



## MEDICATION POLICY

**Generic Name:** Riluzole

**Therapeutic Class or Brand Name:** Rilutek®

**Applicable Drugs** (if Therapeutic Class):

Preferred: Riluzole tablets (generic)

Non-Preferred: Rilutek® tablets

**Date of Origin:** 2/1/13

**Date Last Reviewed/Revised:** 10/7/16

**GPI Code:** 7450307000

### Prior Authorization Criteria (may be considered medically necessary when criteria I through IV are met):

- I. Documented diagnosis of Amyotrophic Lateral Sclerosis (ALS).
- II. Minimum age requirement: 18 years old.
- III. Must be prescribed by a neurologist.
- IV. Non-preferred products (i.e. Rilutek® tablets) require a documented clinical reason containing details as to why generic riluzole is not appropriate or is contraindicated.

### Exclusion Criteria:

- N/A

### Other Criteria:

- N/A

### Quantity/Days Supply Restrictions:

- 60 tablets per 30 days.

### Approval Length:

- **Authorization:** 1 year.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and a positive clinical response.

### Appendix:

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N/A

### References:

1. [http://www.mda.org/sites/default/files/publications/ALSCareGuidelines\\_drugsdiet.pdf](http://www.mda.org/sites/default/files/publications/ALSCareGuidelines_drugsdiet.pdf).
2. [https://www.optumrx.com/rxsol/live/PAGDocs/Guideline\\_7522.pdf](https://www.optumrx.com/rxsol/live/PAGDocs/Guideline_7522.pdf).
3. [Medi-Span](#).
4. <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=10c8d5e6-cb9f-402d-ab8e-65c1aa049e89>.

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**MEDICATION POLICY**

| <b>Historical Tracking Of Changes Made To Policy</b> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 10/7/2016                                            | <ol style="list-style-type: none"> <li>1. <b>Changed</b> “N/A” to “Preferred: Riluzole tablets (generic); Non-Preferred: Rilutek® tablets” <b>following Applicable Drugs.</b></li> <li>2. <b>Added</b> “IV. Non-preferred products (i.e. Rilutek® tablets) require a documented clinical reason containing details as to why generic riluzole is not appropriate or is contraindicated” <b>under Prior Authorization Criteria.</b></li> <li>3. <b>Updated</b> “<a href="http://products.sanofi.us/rilutek/rilutek.pdf">http://products.sanofi.us/rilutek/rilutek.pdf</a>” to “<a href="https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=10c8d5e6-cb9f-402d-ab8e-65c1aa049e89">https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=10c8d5e6-cb9f-402d-ab8e-65c1aa049e89</a>” <b>under References.</b></li> </ol>                                                                                                                      |
| 5/7/2015                                             | <ol style="list-style-type: none"> <li>1. <b>Removed</b> “Absence of ventilator dependence (i.e. no tracheostomy or tracheostomy for prevention of aspiration only)” <b>from Prior Authorization Criteria.</b></li> <li>2. <b>Changed</b> “An updated letter of medical necessity or progress notes showing positive clinical response (i.e. stabilization of ALS) AND absence of ventilator dependence (i.e. no tracheostomy or tracheostomy for prevention of aspiration only)” to “An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and a positive clinical response” <b>following Re-Authorization under Approval Length.</b></li> <li>3. <b>Added</b> “<a href="http://www.mda.org/sites/default/files/publications/ALSCareGuidelines_drugsdiet.pdf">http://www.mda.org/sites/default/files/publications/ALSCareGuidelines_drugsdiet.pdf</a>” <b>under References.</b></li> </ol> |
| 12/27/2013                                           | <ol style="list-style-type: none"> <li>1. <b>Adapted policy to new format.</b></li> <li>2. <b>Added GPI code.</b></li> <li>3. <b>Updated references</b> to include Medi-Span.</li> </ol>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |

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