# Pharmacy Management Drug Policy

**SUBJECT: Omisirge (omidubicel-onlv)**
**POLICY NUMBER: PHARMACY-141**
**EFFECTIVE DATE: 02/2026**
**LAST REVIEW DATE: 06/12/2026**

*If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. This drug policy applies to the following line/s of business:*

**Policy Application**

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| **Category**: | ☒ Commercial Group (e.g., EPO, HMO, POS, PPO) | ☒ Medicare Advantage |
| | ☒ On Exchange Qualified Health Plans (QHP) | ☐ Medicare Part D |
| | ☒ Off Exchange Direct Pay | ☒ Essential Plan (EP) |
| | ☒ Medicaid & Health and Recovery Plans (MMC/HARP) | ☒ Child Health Plus (CHP) |
| | ☐ Federal Employee Program (FEP) | ☐ Ancillary Services |
| | ☒ Dual Eligible Special Needs Plan (D-SNP) | |

## DESCRIPTION:

Omisirge (omidubicel-onlv) is an ex-vivo expanded cell therapy derived from umbilical cord blood, engineered to enhance hematopoietic recovery following stem cell transplantation. Omisirge is manufactured using proprietary nicotinamide (NAM) technology, which modifies the stem cells to improve their functionality and speed up recovery. Ex-vivo expansion of cord blood derived hematopoietic progenitor cells (HPCs) in the presence of NAM leads to preservation of their stemness, supports bone marrow (BM) engraftment, and enables rapid neutrophil and multilineage immune recovery as demonstrated in clinical trials. Omisirge is FDA-approved for:

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

Umbilical cord blood (UCB) is a well-established alternative graft source for patients requiring hematopoietic cell transplantation (HCT) who lack a suitable human leukocyte antigen (HLA)-matched related or unrelated donor.[2] Unfortunately, the relatively low number of hematopoietic progenitor cells and mature T cells in a single UCB unit often results in inadequate or delayed engraftment. To address this limitation, transplantation with two UCB units has become standard practice in adults. Despite this, hematopoietic recovery remains slower compared to HCT from related or unrelated donors and is associated with higher treatment-related morbidity and mortality.[3] Consequently, UCB transplantation typically leads to longer hospital stays, increased resource utilization—such as blood product transfusions—and higher overall costs, particularly during the early post-transplant period.[4,5,6]

On April 17, 2023, the FDA approved Omisirge for 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. This approval was supported by data from an open-label, Phase III, multicenter, randomized trial (Study P0501 [NCT02730299]) involving 125 patients eligible for allogenic transplant without a suitable human leukocyte antigen (HLA)-matched related or unrelated donor. In the trial, 62 patients were randomized to receive Omisirge and 63 patients were scheduled to undergo standard umbilical cord blood transplantation. Omisirge (omiduvicel-onlv) met its primary endpoint of faster neutrophil recovery

compared to UCB. In addition, the Omisirge treatment arm demonstrated faster platelet recovery, a reduced rate of infections, and shorter hospital length of stay compared with UCB.[7]

Severe aplastic anemia is a rare, life-threatening hematologic disease characterized by bone marrow failure and low circulating blood cells. Although long term survival for SAA patients can be achieved with immunosuppressive therapy (IST), one quarter to one third will fail to respond and about half of responders will relapse. Hematopoietic stem cell transplant may be curative for SAA, but many refractory SAA pts lack an HLA matched donor for salvage allogeneic stem cell transplantation. Although umbilical cord blood transplantation (UCBT) offers an alternative treatment option for patients with severe aplastic anemia (SAA), it is associated with delayed engraftment and elevated rejection rates. Additionally, many UCB units contain insufficient total nucleated cells (TNCs) and CD34+ cells to achieve optimal transplant outcomes.[8]

On December 5, 2025, the FDA expanded the approval of Omisirge to include the treatment of severe aplastic anemia (SAA) in adults and pediatric patients 6 years and older following reduced intensity conditioning. The efficacy of Omisirge in patients with SAA was evaluated in an open-label, single-center study (17-H-0091 [NCT03173937]) consisting of patients with SAA who had intolerance or failure to respond to immunosuppressive therapy and the availability of at least one ≥ 4/8 human leukocyte antigen (HLA)-matched (HLA-A, B, C, and DR loci) cord blood unit. A total of 14 patients were treated with Omisirge, with 86% of patients experiencing early and sustained neutrophil recovery at 100 days, red blood cell transfusion independence, and platelet recovery ≥ 20,000/μL within a year. In addition, 79% of patients demonstrated platelet transfusion independence.

**POLICY:**

| **Omisirge (omidubicel-onlv) - Medical** |
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| 1. Must be prescribed by a hematologist, oncologist, or physician experienced in the treatment of hematologic malignancies and/or severe aplastic anemia **AND**<br>2. The patient must be eligible for an allogeneic hematopoietic (stem) cell transplant **AND**<br>3. The prescriber must attest that the patient does not have a readily available, matched related donor, matched unrelated donor, mismatched unrelated donor, or a haploidentical related donor<br>a. If a more appropriately matched umbilical cord blood unit is available, a mismatched unrelated donor or haploidentical related donor would not be required **AND**<br>4. The patient must receive therapy at an authorized treatment center **AND**<br>5. The patient must meet ONE of the following (a or b):<br>a. The patient must have a hematologic malignancy **AND**<br>i. The patient must be 12 years of age or older **AND**<br>ii. The prescriber must attest that the umbilical cord unit used will be HLA-matched at a minimum of 4 loci (including HLA-A, B at the antigen-level, and DRB1 at the allele level) **AND**<br>iii. The requested treatment must be used to reduce the time to neutrophil recovery and the incidence of infection **AND**<br>iv. The requested treatment must be used following myeloablative conditioning<br>b. The patient must have severe aplastic anemia (SAA) as documented by the following:<br>i. Bone marrow aspiration (BMA) cellularity of < 30% **AND** at least two of the following:<br>1. Absolute neutrophil count (ANC) < 500 cells/$mm^3$<br>2. Platelet count < 20,000/$mm^3$<br>3. Reticulocyte count < 60,000/$mm^3$<br>ii. The patient must be 6 years of age or older **AND** |

iii. The patient has tried and failed to respond to or had an intolerance to standard immunosuppressive therapy **AND**
iv. The prescriber must attest that the umbilical cord unit used will be HLA-matched at a minimum of ≥ 4/8 loci (HLA-A, B, C and DR loci) **AND**
v. The requested treatment must be used following reduced intensity conditioning **AND**

6. Omisirge is indicated for one-time intravenous administration only and therefore will not be authorized for retreatment. Retreatment will be considered experimental/investigational when any FDA approved gene or cellular therapy, or any other gene or cellular therapy under investigation, has been previously administered.
7. Refer to the Omisirge FDA-approved prescribing information for complete dosage and administration instructions.
8. Omisirge (omidubicel-onlv) is considered investigational for all other non-FDA approved indications.
9. Authorization will be for 6 months to allow sufficient time for administration.

**POLICY GUIDELINES:**

1. Utilization Management are contract dependent. Refer to specific contract/benefit language for exclusions.
   a. Coverage criteria may be dependent on the contract renewal date.
   b. Coverage of drugs listed in this policy are contract dependent.
   c. Not all contracts/benefits allow coverage of healthcare professional administered drugs as part of their pharmacy benefit
   d. Not all contracts/benefits cover all medical infusible drugs.
2. Clinical documentation must be submitted for each request (initial and recertification [if applicable]) unless otherwise specified (e.g., provider attestation required). Supporting documentation includes, but is not limited to, progress notes documenting previous treatments and treatment history, diagnostic testing, laboratory test results, genetic testing or biomarker results, imaging, and other objective or subjective measures of clinical benefit.
3. This policy is based on available evidence as of the last review date. Coverage determinations are subject to applicable plan documents, state and federal regulations, and individual patient circumstances. This policy does not constitute medical advice.
4. For commercial contracts, medical necessity determinations align with the Certificate of Coverage issued by the Health Plan, which states that covered services must be clinically appropriate and not primarily for the convenience of the member, the member's family, or the provider.
5. This policy does not apply to Medicare Part D and D-SNP pharmacy benefits. The drugs in this policy may apply to all other lines of business including Medicare Advantage.
6. For members with Medicare Advantage, medications with a National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) will be covered pursuant to the criteria outlined by the NCD and/or LCD. NCDs/LCDs for applicable medications can be found on the CMS website at https://www.cms.gov/medicare-coverage-database/search.aspx. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS permits a Medicare Advantage Organization (MAO) to establish its own coverage determinations in accordance with 42 CFR § 422.101(b)(6). Indications that have not been addressed by the applicable medication's LCD/NCD will be covered in accordance with criteria determined by the Health Plan. Step therapy requirements may be imposed in addition to LCD/NCD requirements.
7. Unless otherwise indicated within drug specific criteria, the drugs listed in this policy are administered by a healthcare professional and therefore are covered under the medical benefit.

8. All utilization management requirements outlined in this policy are compliant with applicable New York State insurance laws and regulations. Policies will be reviewed and updated as necessary to ensure ongoing compliance with all state and federally mandated coverage requirements.
9. This policy is subject to ongoing revision. Newly marketed drugs and existing drugs with new indications may be subject to prior authorization until formal coverage criteria are established. Inclusion of a drug in this policy does not guarantee its current availability on the market, as some agents may be discontinued, withdrawn, or otherwise unavailable. As product status changes, drugs may be removed from the policy.
10. Manufacturers may either discontinue participation in, or may not participate in, the Medicaid Drug Rebate Program (MDRP). Under New York State Medicaid requirements, physician-administered drugs must be produced by manufacturers that participate in the MDRP. Products made by manufacturers that do not participate in the MDRP will not be covered under Medicaid Managed Care/HARP lines of business. Drug coverage will not be available for any product from a non-participating manufacturer. For a complete list of New/Reinstated & Terminated Labelers please visit: https://www.medicaid.gov/medicaid/prescriptiondrugs/medicaid-drug-rebate-program/newreinstated-terminated-labeler-information/index.html
11. The following applies to all gene and cellular therapies unless otherwise specified within the drug-specific coverage criteria:
    a. Administration, Retreatment, and Treatment with Additional or Other Gene/Cellular Therapies
        i. One-Time Administration
            1. Most gene and cellular therapies, whether autologous, allogeneic (“off-the-shelf”), or in vivo gene-transfer therapies, are designed and studied as one-time treatments.
            2. Repeat dosing, reinfusion, or sequential therapy with other gene or cellular products has not been established as safe, effective, or clinically appropriate.
        ii. Retreatment/Repeat Administration
            1. Retreatment with the same gene or cellular therapy product is considered experimental and investigational because:
                a. Clinical trials evaluated these therapies as single-administration interventions
                b. Safety, efficacy, and durability of a second administration have not been established
                c. Risks of immune activation, insertional mutagenesis, or vector immunity may be increased with repeat dosing
        iii. Treatment with an Additional or Other Gene/Cellular Therapy
            1. Treatment with an additional or different gene or cellular therapy after prior exposure to any gene or cellular therapy is also considered experimental and investigational, unless supported by evidence demonstrating (a-c):
                a. Anticipated clinical benefit beyond available standard therapies
                b. Safety of sequential administration
                c. Justification for selecting a second gene/cellular intervention after a prior one
            2. This includes, but is not limited to:
                a. Switching between CAR-T products (e.g., CD19 → CD19 or CD19 → BCMA)
                b. Switching between autologous and allogeneic cellular therapies
                c. Sequential use of CAR-T, TCR-T, NK-cell therapies, or other genetically engineered cell therapies
                d. Receiving gene therapy after previous gene or cellular therapy exposure

e. Receiving an in vivo gene therapy following any prior vector-based therapy

iv. Prior Gene/Cell Therapy Exposure

1. An individual is generally not eligible for additional gene or cellular therapy if they have previously received:
   a. Any autologous cellular therapy (e.g., CAR-T, TCR-T, TIL),
   b. Any allogeneic genetically modified cellular therapy,
   c. Any in vivo gene therapy (e.g., AAV, lentiviral vector)
   d. Any ex vivo gene-modified cell product
   e. Are being considered for any other gene or cellular therapy without documented evidence supporting safety and anticipated benefit.

12. The requested site of care may impact approval timeframe and is subject to review.

**CODES:**

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key:
Experimental/Investigational = (E/I),
Not medically necessary/ appropriate = (NMN).


**HCPCS**: J3590 (NOC)

**UPDATES:**

| Date | Revision |
|---|---|
| 06/12/2026 | Revised |
| 02/19/2026 | Effective & Posted |
| 02/12/2026 | P&T Committee Approval |
| 01/15/2026 | Created |

**REFERENCE:**

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