Reference number(s)
2066-A

Standard Medicare Part B Management Radicava

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Radicava	edaravone

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[1,3]

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 listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Documentation

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

Chart notes or medical record documentation supporting use as applicable in the coverage criteria and continuation of therapy sections.

- Initial Requests:
    - Diagnosis of definite or probable amyotrophic lateral sclerosis (ALS).

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    - ALS Functional Rating Scale (ALSFRS-R) results.
- Continuation Requests:
    - Documentation of clinical benefit from therapy with the requested medication.

Coverage Criteria

Amyotrophic Lateral Sclerosis (ALS)[1,3]

Authorization of 12 months may be granted for treatment of amyotrophic lateral sclerosis (ALS) when both of the following criteria are met:

- Member has 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).
- Member has scores of at least 2 points on all 12 areas of the revised ALS Functional Rating Scale (ALSFRS-R).

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:

- The member is currently receiving treatment with the requested medication.
- The requested medication is being used for the treatment of definite or probable amyotrophic lateral sclerosis (ALS).
- There is a clinical benefit from therapy with the requested medication.

Summary Of Evidence

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

- The prescribing information for Radicava.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)

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    - Lexi-Drugs
    - Clinical Pharmacology
- 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.

Explanation Of Rationale

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

References

1. Radicava [package insert]. Jersey City, NJ: MT Pharma America, Inc.; November 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.
3. edaravone [package insert]. Big Flats, NY: XGen Pharmaceuticals DJB, Inc.; September 2024.

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