Clinical Policy Title:	riluzole
Policy Number:	RxA.669
Drug(s) Applied:	Tiglutik®
Original Policy Date:	03/09/2021
Last Review Date:	03/09/2021
Line of Business Policy Applies to:	All lines of business

Background

Tiglutik® is indicated for the treatment of amyotrophic lateral sclerosis (ALS).

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
riluzole (Tiglutik®)	ALS	50 mg (10 mL), twice daily, taken orally or via percutaneous endoscopic gastrostomy tubes (PEG-tubes), every 12 hours. Take at least 1 hour before or 2 hours after a meal.	100 mg (20mL) per day

Dosage Forms

- Oral suspension: 50 mg/10 mL (5 mg/mL) in 300 mL multiple-dose bottle.

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Amyotrophic Lateral Sclerosis (ALS) (must meet all):

1. Diagnosis of ALS;
2. Member is age 18 years or older;
3. Prescribed by or in consultation with a neurologist;
4. Documentation that serum aminotransferases will be taken before and during treatment;
5. Dose does not exceed 100 mg (20 mL) per day.

Approval Duration

Commercial: 6 months

Medicaid: 6 months

II. Continued Therapy Approval

A. Amyotrophic Lateral Sclerosis (ALS) (must meet all):

1. Currently receiving medication that has been authorized by RxAdvance or documentation supports that member is currently receiving Tiglutik® for ALS and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, requested dose does not exceed 100 mg (20 mL) per day.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
ALS: amyotrophic lateral sclerosis
PO: by mouth

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Maximum Dose
riluzole (Rilutek®) tablets	50 mg PO twice daily, taken at least 1 hour before or 2 hours after a meal. Measure serum aminotransferases before and during treatment.	100 mg per day

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Patients with a history of severe hypersensitivity reactions to riluzole or to any of its components.

- Boxed Warning(s):
  - None.

APPENDIX D: General Information
None.

References

1. Tiglutik® (riluzole) [prescribing information]. Berwyn, PA: ITF Pharma Inc; March 2020.
2. Rilutek® (riluzole) [prescribing information]. Zug, Switzerland: Covis Pharmaceuticals, Inc; March 2020.
3. Miller RG, Jackson CE, Kasarskis EJ, et al. Quality Standards Subcommittee of the American Academy of Neurology. 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 Oct 13;73(15):1218-26. doi: 10.1212/WNL.0b013e3181bc0141. Erratum in: Neurology. 2009 Dec 15;73(24):2134. Erratum in: Neurology. 2010 Mar 2;74(9):781. PMID: 19822872; PMCID: PMC2764727. Reaffirmed 2020. Accessed February 15, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	03/09/2021	03/09/2021