CareSource

PHARMACY POLICY STATEMENT **Indiana 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 has disease duration of 2 years or less documented in chart notes; AND
3. Member can eat a meal, excrete, or move with oneself alone, and do not need assistance in everyday life (chart notes required); AND
4. Member does not have Parkinson's disease, schizophrenia, dementia, renal failure, or hypersensitivity to Radicava (edaravone); AND
5. Member's percent-predicted forced vital capacity [%FVC] is ≥80% (documentation required), AND
6. Member's functionality retained most activities of daily living and defined as scores of 2 points or better on each individual item of the ALS Functional Rating Scale – Revised (ALSFRS-R), and submitted with chart notes (i.e. scores for speech, salivation, swallowing, handwriting, walking, etc.).
7. **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 6 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease; AND
3. Documented member's ALSFRS-R score improvement.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 6 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.

References:

1. 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.
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: 10/01/2017
Revised date: 05/16/2017