CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Arkansas PASSE

DRUG NAME	Aucatzyl (obecabtagene autoleucel)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Aucatzyl, approved by the FDA in 2024, is indicated for the treatment of adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL). ALL is a type of cancer of the blood and bone marrow. Aucatzyl is a CD19-directed genetically modified autologous T cell immunotherapy comprised of the patient's T cells that are transduced with a lentiviral vector to express an anti-CD19 chimeric antigen receptor (CAR). Engagement of anti-CD19 CAR-positive T cells with CD19 expressed on target cells leads to activation of the anti-CD19 CAR-positive T cells and downstream signaling through the CD3-zeta domain. This binding to CD19 results in anti-tumor activity and killing of CD19-expressing target cells.
Unlike previously approved CAR-T therapies, Aucatzyl does not have a Risk Evaluation and Mitigation Strategy (REMS) program.

Aucatzyl (obecabtagene autoleucel) will be considered for coverage when the following criteria are met:

Acute Lymphoblastic Leukemia (ALL)

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by a hematologist/oncologist; AND
3. Member has a diagnosis of B-cell ALL; AND
4. Documentation of one of the following:
   a) Relapsed or refractory Philadelphia chromosome negative (Ph-) disease, or
   b) Relapsed or refractory Philadelphia chromosome positive (Ph+) disease following therapy that has included tyrosine kinase inhibitors (TKIs); AND
5. Documentation of CD19 tumor expression; AND
6. Bone marrow with ≥ 5% lymphoblasts by morphologic assessment; AND
7. Member has an Eastern cooperative oncology group (ECOG) performance status of 0 or 1; AND
8. Member has been or will be screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV); AND
9. Member has NOT had prior CAR-T therapy.
10. **Dosage allowed/Quantity limit:** 410 × 10^6 CD19 CAR-positive viable T cells as a split dose IV infusion on day 1 and day 10 (+/- 2 days).

If all the above requirements are met, the medication will be approved for 3 months.

For **reauthorization**:
1. Aucatzyl will not be reauthorized for continued therapy.

CareSource considers Aucatzyl (obecabtagene autoleucel) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
02/03/2025	New policy for Aucatzyl created.

References:

1. Aucatzyl [prescribing information]. Autolus Inc.; 2024.
2. National Comprehensive Cancer Network. Acute Lymphoblastic Leukemia. (Version 3.2024). https://www.nccn.org/professionals/physician_gls/pdf/all.pdf. Accessed February 4, 2025.

Effective date: 07/01/2025
Revised date: 02/03/2025