SENTARA HEALTH PLAN

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Omisirge® (omidubicel-onlv) (J3590) (Medical)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

A. Quantity Limit (max daily dose) [NDC Unit]:

- Omisirge, 1 kit, NDC: 73441-0800-04, a single dose consisting of:
  - Cultured Fraction (CF): a minimum of 8.0×10^8 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): a minimum of 4.0×10^8 total viable cells with a minimum of 2.4×10^7 CD3+ cells

B. Max Units (per dose and over time):

- 1 dose only (single-use culture containing at least 12×10^8 live cells, which include CD34+ and CD3+ cells)

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CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

❑ Diagnosis: High-Risk Hematologic Malignancy

Authorization Criteria: One-Time Authorization. Coverage may NOT be renewed.

- ❑ Member is 12 years of age or older
- ❑ Provider is a specialist, an oncologist, and/or transplant specialty
- ❑ Member is eligible for allogeneic hematopoietic stem cell transplant (allo-HSCT) and has **NOT** received a prior allo-HSCT **(documentation of medical treatment history verifying prior lines of therapy and/or pre-transplant debulking therapy must be submitted)**
- ❑ Member's has a diagnosis of a high-risk hematologic malignancy and is planned for an umbilical cord blood transplantation (UCBT) following myeloablative conditioning
- ❑ Requested medication will be used to reduce the time to neutrophil recovery and incidence of infection
- ❑ Member will receive prophylactic and supportive therapies for prevention or treatment of transplant complications (e.g., GVHD, infections) according to institutional guidelines
- ❑ Member does **NOT** have a readily available matched related donor (MRD), matched unrelated donor (MUD), mismatched (7/8 matched) unrelated donor (MMUD), or haploidentical (half HLA-matched) related donor
- ❑ Member does **NOT** have a known allergy or hypersensitivity to any of the following: dimethyl sulfoxide (DMSO), dextran 40, gentamicin, human serum albumin or bovine material
- ❑ Member does **NOT** have a clinically significant active/uncontrolled systemic infection
- ❑ Member does **NOT** have active/symptoms of central nervous system (CNS) disease

❑ Diagnosis: Severe Aplastic Anemia

Authorization Criteria: One-Time Authorization. Coverage may NOT be renewed

- ❑ Member is 6 years of age or older
- ❑ Provider is a specialist, a hematologist, and/or transplant specialty
- ❑ Member is eligible for allogeneic hematopoietic stem cell transplant (allo-HSCT) and has **NOT** received a prior allo-HSCT **(documentation of medical treatment history verifying prior lines of therapy and/or pre-transplant debulking therapy must be submitted)**

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- ❑ Member's has a diagnosis of severe aplastic anemia defined by **BOTH** of the following **(submit documentation)**:
  - ❑ Bone marrow biopsy showing less than 25% normal cellularity (or 25-50% cellularity if fewer than 30% of the remaining cells are hematopoietic)
  - ❑ Presence of at least **TWO** of the following three (3) peripheral blood findings **(check all that apply)**:
    - ❑ Absolute Neutrophil Count (ANC) less than 0.5 × 10^9/L (or 500/µL)
    - ❑ Platelet Count less than 20 × 10^9/L (or 20,000/µL)
    - ❑ Absolute Reticulocyte Count less than 20 × 10^9/L (or 60 × 10^9/L using an automated analyzer, or less than 1% manual count)
- ❑ Requested medication will be used to reduce the time to neutrophil recovery and incidence of infection
- ❑ Member will receive prophylactic and supportive therapies for prevention or treatment of transplant complications (e.g., GVHD, infections) according to institutional guidelines
- ❑ Member does **NOT** have a readily available matched related donor (MRD), matched unrelated donor (MUD), mismatched (7/8 matched) unrelated donor (MMUD), or haploidentical (half HLA-matched) related donor
- ❑ Member does **NOT** have a known allergy or hypersensitivity to any of the following: dimethyl sulfoxide (DMSO), dextran 40, gentamicin, human serum albumin or bovine material
- ❑ Member does **NOT** have a clinically significant active/uncontrolled systemic infection
- ❑ Member had a failure to respond to a 6-month regimen of immunosuppressive therapy, or has a contraindication, with Antithymocyte Globulin (ATG) and Cyclosporine A (CsA) **(submit documentation)**
- ❑ Member had a failure to respond to thrombopoietin receptor agonist, Eltrombopag (as monotherapy following insufficient response to initial (IST) or as add-on therapy to above IST criterion) **(submit documentation)**

Reauthorization: Coverage may NOT be renewed

Medication being provided by: Please check applicable box below.

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy**

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.*