I. Medication Description

Lambert-Eaton myasthenic syndrome (LEMS) is a rare autoimmune disorder characterized by the gradual onset of muscle weakness, especially of the pelvic and thigh muscles. In LEMS, the immune system attacks the voltage-gated calcium channels (VGCC) on the motor nerve membrane at the neuromuscular junction. These channels normally conduct calcium into the nerve resulting in release acetylcholine. Acetylcholine helps in the communication between nerve cells and muscles and triggers muscle contraction. With fewer calcium channels, the nerve ending releases less acetylcholine. In people with LEMS, the lowered levels of acetylcholine are not sufficient to cause normal muscle contractions, causing muscle weakness.

Firdapse is a broad spectrum potassium channel blocker that prolongs cell membrane depolarization allowing for more calcium to be transferred to the nerve ending. As a result, the vesicular release of acetylcholine and impulse transmission at central, autonomic, and neuromuscular synapses is increased.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage of Firdapse is available when the following criteria have been met:

- Member is 18 years of age or older AND
- The medication is prescribed by or in consultation with a neurologist and if clinically appropriate, an oncologist AND
- Member has a diagnosis of Lambert-Eaton myasthenic syndrome (LEMS) confirmed by at least ONE of the following:
  - Electromyography (e.g. repetitive nerve stimulation (RNS), nerve conduction studies (NCS)) OR
  - Calcium channel antibody testing (e.g. presence of anti P/Q-type voltage-gated calcium channel (VGCC) antibodies) AND
- Documentation of a baseline clinical muscle strength assessment (examples may include but are not limited to the Quantitative Myasthenia Gravis (QMG) score, Triple Timed Up and Go Walk Test (3TUG), Timed 25-foot Walk test (T25FW)) AND
- Member does not have a history of seizures
IV. **Quantity Limitations**

Coverage is available for up to 240 tablets per 30 days.

V. **Coverage Duration**

Coverage is available for 6 months and may be renewed.

VI. **Coverage Renewal Criteria**

Coverage can be renewed based upon the following criteria:

- Stabilization of disease or improvement in symptoms relative to the natural course of LEMS as evidenced by an improvement in the baseline clinical muscle strength assessment **AND**
- Absence of unacceptable toxicity from the drug

VII. **Billing/Coding Information**

Firdapse is available as 10 mg tablets.

VIII. **Summary of Policy Changes**

- 5/15/19: new policy

IX. **References**

2. UpToDate-Accessed 2/19

*The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.*

*The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.*

*The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.*