Pharmacy Medical Necessity Guidelines:
Radicava ORS® (edaravone)

Effective: July 1, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Radicava ORS (edaravone) is indicated for the treatment of amyotrophic lateral sclerosis.

COVERAGE GUIDELINES

The plan may authorize coverage of Radicava ORS (edaravone) for Members, when the following criteria are met:

1. Documented diagnosis of amyotrophic lateral sclerosis based on **one (1)** of the following:
    a. EI Escorial revised criteria
    b. Gold Coast criteria

AND

2. Prescribed by or in consultation with a neurologist

AND

3. Documentation of one of the following:
    a. Patient is stable on riluzole
    b. Clinical inappropriateness of riluzole

AND

4. Documentation of a score of at least 2 points on each individual item of the ALS Functional Rating Scale – Revised (ALSFRS-R)

LIMITATIONS

- None

CODES

None

REFERENCES

1. Abe K, Aoki M, Tsuji S, et al. Safety and efficacy of edaravone in well defined patients with amyotrophic lateral sclerosis: a randomised, double-blind, placebo-controlled trial. *Lancet Neurol.* 2017; 16:505-512.
2. Abe K, itoyama Y, Sobue G, et al. Confirmatory double-blind, parallel-group, placebo-controlled study of efficacy and safety of edaravone (MCI-186) in amyotrophic lateral sclerosis patients. *Amyotroph Lateral Scler Frontotemporal Degener*. 2014; 15:610-7.
3. Brooks BR, Miller RG, Swash M, et al. EI Escorial revisited: revised criteria for the diagnosis of amyotrophic lateral sclerosis. Amyotroph Lateral Scler Other Motor Neuron Disord. 2000;1(5):293-99.
4. Cedarbaum JM, Stambler N, Malta E, et al. The ALSFRS-R: a revised ALS functional rating scale that incorporates assessments of respiratory function. BDNF ALS Study Group (Phase III). J Neurol Sci. 1999;169(1-2):13-21.
5. Douglass CP, Kandler RH, Shaw PJ, et al. An evaluation of neurophysiological criteria used in the diagnosis of motor neuron disease. J Neurol Neurosurg Psychiatry. 2010;81(6):646-9.
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*. 2009a; 73:1218-1226.
7. Miller RG, Jackson CE, Kasarskis EJ, et al. Practice parameter update: the care of the patient with amyotrophic lateral sclerosis: multidisciplinary care, symptom management, and cognitive/behavioral impairment (an evidence-based review). *Neurology*. 2009b; 73:1227-1233
8. Radicava (edaravone) [package insert]. Jersey City, NJ: MT Pharma Amercia, Inc.; May 2022.

APPROVAL HISTORY

September 13, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- July 11, 2023: Expanded provider specialty requirements to be prescribed by or in consultation with neurologist. Expanded diagnosis requirements by including Gold Coast Criteria as an option. Administrative update to remove the following Limitation "Radicava ORS (edaravone) is not covered for Tufts Health Together. Refer to Non-Covered Pharmacy Products Medical Necessity Guideline." (effective August 1, 2023).
- June 11, 2024: No changes (eff 6/11/24)
- June 10, 2025: No changes (eff 6/10/25)
- June 9, 2026: Updated criteria to remove Rilutek and to refer riluzole by generic ingredient name (eff 7/1/26).

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services