Firdapse Ruzurgi

**Description**

Firdapse, Ruzurgi (amifampridine)

**Background**

Firdapse (amifampridine) and Ruzurgi (amifampridine) are broad spectrum potassium channel blockers used to treat Lambert-Eaton myasthenic syndrome (LEMS). LEMS is a rare autoimmune disorder that affects the connection between nerves and muscles and causes weakness and other symptoms in affected patients. LEMS may be associated with other autoimmune diseases, but more commonly occurs in patients with cancer such as small cell lung cancer, where its onset precedes or coincides with the diagnosis of cancer (1-3).

**Regulatory Status**

FDA-approved indication:

Firdapse is a potassium channel blocker indicated for the treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults (1).

Ruzurgi is a potassium channel blocker indicated for the treatment of Labert-Eaton myasthenic syndrome (LEMS) in patients 6 to less than 17 years of age (2).

Firdapse and Ruzurgi can cause seizures. Seizures may be dose-dependent. The concomitant use of Firdapse and drugs that lower the seizure threshold may lead to an increased risk of seizures. Discontinuation or dose-reduction of Firdapse or Ruzurgi should be considered in patients who have a seizure while on treatment. Firdapse is contraindicated in patients with a history of seizures (1-2).
The safety and effectiveness of Firdapse in pediatric patients have not been established (1). The safety and effectiveness of Ruzurgi in pediatric patients below the age of 6 years have not been established (2).

### Related policies

**Policy**

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Firdapse and Ruzurgi may be considered medically necessary in patients with Lambert-Eaton myasthenic syndrome (LEMS) and if the conditions indicated below are met.

Firdapse and Ruzurgi are considered investigational for all other indications.

### Prior-Approval Requirements

**Age**

**Firdapse only:** 18 years of age or older  
**Ruzurgi only:** 6 to 16 years of age

**Diagnosis**

Patient must have the following:

Lambert-Eaton myasthenic syndrome (LEMS)

AND ALL of the following:

1. LEMS diagnosis confirmed using ONE of the following:
   a. Decreased amplitude of compound muscle action potential (CMAP) to a single supramaximal stimulus
   b. Positive autoantibody test against voltage-gated calcium channels (VGCC)

2. Patient does NOT have a history of seizures

3. Prescriber agrees to monitor for use with acetylcholinesterase inhibitors (which enhance the cholinergic effect of Firdapse/Ruzurgi) or other medications that can lower the seizure threshold
Prior – Approval *Renewal* Requirements

**Age**
- **Firdapse only:** 18 years of age or older
- **Ruzurgi only:** 6 to 16 years of age

**Diagnosis**

Patient must have the following:

Lambert-Eaton myasthenic syndrome (LEMS)

**AND ALL** of the following:
1. Patient does **NOT** have a history of seizures
2. Prescriber agrees to monitor for use with acetylcholinesterase inhibitors or other medications that can lower the seizure threshold
3. Patient has a documented improvement since beginning therapy

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**Policy Guidelines**

**Pre - PA Allowance**
None

**Prior - Approval Limits**

**Quantity**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Quantity</th>
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<tbody>
<tr>
<td>Ruzurgi</td>
<td>900 tablets per 90 days <strong>OR</strong></td>
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<tr>
<td>Firdapse</td>
<td>720 tablets per 90 days</td>
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**Duration**
12 months

**Prior – Approval *Renewal* Limits**
Same as above

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**Rationale**

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**Summary**
Firdapse (amifampridine) and Ruzurgi (amifampridine) are broad spectrum potassium channel blockers used to treat Lambert-Eaton myasthenic syndrome (LEMS). LEMS is a rare autoimmune disorder that affects the connection between nerves and muscles and causes weakness and other symptoms in affected patients. LEMS may be associated with other autoimmune diseases, but more commonly occurs in patients with cancer such as small cell lung cancer, where its onset precedes or coincides with the diagnosis of cancer. The safety and effectiveness of Firdapse in pediatric patients have not been established. The safety and effectiveness of Ruzurgi in pediatric patients below the age of 6 years have not been established (1-2).

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of Firdapse and Ruzurgi while maintaining optimal therapeutic outcomes.

References