Neighborhood Health Plan OF RHODE ISLAND™
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Radicava (edaravone)
(Intravenous)

Effective Date: 12/4/2019
Review date: 12/4/2019, 1/29/2020, 9/14/2020, 6/24/2021, 1/06/2022, 8/4/2022, 1/12/2023, 12/21/2023, 01/10/2024, 03/05/2025

Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

I. Length of Authorization

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

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Radicava 30 mg/100 mL single-dose bag: 2 bags per day for 14 days of a 28 day cycle initially, followed by 2 bags per day for 10 days of a 28 day cycle

B. Max Units (per dose and over time) [HCPCS Unit]:

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

III. Prescriber Specialties

This medication must be prescribed by or in consultation with a neurologist, neuromuscular specialist or physician specializing in the treatment of amyotrophic lateral sclerosis (ALS).

IV. Summary of Evidence

Clinical trials evaluating the efficacy and safety of Radicava for the treatment of ALS have demonstrated statistically significant benefits in slowing the decline in the rate of functional decline in patients with ALS. In two Phase 3 clinical trials Radicava showed a statistically significant reduction in the decline of the ALS Functional Rating Scale-Revised (ALSFRS-R) score compared to placebo. The ALSFRS-R is a validated measure of functional status in patients with ALS, assessing respiratory function, speech, swallowing, and limb strength. Radicava-treated patients experienced a slower rate of decline in ALSFRS-R scores compared to placebo, suggesting a potential benefit in preserving functional status. Although the clinical significance of the observed treatment effect may be modest, the findings from these trials led to the approval of Radicava by regulatory agencies, including the FDA, for the

treatment of ALS. Common adverse reactions reported in clinical trials include contusion, gait disturbance, headache, and ecchymosis.

V. Initial Approval Criteria [1]

MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.
Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**
- Will not be used in combination with other formulations of edaravone (i.e., oral); AND

Amyotrophic lateral sclerosis (ALS) † Φ [1,2,7,8]

- Patient has a diagnosis of clinically definite or probable ALS; **AND**
- Patient has a disease duration of 2 years or less; **AND**
- 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)]

*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-approved indication(s); ‡ Compendium Recommended Indication(s); **Φ** Orphan Drug

VI. Renewal Criteria [1,3]

- Patient has a diagnosis of clinically definite or probable ALS; **AND**
- Patient has a percent-predicted forced vital capacity (%FVC) ≥ 80%
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity are hypersensitivity reactions (e.g., redness, wheals, and erythema multiforme), anaphylaxis (e.g., urticaria, decreased blood pressure, and dyspnea), sulfite allergic reactions, etc.; **AND**
- 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**
- Patient does not have a cumulative score on the ALSFRS-R of ≤ 3 (The cumulative possible score on the ALSFRS-R is 48; a cumulative score of 3 indicates loss/significant impairment [i.e., item score of zero] in nine or more items on the 12-item questionnaire); **AND**

- Patient's respiratory status does not require invasive ventilation or tracheostomy
- Will not be used in combination with other formulations of edaravone (i.e., oral)

VII. Dosage/Administration [1]

Indication	Dose
ALS	60 mg (two 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

Do not use if the oxygen indicator has turned blue or purple before opening the package. Once the overwrap package is opened, use within 24 hours.

VIII. Billing Code/Availability Information

HCPCS Code:

- J1301 – Injection, edaravone, 1 mg; 1 billable unit = 1 mg

NDC:

- Radicava 30 mg/100 mL single-dose bag: 70510-2172-xx

IX. References

1. Radicava [package insert]. Jersey City, NJ; Mitsubishi Tanabe Pharma America, Inc; December 2024. Accessed February 2025.
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. 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.
4. 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.
5. Kinsley L, Siddique T. Amyotrophic Lateral Sclerosis Overview. GeneReviews. February 12, 2015; http://www.ncbi.nlm.nih.gov/books/NBK1450/.

6. Hardiman O, van den Berg LH, Kiernan MC. Clinical diagnosis and management of amyotrophic lateral sclerosis. Nat Rev Neurol. 2011 Oct 11;7(11):639-49.
7. Costa J, Swash M, de Carvalho M. Awaji criteria for the diagnosis of amyotrophic lateral sclerosis: a systematic review. Arch Neurol. 2012 Nov;69(11):1410-6.
8. Writing Group; Edaravone (MCI-186) ALS 19 Study Group. Safety and efficacy of edaravone in well defined patients with amyotrophic lateral sclerosis: a randomised, double-blind, placebo-controlled trial. Lancet Neurol. 2017;16(7):505-512. doi:10.1016/S1474-4422(17)30115-1.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
G12.21	Amyotrophic lateral sclerosis

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
15	KY, OH	CGS Administrators, LLC

Policy Rationale:

Radicava was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Radicava according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For INTEGRITY (Medicare-Medicaid Plan) members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.