

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 All Members (initial and reauthorization):

- 1) Radicava is prescribed by or in consultation with a neurologist, a neuromuscular disease specialist, or a physician specializing in the treatment of ALS

Initial authorization (6 months);

The individual meets **all** of the following criteria for initial authorization.

- 1) According to the prescribing physician, the patient 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; AND
Clinically Definite-clinical evidence alone by the presence of upper motor neuron (UMN), as well as lower motor neuron (LMN) signs in three spinal regions
Clinically Probable- clinical evidence along by UMN and LMN signs in at least two regions with some UMN signs necessarily rostral to the LMN signs
Clinically Probable ALS – Laboratory-supported: clinical signs of UMN and LMN dysfunction are in only one region, or when UMN signs alone are present in one region, and LMN signs defined by EMG criteria are present in at least two regions, with proper application of neuroimaging and clinical laboratory protocols to exclude other causes.
- 2) Patient has a score of two 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]; AND
- 3) Patient has a percent-predicted forced vital capacity (FVC) $\geq 80\%$ (i.e., has normal respiratory function); AND
- 4) Patient has been diagnosed with ALS for ≤ 2 years; AND
- 5) Patient has received or is currently receiving riluzole tablets (Rilutek®, generics) or Tiglutik® (riluzole oral suspension); AND

Reauthorization (1 year):

The individual must meet **all** of the following criteria for reauthorization.

- 1) According to the prescribing physician, the patient continues to benefit from therapy; AND
- 2) Does not requiring invasive ventilation

Recommended Dosing

60 mg daily for 15 days followed by a 14 day drug free period, then 60mg qd for 10 days out of every 14 day period followed by a 14 day drug free period.

References

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4. Abe K, Aoki M, Tsuji S, et al. on behalf of the edaravone (MCI-186) ALS 19 study group. Safety and efficacy of edaravone in well-defined patients with amyotrophic lateral sclerosis: a randomized, double-blind, placebo-controlled trial. *Lancet Neurol.* 2017; 16:505-512.
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6. Munakata A, Ohkuma H, Nakano T, et al. Effect of a free radical scavenger, edaravone, in the treatment of patients with aneurysmal subarachnoid hemorrhage. *Neurosurgery.* 2009; 64(3):423-428.
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8. Tang Y, Rong X, Hu W, et al. Effect of edaravone on radiation-induced brain necrosis in patients with nasopharyngeal carcinoma after radiotherapy: a randomized controlled trial. *J Neurooncol.* 2014; 120(2):441-447.
9. Maeno T, Tano R, Takenaka H, et al. Edaravone (MCI-186) is effective as a free radical scavenger following arteriovenous sheathotomy for treatment of macular edema associated with branch retinal vein occlusion. *Br J Ophthalmol.* 2009; 93(11):1479-1482.
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12. The Writing Group on Behalf of the Edaravone (MCI-186) ALS 19 Study Group. Open-label 24-week extension study of edaravone (MCI-186) in amyotrophic lateral sclerosis. *Amyotroph Lateral Scler Frontotemporal Degener.* 2017; 18(sup1):55-63.