Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs

Omisirge (omidubicel-onlv)

Effective: October 1, 2026

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request to the FAX numbers below	Yes ☒ No ☐
Notification Required IF REQUIRED, concurrent review may apply	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 or notifying Point32Health, as a condition of payment you will need to ensure that any necessary prior authorization has been obtained and/or Point32Health has received proper notification. If notification is required, providers may additionally be required to provide updated clinical information to qualify for continued service.

Overview

Hematologic malignancies are a diverse group of diseases with unique illness paths and treatments, and potential for curability. It constitutes an umbrella term for cancers that begin in blood-forming tissue, such as bone marrow, or the cells of the immune system. There are three main types of hematologic malignancy: lymphoma, leukemia, and multiple myeloma. Treatments for hematologic malignancies include blood transfusions, radiation therapy, chimeric antigen receptor (CAR) T-cell therapies, and Omisirge (omidubicel-onlv).

According to the Leukemia & Lymphoma Society, one person in the U.S. is diagnosed with a hematologic malignancy approximately every three minutes. An estimated 1,629,474 people in the U.S. are living with or in remission from a hematologic malignancy.

Food and Drug Administration (FDA) Approved Indications:

- Omisirge is a nicotinamide modified allogeneic hematopoietic progenitor cell therapy derived from cord blood indicated for use in adults and pediatric patients 12 years and older with hematologic malignancies who are planned for umbilical cord blood transplantation following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infection.

Clinical Guideline Coverage Criteria

The Plan may cover Omisirge (one dose total) for Members aged 12 years or over when **All** of the following clinical criteria are met:

1. The Member has been diagnosed with a hematologic malignancy.

AND

2. The Member is candidate for myeloablative allogeneic hematopoietic stem cell transplantation (HSCT) following myeloablative conditioning.

AND

3. The treatment is being used to reduce the time to neutrophil recovery and incidence of infection.

AND

4. The Member does not have a suitable matched related donor (MRD), matched unrelated donor (MUD), mismatched unrelated donor (MMUD), or haploidentical donor readily available.

AND

5. The Member has not received prior allogenic hematopoietic stem cell transplant.

AND

6. Omisirge is prescribed by or in consultation a hematologist or oncologist.

Limitations

- Treatment is limited to one treatment course per lifetime.

Codes

The following code(s) require prior authorization:

Table 1: CPT/HCPCS Codes

Code	Description
J3406	Injection, omidubicel-onlv, per therapeutic dose

References:

1. Horwitz ME. et. al. Omidubicel vs standard myeloablative umbilical cord blood transplantation: results of a phase 3 randomized study. Blood. 2021 Oct 21;138(16):1429-1440. doi: 10.1182/blood.2021011719. PMID: 34157093; PMCID: PMC9710469.
2. Leukemia and Lymphoma Society. Facts and Statistics Overview. https://www.lls.org/facts-and-statistics/facts-and-statistics-overview. Accessed April 12, 2024
3. Lin C, et. al. Multicenter long-term follow-up of allogeneic hematopoietic cell transplantation with omidubicel: a pooled analysis of five prospective clinical trials. Transplantation and Cellular Therapy 2023;29(5):338.e1-338.e6.
4. Omisirge (omidubicel-onlv) [package insert]. Boston, MA. Gamida Cell. April 2023.
5. Selection of an umbilical cord blood graft for hematopoietic cell transplantation. UpToDate.com/login [via subscription only]. Published March 20, 2024. Accessed September 24, 2025.
6. Horwitz ME, et. al. Omidubicel-onlv Transplantation for Hematologic Malignancies: Results of a Multicenter Expanded Access Program. Transplant Cell Ther. 2025 Jul;31(7):436-447. doi: 10.1016/j.jtct.2025.04.005. Epub 2025 Apr 8. PMID: 40204073.
7. Morse AL, Kurz H, Moore DC. Omidubicel for Hematopoietic Cell Transplants: Considerations for Patients and Treatment Outcomes. Patient Prefer Adherence. 2024 Nov 5;18:2217-2223. doi: 10.2147/PPA.S419253. PMID: 39525609; PMCID: PMC11549910.
8. Khera N, et. al. Projected Impact of Omidubicel-onlv on Racial/Ethnic Disparities in Allogeneic Hematopoietic Cell Transplantation (Allo-HCT) Outcomes in Hematologic Malignancies. Adv Ther. 2024 Apr;41(4):1637-1651. doi: 10.1007/s12325-023-02771-z. Epub 2024 Mar 1. Erratum in: Adv Ther. 2024 Jul;41(7):3013. doi: 10.1007/s12325-024-02894-x. PMID: 38427220; PMCID: PMC10960759.
9. Majhail NS, et. al. Hospitalization and Healthcare Resource Utilization of Omidubicel-Onlv versus Umbilical Cord Blood Transplantation for Hematologic Malignancies: Secondary Analysis from a Pivotal Phase 3 Clinical Trial. Transplant Cell Ther. 2023 Dec;29(12):749.e1-749.e5. doi: 10.1016/j.jtct.2023.09.004. Epub 2023 Sep 12. PMID:

37703995.
10. Lassiter M, Lail C. Omidubicel-Onlv: The First Commercially Available Alternative Allogeneic Hematopoietic Stem Cell Transplantation Donor Source. Clin J Oncol Nurs. 2025 May 19;29(3):230-236. doi: 10.1188/25.CJON.230-236. PMID: 40401840; PMCID: PMC12124889.
11. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines: Hematopoietic Cell Transplantation (HCT) (Version 2. 2025). June 3, 2025. Accessed September 18, 2025. https://www.nccn.org/professionals/physician_gls/pdf/hct.pdf
12. Sureda A, Corbacioglu S, Greco R, Kröger N, Carreras E, editors. The EBMT Handbook: Hematopoietic Cell Transplantation and Cellular Therapies [Internet]. 8th ed. Cham (CH): Springer; 2024. PMID: 39437029.

Approval And Revision History

August 30, 2024: Reviewed by the Medical Policy Approval Committee (MPAC) for effective date of October 1, 2024.

Subsequent endorsement date(s) and changes made:
- November 21, 2024: Reviewed by MPAC, renewed without changes, effective January 1, 2025
- February 19, 2025: Reviewed by MPAC, added “suitable” to matched related donor, effective March 12, 2025
- November 19, 2025: Reviewed by MPAC for annual review, renewed without changes, references updated effective January 1, 2026
- December 2025: Administrative updates effective January 1, 2026
- October 1, 2026: Coding updated per CMS HCPCS, replaced J3590 with J3406, effective October 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.