Omisirge (omidubicel-onlv)

INDEPENDENT CARE HEALTH PLAN

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Line of Business: Medicare

Medicare Advantage Medical Coverage Policy

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Related Medicare Advantage Medical/Pharmacy Coverage Policies

None

Related Documents

Please refer to CMS website for the most current applicable CMS Online Manual System (IOMs)/National Coverage Determination (NCD)/ Local Coverage Determination (LCD)/Local Coverage Article (LCA)/ Transmittals.

There are no NCD and/or LCDs for Omisirge (omidubicel-onlv).

Description

Hematologic malignancies (blood cancers) are caused by abnormal cell growth in the bone marrow, where stem cells form into different types of blood cells.

Hematopoietic stem cell transplantation (HSCT) is a potentially curative therapy for a variety of conditions, most commonly blood or bone marrow cancers, in which an individual cannot produce enough normal blood cells. It involves transplanting stem cells isolated from either the individual (autologous or auto-HSCT) or a donor (allogeneic or allo-HSCT), growing them in number, and transplanting them into an individual who lacks sufficient functional stem cells of their own.

A common treatment for blood cancers is stem cell transplantation from umbilical cord blood (UCB), the blood remaining in the umbilical cord and placenta following the birth of an infant. A major disadvantage of UCB is the low stem cell dose available for transplantation, compared to mobilized peripheral blood or bone marrow. This low stem cell dose can compromise the chances of engraftment and contributes to delayed kinetics of neutrophil and platelet recovery, as well as other transplant outcomes. The aim of ex vivo (outside the living body) expansion of cord blood is to provide a graft with sufficient numbers of cells that have rapid and robust in vivo (inside the living body) neutrophil and platelet producing potential to enable successful transplantation**.**

Omisirge (omidubicel-onlv) is a nicotinamide (NAM) modified allogeneic hematopoietic progenitor cell therapy, given as a single dose and one-time infusion.

The infusion is a mixture of hematopoietic stem cells and differentiated immune cells, derived from a single unit of UCB. Omisirge purportedly enhances the treatment of an individual undergoing allo-HSCT who has no matched donor for bone marrow or peripheral blood. In addition, the therapy purports to restore blood and immune cells and improve resistance to infections and related complications efficiently and quickly.

Omisirge is indicated for use in adult and pediatric individuals, 12 years of age and older, with hematologic malignancies who are planned for UCB transplantation following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infection. The two components of cryopreserved cell therapy, a cultured fraction (CF) and a non-cultured fraction (NF), are derived from the same individual-specific cord blood unit (CBU).

- For CF: a minimum of 8.0 × 108 total viable cells of which a minimum of 8.7% is CD34+ cells and a minimum of 9.2 × 107 CD34+ cells
- For NF: a minimum of 4.0 × 108 total viable cells with a minimum of 2.4 × 107 CD3+ cells

Coverage Determination

iCare follows the CMS requirements that only allows coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the following criteria:

Omisirge

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
No code(s) identified		
CPT® Category III Code(s)	**Description**	**Comments**
No code(s) identified		
HCPCS Code(s)	**Description**	**Comments**
J3590	Unclassified biologics	
C9399	Unclassified drugs or biologicals	

Change Summary

- 01/01/2024 New Policy.
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