RxAdvance

Clinical Policy Title:	riluzole
Policy Number:	RxA.669
Drug(s) Applied:	Tiglutik®
Original Policy Date:	03/09/2021
Last Review Date:	12/11/2025
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. **Initial Approval Criteria**
   A. **Amyotrophic Lateral Sclerosis (ALS)** (must meet all):
      1. Diagnosis of ALS;
      2. Documentation that serum aminotransferases will be measured before and during treatment;
      3. Documentation supporting member is unable to ingest a solid dosage form (e.g., an oral tablet or capsule) due to age, oral/motor difficulties, or dysphagia.

   Approval Duration
   All Lines of Business (except Medicare): 6 months

II. **Continued Therapy Approval**
   A. **Amyotrophic Lateral Sclerosis (ALS)** (must meet all):
      1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

   Approval Duration
   All Lines of Business (except Medicare): 12 months

References

1. 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. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2764727/. Accessed August 28, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	03/09/2021	03/09/2021
Policy was reviewed: 1. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...".	12/03/2021	01/17/2022

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2. References were reviewed and updated.		
Policy was reviewed: 1. Initial Approval Criteria, I.A.5: Updated to include new documentation criteria Documentation supporting member is unable to ingest a solid dosage form (e.g., an oral tablet or capsule) due to age, oral/motor difficulties, or dysphagia. 2. References were reviewed and updated.	10/21/2022	01/17/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions. 4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 5. Removed reauthorization requirement for positive response to therapy. 6. Updated approval duration verbiage. 7. Reference was reviewed and updated.	08/28/2024	09/13/2024
Policy was reviewed.	12/05/2024	N/A
Policy reviewed.	12/11/2025	12/11/2025

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