

PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable – CAR-T) – Aucatzyl Prior Authorization Policy

- Aucatzyl® (obecabtagene autoleucl intravenous infusion – Autolus)

REVIEW DATE: 11/20/2024

OVERVIEW

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

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 prescription benefit coverage of Aucatzyl. 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 Indications

- 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 autoleucl intravenous infusion), Breyanzi (lisocabtagene maraleucl intravenous infusion), Kymriah (tisagenlecleucl intravenous infusion), Yescarta (axicabtagene intravenous infusion) and Abecma (idecabtagene vicleucl intravenous infusion).

 - F) Aucatzyl is prescribed by or consultation with an oncologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

11/20/2024

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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.