



Lenmeldy
Lenmeldy (Atidarsagene Autotemcel) J3391
Prior Authorization Request
Medicare Part B Form

Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.

<input type="checkbox"/>	Standard Request– (72 Hours)	<input type="checkbox"/>	Urgent Request (standard time frame could place the member's life, health or ability in serious jeopardy)
Date Requested _____			
Requestor _____ Clinic name: _____ Phone _____ / Fax _____			

MEMBER INFORMATION

*Name: _____ *ID#: _____ *DOB: _____

PRESCRIBER INFORMATION

*Name: _____ MD FNP DO NP PA *Phone: _____

*Address: _____ *Fax: _____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name: _____ Phone: _____

*Address: _____ Fax: _____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht: _____)	Frequency	End Date if known

Self-administered Provider-administered Home Infusion

Chart notes attached. **Other important information:** _____

Diagnosis: ICD10: _____ **Description:** _____

Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

New Start or Initial Request: (Clinical documentation required for all requests)

Metachromatic Leukodystrophy (MLD)

- Patient is pediatric (typically <3 years of age for late-infantile form; <7 years for early-juvenile form) AND
- Confirmed diagnosis of MLD via:
 - Documented biallelic mutations in ARSA gene AND
 - Documented deficient arylsulfatase A enzyme activity AND
 - Characteristic clinical findings AND
- Patient is presymptomatic or early-symptomatic with:
 - No evidence of cognitive decline OR
 - Minimal motor involvement but able to walk independently AND
 - IQ ≥85 (age-appropriate) AND
- No evidence of rapid disease progression AND
- Prescribed by or in consultation with metabolic disease specialist or neurologist at qualified treatment center

If not, please provide **clinical rationale** for formulary exception: _____

Continuation Requests: (Clinical documentation required for all requests)

Patient had an **adequate response** or **significant improvement** while on this medication.

Medical record documentation of positive response is included

If not, please provide clinical rationale for continuing this medication: _____

ACKNOWLEDGEMENT

Request By (Signature Required): _____ **Date:** ____ / ____ / ____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT. PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.**

Prior Authorization Group – Lenmeldy Prior Authorization

Drug Name(s):

LENMELDY

ATIDARSAGENE AUTOTEMCEL

Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.
 - If the member meets all these criteria, they may be approved by the Plan for the requested drug.
 - Quantity limits and Tiering will be determined by the Plan, in accordance with the Label.
 - Continuation Requests: Provider must verify continued clinical benefit in confirmatory trial(s).

Exclusion Criteria:

N/A

Prescriber Restrictions:

Neurologist, Metabolic Disease specialist or other related specialist

Coverage Duration:

Approval will be for 6 months

FDA Indications:

Lenmeldy

- Metachromatic leukodystrophy, early juvenile type, Pre-symptomatic or early symptomatic
- Metachromatic leukodystrophy, late infantile type, Pre-symptomatic

Off-Label Uses:

N/A

Age Restrictions:

N/A

Other Clinical Consideration:

N/A

Resources:

<https://www.micromedexsolutions.com/micromedex2/librarian/PFDefaultActionId/evidencexpert.DoIntegratedSearch?SearchTerm=lenmeldy&SearchFilter=filterNone#>