| Effective Date: 1/1/2023 |
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| Last Reviewed: 9/2022, 1/2023, 12/2023, 03/2024, 03/2025<br>Scope: Medicaid |

# 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 ORS is indicated for the treatment of amyotrophic lateral sclerosis (ALS).

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

### II. 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).

### III. CRITERIA FOR INITIAL APPROVAL

**Amyotrophic lateral sclerosis (ALS)**
Authorization of 6 months may be granted for members when all the following criteria are met:

1. Documentation that the member is 18 years of age or older
2. Documentation that the member has a diagnosis of clinically definite or probable ALS
3. Documentation that the member has a disease duration of 2 years or less
4. Documentation that the member has a percent-predicted forced vital capacity (%FVC) ≥ 80%
5. Baseline documentation of retained functionality for most activities of daily living [i.e., score of 2 or better on each* individual item of the ALS Functional Rating Scale – Revised (ALSFRS-R)]
6. Documentation that Radicava ORS will not be used in combination with other formulations of edaravone (i.e., intravenous)

***Note**: the ALSFRS-R is a 12-item questionnaire assessing functional disease progression across four domains including bulbar, fine motor, gross motor, and respiratory. Each item is scored on a five-point ordinal scale from 0 (loss or significant impairment) up to 4 (normal function) with a possible cumulative score of 48. A score of 2 or better on each item would correspond to a minimum ALSFRS-R score of 24.

### IV. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for members requesting continuation of therapy when all of the following criteria are met:

1. Documentation that the member has a diagnosis of clinically definite or probable ALS

2. Documentation that the member has a percent-predicted forced vital capacity (%FVC) ≥ 80%
3. Documentation that the member has responded to therapy compared to pretreatment baseline with disease stability or mild progression indicating a slowing of decline on the ALSFRS-R (patient has not experienced rapid disease progression while on therapy)
4. Documentation that the member does not have a cumulative score on the ALSFRS-R of ≤ 3 (The cumulative possible score on the ALSFRS-R is 48; a cumulative score of 3 indicates loss/significant impairment [i.e., item score of zero] in nine or more items on the 12-item questionnaire)
5. Documentation that the member has not experienced any unacceptable toxicity from the drug. Examples of unacceptable toxicity are hypersensitivity reactions (e.g., redness, wheals, and erythema multiforme), anaphylaxis (e.g., urticaria, decreased blood pressure, and dyspnea), and sulfite allergic reactions.
6. Documentation that the member's respiratory status does not require invasive ventilation or tracheostomy
7. Documentation that Radicava ORS will not be used in combination with other formulations of edaravone (i.e., intravenous)

## V. QUANITY LIMIT

Radicava ORS has a quantity limit of 50 ml per 28 days, with post-limit for initial treatment cycle of 70 ml per 28 days.

| Indication | Dose |
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| ALS | 105 mg (5 mL) taken orally or via feeding tube in the morning after overnight fasting<br><br>• Initial treatment cycle: daily dosing for 14 days, followed by a 14-day drug-free period<br>• Subsequent treatment cycles: daily dosing for 10 days out of 14-day periods, followed by 14-day drug-free periods<br><br>Switching from Radicava to Radicava ORS:<br>• Patients treated with 60 mg of Radicava intravenous infusion may be switched to 105 mg (5 mL) Radicava ORS using the same dosing frequency. Upon switching to Radicava ORS, patients should follow dosing recommendations with regards to food consumption. |

## VI. REFERENCES

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3. Cedarbaum JM, Stambler N, Malta E, et al. The ALSFRS-R: a revised ALS functional rating scale that incorporates assessments of respiratory function. BDNF ALS Study Group (Phase III). J Neurol Sci. 1999 Oct 31;169(1-2):13-21.

4. Miller RG, Jackson CE, Kasarskis EJ, et al. Practice parameter update: the care of the patient with amyotrophic lateral sclerosis: drug, nutritional, and respiratory therapies (an evidence-based review): report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology. 2009 Oct 13;73(15):1218-26.
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6. Hardiman O, van den Berg LH, Kiernan MC. Clinical diagnosis and management of amyotrophic lateral sclerosis. Nat Rev Neurol. 2011 Oct 11;7(11):639-49.
7. Costa J, Swash M, de Carvalho M. Awaji criteria for the diagnosis of amyotrophic lateral sclerosis: a systematic review. Arch Neurol. 2012 Nov;69(11):1410-6.
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