

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2177-8
Program	Prior Authorization/Medical Necessity
Medication	Firdapse® (amifampridine)
P&T Approval Date	11/2019, 11/2020, 11/2021, 3/2022, 11/2022, 11/2023, 11/2024, 11/2025
Effective Date	2/1/2026

1. Background:

Firdapse (amifampridine) is a potassium channel blocker indicated for the treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults and pediatric patients 6 years of age and older.

2. Coverage Criteria^a:

A. Initial Authorization

1. **Firdapse** will be approved based on **all** of the following criteria:

a. Diagnosis of Lambert-Eaton myasthenic syndrome (LEMS)

-AND-

b. Diagnosis confirmed by **one** of the following:

(1) Increased compound muscle action potential (CMAP) amplitude after exercise or with high-frequency repetitive nerve stimulation (RNS)

-OR-

(2) A high titer P/Q-type voltage-gated calcium channels (VGCC) antibody

-AND-

c. Prescribed by or in consultation with a specialist in the treatment of LEMS (e.g., neurologist, oncologist)

Authorization will be issued for 12 months.

B. Reauthorization

1. **Firdapse** will be approved based on the following criterion:

a. Documentation of positive clinical response to Firdapse therapy (e.g., improved muscle strength, improved mobility)

Authorization will be issued for 12 months.

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Firdapse [package insert]. 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(5):717-725.
3. Kesner VG, Oh SJ, Dimachkie MM, Barohn RJ. Lambert-Eaton Myasthenic Syndrome. *Neurol Clin*. 2018;36(2):379-394.

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Change Control	
11/2019	New program
11/2020	Annual review with no changes to coverage criteria. Updated references.
11/2021	Annual review with no changes to coverage criteria. Updated references.
3/2022	Removed step through Ruzurgi due to FDAs conversion of Ruzurgi from full approval to tentative approval.
11/2022	Updated background to reflect new pediatric indication for patients 6 years of age and older.
11/2023	Added “Diagnosis of” to initial criteria with no change to clinical intent.
11/2024	Annual review with no changes to coverage criteria. Updated reference.
11/2025	Annual review. Within initial authorization criteria, added confirmation of diagnosis and removed requirement for no concomitant use with similar potassium channel blockers. Added examples of positive clinical response within reauthorization criteria. Updated references.