Utilization Review Policy 355

POLICY: Oncology (Injectable – CAR-T) – Aucatzyl Utilization Management Medical Policy
- Aucatzyl® (obecabtagene autoleucel intravenous infusion – Autolus)

EFFECTIVE DATE: 5/1/2025
LAST REVISION DATE: 11/20/2024

COVERAGE CRITERIA FOR: All Aspirus Plans

OVERVIEW

Aucatzyl, a CD19-directed genetically modified autologous T cell immunotherapy, is indicated for the treatment of relapsed or refractory **B-cell precursor acute lymphoblast leukemia** in adults.[1]

Dosing Information

The recommended total dose of Aucatzyl is 410 x 10^6 CD19 chimeric antigen receptor (CAR)-positive viable T cells.[1] The dose is split, based on the percentage of blasts in the bone marrow within 7 days of starting lymphodepleting chemotherapy, and administered on Days 1 and 10 (± 2 days). The specific dosing schedule of Aucatzyl based on the percentage of blasts in the bone marrow is summarized in Table 1.

Table 1. Aucatzyl Dosing Schedule Based on the Percentage of Blasts in the Bone Marrow.[1]

	Day 1	Day 10 (± 2 days)
Bone marrow blasts > 20%	10 x 10^6 CAR-T cells	400 x 10^6 CAR-T cells
Bone marrow blasts ≤ 20%	100 x 10^6 CAR-T cells	310 x 10^6 CAR-T cells

CAR – Chimeric antigen receptor.

Guidelines

Aucatzyl has not been addressed by the National Comprehensive Cancer Network.

Safety

Aucatzyl has a Boxed Warning concerning cytokine release syndrome, neurologic toxicity including immune effector cell-associated neurotoxicity syndrome, and secondary hematological malignancies.[1]

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Aucatzyl. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Because of the specialized skills required for evaluation and diagnosis of patients treated with Aucatzyl as well as the monitoring required for adverse events and long-term efficacy, approval requires Aucatzyl to be prescribed by or in consultation with a physician who specializes in the condition being treated. The approval duration is 6 months to allow for an adequate time frame to prepare and administer 1 dose of therapy.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Aucatzyl is recommended in those who meet the following criteria:

FDA-Approved Indication

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1. Acute Lymphoblastic Leukemia. Approve a single dose if the patient meets ALL of the following (A, B, C, D, E, and F):

- **A)** Patient is ≥ 18 years of age; AND
- **B)** Patient has B-cell precursor disease; AND
- **C)** Patient has relapsed or refractory disease; AND
- **D)** Patient received or plans to receive lymphodepleting chemotherapy prior to infusion of Aucatzyl; AND
- **E)** Patient has not been previously treated with CAR-T therapy; AND
  Note: Examples of CAR-T therapy include Aucatzyl, Tecartus (brexucabtagene autoleucel intravenous infusion), Breyanzi (lisocabtagene maraleucel intravenous infusion), Kymriah (tisagenlecleucel intravenous infusion), Yescarta (axicabtagene intravenous infusion) and Abecma (idecabtagene vicleucel intravenous infusion).
- **F)** Aucatzyl is prescribed by or in consultation with an oncologist.

Dosing. Approve the following dosing regimen (A and B):

- **A)** Administer a total dose of 410×10^6 CAR-T cells by intravenous infusion; AND
- **B)** The dose is split and administered on Days 1 and 10 (± 2 days).

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Aucatzyl is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Aucatzyl® intravenous infusion [prescribing information]. Gaithersburg, MD: Autolus; November 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	11/20/2024
Aspirus P&T Review	Policy reviewed and approved by Aspirus P&T committee. Annual review process	03/10/2025