# Skysona (elivaldogene autotemcel)

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## Medicare Advantage Medical Coverage Policy

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## Related Medicare Advantage Medical/Pharmacy Coverage Policies

None

## Related Documents

**Please refer to CMS website for the most current applicable CMS Online Manual System (IOMs)/National Coverage Determination (NCD)/ Local Coverage Determination (LCD)/Local Coverage Article (LCA)/ Transmittals.**

**There are no NCD and/or LCDs for Skysona (elivaldogene autotemcel)**

## Description

**Skysona (elivaldogene autotemcel)** is a lentiviral vector (LVV)-based autologous hematopoietic stem cell (HSC) gene therapy designed to add functional copies of the *ABCD1* complementary deoxyribonucleic acid (DNA) into HSCs through transduction of autologous CD34+ cells with Lenti-D LVV. After Skysona (elivaldogene autotemcel) infusion, transduced CD34+ HSCs engraft in the bone marrow and differentiate into various cell types, including monocytes (CD14+) capable of producing functional human adrenoleukodystrophy protein (ALDP). Functional ALDP can then participate in the local degradation of very long chain fatty acids (VLCFAs), which is believed to slow or possibly prevent further inflammation and demyelination.

Skysona (elivaldogene autotemcel) is indicated, as a single dose per lifetime, to slow the progression of neurological dysfunction in male pediatric patients diagnosed with cerebral adrenoleukodystrophy (CALD), a rare neurologic disease caused by mutations in the *ABCD1* gene that leads to a buildup of VLCFA causing inflammation and damage in the brain.

Skysona (elivaldogene autotemcel) is a cell suspension for intravenous infusion. A single dose of Skysona contains a minimum of 5.0 × 106 CD34+ cells/kg of body weight, suspended in a solution containing 5% dimethyl sulfoxide.

Individuals must undergo HSC mobilization and apheresis to obtain CD34+ cells for Skysona (elivaldogene autotemcel) manufacturing. Dosing is based on the number of CD34+ cells in the infusion bag(s) per kg of body weight. Full myeloablative and lymphodepleting conditioning must be administered prior to infusion of Skysona (elivaldogene autotemcel).

## Coverage Determination

*iCare follows the CMS requirements that only allows coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.*

*In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the following criteria:*

Skysona

*The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.*

## Coverage Limitations

US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage

## Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

| CPT® Code(s) | Description | Comments |
|---|---|---|
| No code(s) identified | | |
| **CPT® Category III Code(s)** | **Description** | **Comments** |
| No code(s) identified | | |
| **HCPCS Code(s)** | **Description** | **Comments** |
| J3590 | Unclassified biologics | |
| C9399 | Unclassified drugs or biologicals | |

## Change Summary

- 01/01/2024 New Policy.
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