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)
- Teglutik® (riluzole oral suspension – Seqirus)

REVIEW DATE: 02/28/2024

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.[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.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of riluzole is recommended in those who meet the following criteria:

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 RECOMMENDED FOR APPROVAL

Coverage of riluzole is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. 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. 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.