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Section:	Prescription Drugs	**Effective Date:**	October 1, 2023
Subsection:	Hematological Agents	**Original Policy Date:**	June 2, 2023
Subject:	Omisirge	**Page:**	1 of 3

Last Review Date: September 8, 2023

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 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 (1).

Omisirge has boxed warnings for infusion reactions, Graft-vs-Host Disease (GvHD), engraftment syndrome, 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 risk of GvHD. If engraftment syndrome occurs, treat promptly with corticosteroids. Graft failure, defined as failure to achieve an absolute neutrophil count greater than 500 per microliter blood by Day 42 after transplant, may occur. 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 12 years of age 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

Age 12 years of age or older

Diagnosis

Patient must have the following:

1. Hematologic malignancy

AND ALL of the following

1. Planned for umbilical cord blood transplantation following myeloablative conditioning
2. Used to reduce the time to neutrophil recovery and the incidence of infection
3. No human leukocyte antigen-matched donor available

Prior – Approval *Renewal* Requirements

Same as above

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 used for 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. Patients should be monitored for infusion reactions, Graft-vs-Host Disease (GvHD), 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.; April 2023.

Policy History

Date	Action
June 2023	Addition to PA. Annual review
September 2023	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 8, 2023 and is effective on October 1, 2023.