**elivaldogene autotemcel (Skysona)**

**Commercial Medical Benefit Drug Policy**

**Place of Service**
Hospital Administration

## Drug Details

**USP Category:** GENETIC OR ENZYME OR PROTEIN DISORDER: REPLACEMENT, MODIFIERS, TREATMENT
**Mechanism of Action:** Gene therapy
**HCPCS:**
J3387:Injection, elivaldogene autotemcel, per treatment
**How Supplied:**
A single dose contains a minimum of 5.0 × 10^6 CD34+cells/kg of body weight, suspended in a solution containing 5% dimethyl sulfoxide (DMSO)

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

- Cerebral Adrenoleukodystrophy (CALD)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

## Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

## Coverage Criteria

**The following condition(s) require Prior Authorization/Preservice.**

**Cerebral Adrenoleukodystrophy (CALD)**
**Meets medical necessity if all the following are met:**

1. Patient is 4 – 17 years of age
2. Active early-stage CALD confirmed with both of the following:
   a. Patient is asymptomatic or mildly symptomatic (neurologic function score ≤1)
   b. Magnetic resonance imaging (MRI) demonstrating Loes score of 0.5-9
3. Patient is clinically stable and eligible to undergo myeloablative and lymphodepleting conditioning before infusion of Skysona

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)
5. Patient has no prior history of allogeneic hematopoietic stem cell transplant (HSCT)
6. ***Effective 2/1/2026 and after:*** Patient does not have an available human leukocyte antigen (HLA)-matched donor for allogeneic HSCT

**Covered Doses:**
Minimum recommended dose of $5.0 \times 10^6$ CD34+ cells/kg

**Coverage Period:**
One treatment per lifetime

**ICD-10:**
E71.520

## References


1. AHFS. Available by subscription at http://www.lexi.com
2. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
3. Skysona (elivaldogene autotemcel) [prescribing information]. Somerville, MA: Bluebird Bio Inc; August 2025.


## Review History

Date of Last Annual Review: 4Q2025
Changes from previous policy version:

- HCPCS: Added J3387, effective 1/1/2026.

*Blue Shield of California Medication Policy to Determine Medical Necessity*
*Reviewed by P&T Committee*