CarePartners of Connecticut MEDICARE ADVANTAGE

Medical Necessity Guidelines

Medical Benefit Drugs

# Omisirge (omidubicel-onlv)

*Effective: January 1, 2025*

| | |
|---|---|
| **Prior Authorization Required**<br>If REQUIRED, submit supporting clinical documentation pertinent to service request to the FAX numbers blow. | Yes ☒ No ☐ |
| **Notification Required**<br>IF REQUIRED, concurrent review may apply | Yes ☐ No ☒ |

**Applies to:**

☒ CarePartners of Connecticut Medicare Advantage HMO plans, Fax 617-673-0956

☒ CarePartners of Connecticut Medicare Advantage PPO plans, 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

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.

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.

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

The Plan considers Omisirge, as reasonable and medically necessary when ALL of the following clinical criteria are met:

1. The Member has the appropriate diagnosis; **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.

## Codes

The following codes are associated with this service:

**Table 1:**

| Code | Description |
|---|---|
| J3590 | Unclassified biologics |

**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. April 2023.


## 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 changes, effective January 1, 2025
- December 13, 2024: Reviewed and approved by the UM Committee, effective January 1, 2025

## 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.

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.