Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 154.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Radicava (edaravone)

I. Policy:
Radicava (edaravone)

II. Purpose/Objective:
To provide a policy of coverage regarding Radicava (edaravone)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Radicava (edaravone) is a free radical scavenger with anti-oxidative properties that protects motor neurons from oxidative stress and damage. Oxidative signaling pathways and stress are hypothesized as contributory in the early pathogenesis of amyotrophic lateral sclerosis (ALS).

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Radicava (edaravone) will be considered medically necessary for all lines of business when ALL of the following criteria are met:

- Prescription written by or in consultation with a neurologist **AND**
- Medical record documentation of a diagnosis of ALS (amyotrophic lateral sclerosis) **AND**
- Medical record documentation of baseline functional status (as evidenced by a scoring system such as the ALS Function Rating Scale-Revised [ALSFRS-R], or by physician documentation of subjective reports on speech, motor function, pulmonary function, etc.) **AND**
- Medical record documentation that Radicava is being given in combination with riluzole OR intolerance or contraindication to riluzole

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require the following criteria.

- Medical record documentation that member is tolerating and compliant with prescribed edaravone regimen **AND**
- Medical record documentation of regular physician follow-up

Quantity Limit:
Initial Cycle: 2800mL per 28 days (28 [30mg/100mL] bags per 28 days)
Subsequent Cycles: 2000mL per 28 days (20 [30mg/100mL] bags per 28 days)

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Radicava injection [prescribing information]. Jersey City, NJ: Mitsubishi Tanabe Pharma America Inc; November 2022.
2. 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). American Academy of Neurology (AAN). Neurology; 2009 Oct 12; 7(15):1218-1226 [cited 2023 Dec 26]. Available from: https://www.neurology.org/doi/pdf/10.1212/WNL.0b013e3181bc0141

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 7/18/17

Revised: 1/19/23 (LOB carve out, Medicaid PARP statement, Medicaid business segment)**,** 12/30/23 (references added)

Reviewed: 7/10/18, 5/31/19, 2/1/20, 1/28/21, 1/21/22, 1/15/23

MA UM Committee approval: 12/31/23