



MVP Health Care Medical Policy

Medicare Part B: Omidubicel

Type of Policy:	Medical Therapy (administered by the pharmacy department)
Prior Approval Date:	08/01/2025
Approval Date:	08/01/2026
Effective Date:	10/01/2026
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.

Refer to relevant CMS LCDs/NCDs/Policy Articles for most up to date Medicare Part B guidance if available

Drugs Requiring Prior Authorization under the medical benefit

J3590 omidubicel (Omsirge), cell therapy suspension for infusion

Overview/Summary of Evidence

Omidubicel is a nicotinamide-modified allogeneic hematopoietic progenitor cell therapy derived from cord blood indicated for the treatment of 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. Omidubicel is also indicated for the treatment of adult and pediatric patients 6 years and older with severe aplastic anemia (SAA) following reduced intensity conditioning. The FDA has designated omidubicel as an orphan drug for both indications.

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: [Find an Omisurge® \(omidubicel-only\) treatment near you](#)
- 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
 - Human serum albumin
 - Bovine material

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.

Severe Aplastic Anemia

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

- Member is 6 years of age or older
- Member has a documented diagnosis of severe aplastic anemia

- Member has received or will receive reduced intensity conditioning prior to administration of omidubicel
- Documentation that the member has not received a prior allogeneic hematopoietic stem cell transplant (allo-HSCT)
- 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: [Find an Omisurge® \(omidubicel-only\) treatment near you](#)
- Documentation that administration of omidubicel will be under the supervision of a physician experienced in treatment of severe aplastic anemia
- Documentation that the member does not have a known allergy or hypersensitivity to the following:
 - Dimethyl sulfoxide (DMSO)
 - Dextran 40
 - Gentamicin
 - Human serum albumin
 - Bovine material

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 02/18/2026. Accessed July 23, 2026.

2. Prescribing Information. Omisirge. Gamida Cell, Inc. Boston, MA. Initial Approval 2023. Revised 02/2026. [Omisirge-final-PI.pdf \(gamida-cell.com\)](#)