

Edaravone Intravenous (Radicava, generic)

When requesting an edaravone intravenous product (Radicava, generic), 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

Edaravone intravenous 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 adequate respiratory function and does not require invasive ventilation;
- Has received or is currently receiving riluzole tablets (Rilutek®, generics), Tiglutik® (riluzole oral suspension), or Exservan (riluzole oral film);
- Edaravone intravenous 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 edaravone intravenous therapy;
- Does not require invasive ventilation;
- Edaravone intravenous 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 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

1. Radicava™ injection [prescribing information]. Jersey City, NJ: Mitsubishi Tanabe Pharma Corporation; November 2022.
2. 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.
3. Abe K, Itoyama Y, Sobue G, et al. Confirmatory double-blind, parallel-group, placebo-controlled study of efficacy and safety of edaravone (MCI-186) in amyotrophic lateral sclerosis patients. *Amyotroph Lateral Scler Frontotemporal Degener.* 2014;15(7-8):610-617.
4. Miller RG, Jackson CE, Kasarskis EJ, et al. Practice parameter update: the care of the patient with amyotrophic lateral sclerosis: multidisciplinary care, symptom management, and cognitive/behavioral impairment (an evidence-based review). *Neurology.* 2009;73(15):1227-1233.
5. Miller RG, Jackson CE, Kasarskis EJ, et al. Practice parameter update: the care of the patient with amyotrophic lateral sclerosis: drug, nutritional, and respiratory therapies (an evidence-based review). *Neurology.* 2009;73:1218-1226.
6. Andersen PM, Abrahams S, Borasio GD, et al. EFNS guidelines on the clinical management of amyotrophic lateral sclerosis (MALS) – revised report of an EFNS task force. *Eur J Neurol.* 2012;19(3):360-375.
7. 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.
8. Tsujita K, Shimomura H, Kaikita K, et al. Long-term efficacy of edaravone in patients with acute myocardial infarction. *Circ J.* 2006;70(7):832-837.
9. 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.
10. 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.
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.
13. Feng S, Yang Q, Liu M, et al. Edaravone for acute ischaemic stroke. *Cochrane Database Syst Rev.* 2011;12:CD007230.
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].
15. Edaravone intravenous infusion [prescribing information]. Rosemont, IL: Long Grove; May 2024.
16. Brooks BR, Heiman-Patterson T, Wiedau-Pazos M, et al. Edaravone efficacy in amyotrophic lateral sclerosis with reduced forced vital capacity: Post-hoc analysis of Study 19 (MCI186-19) [clinical trial NCT01492686]. *PLOS ONE.* 2022 June 14 [Online ahead of print].