

## PHARMACY POLICY STATEMENT

### Georgia Medicaid

<b>DRUG NAME</b>	<b>Aucatzyl (obecabtagene autoleucel)</b>
<b>BENEFIT TYPE</b>	Medical
<b>STATUS</b>	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  $\geq 5\%$  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:**  $410 \times 10^6$  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](https://www.nccn.org/professionals/physician_gls/pdf/all.pdf). Accessed February 4, 2025.

Effective date: 02/01/2026

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