Omisirge® (omidubicel-onlv)
(Intravenous)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for one treatment course (1 dose).
- Renewal: Prior authorization validity may NOT be renewed.

II. Dosing Limits

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

Submission of supporting clinical documentation (including but not limited to medical records, chart notes, lab results, and confirmatory diagnostics) related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission as part of the evaluation of this request. Please provide documentation related to diagnosis, step therapy, and clinical markers (i.e., genetic, and mutational testing) supporting initiation when applicable. Please provide documentation via direct upload through the PA web portal or by fax**.** Failure to submit the medical records may result in the denial of the request due to inability to establish medical necessity in accordance with policy guidelines.

Prior authorization validity is provided in the following conditions:

- Member does not have any FDA labeled contraindications to the requested agent; **AND**
- Member will receive prophylactic and supportive therapies for prevention or treatment of transplant complications (e.g., GvHD, infections, etc.) according to institutional guidelines; **AND**

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

- Member is at least 12 years of age; **AND**

- Member is eligible for allogeneic hematopoietic stem cell transplant (allo-HSCT) and has not received a prior allo-HSCT; **AND**
- Member 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**
- Member 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

Severe aplastic anemia (SAA) following reduced intensity conditioning † Φ [1]

- Member is at least 6 years of age; **AND**
- Member has a diagnosis of severe aplastic anemia (SAA) with severe neutropenia (i.e., ANC<1000 cells/μL) following reduced intensity conditioning; **AND**
- Member has tried and failed on or has an intolerance to standard immunosuppressive therapy; **AND**
- Member has an ECOG score of ≤1; **AND**
- Member has no readily available HLA identical (12/12) matched related or unrelated donor

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

IV. Renewal Criteria [1]

Duration of authorization has not been exceeded *(refer to Section I)*

V. Dosage/Administration [1]

Indication	Dose
All Indications	• 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 9.2×10^7 CD34+ cells, and – Non-cultured Fraction (NF): a minimum of 4.0×10^8 total viable cells with a minimum of 2.4×10^7 CD3+ cells • The CF and NF are supplied cryopreserved. 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 of the prescribing information under "Planning prior to Omisirge preparation".
– *For intravenous use only. Do not irradiate.*	

- *Do NOT use a leukodepleting filter.*
- *Verify member's identity upon receipt, 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 or SAA, as appropriate, in centers with expertise in hematopoietic stem cell transplants.*

VI. Billing Code/Availability Information

HCPCS Code(s):

- J3590 – Unclassified biologics
- C9399 – Unclassified drugs or biologicals *(Hospital Outpatient Use ONLY)*

NDC:

- 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]. Naples, FL; Gamida Cell, Inc.; February 2026. Accessed March 2026.
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 Transplantation 2.2026. National Comprehensive Cancer Network, 2026. 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 April 2026.
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
7. Richard Childs, Xin Tian, Neal Young, et al; Outcomes of omidubicel-expanded umbilical cord blood transplantation in patients with severe aplastic anemia. *Blood* 2025; 146 (Supplement 1): 5963. doi: https://doi.org/10.1182/blood-2025-5963

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	Yes: Consider for PA
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
D61.9	Aplastic anemia, unspecified
Z94.81	Bone marrow transplant status

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

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied 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
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
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