HIGHMARK HEALTH OPTIONS

Updated: 10/2022
DMMA Approved: 11/2022

Request for Prior Authorization for Skysona (elivaldogene autotemcel)
Website Form – www.highmarkhealthoptions.com
Submit request via: Fax - 1-855-476-4158

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

Skysona (elivaldogene autotemcel) Prior Authorization Criteria:

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.
- 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.

Drugs are authorized in generic form unless the branded product is on the preferred drug list or the prescriber has indicated in writing that the branded product is medically necessary. If only the branded product is on the preferred drug list, the generic form will be considered non-preferred and shall not require the prescriber to indicate in writing that the branded product 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 Health Options Pharmacy Services. **FAX: (855) 476-4158**
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (844) 325-6251 Mon – Fri 8:00 am to 7:00 pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
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:	

Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? ☐ Yes ☐ No

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? ☐ Yes ☐ No Value: _____
Has the member had an MRI establishing active CNS disease with GdE+ of demyelinating lesions? ☐ Yes ☐ No
What is the Loes score? _____
What is the NFS score? _____
Does the member have confirmed mutations in the ABCD1 gene? ☐ Yes ☐ No
Does the member have an active infection?
Does the member have HIV?
Has the member received an allogenic transplant or gene therapy previously?

CURRENT or PREVIOUS THERAPY

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

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date