# Medical Policy:

## Aucatzyl (obecabtagene autoleucel)

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



## 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 $10^6$ 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 x $10^6$ CAR-T cells by intravenous infusion; **AND**
B. The dose is split and administered on Days 1 and 10 (± 2 days).

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

| | 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 |

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 × $10^6$ CD19 CAR-positive viable T cells is supplied in three to five infusion bags: as follows |
| 83047-0010-xx | 10 × $10^6$ CD19 CAR-positive viable T cells in one 50mL infusion bag (Blue) |
| 83047-0100-xx | 100 × $10^6$ CD19 CAR-positive viable T cells in one 50mL infusion bag (Orange) |
| 83047-0100-xx | 100 × $10^6$ CD19 CAR-positive viable T cells in one 250mL infusion bag (Orange) |
| 83047-0300-xx | 300 × $10^6$ 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