POLICY AND PROCEDURE

POLICY NAME: Elivaldogene autotemcel (Skysona)	**POLICY ID:** TX.PHAR.110
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy
EFFECTIVE DATE: 8/1/23	**PRODUCT(S):** STAR, STAR Kids, STAR Health, STAR Plus, CHIP, CHIP Perinate
REVIEWED/REVISED DATE:	
REGULATOR MOST RECENT APPROVAL DATE(S): N/A	

POLICY STATEMENT:
It is the policy of Superior HealthPlan to follow state guidance for medical necessity review of Elivaldogene autotemcel (Skysona).

PURPOSE:
This medication is a pass through drug (non-risk based payment drug) and should follow state guidance for medical necessity review for Medicaid/CHIP due to the manner in which it is reimbursed. All determinations will be performed by a Superior Medical Director. A pharmacy clinician will review the prior authorization request and make a recommendation to the Medical Director but will not make the ultimate determination on any case.

In addition, Elivaldogene autotemcel (Skysona), J3590 requests are limited to one approval per lifetime, by any provider.

Refer to the Outpatient Drug Services Handbook of the Texas Medicaid Provider Procedure Manual for more details on the clinical policy and prior authorization requirements.

SCOPE:
Superior HealthPlan Pharmacy Department, Medical Directors

DEFINITIONS: NRB = non-risk based

POLICY:
It is the policy of Superior HealthPlan to follow state guidance for medical necessity review of Elivaldogene autotemcel (Skysona).

Description/Mechanism of Action:
Elivaldogene autotemcel (Skysona) is an autologous hematopoietic stem cell-based gene therapy indicated to slow the progression of neurologic dysfunction in male patients 4 to 17 years old with early, active cerebral adrenoleukodystrophy (CALD).

Formulations:
Elivaldogene autotemcel (Skysona): Cell suspension for intravenous infusion. A single dose contains a minimum of 5.0 x 10^6 CD34+ cells/kg of body weight, suspended in a solution containing 5% dimethyl sulfoxide (DMSO).

FDA Approved Indications:
Elivaldogene autotemcel (Skysona) is indicated to slow the progression of neurologic dysfunction in male patients 4 to 17 years old with early, active cerebral adrenoleukodystrophy (CALD).

PROCEDURE:
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

I. Initial Approval Criteria:

A. Cerebral Adrenoleukodystrophy (CALD)

1. All prior authorization approvals or denials will be determined by a Superior HealthPlan Medical Director.
2. Client is a male between the ages of 4 years to 17 years.
3. Client has a documented diagnosis of cerebral adrenoleukodystrophy (ICD 10 - E71.511, E71.520, E71.521,

E71.528, and E71.529).
4. Client has a variant in the ABCD1 gene as evident by a genetic test.
5. Client's CALD is caused by the presence of a variant of the ABCD1 gene causing elevated very long fatty acid (VLCFA) and not secondary to head trauma.
6. Client has early, active CALD as defined by all of the following:
   - Client is asymptomatic or mildly symptomatic with neurologic function score (NFS) of less than or equal to 1;
   - Client has gadolinium enhancement on brain magnetic resonance imaging (MRI);
   - Client has a Loes score ranging from 0.5 to 9
7. Client has not had hematopoietic stem cell transplant (HSCT), is eligible for HSCT, and is unable to find a matched related donor.
8. Client's screening result is negative for hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus 1 & 2 (HIV-1/HIV-2) and Human T-lymphotropic virus 1 & 2 (HTLV-1/HTLV-2) prior to the collection of cells for manufacturing.
9. Prescriber must attest to monitor client closely for evidence of life-threatening hematological malignancy through complete blood count (CBC) at least every six months and through assessment for possible clonal expansion a least twice in the first year and annually thereafter.
10. Prescriber must attest to monitor client for signs of bleeding and infections after the treatment with Skysona as life threatening bacterial/viral infection may occur as well as thrombocytopenia and prolonged cytopenia.
11. Client must avoid taking anti-retroviral medications for at least one month prior to initiating medication for stem cell mobilization and for the expected duration for elimination of the medications, and until all cycles of apheresis are complete.

Approval duration: Only 1 dose per lifetime will be provided on this drug regardless of Provider

REFERENCES:

Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook.

ATTACHMENTS: N/A

ROLES & RESPONSIBILITIES: N/A

REGULATORY REPORTING REQUIREMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Policy Document		8/1/2023

POLICY AND PROCEDURE APPROVAL

The electronic approval retained in RSA Archer, the Company's P&P management software, is considered equivalent to a signature.