omidubicel-onlv (Omisirge)

Commercial Medical Benefit Drug Policy

Place of Service
Hospital Administration

Drug Details

USP Category: ANTINEOPLASTICS
Mechanism of Action: Nicotinamide modified allogeneic hematopoietic progenitor cell therapy
HCPCS:
C9399:Unclassified drugs or biologicals
J3490:Unclassified drugs
J3590:Unclassified biologics
J9999:Not otherwise classified, antineoplastic drugs
How Supplied:
NDCs:

- 73441-800-04: two shipping containers: (1) liquid nitrogen dry vapor shipper containing two cryopreserved cell fractions and a Chimerism Testing Sample(s), and (2) refrigerated shipping container containing two Infusion Solutions
- 73441-100-01: cryopreserved bag containing Cultured Fraction (CF)
- 73441-200-01: cryopreserved bag containing Non-cultured fraction (NF)
- 73441-300-01: Infusion Solution for CF
- 73441-400-01: Infusion Solution for NF

Condition(s) listed in policy *(see coverage criteria for details)*

- Hematologic Malignancies

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Hematologic Malignancies
Meets medical necessity if all the following are met:

1. Patient has a hematologic malignancy [e.g., acute myelogenous leukemia (AML), acute lymphoblastic leukemia (ALL), myelodysplastic syndrome (MDS), non-Hodgkin lymphoma (NHL), myeloproliferative neoplasms (MPN)]
2. Patient is a candidate for umbilical cord blood transplantation following myeloablative conditioning
3. Patient does not have a readily available matched sibling or matched unrelated donor
4. Patient has not received a prior allogeneic hematopoietic stem cell transplantation

Covered Doses:
Omisirge is a cell suspension for intravenous infusion. A single dose of OMISIRGE consists of:

- a Cultured Fraction (CF): a minimum of 8.0×10^8 total viable cells of which a minimum of 8.7% is CD34+ cells and a minimum of 9.2×10^7 CD34+ cells
- a Non-cultured Fraction (NF): a minimum of 4.0×10^8 total viable cells with a minimum of 2.4×10^7 CD3+ cells

Coverage Period:
One treatment course per lifetime

ICD-10:
D70.0, D70.9

References

1. AHFS. Available by subscription at http://www.lexi.com
2. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
3. Omisirge (omidubicel) [prescribing information]. Boston, MA: Gamida Cell Inc; 1/2025.

Review History

Date of Last Annual Review: 3Q2025
Changes from previous policy version:

- No clinical change following annual review.

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee