HIGHMARK WHOLECARE

Updated: 6/2024
PARP Approved: 8/2024

Prior Authorization Criteria

Amyotrophic lateral sclerosis (ALS) Medications

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
- 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.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication 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 Wholecare Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (800) 392-1147 Mon – Fri 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
State License #:	Office NPI:
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:	

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: ☐ Amyotrophic Lateral Sclerosis (ALS) ☐ Other: _____ ICD-10 Code: _____

ALSFRS-R Score:

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