TRUECARE

PHARMACY POLICY STATEMENT
Mississippi Medicaid

DRUG NAME	Radicava (edaravone injection); Radicava ORS (edaravone oral suspension)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Radicava is a pyrazolone free radical scavenger initially approved by the FDA in 2017 as an IV formulation. It is the second drug to be approved for the treatment of patients with Amyotrophic Lateral Sclerosis (ALS) behind Riluzole. In May of 2022, the FDA approved a new oral suspension formulation, Radicava ORS. ALS is a progressive neurodegenerative disease characterized by the weakness of voluntary muscles due to the loss of motor neurons. Although the exact mechanism of action is unknown, it is hypothesized Radicava works via a mechanism involving antioxidants, which nullifies the oxidative stress believed to be involved in ALS.

Radicava (edaravone) will be considered for coverage when the following criteria are met:

Amyotrophic Lateral Sclerosis (ALS)

For **initial** authorization:

1. Member must be at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a neurologist or a physician specializing in ALS; AND
3. Member must have detailed chart notes confirming member's Definite or Probable ALS based on EL Escorial revised criteria[3]; AND
4. Member must have had the diagnosis of ALS for a duration of 2 years or less; AND
5. Member must have a baseline percent forced vital capacity (FVC%) of 80% or greater; AND
6. Member must have a baseline score of 2 points or greater for each individual item of the ALS Functional Rating Scale-Revised (ALSFRS-R),

   *Note: Should be a minimum score of 24[4].

7. **Dosage allowed/Quantity limit:**
   a. Radicava: 60 mg (two 30mg bags) administered as an IV infusion over 60 minutes as follows: 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. Quantity Limit: 20 bags per 28 days
   b. Radicava ORS: Initial treatment cycle: 105 mg (5 mL) taken orally or via feeding tube daily 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. Quantity limit: 50mL per 28 days

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Member has documentation of disease stability or clinical benefit from therapy, such as improved ALS functional rating scale score or no rapid disease progression while on therapy; AND
2. Member does not require invasive ventilation.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Appendix:

Diagnostic Criteria for ALS.

Diagnosis	El Escorial Revised Airlie House Criteria
Definite ALS	UMN (clinical exam) and LMN (clinical, electrophysiological or neuropathological exam) signs: • Bulbar region and > two spinal regions OR • Three spinal regions
Probable ALS	UMN and LMN signs in > two regions and UMN signs rostral to LMN signs
Probable ALS – laboratory-supported	• UMN + LMN signs in one region OR • UMN signs alone in one region and LMN signs via electrophysiological criteria of LMN loss > two regions
Possible ALS	• UMN and LMN signs in one region OR • UMN signs alone in > two regions OR • LMN rostral to UMN and unable to prove clinically probably ALS

UMN – Upper motor neuron; LMN – Lower motor neuron.

TrueCare considers Radicava (edaravone) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
05/16/2017	New policy for Radicava created.
09/15/2017	Disease duration and percent-predicted forced vital capacity (%FVC) requirements were removed. ALSFRS-R score requirement was modified.
08/23/2022	Annual Review. Transferred to new format. Added J code Added new oral formulation dosing. Clarified reauthorization criteria. Added neurology specialty prescriber. Added age requirement. Reduced initial authorization duration to 6 months. Removed exclusion criteria. Removed daily function requirement and clarified ALSFRS-R criteria. Updated references.

References:

1. Radicava [package insert]. Jersey City, NJ: MT Pharma America, Inc.; May 2022.
2. Cedarbaum JM, Stambler N, Malta E, at el. The ALSFRS-R: a revised ALS functional rating scale that incorporates assessments of respiratory function. Journal of the Neurological Sciences, 169 (1999) 13 –21.
3. ALS Association. El Escorial World Federation of Neurology criteria for the diagnosis of ALS. www.alsa.org/assets/pdfs/fyi/criteria_for_diagnosis-1.pdf.
4. ALS Functional Rating Scale. Available at: http://www.outcomes-umassmed.org/als/alsscale.aspx.
5. Abe, K., Aoki, M., et al. Safety and efficacy of edaravone in well-defined patients with amyotrophic lateral sclerosis: a randomised, double- blind, placebo-controlled trial. The Lancet Neurology. 2017; 16(7), 505-512.
6. Witzel S, Maier A, Steinbach R, et al. Safety and Effectiveness of Long-term Intravenous Administration of Edaravone for Treatment of Patients with Amyotrophic Lateral Sclerosis. *JAMA Neurol.* 2022;79(2):121–130.
7. Shimizu H, Nishimura Y, Shiide Y, et al. Bioequivalence study of oral suspension and intravenous formulation of edaravone in healthy adult subjects. *Clin Pharmacol Drug Dev.* 2021;10(10):1188-1197

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