Omisirge® (omidubicel-onlv)
(Intravenous)

Document Number: IC-0707

Last Review Date: 06/01/2023
Date of Origin: 06/01/2023
Dates Reviewed: 06/2023

I. Length of Authorization

Coverage will be provided for 1 dose only

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Omisirge single-use culture containing at least 12×10^8 live cells, which include CD34+ and CD3+ cells: 1 dose only

B. Max Units (per dose and over time) [HCPCS Unit]:

- 1 dose only (single-use culture containing at least 12×10^8 live cells, which include CD34+ and CD3+ cells)

III. Initial Approval Criteria

Coverage is provided in the following conditions:

Umbilical cord blood transplantation (UCBT) following myeloablative conditioning in patients with hematologic malignancies to reduce the time to neutrophil recovery and incidence of infection † Φ [1-3]

- Patient is 12 years of age or older; **AND**
- Patient is eligible for allogeneic hematopoietic stem cell transplant (allo-HSCT) and has not received a prior allo-HSCT; **AND**
- Patient has a diagnosis of a high-risk hematologic malignancy and is planned for an umbilical cord blood transplantation (UCBT) following myeloablative conditioning; **AND**
- Therapy is used to reduce the time to neutrophil recovery and incidence of infection; **AND**
- Patient will receive prophylactic and supportive therapies for prevention or treatment of transplant complications (e.g., GVHD, infections, etc.) according to institutional guidelines; **AND**

- Patient does not have a known allergy or hypersensitivity to any of the following:
  - Dimethyl Sulfoxide (DMSO)
  - Dextran 40
  - Gentamicin
  - Human serum albumin or bovine material; **AND**
- Patients has no readily available matched related donor (MRD), matched unrelated donor (MUD), mismatched (7/8 matched) unrelated donor (MMUD), or haploidentical (half HLA-matched) related donor

† FDA Approved Indication(s); ‡ Compendia recommended indication(s); Φ Orphan Drug

IV. Renewal Criteria [1]

Coverage cannot be renewed.

V. Dosage/Administration [1]

Indication	Dose
Reduce the time to neutrophil recovery and the incidence of infection following myeloablative conditioning	• A single dose of Omisirge consists of – 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 × 107 CD34+ cells, and – Non-cultured Fraction (NF): a minimum of 4.0×10^8 total viable cells with a minimum of 2.4 × 107 CD3+ cells • The CF and NF are supplied cryopreserved separately in two bags. Omisirge requires thaw and dilution with two infusion solution (IS) bags (one IS bag for the CF, and one IS bag for the NF) prior to administration. Infusion of the NF bag should begin within 1 hour after completion of the CF infusion. For timing of dosing of each fraction, refer to section 2.2 under "Planning prior to Omisirge preparation".
– *For intravenous use only. Do not irradiate.* – *Do NOT use a leukodepleting filter.* – *Verify patient's identity upon receipt. Do NOT open the metal cassettes until time of thaw.* – *Verify patient's identity prior to thaw and prior to infusion.* – *Thawing should only take place immediately prior to use.* – *Administration of Omisirge should be under the supervision of a physician experienced in treatment of hematologic malignancies, in a center with expertise in hematopoietic stem cell transplants.*	

VI. Billing Code/Availability Information

HCPCS code:

- J3590 – Unclassified biologics
- C9399 – Unclassified drugs or biologicals

- NDC(s):

  Omisirge single-use cryopreserved cell fractions culture containing at least 12×10^8 live cells *(At the time of cryopreservation, the CF contains a minimum of 8.0×10^8 total viable cells with a minimum of 8.7% CD34+ cells and a minimum of 9.2×10^7 CD34+ cells suspended in 20 mL of a cryopreservation solution containing 10% DMSO)*: 73441-0800-xx

VII. References

1. Omisirge [package insert]. Boston, MA; Gamida Cell, Inc.; April 2023. Accessed May 2023.
2. Horwitz ME, Stiff PJ, Cutler C, et al. Omidubicel vs standard myeloablative umbilical cord blood transplantation: results of a phase 3 randomized study. Blood. 2021 Oct 21;138(16):1429-1440. doi: 10.1182/blood.2021011719.
3. Kanate AS, Majhail NS, Savani BN, et al. Indications for Hematopoietic Cell Transplantation and Immune Effector Cell Therapy: Guidelines from the American Society for Transplantation and Cellular Therapy (ASTCT). Transplantation and Cellular Therapy. Volume 26, Issue 7, P1247-1256, July 2020. DOI: https://doi.org/10.1016/j.bbmt.2020.03.002
4. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Hematopoietic Cell Transplantation1.2023. National Comprehensive Cancer Network, 2023. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed May 2023.
5. Sivaraman S, Sajeev G, Song Y, et al. Clinical Outcomes Following Allogeneic Hematopoietic Cell Transplantation with Omidubicel or Other Donor Sources in Patients with Hematologic Malignancies: Comparison of Clinical Trial Results to Center for International Blood and Marrow Transplant Research Database Controls. *Blood* (2022) 140 (Supplement 1): 660–661. https://doi.org/10.1182/blood-2022-162439
6. Natasha Kekre, Joseph H. Antin; Hematopoietic stem cell transplantation donor sources in the 21st century: choosing the ideal donor when a perfect match does not exist. *Blood* 2014; 124 (3): 334–343. doi: https://doi.org/10.1182/blood-2014-02-514760

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
Z94.81	Bone marrow transplant status

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage

Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC