



Radicava® (edaravone)

When requesting Radicava® (edaravone) injection, the individual requiring treatment must be diagnosed with an 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

For the treatment of amyotrophic lateral sclerosis (ALS)

Initial Authorization:

The individual must meet ALL of the following criteria for approval:

- 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 force 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.

Re-authorization:

The individual must meet ALL of the following criteria for approval:

- 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

Recommended Dosing

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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11. Sano H, Kamijo T, Ino T, et al. Edaravone, a free radical scavenger, in the treatment of idiopathic sudden sensorineural hearing loss with profound hearing loss. *Auris Nasus Larynx.* 2010;37(1):42-46.
12. Data on file. Radicava™ Product Dossier: Based on AMCP guidelines for formulary submission, version 2.1. MT Pharma America, Inc.; received June 14, 2017.
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