MEDICAL MUTUAL

Drug Policy

Policy:	**201729**	**Initial Effective Date: 07/20/2017**
Code(s):	**HCPCS J1301**	**Annual Review Date: 07/19/2018**
SUBJECT:	**Radicava ® (edaravone)**	**Last Revised Date: 12/26/2018**

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

OVERVIEW

Radicava is indicated for the treatment of amyotrophic lateral sclerosis (ALS). Radicava is a free radical scavenger, being classified as an anti-oxidative agent. Administration is via intravenous (IV) infusion; the maximum plasma concentration of the drug is reached by the end of the infusion. In a 24-week clinical study of relatively well-functioning adults with ALS, including more than 90% taking concomitant riluzole, Amyotrophic Lateral Sclerosis Functional Rating Scale-Revised (ALSFRS-R) scores worsened to a significantly lesser degree compared with placebo.

POLICY STATEMENT

Prior authorization is recommended for pharmacy and medical benefit coverage of Radicava. All approvals are provided for 6 months in duration unless otherwise noted below. **Waste Management** applies for all covered conditions administered by a healthcare professional. *The Site of Care Medical Necessity Criteria applies to initial therapy and reauthorizations under the medical benefit.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Radicava is recommended in those who meet the following criteria:

Food and Drug Administration (FDA)-Approved Indications

1. **Amyotrophic Lateral Sclerosis (ALS)**

   For initial therapy, approve for 6 months in patients who meet the following criteria (a, b, c, d, e, f, and g):

   a) Patient is 18 years of age or older; AND
   b) The diagnosis date of ALS is provided and the patient has been diagnosed within the past 2 years of receiving potential therapy; AND
   c) Baseline ALS Functional Rating Scale-Revised (ALSFRS-R) score measured ; AND
   d) Patient has normal respiratory function (defined as percent-predicted forced vital capacity values of [%FVC] greater than or equal to 80 %); AND
   e) Radicava is prescribed by or in consultation with a neurologist or physician who specializes in the treatment of ALS; AND
   f) Patient must have previously tried therapy with Riluzole; AND
   g) Site of care medical necessity is met.*

MEDICAL MUTUAL®

Drug Policy

Dosing of Amyotrophic lateral sclerosis (ALS): IV:

Initial cycle: 60 mg once daily for 14 days, followed by a 14-day drug-free period.

2. Amyotrophic Lateral Sclerosis (ALS)

For continuation of therapy, approvefor 6 months in patients who meet the following criteria (a, b, and c):

a) Patient's ALS Fucntional Rating Scale-Revised (ALSFRS-R) score indicate stabilization or improvement in overall function; AND
b) Radicava is prescribed by or in consultation with a neurologist or physician who specializes in the treatment of ALS; AND
c)Site of care medical necessity is met.*

Dosing of Amyotrophic lateral sclerosis (ALS): IV:

Subsequent cycles: 60 mg once daily for 10 days within a 14-day period, followed by a 14-day drug-free period.

Initial Approval/ Extended Approval.
A) *Initial Approval:*6 months
B) *Extended Approval:* 6 months

Waste Management for All Indications.
Available as a 30mg/100ml single-dose polypropylene bag.

CONDITIONS NOT RECOMMENDED FOR APPROVAL
Radicava has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. **For the treatment of Acute Ischemic Stroke within 24 hours of onset to improve the neurological symptoms, disorders of activities of daily living, and functional outcomes.** The efficacy and safety of Radicava has not been established in patients with AIS in current trials demonstrated in the United States.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

MEDICAL MUTUAL®

Drug Policy

REFERENCES

1. Radicava™ injection [prescribing information]. Jersey City, NJ: Mitsubishi Tanabe Pharma Corporation; May 2017.
2. Abe K, Aoki M, Tsuji S, et al. on behalf of the edaravone (MCI-186) ALS 19 study group. Safety and efficacy of edaravone in well defined patients with amyotrophic lateral sclerosis: a randomized, double-blind, placebo-controlled trial. *Lancet Neurol*. 2017;16:505-512.
3. Miyaji, Yuki, et al. "Effect of Edaravone on Favorable Outcome in Patients with Acute Cerebral Large Vessel Occlusion: Subanalysis of RESCUE-Japan Registry." Neurologia Medico-Chirurgica, The Japan Neurosurgical Society, Mar. 2015,
4. Tanaka M, Akimoto M, Palumbo J, et al. A double-blind, parallel-group, placebo-controlled, 24-week, exploratory study of edaravone (MCI-186) for the treatment of advanced amyotrophic lateral sclerosis (ALS) [abstract P3.191]. Presented at: the American Academy of Neurology 68th Annual Meeting; Vancouver, BC, Canada; April 16-21, 2016.

FOR MEDICAL BENEFIT COVERAGE REQUESTS:

***MMO Site of Care Medical Necessity Criteria:**

Medications in this policy will be administered in a place of service that is a non-hospital facility based location (i.e., home infusion provider, provider's office, free-standing ambulatory infusion center) unless *at least one* of the following are met†:

1. Age less than 18*years; or
2. Clinically unstable based upon documented medical history (e.g., patient is hemodynamically unstable); or
3. History of a severe adverse event from previous administration of the prescribed medication; or
4. Requested medication is being administered as follows:
   - part of a chemotherapy regimen (e.g., anti-neoplastic agent, colony stimulating factor, erythropoiesis-stimulating agent, anti-emetic) for treatment of cancer; or
   - administered with dialysis; or
5. Physical or cognitive impairment and caregiver is not available to assist with safe administration of prescribed medication in the home; or
6. Radicava: No doses in a hospital based outpatient facility doses. All doses need to be at NHFBL
7. Experiencing adverse events that are not managed by premedication or resources available at a non-hospital facility based location.

* Effective 01/01/2019, age criterion applies to 18 years of older. Age at original effective date (03/01/2016) was 21 years or older.

Prior approval is required for HCPCS Codes J1301

HCPCS Code(s):	
J1301	Injection, edaravone, 1 mg (effective 1/1/2019)