

Pharmacy Policy Bulletin

Title: Edaravone (Radicava ORS)

Policy #: Rx.01.268

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria for **Edaravone (Radicava ORS®)** as provided under the member's prescription drug benefit.

Description:

Amyotrophic lateral sclerosis (ALS) is a progressive neurodegenerative disorder that causes muscle weakness, disability, and eventually death, with a median survival of three to five years. The hallmark of ALS is the combination of upper motor neuron (UMN) and lower motor neuron (LMN) involvement. The LMN findings of weakness, atrophy, and fasciculations are a direct consequence of muscle denervation. The UMN findings of hyperreflexia and spasticity result from degeneration of the lateral corticospinal tracts in the spinal cord.

Edaravone is an oral suspension indicated for the treatment of amyotrophic lateral sclerosis (ALS).

Edaravone is neuroprotective agent working in the central nervous system. Edaravone is a free radical and peroxynitrite scavenger that prevents oxidative damage to the cell membranes and may contribute to inhibiting the progression of ALD. However, the mechanism of edaravone slowing the decline of physical function in patients with ALS is unknown.

Policy:

INITIAL CRITERIA: Edaravone (Radicava ORS®) is approved when ALL of the following are met:

1. Diagnosis of "definite" or "probable" amyotrophic lateral sclerosis (ALS) per the revised EL Escorial and Airlie House diagnostic criteria; and
2. Prescribed by or in consultation with a neurologist with expertise in the diagnosis of ALS; and
3. Member has scores greater than or equal to 2 in all items of the ALS Functional Rating Scale-Revised (ALSFRS-R) criteria at the start of treatment; and
4. Member has a percent (%) forced vital capacity (%FVC) greater than or equal to 80% at the start of treatment

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA: Edaravone (Radicava ORS®) is re-approved when BOTH of the following are met:

1. Documentation of positive clinical response to therapy (e.g., slowing in the decline of functional abilities); and
2. Member is not dependent on invasive ventilation of tracheostomy

Reauthorization duration: 12 months

Black Box Warning as shown in the drug Prescribing Information:

N/A

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

Radicava ORS® (Edaravone) [package insert]. Jersey City, NJ: Mitsubishi Tanabe Pharma America, Inc. May 2022. Available from: <https://www.radicava.com/pdfs/radicava-prescribing-information.pdf>. Accessed April 19, 2023.

Goyal NA. Disease-modifying treatment of amyotrophic lateral sclerosis. UpToDate website. Last updated January 2023. Available at: www.uptodate.com. Accessed April 19, 2023.

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

| Brand Name | Generic Name |
|---------------|--------------|
| Radicava ORS® | Edaravone |

Cross References:

Rx.01.33 Off Label Use

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|-----------------------------------|----------------|
| Policy Version Number: | 2.00 |
| P&T Approval Date: | March 16, 2023 |
| Policy Effective Date: | July 01, 2023 |
| Next Required Review Date: | March 16, 2024 |

The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.

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