PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 08/30/2023

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. 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 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. New guidelines on the management of ALS were presented at the European Academy of Neurology 2023 meeting and are expected to be published before the end of 2023.[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.

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.

- **Exservan™ (riluzole oral film – Mitsubishi Tanabe Pharma America)**
- **Rilutek® (riluzole tablets – Covis Pharma, generic)**
- **Tiglutik® (riluzole oral suspension – ITF Pharma)**

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 agent 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)**
- **Rilutek® (riluzole tablets – Covis Pharma, generic)**
- **Tiglutik® (riluzole oral suspension – ITF Pharma)**

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. Physican'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.

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