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: Aucatzyl® (obecabtagene autoleucel) **(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]:

- The total recommended dose of Aucatzyl is 410×10^6 CD19 chimeric antigen receptor (CAR)-positive viable T cells

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

- One treatment (dose) per lifetime.
- Aucatzyl contains a total recommended dose of 410 x 10^6 CD19 CAR-positive viable T cells supplied in 3 to 5 infusion bag.
- The treatment regimen consists of a split dose infusion to be administered on Day 1 and Day 10 (± 2 days). Dose to be administered is determined by the patient bone marrow blast assessment.

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 18 years of age or older
- ❑ Provider is an oncologist and the administrating healthcare facility providers have received training on the management of cytokine release syndrome (CRS) and neurological toxicities
- ❑ Member has **NOT** received prior CAR-T therapy
- ❑ Member must meet **ONE** of the following:
  - ❑ 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
- ❑ Medication will be used as single agent therapy (not applicable to lymphodepleting or additional chemotherapy while awaiting manufacture)
- ❑ 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)
- ❑ Member does **NOT** have a clinically significant active systemic infection or inflammatory disorder
- ❑ Prophylaxis for infection has been followed according to local guidelines
- ❑ Member has **NOT** received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy, during obecabtagene autoleucel treatment, and will **NOT** receive live vaccines until immune recovery following treatment
- ❑ Member has a diagnosis of relapsed or refractory B-Cell Precursor Acute Lymphoblastic Leukemia (ALL)
- ❑ Bone Marrow Blast Percentage has been assessed and the laboratory documentation has been provided to meet **ONE** of the following dose recommendations:
  - ❑ Bone Marrow Blast > 20%: Day 1 infusion with a dose of 10×10^6; Day 10 (±2 days) 100×10^6 Dose and 300×10^6 Dose
  - ❑ Bone Marrow Blast ≤ 20%: Day 1 infusion with a dose of 100×10^6; Day 10 (±2 days) 10×10^6 Dose and 300×10^6 Dose

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- ❑ Member's condition meets **ONE** of the following:
  - ❑ Philadelphia Chromosome (Ph)-Positive disease with prior therapy that includes a tyrosine kinase inhibitor (e.g., bosutinib, dasatinib, imatinib)
  - ❑ Philadelphia Chromosome (Ph)-Negative disease

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**: **1/23/2025**
REVISED/UPDATED/REFORMATTED: 2/18/2025