

RX.PA.117.MPC Omisirge (omidubicel-only)

The purpose of this policy is to define the prior authorization process for Omisirge®(omidubicel-only), 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
- Adults and pediatric patients 6 years and older with severe aplastic anemia (SAA) following reduced intensity conditioning

PROCEDURE

A. Initial Authorization Criteria

1. Planned Umbilical Cord Blood Transplantation

- Must be 12 years of age or older
- Must have a documented hematologic malignancy
 - Examples include: ALL, AML, CML, MDS or Lymphoma
- Member does not have a human leukocyte antigen matched related donor or matched unrelated donor
- Must not have had prior allogeneic hematopoietic stem cell transplantation
- Must be prescribed by a hematologist, oncologist, or a transplant specialist
- Must have documentation of a planned umbilical cord blood transplantation following myeloablative conditioning
- Member must not have a known allergy to dimethyl sulfoxide (DMSO), Dextra 40, gentamicin, human serum albumin, or bovine material
- Provider attestation that the requested medication will be used to reduce the time to neutrophil recovery and incidence of infection
- Provider attestation to monitor the member for any hematologic malignancies and infections
- Must not have had prior treatment with Omisirge

2. Severe Aplastic Anemia (SAA)

- Must be 6 years of age or older
- Documented diagnosis of severe aplastic anemia (SAA) evidenced with:
 - Bone marrow cellularity < 30% (excluding lymphocytes) OR
 - Absolute neutrophil count (ANC) <1000 cells/microL

- Must be prescribed by a hematologist or a physician experienced in treatment of hematologic malignancies or SAA
- Member must not have a known allergy to dimethyl sulfoxide (DMSO), Dextra 40, gentamicin, human serum albumin, or bovine material
- Provider attestation to monitor the member for any hematologic malignancies and infections
- Must have trial and failure, intolerance to, or contraindication to an immunosuppressant therapy (at least 3 months)
 - [Note: Examples of therapies are cyclosporine, Atgam [lymphocyte immune globulin, anti-thymocyte globulin [equine] sterile solution for intravenous use only], mycophenolate mofetil, sirolimus.]
- Must have documentation of a reduced intensity conditioning regimen prior to omisirge administration
- Must not have had prior treatment with Omisirge

B. Must be prescribed at a dose within the manufacturer’s dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.

C. Omisirge treatments will be considered investigational or experimental for any other use and will not be covered.

D. Reauthorization Criteria:

- No reauthorization allowed

Length of Authorization (if above criteria met)	
Initial Authorization	Limited to 1 time infusion
Reauthorization	No Reauthorization Allowed

APPLICABLE CODES

Code	Description
J3590	Unclassified biologics

References

1. Omisirge [package insert]. Kiryat gat 8258412, Isreal: Gamida Cell Ltd.; February 2026.

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REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
<i>New Policy</i>	<i>04/2026</i>