Pharmacy Policy Bulletin: J-0823 Non-Preferred Riluzole Products – Commercial and Healthcare Reform	
Number: J-0823	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Miscellaneous Specialty Drugs Oral = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0823-009	**Original Date:** 11/07/2018
Effective Date: 12/20/2024	**Review Date:** 12/04/2024

Drugs Product(s):	• Teglutik (riluzole) • Tiglutik (riluzole) • Exservan (riluzole)
FDA-Approved Indication(s):	• Treatment of amyotrophic lateral sclerosis (ALS)

Background:	• Although the mechanism by which riluzole exerts its therapeutic effects in patients with amyotrophic lateral sclerosis (ALS) is unknown, riluzole has been shown to have neuroprotective effects that are mediated through its ability to block glutamate transmission, stabilize sodium channels, and block gamma-aminobutyric acid (GABA) reuptake. • ALS is a progressive neurodegenerative disease that affects nerve cells in the brain and spinal cord. ALS currently has no cure and all available products are not curative, but have been shown to prolong survival (riluzole) or slow decline of functional symptoms (edaravone and Relyvrio). • The 2009 American Academy of Neurology treatment guidelines recommended riluzole as a Level A recommendation for slowing ALS disease progression. • Exservan oral film, Teglutik and Tiglutik oral suspension offer patients non-solid oral dosage forms of riluzole. This may be favorable in pediatric patients and those unable to swallow solid oral dosage forms. To note, ALS patients can have difficulties with swallowing (dysphagia) due to muscle weakness or spasticity in the tongue, lips, palate, jaw, pharynx, larynx, and upper trunk. • Teglutik is a temporary imported product to mitigate the shortage of Tiglutik in the United States. • Prescribing Considerations: ○ Exservan, Teglutik and Tiglutik have warnings for hepatic injury, neutropenia and interstitial lung disease. Serum aminotransferases should be measured before and during treatment.

	○ Exservan, Teglutik and Tiglutik have drug interactions with strong to moderate CYP1A2 inhibitors resulting in increased adverse reactions and with strong to moderate CYP1A2 inducers resulting in decreased efficacy.

Approval Criteria

I. Approval Criteria
When a benefit, coverage of Teglutik, Exservan, or Tiglutik may be approved when all of the following criteria are met **(A. and B.)**:
A. The member has a diagnosis of amyotrophic lateral sclerosis (ALS). (ICD-10: G12.21)
B. The member has an inability to swallow tablets.

II. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indication should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.
II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Exservan [package insert]. Warren, NJ: Aquestive Therapeutics, Inc.; May 2020.
2. Tiglutik [package insert]. Berwyn, PA: ITF Pharma, Inc.; May 2020.
3. Teglutik [package insert]. Berwyn, PA: ITF Pharma; January 2024.
4. ALS Association. Understanding ALS. Available at: https://www.als.org/understanding-als. Accessed October 11, 2024.
5. Kretschmer BD, Kratzer U, Schmidt WJ. Riluzole, a glutamate release inhibitor, and motor behavior. *Naunyn Schmiedebergs Arch Pharmacol*. 1998;358(2):181-190.
6. 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): report of the Quality Standards Subcommittee of the American Academy of Neurology *Neurology*. 2009;73(15):1218-1226.
7. Teglutik. Available at: https://www.drugs.com/pro/teglutik.html. Accessed November 6, 2024.