



Drug Coverage Policy

Effective Date 6/1/2024

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 and have discretion in making individual coverage determinations. 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.

Cigna Healthcare Coverage Policy

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. New guidelines on the management of ALS were presented at the European Academy of Neurology 2023 meeting.⁷ The recommendations during this meeting stated the riluzole should be offered lifelong to all ALS patients at diagnosis and a single daily dose of 50 mg can be effective.⁷ 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.⁸ Riluzole should be started soon after the diagnosis of ALS.

Medical Necessity Criteria

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 is 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 (riluzole oral suspension)	ONE of the following: 1. Patient has tried generic riluzole tablets 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
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When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven (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 August 3, 2023.
8. 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	<p>Amyotrophic lateral sclerosis (ALS). Removed Documented diagnosis of Amyotrophic Lateral Sclerosis (ALS)</p> <p>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</p>	7/1/2024

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

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