HIGHMARK WHOLECARE

Updated: 10/2022
PARP Approved: 11/2022

Prior Authorization Criteria

Skysona (elivaldogene autotemcel)

All requests for Skysona (elivaldogene autotemcel) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Coverage may be provided with a diagnosis of **cerebral adrenoleukodystrophy (CALD)** and the following criteria is met:

- Member must be a male between the ages of 4-17 years of age
- Must have early, active CALD defined by:
    - Elevated very long chain fatty acids (VLCFA) values
    - Active CNS disease established by central radiographic review of brain magnetic resonance imaging (MRI)
    - Loes score between 0.5 and 9
    - Gadolinium enhancement (GdE+) on MRI of demyelinating lesions
    - Neurologic function score (NFS) of ≤ 1 demonstrating asymptomatic or mild disease
- Member must have confirmed mutations in the ABCD1 gene
- Must be prescribed by a neurologist or ALD specialist. Adrenal symptoms must be managed by an endocrinologist.
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- Skysona should not be administered in members with active infections.
- Member must have a negative serology test for HIV.
- Member must not have been a recipient of an allogenic transplant or gene therapy
- **Duration of Approval:** One treatment per lifetime

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

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SKYSONA (ELIVALDOGENE AUTOTEMCEL)
PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Wholecare Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (800) 392-1147 Mon – Fri 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	Provider NPI:
Provider Specialty:	Office Contact:
State license #:	Office NPI:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Member weight:	Height:

REQUESTED DRUG INFORMATION

Medication:	Strength:	
Directions:	Quantity:	Refills:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:	

Billing Information

This medication will be billed: ☐ at a pharmacy **OR** ☐ medically, JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis:	ICD Code:

Does the member have early, active CALD? ☐ Yes ☐ No
Does the member have elevated VLCFA values? ☐ Yes ☐ No
Was active CNS disease established by central radiographic review of brain MRI? ☐ Yes ☐ No
What is the member's Loes score? _____
Was Gadolinium enhancement on MRI of demyelinating lesions completed? ☐ Yes ☐ No
What is the members neurologic function score? _____

Does the member have confirmed mutations in the ABCD1 gene? ☐ Yes ☐ No

Is Skysona being administered to a member with an active infection? ☐ Yes ☐ No

Does the member have a negative serology test for HIV? ☐ Yes ☐ No

Has the member been a recipient of an allogenic transplant or gene therapy? ☐ Yes ☐ No

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date