

Ruzurgi (amifampridine)

Override(s)	Approval Duration
Prior Authorization	Initial request: 3 months
Quantity Limit	Maintenance therapy: 12 months (1 year)

Medications	Quantity Limit
Ruzurgi (amifampridine)	May be subject to quantity limit

APPROVAL CRITERIA

Initial requests for Ruzurgi (amifampridine) may be approved if the following criteria are met:

- I. Individual is 6 years of age to less than 17 years of age; **AND**
- II. Individual has a diagnosis of Lambert-Eaton myasthenic syndrome; **AND**
- III. Documentation is provided that diagnosis has been confirmed by one of the following:
 - A. Presence of anti-P/Q-type voltage-gated calcium channel (VGCC) antibodies;**OR**
 - B. Characteristic electromyography findings using nerve conduction tests, repetitive nerve stimulation (RNS), exercise testing, or single fiber electromyography (SFEMG).

Maintenance therapy requests for Ruzurgi (amifampridine) may be approved if the following criteria are met:

- I. Documentation is provided showing objective evidence that individual achieved and sustained meaningful improvement in muscle strength.

Requests for Ruzurgi (amifampridine) may **not** be approved for the following:

- I. Individual has a history of seizures; **OR**
- II. Individual is using in combination with compounded form of 3,4 diaminopyridine.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2021. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: August 12, 2021.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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