

Skysona[®] (Elivaldogene Autotemcel) Prior Authorization Form

Member Name: _____ Date of Birth: _____ Member ID#: _____

Drug Information

Physician billing (HCPCS code: _____) Start Date: _____

Billing Provider Information

Provider NPI: _____ Provider Name: _____

Provider Phone: _____ Provider Fax: _____

Prescriber Information

Prescriber NPI: _____ Prescriber Name: _____

Prescriber Phone: _____ Prescriber Fax: _____ Specialty: _____

Criteria

For Authorization: (Only one Skysona[®] infusion will be approved per member per lifetime):

1. Does the member have a diagnosis of Cerebral Adrenoleukodystrophy (CALD)? Yes No
2. Was CALD diagnosis confirmed by the following?:
 - A. Molecular genetic testing confirming a mutation in the ABCD1 gene: Yes No
 - i. Does member have a full deletion of the ABCD1 gene? Yes No
 - B. Lab results indicating elevated very-long chain fatty acids (VLCFAs): Yes No
 - C. Active central nervous system (CNS) disease established by central radiographic review of brain magnetic resonance imaging (MRI) demonstrating the following:
 - i. Loes score between 0.5 and 9 on the 34-point scale: Yes No
 - ii. Gadolinium enhancement (GdE+) on MRI of demyelinating lesions: Yes No
 - D. Neurological Function Score (NFS) of ≤ 1 : Yes No
3. Is Skysona[®] prescribed by a neurologist, endocrinologist, or hematologist/oncologist with expertise in the treatment of CALD and the administration of Skysona[®]? Yes No
4. Does the member have a known and available human leukocyte antigen (HLA)-matched sibling donor? Yes No
5. Does the member have a prior history of hematopoietic stem cell transplantation (HSCT)? Yes No
6. Does the member take statins, Lorenzo's oil, or dietary regimens used to lower VLCFA levels? Yes No
7. Does the member have an immediate family member with known or suspected familial cancer syndrome (FCS)? Yes No
8. Does the member have a negative serology test for human immunodeficiency virus (HIV) prior to apheresis? Yes No
9. Has prescriber verified the member is clinically stable and eligible to undergo HSCT? Yes No
10. If member is of reproductive potential, will they use an effective method of contraception from the start of mobilization through at least 6 months after administration of Skysona[®]? Yes No
11. If member is of reproductive potential, have they been counseled on the potential effects of myeloablative conditioning on fertility and the potential risk of infertility is acceptable to the member or the member's caregiver? Yes No
12. Will the prescriber evaluate the potential for drug interactions, according to package labeling, prior to and after administration of Skysona[®]? Yes No

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Fax completed prior authorization request form to **888-601-8461** or submit Electronic Prior Authorization through CoverMyMeds[®] or SureScripts.
All requested data must be provided. Incomplete forms or forms without the chart notes will be returned. Pharmacy Coverage Guidelines are available at AetnaBetterHealth.com/Oklahoma.

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Criteria

***Page 2 of 2—Please complete and return all pages. Failure to complete all pages will result in processing delays.*
For Authorization, continued:**

- 13. Will member be monitored for hematologic malignancies lifelong, with a complete blood count (with differential) performed at month 6 and month 12 after treatment with Skysona®, then at least annually thereafter for at least 15 years, and with integration site analysis months 6, 12 and as warranted? Yes No
- 14. Will Skysona® be administered at a Skysona® qualified treatment center? Yes No
A. Please provide name of treatment center: _____
- 15. Does the receiving facility have a mechanism in place to track the patient-specific Skysona® dose from receipt to storage to administration? Yes No
A. Please provide name of facility: _____

Additional information: _____

Prescriber Signature: _____ Date: _____

I certify that the indicated treatment is medically necessary and all information is true and correct to the best of my knowledge. Failure to complete this form in full and attach requested clinical notes will result in processing delays.

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