Radicava (edaravone)
(Intravenous)

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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 60 mg/100 mL single-dose bag: 1 bag per day for 14 days of a 28 day cycle initially, followed by 1 bag 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. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

Patient is required to meet Site of Service specialty infusion program requirements (refer to the Medica Site of Service Policy).

- Patient is at least 18 years of age; **AND**

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

- Patient has a diagnosis of clinically definite or probable ALS based on El Escorial revised criteria or Awaji criteria; **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 points or better on each individual item of the ALS Functional Rating Scale – Revised (ALSFRS-R)]

† FDA-approved indication(s); Φ Orphan Drug

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IV. Renewal Criteria [1,3]

- Patient continues to meet the indication-specific relevant criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: hypersensitivity reactions, 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

V. Dosage/Administration [1]

Indication	Dose
ALS	60 mg (one 60 mg infusion bag) 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.

VI. Billing Code/Availability Information

HCPCS Code:

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

NDC:

- Radicava 60 mg/100 mL single-dose bag: 70510-2172-xx

VII. References

1. Radicava [package insert]. Jersey City, NJ; Mitsubishi Tanabe Pharma America, Inc; July 2019. Accessed July 2020.
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.

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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)
15	KY, OH	CGS Administrators, LLC

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