

**Pharmacy Policy**

**Lambert Eaton Myasthenic Syndrome**

**Policy Number:** 9.135

**Revision Number:** R0

**Version Effective Date:** 1/1/2021

Product Applicability <input type="checkbox"/> All Plan+ Products	
<b>Well Sense Health Plan</b> <input checked="" type="checkbox"/> New Hampshire Medicaid	<b>Boston Medical Center HealthNet Plan</b> <input type="checkbox"/> MassHealth- MCO <input type="checkbox"/> MassHealth- ACO <input type="checkbox"/> Qualified Health Plans/ConnectorCare/Employer Choice Direct <input type="checkbox"/> Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

**Prior Authorization Policy**

**Products Affected:**

- Firdapse (amifampridine)
- Ruzurgi (amifampridine)

The Plan may authorize coverage of the above products for members meeting the following criteria:

<b>Covered Use</b>	All medically excepted indications unless otherwise excluded
<b>Exclusion Criteria</b>	History of seizures
<b>Required Medical Information</b>	1. Diagnosis of Lambert-Eaton myasthenic syndrome (LEMS); AND 2. Prescriber attestation that member is experiencing moderate to severe weakness that interferes with daily function; AND 3. For Firdapse, an inadequate response, intolerance, or contraindication to Ruzurgi or

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	a clinical rationale for use of the requested agent instead of Ruzurgi.
<b>Age Restrictions</b>	Firdapse: 18 years of age and older Ruzurgi: 6 years of age and older
<b>Prescriber Restriction</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	12 months
<b>Quantity Limit</b>	Firdapse: 8 per day Ruzurgi: 10 per day
<b>Other criteria</b>	Reauthorization 1. Prescriber attestation that the patient's clinical condition has improved with the current therapy with no significant adverse events.

### Clinical Background Information and References

1. Firdapse (amifampridine) [prescribing information]. Catalyst Pharmaceuticals Inc., Coral Gables, FL 33134. Nov 2018.
2. Ruzurgi (amifampridine) [prescribing information]. Plainsboro, NJ: Jacobus Pharmaceutical Company, Inc.; May 2019.
3. Weinberg DH. Lambert-Eaton myasthenic syndrome: Treatment and prognosis. UptoDate. Last updated May 20, 2019.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
09/10/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee, NH DHHS

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date	Approved by
9/10/2020	9.650 Lambert Eaton Myasthenic Syndrome Policy retired, new policy created. Removed reauthorization criteria for meeting initial criteria	1/1/2021	P&T Committee, NH DHHS

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## **Next Review Date**

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August 2021

## **Reference to Applicable Laws and Regulations, If Any**

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### **Disclaimer Information**

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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