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).

The Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) and MassHealth for coverage determinations for its Dual Product Eligible plan members, and Centers for Medicare and Medicaid Services (CMS) for coverage determinations for its Medicare Advantage plan members. CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and documentation included in the Medicare manuals and MassHealth Medical Necessity Determinations are the basis for coverage determinations where available. For the Plan's members, the following criteria is used: Chimeric Antigen Receptor (CAR) T- cell Therapy NCD 110.24

Clinical Guideline Coverage Criteria

The Plan may cover Aucatzyl when all the following clinical criteria is met:

1. The Member has a diagnosis of B-cell precursor acute lymphoblastic leukemia (ALL); **AND**
2. The Member is ≥ 18 years of age on treatment date; **AND**
3. The Member has not received prior treatment with CAR-T therapy; **AND**

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.

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

Limitations

- 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.
- Authorization for Aucatzyl is limited to a one-time infusion.
- All other indications other than those listed above are considered experimental/investigational and not medically necessary.

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. National Comprehensive Cancer Network. Acute Lymphoblastic Leukemia (Version 2.2025). June 27, 2025. https://www.nccn.org/professionals/physician_gls/pdf/all.pdf
2. Center for Medicare and Medicaid National Coverage Determination (NCD) for Chimeric Antigen Receptor (CAR) T-cell Therapy. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=374&bc=CAAAAAAAAAAA .
3. Aucatzyl® [package insert]. Gaithersburg (MD): Autolus Inc.; November 2024.
4. 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.
5. Treatment of relapsed or refractory acute lymphoblastic leukemia in adults. UpToDate.com/login [via subscription only]. Published March 3, 2025. Accessed May 4, 2026.
6. 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.
7. 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.
8. 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

- February 19, 2025: Reviewed by the Medical Policy Approval Committee (MPAC); effective April 1, 2025.
- May 13, 2025: Coding updated per AMA HCPCS, replaced C9301 with Q2058, effective July 1, 2025.
- June 18, 2025: Reviewed by MPAC. Annual review.
- July 16, 2025: Reviewed by MPAC. References updated. No other changes. Effective 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.