MVP Health Care Medical Policy

Medicare Part B: Omidubicel

Type of Policy:	Medical Therapy (administered by the pharmacy department)
Prior Approval Date:	**NA**
Approval Date:	**02/01/2024**
Effective Date:	**02/01/2024**
Related Policies:	Donislecel Experimental or Investigational Procedures, Behavioral Health Services, Drugs and Treatments, Off-Label use of FDA Approved Drugs, and Clinical Trials

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

Drugs Requiring Prior Authorization under the medical benefit

J3590 omidubicel, cell therapy suspension for infusion

Overview/Summary of Evidence

Omidubicel is approved for use in hematopoietic stem cell transplant following myeloablative conditioning in patients with hematologic malignancies to reduce the time to neutrophil recovery and incidence of infection. It has been designated an orphan drug for this indication. Omidubicel 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.

Indications/Criteria

Hematologic Malignancy

Omidubicel may be considered for coverage when all of the following criteria are met:

- Member is 12 years of age or older
- Member has a documented hematologic malignancy, and the medication is being used to reduce the time to neutrophil recovery and incidence of infection.
- Documentation that the member has not received a prior allogeneic hematopoietic stem cell transplant (allo-HSCT)
- Documentation of planned umbilical cord blood transplantation
- Documentation that member will receive myeloablative conditioning.
- Prescribed by or in consultation with a hematologist or oncologist
- Must be administered at a transplant center who is activated and able to administer omidubicel
    - Treatment centers that can administer are: OMISIRGE™ (omidubicel-onlv) | Allogeneic Hematopoietic Progenitor Cell Therapy
- Documentation that administration of omidubicel will be under the supervision of a physician experienced in treatment of hematologic malignancies
- Documentation that the member does not have a known allergy or hypersensitivity to the following:
    - Dimethyl sulfoxide (DMSO)
    - Dextran 40
    - Gentamicin aminoglycoside albumin
    - Bovine protein hypersensitivity

If approved, coverage will be for one infusion of Omidubicel and will not be renewed. Requests for replacement due to lost or damaged product will not be covered. Coverage is contingent on eligibility at the time of infusion.

Exclusions

The use of Omidubicel will not be covered for the following situations:

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling.
- More than one infusion per lifetime

References

1. Omidubicel. Clinical Pharmacology. Revised May 2, 2023. Accessed December 6, 2023.

2. Prescribing Information. Omisirge. Gamida Cell, Inc. Boston, MA. Revised April 2023. Omisirge-final-PI.pdf (gamida-cell.com)