

Radicava® (edaravone injection) **J3490**



When requesting Radicava® (edaravone injection), the individual requiring treatment must be diagnosed with an FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved indication

Radicava is indicated for the treatment of amyotrophic lateral sclerosis (ALS).

Approved Off-label Compendial use(s)

None

Coverage Guidelines

The individual must meet **all** of the following criteria for approval:

- Meet the following El Escorial revised criteria for the diagnosis of amyotrophic lateral sclerosis (ALS):
 - ❖ Has signs of degeneration of lower motor neurons
 - ❖ Has signs of degeneration of upper motor neurons
 - ❖ Has progressive spread of signs within a region or to other regions
 - ❖ No evidence of other disease process that might explain the observed clinical and electrophysiological signs
- Has normal respiratory function defined as percent-predicted forced vital capacity [%FVC] greater than or equal to 80%
- Is retaining functionality in most activities of daily living (i.e., defined as scores of 2 points or better on each individual item of the ALS functional Rating Scale-Revised [ALSFRS-R])
- Is 18 years of age or older
- For an initial authorization, an individual's disease duration has been 2 years or less
- For re-authorization, an individual is benefiting from Radicava therapy (e.g., delayed progression of ALS, less decline in ALS Functional Rating Scale-Revised [ALSFRS-R] score)

Approval duration (initial and renewal): 12 months

References

1. Radicava [prescribing information]. Jersey City, NJ; Mitsubishi Tanabe Pharma Corporation. May 2017. Available at: <https://www.radicava.com/assets/dist/pdfs/radicava-prescribing-information.pdf> . Accessed on October 10, 2017.
2. Miller RG, Jackson CE, Kasarskis EJ, et al. Practice Parameter update: The care of the patient with amyotrophic lateral sclerosis: Drug, nutritional, and respiratory therapies (evidence-based review). *Neurology*. 2009;73:1218-1226
3. Safety and efficacy of edaravone in well defined patients with amyotrophic lateral sclerosis: a randomised, double-blind, placebo-controlled trial. *Lancet Neurol*. 2017;16(7):505-512
4. U.S. Food & Drug Administration. Drug Trials Snapshots: Radicava. Available at: <https://www.fda.gov/Drugs/InformationOnDrugs/ucm558438.htm> . Accessed on October 11, 2017.\
5. El Escorial World Federation of Neurology Criteria for the Diagnosis of ALS. The ALS Association. Available at: <http://www.alsa.org/als-care/resources/publications-videos/factsheets/criteria-for-diagnosis.html> . Accessed on October 30, 2017.