

Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Rilutek (riluzole), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must be prescribed by a neurologist
- Must have a diagnosis of definite or probable amyotrophic lateral sclerosis (ALS)

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation from the provider that the member is still a candidate for treatment with Rilutek (riluzole) based upon the prescriber's assessment while on therapy.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 year
Reauthorization	Same as initial
Quantity Level Limit	
Rilutek	60 tablets per 30 days

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Rilutek [package insert]. Bridgewater, NJ: sanofi-aventis U.S. LLC; 2009
2. Miller RG, Jackson CE, Kasarkis EJ, et al. Practice parameter update: the care of the patient with amyotrophic lateral sclerosis: drug, nutritional, and respiratory therapies (an evidence-based review). *Neurology* 2009;73:1218-1226
3. Quality Standards Subcommittee of the American Academy of Neurology. Practice advisory on the treatment of amyotrophic lateral sclerosis with riluzole: a report of the quality standards subcommittee of the American Academy of Neurology. *Neurology* 1997;49:657-659
4. Bensimon G, Lacomblez L, Meininger et al. A controlled trial of riluzole in amyotrophic lateral sclerosis. *N Engl J Med* 1994;330:585-91



Rilutek (riluzole)

POLICY NUMBER: RX.PA.185.E

REVISION DATE: 05/14

PAGE NUMBER: 3 of 3

5. Lacomblez M, Bensimon G, Leigh PN, et al. A confirmatory dose-ranging study of riluzole in ALS. *Neurology* 1996;47 (suppl 4):S242-250
6. Bensimon G, Lacomblez L, Delumeau JC, et al. A study of riluzole in the treatment of advanced stage or elderly patients with amyotrophic lateral sclerosis. *J Neurol* 2002;249:609-615
7. Miller RG, Mitchell JD, Moore DH, et al. Riluzole for amyotrophic lateral sclerosis (ALS)/motor neuron disease (MND). *Cochrane Database of Systematic Reviews* 2012, Issue 3. Art. No.: CD001447. DOI: 10.1002/14651858.CD001447.pub3
8. Brooks BR, Miller RG, Swash M, et al. El Escorial revisited: revised criteria for the diagnosis of amyotrophic lateral sclerosis. *ALS and Other Motor Neuron Disorders* 2000;1:293-299
9. Traynor BJ, Alexander M, Corr B, et al. An outcome study of riluzole in amyotrophic lateral sclerosis: a population based study in Ireland 1996-2000. *J Neurol* 2003;250:473-479

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	02/17, 02/18

