Name:	Radicava ORS (oral suspension)	Page:	1 of 2
Effective Date:	3/7/2025	Last Review Date:	01/27/2025
Applies to:	☒Illinois ☒New Jersey ☒Maryland ☒Florida Kids ☒Pennsylvania Kids ☒Virginia		

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Radicava ORS (oral suspension) under the patient's prescription drug benefit.

Description:

FDA-Approved Indication

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

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

Applicable Drug List:

Radicava ORS (oral suspension)

Policy/Guideline:

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).

Initial 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.

Approval Duration and Quantity Restrictions:

Initial and Renewal Approval: 12 Months

Quantity Level Limit:

Medication	Quantity Limit
Radicava ORS Starter Kit 735mg/35mL (105mg/5mL dose)	Initial treatment cycle: 70mL (2 bottles) per 30 days
Radicava ORS Kit 1050mg/50mL (105mg/5mL dose)	50mL (1 bottle) per 30 days

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.