

(except Medicare)Clinical Policy Title:	edaravone
Policy Number:	RxA.260
Drug(s) Applied:	Radicava ORS®
Original Policy Date:	02/07/2020
Last Review Date:	09/04/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Amyotrophic Lateral Sclerosis (ALS) (must meet all):

1. Diagnosis of definite or probable ALS per El Escorial diagnostic criteria;
2. The member's therapy includes concomitant use of riluzole at maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
3. Member is of independent living status (defined as patients who can eat a meal, excrete, or move with oneself alone, and do not need assistance in everyday life);
 - a. Member's forced vital capacity of 80% or greater;
 4. Member disease duration is of 2 years or less;
 5. Member's baseline revised ALS Functional Rating Scale (ALSFRS-R) score with 2 points or greater in each of the 12 items.

Approval Duration

All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

A. Amyotrophic Lateral Sclerosis (must meet all):

1. Member is currently receiving or has been treated with this medication within the past 120 days, excluding manufacturer samples;
2. Member continues to meet the following criteria (a, b, and c):
 - a. Independent living status;
 - b. Forced vital capacity of 80% or greater;1
 - c. Revised ALSFRS-R score with 2 points or greater in each of the 12 items.

Approval Duration

All Lines of Business (except Medicare): 6 months

References

1. Abe K, Itoyama Y, Sobue G, et al. Confirmatory double-blind, parallel-group, placebo-controlled study of efficacy and safety of edaravone (MCI-186) in amyotrophic lateral sclerosis patients. *Amyotrophic Lateral Sclerosis and Frontotemporal Degeneration*. 2014;15(7-8), 610-617. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4266079/>. Accessed September 4, 2024.

Review/Revision History	Review/Revised Date	P&T Approval Date
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This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

Policy established.	01/2020	02/07/2020
<p>Policy reviewed.</p> <ol style="list-style-type: none"> 1. Formatting updated. 2. References updated. 3. Clinical Policy Title updated. 4. Drug(s) Applied updated. 5. Line of Business updated. 6. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 	06/21/2020	09/14/2020
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Policy title table updated. 2. Continued therapy criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 3. References were updated. 	04/22/2021	06/10/2021
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Initial Approval Criteria, I.A.3: Updated age criteria from age is ≥ 20 years to Age is ≥ 18 years. 2. Initial Approval Criteria I.A.4: Updated to remove independent living status (defined as patients who can eat a meal, excrete, or move with oneself alone, and do not need assistance in everyday life). 3. Continued Therapy Criteria II.A 3.a: Updated to remove Independent living status. 4. References were reviewed and updated. 	01/21/2022	04/18/2022
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Initial Approval Criteria, I.A.5: Updated to include new diagnostic criteria independent living status (defined as patients who can eat a meal, excrete, or move with oneself alone, and do not need assistance in everyday life). 2. Continued Therapy Approval Criteria, II.A.3.a: Updated to include Independent living status; 	12/30/2022	04/13/2023

3. References were reviewed and updated.		
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed Radicava from policy.	03/15/2024	02/28/2024
Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions. 4. Updated Continued therapy approval with the new verbiage containing 120 days lookback period. 5. Removed reauthorization requirements for positive response to therapy. 6. Updated approval duration verbiage. 7. References were reviewed and updated.	9/4/2024	09/12/2024