

PHARMACY POLICY STATEMENT

Ohio Medicaid

DRUG NAME

Radicava (edaravone injection); Radicava ORS (edaravone oral suspension)

BILLING CODE

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 criteria³; 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 (ALSFRRS-R),

*Note: Should be a minimum score of 24⁴.

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

