edaravone (RADICAVA)

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 California Code of Regulations (CCR), Title 22, Section 51303 and 51313 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.

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

Amyotrophic Lateral Sclerosis (ALS)
Meets medical necessity if all the following are met:
Initial
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] ≥ 80%)

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4. Patient has received concurrent or prior treatment with riluzole OR patient is unable to take riluzole

Reauthorization

1. Patient is responding to therapy
2. Patient has not progressed to become dependent on a ventilator

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:
6 months

ICD-10:
G12.21

References

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]. Florham Park, NJ: Shionogi Inc; May 2026.
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: 3Q2026
Changes from previous policy version:

- No clinical changes following annual review.

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee