PriorityHealth

Medical prior authorization form

Fax completed form to: 877.974.4411 toll free, or 616.942.8206

This form applies to: ☒ **Commercial (Traditional)** ☒ **Commercial (Individual/Optimized)**
☐ **Medicaid**

This request is: ☐ **Urgent** (life threatening) ☐ **Non-Urgent** (standard review)

Urgent means the standard review time may seriously jeopardize the life or health of the patient or the patient's ability to regain maximum function.

Radicava® (endaravone)

Member

Last Name: ______________________ First Name: ______________________

ID #: ______________________ DOB: ______________ Gender: ______________

Primary Care Physician: ______________________

Requesting Physician: ______________________ Phys. Phone: ______________ Phys. Fax: ______________

Physician Address: ______________________

Physician NPI: ______________________ Contact Name: ______________________

Provider Signature: ______________________ Date: ______________

Product and Billing Information

☐ New Request ☐ Continuation Request

Drug product: ☐ Radicava 30mg/100mL solution

Dose:__________ **Dose Frequency**:______________________

Start date (or date of next dose): ______________________

Date of last dose (if applicable): ______________________

Date of next dose: ______________________

Place of administration:

☐ Physician's office

☐ Outpatient infusion

Facility: ______________ NPI:______________ Fax:______________

☐ Home infusion

Facility: ______________ NPI:______________ Fax:______________

Billing:

☐ Physician to buy and bill

☐ Facility to buy and bill

☐ Specialty Pharmacy

Pharmacy:______________ NPI:______________ Fax:______________

ICD-10 Diagnosis code(s): ______________________

Precertification Requirements

Before this drug is covered, the patient must meet all of the following requirements:

1. Diagnosis of "definite" or "probable" amyotrophic lateral sclerosis (ALS) as defined by the revised El Escorial World Federation of Neurology /Arlie House criteria[1]
   - Please provide clinical documentation to support
2. Disease duration of ≤ 2 years
   - Please provide date of diagnosis
3. Age 20 to 75 years
4. Living independently
5. Score of ≥ 2 on each individual item of the revised ALS functional rating scale (ALSFRS-R)[2]

All fields must be complete and legible for review. Your office will receive a response via fax.

New 09/2018
Last reviewed 09/2018

PriorityHealth

- Please provide a completed copy of ALSFRS-R

6. Forced vital capacity (FVC) ≥ 80%

If the above criteria are met, initial approval will be for a total of 6 treatment cycles for 6 months. For continuation (one additional 6-month approval), patient must have met the following requirements:

1. FCV of greater than or equal to 30%, does not require tracheostomy/artificial ventilation, and is not on continuous Bilevel Positive Airway Pressure (BiPAP)
2. Ambulatory (able to walk with or without assistance)
3. Able to self-feed

Note: Authorization for indications, dosing, or a route of administration not approved by the Food and Drug Administration (FDA) or recognized in CMS-accepted compendia (e.g. DrugDex, AHFS, U.S. Pharmacopeia, and also Clinical Pharmacology for oncology indications only) require supporting evidence for coverage. Please provide two published peer-reviewed literature articles supporting the appropriateness of the drug, the dosing of the drug, or the route of administration to be used for the identified indication.

Priority Health Precertification Documentation

A. What condition is this drug being requested for?

☐ "Definite" or "Probable" ALS
☐ Other – rationale for use: ______________________________

B. Has clinical documentation been provided to support diagnosis of "definite" or "probable" ALS?

☐ Yes ☐ No

C. Disease duration

☐ Less than or equal to 2 years Date of diagnosis _______________

☐ Greater than 2 years Date of diagnosis _______________

D. Is the patient currently living independently?

☐ Yes ☐ No

E. Has a completed copy of the patient's ALSFRS-R been provided?

☐ Yes ☐ No

F. Does the patient have a score of ≥ 2 on each individual ALSFRS-R item?

☐ Yes ☐ No

G. What is the patient's FVC?

☐ FVC _______________ Date ________________

For continuation of previously authorized requests:

H. Does the patient have FCV of greater than or equal to 30%, does not require tracheostomy/artificial ventilation, and is not on continuous Bilevel Positive Airway Pressure (BiPAP)?

☐ Yes ☐ No

I. Is the patient ambulatory (able to walk with or without assistance)?

☐ Yes ☐ No

J. Is the patient able to self-feed?

☐ Yes ☐ No

[1]Revised El Escorial (Arlie House) criteria

B. R. Brooks, R. G. Miller, M. Swash, T. L. El Escorial revisited: revised criteria for the diagnosis of amyotrophic lateral sclerosis. Munsat, World Federation of Neurology Research Group on Motor Neuron Diseases. Amyotroph Lateral Scler Other Motor Neuron Disord. 2000 Dec; 1(5): 293–299.

- **Clinically Definite ALS**
  Defined on clinical evidence alone by the presence of upper motor neuron (UMN), as well as lower motor neuron (LMN) signs, in three regions: either (1) one in bulbar regions and at two in spinal regions or (2) three in the spinal regions.

- **Clinically Probable ALS**
  Defined on clinical evidence alone by UMN and LMN signs in at least two regions with some UMN signs necessarily rostral to (above) the LMN signs.

[2]ALS functional rating scale (revised) (ALSFRS-R)

Cedarbaum JM, Stambler N, Malta E, et al. The ALSFRS-R: a revised ALS functional rating scale that incorporates assessments of respiratory function. J Neurol Sci. 1999;169:13–21. doi: 10.1016/S0022-510X(99)00210-5.

Speech • 4 Normal speech processes • 3 Detectable speech disturbance • 2 Intelligible with repeating • 1 Speech combined with nonvocal communication • 0 Loss of useful speech	Turning in bed and adjusting bed clothes • 4 Normal • 3 Somewhat slow and clumsy, but no help needed • 2 Can turn alone or adjust sheets, but with great difficulty • 1 Can initiate, but not turn or adjust sheets alone • 0 Helpless
Salivation • 4 Normal • 3 Slight but definite excess of saliva in mouth; may have nighttime drooling • 2 Moderately excessive saliva; may have minimal drooling • 1 Marked excess of saliva with some drooling • 0 Marked drooling; requires constant tissue or handkerchief	Walking • 4 Normal • 3 Early ambulation difficulties • 2 Walks with assistance • 1 Nonambulatory functional movement • 0 No purposeful leg movement
Swallowing • 4 Normal eating habits • 3 Early eating problems — occasional choking • 2 Dietary consistency changes • 1 Needs supplemental tube feeding • 0 NPO (exclusively parenteral or enteral feeding)	Climbing stairs • 4 Normal • 3 Slow • 2 Mild unsteadiness or fatigue • 1 Needs assistance • 0 Cannot do
Handwriting • 4 Normal • 3 Slow or sloppy: all words are legible • 2 Not all words are legible • 1 Able to grip pen but unable to write • 0 Unable to grip pen	Dyspnea (new) • 4 None • 3 Occurs when walking • 2 Occurs with one or more of the following: eating, bathing, dressing (ADL) • 1 Occurs at rest, difficulty breathing when either sitting or lying • 0 Significant difficulty, considering using mechanical respiratory support
Cutting food and handling utensils (patients without gastrostomy) • 4 Normal • 3 Somewhat slow and clumsy, but no help needed • 2 Can cut most foods, although clumsy and slow; some help needed • 1 Food must be cut by someone, but can still feed slowly • 0 Needs to be fed	Orthopnea (new) • 4 None • 3 Some difficulty sleeping at night due to shortness of breath, does not routinely use more than two pillows • 2 Needs extra pillows in order to sleep (more than two) • 1 Can only sleep sitting up • 0 Unable to sleep
Cutting food and handling utensils (alternate scale for patients with gastrostomy) • 4 Normal • 3 Clumsy but able to perform all manipulations independently • 2 Some help needed with closures and fasteners • 1 Provides minimal assistance to caregiver • 0 Unable to perform any aspect of task	Respiratory insufficiency (new) • 4 None • 3 Intermittent use of BiPAP • 2 Continuous use of BiPAP during the night • 1 Continuous use of BiPAP during the night and day • 0 Invasive mechanical ventilation by intubation or tracheostomy
Dressing and hygiene • 4 Normal function • 3 Independent and complete self-care with effort or decreased efficiency • 2 Intermittent assistance or substitute methods • 1 Needs attendant for self-care • 0 Total dependence	*Interpretation* minimum score: 0 maximum score: 48 (The higher the score the more function is retained)

Authorized dosing:

Initial cycle: 60mg IV infusion daily for 14 days, followed by a 14-day drug-free period.

Subsequent cycles: 60mg IV infusion daily 10 days out of 14-day periods, followed by 14-day drug-free periods.