



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EDARAVONE ORAL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EDARAVONE	RADICAVA ORS		52318	GPI-14 (74509030001820)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of amyotrophic lateral sclerosis (ALS) and meet **ALL** the following?
 - Therapy is prescribed by or in consultation with a neurologist or ALS specialist at an ALS Specialty Center or Care Clinic
 - The duration of patient's disease (from onset of symptoms) is 3 years or less
 - The patient has a forced vital capacity (FVC) greater than 70%
 - The patient has mild to moderate ALS with a score of 2 or higher in all of the following 12 items of the Amyotrophic Lateral Sclerosis Functional Rating Scale Revised (ALSFRS-R): speech, salivation, swallowing, handwriting, cutting food, dressing and hygiene, turning in bed, walking, climbing stairs, dyspnea, orthopnea, respiratory insufficiency
 - The patient has tried riluzole OR is currently taking riluzole

If yes, enter two approvals by GPID or GPI-14 for a total of 6 months as follows:

- **FIRST APPROVAL:** Approve for 30 days with a quantity limit of #70mL per 28 days.
- **SECOND APPROVAL:** Approve for 5 months with a quantity limit of #50mL per 28 days (Enter a start date of 2 days before the end of the first approval).

If no, do not approve.

INITIAL DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.*

Our guideline named **EDARAVONE ORAL (Radicava ORS)** requires the following rule(s) be met for approval:

- A. You have amyotrophic lateral sclerosis (ALS: a type of brain and nerve condition)
- B. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor) or ALS specialist at an ALS Specialty Center or Care Clinic
- C. You have had ALS (from onset of symptoms) for 3 years or less
- D. You have a forced vital capacity (FVC: amount of air exhaled from lungs) of greater than 70 percent
- E. You have tried riluzole OR are currently taking riluzole
(Initial denial text continued on next page)

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INITIAL CRITERIA (CONTINUED)

- F. You have mild to moderate ALS with a score of 2 or higher in all of the following 12 items of the Amyotrophic Lateral Sclerosis Functional Rating Scale Revised (ALSFERS-R: a tool for evaluating functional status): speech, salivation, swallowing, handwriting, cutting food, dressing and hygiene, turning in bed, walking, climbing stairs, dyspnea (difficulty breathing), orthopnea (shortness of breath while lying down), respiratory insufficiency (a type of breathing condition)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of amyotrophic lateral sclerosis (ALS) and meet **ALL** of the following criteria?
 - The patient does not require invasive ventilation
 - The patient has improved baseline functional ability OR the patient has maintained a score of 2 or greater in all 12 items of the ALSFRS-R

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #50mL per 28 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **EDARAVONE ORAL (Radicava ORS)** requires the following rule(s) be met for renewal:

- A. You have amyotrophic lateral sclerosis (ALS: a type of brain and nerve condition)
- B. You do not require invasive ventilation (inserting a breathing tube into your throat)
- C. You have improved baseline functional ability OR you have maintained a score of 2 or greater in all 12 items of the Amyotrophic Lateral Sclerosis Functional Rating Scale Revised (ALSFERS-R)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Radicava ORS.

REFERENCES

- Radicava ORS [Prescribing Information].]. Jersey City, NJ: Mitsubishi Tanabe Pharma America, Inc.; May 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 06/15/22

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P&T Approval: 04/22