

**DRAFT Medical Coverage Policy | Edaravone
(Radicava)**



EFFECTIVE DATE:XXXXXX
POLICY LAST UPDATED: XXXXXX

OVERVIEW

Amyotrophic Lateral Sclerosis (also known as Lou Gehrig’s disease) is a progressive and degenerative motor neuron disease. ALS is characterized by muscle weakness, disability, and eventual death. Progressive neuromuscular respiratory failure is the most common cause of death in ALS patients. A diagnosis of ALS is based upon evidence of upper and lower motor neuron signs, relentless disease progression, and the absence of an alternative etiology. ALS, as with other motor neuron diseases, does not have a diagnostic test that can confirm or entirely exclude its diagnosis. The mainstay of ALS management is symptomatic treatment and palliative care. There are currently two FDA approved therapies for management of ALS; these are riluzole and edaravone.

MEDICAL CRITERIA

Edaravone (Radicava) is medically necessary for initial use when ALL of the following are met:

1. The patient has a diagnosis of amyotrophic lateral sclerosis (ALS) [also known as Lou Gehrig’s disease]
AND
2. ALL of the following:
 - a. The patient has had the diagnosis of ALS for a duration of 2 years or less
AND
 - b. The patient has normal respiratory function defined as having a percent-predicted forced vital capacity (%FVC) of greater than or equal to 80%
AND
 - c. The patient is able to perform most activities of daily living
AND
3. The patient does not have an FDA labeled contraindication to therapy with the requested agent
AND
4. The requested agent has been prescribed by a specialist (e.g. neurologist) or in consultation with a specialist
AND
5. The requested dose is within FDA labeling

Length of Approval: 6 months.

Criteria for Continued Use

Edaravone (Radicava) is medically necessary for continued use when ALL of the following are met:

1. The patient has been previously approved for the requested agent through Medical Drug Review process
AND
2. The prescriber indicates the patient has shown clinical benefit from the requested agent
AND
3. The patient does not have an FDA labeled contraindication to therapy with the requested agent
AND
4. The requested agent has been prescribed by a specialist (e.g. neurologist) or in consultation with a specialist
AND
5. The requested dose is within FDA labeling

Length of Approval: 12 months.

PRIOR AUTHORIZATION

Prior authorization is required for BlueCHiP for Medicare and recommended for Commercial Products

POLICY STATEMENT

BlueCHiP for Medicare and Commercial

Edaravone (Radicava) is medically necessary when the above criteria have been met.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable physician administered drug benefits/coverage.

BACKGROUND

Efficacy

The efficacy of edaravone was evaluated in a post-hoc analysis of a 6-month, phase III randomized, placebo-controlled, double-blind study, in patients aged 20 to 75 years with ALS. All study patients had to meet all of the following criteria at screening:

1. Functionality retained most activities of daily living (defined as scores of 2 points or better on each individual item of the ALS Functional Rating Scale – Revised [ALSFRS-R])
2. Normal respiratory function (defined as percent-predicted forced vital capacity [%FVC] values of greater than or equal to 80%)
3. Definite or probable ALS based on the El Escorial revised criteria
4. Disease duration of 2 years or less

Patients who met the criteria above (n= 137) were randomized to receive either edaravone 60 mg intravenously (IV) or placebo for 6 cycles (4 weeks per cycle with 2 weeks on, 2 weeks off). 91% of patients in both the edaravone and placebo group were also receiving treatment with riluzole. The primary efficacy endpoint was change in the Revised ALS Functional Rating Scale (ALSFRS-R) score from baseline to 24 weeks or therapy discontinuation (if discontinuation occurred after the third cycle) after randomization. The change in ALSFRS-R score was -5.01 (SE 0.64) and -7.50 (0.66) in the edaravone and placebo group respectively. The trial authors concluded edaravone showed efficacy in a small subset of patients (i.e. those meeting the criteria noted above) and that “there is no indication that edaravone might be effective in a wider population of patients with ALS who do not meet the criteria”.

Safety

The most common adverse events associated with edaravone are contusion, gait disturbance, and headache. Adverse events observed post FDA approval of edaravone include hypersensitivity reactions and anaphylaxis. Edaravone is contraindicated in patients with history of hypersensitivity to edaravone or any of its inactive ingredients.

Compendia Supported Indications

For the purposes of the oncology criteria, indications deemed appropriate are those that are supported by NCCN Drugs & Biologics compendia with a category 1 or 2A recommendation.

CODING

There is no specific HCPCS code at this time, claims must be filed with an unlisted code such as J3490 and the NDC number.

RELATED POLICIES

None

PUBLISHED

Provider Update, September 2017

REFERENCES:

1. Radicava prescribing information. MT Pharma. May 2017.
2. UpToDate. Diagnosis of amyotrophic lateral sclerosis. Accessed June 2017
3. Koji Abe, Mashashi Aoki, Shoji Tsuji, et al. Safety and efficacy of edaravone in well defined patients with amyotrophic lateral sclerosis: a randomized double-blind, placebo-controlled trial. *Lancet Neurology*. 2017 May 15, S1474-4422(17)30115-1

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