SENTARA COMMUNITY PLAN
(MEDICAID)

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 1-844-305-2331**. 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**.

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 Name/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 bag

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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.

Authorization Criteria: Coverage will be provided for one treatment course (1 dose of Skysona) and may not be renewed.

- ❑ Member is assigned male at birth, at least 4 years of age and less than 18 years of age
- ❑ Member has a documented diagnosis of cerebral adrenoleukodystrophy (CALD) as defined by at least **ONE** the following **(laboratory results MUST be submitted)**:
  - ❑ Elevated very long chain fatty acids (VLCFA) as confirmed by **ONE** the following:
    - ❑ Plasma C26:0- lysophosphatidylcholine (C26:0-LPC) level
    - ❑ Fasting plasma VLCFA levels: C26:0, ratio of C24:0 to C22:0, AND ratio of C26:0 to C22:0
    - ❑ Pathogenic variants in the ABCD1 gene as detected by genetic testing
- ❑ Member has active central nervous system (CNS) disease established by central radiographic review of brain magnetic resonance imaging (MRI) demonstrating **BOTH** of the following:
  - ❑ Loes score between 0.5 and 9 (inclusive) on the 34-point scale
  - ❑ Gadolinium enhancement on MRI of demyelinating lesions
- ❑ Member does **NOT** have a full ABCD1-gene deletion **(Note: Rapid loss of efficacy due to immune response may result)**
- ❑ Neurologic Function Score (NFS) ≤ 1 (asymptomatic or mildly symptomatic disease)
- ❑ Member has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), human T-lymphotrophic virus 1 & 2 (HTLV-1/HTLV-2), and human immunodeficiency virus 1 &2 (HIV-1/HIV-2) in accordance with clinical guidelines prior to collection of cells for manufacturing
- ❑ Member does **NOT** have an active infection, including clinically important localized infections
- ❑ Member will be administered prophylaxis for infection according to best clinical practices and guidelines
- ❑ Vaccinations will **NOT** be administered within the 6-weeks prior to the start of therapy and will **NOT** be administered concurrently while on therapy **AND** member is up to date with all age-appropriate vaccinations, in accordance with current vaccination guidelines, prior to initiating therapy
- ❑ Requested medication will be used as single agent therapy (not applicable to lymphodepleting or bridging therapy while awaiting manufacture)
- ❑ Member will receive periodic life-long monitoring for hematological malignancies (Myelodysplastic syndrome [MDS] has developed in patients treated in clinical studies with a varied clinical presentation)
- ❑ Member will avoid concomitant therapy with anti-retroviral medications for at least one month prior to initiating medications for stem cell mobilization and for the expected duration for elimination of the medications, and until all cycles of apheresis are completed **(Note: if a member requires anti-retroviral for HIV prophylaxis, confirm a negative test for HIV before beginning mobilization)**

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- ❑ Member does **NOT** have disease secondary to head trauma
- ❑ Medication will **NOT** be used to prevent the development of or treat adrenal insufficiency due to adrenoleukodystrophy
- ❑ Member is eligible* to undergo hematopoietic stem cell transplant (HSCT) and has not had a prior allogeneic-HSCT
- ❑ Member does **NOT** have an available human leukocyte antigen (HLA)-matched donor for allogeneic hematopoietic stem cell transplant (HSCT)
- ❑ Males capable of fathering a child and their female partners of childbearing potential should use an effective method of contraception (e.g., intra-uterine device or combination of hormonal and barrier contraception) from start of mobilization through at least 6 months after administration of Skysona

* Eligibility criteria for allogeneic HCT are not absolute and vary by center. In general, members are considered eligible for allogeneic HCT if they meet certain criteria like functional capacity, organ function, social support, etc.

Medication being provided by: Please check applicable box below.

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

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy – PropriumRx**

For urgent reviews: Practitioner should call Sentara Health Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health'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**
REVISED/UPDATED/REFORMATTED: ~~11/29/2022; 4/10/2025; 4/25/2025,~~ **8/26/2025**