Reference number(s)
1961-A

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

1. Radicava [package insert]. Jersey City, NJ: MT Pharma America, Inc.; November 2022.

2. 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.
3. 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.
4. edaravone [package insert]. Big Flats, NY: XGen Pharmaceuticals DJB, Inc.; September 2024.