Drug Coverage Policy

Effective Date 5/15/2025
Coverage Policy Number.....IP0258
Policy Title..... Riluzole Products

Neurology – Riluzole Products

- Exservan™ (riluzole oral film – Mitsubishi Tanabe Pharma America)
- Tiglutik® (riluzole oral suspension – ITF Pharma)
- Teglutik® (riluzole oral suspension – Seqirus)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

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.

Coverage Policy

Policy Statement
Prior Authorization is recommended for prescription benefit coverage of Riluzole. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. 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 a physician who has consulted with or who specializes in the condition.

Riluzole products are considered medically necessary when the following are met:

1. **Amyotrophic Lateral Sclerosis (ALS).** Approve for 1 year if the patient meets **BOTH** of the following (A and B):
    A. The agent is prescribed by or in consultation with a neurologist, a neuromuscular disease specialist, or a physician specializing in the treatment of ALS.
    B. Preferred product criteria are met for the product(s) as listed in the below table(s)

Employer Plans:

Product	Criteria
Exservan (riluzole oral film)	**ONE** of the following: 1. Patient has tried **BOTH** of the following: a. Generic riluzole tablets b. Teglutik/Tiglutik oral suspension [requires prior authorization] 2. If the patient cannot swallow or has difficulty swallowing tablets, patient has tried Teglutik/Tiglutik oral suspension [requires prior authorization]
Teglutik (riluzole oral suspension)	**ONE** of the following: 1. Patient has tried generic riluzole tablets 2. Patient cannot swallow or has difficulty swallowing tablets
Tiglutik	**ONE** of the following: 1. Patient has tried generic riluzole tablets

(riluzole oral suspension)	2. Patient cannot swallow or has difficulty swallowing tablets

Individual and Family Plans:

Product	Criteria
Exservan (riluzole oral film)	**ONE** of the following: 1. Patient has tried generic riluzole tablets 2. Patient cannot swallow or has difficulty swallowing tablets
Teglutik (riluzole oral suspension)	**ONE** of the following: 1. Patient has tried generic riluzole tablets 2. Patient cannot swallow or has difficulty swallowing tablets
Tiglutik (riluzole oral suspension)	**ONE** of the following: 1. Patient has tried generic riluzole tablets 2. Patient cannot swallow or has difficulty swallowing tablets

Riluzole for any other use is considered not medically necessary. Criteria will be updated as new published data are available.

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.

Revision Details

Type of Revision	Summary of Changes	Date

Annual Review	**Amyotrophic lateral sclerosis (ALS).** Removed Documented diagnosis of Amyotrophic Lateral Sclerosis (ALS) **Preferred product table**: (1) **Added** Teglutik (riluzole oral suspension) for IFP and Emp. (2) **Updated** criteria for Exservan, Tiglutik (added additional 'tried' criteria for required alternatives), (3) **Added** Exservan, Tiglutik for IFP to policy	7/1/2024
Annual Revision	No criteria changes.	5/15/2025

The policy effective date is in force until updated or retired.