CVS/caremark™

POLICY Document for RADICAVA (edaravone)

The overall objective of this policy is to support the appropriate and cost-effective use of the medication, specific to use of preferred medication options, lower cost site of care and overall, clinically appropriate use. This document provides specific information to each of the three sections of the overall policy.

Section 1: Site of Care

- Policy information specific to site of care (outpatient, hospital outpatient, home infusion)

Section 2: Clinical Criteria

- Policy information specific to the clinical appropriateness for the medication

Section 1: Site of Care

Site of Care Criteria
Radicava

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Radicava	edaravone	intravenous

Criteria for Approval for Administration in Outpatient Hospital Setting

This policy provides coverage for administration of Radicava in an outpatient hospital setting for up to 45 days when a member is new to therapy or is reinitiating therapy after not being on therapy for at least 6 months.

This policy provides coverage for administration of Radicava in an outpatient hospital setting for a longer course of treatment when ANY of the following criteria are met:

- The member has experienced an adverse reaction to the drug or other sulfite containing product that did not respond to conventional interventions (e.g., acetaminophen, steroids,

diphenhydramine, fluids or other pre-medications) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after an infusion.
- The member is medically unstable (e.g., respiratory, cardiovascular, or renal conditions).
- The member has severe venous access issues that require the use of special interventions only available in the outpatient hospital setting.
- The member has significant behavioral issues and/or physical or cognitive impairment that would impact the safety of the infusion therapy AND the patient does not have access to a caregiver.
- Alternative infusion sites (pharmacy, physician office, ambulatory care, etc.) are greater than 30 miles from the member's home.
- The member is less than 14 years of age.

For situations where administration of Radicava does not meet the criteria for outpatient hospital infusion, coverage for Radicava is provided when administered in alternative sites such as physician office, home infusion or ambulatory care.

Required Documentation

The following information is necessary to initiate the site of care prior authorization review (where applicable):

- Medical records supporting the member has experienced an adverse reaction that did not respond to conventional interventions or a severe adverse event during or immediately after an infusion
- Medical records supporting the member is medically unstable
- Medical records supporting the member has severe venous access issues that requires specialized interventions only available in the outpatient hospital setting
- Medical records supporting the member has behavioral issues and/or physical or cognitive impairment and no access to a caregiver
- Records supporting alternative infusion sites are greater than 30 miles from the member's home
- Medical records supporting the member is new to therapy

Section 2: Clinical Criteria

Specialty Guideline Management
Radicava-Radicava ORS

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Radicava	edaravone
Radicava ORS	edaravone

Indications

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

FDA-Approved Indications

Radicava and Radicava ORS are indicated for the treatment of amyotrophic lateral sclerosis (ALS).

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Chart notes or medical record documentation supporting use as applicable in the coverage criteria and continuation of therapy sections.

- Initial Requests:
  - Diagnosis of definite or probable ALS.
  - ALS Functional Rating Scale (ALSFRS-R) results.
- Continuation Requests:
  - Documentation of clinical benefit from therapy with the requested medication.

Prescriber Specialties

This medication must be prescribed by or in consultation with a neurologist, neuromuscular specialist, or physician specializing in the treatment of amyotrophic lateral sclerosis (ALS).

Coverage Criteria

Amyotrophic Lateral Sclerosis (ALS)

Authorization of 12 months may be granted for treatment of ALS when all of the following criteria are met:

- Member has a diagnosis of definite or probable ALS (e.g., medical history and/or diagnostic testing including, nerve conduction studies, imaging, and laboratory values to support the diagnosis).
- Member has scores of at least 2 points on all 12 areas of the revised ALS Functional Rating Scale (ALSFRS-R).
- Continuous use of ventilatory support during the day and night is not required (noninvasive or invasive).

Continuation of Therapy

Authorization of 12 months may be granted for members requesting continuation of therapy when all of the following criteria are met:

- Member has a diagnosis of definite or probable ALS.
- Member has had a clinical benefit from therapy with the requested medication.
- Invasive ventilation is not required.

REFERENCES

SECTION 1

1. Radicava [package insert]. Jersey City, NJ: Mitsubishi Tanabe Pharma America, Inc, December 2024.

SECTION 2

2. Radicava [package insert]. Jersey City, NJ: MT Pharma America, Inc.; November 2022.
3. EFNS Task Force on Diagnosis and Management of Amyotrophic Lateral Sclerosis; Andersen PM, et al. EFNS guidelines on the Clinical Management of Amyotrophic Lateral Sclerosis (MALS) – revised report of an EFNS task force. Eur J Neurol. 2012;19(3):360-75.
4. Writing Group, Edaravone (MCI-186) ALS 19 Study Group. Safety and efficacy of edaravone in well defined patients with amyotrophic lateral sclerosis: a randomized, double-blind, placebo-controlled trial. Lancet Neurol. 2017; 16:505-512.
5. edaravone [package insert]. Big Flats, NY: XGen Pharmaceuticals DJB, Inc.; September 2024.