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Section:	Prescription Drugs	**Effective Date:**	January 1, 2026
Subsection:	Neuromuscular Agents	**Original Policy Date:**	May 26, 2017
Subject:	Radicava	**Page:**	1 of 4

Last Review Date: December 12, 2025

Radicava

Description

Radicava ORS (edaravone)

Background
Radicava ORS (edaravone) are indicated for the treatment of patients with amyotrophic lateral sclerosis (ALS). It is thought that Radicava ORS is a potent free radical scavenger 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 ORS is 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 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 ORS may be considered **medically necessary** if the conditions indicated below are met.

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 ORS is a potent free radical scavenger 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 ORS [package insert]. Jersey City, NJ: Mitsubishi Tanabe Pharma America, Inc.; November 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 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
September 2024	Annual review and reference update
December 2024	Annual review
September 2025	Annual review
December 2025	Annual review and reference update. Removed Radicava injection per gap analysis

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 12, 2025 and is effective on January 1, 2026.