



MVP Health Care Medical Policy

Medicare Part B: Radicava

Type of Policy: Medical Therapy
Prior Approval Date: 11/01/2023
Approval Date: 11/01/2024
Effective Date: 01/01/2025
Related Policies: N/A

Refer to the MVP website for the Medicare Part D formulary for drugs that may be covered under the Part D benefit.

Please refer to relevant CMS LCDs/NCDs/Policy Articles for most up to date Medicare Part B guidance if available

Codes Requiring Prior Authorization (covered under the medical benefit)

J1301 Radicava (edaravone, 1mg)

Overview/Summary of Evidence

Amyotrophic lateral sclerosis (ALS) is a progressive neurodegenerative disorder that causes muscle weakness, disability, and eventually death. The median survival is three to five years after diagnosis with 10 to 20 percent of patients surviving for greater than 10 years. Long-term survival is associated with a younger age at symptom onset, male gender, and limb rather than bulbar symptom onset.

The mechanism by which Radicava exerts its therapeutic effect in patients with ALS is unknown. It has been characterized as a free radical scavenger, which is thought to block radicals that mediate both neuronal and vascular damage.

Radicava IV is dosed as 60 mg IV once daily for 14 days followed by a 14-day drug-free period for an initial treatment cycle. For subsequent treatment cycles, administer for 10 days out of 14-day periods followed by 14-day drug-free periods. Members treated with intravenous Radicava (edaravone) may be switched to oral edaravone using the same dosing frequency.

Indications/Criteria

Radicava/edaravone IV or oral suspension may be considered for coverage when the following criteria are met:

- Prescribed by a Neurologist
- Chart notes documenting a confirmed diagnosis of ALS Diagnosis of ALS within the past 2 years
- Submission of the most recent ALS Functional Rating Scale-Revised (ALSFRS-R) score with results identifying a score of 2 points or better on each individual item showing that the member has functionality retained most activities of daily living. <http://www.outcomes-umassmed.org/als/alsscale.aspx>
- Chart notes identifying current % forced vital capacity (%FVC) greater than or equal to 80%
- The member is currently receiving riluzole unless contraindicated

Initial approval will be for 6 cycles or 24 weeks (64 doses)

Extension requests will be approved if the member meets the following criteria:

- Member must not be dependent on invasive ventilation
- Member has not experienced rapid disease progression while on therapy and can still perform some activities of daily living independently. ALSFRS-R score must not have declined 50% from baseline
- Approval will be for 24 weeks (60 doses)

Exclusions

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Member is dependent on invasive ventilation
- Member requires total assistance for activities of daily living

References

1. Radicava (edaravone) Injection. Prescribing Information. Jersey City, NJ: MT Pharma America, Inc. May 2017. Revised November 2022.

2. The ALS Care Program . [ALS Functional Rating Scale \(outcomes-umassmed.org\)](#)
3. Amyotrophic lateral sclerosis (ALS). Mayo Clinic. Accessed October 3 2024. [Amyotrophic lateral sclerosis \(ALS\) - Diagnosis and treatment - Mayo Clinic](#)