Radicava (edaravone)

Background
Radicava (edaravone) is an injectable medication indicated for the treatment of patients with amyotrophic lateral sclerosis (ALS). It is thought that Radicava is a potent free radical scavenger and antioxidant that may provide neuroprotection against oxidative stress. In motor neurons, oxidative stress may contribute to neurodegeneration and the development of ALS (2). ALS is a progressive neurodegenerative disease that affects nerve cells in the brain and spinal cord. The progressive degeneration of the motor neurons in ALS eventually leads to their death. When the motor neurons die, the ability of the brain to initiate and control muscle movement is lost. With voluntary muscle action progressively affected, patients in the later stages of the disease may become totally paralyzed (3).

Regulatory Status
FDA-approved indication: Radicava is indicated for the treatment of patients with amyotrophic lateral sclerosis (ALS) (1).

Studies have shown that riluzole is safe and effective for slowing disease progression to a modest degree in ALS. Riluzole is considered first-line therapy along with nutritional supplements for patients with ALS (4).

The safety and effectiveness of Radicava in pediatric patients have not been established (1).
Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Radicava may be considered medically necessary in patients 18 years or age or older for amyotrophic lateral sclerosis (ALS) and if the conditions indicated below are met.

Radicava is considered investigational in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

The patient must have the following:

Amyotrophic lateral sclerosis (ALS)

AND ALL of the following:

1. Patient has had an inadequate response to riluzole or will continue to take riluzole
2. Baseline evaluation of the condition using ONE of the following scoring tools:
   a. ALS Functional Rating Scale-Revised (ALSFRS-R) with a score of 2 or greater on each individual item of the scale
   b. Japanese ALS Severity Scale with a grade of 1 or 2
3. Normal respiratory function %FVC ≥ 80%
4. Prescribed by or recommended by a neurologist

Prior – Approval Renewal Requirements

Age 18 years of age and older

Diagnosis

The patient must have the following:
Amyotrophic lateral sclerosis (ALS)

AND ALL of the following:
1. Documented stabilization, slowing of disease progression, or improvement of the condition using ONE of the following scoring tools:
   a. ALSFRS-R score – stable or improvement in functional abilities
   b. Japanese ALS Severity Scale – stable or improvement in functional abilities

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits
Duration 12 months

Prior – Approval Renewal Limits
Same as above

Rationale

Summary
Radicava is a potent free radical scavenger and antioxidant used for patient with ALS. The safety and effectiveness of Radicava in pediatric patients have not been established (1). Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of Radicava while maintaining optimal therapeutic outcomes.

References

Policy History

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<td>May 2017</td>
<td>Addition to PA</td>
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<td>September 2017</td>
<td>Annual review</td>
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<td>Addition of ALS Japanese Severity Scale to baseline and improvement</td>
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<td>questions and the inadequate and intolerance and contraindication to</td>
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<td>riluzole was reworded. Addition of prescriber agreeing to consult with</td>
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<td>a neurologist during therapy per SME</td>
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<td>December 2017</td>
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<tr>
<td>August 2018</td>
<td>Addition of requirements of stabilization or slowed progression for</td>
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<td>continuation, removal of requirements for no hepatic or renal impairment</td>
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<td>September 2018</td>
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<td>September 2019</td>
<td>Annual review and reference update</td>
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<td>September 2020</td>
<td>Annual editorial review. Revised initiation wording to “prescribed by or</td>
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<td>recommended by a neurologist”</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 11, 2020 and is effective on October 1, 2020.