Medical Policy:

Radicava (edaravone) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.121	February 24, 2025	June 2017

Definitions

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

Length of Authorization

Coverage will be provided for 6 months and may be renewed.

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):

- **Initial dose:** 60 billable units (mg) daily for 14 days, followed by 14 days off per 28-day cycle
- **Subsequent doses:** 60 billable units (mg) daily for 10 days out of 14 days, followed by 14 days off per 28-day cycle

Guideline

I. Initial Approval Criteria

Radicava *may be considered medically necessary if one of the below conditions are met* ***AND*** *use is consistent with the medical necessity criteria that follows:*

1. Amyotrophic Lateral Sclerosis (ALS) †

A. Patient must have a clinically definite or probable diagnosis of ALS based on El Escorial revised criteria or Awaji criteria; **AND**
B. Patient has disease duration for two years or less; **AND**
C. Patient must be at least 18 years of age; **AND**
D. The medication is being prescribed by a neurologist that specializes in ALS and/or neuromuscular disorders; **AND**
E. The patient has had an inadequate response, intolerance, or contraindication to riluzole (Rilutek); **AND**
F. Patient has a percent-predicted forced vital capacity (%FVC) ≥ 80%; **AND**
G. Baseline documentation of retained functionality for most activities of daily living [i.e., score of 2 or better on each* individual item of the ALS Functional Rating Scale – Revised (ALSFRS-R)]
**Note: the ALSFRS-R is a 12-item questionnaire assessing functional disease progression across four domains including bulbar, fine motor, gross motor, and respiratory. Each item is scored on a five-point ordinal scale from 0 (loss or significant impairment) up to 4 (normal function) with a possible cumulative score of 48. A score of 2 or better on each item would correspond to a minimum ALSFRS-R score of 24.*

† FDA-labeled indication(s)

Limitations/Exclusions

If the above criteria is met, authorization may be granted for a 14 day period, followed by a 14 day drug-free period for initial treatment cycle.

II. Renewal Criteria

1. Patient continues to meet the Initial Approval Criteria; **AND**
2. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: hypersensitivity reactions, sulfite allergic reactions, etc.; **AND**
3. Patient has responded to therapy compared to pretreatment baseline with disease stability or mild progression indicating a slowing of decline on the ALSFRS-R (patient has not experienced rapid disease progression while on therapy); **AND**
4. Patient does not have a cumulative score on the ALSFRS-R of ≤ 3

Dosage/Administration

Indication	Dose
ALS	60 mg (two consecutive 30 mg infusion bags) administered as an intravenous infusion over 60 minutes 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 14-day periods, followed by 14-day drug-free periods

Applicable Procedure Codes

Code	Description
J1301	Injection, edaravone, 1 mg

Applicable NDCs

Code	Description
70510-2172-XX	Radicava 30 mg/100ml single dose bag

ICD-10 Diagnoses

Code	Description
G12.21	Amyotrophic lateral sclerosis

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	2/24/2025	Annual Review: No criteria changes.
EmblemHealth & ConnectiCare	1/11/2024	Annual Review: Updated NDC. Initial Criteria: Amyotrophic Lateral Sclerosis (ALS) Reworded diagnosis to: "Patient must have a clinically definite or probable diagnosis of ALS based on El Escorial revised criteria or Awaji criteria; AND" Removed: "NO severe renal impairment (CrCl less than 30 mL/min) or end stage renal disease; AND NO moderate to severe hepatic impairment (Child-Pugh Class C); AND" Added: "Patient has a percent-predicted forced vital capacity (%FVC) ≥ 80%; AND Baseline documentation of retained functionality for most activities of daily living [i.e., score of 2 or better on each* individual item of the ALS Functional Rating Scale – Revised (ALSFRS-R)]"
EmblemHealth & ConnectiCare	5/15/2023	Annual Review: no criteria changes
EmblemHealth & ConnectiCare	10/13/2022	Transferred policy to new template
EmblemHealth & ConnectiCare	02/06/2020	Removed Under Initial Approval Criteria the following: •The patient has a Baseline ALS Functional Rating Scale-Revised (ALSFRS-R) with a score of 2 or greater on each individual item of the scale •Normal respiratory function %FVC ≥ 80% (approved in Medical Policy Subcommittee Meeting, on 02/06/2020)

References

1. Radicava [package insert]. Jersey City, NJ; MT Pharma America, Inc; August 2018. Accessed December 2019.
2. Tanaka M, Sakata T, Palumbo J, et al. A 24-Week, Phase III, Double-Blind, Parallel-Group Study of Edaravone (MCI-186) for Treatment of Amyotrophic Lateral Sclerosis (ALS). Neurology April 5, 2016 vol. 86 no. 16 Supplement P3.189.
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 Dec;15(7-8):610-7.

4. Cedarbaum JM, Stambler N, Malta E, 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.
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): report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology. 2009 Oct 13;73(15):1218-26.