Amyotrophic lateral sclerosis (ALS), commonly referred to as Lou Gehrig’s disease, is a progressive neurodegenerative disease that affects nerve cells of the brain and the spinal cord. ALS involves both upper motor neuron and lower motor neurons and causes muscle weakness, disability, and eventually death. Those affected may experience atrophy, weakness, spasticity and hyperreflexia. They may lose the ability to speak, eat, move and eventually, breathe. The average length of survival is three to five years from when symptoms first appear.
frequently, people with ALS die from respiratory failure.\textsuperscript{1,2,3}

ALS most commonly occurs in people between the ages of 40 and 70. The Centers for Disease Control and Prevention estimates that approximately 12,000-15,000 Americans are living with ALS.\textsuperscript{1,2}

**Radicava® (edaravone)**

Although there is no cure for ALS, researchers have been working to find treatments to slow the progression of the disease. On May 5, 2017 The U.S. Food and Drug Administration approved Radicava® (edaravone) as a treatment for patients with ALS. Edaravone is a free radical scavenger thought to reduce oxidative stress, which has been linked to the pathogenesis of ALS. Edaravone was previously approved in 2015 in Japan and Korea for the treatment of ALS.\textsuperscript{2,3}

In a six month Japanese clinical trial on the efficacy of edaravone for the treatment of ALS, participants who were given edaravone showed less clinical decline than those in the placebo group. The trial consisted of 137 participants who were randomized to receive edaravone or placebo. At the 24th week individuals receiving edaravone declined less on a clinical assessment of daily functioning compared to those receiving a placebo. This change was considered clinically significant, with a slowing of approximately 33 percent. Additionally, the participants given edaravone experienced less decline on the ALS Assessment Questionnaire.\textsuperscript{2,3}

The Radicava® package insert states that Radicava® (edarovone) is indicated for the treatment of amyotrophic lateral sclerosis (ALS). Dosing is 60 mg administered as an intravenous infusion over 60 minutes. The initial treatment cycle is daily dosing for 14 days followed by a 14-day drug-free period. Subsequent treatment cycles are daily dosing for 10 days out of 14-day periods, followed by 14-day drug-free periods. Radicava® contains sodium bisulfite, which can cause allergic type reactions. The most common adverse reactions are contusion, gait disturbance, and headache.\textsuperscript{4}

The estimated yearly cost of edaravone in the United States is approximately $146,000.\textsuperscript{3}

**POSITION STATEMENT**

**Applicable To:**

- Medicare

**Coverage\textsuperscript{4,5,6,7}**

**Initial authorization: 6 months**

**Initial infusion of Radicava® (edaravone) is considered medically necessary** when all of the following criteria are met:

- Member is 18 years of age or older; **AND**,  
- Medication has been prescribed by a neurologist; **AND**,  
- Member has a documented diagnosis of amyotrophic lateral sclerosis (ALS, Lou Gehrig's Disease) that is confirmed based on El Escorial criteria:  
- Signs of degeneration of lower motor neurons, which are in the spinal cord and brainstem, by clinical examination or specialized testing; **AND**,  
- Signs of degeneration of upper motor neurons, which are in the brain, by clinical examination; **AND**,  
- Progressive spread of signs within a region to other regions; **AND**,  
- The absence of evidence of other disease processes that might explain the observed clinical and electrophysiological signs; **AND**,  
- Member's normal respiratory function: FVC greater than or equal to 80%; **AND**,  

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☑️ Member has had a disease duration of 2 years or less; AND,
☑️ Member has retention of most activities of daily living – defined as scores of 2 or more points on each individual item of the ALS Functional Rating Scale-Revised (ALSFRS-R); AND,
☑️ Radicava® will be used concurrently with riluzole; AND,
☑️ Dosing is as follows: An initial treatment cycle with daily dosing for 14 days, followed by a 14-day drug free period (Cycle 1). Subsequent treatment cycles with daily dosing for 10 days of 14-day periods, followed by 14-day drug-free periods (Cycles 2-6).

Reauthorization: 12 months

Continued infusion of Radicava® (edaravone) is considered medically necessary when all of the following criteria are met:
☑️ Member is 18 years of age or older; AND,
☑️ Medication has been prescribed by a neurologist; AND,
☑️ Member has a documented diagnosis of amyotrophic lateral sclerosis (ALS, Lou Gehrig’s Disease) that is confirmed based on El Escorial criteria:
☑️ Signs of degeneration of lower motor neurons, which are in the spinal cord and brainstem, by clinical examination or specialized testing; AND,
☑️ Signs of degeneration of upper motor neurons, which are in the brain, by clinical examination; AND,
☑️ Progressive spread of signs within a region to other regions; AND,
☑️ The absence of evidence of other disease processes that might explain the observed clinical and electrophysiological signs;
☑️ Radicava® will be used concurrently with riluzole; AND,
☑️ Per prescriber’s assessment, member is benefiting from treatment; AND,
☑️ Subsequent treatment cycles with daily dosing for 10 days of 14-day periods, followed by 14-day drug-free periods.

CODING

Covered CPT Codes – None listed.

Covered HCPCS Codes
C9493 Injection, Edaravone, 1 mg
J3490 Unclassified drug

Covered ICD-10 Code
G12.21 Amyotrophic lateral sclerosis

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member’s benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal/ state laws.

REFERENCES

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7. Safety and efficacy of edaravone in well defined patients with amyotrophic lateral sclerosis: a randomised, double-blind, placebo-controlled trial. Lancer Neurol. 2017

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