HIGHMARK HEALTH OPTIONS

Updated: 07/2023
DMMA Approved: 08/2023

Request for Prior Authorization for Amyotrophic lateral sclerosis (ALS) Medications
Website Form – www.highmarkhealthoptions.com
Submit request via: Fax - 1-855-476-4158

All requests for ALS Medications require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

ALS Medications include Radicava (edaravone), Relyvrio (sodium phenylbutyrate/taurursodiol), and Qalsody (tofersen). New products with this classification will require the same documentation.

Coverage may be provided with a diagnosis of **amyotropic lateral sclerosis (ALS)** and the following criteria is met:

- Must be prescribed by or in consultation with a neurologist
- Must be able to perform activities of daily living (ADLs) such as eating and moving around independently
- Provide an ALSFRS-R (Revised ALS functional rating scale) score within the past 6 months
- Must be age-appropriate according to FDA-approved labeling, nationally recognized compendia, or evidence-based practice guidelines
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- For Radicava (edaravone), must have a forced vital capacity (FVC) ≥ 80% AND must be used in combination with riluzole unless there is documentation of intolerance or contraindication to riluzole
- For Relyvrio (sodium phenylbutyrate/taurursodiol), must have a slow vital capacity (SVC) > 60% of predicted
- For Qalsody (tofersen), must have a mutation in the superoxide dismutase 1 (*SOD1*) gene.
- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria:**
    - Continues to experience clinical benefit based on the prescriber's assessment
    - Provide an ALSFRS-R score within the past 12 months
- **Reauthorization Duration of Approval:** 12 months

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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ALS MEDICATIONS
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:

ALSFRS-R Score: _____
Is the member able to perform activities of daily living such as eating and moving around independently? ☐ Yes ☐ No

For Radicava (edaravone):
Provide forced vital capacity (FVC): _____ %
Will this be used in combination with riluzole? ☐ Yes ☐ No

For Relyvrio (sodium phenylbutyrate/taurursodiol): provide slow vital capacity (SVC): %

For Qalsody (tofersen): is there a mutation in the *SOD1* gene? ☐ Yes ☐ No

CURRENT or PREVIOUS THERAPY

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

REAUTHORIZATION

Has the member experienced clinical benefit with treatment? ☐ Yes ☐ No

ALSFRS-R Score:

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date