Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs

Omisirge (omidubicel-onlv)

Effective: November 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.

Severe aplastic anemia (SAA) is a rare, life-threatening bone marrow failure disorder characterized by markedly hypocellular bone marrow and pancytopenia, resulting in profound anemia, neutropenia, and thrombocytopenia. The disease is most commonly immune mediated, with destruction of hematopoietic stem and progenitor cells leading to inadequate production of blood cells and an increased risk of severe infection, bleeding complications, and death if left untreated. Current management strategies include immunosuppressive therapy and allogeneic hematopoietic stem cell transplantation, which remains the preferred curative treatment for eligible patients.

Food and Drug Administration (FDA) Approved Indications:

Omisirge is a nicotinamide modified allogeneic hematopoietic progenitor cell therapy derived from cord blood indicated for the treatment of:

- 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.
- Adults and pediatric patients 6 years and older with severe aplastic anemia (SAA) following reduced intensity conditioning.

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 CMS 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. When CMS and MassHealth do not provide guidance, the Plan's internally developed medical necessity guidelines are used. CMS coverage guidelines are not established for this service.

For the therapy Omisirge, evidence is sufficient for coverage. Omisirge received FDA approval in April 2023 supported by the results of an open-label, multicenter, randomized Phase 3 P0501 trial. Safety and efficacy were evaluated in the study in which 125 patients were randomized 1:1 to receive either Omisirge transplantation or standard umbilical cord blood transplantation, both following myeloablative chemotherapy. The primary end point measured was time to neutrophil recovery following transplantation and the incidence of Blood and Marrow Transplant Clinical Trials Network (BMT CTN) Grade 2/3 bacterial or Grade 3 fungal infections through Day 100 post transplantation. The median time to neutrophil recovery was 12 days for those receiving Omisirge (95% CI: 10-15 days) and 22 days in the UCB arm (95% CI: 19-25 days). Eighty-seven percent in the Omisirge arm and 83% percent in the UCB arm achieved neutrophil recovery. The incidence of BMT CTN Grade 2/3 bacterial or Grade 3 fungal infections through Day 100 post-transplantation was 39% and 60%, respectively, in the two groups.

On December 8, 2025, the FDA granted approval to Omisirge as the first hematopoietic stem cell transplant (HSCT) therapy to treat patients with severe aplastic anemia (SAA). The approval was based on data from study 17- H-0091 (NCT03173937) an open-label, single center study. The study enrolled patients 6 years of age and older with SAA who had intolerance or failure to respond to immunosuppressive therapy and availability of at least one ≥4/8 human leukocyte antigen (HLA)-matched (HLA-A, B, C and DR loci) cord blood unit. Omisirge demonstrated early and sustained engraftment in 12 of 14 patients in the efficacy population with a median time to neutrophil recovery of 11 days.

The use of this criteria in the utilization management process will ensure access to evidence based clinically appropriate care. See References section below for all evidence accessed in the development of these criteria.

Clinical Guideline Coverage Criteria

For Hematologic Malignancies

The Plan may cover Omisirge for Members when **All** of the following clinical criteria are met:

1. The Member has a hematologic malignancy; **and**
2. Omisirge is prescribed by a hematologist or oncologist; **and**
3. The Member is ≥ 12 years of age on treatment date; **and**
4. The Member is planned for umbilical cord blood transplantation following myeloablative condition; **and**
5. Appropriate dosing of one-time treatment; **and**
6. Omisirge is administered under the supervision of a physician experienced in treatment of hematologic malignancies in centers with expertise in hematopoietic stem cell transplants.

For Severe Aplastic Anemia (SAA)

The Plan may cover Omisirge for Members when **All** of the following clinical criteria are met:

1. The Member has a diagnosis of severe aplastic anemia; **and**
2. Omisirge is prescribed by a hematologist or oncologist; **and**
3. The Member is ≥ 6 years of age on treatment date; **and**
4. The Member is planned for umbilical cord blood transplantation following myeloablative condition; **and**
5. Appropriate dosing of one-time treatment; and
6. Omisirge is administered under the supervision of a physician experienced in treatment of SAA, in centers with expertise in hematopoietic stem cell transplants.

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. MassHealth Drug List- Health and Human Services. Table 72: Agents not Otherwise Classified – Stem Cell Therapies. April 2024. Accessed July 1, 2024. https://mhdl.pharmacy.services.conduent.com/MHDL/pubtheradetail.do?id=2445&drugId=8660
5. Omisirge (omidubicel-onlv) [package insert]. Boston, MA. Gamida Cell. February 2026.
6. Selection of an umbilical cord blood graft for hematopoietic cell transplantation. UpToDate.com/login [via subscription only]. Published June 10, 2026. Accessed September 15, 2026.
7. 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.
8. 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.
9. 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.
10. 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.
11. 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.
12. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines: Hematopoietic Cell Transplantation (HCT) (Version 3. 2026). July 30, 2026. Accessed September 15, 2026. https://www.nccn.org/professionals/physician_gls/pdf/hct.pdf
13. 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.
14. Childs RW, Tian X, Young N, Hur J, Lonskaya I, Cole K, et al. Outcomes of omidubicel-expanded umbilical cord blood transplantation in patients with severe aplastic anemia. Blood. 2025;146(Suppl 1):5963. Presented at: American Society of Hematology Annual Meeting; 2025. doi:10.1182/blood-2025-5963.
15. Scheinberg P. et. al. American Society of Hematology 2026 guidelines for the diagnosis and management of severe and very severe acquired aplastic anemia. Blood Adv. 2026 Sep 8;10(17):5962-5990. doi: 10.1182/bloodadvances.2025019051. PMID: 41920091; PMCID: PMC13546908.
16. National Heart, Lung, and Blood Institute (NHLBI). Aplastic Anemia. National Institutes of Health. Updated March 24, 2022. Accessed October 1, 2026. Available at: NHLBI Aplastic Anemia.

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:

- September 17, 2024: Reviewed and approved by UM Committee effective October 1, 2024
- November 21, 2024: Reviewed by MPAC, renewed without any changes, effective January 1, 2025
- December 13, 2024: Reviewed and approved by the UM Committee effective January 1, 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
- December 8, 2025: Reviewed by UM Committee for annual review, renewed without changes effective January 1, 2026.
- September 16, 2026: Reviewed by MPAC. Criteria updated to include Severe Aplastic Anemia consistent with MassHealth coverage which adopted the FDA label expansion. Overview and references updated, effective November 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.