

## Medical Policy:

### Aucatzyl (obecabtagene autoleucel)

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.419	January 30, 2025	January 30, 2025

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth 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). EmblemHealth 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 EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. 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 web site links are accurate at time of publication.

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## Definitions

Obecabtagene autoleucel CD19-directed genetically modified autologous T-cell immunotherapy is indicated for the treatment of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) in adults.

## Length of Authorization

Coverage will be provided for 1 dose and may not be renewed. 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).

## Dosing Limits [Medical Benefit]

Aucatzyl is 410 x 10<sup>6</sup> CAR T-cells administered by intravenous (IV) infusion. The total dose is split with part of the dose administered on Day 1 and the remainder of the dose given on Day 10 (± 2 days).

## Guideline

### I. Initial

1. Acute Lymphoblastic Leukemia - Approve a single dose if the patient meets ALL of the following (A, B, C,

D, E, F, G, H, I, J, K, L **AND** M):

- A. Prescribed by or in consultation with an oncologist **AND**
- B. Patient is at least 18 years of age; **AND**
- C. Patient has a diagnosis of relapsed or refractory disease; **AND**
  - i. Patient has Philadelphia chromosome (Ph)-positive disease; **AND**
    - a. Previous therapy has included tyrosine kinase inhibitors (TKIs) **OR**  
*Note: Examples include bosutinib, dasatinib, imatinib, nilotinib, or ponatinib*
  - ii. Patient has Philadelphia chromosome (Ph)-negative disease **AND**
- D. Patient does not have a clinically significant active infection or inflammatory disorder; **AND**
- E. Patient has not received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy, and will not receive live vaccines during Aucatzyl treatment and until immune recovery following treatment; **AND**
- F. Patient has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to collection of cells (leukapheresis); **AND**
- G. Prophylaxis for infection will be followed according to local guidelines; **AND**
- H. Patient has not received prior CAR-T therapy; **AND**
- I. Patient has not received other anti-CD19 therapy **OR**  
*Note: Example: blinatumomab*
- J. Patient previously received other anti-CD19 therapy and re-biopsy indicates CD-19 positive disease; **AND**
- K. Used as single agent therapy (*not applicable to lymphodepleting or bridging chemotherapy while awaiting manufacture*) **AND**
- L. Patient will be monitored for signs and symptoms of Cytokine Release Syndrome (CRS) for at least 14 days after treatment with Aucatzyl and will be counselled to seek immediate medical attention should signs and symptoms of CRS or a neurological event occur at any time; **AND**
- M. Patient will stay within proximity of the Aucatzyl infusion center for at least 4 weeks following infusion

### Dosing:

Approve the following dosing regimen (A **AND** B):

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

**Aucatzyl Dosing Schedule Based on the Percentage of Blasts in the Bone Marrow.**

	Day 1	Day 10 ( $\pm 2$ days)
<b>Bone marrow blasts &gt; 20%</b>	$10 \times 10^6$ CAR-T cells	$400 \times 10^6$ CAR-T cells
<b>Bone marrow blasts <math>\leq</math> 20%</b>	$100 \times 10^6$ CAR-T cells	$310 \times 10^6$ CAR-T cells

### II. Renewal

Coverage cannot be renewed, a maximum of one dose per lifetime will apply

### Applicable Procedure Codes

Code	Description
J9999	Not otherwise classified, antineoplastic drugs
C9399	Unclassified drugs or biologicals

## Applicable NDCs

Code	Description
83047-0410-xx	Aucatzyl 410 × 10 <sup>6</sup> CD19 CAR-positive viable T cells is supplied in three to five infusion bags: as follows
83047-0010-xx	10 × 10 <sup>6</sup> CD19 CAR-positive viable T cells in one 50mL infusion bag (Blue)
83047-0100-xx	100 × 10 <sup>6</sup> CD19 CAR-positive viable T cells in one 50mL infusion bag (Orange)
83047-0100-xx	100 × 10 <sup>6</sup> CD19 CAR-positive viable T cells in one 250mL infusion bag (Orange)
83047-0300-xx	300 × 10 <sup>6</sup> CD19 CAR-positive viable T cells in one 250mL infusion bag (Red)

## ICD-10 Diagnoses

Code	Description
C91.00	Acute Lymphoblastic Leukemia Not Having Achieved Remission
C91.02	Acute Lymphoblastic Leukemia, In Relapse

## Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	01/30/2025	New Policy

## References

1. Aucatzyl® intravenous infusion [prescribing information]. Gaithersburg, MD: Autolus; January 2025