Radicava® (Edaravone) (Intravenous)

Last Review Date: January 1, 2019	Number: MG.MM.PH.121

Definition

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

Max Units (per dose and over time) [Medical Benefit]:

- **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:*

Amyotrophic Lateral Sclerosis †

- Patient must have a diagnosis of ALS (disease duration for two years or less)
- Patient must be at least 18 years of age; **AND**
- The medication is being prescribed by a neurologist that specializes in ALS and/or neuromuscular disorders
- The patient has had an inadequate response, intolerance, or contraindication to riluzole (Rilutek)

- 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%
- NO severe renal impairment (CrCl less than 30 mL/min) or end stage renal disease
- NO moderate to severe hepatic impairment (Child-Pugh Class C)

† FDA-labeled indication(s)

Limitations/Exclusions

If the above criteria are 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

- Patient continues to meet the Initial Approval Criteria; **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

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

J1301	Injection, edaravone, 1 mg

Applicable NDCs

70510-2171-XX	Radicava 30 mg/100ml single dose bag

Applicable Diagnosis Codes

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

References

1. Radicava [package insert]. Jersey City, NJ; MT Pharma America, Inc; May 2017. Accessed February 2018.

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.