SENTARA HEALTH PLANS

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: Skysona™ (elivaldogene autotemcel) **(J3387) (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.

Dosing Limits

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

- Skysona™ up to 2 infusion bags, 20 mL/infusion bag, overwrap, and metal cassette: 73554-2111-xx
- A single dose of Skysona™ containing a minimum of 5.0×10^6 CD34+ cells/kg of body weight, in one or more infusion bags

B. Max Units (per dose and over time) [HCPCS Unit]:

- A single dose of Skysona™ containing a minimum of 5.0×10^6 CD34+ cells/kg of body weight, in one or more infusion bags

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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.

Coverage will be provided for one treatment course and may NOT be renewed.

- ❑ Member is a male [**NOTE**: the specified gender is defined as follows: males are defined as individuals with the biological traits of a man, regardless of the individual's gender identity or gender expression]
- ❑ Member is ≥ 4 and < 18 years of age
- ❑ Medication is prescribed by a hematologist, a neurologist, and/or a stem cell transplant specialist physician
- ❑ Member has early, active cerebral adrenoleukodystrophy as demonstrated by **ALL** the following **(submit documentation)**:
  - ❑ Member has a neurologic function score ≤ 1
  - ❑ Member has gadolinium enhancement on brain magnetic resonance imaging (MRI)
  - ❑ Member has a Loes score between 0.5 and 9
- ❑ Member has a confirmed mutation in the adenosine triphosphate binding cassette, sub family D member 1 (ABCD1) gene **(submit documentation)**
- ❑ Member has elevated very long chain fatty acid levels according to the standard reference values of the laboratory **(submit documentation)**
- ❑ Member does **NOT** have a Human Leukocyte Antigen (HLA)-matched family donor **(submit documentation)**
- ❑ According to the prescribing physician, member is able to undergo monitoring by magnetic resonance imaging
- ❑ Member does **NOT** currently have an active bacterial, viral, fungal, or parasitic infection
- ❑ Member does **NOT** have any of the following:
  - Prior or current hematologic malignancy or myeloproliferative disorder
  - Familial cancer syndrome or a history of such in his immediate family
- ❑ According to the prescribing physician, hematopoietic stem cell transplantation is appropriate for the member
- ❑ Member has adequate hepatic function as defined by meeting **ALL** the following **(submit documentation)**:
  - ❑ Aspartate aminotransferase values are normal or ≤ 2.5 times the upper limit of normal
  - ❑ Alanine aminotransferase values are normal or ≤ 2.5 times the upper limit of normal
  - ❑ Total bilirubin values are normal or ≤ 3.0 mg/dL
- ❑ Member has adequate renal function as defined by meeting **ONE** of the following **(submit documentation)**:
  - ❑ Estimated creatinine clearance is ≥ 50 mL/min
  - ❑ Estimated glomerular filtration rate is ≥ 70 mL/minute/1.73 m^2

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- ❑ According to the prescribing physician, member does **NOT** have evidence of cardiac compromise
- ❑ Prior to collection of cells for manufacturing, member screening is negative for **ALL** the following **(submit documentation)**:
  - ❑ Hepatitis B virus
  - ❑ Hepatitis C virus
  - ❑ Human T-lymphotropic virus 1 and 2
  - ❑ Human immunodeficiency virus 1 and 2
- ❑ Prior to therapy member must **NOT** have evidence of hematological compromise as defined by meeting **ALL** the following **(submit documentation)**:
  - ❑ Peripheral blood absolute neutrophil count ≥ 1,500 cells/mm^3
  - ❑ Platelet count ≥ 100,000 cells/mm^3
  - ❑ Hemoglobin ≥ 10 g/dL
  - ❑ Member does **NOT** have an uncorrected bleeding disorder
- ❑ Member meets **ALL** the following:
  - ❑ Member will undergo mobilization, apheresis, myeloablative conditioning, and lymphodepletion
  - ❑ A granulocyte-colony stimulating factor product will be used for mobilization
  - ❑ Busulfan will be used for myeloablative conditioning
  - ❑ Cyclophosphamide or fludarabine will be used for lymphodepletion
- ❑ Member has received or is planning to receive prophylaxis for hepatic veno-occlusive disease/hepatic sinusoidal obstruction syndrome before conditioning [**NOTE**: Examples of medications used include ursodeoxycholic acid or Defitelio® (defibrotide intravenous infusion)]
- ❑ Provider confirms that the member or his partner of childbearing potential will be using an effective method of contraception from the start of mobilization through at least 6 months after administration of Skysona™
- ❑ Member has **NOT** received Skysona™ in the past **(verified by medical paid claims)** [**NOTE**: Verify through claims history that the patient has not previously received Skysona™ **AND**, if no claim for Skysona™ is present, the prescribing physician confirms that the member has not previously received Skysona™]

Medication being provided by: Please check applicable box below.

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

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy – Proprium Rx**

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For urgent reviews: Practitioner should call Sentara Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health Plan's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

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.

***Approved by Pharmacy and Therapeutics Committee**: ~~11/18/2022;~~ **1/23/2025**
REVISED/UPDATED/REFORMATTED: ~~11/29/2022; 01/02/2025,~~ **1/02/2026**