Medical Policy

Skysona® (elivaldogene autotemcel)	
MEDICAL POLICY NUMBER	MED_Clin_Ops_131
CURRENT VERSION EFFECTIVE DATE	01/01/2024
APPLICABLE PRODUCT AND MARKET	Individual Family Plan: ALL Small Group: ALL Medicare Advantage: ALL

PURPOSE

To promote consistency between reviewers in clinical coverage decision-making by providing the criteria that generally determine the medical necessity of Skysona® (elivaldogene autotemcel) therapy.

POLICY/CRITERIA

Prior Authorization and Medical Review is required.

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

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

- A single dose of Skysona containing a minimum of 5.0 × 106 CD34+ cells/kg of body weight, in one or more infusion bags

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1. Patient is a male at least 4 years of age and less than 18 years of age; **AND**
2. Patient 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 (leukapheresis); **AND**
3. Patient does not have an active infection, including clinically important localized infections; **AND**
4. Prophylaxis for infection will be followed according to standard institutional guidelines; **AND**
5. 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 patient is up to date with all age-appropriate vaccinations, in accordance with current vaccination guidelines, prior to initiating therapy; **AND**
6. Skysona will be used as single agent therapy (not applicable to lymphodepleting or bridging therapy while awaiting manufacture); **AND**
7. Patient 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); **AND**
8. Patient does not have a full ABCD1-gene deletion; **AND**
9. Patient 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 patient requires anti-retroviral for HIV prophylaxis, confirm a negative test for HIV before beginning mobilization); **AND**
10. Patient does not have head trauma induced disease; **AND**
11. Therapy will not be used to prevent the development of or treat adrenal insufficiency due to adrenoleukodystrophy; **AND**
12. Patient is eligible§ to undergo hematopoietic stem cell transplant (HSCT) and has not had a prior allogeneic-HSCT; **AND**
13. 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; **AND**
14. Patient has a documented diagnosis of cerebral adrenoleukodystrophy (CALD) as defined by one or more of the following:
    a. Elevated very long chain fatty acids (VLCFA) value for ALL of the following:
        i. Concentration of C26:0
        ii. Ratio of C24:0 to C22:0
        iii. Ratio of C26:0 to C22:0; **OR**
    b. Pathogenic variants in the ABCD1 gene detected by molecular genetic testing; **AND**
15. Patient has active central nervous system (CNS) disease established by central radiographic review of brain magnetic resonance imaging (MRI) demonstrating BOTH of the following:
    a. Loes score between 0.5 and 9 (inclusive) on the 34-point scale; **AND**
    b. Gadolinium enhancement on MRI of demyelinating lesions; **AND**
16. Neurologic Function Score (NFS) ≤ 1 (asymptomatic or mildly symptomatic disease)

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

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value
2. patients with CALD secondary to head trauma.

CODING

Applicable NDC Codes	
73554-2111 -01	Skysona up to 2 infusion bags, 20 mL/infusion bag, overwrap, and metal cassette

Applicable Procedure Code	
J3590	Unclassified biologics

Applicable ICD-10 Codes	
E71.511	Neonatal adrenoleukodystrophy
E71.520	Childhood cerebral X-linked adrenoleukodystrophy
E71.521	Adolescent X-linked adrenoleukodystrophy
E71.528	Other X-linked adrenoleukodystrophy
E71.529	X-linked adrenoleukodystrophy, unspecified type

EVIDENCE BASED REFERENCES

1. Skysona [package insert]. Somerville, MA; Bluebird bio, Inc: September 2022. Accessed October 2022.

POLICY HISTORY

Revision History	Month Day, Year	Updates
Original Effective Date	NOVEMBER 8, 2022	
Revision	MARCH 1, 2023	Adopted by MA UM Committee
P&T Committee Endorsement	NOVEMBER 8, 2022	
Revision	January 1, 2024	Updated to Brand New Day/Central Health Medicare Plan/Central Health Medicare Plan