

Policy Name:	Firdapse (amifampridine)	Policy #:	2713P
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Purpose of the Policy

The purpose of this policy is to establish the prior authorization guidelines for Firdapse.

Statement of the Policy

Health Alliance Medical Plans and Health Alliance Northwest will approve the use of Firdapse under the specialty pharmacy benefit when the following criteria have been met.

Criteria

1. Coverage Criteria

- 1.1 Documented diagnosis of Lambert-Eaton myasthenic syndrome (LEMS) confirmed by at least one electro diagnostic study (e.g., repetitive nerve stimulation) or anti-P/Q-type voltage-gated calcium channel antibody test
- 1.2 Age 18 years or older
- 1.3 Documented moderate to severe weakness without muscle atrophy that interferes with daily functions
- 1.4 Ordered by or in consultation with a neurologist (doctor of the brain and nervous system) or oncologist (cancer doctor)
- 1.5 Requests for treatment in patients with an active cancer diagnosis will be reviewed on a case-by-case basis by a pharmacist and medical director.

2. Exclusion Criteria

- 2.1 Patients with known epilepsy or other seizure disorder

3. Approval Period

- 3.1 Initial Approval: 12 Months
- 3.2 Reapproval: 12 months with documentation of benefit to therapy (improved muscle strength, improvements in mobility, etc.)

References

1. Firdapse (amifampridine) [prescribing information]. Coral Gables, FL: Catalyst Pharmaceuticals, Inc; May 2023.
2. Oh SJ, Shcherbakova N, Kostera-Pruszczyk A, et al. Amifampridine phosphate (Firdapse®) is effective and safe in a phase 3 clinical trial in LEMS. *Muscle Nerve* 2016; 53:717.
3. Shieh P, Sharma K, Kohrman B, et al: Amifampridine phosphate (Firdapse) is effective in a confirmatory phase 3 clinical trial in LEMS. *J Clin Neuromuscul Dis* 2019; 20(3):111-119.
4. GO Skeie, S Apostolski, E Evoli, etc al. Guidelines for treatment of autoimmune neuromuscular transmission disorders. EFNS Guideline. *Euro Journal of Neuro*. 2010,17:893–902.

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DISCLAIMER This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the

most Statement of the Policy Criteria Purpose of the Policy References appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage