

edaravone (Radicava)

Commercial Medical Benefit Drug Policy

Place of Service

Home Infusion Administration

Infusion Center Administration

Office Administration

Outpatient Facility Administration

Drug Details

USP Category: CENTRAL NERVOUS SYSTEM AGENTS

Mechanism of Action: free radical scavenger

HCPCS:

J1301:Injection, edaravone, 1 mg

How Supplied:

30 mg/100 mL (0.3 mg/mL) single-dose bag

Condition(s) listed in policy (see coverage criteria for details)

- Amyotrophic Lateral Sclerosis (ALS)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, ASO, Shared Advantage, HMO (non-direct)** may be required to have their medication administered at a preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

edaravone (Radicava)

CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION

MCG Care Guidelines, 19th edition, 2015

ADMINISTRATION OF RADICAVA IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE

REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted*)

1. Patient is receiving their first 14-day course of infusions of Radicava or is being re-initiated on Radicava after at least 6 months off therapy. *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

OR

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. Patient has experienced a previous severe adverse event on Radicava based on documentation submitted.
3. Patient continues to experience moderate to severe adverse events on Radicava based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.
4. Patient is clinically unstable based on documentation submitted.
5. Patient is physically or cognitively unstable based on documentation submitted.

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice.

Amyotrophic Lateral Sclerosis (ALS)

Meets medical necessity if all the following are met:

1. Diagnosed by neurologist for Definite or Probable ALS based on El Escorial criteria
2. Functionality retained in 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)
3. Normal respiratory function (%-predicted forced vital capacity values of [%FVC] $\geq 80\%$)
4. Patient has received concurrent or prior treatment with riluzole OR patient is unable to take riluzole

Covered Doses:

Initial cycle: up to 60 mg given intravenously once daily on days 1-14 of a 28-day cycle

Subsequent cycles: up to 60 mg given intravenously on 10 out of the first 14 days of each 28-day cycle

Coverage Period:

Every 6 months based on continued response and patient has not progressed to become dependent on a ventilator.

ICD-10:

G12.21

References

edaravone (Radicava)

1. AHFS. Available by subscription at <http://www.lexi.com>
2. DrugDex. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
3. Radicava (edaravone) Prescribing Information. Mitsubishi Tanabe Pharma America Inc., Jersey City, NJ: 11/2022.
4. 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 (an evidence-based review): report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology*. 2009;73(15):1218-1226. Reaffirmed January 25, 2023. Available at: <https://www.aan.com/Guidelines/home/GuidelineDetail/370>.
5. Van Damme P, Al-Chalabi A, Andersen PM, et al. European Academy of Neurology (EAN) guideline on the management of amyotrophic lateral sclerosis in collaboration with European Reference Network for Neuromuscular Diseases (ERN EURO-NMD). *Eur J Neurol*. 2024;31(6):e16264. Available at: <https://onlinelibrary.wiley.com/doi/10.1111/ene.16264>.

Review History

Date of Last Annual Review: 3Q2025

Changes from previous policy version:

- No clinical change following annual review.

Blue Shield of California Medication Policy to Determine Medical Necessity

Reviewed by P&T Committee

edaravone (Radicava)