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

Reference Number: LA.CP.MP.249 Coding Implications
Last Review Date: 07/~~23~~24 Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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.[1]

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]~~healthy donors instead of from the patients themselves.[2,3] 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.[2,3] All stem cell ~~transplants (SCTs~~transplant (SCT) 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.[3,4] 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.[3,4] Extensive pancytopenia occurs within one to three weeks after administration of a MAC regimen and is typically irreversible.[3,4]

Omisirge (omidubicel)
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.[41,5]

A randomized, multicenter study with 125 enrollees comparing transplantation of Omisirge to transplantation of umbilical cord blood supports the safety and effectiveness of Omisirge.[45,6,7] 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.[4,6,75,6,7] Further analysis of this study regarding healthcare resource utilization showed that in the first 100 days after transplantation, patients who received Omisirge had fewer days in the intensive care unit, a shorter total hospital length of stay, and fewer deaths compared to the group of patients who received umbilical cord blood transplantation.[8] These findings suggest that the use of Omisirge is associated with reduced healthcare resources due to faster hematopoietic recovery.[8]

Coding Implications
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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.

HCPCS Codes	Description
~~J3490~~	~~Unclassified drugs~~
J3590	Unclassified biologics
C9399	Unclassified drugs or biologicals

Reviews, Revisions, and Approvals	Review Date	Approval Date
Converted corporate to local policy	07/23	9/13/23
Policy/Criteria I. Background updated with no impact on criteria. References reviewed and updated. Reviewed by external specialist.	07/24	

~~**References**~~

References

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Important Reminder

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