Clinical Policy Title:	amifampridine
Policy Number:	RxA.120
Drug(s) Applied:	Firdapse®
Original Policy Date:	2/7/2020
Last Review Date:	08/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Lambert-Eaton Myasthenic Syndrome (LEMS) (must meet all):

1. Diagnosis of LEMS confirmed by (a or b):
   a. Electromyography showing compound muscle action potential;
   b. Anti-P/Q type voltage-gated calcium channel antibody test;
2. Documentation of a baseline clinical muscle strength assessment is provided (examples may include, but are not limited to, the Quantitative Myasthenia Gravis (QMG) score, triple-timed up-and-go test (3TUG), Timed 25-foot Walk test (T25FW)).

Approval duration

All Lines of Business (except Medicare): 6 months

Continued Therapy Approval

A. Lambert-Eaton Myasthenic Syndrome (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. National Organization of Rare Disease. Lambert-Eaton Myasthenic Syndrome. Available at: https://rarediseases.org/rare-diseases/lambert-eaton-myasthenic-syndrome/. Accessed August 28, 2024.
2. Kesner VG, Oh SJ, Dimachkie MM, et al. Lambert-Eaton Myasthenic Syndrome. Neurol Clin. 2018;36(2):379-39. Available at: https://pubmed.ncbi.nlm.nih.gov/29655456/. Accessed August 28, 2024.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy was established	01/2020	02/07/2020
Policy was reviewed and updated. 1. Updated references.	04/30/2020	05/20/2020
Policy was reviewed: 1. Clinical policy title & lines of business updated. 2. Initial criteria for approval updated.	01/13/2021	03/09/2021

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

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3. Duration of approval (both sections) updated. 4. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance…". 5. References updated.		
Policy was reviewed: 1. Initial approval criteria I.A.3 was updated to modify age criteria for Firdapse®, it was 6 years of age previously and was updated to ≥ 18 years of age. 2. Continued Therapy Approval Criteria, II.A.4: Updated to include new seizures criteria Member does not have history seizures. 3. References were reviewed and updated.	11/25/2021	01/17/2022
Policy was reviewed: 1. Initial Approval Criteria I.A.4: Updated to remove member has proximal muscle weakness. 2. Initial Approval Criteria I.A.5: Updated to remove member does not have a history of seizures. 3. Initial Approval Criteria I.A.6: Updated to remove member is not receiving amifampridine in combination with similar potassium blockers (e.g., dalfampridine). 4. Initial Approval Criteria, I.A.3.a: Updated age criteria from ≥ 18 years of age for Firdapse® to Age ≥ 6 years for Firdapse®. 5. Initial Approval Criteria, I.A.8.a.ii and iii: Updated to include new dosing criteria: a. Pediatric (6 to 17 years) (Less than 45 kg): 40 mg/day. b. Pediatric (6 to 17 years) (45 kg or greater): 80 mg/day. 6. Continued Therapy Approval, II.A.5.a.ii and iii: Updated to include new dosing criteria: a. Pediatric (6 to 17 years) (Less than 45 kg): 40 mg/day. b. Pediatric (6 to 17 years) (45 kg or greater): 80 mg/day. 7. References were reviewed and updated.	10/12/2022	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 other reauthorization requirements including positive response to therapy. 6. Updated approval duration verbiage. 7. References were reviewed and updated.	08/28/2024	09/13/2024

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