Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs
Radicava® (edaravone)

Effective: January 1, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Public Plans Products

☒ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956
*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☒ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☒ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☒ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Approval of Radicava is based on clinical trials performed in Japan and include the MCI186-19 trial in which 137 patients were enrolled. Inclusion criteria limited enrollment to patients with a diagnosis of ALS within the previous 2 years, normal respiratory function, and ability to perform most activities of daily living. Patients also continued to receive standard of care treatment, which included riluzole. At week 24, Radicava-treated patients declined 33% less in physical function (as measured by the ALS Functional Rating Scale) compared to placebo-treated patients. In addition, a trend favoring Radicava on a respiratory subscale and less deterioration in quality of life were observed as assessed with the 40-item ALS assessment Questionnaire. There was no difference in grip strength or death in either treatment group. There was an additional 24-week open-label continuation study looking at 123 patients from the MCI186-19 trial who received Radicava regardless of their initial treatment. Results demonstrated, Radicava-treated patients who had received Radicava initially had lower decline than those who had initially received placebo.

Food and Drug Administration - Approved Indications
Radicava (edaravone) is indicated for the treatment of amyotrophic lateral sclerosis (ALS).

Clinical Guideline Coverage Criteria

The plan may authorize coverage for Radicava for Members when **ALL** of the following criteria is met:

1. Documented diagnosis of amyotrophic lateral sclerosis

AND

2. Prescribed by or in consultation with a neurologist

Limitations

- None

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	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. 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.
4. 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 evidenced-based review). Neurology. 2009b; 73:1227-1233
5. Radicava (edaravone) [package insert]. Jersey City, NJ: Mitsubishi Tanabe Pharma America, Inc.; December 2023.

Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T)

September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)

Subsequent endorsement date(s) and changes made:

- November 14, 2023: Removed Limitation Any indications other than those listed are considered experimental or investigational and will not be approved by the health plan. Minor wording updates (eff 12/1/2023).
- November 2023: Administrative Updates: Rebranded from Tufts Health Unify to Tufts Health One Care for 2024 and administrative update in support of calendar year 2024 Medicare Advantage and PDP Final Rule.
- September 2024: Joint Medical Policy and Health Care Services UM Committee review (eff 10/1/24)
- September 10, 2024: No changes
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- December 9, 2025: No changes (eff 1/1/26)
- December 2025: Joint Medical Policy and Health Care Services UM Committee review (effective 1/1/26)

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

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