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Policy:	Oncology (Injectable – CAR-T) – Aucatzyl Utilization Management Medical Policy • Aucatzyl® (obecabtagene autoleucel intravenous infusion – Autolus)
Date:	06/03/2025
Applicable Lines of Business:	Medicare Advantage - Medical
Applicable States:	All States
Applicable NCDs, LCDs, and/or LCAs	NCD 110.24

SUMMARY OF EVIDENCE

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** (ALL) 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

The National Comprehensive Cancer Network ALL (version 3.2024 – December 20, 2024) guidelines recommend Aucatzyl for the treatment of relapsed or refractory Philadelphia chromosome negative B-cell ALL as a "Preferred Regimen" (category 2A) and Philadelphia chromosome positive B-cell ALL following treatment with a tyrosine kinase inhibitor as an "Other Recommended Regimen" (category 2A).[2,3]

Safety

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

ANALYSIS OF EVIDENCE

The information provided in the summary of evidence is supported by labeled indications, CMS-approved compendia, published clinical literature, clinical practice guidelines, and/or applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs). Refer to the Sources of Information section of this policy for additional information.

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. The approval duration is 6 months to allow for an adequate time frame to prepare and administer 1 dose of therapy.

This policy incorporates Medicare coverage guidance as set forth in National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs), as well as in companion policy articles and other guidance applicable to the relevant service areas. These documents are cited in the Sources of Information section of this policy. In some cases, this guidance includes specific lists of HCPCS and ICD-10 codes to help inform the coverage determination process. The Articles that include specific lists for billing and coding purposes will be included in the Sources of Information section of this policy. However, to the extent that this policy cites such lists of HCPCS and ICD-10 codes, they should be used for reference purposes only. The presence of a specific HCPCS or ICD-10 code in a chart or companion article to an LCD is not by itself sufficient to approve coverage. Similarly, the absence of such a code does not necessarily mean that the applicable condition or diagnosis is excluded from coverage.

Note: Conditions for coverage outlined in this Medicare Advantage Medical Policy may be less restrictive than those found in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles. Examples of situations where this clinical policy may be less restrictive include, but are not limited to, coverage of additional indications supported by CMS-approved compendia and the exclusion from this policy of additional coverage criteria requirements outlined in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles.

Indications with a ^ below are referenced in both the corresponding Standard Medical Utilization Management Internal Policy AND applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and/or Local Coverage Articles (LCAs). Coverage criteria for these indications may be internally developed and/or referenced in applicable NCDs, LCDs, and/or LCAs. For these indications, internally developed coverage criteria is denoted throughout the policy in the following manner: 1) IC-L (internal criteria supported by the labeled indication), 2) IC-COMP (internal criteria supported by CMS-approved compendia), 3) IC-ISGP (internal criteria intended to interpret or supplement general provisions outlined in applicable NCDs, LCDs, and/or LCAs), or 4) IC-EC (internal criteria intended to expand coverage beyond the coverage outlined in applicable NCDs, LCDs, and/or LCAs). For these indications, coverage criteria that is NOT denoted with one of the above indicators is referenced in applicable NCDs, LCDs, and/or LCAs. Additional information supporting the rationale for determination of internal coverage criteria can be found via the Sources of Information section.

Indications with a @ below are referenced in the corresponding Standard Medical Utilization Management Internal Policy, but are NOT directly referenced in applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and/or Local Coverage Articles (LCAs). Coverage criteria for these indications is internally developed. These indications and their respective coverage criteria represent expanded coverage beyond the coverage outlined in applicable NCDs, LCDs, and/or LCAs.

Indications with a # below are supported and referenced in applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and/or Local Coverage Articles (LCAs), but are NOT directly referenced in the corresponding Standard Medical Utilization Management Internal Policy. Coverage criteria for these indications is referenced in applicable NCDs, LCDs, and/or LCAs.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indication

1. Acute Lymphoblastic Leukemia. ^

Criteria. Approve a single dose if the patient meets ALL of the following (A, B, C, D, and E):
A) Patient is ≥ 18 years of age; IC-COMP AND
B) Patient has B-cell precursor disease; IC-COMP AND
C) Patient has relapsed or refractory disease; IC-COMP AND
D) Patient received or plans to receive lymphodepleting chemotherapy prior to infusion of Aucatzyl; IC-COMP AND
E) Patient has not been previously treated with CAR-T therapy. IC-COMP
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).

Dosing. Approve the following dosing regimen (A and B):
A) Administer a total dose of 410 x 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.

SOURCES OF INFORMATION

1. Aucatzyl® intravenous infusion [prescribing information]. Gaithersburg, MD: Autolus; November 2024.
2. The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 27, 2024. Search term: obecabtagene.
3. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 3.2024 – December 20, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 27, 2024.
4. Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) for Chimeric Antigen Receptor (CAR) T-cell Therapy (110.24). Original effective date 8/7/2019. Implementation date 2/16/2021. Revision date: 03/2025. Accessed June 3, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	12/30/2024
Policy revision	No criteria changes. Formatting and notation updates.	03/10/2025
Policy review	No criteria changes. Review based on NCD surveillance review.	06/03/2025