

Pharmacy Medical Necessity Guidelines: Radicava® (edaravone)

Effective: April 20, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	MED	Department to Review	PRECERT /MM
<p>These pharmacy medical necessity guidelines apply to the following:</p> <p>Commercial Products</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Tufts Health Plan Commercial products – large group plans <input checked="" type="checkbox"/> Tufts Health Plan Commercial products – small group and individual plans <input checked="" type="checkbox"/> Tufts Health Freedom Plan products – large group plans <input checked="" type="checkbox"/> Tufts Health Freedom Plan products – small group plans • CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization <p>Tufts Health Public Plans Products</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product) <input checked="" type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans <input checked="" type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan 		<p>Fax Numbers:</p> <p>All plans except Tufts Health Public Plans PRECERT: 617.972.9409</p> <p>Tufts Health Public Plans MM: 888.415.9055</p>	

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

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

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

COVERAGE GUIDELINES

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

1. Documented diagnosis of amyotrophic lateral sclerosis based on EI Escorial revised criteria
- AND**
2. The prescribing physician is a neurologist
- AND**
3. Documentation of one of the following:
 - a. Member is stable on Rilutek (riluzole)
 - b. Prescriber has indicated clinical inappropriateness of Rilutek (riluzole)
- AND**
4. Documentation of a score of at least 2 points on each individual item of the ALS Functional Rating Scale – Revised (ALSF_{RS}-R)

LIMITATIONS

- None

CODES

The following HCPCS/CPT code(s) are:

Code	Description
J1301	Injection, edaravone, 1 mg

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.; August 2017.

APPROVAL HISTORY

January 9, 2018: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. January 1, 2019: Administrative update: added new J code (J1301) to Medical Necessity Guideline and removed expired C code C9493 from the Medical Necessity Guideline.
2. January 8, 2018: No changes.
3. April 14, 2020: Removed Reauthorization Criteria. Removed the following requirements: "Documentation of normal respiratory function defined as percent-predicted forced vital capacity values of $\geq 80\%$ " and "Disease duration of 2 years or less."

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.

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