Pharmacy Policy Bulletin: J-1230 Radicava ORS (edaravone) – Commercial and Healthcare Reform	
Number: J-1230	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** 1. Miscellaneous Specialty Drugs Oral = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-1230-003	**Original Date:** 08/03/2022
Effective Date: 08/23/2024	**Review Date:** 08/07/2024

Drugs Product(s):	• Radicava ORS (edaravone)
FDA-Approved Indication(s):	• Treatment of amyotrophic lateral sclerosis (ALS)

Background:	• The mechanism by which Radicava ORS exerts its therapeutic effect in patients with ALS is unknown. It is thought to be a free radical scavenger and antioxidant that provides neuroprotection against oxidative stress. • ALS, often called Lou Gehrig's disease, is a rare neurological disease that primarily affects the nerve cells responsible for controlling voluntary muscle movement. The incidence of ALS is 2 new cases per 100,000 people each year. The prevalence of ALS is approximately 15,000 to 21,000 patients in the US. The average age of diagnosis is between 55 and 65. Early symptoms include muscle twitches, cramps, spasms, weakness, slurred speech, and difficulty chewing or swallowing. As the disease progresses, symptoms include dysphagia and inability to stand, walk, or breathe independently. Most people with ALS die from respiratory failure within 3 to 5 years of symptom onset, but about 10% of ALS patients survive for 10 or more years. • The El Escorial criteria, also known as Airlie House criteria, requires the following for diagnosis of ALS: o Signs of degeneration of lower motor neurons by clinical examination or specialized testing o Signs of degeneration of upper motor neurons by clinical examination o Progressive spread of signs within a region to other regions o Absences of electrophysiological, pathological, or neuroimaging evidence of other disease processes that might explain the observed clinical signs • The ALS Functional Rating Scale-Revised (ALSFRS-R) scale is the most widely used test in clinical trials to track changes in a person's physical function over time. It measures 12 aspects of physical function, ranging from one's ability to

	swallow and use utensils to climbing stairs and breathing. Patients with higher scores have more physical function. • Prescribing Considerations: o Radicava ORS contains sodium bisulfite which may cause allergic type reactions, including anaphylactic symptoms and asthmatic episodes in susceptible people. o Patients should discard Radicava ORS 15 days after opening the bottle or if unopened 30 days from the shipment date indicated on the carton pharmacy label. o Patients treated with Radicava IV infusion 60 mg maybe switched to Radicava ORS 105 mg using the same dosing frequency.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Radicava ORS may be approved when all of the following criteria are met **(A. through G.)**:

A. The member is 18 years of age or older.
B. The member has a diagnosis of ALS (ICD-10: G12.21).
C. The member has "Definite" or "Probable" ALS based on the El Escorial revised criteria.
D. The member has an ALS Functional Rating Scale-Revised (ALSFRS-R) score ≥ 2 in all items of the ALSFRS-R criteria at the initiation of treatment with Radicava or Radicava ORS.
E. The member has a baseline forced vital capacity (FVC) of at least 80%.
F. The member is not dependent on invasive ventilation or tracheostomy.
G. When the member first initiated therapy with Radicava or Radicava ORS, disease duration was less than 2 years.

II. Reauthorization

When a benefit, reauthorization of Radicava ORS may be approved when all of the following criteria are met **(A. and B.)**:

A. The prescriber attests that the member has experienced stability or improvement in symptoms of ALS.
B. The member is not dependent on invasive ventilation or tracheostomy.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.
II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Radicava ORS [package insert]. Jersey City, NJ: Mitsubishi Tanabe Pharma America, Inc.; November 2022.
2. The Writing Group on behalf of the Edaravone (MCI-186) ALS 19 Study Group. Safety and efficacy of edaravone in well defined patients with amyotrophic lateral sclerosis: a randomised, double-blind, placebo-controlled trial. *Lancet Neurol* 2017; 16: 505–12.
3. National Institute of Neurological Disorders and Stroke. Amyotrophic Lateral Sclerosis (ALS) Fact Sheet. Available at: https://www.ninds.nih.gov/health-information/patient-caregiver-education/fact-sheets/amyotrophic-lateral-sclerosis-als-fact-sheet. Accessed Jun 21, 2024.
4. Centers for Disease Control and Prevention. Prevalence of Amyotrophic Lateral Sclerosis — United States, 2014. Available at: https://www.cdc.gov/mmwr/volumes/67/wr/mm6707a3.htm. Accessed June 21, 2024.
5. ALS Association. FYI: Epidemiology of ALS and Suspected Clusters. Available at: https://www.als.org/navigating-als/resources/fyi-epidemiology-als-and-suspected-clusters. Accessed June 21, 2024.
6. Miller RG, Jackson CE, Kasarskis EJ, et al. Practice Parameter update: The care of the patient with amyotrophic lateral sclerosis: Drug, nutritional, and respiratory therapies (an evidence-based review). Neurology Oct 2009, 73 (15) 1218-1226.
7. Muscular Dystrophy Association. Amyotrophic Lateral Sclerosis. Available at: https://www.mda.org/disease/amyotrophic-lateral-sclerosis/diagnosis. Accessed June 21, 2024.
8. ALS Pathways. Monitoring ALS Function With the ALSFRS-R. Available at: https://www.alspathways.com/assessing-function/. Accessed June 21, 2024.