AMIFAMPRIDINE

Generic	Brand	HICL	GCN	Exception/Other
AMIFAMPRIDINE	FIRDAPSE	36930		
AMIFAMPRIDINE	RUZURGI		46265	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Lambert-Eaton myasthenic syndrome (LEMS) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a neurologist or hematologist-oncologist
   - Diagnosis is confirmed by **ALL** of the following:
     - Electrodiagnostic studies (e.g., reduced compound muscle action potential (CMAP)) and/or voltage-gated calcium channel (VGCC) antibody testing
     - Clinical triad of muscle weakness, autonomic dysfunction, and decreased tendon reflexes

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the request for **Firdapse** and the patient meets the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL with a quantity limit of #8 tablets per day.**
   APPROVAL TEXT: Renewal requires physician attestation of improvement or stabilization in muscle weakness compared to baseline.

   If no, continue to #3.

3. Is the request for **Ruzurgi** and the patient meets the following criterion?
   - Documentation of patient's weight

   If yes, **approve for 12 months by GPID (46265) as follows:**
   - **Weight < 45kg: #150 tablets per 30 days.**
   - **Weight ≥ 45kg: #300 tablets per 30 days.**

   APPROVAL TEXT: Renewal requires physician attestation of improvement or stabilization in muscle weakness compared to baseline.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

CONTINUED ON NEXT PAGE

AMIFAMPRIDINE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **AMIFAMPRIDINE (Firdapse, Ruzurgi)** requires a diagnosis of Lambert-Eaton myasthenic syndrome (LEMS). In addition, the following criteria must be met:

- Therapy is prescribed by or in consultation with a neurologist or hematologist-oncologist
- Diagnosis is confirmed by electrodiagnostic studies and/or voltage-gated calcium channel (VGCC) antibody testing **AND** clinical triad of muscle weakness, autonomic dysfunction, and decreased tendon reflexes

Request for Firdapse also requires the following:

- The patient is 18 years of age or older

Request for Ruzurgi also requires the following:

- Documentation of patient's weight

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Lambert-Eaton myasthenic syndrome (LEMS) **AND** meet the following criterion?
   - Physician attestation of improvement or stabilization in muscle weakness compared to baseline

   If yes, **approve for 12 months as follows:**
   - **Firdapse: Approve by HICL with a quantity limit of #8 tablets per day.**
   - **Ruzurgi: Approve by GPID (46265) as follows:**
     - **Weight < 45kg: #150 tablets per 30 days.**
     - **Weight ≥ 45kg: #300 tablets per 30 days.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: The guideline named **AMIFAMPRIDINE (Firdapse, Ruzurgi)** requires a diagnosis of Lambert-Eaton myasthenic syndrome (LEMS). In addition, the following criterion must be met:
   - Physician attestation of improvement or stabilization in muscle weakness compared to baseline

CONTINUED ON NEXT PAGE

AMIFAMPRIDINE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Firdapse and Ruzurgi.

REFERENCES

- Firdapse [Prescribing Information]. Coral Gables, FL: Catalyst Pharmaceuticals, Inc: November 2018.
- Ruzurgi [Prescribing Information]. Princeton, NJ: Jacobus Pharmaceutical Company, Inc., May 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/19
Created: 02/19
Client Approval: 08/19
P&T Approval: 07/19