



Missouri Care

'Ohana Health Plan, a plan offered by WellCare Health Insurance of Arizona

Children's Medical Services Health Plan (CMS Health Plan)

Staywell of Florida

WellCare (Alabama, Arizona, Arkansas, California, Connecticut, Florida, Georgia, Illinois, Indiana, Kentucky, Louisiana, Maine, Michigan, Mississippi, Missouri, New Hampshire, New Jersey, New York, North Carolina, Ohio, South Carolina, Tennessee, Texas, Washington)

WellCare Prescription Drug Plans (PDP)

WellCare Heritage Health

WellCare TexanPlus (Medicare – Dallas & Houston markets)

Radicava®

Policy Number: HS-323

Original Effective Date: 1/11/2018

Revised Date(s): 2/7/2019; 3/10/2020

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific Medicaid mandates. Links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change. Lines of business are also subject to change without notice and are noted on www.wellcare.com. Guidelines are also available on the site by selecting the Provider tab, then "Tools" and "Clinical Guidelines".

BACKGROUND

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. Most frequently, people with ALS die from respiratory failure.^{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.^{1,2}

Clinical Coverage Guideline

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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.^{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.^{2,3}

The Radicava® package insert states that Radicava® (edaravone) 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.⁴

The estimated yearly cost of edaravone in the United States is approximately \$146,000.³

POSITION STATEMENT

Applicable To:

- Medicaid – All Markets excluding KY
- Children's Medical Services Health Plan (CHIP)
- Medicare – All Markets

Coverage^{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:

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

AND,

4. Member's normal respiratory function: FVC greater than or equal to 80%; **AND**,
5. Member has had a disease duration of 2 years or less; **AND**,
6. 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**,

7. Radicava® will be used concurrently with riluzole; **AND**,
8. 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:

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

AND,

4. Radicava® will be used concurrently with riluzole; **AND**,
5. Per prescriber's assessment, member is benefiting from treatment; **AND**,
6. 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

J1301 Injection, edaravone, 1 mg

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

1. What is ALS? ALS Association Website <http://www.alsa.org/about-als/what-is-als.html>. Published 2017. Accessed February 10, 2020.
2. FDA approves drug to treat ALS. Food and Drug Administration Web site. <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm557102.htm>. Published May 5, 2017. Accessed February 10, 2020.
3. Choudry, R.B., Galvez-Jimenez, N., Cudkowicz, M.E. Disease modifying treatment of amyotrophic lateral sclerosis. UpToDate Web site https://www.uptodate.com/contents/disease-modifying-treatment-of-amyotrophic-lateral-sclerosis?source=search_result&search=radicava&selectedTitle=4-8. Published June 1, 2017. Updated January 17, 2020. Accessed February 10, 2020.
4. Radicava [package insert]. MT Pharma America, Inc. Jersey City, NJ. May 2017
5. Cedarbaum JM, Stambler N, Malta E, et al. The ALSFRS-R: a revised ALS functional rating scale that incorporates assessments of respiratory function. BDNF ALS Study Group (Phase III). J Neurol Sci. 1999;169(1-2):13-21.
6. 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(7-8):610-7.
7. Safety and efficacy of edaravone in well defined patients with amyotrophic lateral sclerosis: a randomised, double-blind, placebo-controlled trial. Lancet Neurol. 2017

MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

Date	Action
3/10/2020, 2/7/2019	• Approved by MPC. No changes.
1/11/2018	• Approved by MPC. New.