| 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[1,4]

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 amyotrophic lateral sclerosis (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)[1-4]

Authorization of 12 months may be granted for treatment of amyotrophic lateral sclerosis (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 amyotrophic lateral sclerosis (ALS).
- Member has had a clinical benefit from therapy with the requested medication.
- Invasive ventilation is not required.

# References

1. Radicava/Radicava ORS [package insert]. Jersey City, NJ: MT Pharma America, Inc.; December 2024.
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.