blue california
Promise Health Plan

elivaldogene autotemcel (Skysona)

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 California Code of Regulations (CCR), Title 22, Section 51303 and 51313 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.

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 5.0×10^6 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