# Sample Letter of Medical Necessity for EXSERVAN™ (riluzole) oral film

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 EXSERVAN™. 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 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 EXSERVAN™ 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 1,3 and 4 of this document

**Example Checklist Summary**

- ❑ Appeal 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 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 EXSERVAN™ (riluzole) oral film is medically appropriate and necessary and should be covered and reimbursed. This letter outlines my conclusion of medical necessity for EXSERVAN™ and provides details about [Insert Patient Name]'s medical history, prognosis, and treatment rationale for EXSERVAN™. A copy of the Prescribing Information for EXSERVAN™, which is indicated for this condition, may be accessed at exservan.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]
- [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 need for EXSERVAN™]

**Rationale for Treatment**

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

**Facts about EXSERVAN™:**

- [The FDA approved EXSERVAN™ for the treatment of amyotrophic lateral sclerosis (ALS)]
- [EXSERVAN™ addresses the needs of ALS patients experiencing difficulty swallowing certain medications and who can still swallow saliva in a normal manner. EXSERVAN™ is bioequivalent to riluzole tablets]
- [The most common side effects of EXSERVAN™ include oral hypoesthesia, asthenia, nausea, decreased lung function, hypertension, and abdominal pain]

**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]

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 $mm^3$) 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.**




For US audiences only.
Mitsubishi Tanabe Pharma America, Inc.
525 Washington Boulevard, Suite 400
Jersey City, NJ 07310
 CP-EV-US-0016 06/21