Priority Health Medicare prior authorization form

Fax completed form to: 877.974.4411 toll free, or 616.942.8206

This form applies to: ☐ **Medicare Part B** ☐ **Medicare Part D**

This request is: ☐ **Expedited request** ☐ **Standard request**

Your request will be expedited if you haven't gotten the prescription and Priority Health Medicare determines, or your prescriber tells us, that your life or health may be at risk by waiting.

Radicava™ (edaravone)

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: _____

Drug information

☐ New request ☐ Continuation request

Drug product: ☒ Radicava 30mg/100mL solution

Dose:_____ **Dose Frequency**:_____

Start date: _____

Date of last dose: _____

Date of next dose: _____

ICD-10 Diagnosis code(s):_____

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:_____

☐ Patient to obtain from pharmacy **(office is requesting this to be billed under Part D benefit)**

Prior authorization criteria

The following requirements need to be met before this drug is covered by Priority Health Medicare. These requirements have been approved by the Centers for Medicare and Medicaid Services (CMS), but you may ask us for an exception if you believe one or more of these requirements should be waived.

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

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Last reviewed 09/2017

For this drug to be covered, the patient must meet the following criteria:

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
   a. 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]
   a. 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

Medically accepted indication

This drug is only covered under Medicare Part D when it is used for a medically accepted indication. A medically accepted indication is a use of the drug that is *either*:

- approved by the Food and Drug Administration. (That is, the Food and Drug Administration has approved the drug for the diagnosis or condition for which it is being prescribed.)
- — *or* — supported by certain reference books. (These reference books are the American Hospital Formulary Service Drug Information and the DRUGDEX Information System)

New request
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

☐ ≤ 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)?

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☐ 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.

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Priority Health Medicare plans

Note: Priority Health Medicare applies CMS national and local coverage determination criteria when available for Part B drugs. If no national determination criteria or local coverage determination criteria is available for the state in which the member is receiving the services, the above prior authorization criteria must be met.

WPS-Medicare LCD G12.21

Priority Health Medicare exception request

Do you believe one or more of the prior authorization requirements should be waived? ☐ Yes ☐ No
If yes, you must provide a statement explaining the medical reason why the exception should be approved.

Would Radicava likely be the most effective option for this patient?
☐ No
☐ Yes, because:_____

_____

_____

If the patient is currently using Radicava, would changing the patient's current regimen likely result in adverse effects for the patient?
☐ No
☐ Yes, because:_____

_____

_____

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