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| **Clinical Policy Title:** | amifampridine |
| **Policy Number:** | RxA.120 |
| **Drug(s) Applied:** | Firdapse®, Ruzurgi |
| **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 |
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| Policy was established | 01/2020 | 02/07/2020 |
| Policy was reviewed and updated.<br>1. Updated references. | 04/30/2020 | 05/20/2020 |
| Policy was reviewed:<br>1. Clinical policy title & lines of business updated.<br>2. Initial criteria for approval updated. | 01/13/2021 | 03/09/2021 |

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| 3. Duration of approval (both sections) updated.<br>4. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance…".<br>5. References updated. | | |
| Policy was reviewed:<br>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.<br>2. Continued Therapy Approval Criteria, II.A.4: Updated to include new seizures criteria Member does not have history seizures.<br>3. References were reviewed and updated. | 11/25/2021 | 01/17/2022 |
| Policy was reviewed:<br>1. Initial Approval Criteria I.A.4: Updated to remove member has proximal muscle weakness.<br>2. Initial Approval Criteria I.A.5: Updated to remove member does not have a history of seizures.<br>3. Initial Approval Criteria I.A.6: Updated to remove member is not receiving amifampridine in combination with similar potassium blockers (e.g., dalfampridine).<br>4. Initial Approval Criteria, I.A.3.a: Updated age criteria from ≥ 18 years of age for Firdapse® to Age ≥ 6 years for Firdapse®.<br>5. Initial Approval Criteria, I.A.8.a.ii and iii: Updated to include new dosing criteria:<br>a. Pediatric (6 to 17 years) (Less than 45 kg): 40 mg/day.<br>b. Pediatric (6 to 17 years) (45 kg or greater): 80 mg/day.<br>6. Continued Therapy Approval, II.A.5.a.ii and iii: Updated to include new dosing criteria:<br>a. Pediatric (6 to 17 years) (Less than 45 kg): 40 mg/day.<br>b. Pediatric (6 to 17 years) (45 kg or greater): 80 mg/day.<br>7. References were reviewed and updated. | 10/12/2022 | 01/17/2023 |
| Policy was reviewed. | 10/19/2023 | 10/19/2023 |
| Policy was reviewed:<br>1. Removed age restrictions.<br>2. Removed prescriber restrictions.<br>3. Removed dose restrictions.<br>4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days.<br>5. Removed other reauthorization requirements including positive response to therapy.<br>6. Updated approval duration verbiage.<br>7. References were reviewed and updated. | 08/28/2024 | 09/13/2024 |