Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Radicava (edaravone)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***August 2017***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Radicavs (edaravone).

Radicava (edaravone) is indicated for the treatment of patients with amyotrophic lateral scleroses (ALS). Radicava (edaravone) may slow the rate of functional decline in some patients.

DEFINITIONS

Amyotrophic Lateral Sclerosis (ALS) – a progressive and fatal neurodegenerative disorder characterized by loss of motor neurons in the spinal cord, brainstem, and motor cortex resulting in signs and symptoms of muscle wasting and weakness, spasticity, fasciculation, cramps, and respiratory failure leading to death.

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002

Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Radicava (edaravone), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must be over the age of 18
- Prescribed by a neurologist
- Must have a diagnosis of definite or probable amyotrophic lateral sclerosis (ALS)
- Must provide statement that patient has been evaluated for risk of hypersensitivity reactions
    - No sulfite allergy
    - No history of asthma
    - If history of asthma: statement that the risk of hypersensitivity has been evaluated
- Must be prescribing within recommended dosing

Reauthorization Criteria:

All prior authorization renewals are reviewed on a bi-annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 6 month intervals based upon chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy. Improvement in this condition may be limited to documentation indicating slowing of functional decline.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 6 cycles (6 months)
Reauthorization	Same as initial

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Radicava(R) [package insert]. Mitsubishi Tanabe Pharma America, Inc., Jersey City, NJ. 2017

2. Abe K, Itoyama Y, Sobue G, et al. Confirmatory double-blind, parallel-group, placebo-controlled study of efficacy and safety of edaravone (MCI-186) in amyotrophic lateral sclerosis patients. *Amyotroph Lateral Scler Frontotemporal Degener* 2014; **15:** 610–17.
3. The Writing Group. Safety and efficacy of edaravone in well defined patients with amyotrophic lateral sclerosis: a randomized , double-blind, placebo-controlled trial. *The Lancet* 2017;16(7):505-512.
4. Radicava. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: http://www.micromedexsolutions.com. Accessed July 13, 2017.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
New Policy	*08/17*
Annual Review	*02/18*