

Sample Letter of Medical Necessity for RADICAVA® (edaravone)

This letter provides an example of the types of information that may be included when responding to a request from a patient's insurance company to provide a Letter of Medical Necessity for RADICAVA®. Use of the information in this letter does not guarantee that the health plan will provide reimbursement for RADICAVA®, and it is not intended to be a substitute for, or to influence, the independent medical judgment of the physician.

Helpful tips

- You may consider including a letter of medical necessity (like the example on page 2 of this document) with your prior authorization (PA) request to emphasize the medical necessity for RADICAVA® or in addition to your appeal letter, as needed
- Letters of medical necessity should be signed by the **physician only**
- Be sure to include an appropriate *International Classification of Diseases, Tenth Revision, Clinical Modification* (ICD-10-CM) that matches your patient's diagnosis
- When you download this document, **make certain to delete pages 1 and 3 of this document**

Example Checklist Summary

- Example chart notes
 - Date of initial diagnosis
 - ALSFRS-R score
 - FVC score
 - Brief description of the patients' recent symptoms and conditions, including current motor function
 - Previous therapies the patient has undergone for the symptoms associated with their condition, and patient's response to these therapies
- A PDF of the Prescribing Information for RADICAVA®

INDICATION

Radicava® (edaravone) is indicated for the treatment of amyotrophic lateral sclerosis (ALS).

IMPORTANT SAFETY INFORMATION

Hypersensitivity Reactions

Radicava® is contraindicated in patients with a history of hypersensitivity to edaravone or any of the inactive ingredients in Radicava®. Hypersensitivity reactions (redness, wheals, and erythema multiforme) and cases of anaphylaxis (urticaria, decreased blood pressure, and dyspnea) have been reported. Patients should be monitored carefully for hypersensitivity reactions, and if they occur, discontinue Radicava®, treat per standard of care, and monitor until the condition resolves.

Please see Indication and full Important Safety Information on last page and Prescribing Information for RADICAVA®, also available at radicava.com.

Sample Format Letter of Medical Necessity

[Insert Your Practice/Physician Letterhead]

Attn: [Insert Medical Director's Name]

RE: [Insert Patient Name]
[Insert Name of Insurance Company]
[Insert Address]
[Insert City, State ZIP Code]

DOB: [Insert Patient's Date of Birth]
Policy Number: [Insert Patient Policy Number]
Claim Number: [Insert Patient Claim Number]

[Date]

Dear [Insert Contact Name]:

[Insert Patient Name] has been under my care for [Insert diagnosis] [Insert ICD-10-CM code] since [Insert Date]. Treatment of [Insert Patient name] with RADICAVA® (edaravone) is medically appropriate and necessary and should be covered and reimbursed. This letter outlines my conclusion of medical necessity for RADICAVA® and provides details about [Insert Patient Name]'s medical history, prognosis, and treatment rationale for RADICAVA®. A copy of the prescribing information for RADICAVA®, which is indicated for this condition, may be accessed at radicavahcp.com.

[NOTE: Exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition. You may want to include:]

Summary of Patient's Medical History:

- [Patient's diagnosis, date of diagnosis, condition, and history, including ALSFRS-R and FVC scores]
- [Previous therapies used for treating the symptoms associated with the condition]
- [Patient's response to these therapies]
- [Brief description of the patient's recent symptoms and conditions, including current motor function]
- [Summary of your professional opinion of the patient's prognosis and need for RADICAVA®]

Rationale for Treatment

[NOTE: This section should include your clinical rationale and reasons for urgency for the patient's treatment with RADICAVA®. You may consider the following:]

Fact about RADICAVA®

- [The FDA approved RADICAVA® for the treatment of amyotrophic lateral sclerosis (ALS). The FDA-approved label should be the primary basis for the criteria used to determine insurance coverage.]
- [RADICAVA® has demonstrated in clinical trials to slow the decline in the loss of physical function.]
- [The most common side effects of RADICAVA® include bruising (contusion), problem walking (gait disturbance), and headache.]

About ALS

- [The importance of early diagnosis]

Please call my office at [Insert primary phone number] if I can provide you with any additional information. I look forward to receiving your timely response and approval of this claim.

Sincerely,

[Insert physician's name and participating provider number]

RADICAVA® (edaravone) INDICATION AND IMPORTANT SAFETY INFORMATION

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Sulfite Allergic Reactions

Radicava® contains sodium bisulfite, and may cause allergic type reactions, including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown, but occurs more frequently in asthmatic people.

Most Common Adverse Reactions

Most common adverse reactions (at least 10% and greater than placebo) are contusion, gait disturbance, and headache.

Pregnancy

Based on animal data, Radicava® may cause fetal harm.

Geriatric Use

No overall differences in safety or effectiveness were observed between patients 65 years of age and older and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

To report suspected adverse reactions or product complaints, contact Mitsubishi Tanabe Pharma America, Inc. at 1-888-292-0058. You may also report suspected adverse reactions to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see Prescribing Information for RADICAVA®, also available at radicava.com.

RADICAVA is a registered trademark of Mitsubishi Tanabe Pharma Corporation.

For US audiences only.

Mitsubishi Tanabe Pharma America, Inc.

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