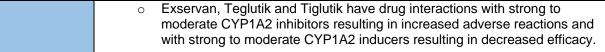
Pharmacy Policy Bulletin: J-0823 Non-Preferred Riluzole Products –			
Number: J-0823 Category: Prior Authorization			
Line(s) of Business:		Benefit(s):	
⊠ Commercial		Commercial:	
□ Healthcare Reform		Prior Authorization (1.):	
☐ Medicare		1. Miscellaneous Specialty Drugs Oral =	
- Medicare		Yes w/ Prior Authorization	
		Healthcare Reform: Not Applicable	
Region(s):		Additional Restriction(s):	
⊠ All		None	
☐ Delaware			
☐ New York			
☐ Pennsylvania			
☐ West Virginia			
Version: J-0823-009		Original Date: 11/07/2018	
Effective Date: 12/20/2024		Review Date: 12/04/2024	
Drugs	Teglutik (riluzole)		
Product(s): • Tiglutik (riluzole)			
	Exservan (riluzole)		
FDA-	 Treatment of amyotrophic 	Treatment of amyotrophic lateral sclerosis (ALS)	
Approved Indication(s):			
indication(s).			
Background:	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:		
	neutropenia and ir	iterstitial lung disease. Serum aminotransferases should	
	be measured before and during treatment.		



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.
- 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.

Pharmacy policies do not constitute medical advice, nor are they intended to govern physicians' prescribing or the practice of medicine. They are intended to reflect the plan's coverage and reimbursement guidelines. Coverage may vary for individual members, based on the terms of the benefit contract.

The plan retains the right to review and update its pharmacy policy at its sole discretion. These guidelines are the proprietary information of the plan. Any sale, copying or dissemination of the pharmacy policies is prohibited; however, limited copying of pharmacy policies is permitted for individual use.