CARECONTINUUM™

# UTILIZATION MANAGEMENT MEDICAL POLICY

**POLICY:** Transplantation – Omisirge Utilization Management Medical Policy
- Omisirge® (omidubicel-onlv intravenous infusion – Gamida)

**REVIEW DATE:** 09/11/2024

## OVERVIEW

Omisirge, a nicotinamide modified allogeneic hematopoietic progenitor cell therapy derived from cord blood, is indicated for use in patients with hematologic malignancies who are planning to undergo umbilical cord blood transplantation following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infection in adults and pediatric patients ≥ 12 years of age.[1]

### Disease Overview

Stem cell transplantation is used to treat various hematologic malignancies and involves placing healthy stem cells into the patient to restore the normal production and function of blood cells.[2-6] Umbilical cord blood is one source of healthy stems cells used for allogeneic transplantation; others can be obtained from peripheral blood or bone marrow. After birth, the blood present in the umbilical cord and placenta contains valuable hematopoietic stems cells that are typically discarded as medical waste. However, through donation, umbilical cord blood cells can be stored and used later for patients with conditions such as hematologic malignancies. Around 70% of patients do not have an optimal matched family donor; therefore, cells can be obtained from an unrelated donor. Patients who are non-White generally have more difficulties finding a suitable donor.

### Dosing Information

Omisirge is given as a single intravenous dose.[1] Omisirge is provided in two bags containing the two cryopreserved cell fractions (i.e., cultured fraction and non-cultured fraction). After it is made from the umbilical cord blood donor source, which takes about 21 days, Omisirge is shipped to the transplant center for a specific patient.

### Guidelines

The National Comprehensive Cancer Network guidelines for hematopoietic cell transplantation (version 2.024 – August 30, 2024) address Omisirge.[2] The guidelines note that if umbilical cord blood transplantation is being used, Omisirge has been demonstrated to shorten the time to engraftment and reduce the risk of some infections. In a Phase III trial, the median time to neutrophil engraftment for umbilical cord blood transplantation with Omisirge was only 12 days compared with 22 days for standard umbilical cord blood transplantation. Also, platelet recovery was shorter in the Omisirge arm (55% vs. 35% recovery at 42 days). Grade 2 to 3 bacterial or invasive fungal infections were also less common in the Omisirge group (37% vs. 57%).

### Safety

Omisirge has a Boxed Warning regarding infusion reactions, graft versus host disease, engraftment syndrome, and graft failure.[1]

## POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Omisirge. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for one dose. The approval duration is 6 months to allow for an adequate timeframe to prepare and administer one dose of therapy.

**Automation:** None.

## RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Omisirge is recommended in those who meet the following criteria:

### FDA-Approved Indication

1. **Umbilical Cord Blood Transplantation.** Approve for one dose if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient is ≥ 12 years of age; AND
   - **B)** Patient has a hematologic malignancy; AND
     Note: Examples of hematologic malignancies are acute myelogenous leukemia, acute lymphoblastic leukemia, and chronic myeloid leukemia.
   - **C)** Omisirge is prescribed by or in consultation with a hematologist, oncologist, transplant specialist physician, or a physician associated with a transplant center.

   **Dosing.** Approve a single dose of Omisirge given by intravenous infusion.
   Note: Omisirge is provided in two separate bags containing the two cryopreserved cell fractions (i.e., cultured fraction and non-cultured fraction).

## CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Omisirge is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

## REFERENCES

1. Omisirge® intravenous infusion [prescribing information]. Boston, MA: Gamida; April 2023.
2. The NCCN Hematopoietic Cell Transplantation (HCT) Guidelines in Oncology (version 2.2024 – August 30, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 5, 2024.
3. Bazinet A, Popradi G. A general practitioner's guide to hematopoietic stem-cell transplantation. *Curr Oncol*. 2019;26(3):187-191.
4. Sanchez-Petitto G, Rezvani K, Daher M, et al. Umbilical cord blood transplantation: connecting its origin to its future. *Stem Cells Transl Med*. 2023;12(2):55-71.
5. Gandhi AP, Newell LF, Maziarz RT. A new beginning: can omidubicel emerge as the next viable alternative donor source? *Ther Adv Hematol*. 2023;14:1-14.
6. Dehn J, Spellman S, Hurley CK, et al. Selection of unrelated donors and cord blood units for hematopoietic cell transplantation: guidelines from the NMDP/CIBMTR. *Blood*. 2019;134(12):924-934.

## HISTORY

| Type of Revision | Summary of Changes | Review Date |
|---|---|---|
| New Policy | -- | 08/09/2023 |
| Annual Revision | No criteria changes. | 09/11/2024 |