

PHARMACY POLICY STATEMENT

Ohio Medicaid

DRUG NAME	Radicava (edaravone injection)
BILLING CODE	J3590
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Outpatient Hospital/Office
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT – N/A
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

Radicava (edaravone injection) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

AMYOTROPHIC LATERAL SCLEROSIS (ALS)

For **initial** authorization:

1. Provider submitted detailed chart notes confirming member's Definite or Probable ALS based on El Escorial revised criteria; AND
2. Member can eat a meal, excrete, or move with oneself alone, and perform most functions of everyday life with little to no assistance (chart notes required); AND
3. Member does not have Parkinson's disease, schizophrenia, dementia, renal failure, or hypersensitivity to Radicava (edaravone); AND
4. Member's functionality retained most activities of daily living and defined as a total of 20 points or better on the ALS Functional Rating Scale – Revised (ALSFRS-R), and submitted with chart notes (i.e. scores for speech, salivation, swallowing, handwriting, walking, etc.).
5. **Dosage allowed:** 60 mg administered as an intravenous 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.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Radicava (edaravone injection) not medically necessary for the treatment of the diseases that are not listed in this document.

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.

References:

1. Cedarbaum JM, Stambler N, Malta E, et al. The ALSFRS-R: a revised ALS functional rating scale that incorporates assessments of respiratory function. *Journal of the Neurological Sciences*, 169 (1999) 13 –21.
2. ALS Functional Rating Scale. Available at: <http://www.outcomes-umassmed.org/als/alsscale.aspx>. Accessed May 16, 2017.
3. The ALS Association. Criteria for the Diagnosis of ALS. El Escorial World Federation of Neurology. Available at: <http://www.alsa.org/als-care/resources/publications-videos/factsheets/criteria-for-diagnosis.html>. Accessed May 16, 2017.
4. Radicava [package insert]. Jersey City, NJ: MT Pharma America, Inc.; May, 2017.
5. ClinicalTrials.gov [Internet]. Identifier NCT01492686, Phase 3 Study of MCI-186 for Treatment of Amyotrophic Lateral Sclerosis; 2015 Jun 18 [cited 2017 May 16]; [about 4 screens]. Available from: <https://clinicaltrials.gov/ct2/show/study/NCT01492686>.

Effective date: 11/08/2017

Revised date: 09/15/2017