# Radicava (edaravone)

## NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

## BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

## DESCRIPTION

The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Radicava is indicated for the treatment of amyotrophic lateral sclerosis (ALS).

## POLICY

Prescriber Specialties
This medication must be prescribed by or in consultation with a neuromuscular specialist.

Required Documentation
The following information is necessary to initiate the prior authorization review:

1. Documentation supporting ALSFRS-R score
2. Documentation of respiratory function
3. Documentation supporting patient’s ventilator or tracheostomy status

Criteria for Initial Approval
Authorization of 6 months may be granted for treatment of ALS when all of the following criteria are met:

1. Diagnosis of definite or probable ALS
2. Duration of ALS is 2 years or less from symptom onset
3. Functional ability is retained for most activities of daily living defined as scores of 2 points or better on each individual item of the ALS Functional Rating Scale – Revised [ALSFRS-R] confirmed by medical records

4. Normal respiratory function retained (defined as percent predicted forced vital capacity (FVC) values of 80%) confirmed by medical records
5. Concomitant use of riluzole (at up to maximally indicated doses) unless contraindicated or clinically significant adverse effects are experienced

Continuation of Therapy

Authorization of 6 months may be granted for members continuing with Radicava therapy when the following criteria are met:

1. Diagnosis of definite or probable ALS
2. There is a clinical benefit from Radicava therapy such as stabilization of functional ability and maintenance of activities of daily living (defined as scores of 2 points or better on each individual item of the ALS Functional Rating Scale – Revised [ALSFRS-R]) confirmed by medical records
3. Not dependent on invasive ventilation or tracheostomy confirmed by medical records

Radicava is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

## APPENDIX

ALS functional rating scale (revised) (ALSFRS-R) is a commonly used functional rating system for persons with ALS. The ALSFRS-R scale consists of 12 questions that evaluate the fine motor, gross motor, bulbar, and respiratory function of patients with ALS (speech, salivation, swallowing, handwriting, cutting food, dressing/hygiene, turning in bed, walking, climbing stairs, dyspnea, orthopnea, and respiratory insufficiency). Each item is scored from 0 to 4, with higher scores representing greater functional ability.

- Item 1: Speech
  - 4 Normal speech processes
  - 3 Detectable speech disturbance
  - 2 Intelligible with repeating
  - 1 Speech combined with nonvocal communication
  - 0 Loss of useful speech
- Item 2: 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
- Item 3: 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)
- Item 4: 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
- Item 5a: Cutting food and handling utensils (patients without gastrostomy -> use item 5b if >50% is through g-tube)

    - 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
- Item 5b: 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
- Item 6: 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
- Item 7: 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
- Item 8: Walking
    - 4 Normal
    - 3 Early ambulation difficulties
    - 2 Walks with assistance
    - 1 Nonambulatory functional movement
    - 0 No purposeful leg movement
- Item 9: Climbing stairs
    - 4 Normal
    - 3 Slow
    - 2 Mild unsteadiness or fatigue
    - 1 Needs assistance
    - 0 Cannot do
- Item 10: Dyspnea
    - 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
- Item 11: Orthopnea
    - 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
- Item 12: Respiratory insufficiency
    - 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

## PROCEDURES AND BILLING CODES

**To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.**

- C9493 – injection, edaravone, 1mg (deleted 12-31-2018)
- J1301 – Radicava, Injection, edaravone, 1mg (effective 1-1-2019)

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## POLICY HISTORY

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