MVP Health Care Medical Policy

Medicare Part B: Radicava

Type of Policy:	**Medical Therapy**
Prior Approval Date:	**N/A**
Approval Date:	**11/01/2023**
Effective Date:	**01/01/2024**
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.

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.

Indications/Criteria

- Prescribed by a Neurologist
- Chart notes identifying the diagnosis of ALS per the revised EL Escorial or Awaji criteria
- 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
- Documentation from provider identifying anticipated clinical benefit from Radicava therapy

Initial approval will be for 6 cycles or 24 weeks (64 doses): Cycle 1=daily dosing for 14 days followed by 14-day drug free period and Cycle 2-6=daily dosing for 10 days out of 14-day period followed by 14-day drug free period.

For continuation of therapy:

- Patient must not be dependent on invasive ventilation
- Patient 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

- Dose above FDA approved maximum
- Patient dependent on invasive ventilation
- Patients require total assistants for activities of daily living
- Patients with a history of hypersensitivity to edavarone or any of the inactive ingredients in the product, including sulfite hypersensitivity

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References

1. Costa J, Swash M, de Carvalho M. Awaji criteria for the diagnosis of amyotrophic lateral sclerosis: A systemic review. Arch Neurol. 2012;69(11):1410
2. Brooks BR, Miller RG, Swash M, et al. El Escorial revisited: Revised Criteria for the Diagnosis of Amyotrophic lateral Sclerosis. Amyotroph Lateral Scler Other Motor Neuron Disord. 2000;1(5):293
3. Radicava (edaravone) Injection. Prescribing Information. Jersey City, NJ: MT Pharma America, Inc. May 2017. Revised May 2022.