

Reference number
1961-A

# 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 one initiation cycle (14 days of daily treatment and 14 days of rest) and five continuation cycles (14 days containing ten days of treatment followed by 14 days of rest) may be granted for treatment of ALS when all of the following criteria are met:

- A. Prescription was performed or certified by a neurologist specializing in the diagnosis and treatment of ALS;
- B. Diagnosis of “definite” or “probable” ALS using the Revised EL Escorial and Airlie House criteria;
- C. Duration of ALS is 2 years or less;
- D. Functional ability is rated at least two on the ALS Functional Rating Scale – Revised (ALSFRS – R) for all assessed activities of daily living (ADLs) at time of assessment for treatment;
- E. Ventilatory support, noninvasive or invasive, is not required, as indicated by a forced vital lung capacity of at least 80%, at time of assessment for treatment

#### IV. CONTINUATION OF THERAPY

Authorization of six continuation cycles (14 days containing ten treatments followed by 14 days of rest) may be granted for members continuing with Radicava therapy when the following criteria are met:

- A. Diagnosis of “definite” or “probable” ALS using the Revised EL Escorial and Airlie House criteria is 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.
3. Geevasinga N, Menon P, Scherman DB, Simon N, Yiannikas C, Henderson RD, Kiernan MC, and Vucic S. Diagnostic criteria in amyotrophic lateral sclerosis: A multicenter prospective study. *Neurology.* 2016 Aug 16; 87(7): 684 - 90.

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4. Nagase M, Yamamoto Y, Miyazaki Y, Yoshino H. Increased oxidative stress in patients with amyotrophic lateral sclerosis and the effect of edaravone administration. Redox Rep. 2016 May;21(3):104 - 12.