

Clinical Policy: Omisirge (omidubicel): Nicotinamide-modified allogeneic hematopoietic progenitor cell therapy

Reference Number: LA.CP.MP.249

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[Last Review Date: 07/23](#)

[Revision Log](#)

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Description

This policy describes the medical necessity criteria for Omisirge (omidubicel), a nicotinamide-modified allogeneic hematopoietic progenitor cell therapy, to be delivered following myeloablative conditioning for hematologic malignancies.

Policy/Criteria

- I. **It is the policy of Louisiana Healthcare Connections that Omisirge (omidubicel) is medically necessary when all of the following criteria are met:**
 - A. **Member/enrollee is ≥ 12 years of age;**
 - B. **Diagnosis of hematologic malignancies;**
 - C. **Member/enrollee is planned for an umbilical cord blood transplantation following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infection;**
 - D. **Request is for one administration post-myeloablative conditioning.**

Background

Allogeneic hematopoietic cell transplantation (HCT) has been used as a treatment for cancer and diseases of the blood system for decades. For this treatment, stem cells are collected from either related or unrelated donors.¹ During the conditioning phase, high doses of chemotherapy (HDC), with or without radiation therapy, are used to eradicate the disease and this is followed by infusion of stem cells to rescue bone marrow and restore normal immune function. Major limitations of this technique include the increased risk of high morbidity and mortality related to increased age, relapsed or refractory disease or disease with an elevated risk of relapse following HCT, a history of aggressive chemotherapy, and comorbidities.² All stem cell transplants (SCTs) preparative regimens have the potential for extensive toxicity. Loss of appetite and energy, alopecia, and nausea/vomiting occur frequently and contribute to poor physical and emotional tolerance of the transplant procedure. In addition, mucositis, diarrhea, and transient pancytopenia are inevitable side effects of most preparative regimens, and these complications are synergistic in dramatically increasing the risk of infections during and post-transplant.³ Any decrease in toxicity, without concomitant loss of efficacy, would be desirable.

Myeloablative means that the treatment kills (ablates) the stem cells in the bone marrow; the cells that produce new blood cells. Myeloablative conditioning (MAC) is a regimen that consists of a single agent or combination of agents that are anticipated to destroy the hematopoietic cells in the bone marrow.³ Extensive pancytopenia occurs within one to three weeks after administration of a MAC regimen and is typically irreversible.³

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In April 2023, the U.S. Food and Drug Administration (FDA) approved Omisirge, a nicotinamide-modified allogeneic hematopoietic progenitor cell therapy. Omisirge is derived from cord blood and quickens the recovery of neutrophils in the body and reduces the incidence of infection. The product is intended to be used in patients ≥ 12 years of age with blood malignancies who have a planned umbilical cord blood transplantation following myeloablative conditioning.^{4,5}

A randomized, multicenter study with 125 enrollees comparing transplantation of Omisirge to transplantation of umbilical cord blood supports the safety and effectiveness of Omisirge.^{4,6,7} The study found that 87% of subjects who received Omisirge attained neutrophil recovery in an average of 12 days after treatment. In comparison, neutrophil recovery was achieved in an average of 22 days in 83% of subjects who received umbilical cord blood transplantation.^{6,7} Additionally, subjects in the study who received Omisirge had fewer bacterial or fungal infections than the group of subjects who received umbilical cord blood transplantation.^{4,6,7}

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2022, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only and may not support medical necessity. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

NOTE: Coverage is subject to each requested code's inclusion on the corresponding LDH fee schedule. Non-covered codes are denoted (*) and are reviewed for Medical Necessity for members under 21 years of age on a per case basis.

<u>HCPCS Codes</u>	<u>Description</u>
<u>J3490</u>	<u>Unclassified drugs</u>
<u>J3590</u>	<u>Unclassified biologics</u>
<u>C9399</u>	<u>Unclassified drugs or biologics</u>

<u>Reviews, Revisions, and Approvals</u>	<u>Review Date</u>	<u>Approval Date</u>
<u>Converted corporate to local policy</u>	<u>07/23</u>	

References

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2. Deeg HJ, Sandmaier BM. Determining eligibility for allogeneic hematopoietic cell transplantation. UpToDate. www.uptodate.com. Updated February 21, 2022. Accessed December 21, 2022.
3. Negrin RS. Early complications of hematopoietic cell transplantation. UpToDate. www.uptodate.com. Updated June 30, 2022. Accessed December 21, 2022.
4. U.S. Food and Drug Administration. FDA Approves Cell Therapy for Patients with Blood Cancers to Reduce Risk of Infection Following Stem Cell Transplantation. <https://www.fda.gov/news-events/press-announcements/fda-approves-cell-therapy-patients-blood-cancers-reduce-risk-infection-following-stem-cell>. Published April 17, 2023. Accessed April 28, 2023.
5. Omisirge. [package insert]. Jerusalem, Israel: Gamida Cell Ltd.; 2023.
6. 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;138(16):1429 to 1440. doi:10.1182/blood.2021011719
7. Chou NJ. Selection of an umbilical cord blood graft for hematopoietic cell transplantation. UpToDate. www.uptodate.com. Published April 07, 2022. Accessed April 28, 2023.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

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This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable

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This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

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