MetroPlus Health

Policy and Procedure

Title: Aucatzyl (obecabtagene autoleucel)	Division: Medical Management Department: Utilization Management
Approval Date: 3.17.2026	LOB: Medicaid, SNP, HARP, CHP, QHP, EP, Gold, Goldcare,
Effective Date: 3.17.2026	Policy Number: UM-MP355
Review Date: 6.16.2026	Cross Reference Number:
Retired Date:	Page 1 of 6

I. POLICY DESCRIPTION

Medical Oncology – Anti-CD19 Chimeric Antigen Receptor T-cell (CAR-T) immunotherapy, Aucatzyl (obecabtagene autoleucel).

II. RESPONSIBLE PARTIES

Medical Management Administration, Utilization Management, Integrated Care Management, Pharmacy, Claims Department, Provider Contracting.

III. DEFINITIONS

Aucatzyl (obecabtagene autoleucel) is a CD19-directed genetically modified autologous T-cell immunotherapy. Patient T-cells are collected via leukapheresis and genetically modified ex vivo to express a chimeric antigen receptor (CAR) targeting CD19 on malignant B-cells. Following anti-CD19 CAR-T cell engagement with CD19-expressing target cells, intracellular signaling domains activate downstream signaling pathways resulting in T-cell activation, proliferation, cytokine release, and cytotoxic killing of leukemic cells.

Aucatzyl is indicated for the treatment of adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

All other uses are considered experimental and investigational.

IV. POLICY

For Medicare and Ultracare Only: MetroPlusHealth determines medical necessity based on applicable Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD).
https://www.cms.gov/medicare-coverage-database/search.aspx

For all other LOBs:
Aucatzyl will be considered medically necessary once the following coverage criteria are met. Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and evidence-based practice guidelines.

INITIAL REQUEST:

1. **Adult Relapse or Refractory B-cell precursor Acute Lymphoblastic Leukemia (B-ALL)**
   A. Member is 18 years of age or older;
   AND

B. Member has a diagnosis confirmed by submitted documentation including chart notes of B-cell precursor Acute Lymphoblastic Leukemia (B-ALL) that is in relapse or refractory;

AND

C. ONE of the following:

- **a.** Member has Philadelphia chromosome-negative disease that is relapsed or refractory as defined as ONE of the following:
  - **i.** Primary refractory disease;

  OR
  - **ii.** First relapse with remission of 12 months or less;

  OR
  - **iii.** Relapsed or refractory disease after at least two previous lines of systemic therapy;

  OR
  - **iv.** Relapsed or refractory disease after allogeneic stem cell transplant;

OR

- **b.** Member has Philadelphia chromosome-positive disease that meets any ONE of the following:
  - **i.** Member has relapsed or refractory disease despite treatment with at least two different tyrosine kinase inhibitors (TKIs) (e.g., Bosulif (bosutinib), Sprycel (dasatinib), Gleevec (imatinib), Tasigna (nilotinib), Iclusig (ponatinib));

  OR
  - **ii.** Member is intolerant to TKI therapy;

AND

D. Member has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1;

AND

E. Member is screened for HBV, HCV, and HIV in accordance with clinical guidelines prior to collection of cells for manufacturing;

AND

F. Member has not received any live vaccines within the past 6 weeks;

AND

G. Member does not have an active systemic infection or inflammatory disorder**;**

AND

H. Member has not previously been treated with Aucatzyl or any other CAR-T therapy;

AND

I. Authorization is for no more than one dose.

Initial Duration of Approval: *One single dose per lifetime*

RENEWAL REQUEST: Repeat administration of Aucatzyl is investigational and will not be covered.

Renewal Duration of Approval: *Not Applicable*

V. LIMITATIONS/EXCLUSIONS:

A. Repeat administration of Aucatzyl (obecabtagene autoleucel) is considered experimental and investigational because there have been no established studies to demonstrate effectiveness.

B. Aucatzyl is also considered experimental or investigational for the following indications due to no established studies of clinical efficacy:

- **a.** Diffuse large B-cell lymphoma (DLBCL)
- **b.** Follicular lymphoma
- **c.** Mantle cell lymphoma
- **d.** Marginal zone lymphoma
- **e.** Indolent non-Hodgkin lymphoma
- **f.** Primary central nervous system (CNS) lymphoma

C. Aucatzyl is not indicated for the treatment of patients with primary central nervous system leukemia or lymphoma.

VI. APPLICABLE PROCEDURE CODES:

CPT	Description
Q2058	Obecabtagene autoleucel, 10 up to 400 million cd19 car-positive viable t cells, including leukapheris and dose preparation procedures, per infusion

VII. APPLICABLE DIAGNOSIS CODES:

CODE	Description
C91.00	Acute Lympphoblastic Leukemia Not Having Achieved Remission

C91.02	Acute Lymphoblastic Leukemia, In Relapse

VIII. REFERENCES

1. Aucatzyl (obecabtagene autoleucel). Prescribing information. Waltham, MA: Autolus Therapeutics; 2024. Available at: https://www.fda.gov. Accessed March 2026.
2. Claire Roddie, Andrew C. Logan, Elias Jabbour, et al. Obecabtagene autoleucel in adults with relapsed or refractory B-cell acute lymphoblastic leukemia. N Engl J Med. 2024. doi:10.1056/NEJMoa2406526.
3. FELIX Trial. CD19-targeted CAR-T cell therapy (obecabtagene autoleucel) in adult patients with relapsed or refractory B-cell acute lymphoblastic leukemia. ClinicalTrials.gov. https://clinicaltrials.gov/study/NCT04404660. Accessed March 2026.
4. National Comprehensive Cancer Network. Acute Lymphoblastic Leukemia (ALL). NCCN Clinical Practice Guidelines in Oncology. Version 2025. https://www.nccn.org.
5. Micromedex. Obecabtagene autoleucel drug monograph. IBM Watson Health. Accessed March 2026.
6. Lexicomp. Obecabtagene autoleucel: Drug information. Wolters Kluwer Health. Accessed March 2026.
7. IPD Analytics. Obecabtagene autoleucel coverage and coding information. https://www.ipdanalytics.com. Accessed March 2026.
8. U.S. Food and Drug Administration. FDA approval of obecabtagene autoleucel for relapsed or refractory B-cell acute lymphoblastic leukemia. 2024. https://www.fda.gov.

REVISION LOG:

REVISIONS	DATE
Creation date	3/12/2026
Review	3/17/2026
Update	6/16/2026
Annual Review	
Annual Review	
Annual Review	
Review	

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Updated review	

	Approved: **Date:**
	Sanjiv Shah, MD **Chief Medical Officer**

Medical Guideline Disclaimer:

 The treating physician or primary care provider must submit MetroPlus Health Plan clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, MetroPlus Health Plan will not be able to properly review the request for prior authorization. The clinical review criteria expressed in this policy reflects how MetroPlus Health Plan determines whether certain services or supplies are medically necessary. MetroPlus Health Plan established the clinical review criteria based upon a review of currently available clinical information(including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). MetroPlus Health Plan expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by MetroPlus Health Plan, as some programs exclude coverage for services or supplies that MetroPlus Health Plan considers medically necessary. If there is a discrepancy between this guidelines and a member's benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for

Medicare and Medicaid members. All coding and website links are accurate at time of publication.