

## omidubicel-ONLY (Omisirge)

### Commercial Medical Benefit Drug Policy

#### Place of Service

Hospital Administration

#### Drug Details

**USP Category:** ANTINEOPLASTICS

**Mechanism of Action:** Nicotinamide modified allogeneic hematopoietic progenitor cell therapy

#### **HCPCS:**

C9399:Unclassified drugs or biologicals

J3490:Unclassified drugs

J3590:Unclassified biologics

J9999:Not otherwise classified, antineoplastic drugs

#### **How Supplied:**

##### **NDCs:**

- 73441-800-04: two shipping containers: (1) liquid nitrogen dry vapor shipper containing two cryopreserved cell fractions and a Chimerism Testing Sample(s), and (2) refrigerated shipping container containing two Infusion Solutions
- 73441-100-01: cryopreserved bag containing Cultured Fraction (CF)
- 73441-200-01: cryopreserved bag containing Non-cultured fraction (NF)
- 73441-300-01: Infusion Solution for CF
- 73441-400-01: Infusion Solution for NF

#### **Condition(s) listed in policy** *(see coverage criteria for details)*

- Hematologic Malignancies
- Severe Aplastic Anemia

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

#### **Special Instructions and Pertinent Information**

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

#### **Coverage Criteria**

**The following condition(s) require Prior Authorization/Preservice.**

## **Hematologic Malignancies**

### **Meets medical necessity if all the following are met:**

1. Patient has a hematologic malignancy [e.g., acute myelogenous leukemia (AML), acute lymphoblastic leukemia (ALL), myelodysplastic syndrome (MDS), non-Hodgkin lymphoma (NHL), myeloproliferative neoplasms (MPN)]
2. Patient is a candidate for umbilical cord blood transplantation following myeloablative conditioning
3. Patient does not have a readily available matched sibling or matched unrelated donor
4. Patient has not received a prior allogeneic hematopoietic stem cell transplantation
5. Dose does not exceed FDA-approved maximum

### **Covered Doses:**

Omisirge is a cell suspension for intravenous infusion. A single dose of OMISIRGE consists of:

- a Cultured Fraction (CF): a minimum of  $8.0 \times 10^8$  total viable cells of which a minimum of 8.7% is CD34+ cells and a minimum of  $9.2 \times 10^7$  CD34+ cells
- a Non-cultured Fraction (NF): a minimum of  $4.0 \times 10^8$  total viable cells with a minimum of  $2.4 \times 10^7$  CD3+ cells

### **Coverage Period:**

One treatment course per lifetime

### **ICD-10:**

D70.0, D70.9

## **Severe Aplastic Anemia**

### **Meets medical necessity if all the following are met:**

1. Age is consistent with FDA indication (6 years of age and older)
2. Prescribed by or in consultation with a hematologist
3. Documentation of diagnosis of severe aplastic anemia
4. Patient does not have a readily available matched sibling or matched unrelated donor
5. Dose does not exceed FDA-approved maximum

### **Covered Doses:**

Omisirge is a cell suspension for intravenous infusion. A single dose of OMISIRGE consists of:

- a Cultured Fraction (CF): a minimum of  $8.0 \times 10^8$  total viable cells of which a minimum of 8.7% is CD34+ cells and a minimum of  $9.2 \times 10^7$  CD34+ cells
- a Non-cultured Fraction (NF): a minimum of  $4.0 \times 10^8$  total viable cells with a minimum of  $2.4 \times 10^7$  CD3+ cells

### **Coverage Period:**

One treatment course per lifetime

### **ICD-10:**

D61.1, D61.3, D61.9

## **References**

1. AHFS. Available by subscription at <http://www.lexi.com>

2. DrugDex. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
3. Omisirge (omidubicel) Prescribing Information. Gamida Cell Ltd, Israel: 12/2025.

### **Review History**

Date of Last Annual Review: 3Q2025

Changes from previous policy version:

- Severe aplastic anemia: Added new coverage (Rationale: In December 2025, FDA approved Omisirge for the treatment of adults and pediatric patients 6 years and older with severe aplastic anemia (SAA) following reduced intensity conditioning)

*Blue Shield of California Medication Policy to Determine Medical Necessity*

*Reviewed by P&T Committee*