

STANDARD MEDICARE PART B MANAGEMENT

RADICAVA (edaravone)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

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

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. REQUIRED DOCUMENTATION

The following documentation must be available upon request for all submissions:

- A. For initial approval, chart notes confirming diagnosis of definite or probable ALS (e.g., medical history and diagnostic testing including, nerve conduction studies, imaging and laboratory values to support the diagnosis)
- B. For initial approval, chart notes or documentation confirming the member has scores of at least 2 points on all 12 areas of the revised ALS Functional Rating Scale (ALSFRS-R)
- C. For continuation of therapy, documentation of clinical benefit from Radicava therapy

III. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with a neurologist, neuromuscular specialist, or physician specializing in the treatment of amyotrophic lateral sclerosis (ALS).

IV. CRITERIA FOR INITIAL APPROVAL

Amyotrophic Lateral Sclerosis (ALS)

Authorization of 12 months may be granted for treatment of ALS when both of the following criteria are met:

- A. Diagnosis of definite or probable ALS (e.g., medical history and diagnostic testing including, nerve conduction studies, imaging and laboratory values to support the diagnosis)
- B. Member has scores of at least 2 points on all 12 areas of the revised ALS Functional Rating Scale (ALSFRS-R)

V. CONTINUATION OF THERAPY

Reference number(s)
2066-A

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- A. The member is currently receiving treatment with Radicava.
- B. Radicava is being used for the treatment of definite or probable ALS.
- C. There is a clinical benefit from Radicava therapy.

VI. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:

- 1. The prescribing information for Radicava.
- 2. The available compendium
 - a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
 - b. Micromedex DrugDex
 - c. American Hospital Formulary Service- Drug Information (AHFS-DI)
 - d. Lexi-Drugs
 - e. Clinical Pharmacology
- 3. EFNS guidelines on the Clinical Management of Amyotrophic Lateral Sclerosis (MALS) – revised report of an EFNS task force

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Radicava are covered.

VII. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

VIII. REFERENCES

- 1. Radicava [package insert]. Jersey City, NJ: MT Pharma America, Inc.; May 2022.
- 2. EFNS Task Force on Diagnosis and Management of Amyotrophic Lateral Sclerosis; Andersen PM, et al. EFNS guidelines on the Clinical Management of Amyotrophic Lateral Sclerosis (MALS) – revised report of an EFNS task force. *Eur J Neurol.* 2012;19(3):360-75.