Reference number(s)
6730-A

Specialty Guideline 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

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

All other indications are considered experimental/investigational and not medically necessary.

Documentation

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

- Chart notes, medical record documentation or claims history supporting previous lines of therapy.
- Testing or analysis confirming morphological disease in the bone marrow (≥ 5% blasts).

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)

Authorization of 3 months may be granted for the treatment of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) 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
- The member has morphological disease in the bone marrow ($\geq$5% blasts)

References

1. Aucatzyl [package insert]. Gaithersburg, MD: Autolus Inc.; November 2024.
2. NCCN Clinical Practice Guidelines in Oncology® Acute Lymphoblastic Leukemia (Version 2.2024). © 2024 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed November 19, 2024.