OKLAHOMA Health Care Authority

State of Oklahoma SoonerCare

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 <u>one</u> 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☐

PLEASE PROVIDE THE INFORMATION REQUESTED AND RETURN TO:

University of Oklahoma College of Pharmacy
Pharmacy Management Consultants
Product Based Prior Authorization Unit
Fax: 1-800-224-4014
Phone: 1-800-522-0114 Option 4

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Criteria

Page 2 of 2—Please complete and return <u>all</u> 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: _____

_____

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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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