



PRIOR AUTHORIZATION POLICY

- POLICY:** Neurology – Riluzole Products Prior Authorization Policy
- Exservan™ (riluzole oral film – Mitsubishi Tanabe Pharma America) [obsolete]
 - Rilutek® (riluzole tablets – Covis Pharma, generic)
 - Teglutik® (riluzole oral suspension – ITF Pharma)
 - Teglutik® (riluzole oral suspension – Seqirus)

REVIEW DATE: 02/19/2025

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CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

All of the available riluzole products are indicated for the treatment of **amyotrophic lateral sclerosis (ALS)**.¹⁻³

Guidelines

The American Academy of Neurology (AAN) practice parameter on the care of patients with ALS (last updated 2009; reaffirmed 2023) states that riluzole should be offered to patients with ALS (Level A recommendation), as it is safe and effective for modestly slowing disease progression.^{4,5} Based on available clinical trial data, the AAN estimates riluzole prolongs survival by 2 to 3 months. However, some large cohort studies estimate survival to be prolonged for up to 21 months. The European Federation of Neurological Societies guidelines on the clinical management of ALS (2012) also recommend patients be offered treatment with riluzole as early as possible after diagnosis.⁶ While it is noted that riluzole may be less effective in patients with late-stage disease, it is unclear when or if treatment should be discontinued. The European Academy of Neurology in collaboration with European Reference Network for Neuromuscular Diseases (2024) state that riluzole should be offered lifelong to all ALS patients at diagnosis. If adverse events are noted, consider reducing the dose and reevaluate. If adverse events still persist, consider stopping riluzole.

The recommended dosage is 50 mg twice daily.^{7,8} The Canadian best practice recommendations for the management of ALS state that riluzole has demonstrated efficacy in improving survival in ALS and there is evidence that riluzole prolongs survival by a median duration of 3 months.⁹ Riluzole should be started soon after the diagnosis of ALS.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of riluzole. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with riluzole as well as the monitoring required for adverse events and long-term efficacy, approval requires riluzole to be prescribed by or in consultation with a physician who specializes in the condition being treated.

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is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

- 1. Amyotrophic Lateral Sclerosis (ALS).** Approve for 1 year if the medication is prescribed by or in consultation with a neurologist, a neuromuscular disease specialist, or a physician specializing in the treatment of ALS.

CONDITIONS NOT COVERED

- **Exservan™ (riluzole oral film – Mitsubishi Tanabe Pharma America)**
[obsolete]
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- **Teglutik® (riluzole oral suspension – Seqirus)**

is(are) considered experimental, investigational, or unproven for ANY other use(s).

REFERENCES

1. Rilutek® tablets [prescribing information]. Zug, Switzerland: Covis Pharma; December 2021.
2. Tiglutik® oral suspension [prescribing information]. Berwyn, PA: ITF Pharma; March 2020.
3. Exservan™ oral film [prescribing information]. Jersey City, NJ: Mitsubishi Tanabe Pharma America; April 2021.
4. Miller RG, Jackson CE, Kasarskis EJ, et al. Practice parameter update: the care of the patient with amyotrophic lateral sclerosis: multidisciplinary care, symptom management, and cognitive/behavioral impairment (an evidence-based review). *Neurology*. 2009;73(15):1227-1233.
5. Miller RG, Jackson CE, Kasarskis EJ, et al. Practice parameter update: the care of the patient with amyotrophic lateral sclerosis: drug, nutritional, and respiratory therapies (an evidence-based review). *Neurology*. 2009; 73:1218-1226.

6. Andersen PM, Abrahams S, Borasio GD, et al. EFNS guidelines on the clinical management of amyotrophic lateral sclerosis (MALS) – revised report of an EFNS task force. *Eur J Neurol*. 2012;19(3):360-375.
7. New EAN Guidelines on ALS Management. Physician's Weekly. July 10, 2023. Available at: <https://www.physiciansweekly.com/new-ean-guidelines-on-als-management/>. Accessed on February 19, 2025.
8. Damme PV, Al-Chalabi A, Andersen PM, et al. European Academy of Neurology (EAN) guideline on the management of amyotrophic lateral sclerosis in collaboration with European Reference Network for Neuromuscular Diseases (ERN EURO-NMD). *Eur J Neurol*. 2024 Mar 12 [Epub ahead of print].
9. Shoesmith C, Abrahao A, Benstead T, et al. Canadian best practice recommendations for the management of amyotrophic lateral sclerosis. *CMAJ*. 2020;192(46): E1453-E1468.

HISTORY

| Type of Revision | Summary of Changes | Review Date |
|-----------------------|---|-------------|
| Annual Revision | No criteria changes. | 08/10/2022 |
| Annual Revision | No criteria changes. | 08/30/2023 |
| Early Annual Revision | Teglutik® (riluzole oral suspension – Seqirus): This medication was added to policy with the same criteria applied as the other riluzole products. | 02/28/2024 |
| Annual Revision | No criteria changes. | 02/19/2025 |

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