

Medical Policy:

Radicava (edaravone) Intravenous

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

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

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) $\geq 80\%$; **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 <u>Initial treatment cycle</u> : daily dosing for 14 days followed by a 14-day drug-free period <u>Subsequent treatment cycles</u> : 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: <ul style="list-style-type: none"> •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.