Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	September 22, 2020

FIRDAPSE® and RUZURGI® (amifampridine)

LENGTH OF AUTHORIZATION: 6 MONTHS

REVIEW CRITERIA:

- Patient is ≥ 18 years old for Firdapse and 6 to ≤ 17 years old for Ruzurgi; **AND**
- Patient has a diagnosis of Lambert-Eaton Myasthenic Syndrome (LEMS) confirmed by a positive anti-P/Q type voltage-gated calcium channel antibody test; **AND**
- Patient does not have a history of seizures; **AND**
- Patient does not have a hypersensitivity to amifampridine or another aminopyridine (such as dalfampridine [Ampyra®]).

CONTINUATION OF THERAPY:

- Patient met initial review criteria; **AND**
- Patient must demonstrate disease improvement, stabilization, and/or slowing in the rate of decline as a result of the medication; **AND**
- Patient has not experienced any treatment-restricting adverse effects.

DOSING AND ADMINISTRATION:

- Firdapse recommended starting dose: 15 mg to 30 mg daily, taken orally in 3 to 4 divided doses. Every 3 or 4 days, the dose can be increased by 5 mg daily to a recommended maximum daily dose of 80 mg (20 mg maximum per dose).
- Ruzurgi recommended dose:
    - Patients ≥ 45 kg: 15 mg to 30 mg daily, taken orally in divided doses. Increase daily in 5 to 10 mg increments, divided in up to 5 doses daily to a recommended maximum daily dose of 100 mg (30 mg maximum per dose).
    - Patients < 45 kg: 7.5 mg to 15 mg daily, taken orally in divided doses. Increase daily in 2.5 to 5 mg increments, divided in up to 5 doses daily to a recommended maximum daily dose of 50 mg (15 mg maximum per dose).