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: Waskyra™ (etuvetidigene 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]:

- Waskyra is supplied in 1 to 8 infusion bags containing a frozen suspension of genetically modified autologous cells enriched for CD34+ cells. Each bag contains 10 to 20 mL of suspension. **[NDC]**
- The minimum recommended dose of Waskyra is 7×10^6 CD34+ cells/kg based on patient's body weight at the time of infusion; The maximum volume of to be administered should remain < 20% of the patient's estimated plasma volume

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

- One treatment (dose) per lifetime

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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.

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

- ❑ Member is male [specified gender is defined as follows: males are defined as individuals with the biological traits of a man, regardless of the individual's gender identity or gender expression]
- ❑ Member is ≥ 6 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 Wiskott-Aldrich Syndrome
- ❑ 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 has **NOT** received a prior allogeneic hematopoietic stem cell transplantation within the last 6 months prior to the administration plan for Waskyra treatment showing evidence of residual donor cells **(submit laboratory documentation; verified by medical paid claims)**
- ❑ 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 Wiskott-Aldrich Syndrome confirmed by genetic testing **AND** showing **ONE** of the following:
  - ❑ Severe Wiskott-Aldrich Syndrome (WAS) gene mutation, defined by literature data or genotype/phenotype studies (e.g., c.631C>T (p.Arg211X), c.394_395insA (p.Glu132Argfs*14), c.777+1G>A, c.389G>A (p.Cys130Tyr)) **(submit documentation)**
  - ❑ Absent WAS protein expression, assessed by flow cytometry **(submit documentation)**
  - ❑ Severe clinical score defined by Zhu clinical score ≥ 3 (e.g., treatment-resistant eczema, recurrent infections, autoimmunity, etc.) **(submit documentation; see Appendix A)**
- ❑ Member does **NOT** have a history any cytogenetic alterations characteristic of myelodysplastic syndrome and acute myeloid leukaemia , or other serious hematological disorders **(submit documentation)**
- ❑ According to the prescribing physician, member meets **ALL** the following:
  - ❑ Member will undergo mobilization, apheresis, and myeloablative conditioning with busulfan and fludaribine
  - ❑ 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]
  - ❑ Member will undergo pretreatment with rituximab on Day 22 (±1 day) prior to planned administration of Waskyra™

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- ❑ Prior to collection of cells for manufacturing, member cellular screening is negative for **ALL** the following **(submit documentation)**:
  - ❑ Human immunodeficiency virus-1 and -2
  - ❑ Hepatitis B virus (acute or chronic stable disease)
  - ❑ Hepatitis C virus (presence of positive Hepatitis C RNA test result)
  - ❑ Human T-lymphotrophic virus-1 and -2
- ❑ Member does **NOT** currently display symptomatic herpes zoster that is not responsive to treatment **(submit documentation)**
- ❑ Member does **NOT** currently display evidence of acute tuberculosis **(submit documentation)**
- ❑ Members with reproductive potential will use an effective method of contraception from the start of mobilization through at least 6 months after administration of Waskyra™
- ❑ Member's current body weight has been obtained within 30 days **(submit documentation)**

Appendix A

WAS-Related Disorders: Zhu Clinical Scoring System[1]

Feature					Score	Phenotype
Thrombocytopenia	**Eczema**	**Immunodeficiency**	**Autoimmune disorder**	**Malignancy**		
Absent	Absent	Absent	Absent	Absent	0	XLN / myelodysplasia
Present	Absent	Absent	Absent	Absent	1	XLT
Present	Mild or transient	Infrequent infections	Absent	Absent	2	
Present	Persistent but responsive	Recurrent infections	Absent	Absent	3	Wiskott-Aldrich syndrome
Present	Severe, not controlled	Severe infections	Absent	Absent	4	
Present	Any	Any	Present	Present	5	XLT / Wiskott-Aldrich syndrome w/ autoimmunity &/or malignancy

1. Chandra S, Nagaraj CB, Sun M, et al. WAS-Related Disorders. 2004 Sep 30 [Updated 2026 Feb 26]. In: Adam MP, Bick S, Mirzaa GM, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2026

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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**

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**: 5/28/2026
REVISED/UPDATED/REFORMATTED: 6/15/2026