Mass General Brigham
Health Plan

Omisirge
(omidubicel-onlv)

Policy Number: 074

	Commercial and Qualified Health Plans	MassHealth	Medicare Advantage
Authorization Required	X	X	X
No Prior Authorization			
Not covered			

Omisirge (omidubicel-onlv) is a nicotinamide-modified allogeneic hematopoietic progenitor cell therapy derived from cord blood that is indicated for treatment of hematologic malignancies in certain patients who require umbilical cord blood (UCB) transplantation.

FDA-approved indication
For use in adults and pediatric patients 12 years and older with hematologic malignancies planned for umbilical cord blood transplantation following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infection.

Coverage guidelines
Mass General Brigham Health Plan covers Omisirge when all of the following have been met:

1. Member is at least 12 years old
2. High-risk hematologic malignancy treated with myeloablative conditioning
3. No matched-related donor, matched-unrelated donor, or unrelated donor available

MassHealth variation
Prior authorization requests for Omisirge for Mass General Brigham ACO members should be submitted to the MassHealth Drug Utilization Review Program. Criteria for Omisirge are found in Table 72: Agents Not Otherwise Specified.

Medicare variation
Mass General Brigham Health Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) for coverage determinations for its Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and documentation included in the Medicare manuals are the basis for coverage determinations. When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan's medical policies are used for coverage determinations. **At the time of Mass General Brigham Health Plan's most recent policy review, Medicare had no NCD or LCD for Omisirge (omidubicel-onlv).**

Codes

The following codes are included for informational purposes only; inclusion of a code does not constitute or imply coverage.

The list of codes applies to commercial and MassHealth plans only.

Authorized CPT/HCPCS Codes	Code Description

J3490	Unclassified drugs
J3590	Unclassified biologics
C9399	Unclassified drugs or biologicals
J9999	Antineoplastic drugs, not otherwise classified
S2140	Cord blood harvesting for transplantation, allogeneic
S2142	Cord blood-derived stem-cell transplantation, allogeneic

Summary of Evidence

Omidubicel-onlv (Omisirge) received FDA approval based on compelling evidence from a pivotal Phase 3 randomized controlled trial, as reported by Horwitz et al. (2021). This landmark study compared the therapy to standard myeloablative umbilical cord blood transplantation (UCBT) in patients with various hematologic malignancies, including acute myeloid leukemia (AML), acute lymphoblastic leukemia (ALL), myelodysplastic syndromes (MDS), and chronic myelogenous leukemia (CML).

The trial carefully defined its target population through specific inclusion and exclusion criteria. Eligible patients were between 12 and 65 years of age, diagnosed with hematologic malignancies requiring allogeneic hematopoietic stem cell transplantation, and lacked suitable matched sibling or unrelated donors. Importantly, patients needed to be eligible for myeloablative conditioning. The study excluded patients with uncontrolled infections, organ dysfunction, previous allogeneic transplantation history, active CNS involvement of malignancy, or concurrent participation in other investigational therapy trials.

The primary endpoint, median time to neutrophil engraftment, was 12 days (95% CI: 10-15) for Omidubicel compared to 22 days (95% CI: 19-25) for standard UCBT ($p < 0.0001$). The engraftment success rate was also higher, with 96% of Omidubicel patients achieving neutrophil engraftment versus 89% in the control group. Secondary endpoints, including platelet engraftment and infections, were also superior with omidubicel than with standard UCBT. In a secondary analysis of the same study by Majhail et al. (2023), patients treated with omidubicel had a shorter length of hospital stay in the first 100 days following transplantation than did those treated with standard UCBT, as well as lower utilization of other healthcare services (including days in ICU, outpatient visits, and transfusions).

A pooled analysis by Lin et al. (2023) included patients enrolled in the study above as well as four smaller phase 1-2 trials in patients with hematologic malignancies (Horwitz et al. 2018) and sickle-cell disease (Parikh et al. 2021). In the pooled analysis, after median follow-up of 22 months (36 months among survivors), durable trilineage hematopoiesis was observed, and secondary graft failure occurred in 5%; estimated 3-year overall survival was 63% and disease-free survival was 56%, with a 37% cumulative 3-year incidence of chronic graft-versus-host disease. Post-transplantation lymphoproliferative disorder occurred in 2%, and donor-derived myelodysplastic syndrome in 1%.

Future studies will need to address real-world experience and cost-effectiveness of omidubicel compared with standard UCBT. Consistent with FDA labeling, MGB Health Plan considers Omisirge to be medically necessary for members who have a hematologic malignancy that is treated with allogeneic transplantation, who have no appropriate donor available and therefore need umbilical cord cell transplantation, and who meet criteria similar to those in the pivotal trial by Horwitz et al. (2021).

Effective

April 2025: Annual review. Fixed a typo in the Medicare variation. MassHealth variation updated to include new prior authorization process.
March 2025: Ad hoc update. Summary of evidence added.
April 2024: Effective date.

References

Gabida Cell, Inc. Omisirge (omidubicel-onlv) prescribing information. Boston, MA; Gabida Cell, Inc: April 2023.

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):1429-40.

Lin C, Schwarzbach A, Sanz J, et al. Multicenter long-term follow-up of allogeneic hematopoietic cell transplantation with omidubicel: a pooled analysis of five prospective clinical trials. Transplantation and Cellular Therapy 2023;29(5):338.e1-338.e6.

Majhail NS, Miller B, Dean R, et al. Hospitalization and healthcare resource utilization of omidubicel-onlv versus umbilical cord blood transplantation for hematologic malignancies: secondary analysis from a pivotal phase 3 clinical trial. Transplantation and Cellular Therapy 2023;29(12):749.e1-749e5.