Reference number(s)
6731-A

Standard Medicare Part B Management Aucatzyl

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Aucatzyl	obecabtagene autoleucel

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

Adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

Compendial Uses[3]

Lymphoblastic lymphoma

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Documentation

The following documentation must be available, upon request, for all submissions:

- Chart notes or medical record documentation demonstrating failure of previous lines of therapy.

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- Testing or analysis confirming CD19 expression on leukemic blasts in the bone marrow, peripheral blood, or cerebrospinal fluid.

Exclusions

Coverage will not be provided for members with any of the following exclusions:

- Age less than 18 years
- Eastern Cooperative Oncology Group (ECOG) performance status greater than or equal to 3 (member is not ambulatory and not capable of all self-care, confined to bed or chair more than 50% of waking hours)
- Inadequate and unstable kidney, liver, pulmonary or cardiac function
- Active hepatitis B, active hepatitis C or any active uncontrolled infection
- Active inflammatory disorder
- History or presence of clinically relevant central nervous system (CNS) pathology
- Active graft versus host disease

Coverage Criteria

Adult Relapsed or Refractory B-cell Precursor Acute Lymphoblastic Leukemia (ALL)/Lymphoblastic Lymphoma (LL)[1-4]

Authorization of 3 months (one split-dose) may be granted for the treatment of relapsed or refractory B-cell precursor ALL/LL when all of the following criteria are met:

- The member has not received a previous treatment course of the requested medication or another CD19-directed chimeric antigen receptor (CAR-T) therapy, or any prior CD19 directed therapy other than blinatumomab.
- The member meets either of the following criteria:
    - Member has Philadelphia chromosome-negative disease that is relapsed or refractory as defined as one of the following:
        - Primary refractory disease
        - First relapse with remission of 12 months or less
        - Relapsed or refractory disease after at least 2 previous lines of systemic therapy
        - Relapsed or refractory disease after allogeneic stem cell transplant (allo-SCT)
    - Member has Philadelphia chromosome-positive disease and meets any of the following:
        - The member has relapsed or refractory disease despite treatment with at least 2 different tyrosine kinase inhibitors (TKIs) (e.g., bosutinib, dasatinib, imatinib, nilotinib, ponatinib) or one line of second-generation TKI
        - The member is intolerant to TKI therapy or TKI therapy is contraindicated

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- Disease is CD19 positive

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Aucatzyl.
- The available compendium
  - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
  - Micromedex DrugDex
  - American Hospital Formulary Service- Drug Information (AHFS-DI)
  - Lexi-Drugs
  - Clinical Pharmacology
- NCCN Guideline: Acute lymphoblastic leukemia
- National Coverage Determination: Chimeric Antigen Receptor (CAR) T-cell Therapy

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Aucatzyl are covered in addition to lymphoblastic lymphoma.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

All FDA-approved indications are covered according to the conditions outlined in National Coverage Determination Manual section 110.24 (Chimeric Antigen Receptor [CAR] T-cell Therapy).

Support for using Aucatzyl to treat lymphoblastic lymphoma can be found in the NCCN clinical practice guidelines in oncology for acute lymphoblastic leukemia. Use of information in the NCCN clinical practice guidelines in oncology for off-label use of drugs and biologics in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

References

1. Aucatzyl [package insert]. Gaithersburg, MD: Autolus Inc.; March 2025.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed June 13, 2025.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Acute Lymphoblastic Leukemia. Version 2.2025. Available at: https://nccn.org. Accessed October 28, 2025.
4. National Coverage Determination (NCD) for Chimeric Antigen Receptor (CAR) T-cell Therapy (110.24-Version 1). https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=344&ncdver=1&DocID=110.22&from2=search.asp&bc=gAAAAAgAAAAA& Accessed June 13, 2025.

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