Policy Title:	Radicava (edaravone) (Intravenous)		
		Department:	PHA
Effective Date:	12/04/2019		
Review Date:	12/04/2019		
Revision Date:	12/04/2019		

Purpose: To support safe, effective and appropriate use of Radicava (edaravone).

Scope: Medicaid, Exchange, Medicare-Medicaid Plan (MMP)

Policy Statement:

Radicava (edaravone) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure:

Coverage of Radicava (edaravone) will be reviewed prospectively via the prior authorization process based on criteria below.

Initial Criteria:

- Patient is 18 years of age or older: AND
- Patient has disease duration of 2 years or less; AND
- Provider must submit medical records (e.g., chart notes, previous medical history, diagnostic testing including: imaging, nerve conduction studies, laboratory values) to support the diagnosis of "definite" or "probable" ALS per the El Escorial/revised Airlie House diagnostic criteria, and prescribed by, or in consultation with, a neurologist with expertise in the diagnosis of ALS; AND
- Provider must submit medical records (e.g., chart notes, laboratory values) confirming that the patient has a % forced vital capacity (%FVC) ≥ 80% at the start of treatment; AND
- Baseline documentation of retained functionality for most activities of daily living [i.e., score of 2 points or better on each individual item of the ALS Functional Rating Scale – Revised (ALSFRS-R)]
- Radicava dosing for ALS is in accordance with the United States Food and Drug Administration approved labeling

Continuation of Therapy Criteria:

- Diagnosis of "definite" or "probable" ALS per the El Escorial/revised Airlie House diagnostic criteria, and prescribed by, or in consultation with, a neurologist with expertise in the diagnosis of ALS; AND
- Patient is currently receiving Radicava therapy; AND
- Patient has responded to therapy compared to pretreatment baseline with disease stability or mild progression indicating a slowing of decline on the ALSFRS-R (patient has not experienced rapid disease progression while on therapy); AND
- Patient does not have a cumulative score on the ALSFRS-R of ≤ 3
- Patient is not dependent on invasive ventilation or tracheostomy; AND
- Radicava dosing for ALS is in accordance with the United States Food and Drug Administration approved labeling

Coverage durations:

- Initial coverage: 6 months
- Continuation of therapy coverage: 6 months

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable.***

Dosage/Administration:

Indication	**Dose**	**Maximum dose (1 billable unit = *1* mg)**
ALS	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	Initial dose: • 60 billable units (mg) daily for 14 days, followed by 14 days off per 28-day cycle Subsequent doses: • 60 billable units (mg) daily for 10 days out of 14 days, followed by 14 days off per 28-day cycle

Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug

information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:
Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
J1301	Injection, edaravone, 1 mg

References:

1. Radicava [package insert]. Jersey City, NJ; MT Pharma America, Inc; Aug 2017. Accessed June 2018.
2. Tanaka M, Sakata T, Palumbo J, et al. A 24-Week, Phase III, Double-Blind, Parallel-Group Study of Edaravone (MCI-186) for Treatment of Amyotrophic Lateral Sclerosis (ALS). Neurology April 5, 2016 vol. 86 no. 16 Supplement P3.189.
3. . Abe K, Itoyama Y, Sobue G, et al. Confirmatory double-blind, parallel-group, placebocontrolled study of efficacy and safety of edaravone (MCI-186) in amyotrophic lateral sclerosis patients. Amyotroph Lateral Scler Frontotemporal Degener. 2014 Dec;15(7-8):610-7.
4. Cedarbaum JM, Stambler N, Malta E, et al. The ALSFRS-R: a revised ALS functional rating scale that incorporates assessments of respiratory function. BDNF ALS Study Group (Phase III). J Neurol Sci. 1999 Oct 31;169(1-2):13-21.
5. Miller RG, Jackson CE, Kasarskis EJ, et al. Practice parameter update: the care of the patient with amyotrophic lateral sclerosis: drug, nutritional, and respiratory therapies (an evidence-based review): report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology. 2009 Oct 13;73(15):1218-26.
6. Kinsley L, Siddique T. Amyotrophic Lateral Sclerosis Overview. GeneReviews. February 12, 2015; http://www.ncbi.nlm.nih.gov/books/NBK1450/.
7. Hardiman O, van den Berg LH, Kiernan MC. Clinical diagnosis and management of amyotrophic lateral sclerosis. Nat Rev Neurol. 2011 Oct 11;7(11):639-49.
8. Costa J, Swash M, de Carvalho M. Awaji criteria for the diagnosis of amyotrophic lateral sclerosis: a systematic review. Arch Neurol. 2012 Nov;69(11):1410-6.