

Sample Exceptions Letter for EXSERVAN™ (riluzole) oral film

This letter provides an example of the types of information that may be included when sending an exceptions letter for EXSERVAN™ to a patient's insurance company. Use of the information in this letter does not guarantee that the health plan will provide reimbursement for EXSERVAN™, 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 exceptions letter (like the example on page 2 of this document) if coverage is denied because EXSERVAN™ is not on your patient's health plan formulary or for another reason
- An exceptions 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, 3, and 4 of this document

Example Checklist Summary

- Exceptions form recommended by the health plan
- Example chart notes
 - Date of initial diagnosis
 - Brief description of the patient's recent symptoms and conditions
 - Previous therapies the patient has undergone for the symptoms associated with their condition, and patient's response to these therapies
- A copy of the full Prescribing Information for EXSERVAN™

INDICATION

EXSERVAN™ (riluzole) oral film is indicated for the treatment of amyotrophic lateral sclerosis (ALS).

IMPORTANT SAFETY INFORMATION FOR EXSERVAN™

Contraindication

EXSERVAN™ is contraindicated in patients with a history of severe hypersensitivity reactions to riluzole or to any of its components (anaphylaxis has occurred).

Warnings and Precautions

Hepatic Injury

EXSERVAN™ can cause liver injury and there have been cases of drug-induced liver injury, some of which were fatal, in patients taking riluzole. Asymptomatic elevations of hepatic transaminases have been reported and, in some patients, have recurred upon re-challenge with riluzole. Maximum increases in ALT occurred within 3 months after starting riluzole. Monitor patients for hepatic injury every month for the first 3 months of treatment, and periodically thereafter.

The use of EXSERVAN™ is not recommended if patients develop hepatic transaminases levels greater than 5 times the ULN. Discontinue EXSERVAN™ if there is evidence of liver dysfunction (e.g., elevated bilirubin). Concomitant use with other hepatotoxic drugs may increase the risk for hepatotoxicity.

Please see Indication and additional Important Safety Information on pages 3 and 4, and full Prescribing Information for EXSERVAN™, also available at exservan.com.

Sample Format for an Exceptions 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]:

[Insert Patient Name] has been under my care for [Insert diagnosis] [Insert ICD-10-CM code] since [Insert Date]. This letter outlines my conclusion of medical necessity for EXSERVAN™ (riluzole) oral film for this patient. 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]
- [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]
- [Summary of your professional opinion of the patient's prognosis and why EXSERVAN™ is medically necessary for this patient]

On behalf of [Insert Patient Name], we appreciate your reconsideration. If coverage is still in question, I request an expedited exception and review of this documentation by a neurologist specializing in the treatment of ALS.

Please call my office at [Insert primary phone number] if I can be of further assistance or you require additional information. I look forward to receiving your timely response and approval of this claim.

Sincerely,

[Insert physician's name and participating provider number]

[Insert patient/legal representative signature, if required]

Enclosure

EXSERVAN™ (riluzole) INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION

EXSERVAN™ (riluzole) oral film is indicated for the treatment of amyotrophic lateral sclerosis (ALS).

IMPORTANT SAFETY INFORMATION FOR EXSERVAN™

Contraindication

EXSERVAN™ is contraindicated in patients with a history of severe hypersensitivity reactions to riluzole or to any of its components (anaphylaxis has occurred).

Warnings and Precautions

Hepatic Injury

EXSERVAN™ can cause liver injury and there have been cases of drug-induced liver injury, some of which were fatal, in patients taking riluzole. Asymptomatic elevations of hepatic transaminases have been reported and, in some patients, have recurred upon re-challenge with riluzole. Maximum increases in ALT occurred within 3 months after starting riluzole. Monitor patients for hepatic injury every month for the first 3 months of treatment, and periodically thereafter.

The use of EXSERVAN™ is not recommended if patients develop hepatic transaminases levels greater than 5 times the ULN. Discontinue EXSERVAN™ if there is evidence of liver dysfunction (e.g., elevated bilirubin). Concomitant use with other hepatotoxic drugs may increase the risk for hepatotoxicity.

Neutropenia

EXSERVAN™ can cause neutropenia. Cases of severe neutropenia (absolute neutrophil count less than 500 per mm³) within the first 2 months of riluzole treatment have been reported. Advise patients to report febrile illnesses.

Interstitial Lung Disease

EXSERVAN™ can cause interstitial lung disease, including hypersensitivity pneumonitis. Discontinue EXSERVAN™ immediately if interstitial lung disease develops.

Adverse Reactions

The most common adverse reactions (incidence greater than or equal to 5% and greater than placebo) of EXSERVAN™ were oral hypoesthesia (38%), asthenia (19%), nausea (16%), decreased lung function (10%), hypertension (5%), and abdominal pain (5%).

Drug Interactions

Coadministration of EXSERVAN™ with strong or moderate CYP1A2 inhibitors, such as ciprofloxacin, enoxacin, fluvoxamine, methoxsalen, mexiletine, oral contraceptives, thiabendazole, vemurafenib, and zileuton, may increase the risk of EXSERVAN™-associated adverse reactions.

Coadministration of EXSERVAN™ with CYP1A2 inducers may result in decreased efficacy of EXSERVAN™.

EXSERVAN™-treated patients that take other hepatotoxic drugs may be at increased risk for hepatotoxicity.

Please see additional Important Safety Information on page 4, and full Prescribing Information for EXSERVAN™, also available at exservan.com.

IMPORTANT SAFETY INFORMATION (cont'd)

Use in Specific Populations

Based on animal data, riluzole may cause fetal harm. Women should be advised of a possible risk to the fetus associated with use of EXSERVAN™ during pregnancy. Riluzole has been detected in the milk of lactating rats. The risks and benefits of riluzole treatment in breastfeeding women should be carefully considered.

Japanese patients are more likely to have higher riluzole concentrations, and thus may be at a greater risk of adverse reactions.

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 full Prescribing Information for EXSERVAN™, also available at exservan.com.

SAMPLE

EXSERVAN is a trademark of Aquestive Therapeutics, Inc.

All other company names, product names, trade/service marks or other trade names are the property of their respective owners.
For US audiences only.

Mitsubishi Tanabe Pharma America, Inc.
525 Washington Boulevard, Suite 400
Jersey City, NJ 07310

© 2021 Mitsubishi Tanabe Pharma America, Inc. All rights reserved. CP-EV-US-0018 06/21