

Field Name	Field Description
Prior Authorization Group Description	Lenmeldy
Drugs	Lenmeldy (atidarsagene autotemcel)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by a neurologist or geneticist
Coverage Duration	If all the criteria are met, the initial request will be approved for a one-time treatment.
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> Member has diagnosis of one of the following metachromatic leukodystrophies (MLD): <ul style="list-style-type: none"> Pre-symptomatic late infantile (PSLI) MLD Pre-symptomatic early juvenile (PSEJ) MLD Early symptomatic early juvenile (ESEJ) MLD Documentation patient has both of the following: <ul style="list-style-type: none"> Arylsulfatase A (ARSA) activity below the normal range (normal range 31-198 nmol/mg/h) Identification of two disease-causing ARSA alleles Medication is prescribed at an FDA approved dose <p>The safety and effectiveness of repeat administration of Lenmeldy has not been evaluated and will not be approved.</p>
Revision/Review Date: 7/2024	<p>If all the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</p>