Pharmacy Drug Policy & Procedure

Policy Name:	Firdapse (amifampridine)	Policy #:	2713P

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 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 2024.
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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