

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 Indications

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. CRITERIA FOR INITIAL APPROVAL

Amyotrophic Lateral Sclerosis (ALS)

Authorization of 12 months may be granted for the treatment of ALS.

III. CONTINUATION OF THERAPY

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 ALS.
- C. There is a clinical benefit from Radicava therapy.

IV. REFERENCES

1. Radicava [package insert]. Jersey City, NJ: MT Pharma America, Inc.; July 2019.
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.
3. Clinical Consult: CVS Caremark Clinical Programs Review. Focus on Hematology/Oncology Clinical Programs. June 2018