Corporate Medical Policy: Omidubicel-onlv (Omisirge®) **"Notification"** **POLICY EFFECTIVE APRIL 1, 2026**

Restricted Product(s):

- omidubicel-onlv (Omisirge®) intravenous infusion for administration by a healthcare professional

FDA Approved Use:

- For the treatment of 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
- For the treatment of adults and pediatric patients 6 years and older with severe aplastic anemia (SAA) following reduced intensity conditioning

Criteria for Medical Necessity:

The restricted product(s) may be considered medically necessary when the following criteria are met:

1. The patient has a diagnosis of a high-risk **hematologic malignancy** (e.g., acute myelogenous leukemia [AML], acute lymphoblastic leukemia [ALL], myelodysplastic syndrome [MDS], non-Hodgkin lymphoma [NHL], myeloproliferative diseases [MPH]) **[medical record documentation required]**; **AND**
    a. The patient is 12 years of age or older; **AND**
    b. The patient is planned for an umbilical cord blood transplantation (UCBT) following myeloablative conditioning **[medical record documentation required]**; **AND**
    c. The requested agent will be used to reduce the time to neutrophil recovery and incidence of infection **[medical record documentation required]**; **AND**
    d. Prior to treatment with the requested agent, the patient will receive a myeloablative conditioning regimen according to institutional guidelines **[medical record documentation required]**; **AND**
    e. The patient is eligible for myeloablative allogeneic hematopoietic stem cell transplantation (allo-HSCT) and has NOT received a prior allo-HSCT **[medical record documentation required]**; **OR**

2. The patient has a diagnosis of **severe aplastic anemia (SAA) [medical record documentation required]**; **AND**
    a. The patient is 6 years of age or older; **AND**
    b. The diagnosis has been confirmed by ALL of the following:
        i. ONE of the following:
            1. Bone marrow cellularity less than 25% **[medical record documentation required]**; **OR**

2. Bone marrow cellularity 25-50% with less than 30% residual hematopoietic cells **[medical record documentation required]**; **AND**

ii. Presence of at least TWO of the following **[medical record documentation required]**:

1. Neutrophils less than 0.5 x 10^9/L; **OR**
2. Platelets less than 20 x 10^9/L; **OR**
3. Reticulocytes less than 60 x 10^9/L; **AND**

c. ONE of the following:

i. The patient has tried and had an inadequate response to a standard immunosuppressive therapy regimen (i.e., horse antithymocyte globulin (hATG) and cyclosporine plus eltrombopag) for at least 3 months of treatment **[medical record documentation required]**; **OR**

ii. The patient has a clinical intolerance/contraindication to ALL immunosuppressive therapy regimens for the treatment of SAA **[medical record documentation required]**; **AND**

d. Prior to treatment with the requested agent, the patient will receive a reduced intensity conditioning regimen according to institutional guidelines **[medical record documentation required]**; **AND**

3. The patient has NO readily available matched related donor (MRD), matched unrelated donor (MUD), mismatched (7/8 matched) unrelated donor (MMUD), or haploidentical (half human leukocyte antigen [HLA]-matched) related donor **[medical record documentation required]**; **AND**
4. The patient will receive prophylactic and supportive therapies (including granulocyte-colony stimulating factor [G-CSF]) for prevention or treatment of transplant complications (e.g., graft vs. host disease [GvHD], infections) according to institutional guidelines **[medical record documentation required]**; **AND**
5. The patient does NOT have any contraindications to the requested agent (i.e., known hypersensitivity to dimethyl sulfoxide [DMSO], Dextran 40, gentamicin, human serum albumin, or bovine material) **[medical record documentation required]**; **AND**
6. The prescriber is a specialist in the area of the patient's diagnosis (i.e., hematologist, oncologist) or has consulted with a specialist in the area of the patient's diagnosis **[medical record documentation required]**; **AND**
7. The requested dose is within FDA labeled dosing for the requested indication, and the requested quantity does NOT exceed the maximum units allowed for the duration of approval (see table below) **[medical record documentation required]**.

Duration of Approval: 365 days (1 year); one-time, single-dose treatment per lifetime

** Please note, for certain identified gene and cellular therapies such as omidubicel-onlv (Omisirge®), when coverage is available and the individual meets medically necessary criteria, distribution from a specialty pharmacy provider due to cost (distribution channel restriction) may be required in order for coverage to be provided. Please contact **BCBS NC** to coordinate this therapy.

FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
omidubicel-onlv (Omisirge®) intravenous (IV) infusion	Reduce the time to neutrophil recovery and the incidence of infection following myeloablative conditioning in patients ≥12 years old with hematologic malignancies who are planned for umbilical cord blood transplantation Severe aplastic anemia in patients ≥6 years old, following reduced intensity conditioning	IV (one-time, single-dose infusion): • Cultured Fraction (CF): minimum of 8.0 x 10^8 total viable cells (of which a minimum of 8.7% is CD34+ cells and a minimum of 9.2 × 10^7 CD34+ cells) • Non-cultured Fraction (NF): minimum of 4.0 x 10^8 total viable cells (with a minimum of 2.4 × 10^7 CD3+ cells)	C9399** J3490** J3590** J9999**	**1**

***Maximum units allowed for duration of approval**
****Non-specific assigned HCPCS codes, must submit requested product NDC**

References: all information referenced is from FDA package insert unless otherwise noted below.

1. Babushok DV, DeZern AE, de Castro CM, et al. Modified Delphi panel consensus recommendations for management of severe aplastic anemia. *Blood Adv* 2024;8(15):3946–3960. doi: https://doi.org/10.1182/bloodadvances.2023011642
2. Horwitz ME, Stiff PJ, Cutler C, et al. Omidubicel vs standard myeloablative umbilical cord blood transplantation: results of a phase 3 randomized study. *Blood*. 2021;138(16):1429–1440. doi: https://doi.org/10.1182/blood.2021011719

Policy Implementation/Update Information: Criteria and treatment protocols are reviewed annually by the Blue Cross NC P&T Committee, regardless of change. This policy is reviewed in Q2 annually.

April 2026: Original medical policy criteria issued. **Policy notification given 1/1/2026 for effective date 4/1/2026.**