

## Omisirge (omidubicel-only)

**Policy Number: 074**

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

Omisirge (omidubicel-only) 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  $\geq$ 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

Mass General Brigham Health Plan uses the [MassHealth Drug List](#) for coverage determinations for members of the MGB ACO. 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-only).**

### 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

### Effective

April 2024: Effective date

### References

Gabida Cell, Inc. Omisirge (omidubicel-only) 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-only 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.

