Reference number
1961-A

SPECIALTY GUIDELINE MANAGEMENT

RADICAVA (edaravone)
RADICAVA ORS (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 and Radicava ORS are indicated for the treatment of amyotrophic lateral sclerosis (ALS).

All other indications are considered experimental/investigational and not medically necessary.

II. REQUIRED DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
Chart notes or medical record documentation supporting use as applicable in section IV and V.

A. Initial Requests:
   1. 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)
   2. Member has scores of at least 2 points on all 12 areas of the revised ALS Functional Rating Scale
B. Continuation Requests:
   1. 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

Authorization of 12 months may be granted for treatment of ALS when all 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)
C. Continuous use of ventilatory support during the day and night is not required (noninvasive or invasive)

V. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for members continuing with Radicava therapy for the treatment of ALS when the following criteria are met:

A. Diagnosis of definite or probable ALS
B. There is a clinical benefit from Radicava therapy
C. Invasive ventilation is not required

VI. 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.
3. Writing Group, Edaravone (MCI-186) ALS 19 Study Group. Safety and efficacy of edaravone in well defined patients with amyotrophic lateral sclerosis: a randomized, double-blind, placebo-controlled trial. *Lancet Neurol*. 2017; 16:505-512.