MASSACHUSETTS

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Gene Therapy for Cerebral Adrenoleukodystrophy – Skysona® (Elivaldogene autotemcel) Prior Authorization Request Form #242

Medical Policy #241 Gene Therapy for Cerebral Adrenoleukodystrophy Skysona® (Elivaldogene autotemcel)

CLINICAL DOCUMENTATION

- Clinical documentation that supports the medical necessity criteria for Skysona must be submitted.
- If the patient does not meet all the criteria listed below, please submit a letter of medical necessity with a request for Clinical Exception (Individual Consideration) explaining why an exception is justified.

Requesting Prior Authorization Using Authorization Manager

Providers will need to use Authorization Manager to submit initial authorization requests for services. Authorization Manager, available 24/7, is the quickest way to review authorization requirements, request authorizations, submit clinical documentation, check existing case status, and view/print the decision letter. For commercial members, the requests must meet medical policy guidelines.

To ensure the request is processed accurately and quickly:

- Enter the facility's NPI or provider ID for where services are being performed.
- Enter the appropriate surgeon's NPI or provider ID as the servicing provider, *not* the billing group.

Authorization Manager Resources

Refer to our Authorization Manager page for tips, guides, and video demonstrations.

Complete Prior Authorization Request Form for Cerebral Adrenoleukodystrophy Skysona® (Elivaldogene autotemcel) (242) using Authorization Manager.

For out of network providers: Requests should still be faxed to 888-973-0726.

Patient Information	
Patient Name:	Today's Date:
BCBSMA ID#:	Date of Treatment:
Date of Birth:	Place of Service: Outpatient ❒ Inpatient ❒ Distributor:

Physician Information	**Facility Information**
Name:	Name:
Address:	Address:
Phone #:	Phone #:
Fax#:	Fax#:
NPI#:	NPI#:

Please check off if the patient has the following diagnosis:	
Active cerebral X-linked adrenoleukodystrophy	❒

Please check off that the patient meets ALL the following criteria:	
Individual is 4 to 17 years of age at the time of infusion of elivaldogene autotemcel	❒
Documented diagnosis of active cerebral X-linked adrenoleukodystrophy as defined by: a. Confirmed mutation in the *ABCD1* gene; **AND** b. Elevated very-long-chain fatty acids (VLCFAs); **AND** c. Presence of active central nervous system (CNS) disease documented by: i. Loes score between 0.5 and 9 (inclusive) on the 34-point scale,]; **AND** ii. Gadolinium enhancement on MRI of demyelinating lesions.	❒
Documented neurologic function score (NFS) score ≤1.	❒

CONTRAINDICATIONS

Please check off that the patient DOES NOT HAVE ANY of the following contraindications:	
a. History of receiving prior gene therapy or allogeneic hematopoietic stem cell transplant.	❒
b. Hematological compromise as evidenced by **ALL** the following: i. Peripheral blood absolute neutrophil count (ANC) count <1500 cells/mm^3; **AND** ii. Platelet count <100,000 cells/mm^3 OR hemoglobin <10 g/Dl; **AND** iii. Uncorrected bleeding disorder.	❒
c. Hepatic compromise as evidenced by: i. Aspartate transaminase (AST) >2.5 × upper limit of normal (ULN); **AND** ii. Alanine transaminase (ALT) >2.5 × ULN; **AND** iii. Total bilirubin value >3.0 mg/dL, except if there is a diagnosis of Gilbert's Syndrome and the participant is otherwise stable.	❒
d. Cardiac compromise as evidenced by left ventricular ejection fraction <40%.	❒
e. Baseline estimated glomerular filtration rate <70 mL/min/1.73 m^2 or actual or calculated creatinine clearance <50 mL/min.	❒
f. Any immediate family member (i.e., parent or siblings) with a known Familial Cancer Syndrome (Including but not limited to hereditary breast and ovarian cancer syndrome, hereditary nonpolyposis colorectal cancer syndrome and family adenomatous polyposis).	❒
g. Any clinically significant uncontrolled, active bacterial, viral, fungal, parasitic, or prion associated infection, including but not limited to positive human immunodeficiency virus (HIV-1 or HIV-2), human T lymphotropic virus 1 (HTLV-1), active hepatitis B virus, and hepatitis C virus.	❒
h. Any condition(s) that are contraindicated for continued MRI studies.	❒
i. Absence of adequate contraception for fertile patients.	❒
j. Any contraindications to the use of granulocyte colony-stimulating factor (G-CSF) or plerixafor during the mobilization of hematopoietic stem cells, and any contraindications to use the use of busulfan or fludarabine, including known hypersensitivity to the active substances or to any of the excipients in their formulations.	❒

HCPCS Codes	Code Description
C9399	Unclassified drugs or biologicals

J3490	Unclassified drugs
J3590	Unclassified biologics

Providers should enter the relevant diagnosis code(s) below:

Code	Description	
		❒
		❒

Providers should enter other relevant code(s) below:

Code	Description	
		❒
		❒