BlueCross BlueShield Federal Employee Program

RADICAVA/ RADICAVA ORS (edaravone)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Radicava and Radicava ORS (edaravone) are indicated for the treatment of patients with amyotrophic lateral sclerosis (ALS). It is thought that Radicava and Radicava ORS are potent free radical scavengers and antioxidants 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 and Radicava ORS are 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 and Radicava ORS in pediatric patients have not been established (1).

Summary

Radicava and Radicava ORS are potent free radical scavengers and antioxidants used for patients with ALS. The safety and effectiveness of Radicava and Radicava ORS in pediatric patients have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Radicava and Radicava ORS while maintaining optimal therapeutic outcomes.

References

1. Radicava / Radicava ORS [package insert]. Jersey City, NJ: Mitsubishi Tanabe Pharma

America, Inc.; November 2022.

2. Edaravone Mechanism of Action. *Clinical Pharmacology*. Accessed December 30, 2022.
3. Simon N, Turner M, et al. Quantifying Disease Progression in Amyotrophic Lateral Sclerosis. Annals of Neurology 2014;76:643–657.
4. Miller R, Jackson C, 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; 73; 1218-1226.
5. Abe K, Itoyama Y, 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 Dec; 15(7-8): 610–617.