

DRUG POLICY

Aucatzyl[®] (obecabtagene autoleucel)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Aucatzyl is approved for the treatment of adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

Compendial Uses

Lymphoblastic lymphoma

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

1. Chart notes or medical record documentation demonstrating failure of previous lines of therapy
2. Testing or analysis confirming morphological disease in the bone marrow ($\geq$ 5% blasts)
3. 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

Criteria for Initial Approval

Adult Relapsed or Refractory B-cell precursor Acute Lymphoblastic Leukemia (ALL)/Lymphoblastic Lymphoma (LL)

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

1. 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.
2. The member meets either of the following criteria:
 - A. Member has Philadelphia chromosome-negative disease that is relapsed or refractory as defined as one of the following:
 - i. Primary refractory disease
 - ii. First relapse with remission of 12 months or less
 - iii. Relapsed or refractory disease after at least 2 previous lines of systemic therapy
 - iv. Relapsed or refractory disease after allogeneic stem cell transplant (allo-SCT)
 - B. Member has Philadelphia chromosome-positive disease and meets any of the following:
 - i. 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
 - ii. The member is intolerant to TKI therapy or TKI therapy is contraindicated
3. The member has morphological disease in the bone marrow ($\geq 5\%$ blasts)
4. Disease is CD19 positive

Other

Aucatzyl is considered **not medically necessary** for members who do not meet the criteria set forth above.

Quantity Limits Apply

Aucatzyl approvals will be limited to one treatment course per lifetime.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- Q2058 – Obecabtagene autoleucel, 10 up to 400 million cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per infusion (effective 7/1/2025)
- C9301 – Obecabtagene autoleucel, up to 410 million cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose (cancelled 7/1/2025)

- J3490 – Unclassified drugs
- J3590 – Unclassified biologics
- J9999 – not otherwise classified, antineoplastic drugs
- C9399 – Unclassified drugs or biologics

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.

POLICY HISTORY

Policy #: 05.05.71

Original Effective Date: February 14, 2025

Reviewed: August 2026

Revised: December 2025

Current Effective Date: January 1, 2026