

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 **amyotrophic 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) $\geq 80\%$ 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.

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? <input type="checkbox"/> Yes <input type="checkbox"/> No Date Medication Initiated:	

Billing Information

This medication will be billed: <input type="checkbox"/> at a pharmacy OR <input type="checkbox"/> medically, JCODE:
Place of Service: <input type="checkbox"/> Hospital <input type="checkbox"/> Provider's office <input type="checkbox"/> Member's home <input type="checkbox"/> Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis: <input type="checkbox"/> Amyotrophic Lateral Sclerosis (ALS) <input type="checkbox"/> 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

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