of a frozen suspension of genetically modified autologous cell; each bag contains 30 mL of suspension. **[NDC 83537-034-01]**
- The minimum recommended dose of Kresladi is 2.8 × 10^6 CD34+ cells/kg based on patient's body weight at the time of infusion

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

- One treatment (dose) per lifetime

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.

Coverage will be provided for one treatment course and may NOT be renewed.

- ❑ Member is ≥ 3 months of age
- ❑ Medication is prescribed by a hematologist, immunologist, or a stem cell transplant physician, or in consultation with a physician experienced in treating patients diagnosed with Leukocyte Adhesion Deficiency Type 1
- ❑ Member has **NOT** received any prior gene therapy **(verified by medical paid claims)**
- ❑ According to the prescribing physician, a hematopoietic stem cell transplantation is appropriate for the member (i.e., medical condition is stable and healthy enough to undergo myeloablative conditioning with subsequent autologous gene therapy procedure)
- ❑ Member meets **ONE** of the following:
  - ❑ Member does **NOT** have a Human Leukocyte Antigen (HLA)-matched donor
  - ❑ Member has an HLA-matched donor, but the individual is not able or is not willing to donate
- ❑ Member has a diagnosis of Leukocyte Adhesion Deficiency Type 1 (LAD-1) confirmed by genetic testing recording biallelic variant mutations in the *ITGB2* gene
- ❑ Member's category of LAD-1 is noted to be severe defined by **ONE** of the following:
  - ❑ Flow cytometry indicating CD18+ expression on <2% neutrophils (polymorphonuclear neutrophils (PMNs)) **(submit documentation)**
  - ❑ CD18+ PMNs ≥2%, and further laboratory measurements are performed to record <2% CD11a or CD11b expressing PMNs AND past medical/family history is well documented showing the presence of LAD-1 **(submit documentation)**
- ❑ Member does **NOT** have active metastatic or locoregionally advanced malignancy, including hematologic malignancy, for which survival is anticipated to be less than 3 years **(submit documentation)**
- ❑ Member does **NOT** have serious infections with persistent bloodstream pathogens prior to treatment with Kresladi **(submit documentation)**
- ❑ Member does **NOT** have hepatic dysfunction as defined by either: bilirubin >1.5× the upper limit of normal (ULN) or alanine aminotransferase (ALT) or aspartate aminotransferase (AST) >2.5×ULN **(submit documentation)**
- ❑ Member does **NOT** have renal dysfunction as defined by either Grade 3 or higher abnormalities in serum sodium, potassium, calcium, magnesium or phosphate, or the requirement for either peritoneal dialysis or hemodialysis **(submit documentation)**

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- ❑ Member does **NOT** have Pulmonary dysfunction as defined by either: need for supplemental oxygen (in absence of acute infection), OR oxygen saturation (by pulse oximetry) <90% prior to Kresladi treatment **(submit documentation)**
- ❑ According to the prescribing physician, member meets **ALL** the following:
  - ❑ Member will undergo mobilization, apheresis, and myeloablative conditioning with busulfan
  - ❑ A hematopoietic stem cell mobilizer will be utilized for mobilization [**NOTE**: Filgrastim products are examples of a granulocyte-colony stimulating factor therapy and Mozobil® (plerixafor subcutaneous injection) is an example of a hematopoietic stem cell mobilizer]
- ❑ Prior to collection of cells for manufacturing, member cellular screening is negative for **ALL** the following **(submit documentation)**:
  - ❑ Human immunodeficiency virus-1 and -2
  - ❑ Human T-lymphotrophic virus-1 and -2
- ❑ Member's current body weight has been obtained within 30 days **(submit documentation)**

Medication being provided by: Please check applicable box below.

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

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy**

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 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**: 7/23/2026
REVISED/UPDATED/REFORMATTED: 8/28/2026