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| **Section:** | Prescription Drugs | **Effective Date:** | October 1, 2023 |
| **Subsection:** | Neuromuscular Agents | **Original Policy Date:** | May 26, 2017 |
| **Subject:** | Radicava | **Page:** | 1 of 4 |

***Last Review Date:*** September 8, 2023

# Radicava

## Description

### Radicava / Radicava ORS (edaravone)

**Background**
Radicava and Radicava ORS (edaravone) are indicated for the treatment of patients with amyotrophic lateral sclerosis (ALS). It is thought that Radicava and Radicava ORS are potent free radical scavengers and antioxidants that may provide neuroprotection against oxidative stress. In motor neurons, oxidative stress may contribute to neurodegeneration and the development of ALS (2). ALS is a progressive neurodegenerative disease that affects nerve cells in the brain and spinal cord. The progressive degeneration of the motor neurons in ALS eventually leads to their death. When the motor neurons die, the ability of the brain to initiate and control muscle movement is lost. With voluntary muscle action progressively affected, patients in the later stages of the disease may become totally paralyzed (3).

**Regulatory Status**
FDA-approved indication: Radicava and Radicava ORS are indicated for the treatment of patients with amyotrophic lateral sclerosis (ALS) (1).

Studies have shown that riluzole is safe and effective for slowing disease progression to a modest degree in ALS. Riluzole is considered first-line therapy along with nutritional supplements for patients with ALS (4).

The safety and effectiveness of Radicava and Radicava ORS in pediatric patients have not been established (1).

**Related policies**
Exservan, Qalsody, Relyvrio

## Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Radicava and Radicava ORS may be considered **medically necessary** if the conditions indicated below are met.

Radicava and Radicava ORS may be considered **investigational** for all other indications.

## Prior-Approval Requirements

**Age** 18 years of age and older

**Diagnosis**

Patient must have the following:

Amyotrophic lateral sclerosis (ALS)

**AND ALL** of the following:

1. Patient has had an inadequate response to riluzole or will continue to take riluzole
2. Baseline evaluation of the condition using **ONE** of the following scoring tools:
    a. ALS Functional Rating Scale-Revised (ALSFRS-R) with a score of 2 or greater on each individual item of the scale
    b. Japanese ALS Severity Scale with a grade of 1 or 2
3. Normal respiratory function %FVC ≥ 80%
4. Prescribed by or recommended by a neurologist

## Prior – Approval *Renewal* Requirements

**Age** 18 years of age and older

**Diagnosis**

Patient must have the following:

Amyotrophic lateral sclerosis (ALS)

**AND ALL** of the following:

1. Documented stabilization, slowing of disease progression, or improvement of the condition using **ONE** of the following scoring tools:
    a. ALSFRS-R score – stable or improvement in functional abilities
    b. Japanese ALS Severity Scale – stable or improvement in functional abilities

## Policy Guidelines

### Pre - PA Allowance

None

### Prior - Approval Limits

**Duration** 12 months

### Prior – Approval *Renewal* Limits

Same as above

## Rationale

**Summary**

Radicava and Radicava ORS are potent free radical scavengers and antioxidants used for patients with ALS. The safety and effectiveness of Radicava and Radicava ORS in pediatric patients have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Radicava and Radicava ORS while maintaining optimal therapeutic outcomes.

**References**

1. Radicava / Radicava ORS [package insert]. Jersey City, NJ: Mitsubishi Tanabe Pharma America, Inc.; May 2022.
2. Edaravone Mechanism of Action. *Clinical Pharmacology*. Accessed December 30, 2022.
3. Simon N, Turner M, et al. Quantifying Disease Progression in Amyotrophic Lateral Sclerosis. Annals of Neurology 2014;76:643–657.

4. Miller R, Jackson C, et al. Practice Parameter update: The care of the patient with amyotrophic lateral sclerosis: Drug, nutritional, and respiratory therapies (an evidence-based review): Report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology 2009; 73; 1218-1226.
5. Abe K, Itoyama Y, et al. Confirmatory double-blind, parallel-group, placebo-controlled study of efficacy and safety of edaravone (MCI-186) in amyotrophic lateral sclerosis patients. Amyotroph Lateral Scler Frontotemporal Degener. 2014 Dec; 15(7-8): 610–617.

## Policy History

| Date | Action |
|---|---|
| May 2017 | Addition to PA |
| September 2017 | Annual review<br>Addition of ALS Japanese Severity Scale to baseline and improvement questions and the inadequate and intolerance and contraindication to riluzole was reworded. Addition of prescriber agreeing to consult with a neurologist during therapy per SME |
| December 2017 | Annual review |
| August 2018 | Addition of requirements of stabilization or slowed progression for continuation, removal of requirements for no hepatic or renal impairment |
| September 2018 | Annual review |
| September 2019 | Annual review and reference update |
| September 2020 | Annual editorial review. Revised initiation wording to “prescribed by or recommended by a neurologist” |
| September 2021 | Annual review and reference update |
| June 2022 | Addition of Radicava ORS (oral suspension) |
| September 2022 | Annual review and reference update |
| March 2023 | Annual review and reference update |
| September 2023 | Annual review |

## Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 8, 2023 and is effective on October 1, 2023.**