

**Radicava (edaravone intravenous injection)
 Radicava ORS (edaravone oral suspension)
 Effective 04/01/2023**

Plan	<input checked="" type="checkbox"/> MassHealth <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX)		<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Specialty Limitations	These medications have been designated specialty and must be filled at a contracted specialty pharmacy when obtained through the pharmacy benefit.		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions			

Overview

Radicava (edaravone) is a free radical and peroxynitrite scavenger that prevents oxidative damage to cell membranes and indicated for the treatment of amyotrophic lateral sclerosis (ALS).

No PA	Drugs that require PA
Rilutek # (riluzole tablet)	Radicava (edaravone injection) Radicava ORS (edaravone suspension) †

This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule or liquid) does not have an FDA "A"-rated generic equivalent.

† Agent does not participate in the federal rebate program. Please see the Non-FDA and Non-rebate products guideline for more information

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for members when all the following criteria are met, and documentation is provided:

1. Prescriber is a neurologist, neuromuscular specialist, or otherspecialist in the treatment of ALS, or consult notes from specialist are provided

1. Medical records supporting the diagnosis of definite, probable, or probable-laboratory supported ALS per El Escorial criteria
2. Prescriber submits a copy of the pre-treatment ALSFRS-R questionnaire including scores on each individual domain and duration of disease
3. **ALL** of the following:
 - a. Pre-treatment ALSFRS-R questionnaire score of ≥ 2 on each individual item
 - b. Pre-treatment FVC $\geq 80\%$
 - c. Member is not dependent on invasive mechanical ventilation by intubation or tracheostomy
4. Appropriate dose
5. **ONE** of the following:
 - a. Requested medication will be used in combination with riluzole
 - b. Adverse reaction or contraindication to riluzole

Continuation of Therapy

Reauthorization may be granted for members when **ALL** the following criteria are met:

1. Prescriber submits a current copy of the ALSFRS-R questionnaire including scores on each individual domain (within the past 12 weeks)
2. Member is not dependent on invasive mechanical ventilation by intubation or tracheostomy

Limitations

1. Initial approvals and reauthorizations will be granted for 6 months.

References

1. Elman LB, McCluskey L. Clinical features of amyotrophic lateral sclerosis and other forms of motor neuron disease. In Eichler AF (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2019[cited 2019 Oct 15]. Available from: <https://www.uptodate.com/contents/search>.
2. National Institute of Neurological Disorders and Stroke. Amyotrophic Lateral Sclerosis (ALS) Fact Sheet. Available from: <https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Amyotrophic-Lateral-Sclerosis-ALS-Fact-Sheet>. [cited 2019 Oct 15].
3. Maragakis NJ, Galvez-Jimenez N. Epidemiology and pathogenesis of amyotrophic lateral sclerosis. In Eichler AF (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2019 [cited 2019 Oct 15]. Available from: <https://www.uptodate.com/contents/search>.
4. Drugs@FDA [database on the Internet]. Rockville (MD): Food and Drug Administration (US), Center for Drug Evaluation and Research; 2019 [cited 2019 Oct 15]. Available from: <http://www.accessdata.fda.gov/>.
5. EFNS Task Force on Diagnosis and Management of Amyotrophic Lateral Sclerosis, Andersen PM, Abrahams S, Borasio GD, de Carvalho M, Chio A, et al. EFNS guidelines on the clinical management of amyotrophic lateral sclerosis (MALS)--revised report of an EFNS task force. *Eur J Neurol*. 2012 Mar;19(3):360-75. doi: 10.1111/j.1468-1331.2011.03501.x. Epub 2011 Sep 14.
6. Galvez-Jimenez N, Goyal NA, Cudkovicz ME. Disease modifying treatment of amyotrophic lateral sclerosis. In Dashe JF (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2019 [cited 2019 Oct 15]. Available from: <https://www.uptodate.com/contents/search>.
7. Miller RG, Jackson CE, Kasarskis EJ, England JD, Forsheew D, Johnston W, 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): report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology*. 2009 Oct 13;73(15):1227-33. doi: 10.1212/WNL.0b013e3181bc01a4.
8. Radicava® [package insert]. Jersey City (NJ): MT Pharma America, Inc.; 2021 Mar.



9. Paganoni S, Cudkowicz M, Berry JD. Outcome measures in amyotrophic lateral sclerosis clinical trials. *Clin Investig (Lond)*. 2014;4(7):605-618.
10. Cedarbaum JM, Stambler N, Malta E, Fuller C, Hilt D, Thurmond B, et al. The ALSFRS-R: a revised ALS functional rating scale that incorporates assessments of respiratory function. BDNF ALS Study Group (Phase III). *J Neurol Sci*. 1999 Oct 31;169(1-2):13-21.
11. Abe K, Itoyama Y, Sobue G, Tsuji S, Aoki M, Doyu M, 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 Dec;15(7-8):610-7. doi: 10.3109/21678421.2014.959024. Epub 2014 Oct 6.
12. Writing Group, On Behalf of the Edaravone (MCI-186) ALS 17 Study Group. Exploratory double-blind, parallel-group, placebo-controlled extension study of edaravone (MCI-186) in amyotrophic lateral sclerosis. *Amyotroph Lateral Scler Frontotemporal Degener*. 2017 Oct;18(sup1):20-31. doi: 10.1080/21678421.2017.1362000.
13. Writing Group, On Behalf of the Edaravone (MCI-186) ALS 18 Study Group. Exploratory double-blind, parallel-group, placebo-controlled study of edaravone (MCI-186) in amyotrophic lateral sclerosis (Japan ALS severity classification: Grade 3, requiring assistance for eating, excretion or ambulation). *Amyotroph Lateral Scler Frontotemporal Degener*. 2017 Oct;18(sup1):40-48. doi: 10.1080/21678421.2017.1361441.
14. Writing Group, 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 May 15. pii: S1474-4422(17)30115-1. doi: 10.1016/S1474-4422(17)30115-1. [Epub ahead of print].
15. 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 Oct;18(sup1):55-63. doi: 10.1080/21678421.2017.1364269.
16. Palumbo JM, Tanaka M, Sakata T, Akimoto M, for the Edaravone (MCI-186) ALS 19 Study Group. Efficacy and safety of edaravone (MCI-186) for the treatment of advanced amyotrophic lateral sclerosis (ALS): a 24-week extension. Poster presented at the Northeast Amyotrophic Lateral Sclerosis Consortium Annual Meeting, 6 October 2016, Clearwater Beach, Florida.
17. Bensimon G, Lacomblez L, Meininger V. A controlled trial of riluzole in amyotrophic lateral sclerosis. ALS/Riluzole Study Group. *N Engl J Med*. 1994;330(9):585.
18. Lacomblez L, Bensimon G, Leigh PN, Guillet P, Meininger V. Dose-ranging study of riluzole in amyotrophic lateral sclerosis. Amyotrophic Lateral Sclerosis/Riluzole Study Group II. *Lancet*. 1996;347(9013):1425.
19. Keating GM. Riluzole oral suspension in amyotrophic lateral sclerosis: a guide to its use. *Drugs Ther Perspect*. 2016;32(7):282-286.
20. Onesti E, Schettino I, Gori MC, et al. Dysphagia in amyotrophic lateral sclerosis: impact on patient behavior, diet adaptation, and riluzole management. *Front Neurol*. 2017;8:94.
21. Dyer AM, Smith A. Riluzole 5 mg/mL oral suspension: for optimized drug delivery in amyotrophic lateral sclerosis. *Drug Des Devel Ther*. 2017; 11: 59–64.
22. Tiglutik (riluzole) [package insert]. Berwyn (PA): ITF Pharma; 2020 Mar.
23. Exservan (riluzole) [package insert]. Jersey City (NJ): Mitsubishi Tanabe Pharma America, Inc.; 2021 Apr.
24. ITF Pharma Announces FDA Approval Of TIGLUTIK™ (Riluzole) Oral Suspension for the Treatment of Amyotrophic Lateral Sclerosis (ALS) [press release on the internet]. Berwyn (PA): PRNewswire; 2018 Sep 06 [cited 2018 Nov 08]. Available from: <https://www.prnewswire.com/news-releases/itf-pharma-announces-fda-approval-of-tiglutik-riluzole-oral-suspension-for-the-treatment-of-amyotrophic-lateral-sclerosis-als-300707653.html>.
25. Radicava® (edaravone) product dossier. June 14, 2017. Version 4. MT Pharma America, Inc. Data on file.



26. Elman LB, McCluskey L. Diagnosis of amyotrophic lateral sclerosis and other forms of motor neuron disease. In Eichler AF (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2019 [cited 2019 Oct 15]. Available from: <https://www.uptodate.com/contents/search>.
27. Brooks BR. El Escorial World Federation of Neurology criteria for the diagnosis of amyotrophic lateral sclerosis. Subcommittee on Motor Neuron Diseases/Amyotrophic Lateral Sclerosis of the World Federation of Neurology Research Group on Neuromuscular Diseases and the El Escorial "Clinical limits of amyotrophic lateral sclerosis" workshop contributors. J Neurol Sci. 1994 Jul;124 Suppl:96-107.
28. de Carvalho M, Dengler R, Eisen A, England JD, Kaji R, Kimura J, et al. Electrodiagnostic criteria for diagnosis of ALS. Clin Neurophysiol. 2008 Mar;119(3):497-503. doi: 10.1016/j.clinph.2007.09.143. Epub 2007 Dec 27.

Review History

9/21/2022 – Created for Sept P&T. Matched MH criteria. Separated out Comm/Exch vs. MH. Effective 11/1/22.
02/08/2023 - Reviewed and updated for Feb P&T. Updated provider specialty by including neuromuscular specialist, or other specialists in the treatment of ALS or consult notes are provided. Updated diagnosis requirement. The following was added to criteria: Pre-treatment ALSFRS-R questionnaire score of ≥ 2 on each individual item, Pre-treatment FVC $\geq 80\%$, Member is not dependent on invasive mechanical ventilation by intubation or tracheostomy. Updated reauth criteria to now require a current copy of ALSFRS-R questionnaire and that member is not dependent on invasive mechanical ventilation by intubation or tracheostomy. Effective 4/1/23.

