SPECIALTY GUIDELINE 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 are considered experimental/investigational and are not a covered benefit.

II. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with a neuromuscular specialist.

III. CRITERIA FOR INITIAL APPROVAL

Authorization of 6 months may be granted for treatment of ALS when all of the following criteria are met:
A. Diagnosis of definite or probable ALS
B. Duration of ALS is 2 years or less
C. Functional ability is retained for most activities of daily living (ADLs)
D. Ventilatory support, noninvasive or invasive, is not required

IV. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for members continuing with Radicava therapy when the following criteria are met:
A. Diagnosis of definite or probable ALS
B. There is a clinical benefit from Radicava therapy such as stabilization of functional ability and maintenance of ADLs
C. Invasive ventilation is not required

V. REFERENCES

1. Radicava [package insert]. Jersey City, NJ: MT Pharma America, Inc.; May 2017.
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.