TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Elivaldogene autotemcel (Skysona®)	**CRITERIA ID:** TX.CC.PHAR.25
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: 4/3/2024	
REGULATOR MOST RECENT APPROVAL DATE(S): N/A	

POLICY STATEMENT:
The purpose of this clinical criteria is to provide a guide to medical necessity reviews for Elivaldogene autotemcel (Skysona®).

PURPOSE:
Consistent with the regulation at 42 CFR Section 438.210 and 42 CFR Section 457.1230(d), services covered under managed care contracts, including clinician-administered drugs, must be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services specified in the state plan. While MCOs may place appropriate limits on drugs, MCOs may not use a standard for determining medical necessity that is more restrictive than what is used in the state plan, i.e., developed by the Vendor Drug Program. For example, if a member is denied a clinician administered drug in managed care because of the MCO's prior authorization criteria but would have received the drug under the criteria specified in the state plan, then the MCO's prior authorization criteria would violate the amount, duration, and scope requirements cited above. HHSC intends to amend the Managed Care Contracts at the next opportunity to include this requirement. This same standard applies to CHIP formulary and CAD coverage.

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

This medication is a non-risk based (NRB) 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 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.

Additionally, this medication is a Precision Drug. Centene's Precision Drug Action Committee (PDAC) creates a standardized approach for Centene to manage precision drugs and the associated costs for their administration, prior to members presenting with a request for one of these agents. All precision drug requests or potential requests must be reported to the PDAC for tracking, regardless of whether agents are carved out, passed through, etc. All precision drug medical necessity determinations will be supported by PDAC UM recommendation, utilizing specialist input as directed and allowed by turnaround times.

The procedure code J3590 (used for Skysona) will be limited to one approval per lifetime, by any provider. If the code is updated in the future, it will still be limited to once per lifetime.

SCOPE:
This criteria applies to all directors, officers, and employees of Centene Corporation, its affiliates, health plans, and subsidiary companies (collectively, the "Company").

DEFINITIONS:
NRB = non-risk based

POLICY:
It is the policy of Superior HealthPlan and Centene Pharmacy Services to follow state guidance for medical necessity review of elivaldogene autotemcel (Skysona®); procedure code: J3590.

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 clients 4 to 17 years old with early, active cerebral adrenoleukodystrophy (CALD).

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

Formulations:
Elivaldogene autotemcel (Skysona®) is a 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).

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. A Medical Director is required to review and approve or deny all requests. A pharmacy clinician will make a recommendation on the prior authorization, but ultimate determination will be made by the Medical Director only.
2. Medical necessity determinations will be supported by PDAC UM recommendation. The pharmacy clinician will review the UM recommendation with the prior authorization request for clinical appropriateness and make a recommendation to the Medical Director but will not make the ultimate determination on any case.
3. The client is a male between the ages of 4 years to 17 years.
4. The client has a confirmed diagnosis of cerebral adrenoleukodystrophy (diagnosis codes: E71.511, E71.520, E71.521, E71.528, and E71.529).
5. The client has a variant in the ABCD1 gene as evident by a genetic test.
6. The 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.
7. The 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.
8. The client has not had hematopoietic stem cell transplant (HSCT), is eligible for HSCT, and is unable to find a matched related donor.
9. The 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.
10. Prescriber attestation that the client will be closely monitored for evidence of life-threatening hematological malignancy through complete blood count (CBC) at least every six months and through assessment for possible clonal expansion at least twice in the first year and annually thereafter.
11. Prescriber attestation that the client will be monitored 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.
12. The 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

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Policy Document		8/1/2023
Ad Hoc Review/	Updated to TX.CC.PHAR format template Added Centene copyright statement and PDAC statement as well as criteria to require PDAC review prior to final determination	4/3/2024

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