

<b>Policy Name:</b>	<b>Radicava (edaravone)</b>	<b>Policy #:</b>	<b>2594P</b>
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## Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Radicava intravenous and Radicava ORS oral solution.

## Statement of the Policy

Health Alliance Medical Plans will approve the use of Radicava under the specialty pharmacy benefit or Medicare Part B when the following criteria have been met.

## Criteria

### 1. Coverage Criteria

- 1.1 Diagnosis of definite or probable Amyotrophic Lateral Sclerosis (ALS) per the revised El Escorial and Airlie House diagnostic criteria
- 1.2 Prescribed by or in consultation with a Neurologist with expertise in the diagnosis of ALS
- 1.3 Submission of the most recent [ALS Functional Rating Scale-Revised \(ALSFRS-R\) score](#) confirming that the patient has scored 2 in ALL items of the ALSFRS-R criteria at the start of treatment
- 1.4 Documentation confirming that the patient has a % forced vital capacity (%FVC) 80% at the start of treatment
- 1.5 Review of chart notes documenting diagnosis and confirming that patient has met all of the above requirements for treatment with Radicava by both a pharmacist and medical director

### 2. Exclusion Criteria

- 2.1 Patient is dependent on invasive ventilation
- 2.2 Patient has a tracheostomy

### 3. Approval Period

- 3.1 Initial Approval: 12 months
- 3.2 Subsequent Approvals: 12 months with documentation that the patient is not dependent on invasive ventilation and does not have a tracheostomy

## CPT Codes

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## HCPCS Codes

J1301	Injection, edaravone, 1mg
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## References

1. Radicava (edaravone) [prescribing information]. Jersey City, NJ: MT Pharma America Inc; November 2022.
2. ALS 16 Study Group. A post-hoc subgroup analysis of outcomes in the first phase III clinical study of edaravone (MCI-186) in amyotrophic lateral sclerosis. *Amyotroph Lateral Scler Frontotemporal Degener.* 2017 Oct;18(sup1):11-19.
3. Oskarsson B, Gendron TF, Staff NP. Amyotrophic Lateral Sclerosis: An Update for 2018. *Mayo Clin Proc.* 2018 Nov;93(11):1617-1628.
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). *Neuro.* 2009 Oct 13;73(15):1218-26. Reaffirmed in 2020.

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#### DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.