CVS Caremark®

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| 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.