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Section:	Prescription Drugs	**Effective Date:**	April 1, 2026
Subsection:	Neuromuscular Agents	**Original Policy Date:**	December 20, 2019
Subject:	Exservan	**Page:**	1 of 4

Last Review Date: March 6, 2026

Exservan

Description

Exservan (riluzole) oral film

Background

Exservan (riluzole) is an oral film indicated for the treatment of patients with amyotrophic lateral sclerosis (ALS) (1). It is thought that Exservan modulates the actions of glutamate. The mechanism by which this happens is not clearly known but may include direct effects on the neurotransmitter itself and target receptors, the inhibition of glutamate release, blockade or inactivation of voltage-dependent sodium channels that are important for glutamate release, interference with intracellular events that result from binding of glutamate to receptors, and/or inhibition of arachidonic acid metabolism (2). Glutamate is a neurotransmitter (cell-signaling molecule) thought to rise to toxic levels in the brain and spinal cord of ALS patients, damaging nearby nerve cells. By reducing the buildup of glutamate, it is thought that Exservan prevents or slows the glutamate-induced deterioration of motor neurons (3).

Regulatory Status

FDA-approved indication: Exservan is indicated for the treatment of amyotrophic lateral sclerosis (ALS) (1).

Studies have shown that riluzole is safe and effective for slowing disease progression to a modest degree in ALS. Riluzole is considered first-line therapy along with nutritional supplements for patients with ALS (4).

Exservan can cause hepatic injury. Asymptomatic elevations of hepatic transaminases have also been reported. The use of Exservan is not recommended if patients develop hepatic

transaminases levels greater than five times the upper limit of normal. Patients should be monitored for signs and symptoms of hepatic injury, every month for the first 3 months of treatment, and periodically thereafter (1).

The use of Exservan can result in neutropenia. Cases of severe neutropenia within the first 2 months of riluzole treatment have been reported. Patients should be advised to report febrile illnesses (1).

Exservan can cause interstitial lung disease, including hypersensitivity pneumonitis. Exservan should be discontinued immediately if interstitial lung disease develops (1).

The safety and effectiveness of Exservan in pediatric patients less than 18 years of age have not been established (1).

Related policies
Qalsody, Radicava, Relyvrio

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Exservan may be considered **medically necessary** if the conditions indicated below are met.

Exservan may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Amyotrophic lateral sclerosis (ALS)

AND ALL of the following:

1. Patient is unable to swallow or has difficulty swallowing riluzole tablets

2. Prescriber agrees to monitor liver function and absolute neutrophil count (ANC)
3. Prescribed by or recommended by a neurologist

Prior – Approval *Renewal* Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Amyotrophic lateral sclerosis (ALS)

AND ALL of the following:

1. Patient is unable to swallow or has difficulty swallowing riluzole tablets
2. Documented stabilization, slowing of disease progression, or improvement of the condition
3. Prescriber agrees to monitor liver function and absolute neutrophil count (ANC)
4. Prescribed by or recommended by a neurologist

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 180 oral films per 90 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Exservan (riluzole) is an oral film indicated for the treatment of patients with amyotrophic lateral sclerosis (ALS) (1). It is thought that Exservan modulates the actions of glutamate. The mechanism by which this happens is not clearly known but may include direct effects on the neurotransmitter itself and target receptors, the inhibition of glutamate release, blockade or inactivation of voltage-dependent sodium channels that are important for glutamate release, interference with intracellular events that result from binding of glutamate to receptors, and/or inhibition of arachidonic acid metabolism (2). The safety and effectiveness of Exservan in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Exservan while maintaining optimal therapeutic outcomes.

References

1. Exservan [package insert]. Warren, NJ: Aquestive Therapeutics; April 2021.
2. Riluzole Mechanism of Action. *Clinical Pharmacology*.
3. Maragakis NJ, Galvez-Jimenez N, et al. Epidemiology and pathogenesis of amyotrophic lateral sclerosis. UpToDate. Waltham, MA: UpToDate Inc.
4. Galvez-Jimenez N, Goyal NA, et al. Practice Parameter update: Disease-modifying treatment of amyotrophic lateral sclerosis. UpToDate. Waltham, MA: UpToDate Inc.

Policy History

Date	Action
December 2019	Addition to PA
March 2020	Annual review
September 2021	Annual review and reference update
March 2022	Annual review and reference update
September 2022	Annual review
March 2023	Annual review
September 2023	Annual review
March 2024	Annual review
December 2024	Annual review
March 2026	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 6, 2026 and is effective on April 1, 2026.