UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2282-3
Program	Prior Authorization/Medical Necessity
Medication	Radicava ORS® (edaravone)
P&T Approval Date	7/2022, 7/2023, 7/2024
Effective Date	10/1/2024

1. Background:

Radicava ORS® is indicated for the treatment of amyotrophic lateral sclerosis (ALS).[1]

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Radicava ORS** will be approved based on **one** of the following criteria:

   a. **Both** of the following criteria:

      (1) Patient has been established on therapy with **Radicava** for amyotrophic lateral sclerosis under an active UnitedHealthcare medical benefit prior authorization

      -AND-

      (2) **All** of the following:

         (a) Diagnosis of "definite" or "probable" ALS per the El Escorial/revised Airlie House diagnostic criteria
         (b) Prescribed by, or in consultation with, a neurologist with expertise in the diagnosis of ALS
         (c) Patient is currently receiving **Radicava** therapy
         (d) Patient is not dependent on invasive ventilation or tracheostomy

      -OR-

   b. **All** of the following criteria:

      (1) Submission of medical records (e.g., chart notes, previous medical history, diagnostic testing including: imaging, nerve conduction studies, laboratory values) to support the diagnosis of "definite" or "probable" ALS per the El Escorial/revised Airlie House diagnostic criteria[2]

      -AND-

      (2) Prescribed by, or in consultation with, a neurologist with expertise in the diagnosis of ALS

      -AND-

(3) Submission of the most recent ALS Functional Rating Scale-Revised (ALSFRS-R) score confirming that the patient has scores ≥ 2 in all items of the ALSFRS-R criteria at the start of treatment[3]

-AND-

(4) Submission of medical records (e.g., chart notes, laboratory values) confirming that the patient has a % forced vital capacity (%FVC) ≥ 80% at the start of treatment[3]

Authorization will be issued for 12 months.

B. Reauthorization

1. **Radicava ORS** will be approved based on **all** of the following criteria:

   a. Diagnosis of "definite" or "probable" ALS per the El Escorial/revised Airlie House diagnostic criteria

   -AND-

   b. Prescribed by, or in consultation with, a neurologist with expertise in the diagnosis of ALS

   -AND-

   c. Patient is currently receiving **Radicava ORS** therapy

   -AND-

   d. Patient is **not** dependent on invasive ventilation or tracheostomy

   Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Radicava ORS [package insert]. Jersey City, NJ: Mitsubishi Tanabe Pharma Corporation. May 2022.

2. Subcommittee on Motor Neuron Diseases of World Federation of Neurology Research Group on Neuromuscular Diseases, El Escorial "Clinical Limits of ALS" Workshop Contributors. El Escorial World Federation of Neurology criteria for the diagnosis of amyotrophic lateral sclerosis. J Neurol Sci 1994; 124: 96–107.
3. Takahashi F, Takei K, Tsuda K, Palumbo J. Post-hoc analysis of MCI186-17, the extension study to MCI186-16, the confirmatory double-blind, parallel-group, placebo-control006Ced study of edaravone in amyotrophic lateral sclerosis. Amyotrophic Lateral Sclerosis and Frontotemporal Degeneration. 2017;18(sup1):32-39.

Program	Prior Authorization/Medical Necessity – Radicava ORS® (edaravone)
Change Control	
7/2022	New program.
7/2023	Annual review with no changes to the coverage criteria.
7/2024	Annual review. Clarified criteria for existing prior authorization for under the medical benefit. Updated initial authorization and reauthorization to 12 months.