Medical Policy:

Omisirge (omidubicel-onlv) intravenous suspension

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.386	March 10, 2025	July 6, 2023

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Omisirge is a nicotinamide modified allogeneic hematopoietic progenitor cell therapy derived from cord blood indicated for use in adults and pediatric patients 12 years and older with hematologic malignancies who are planned for umbilical cord blood transplantation following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infection.

Length of Authorization

Coverage will be provided for 1 dose only

Dosing Limits [Medical Benefit]

Intravenous Suspension: Single dose consists of a Cultured Fraction (CF), a minimum of 8 x 10^8 total viable cells of which a minimum of 8.7% is CD34+ cells and a minimum of 9.2 x 10^7 CD34+ cells, and a Non-cultured Fraction (NF), a minimum of 4 x 10^8 total viable cells with a minimum of 2.4 x 10^7 CD3+ cells

Guideline

1. **Allogenic Hemopoietic Stem Cell Transplantation**

A. Patient must be ≥12 years of age and eligible for allo-HSCT; **AND**
B. Patient must have a hematologic malignancy planned for UCBT following myeloablative conditioning; **AND**
Note: Examples of hematologic malignancies are acute myelogenous leukemia, acute lymphoblastic leukemia, and chronic myeloid leukemia.
C. Therapy is used to reduce the time to neutrophil recovery and incidence of infection; **AND**
D. Patients must not have a matched related donor (MRD), matched unrelated donor (MUD), mismatched unrelated donor (MMUD), or haploidentical donor readily available; **AND**
E. Patient must not have received a prior allo-HSCT; **AND**
F. Omisirge will be used as a one-time treatment; **AND**
G. Omisirge is prescribed by or in consultation with a hematologist, oncologist, transplant specialist physician, or a physician associated with a transplant center.

Limitations/Exclusions

1. Patient does not have a known allergy or hypersensitivity to any of the following:
    a. Dimethyl Sulfoxide (DMSO)
    b. Dextran 40
    c. Gentamicin
    d. Human serum albumin or bovine material

Renewal Criteria

Coverage cannot be renewed.

Applicable Procedure Codes

Code	Description
J3590	Unclassified biologics
C9399	Unclassified drugs or biologicals *(hospital outpatient use)*

Applicable NDCs

Code	Description
73441-0800-04	Omisirge kit

ICD-10 Diagnoses

Code	Description
D70.1	Agranulocytosis secondary to cancer chemotherapy
D70.8	Other neutropenia
D70.9	Neutropenia, unspecified
Z94.81	Bone marrow transplant status

Revision History

Company(ies)	DATE	REVISION

EmblemHealth & ConnectiCare	3/10/2025	Annual Review: No Criteria changes.
EmblemHealth & ConnectiCare	1/31/2024	Annual Review: Added examples of hematologic malignancies, added prescriber restrictions, added Limitations and Exclusions, Added coded Z94.81
EmblemHealth & ConnectiCare	07/06/2023	New Policy

References

1. Product Information: OMISIRGE® intravenous suspension, omidubicel-onlv intravenous suspension. Gamida Cell Inc (per FDA), Boston, MA, 2023.