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| **Section:** | Prescription Drugs | **Effective Date:** | July 1, 2026 |
| **Subsection:** | Hematological Agents | **Original Policy Date:** | June 2, 2023 |
| **Subject:** | Omisirge | **Page:** | 1 of 4 |

***Last Review Date:*** June 11, 2026

# Omisirge

## Description

### Omisirge (omidubicel-onlv) suspension for infusion

**Background**
Omisirge (omidubicel-onlv) is a cryopreserved nicotinamide modified allogeneic hematopoietic progenitor cell therapy derived from cord blood consisting of 2 cell fractions; a Cultured Fraction (CF) and a Non-cultured Fraction (NF) which are both derived from the same patient-specific cord blood unit (CBU) (1).

**Regulatory Status**
FDA-approved indication: Omisirge is a nicotinamide modified allogeneic hematopoietic progenitor cell therapy derived from cord blood indicated for the treatment of: (1)

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

Omisirge has boxed warnings for infusion reactions, Graft-vs-Host Disease (GvHD), engraftment syndrome, autoimmune cytopenias, and graft failure. The patient should be monitored during infusion and the medication should be discontinued if severe reactions occur. Use is contraindicated in patients with known allergy to dimethyl sulfoxide (DMSO), Dextran 40, gentamicin, human serum albumin, or bovine material. Administration of immunosuppressive therapy may decrease the risk of GvHD. If engraftment syndrome occurs, treat promptly with corticosteroids. Monitor blood counts prior to and after infusion. Manage cytopenias according

to local institutional guidelines. Graft failure, defined as failure to achieve an absolute neutrophil count greater than 500 per microliter blood by Day 42 after transplant, may occur and may be fatal. Patients should be monitored for laboratory evidence of hematopoietic recovery (1).

Malignancies originating from the donor, transmission of serious infections, and transmission of rare genetic diseases may occur. The patient should be monitored for life-long secondary malignancies, serious infections, and rare genetic diseases (1).

The safety and effectiveness of Omisirge in pediatric patients less than 6 years of age for the treatment of severe aplastic anemia have not been established. The safety and effectiveness of Omisirge in pediatric patients less than 12 years of age for the treatment of hematologic malignancies have not been established (1).

**Related policies**

## Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Omisirge may be considered **medically necessary** for the indications listed below.

Omisirge may be considered **investigational** for all other indications.

## Prior-Approval Requirements

### Diagnoses

Patient must have **ONE** of the following:

1. Hematologic malignancy
   a. 12 years of age or older
   b. Planned for umbilical cord blood transplantation following myeloablative conditioning
   c. Used to reduce the time to neutrophil recovery and the incidence of infection

2. Severe aplastic anemia (SAA)

a. 6 years of age or older
b. Patient has or will receive a reduced intensity preparative conditioning regimen prior to administration of Omisirge

**AND** the following for **ALL** indications:

1. No human leukocyte antigen-matched donor available

## Prior – Approval *Renewal* Requirements

None

## Policy Guidelines

## Pre - PA Allowance

None

## Prior - Approval Limits

**Duration** One infusion (only one PA approval for one infusion per lifetime)

## Prior – Approval *Renewal* Limits

None

## Rationale

**Summary**

Omisirge is a nicotinamide modified hematopoietic progenitor cell therapy derived from cord blood used as an allogenic stem cell donor source. Omisirge is indicated for the treatment of hematologic malignancies who are planned for umbilical cord blood transplantation following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infections and severe aplastic anemia following reduced intensity conditioning. Patients should be monitored for infusion reactions, Graft-vs-Host Disease (GvHD), autoimmune cytopenias, engraftment syndrome, graft failure, secondary malignancies, serious infections, and rare genetic diseases (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Omisirge while maintaining optimal therapeutic outcomes.

**References**

1. Omisirge [package insert]. Boston, MA: Gamida Cell Inc.; February 2026.

## Policy History

| Date | Action |
|---|---|
| June 2023 | Addition to PA. Annual review |
| September 2023 | Annual review |
| June 2024 | Annual review and reference update |
| June 2025 | Annual review and reference update |
| April 2026 | Per PI update, added indication of SAA |
| June 2026 | Annual review |

## Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 11, 2026 and is effective on July 1, 2026.**