Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs

Aucatzyl (obecabtagene autoleucel)

Effective: September 1, 2026

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	Yes ☒ No ☐

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988
☒ Tufts Health Plan Commercial products; Fax 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988
☐ Tufts Health Together – MassHealth Accountable Care Partnership Plans; Fax 617-673-0939
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939
☐ Tufts Health One Care-- A dual-eligible product; Fax 617-673-0956

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956
☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956
☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Chimeric antigen receptor T-cell therapy (CAR T-cell therapy), a type of immunotherapy which may also be referred to as adoptive T-cell therapy, attempts to program patients' own immune systems to recognize and attack cancer cells. The first step in this therapy is to remove T-cells from the patient via apheresis, a process that removes blood from the body and removes one or more blood components (such as white blood cells, plasma, or platelets). The remaining blood is then returned to the body. The T-cells are then sent to a drug manufacturing facility or laboratory where they are genetically engineered to produce chimeric antigen receptors (CARs) on their surface. These CARs are what allow the T-cells to recognize an antigen on targeted tumor cells. The genetically modified T-cells are grown in the lab until there are enough of them (many millions) to freeze and return to the center treating the patient. There they are infused into the recipient with the expectation that the CAR T-cells will recognize and kill cancerous cells that have the targeted antigen on their surface. Since the CAR T-cells may remain in the body long after the infusion, it is possible the treatment can bring about long-term remission. CAR T-cell therapy can be used to treat certain hematologic malignancies when the disease is relapsed or refractory to standard line(s) of treatment.

Food and Drug Administration (FDA) Approved Indications:

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

NOTE: Aucatzyl can only be administered at an authorized treatment center. For information on locating an authorized treatment center please go to https://www.aucatzyl.com/#treatment-center-locator.

Clinical Guideline Coverage Criteria

The Plan may cover Aucatzyl for Members aged 18 or over when ALL of the following are met:

1. The Member has been diagnosed with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

AND

2. The Member's disease is defined as **one** (1) of the following:

a. Primary refractory ALL
b. First relapse following a remission lasting 12 months or less.
c. Relapsed or refractory ALL after **two** (2) or more lines of systemic therapy including at least one chemotherapy.
d. Relapsed or refractory ALL ≥ 3 months following allogenic stem cell transplantation and there is no indication of active GVHD.

AND

3. The Member has **one** (1) of the following:
   a. The Member has CD19 Philadelphia chromosome-positive (Ph+) ALL; and failed or is intolerant to **two** (2) tyrosine kinase inhibitor (TKI) therapies; **or**
   b. The Member has CD19 Philadelphia chromosome-positive (Ph+) ALL; and failed or is intolerant to one (1) second-generation tyrosine kinase inhibitor therapy; **or**
   c. The Member does not have CD19 Philadelphia chromosome-positive (Ph+) ALL.

AND

4. The Member has an Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 to 1.

AND

5. The Member does not have an uncontrolled inflammatory disorder.

AND

6. The Member does not have active hepatitis B, active hepatitis C, or any untreated active systemic infection.

AND

7. The Member has adequate organ function including bone marrow, cardiac, pulmonary, and neurological with no anticipated decline in organ function in close proximity to apheresis timeframe.

AND

8. The Member does not have a diagnosis of Burkitt's leukemia/lymphoma according to WHO classification or chronic myelogenous leukemia lymphoid in blast crisis.

AND

9. The Member is with morphological disease in the bone marrow (>5% blasts) OR is with minimal residual disease (MRD) positivity as documented by flow cytometry.

AND

10. The Provider is an oncologist.

AND

11. The Provider attests that the treatment regimen Aucatzyl® will consist of a split (two) dose infusion to be administered on day 1 and day 10 (± 2 days).

NOTE: Documentation submitted must list previous lines of treatment/systemic therapies and date of each therapy.

In addition to the above criteria, the Plan may cover Aucatzyl in an outpatient setting when all of the following criteria is met:

1. The provider attests that they have assessed the Member and determined that outpatient administration is clinically appropriate.

AND

2. The provider attests that the Member meets and understands the requirements of safety and monitoring post infusion as required in the Aucatzyl Authorized Treatment Center program.

Note: Prior authorization for Aucatzyl is required regardless of hospital inpatient or outpatient setting.

Limitations

- Aucatzyl therapy is contraindicated for use in pregnancy.
- Members receiving immunosuppressive therapy that is likely (high risk) to interfere with T cell function will not be approved for Aucatzyl.
- The Member has a diagnosis of Burkitt's leukemia/lymphoma according to WHO classification or chronic myelogenous leukemia lymphoid in blast crisis.
- Members with untreated underlying primary immunodeficiency syndromes will not be approved for Aucatzyl therapy.

- Members with active and/or metastatic malignancy that is unlikely to respond to treatment will not be approved for Aucatzyl therapy.
- Authorization of Aucatzyl therapy is limited to a single dose.
- Members who have had prior treatment with any form of CAR T-cell therapy, including therapies in clinical trial settings, will not be approved for additional CAR T therapy.
- Aucatzyl therapy will not be covered if the Member demonstrates clinical decompensation from time of authorization to time of infusion and no longer meets clinical coverage criteria.
- Aucatzyl will not be approved for members with CNS-2 disease or CNS-3 disease with neurological changes (see reference below).
- Any indications for CAR T-cell therapy other than those outlined above are considered investigational and will not be covered.

ECOG Performance Status
0: Fully active, no restrictions on activities. A performance status of 0 means no restrictions in the sense that someone is able to do everything they were able to do prior to their diagnosis.
1: Unable to do strenuous activities, but able to carry out light housework and sedentary activities. This status basically means you can't do heavy work but can do anything else.
2: Able to walk and manage self-care, but unable to work. Out of bed more than 50% of waking hours. In this category, people are usually unable to carry on any work activities, including light office work.
3: Confined to bed or a chair more than 50 percent of waking hours. Capable of limited self-care.
4: Completely disabled. Totally confined to a bed or chair. Unable to do any self-care.
5: Death

Central Nervous System Disease
CNS 1 disease was defined as the absence of leukemia in cerebrospinal fluid. CNS-2 disease was defined as detectable cerebrospinal blasts with less than five white blood cells per mm^3.)
CNS 2: WBC count of less than 5/mL and blasts on cytospin findings, or WBC count of more than 5/mL but negative by Steinherz-Bleyer algorithm findings (if traumatic tap).
CNS 3: WBC count of 5/mL or more and blasts on cytospin findings and/or clinical signs of CNS leukemia (e.g., facial nerve palsy, brain/eye involvement, hypothalamic syndrome

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
Q2058	Obecabtagene Autoleucel, 10 Up To 400 Million CD19 CAR-Positive Viable T Cells, Including Leukapheresis And Dose Preparation Procedures, Per Infusion

References:

1. Aucatzyl® [package insert]. Gaithersburg (MD): Autolus Inc.; November 2024.
2. Roddie C, Sandhu K, et. al. S262: Safety And Efficacy Of Obecabtagene Autoleucel (Obe-Cel), A Fast-Off Rate Cd19 Car In Relapsed/Refractory Adult B-Cell Acute Lymphoblastic Leukaemia: Top Line Results Of The Pivotal Felix Study. Hemasphere. 2023 Aug 8;7(Suppl):e998506d. doi: 10.1097/01.HS9.0000967960.99850.6d. PMCID: PMC10428320.
3. Roddie C, Sandhu KS, Tholouli E, et al. Obecabtagene Autoleucel in Adults with B-Cell Acute Lymphoblastic Leukemia. N Engl J Med. 2024;391(23):2219-2230. doi:10.1056/NEJMoa2406526
4. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Acute Lymphoblastic Leukemia (Version 1.2026). April 6, 2026. https://www.nccn.org/professionals/guidelines
5. IPD Analytics. IPD Analytics Market Forecast Update: Autolus' Aucatzyl Approved for Relapsed/Refractory B-Cell ALL. November 20, 2024
6. Treatment of relapsed or refractory acute lymphoblastic leukemia in adults. UpToDate.com/login [via subscription only]. Published March 3, 2025. Accessed May 4, 2026.
7. Immune effector cell-associated neurotoxicity syndrome (ICANS) and other neurologic toxicities of CAR-T cell and related therapies. UpToDate.com/login [via subscription only]. Published February 11, 2026. Accessed May 4, 2026.
8. Jabbour E, et. al. Tumor burden-guided dosing contributes to mitigation of immunotoxicities following treatment with obecabtagene autoleucel in adult patients with relapsed/refractory B-cell acute lymphoblastic leukemia. Haematologica. 2026 Jan 8. doi: 10.3324/haematol.2025.288587. Epub ahead of print. PMID: 41504229.
9. Yared JA, et. al. Obecabtagene autoleucel, a novel CD19-directed CAR T-cell therapy for relapsed/refractory B-cell

acute lymphoblastic leukemia: the future for reducing toxicity and T-cell exhaustion? Expert Rev Hematol. 2025 Aug;18(8):585-593. doi: 10.1080/17474086.2025.2523551. Epub 2025 Jun 24. PMID: 40550480.

Approval And Revision History

March 19, 2025: Reviewed by the Medical Policy Approval Committee (MPAC), effective April 1, 2025.

Subsequent dates and changes made:

- May 13, 2025: Coding updated per AMA HCPCS, replaced C9301 with Q2058, effective July 1, 2025.
- June 18, 2025: Harvard Pilgrim Health Care Stride Medicare Advantage removed as an applicable product from the template.
- June 18, 2025: Reviewed by MPAC. Annual Review.
- July 16, 2025: Refined the limitation regarding immunosuppressive therapy to specify high risk to interfere with T cell function. References updated. Effective date September 1, 2025.
- July 15, 2026: Reviewed by MPAC. Annual Review. References updated. Effective September 1, 2026.

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member’s benefit document, and in coordination with the Member’s physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment, or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.