TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Omidubicel-onlv (Omisirge)	**CRITERIA ID:** TX.CC.PHAR.60
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy
EFFECTIVE DATE: 07/01/2026	**PRODUCT(S):** STAR, STAR+PLUS, STAR HEALTH, STAR KIDS, CHIP, CHIP Perinate
REVIEWED/REVISED DATE: N/A	**REGULATOR MOST RECENT APPROVAL DATE(S):** N/A

CRITERIA STATEMENT:
The purpose of this clinical criteria is to provide a guide to medical necessity reviews for omidubicel-onlv (Omisirge).

PURPOSE:
Consistent with the regulation at 42 CFR Section 438.210 and 42 CFR Section 457.1230(d), services covered under managed care contracts, including clinician-administered drugs, must be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services specified in the state plan. While MCOs may place appropriate limits on drugs, MCOs may not use a standard for determining medical necessity that is more restrictive than what is used in the state plan, i.e., developed by the Vendor Drug Program. For example, if a member is denied a clinician administered drug in managed care because of the MCO's prior authorization criteria but would have received the drug under the criteria specified in the state plan, then the MCO's prior authorization criteria would violate the amount, duration, and scope requirements cited above. HHSC intends to amend the Managed Care Contracts at the next opportunity to include this requirement. This same standard applies to CHIP formulary and CAD coverage.

Refer to the Outpatient Drug Services Handbook of the Texas Medicaid Provider Procedure Manual for more details on the clinical criteria and prior authorization requirements.

This medication is a non-risk based (NRB) payment drug and should follow state guidance for medical necessity review for Medicaid/CHIP due to the manner in which it is reimbursed. All determinations will be performed by a Medical Director. A pharmacy clinician will review the prior authorization request and make a recommendation to the Medical Director but will not make the ultimate determination on any case.

The procedure code J3590 (used for Omisirge) will be limited to one approval per lifetime, by any provider. If the code is updated in the future it will still be limited to once per lifetime.

This medication is also designated by HHSC as a high-cost clinician-administered drug (HCCAD), allowing separate reimbursement for inpatient use. When inpatient use is required, the drug may be billed on a separate outpatient claim or through specialty pharmacy billing, when available.

SCOPE:
This criteria applies to all directors, officers, and employees of Centene Corporation, its affiliates, health plans, and subsidiary companies (collectively, the "Company").

DEFINITIONS:
CPS = Centene Pharmacy Services
NRB = Non-Risk Based

SHP = Superior HealthPlan
UM = Utilization Management

POLICY:
It is the policy of Superior HealthPlan and Centene Pharmacy Services to follow state guidance for medical necessity review of omidubicel-onlv (Omisirge); procedure code: 3590.

Description/Mechanism of Action:
Omisirge is a nicotinamide modified allogeneic hematopoietic progenitor cell therapy derived from cord blood

FDA Approved Indications:
Omisirge is indicated for the following indications:

- 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 infections
- Adults and pediatric patients 6 years and older with severe aplastic anemia (SAA) following reduced intensity conditioning.

PROCEDURE:
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

I. Initial Approval Criteria:

A. Hematologic malignancies in planned umbilical cord blood transplantation (UCBT):

1. A Medical Director is required to review and approve or deny all requests. A pharmacy clinician will make a recommendation on the prior authorization, but ultimate determination will be made by the Medical Director only.
2. The client is 12 years of age and older.
3. The client has a confirmed diagnosis of a high-risk hematologic malignancy, and is planned for UCBT after undergoing a myeloablative conditioning regimen (e.g., radiation, chemotherapy). Diagnosis code: D70.1, D70.8, D70.9, and Z94.81.
4. Documentation therapy is being used to reduce the time to neutrophil recovery and incidence of infection.
5. The client does not have a matched related or unrelated donor for allogeneic hematopoietic stem cell transplantation (HSCT).
6. The client does not have known sensitivity to dimethyl sulfoxide (DMSO), Dextran 40, gentamicin, human serum albumin, or bovine material.
7. The client does not have a history of receiving prior allogeneic HSCT.
8. Provider attestation to monitor the following:
    a. Monitor for allergic reactions following Omisirge infusion, particularly in patients with a history of allergic reactions to antibiotics.
    b. Monitor for graft failure, Graft-vs-Host Disease (GvHD), engraftment syndrome, infections, secondary malignancies, and other posttransplant complications.

Approval duration: 12 months (Only 1 dose per lifetime will be provided on this drug regardless of Provider).

B. Severe Aplastic Anemia:

1. A Medical Director is required to review and approve or deny all requests. A pharmacy clinician will make a recommendation on the prior authorization, but ultimate determination will be made by the Medical Director only.
2. The client is 6 years of age and older.
3. The client has a confirmed diagnosis of severe aplastic anemia following reduced intensity conditioning regimen (diagnosis code: D61.1, D61.2, D61.89, or D61.9).
4. The client has a history of intolerance or failure to respond to immunosuppressive therapy.
5. The client does not have a matched related or unrelated donor.
6. The client does not have known sensitivity to dimethyl sulfoxide (DMSO), Dextran 40, gentamicin, human serum albumin, or bovine material.
7. Provider attestation to monitor the following:
    a. Monitor for allergic reactions following Omisirge infusion, particularly in patients with a history of allergic reactions to antibiotics.
    b. Monitor for graft failure, Graft-vs-Host Disease (GvHD), engraftment syndrome, infections, secondary malignancies, and other posttransplant complications.

Approval duration: 12 months (Only 1 dose per lifetime will be provided on this drug regardless of Provider).

REFERENCES:
Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook

ATTACHMENTS:

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Policy	N/A	07/01/2026