PHARMACY POLICY STATEMENT
North Carolina Marketplace

DRUG NAME	Radicava (edaravone injection); Radicava ORS (edaravone oral suspension)
BILLING CODE	J1301 or must use valid NDC code
BENEFIT TYPE	Medical or Pharmacy
SITE OF SERVICE ALLOWED	Home/Office/Outpatient
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

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

Effective date: 04/01/2023

Revised date: 08/23/2022