Elivaldogene autotemcel (Skysona®)	Place of Service Hospital Administration HCPCS: J3590 NDC(s): 73554-2111-01, single dose for infusion containing a suspension of CD34+ cells in one or two infusion bags.

Condition(s) listed in policy (*see criteria for details*)

- Cerebral Adrenoleukodystrophy (CALD)

AHFS therapeutic class: Genetic or Enzyme Disorder: Replacement, Modifiers, Treatment

Mechanism of action: gene therapy

(1) Special Instructions and pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Skysona® (Elivaldogene autotemcel) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Cerebral Adrenoleukodystrophy (CALD)

1. Patient is 4 – 17 years of age, **AND**
2. Active early-stage CALD confirmed with both of the following:
    a. Patient is asymptomatic or mildly symptomatic (neurologic function score ≤1), and
    b. Magnetic resonance imaging (MRI) demonstrating Loes score of 0.5-9,

    AND
3. Patient is clinically stable and eligible to undergo myeloablative and lymphodepleting conditioning before infusion of Skysona, **AND**
4. Patient is negative for human immunodeficiency virus 1 and 2 (HIV-1/HIV-2), hepatitis B virus (HBV), hepatitis C virus (HCV), human T-lymphotropic virus 1 and 2 (HTLV-1/HTLV-2), **AND**
5. ***Effective 1/28/2024 and after***: Patient has no prior history of allogeneic hematopoietic stem cell transplant (HSCT)

Covered Doses
Minimum recommended dose of 5.0×10^6 CD34+ cells/kg

Coverage Period
Cover one treatment per lifetime

ICD-10:
E71.520

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Skysona® (Elivaldogene autotemcel)must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT COVERED for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied: single dose for infusion containing a suspension of CD34+ cells in one or two infusion bags containing minimum 5.0 × 106 CD34+ cells/kg

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Skysona® (elivaldogene autotemcel) [Prescribing information]. Somerville, MA: Bluebird bio, 9/2022.

(7) Policy Update

Date of last review: 4Q2023
Date of next review: 4Q2024
Changes from previous policy version:

- Section (2): Cerebral Adrenoleukodystrophy
    - *Effective 1/28/2024 and after*, will manage for no prior history of allogeneic hematopoietic stem cell transplant (HSCT)
    - Remove management for blood related abnormalities

Rationale: Skysona prescribing information

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee