Oscar Clinical Guideline: Omisirge (omidubicel-onlv) (PG149, Ver. 1)

Omisirge (omidubicel-onlv)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Hematologic malignancies encompass a group of cancers that affect the blood, bone marrow, and lymph nodes - all integral components of the body's circulatory and immune systems. Such conditions, including leukemia, lymphoma, and myelodysplastic syndromes, can be severe and life-threatening, often necessitating complex and multidimensional treatment plans.

The management of hematologic malignancies typically depends on various factors such as the specific type and stage of the disease, the patient's overall health, and personal preferences. Common therapeutic strategies frequently involve chemotherapy, radiation therapy, and in certain cases, stem cell transplantation. The choice of specific medicines or biological therapies is usually dictated by the cancer type and the genetic alterations present within the cancer cells.

Stem cell transplantation, including bone marrow transplantation, stands as a cornerstone treatment for a multitude of hematologic malignancies, especially those that exhibit an aggressive course or tend to

recur. This procedure involves replacing the patient's diseased bone marrow with healthy stem cells that are capable of generating new blood cells. These stem cells may be autologous, meaning they originate from the patient, or allogeneic, indicating they are donated by a third party.

Against this backdrop of standard therapies, Omisirge (omidubicel-onlv) emerges as an innovative approach to stem cell transplantation. Unlike traditional methods that use stem cells directly obtained from bone marrow or peripheral blood, Omisirge leverages cultured cells. These cells are grown and enhanced in a laboratory setting to increase their quantity and improve their engraftment capability. This novel methodology aspires to enhance transplantation success, decrease the risk of complications, and shorten the engraftment timeline.

Omisirge is specifically designed for both adults and children aged 12 years and above diagnosed with hematologic malignancies. It is slated for patients poised for umbilical cord blood transplantation following myeloablative conditioning - a potent form of chemotherapy that eradicates the existing bone marrow to prepare for the new, transplanted cells. The therapeutic objectives of Omisirge are twofold: it aims to accelerate neutrophil recovery - a crucial type of white blood cell pivotal for combating infection, and concurrently, it seeks to reduce the incidence of infections among these patients.

In clinical trials, Omisirge showcased its effectiveness by catalyzing faster neutrophil recovery compared to standard umbilical cord blood transplantation. It also demonstrated a reduction in the incidence of severe bacterial and fungal infections. These potential advantages could have profound implications for patient outcomes, considering that delayed engraftment and infections pose significant challenges in stem cell transplantation.

However, while the results from trials are encouraging, it's crucial to underscore that Omisirge is a patient-specific therapy, and the risk of manufacturing failures exists. In addition, akin to other transplant products, it carries potential risks, including hypersensitivity reactions, infusion reactions, Graft-versus-Host-Disease, Engraftment Syndrome, Graft Failure, and the risk of transmitting infectious or genetic diseases.

Therefore, given these considerations, the use of Omisirge should be integrated within a comprehensive treatment plan and be administered under the supervision of a healthcare provider experienced in stem cell transplantation for hematologic malignancies.

Definitions

"**Allogeneic Transplantation**" is a type of stem cell transplantation where the stem cells come from a donor.

"**Autologous Transplantation**" is a type of stem cell transplantation where the patient's own stem cells are harvested, stored, and later returned to the body after intensive treatment.

"**Chemotherapy**" is a cancer treatment method that uses drugs to stop the growth of cancer cells, either by killing the cells or by stopping them from dividing.

"**Engraftment**" is the process by which the transplanted stem cells begin to grow and make healthy blood cells.

"**Engraftment Syndrome**" is a syndrome characterized by fever, rash, respiratory distress, and other symptoms that can occur shortly after stem cell transplantation.

"**Graft Failure**" is a serious complication that occurs when the newly transplanted donor cells (the graft) do not begin to produce new cells quickly enough or at all. This condition can be life-threatening.

"**Graft-versus-Host Disease (GvHD)**" is a complication that might occur after an allogeneic transplant. In GvHD, the newly transplanted donor cells attack the transplant recipient's body.

"**Hematologic Malignancies**" are cancers that affect the blood, bone marrow, and lymph nodes. They include leukemia, lymphoma, and myelodysplastic syndromes.

"**Myeloablative Conditioning**" is a high-dose chemotherapy treatment intended to kill cancer cells and suppress the immune system in preparation for a stem cell or bone marrow transplant. This process essentially makes space for the new cells to grow in the bone marrow.

"**Neutrophil**" is a type of white blood cell that is one of the body's mechanisms for fighting off infections. Neutrophils are produced in the bone marrow.

"**Radiation Therapy**" is a type of cancer treatment that uses high doses of radiation to kill cancer cells and shrink tumors.

"**Stem Cell Transplantation**" is a procedure that infuses healthy blood-forming stem cells into the body. Stem cells may be collected from the bone marrow, peripheral blood, or umbilical cord blood.

"**Umbilical Cord Blood Transplantation**" is a type of allogeneic stem cell transplantation where stem cells are collected from the umbilical cord and placenta of a newborn baby after birth. These stem cells can be used to treat a variety of genetic, hematologic, immunologic, and oncologic disorders.

Medical Necessity Criteria for Authorization

The Plan considers **Omisirge (omidubicel-onlv)** medically necessary when **ALL** of the following criteria are met:

1. The requested therapy is prescribed by or in consultation with a hematologist or oncologist; ***AND***
2. The member is 12 years of age or older; ***AND***
3. The member has a diagnosis of specific hematologic malignancies, such as Acute Myelogenous Leukemia (AML), Acute Lymphoblastic Leukemia (ALL), Myelodysplastic Syndrome (MDS), Chronic Myeloid Leukemia (CML), lymphoma, or other rare leukemias; ***AND***
4. Clinical documentation is provided indicating **ALL** of the following:
    a. The member is considered to be at high-risk and has no available matched sibling or matched unrelated donor; ***and***
    b. The member is planned for umbilical cord blood transplantation following myeloablative conditioning; ***and***
    c. The requested therapy is being used with the intent of reducing the time to neutrophil recovery and the incidence of infection; ***AND***
5. The member does **NOT** have documentation indicating **ANY** of the following:
    a. Known hypersensitivity to any component of Omisirge (omidubicel-onlv), including dimethyl sulfoxide (DMSO), Dextran 40, human serum albumin, or gentamicin; ***or***
    b. Previously received an allogeneic HSCT. However, an exception to this criterion may be made if the treating physician provides a supporting rationale. This rationale must indicate that the prior transplant failed, that the disease recurred, or that the patient's overall condition still makes them suitable for another transplant; ***or***
    c. History of a severe infusion-related reaction, GVHD, engraftment syndrome, or graft failure associated with previous cord blood products.

If the above prior authorization criteria are met, the Plan will approve a single infusion of Omisirge (omidubicel-onlv).

Please note:

1. *This approval is granted for a one-time treatment only, in alignment with the drug's intended use, clinical trial data, and FDA approval.*
2. *Omisirge (omidubicel-onlv) is specifically designed as a single administration therapy. As such, re-authorization for additional Omisirge (omidubicel-onlv) treatment will not be provided.*

Experimental or Investigational / Not Medically Necessary

Omisirge (omidubicel-onlv) for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- treatment of non-hematological malignancies.
- treatment of non-malignant hematologic disorders, such as anemia or thrombocytopenia that are not associated with hematologic malignancies.
- hematologic malignancies in pediatric patients under the age of 12 years, as safety and efficacy have not been established for this age group.
- in patients with a known hypersensitivity to any component of Omisirge, including dimethyl sulfoxide (DMSO), Dextran 40, human serum albumin, or gentamicin.
- prophylactic treatment in patients who are at risk of developing but have not been diagnosed with hematologic malignancies.

Applicable Billing Codes (HCPCS/CPT Codes)

Service(s) name	
CPT/HCPCS Codes considered medically necessary if criteria are met:	
Code	*Description*
38240	Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)

C9399	Unclassified drugs or biologicals [when used for Omisirge (omidubicel-onlv)]
J3590	Unclassified biologics [when used for Omisirge (omidubicel-onlv)]
S2142	Cord blood-derived stem-cell transplantation, allogeneic
ICD-10 codes considered medically necessary if criteria are met:	
Code	*Description*
C81.00 – C81.99	Hodgkin lymphoma
C82.00 – C82.99	Follicular lymphoma
C83.00 – C83.99	Non-follicular lymphoma
C84.00 – C84.99	Mature TNK-cell lymph
C85.10 – C85.99	Other specified and and unspecified types of non-Hodgkin lymphoma
C88.0 – C88.9	Malignant immunoproliferative diseases
C88.0 – C88.9	Malignant immunoproliferative diseases and certain other B-cell lymphomas
C91.00 – C91.92	Lymphoid leukemia [including Acute lymphoblastic leukemia (ALL)]
C92.00 – C92.92	Myeloid leukemia (including Acute myeloblastic leukemia (AML), Chronic myeloid leukemia (CML)]
C91.00 – C91.92:	Lymphoid Leukemia [including Acute lymphoblastic leukemia(ALL)]
C92.00 – C92.92	Myeloid leukemia [including Acute myeloblastic leukemia (AML) and Chronic myeloblastic leukemia (CML)]
C93.00 – C93.92	Monocytic leukemia
C94.00 – C94.82	Other leukemias of specified cell type
C95.00 – C95.92	Leukemia of unspecified cell type

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Clinical Guideline Revision / History Information

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