

omidubicel-ONLY (Omisirge®)

Medical Benefit Drug Policy

Place of Service

Outpatient Facility Administration

Hospital Administration

Infusion Center Administration

Drug Details

USP Category:Class: Antineoplastics:Antineoplastics, Other

Mechanism of Action: Nicotinamide modified allogeneic hematopoietic progenitor cell therapy derived from cord blood

HCPCS: J3490, J3590, J9999

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 bullosa](#)

Special Instructions and pertinent Information

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

Covered under the Medical Benefit, please submit clinical information for prior authorization review

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice:

Hematologic malignancies bullosa

1. Patient has a hematologic malignancy [e.g., acute myelogenous leukemia (AML), acute lymphoblastic leukemia (ALL), myelodysplastic syndrome (MDS), non-Hodgkin lymphoma (NHL), myeloproliferative diseases (MPH)], AND

Promise Health Plan

2. Patient is a candidate for umbilical cord blood transplantation following myeloablative conditioning, AND
3. Patient does not have a readily available matched sibling or matched unrelated donor, AND
4. Patient has not received a prior allogeneic hematopoietic stem cell transplantation

Covered Doses

Omisirge is a cell suspension for IV 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, and
- 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

1 treatment course per lifetime

Additional Information:

There are three primary sources of stem cells for HSCT: bone marrow, peripheral blood, and umbilical cord blood (UCB). Omisirge is a cord blood-based cell therapy that can be used in place of umbilical cord blood transplantation (UCBT) to treat hematologic malignancies. The three main types of hematologic malignancy are lymphoma, leukemia, and multiple myeloma.

Omisirge consists of allogeneic hematopoietic progenitor cells (HPCs) derived from umbilical cord blood that have been processed with nicotinamide (NAM), which enhances HPC enrichment and expansion. Omisirge is administered as a one-time, patient specific dose, and is available for use by transplant specialists at transplant centers.

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-only). [Prescribing information]. Boston, MA: Gamida Cell Inc.; April 2023.

omidubicel-only (Omisirge®)

Policy Update

Date of Last Annual Review: New policy

Date of last revision: New policy

Changes from previous policy version:

- New policy

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