MASSACHUSETTS

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Medical Policy

Omidubicel as Adjunct Treatment for Hematologic Malignancies

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Policy Number: 028

BCBSA Reference Number: 8.01.68 (For Plan internal use only)
NCD/LCD: N/A

Related Policies

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Hematopoietic Cell Transplantation for Acute Myeloid Leukemia, #150
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Prior Authorization Request Form for Omidubicel-onlv (Omisirge®) as Adjunct Treatment for Hematologic Malignancies, #067

Policy[1]

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue[SM] and Medicare PPO Blue[SM] Members

Criteria for initial approval for one-time infusion one treatment course per lifetime

Omidubicel-onlv (Omisirge®) is a nicotinamide modified allogeneic hematopoietic progenitor cell therapy derived from cord blood may be considered **MEDICALLY NECESSARY** when the following criteria are met:

- Individual is 12 years of age and older **AND**
- Individual has a diagnosis of hematologic malignancies who are planned for umbilical cord blood transplantation following myeloablative conditioning to reduce:
  - time to neutrophil recovery **AND**
  - the incidence of infection.
- Individual is candidate for myeloablative allogeneic hematopoietic stem cell transplantation (HSCT) **AND**
- Individual does not have **ANY** of the following:
  - Availability of human leukocyte antigen-identical or human leukocyte antigen-matched donor or human leukocyte antigen-haploidentical donor
  - History of receiving prior allogenic hematopoietic stem cell transplant
  - Other malignancy or significant immunodeficiency disorder

- Active, uncontrolled HCV or HBV infection **AND**
- The medication is being prescribed by or in consultation with hematologist/oncologist.

Omidubicel-onlv (Omisirge®) is considered **INVESTIGATIONAL** for individuals who do not meet the above policy criteria.

Omidubicel-onlv (Omisirge®) is considered **INVESTIGATIONAL** for all other indications.

Policy Guidelines

Continuation of Therapy: This is not a covered service. Approval is limited to one treatment course per lifetime.

Quantity Limits: Treatment is limited to one treatment course per lifetime.

Dosage and Administration: For dosage and administration instructions, see prescribing information. Gamida Cell Inc. 2023

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is **required.**
Commercial PPO and Indemnity	Prior authorization is **required.**
Medicare HMO Blue℠	Prior authorization is **required.**
Medicare PPO Blue℠	Prior authorization is **required.**

Requesting Prior Authorization Using Authorization Manager
Providers will need to use Authorization Manager to submit initial authorization requests for services. Authorization Manager, available 24/7, is the quickest way to review authorization requirements, request authorizations, submit clinical documentation, check existing case status, and view/print the decision letter. For commercial members, the requests must meet medical policy guidelines.

To ensure the request is processed accurately and quickly:

- Enter the facility's NPI or provider ID for where services are being performed.
- Enter the appropriate surgeon's NPI or provider ID as the servicing provider, *not* the billing group.

Authorization Manager Resources

- Refer to our Authorization Manager page for tips, guides, and video demonstrations.

Complete Prior Authorization Request Form for Gene Therapies using Authorization Manager for:

- Omidubicel (Omisirge), (#067)

For out of network providers: Requests should still be faxed to 888-973-0726.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

According to the policy statement above, the following CPT codes are considered medically necessary for the conditions listed for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

HCPCS Codes

HCPCS codes:	Code Description
J3590	Unclassified biologics
C9399	Unclassified drugs or biologicals

Description

Treatment for Hematologic Malignancies
Hematopoietic Stem Cell Transplantation
Hematopoietic cell transplantation (HCT) is a procedure in which hematopoietic stem cells are intravenously infused to restore bone marrow and immune function in cancer patients who receive bone marrow-toxic doses of cytotoxic drugs with or without whole-body radiotherapy. Hematopoietic stem cells may be obtained from the transplant recipient (autologous HCT) or a donor (allogeneic HCT [allo-HCT]). These cells can be harvested from bone marrow, peripheral blood, or the umbilical cord blood shortly after delivery of neonates.

Immunologic compatibility between infused hematopoietic stem cells and the recipient is not an issue in autologous HCT. In allogeneic stem cell transplantation, immunologic compatibility between donor and patient is a critical factor for achieving a successful outcome. Compatibility is established by typing human leukocyte antigens (HLA) using cellular, serologic, or molecular techniques. HLA refers to the gene complex expressed at the HLA-A, -B, and -DR (antigen-D related) loci on each arm of chromosome 6. An acceptable donor will match the patient at all or most of the HLA loci.

Umbilical Cord Blood Grafts
Umbilical cord blood (UCB) transplant utilizes blood remaining in the umbilical cord and placenta following the birth of a child. This provides a source of hematopoietic stem and progenitor cells (HSPCs) for allogenic HCT for individuals who lack an HLA-matched related or unrelated donor. In recent years the demand for UCB transplantation has increased due to: a lack of suitable HLA-matched unrelated donors, this is especially true in individuals who are not of Northern European descent, attrition of donors, timing constraints with identifying and typing a candidate as well as harvesting, and the increased incidence of GVHD when HLA-mismatched donor cells are used. Advantages of using UCB grafts include rapid cell procurement, lower incidence of chronic GVHD, and less stringent HLA-matching requirements. UCB transplantation is typically reserved for patients without an HLA-matched donor and should be performed in centers with expertise in this procedure. Patients without an HLA-matched donor may also be candidates for HCT from a haploidentical, or half HLA-matched, related donor.

Ex Vivo Expansion with Omidubicel
UCB transplantation is limited by the cell doses that can be achieved in recipients with high body weight and is also associated with delayed engraftment, higher risk for graft failure, higher rates of infectious complications, and higher costs for procurement. Omidubicel is a blood-based stem cell therapy derived from a single allogenic UCB unit. The therapy uses a proprietary expansion technology based on nicotinamide, proposed to enable donor cells to grow while maintaining their functionality, increase homing to the recipient's bone marrow, and retention of engraftment capacity. Omidubicel is designed to accelerate the rate of neutrophil recovery and lower the risk of infection in patients with hematologic malignancies planning allogenic hematopoietic stem cell transplant (HSCT) but lacking a matched sibling or unrelated donor source.

Summary

Description

Hematologic malignancies are a heterogeneous group of diseases characterized by distinct biological subtypes, marked by cellular, immunophenotypic, and genetic profile variations. Therapeutic approaches may involve hematopoietic cell transplantation, and in cases where a suitable matched donor is unavailable, umbilical cord blood may serve as a source of hematopoietic stem and progenitor cells for transplantation. *Ex vivo* expansion strategies using nicotinamide have been investigated to expedite hematopoietic recovery and enhance cell volume without inducing differentiation or cellular stress commonly associated with culturing hematopoietic progenitor cells outside their natural environment. Omidubicel is a modified allogeneic hematopoietic progenitor cell therapy derived from cord blood utilizing a proprietary nicotinamide enrichment technology.

Summary of Evidence

For individuals who have hematologic malignancies and are eligible to undergo omidubicel-modified umbilical cord blood transplant, the evidence includes results from a phase 3 randomized trial (Horwitz et al 2021. #NCT02730299). This multicenter, randomized study included 125 patients assigned to the omidubicel treatment group (N=62) vs standard UCBT treatment group (N=63). The effectiveness of omidubicel compared with standard umbilical cord blood transplantation was evaluated. Results from this study show that Omidubicel has proven to be better than standard umbilical cord blood transplantation in several respects and suggests that it could be considered as the new standard of care. The results showed the median time to neutrophil engraftment was 12 days versus 22 days with the standard UCBT. Also, neutrophil engraftment was 96% vs 89% with just UCBT. Those treated with Omidubicel experienced faster platelet recovery and had a lower incidence of grade 2 to 3 bacterial or invasive fungal infection, and individuals spent less time in the hospital than the control group, (39 days vs 52 days for the control group). The use of Omidubicel led to quicker hematopoietic recovery and it reduced early transplant related complications.

In a secondary analysis from the Pivotal Phase 3 Clinical Trial, the authors concluded that based on their assessment, faster hematopoietic recovery in omidubicel-onlv patients is associated with significantly shorter hospital stay and reduced healthcare resource use compared with UCB (Navneet S et al 2023).

Policy History

Date	Action
4/2024	Policy revised to include medically necessary and investigational indications. Prior authorization is required. Effective 4/1/2024.
1/2024	New medical policy describing investigational indications. Omidubicel is considered investigational for individuals with hematologic malignancies planning myeloablative allogenic umbilical cord transplantation. Effective 1/1/2024.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:
Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References

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Endnotes

[1] Based on expert opinion