STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AMIFAMPRIDINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AMIFAMPRIDINE	FIRDAPSE	36930		GPI-10 (7600001210)	
AMIFAMPRIDINE	RUZURGI	34158		GPI-10 (6270104010)	

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 6 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per day.**
   If no, continue to #3.

3. Is the request for **Ruzurgi**?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #10 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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AMIFAMPRIDINE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AMIFAMPRIDINE (Firdapse, Ruzurgi)** requires the following rule(s) be met for approval:

A. You have Lambert-Eaton myasthenic syndrome (a type of muscle disorder)
B. Therapy is prescribed by or in consultation with a neurologist (type of brain doctor) or hematologist-oncologist (a type of blood-cancer doctor)
C. Diagnosis is confirmed by ALL of the following:
    1. Electrodiagnostic studies and/or voltage-gated calcium channel (types of lab tests) antibody testing
    2. Three clinical symptoms of muscle weakness, autonomic dysfunction (nerve dysfunction), and decreased tendon reflexes
D. **If you are requesting Firdapse, approval also requires:**
    1. You are 6 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

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

    If yes, **approve for 12 months for the requested drug as follows:**
    - **Firdapse: Approve by HICL or GPI-10 with a quantity limit of #8 per day.**
    - **Ruzurgi: Approve by HICL or GPI-10 with a quantity limit of #10 per day.**

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

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AMIFAMPRIDINE

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AMIFAMPRIDINE (Firdapse, Ruzurgi)** requires the following rule(s) be met for renewal:

A. You have Lambert-Eaton myasthenic syndrome (a type of muscle disorder)
B. You have experienced improvement or stabilization in muscle weakness compared to baseline

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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; September 2022.
- Ruzurgi [Prescribing Information]. Princeton, NJ: Jacobus Pharmaceutical Company, Inc., May 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/01/22
Created: 02/19
Client Approval: 10/22
P&T Approval: 10/22