Sample Appeal Letter 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 an appeal letter 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 an appeal letter (like the example on page 2 of this document) if coverage is denied because your patient's condition did not meet the plan's criteria for treatment with RADICAVA®
- An appeal letter should be signed by **both** the physician and the patient
- 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

- ❑ Appeal form recommended by health plan
- ❑ 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 copy 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 Appeal Letter

[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]:

This letter serves as the [Select one: 1st/2nd] appeal for approval of treatment with RADICAVA® for my patient, [Insert Patient name]. Based on your letter of denial dated [MM, DD, YYYY], coverage was denied because my patient's condition did not meet the plan's criteria, specifically [Insert the reason(s) provided in denial letter].

[Insert Patient name] has been under my care for [Insert diagnosis] [Insert ICD-10-CM code] since [Insert Date]. Treatment with RADICAVA® is medically appropriate and necessary for [insert Patient name] and should be a covered and reimbursed. Below, this letter outlines [Insert Patient name]'s medical history, prognosis, and treatment rationale.

[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 why RADICAVA® is medically necessary for this patient]

In order for me to provide appropriate care for my patient, it is important that [Insert Plan name] provide adequate coverage for this treatment.

Please call my office at [Insert primary phone number] if I can be of further assistance or you require additional information. Thank you in advance for your immediate attention and prompt response to this request.

Sincerely,

[Insert physician's name and participating provider number]
[Insert patient/legal representative signature, if required]

Enclosure
[Insert a PDF of the Prescribing Information for RADICAVA®]

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.

Mitsubishi Tanabe Pharma America, Inc.
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