

Specialty Guideline Management

Omisirge

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
|------------|-----------------|
| Omisirge | omidubicel-only |

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

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.

All other indications are considered experimental/investigational and not medically necessary.

Coverage Criteria

Umbilical Cord Blood Transplantation

| Reference number(s) |
|---------------------|
| 5904-A |

Authorization of 3 months (one dose total) may be granted for members 12 years of age and older who will receive umbilical cord blood transplantation when all of the following criteria are met:

- The member has a hematologic malignancy.
- The requested medication is being used to reduce the time to neutrophil recovery and incidence of infection.
- The member will receive myeloablative conditioning.

References

1. Omisirge [package insert]. Jerusalem, Israel: Gamidia Cell Ltd.; February 2024.