

Edaravone (Radicava®)

Place of Service

Office Administration

Infusion Center Administration

Home Infusion Administration

Outpatient Facility Administration*

[*Prior authorization required – see section (1)]

HCPCS: J1301 per 1 mg

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

- [Amyotrophic lateral sclerosis](#)

AHFS therapeutic class: Central Nervous System Agents, Miscellaneous

Mechanism of action: Free radical scavenger

(1) Special Instructions and Pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

****CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION****

AAAAI Guidelines 2011, MCG™ Care Guidelines, 19th edition, 2015

Members with the following plans: **PPO, Direct Contract HMO, Medi-Cal, and when applicable, ASO, Shared Advantage, HMO (non-direct contract)**, 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.

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 with 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.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Radicava (edaravone) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Amyotrophic lateral sclerosis (ALS)

1. 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], **AND**
2. Normal respiratory function (%-predicted forced vital capacity values of [%FVC] \geq 80%), **AND**
3. Diagnosis by neurologist of Definite or Probable ALS based on EI Escorial revised criteria, **AND**
4. Patient has received concurrent or prior treatment with riluzole OR has medical reason why riluzole cannot be used.

Covered Doses

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

Subsequent cycles: up to 60 mg IV on 10 of the first 14 days of 28-day cycles

Coverage Period

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

ICD-10: G12.21

(3) The following condition(s) **DO NOT** require Prior Authorization/Preservice

All requests for Radicava® (edaravone) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

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

(6) References

- AHFS®. Available by subscription at <http://www.lexi.com>
- DrugDex®. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
- Radicava® (edaravone) [Prescribing information]. Jersey City, NJ: Mitsubishi Tanabe Pharma Corporation; 5/2022.

(7) Policy Update

Date of last review: 3Q2023

Date of next review: 3Q2024

Changes from previous policy version:

- No clinical change to policy following routine annual review.

*BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee*