

Radicava® (edaravone)

When requesting Radicava® (edaravone) injection, the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved Indication

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

Coverage Guidelines

Amyotrophic lateral sclerosis (ALS)

The individual must meet ALL of the following criteria for initial authorization:

- Has a “definite” or “probable” diagnosis of amyotrophic lateral sclerosis (ALS) based on the application of the El Escorial or the revised Airlie House diagnostic criteria;
- Has a score of 2 points or more on each item of the ALS Functional Rating Scale – Revised (ALSFRS-R) [i.e., has retained most or all activities of daily living];
- Has a percent-predicted forced vital capacity (FVC) greater than or equal to 80% (i.e., has normal respiratory function);
- Has been diagnosed with ALS for ≤2 years;
- Has received or is currently receiving riluzole tablets (Rilutek®, generics), Tiglutik® (riluzole oral suspension), or Exservan (riluzole oral film);
- Radicava is prescribed by or in consultation with a neurologist, a neuromuscular disease specialist, or a physician specializing in the treatment of ALS.

The individual must meet ALL of the following criteria for re-authorization:

- Continues to benefit from Radicava therapy;
- Does not require invasive ventilation;
- Radicava is prescribed by or in consultation with a neurologist, a neuromuscular disease specialist, or a physician specializing in the treatment of ALS.

Approval duration (initial & renewal): 6 months

Dosing Recommendation

The recommended dose of Radicava is 60 mg administered as an intravenous infusion over 60 minutes as follows:

- Initial treatment cycle: daily dosing for 14 days followed by a 14-day drug-free period
- Subsequent treatment cycles: daily dosing for 10 days out of a 14-day period, followed by a 14-day drug-free period

References

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14. Damme PV, Al-Chalabi A, Andersen PM, et al. European Academy of Neurology (EAN) guideline on the management of amyotrophic lateral sclerosis in collaboration with European Reference Network for Neuromuscular Diseases (ERN EURO-NMD). *Eur J Neurol.* 2024 Mar 12 [Epub ahead of print].