

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

1. Requirements for Prior Authorization of Rilutek (riluzole)

A. Prescriptions That Require Prior Authorization

All prescriptions for Rilutek (riluzole) must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for Rilutek (riluzole), the determination of whether the requested prescription is medically necessary will take into account whether the recipient:

1. Is being prescribed Rilutek (riluzole) by, or in consultation with, a neurologist

AND

2. Has documentation of:

- a. A diagnosis of amyotrophic lateral sclerosis (ALS)

OR

- b. A diagnosis other than ALS that is:

- i. Listed in nationally recognized compendia for the determination of medically accepted indications for off-label uses of Rilutek (riluzole)

OR

- ii. Supported by peer reviewed medical literature provided by the prescriber

AND

3. Has baseline monitoring of a complete blood count (CBC) with differential and liver function tests (LFTs)

OR

4. Does not meet the clinical review guidelines listed above, but in the professional judgment of the physician reviewer, the service is medically necessary to meet the medical needs of the recipient.

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AND

5. In addition, if a prescription for Rilutek (riluzole) is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter

FOR RENEWALS OF PRESCRIPTIONS FOR RILUTEK (riluzole): The determination of medical necessity of requests for prior authorization of renewals of prescriptions for Rilutek (riluzole) that were previously approved will take into account whether the recipient:

1. For a diagnosis other than ALS, experienced an improvement or stabilization of symptoms

AND

2. For all diagnoses, had follow-up monitoring of CBC with differential and LFTs monthly for the first 3 months of therapy and then every 3 months thereafter

OR

3. Does not meet the clinical review guidelines listed above, but in the professional judgment of the physician reviewer, the service is medically necessary to meet the medical needs of the recipient.

AND

4. In addition, if a prescription for Rilutek (riluzole) is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above, to assess the medical necessity of the request for a prescription for Rilutek (riluzole). If the guidelines in Section B are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

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D. Dose and Duration of Therapy

The Department will limit authorization of prescriptions as follows:

1. For the initial prescription:
 - a. Up to 12 months for a diagnosis of ALS
 - b. Up to 6 months for all diagnoses other than ALS
2. Up to 12 months for renewals of prescriptions that were previously approved

E. References

1. Choudry RB, Galvez-Jimenez N, Cudkowicz, ME. Disease modifying treatment of amyotrophic lateral sclerosis. UpToDate. Accessed July 25, 2014.
2. Miller RG, Jackson CE, Kasarskis EJ, et al. Practice Parameter update: The care of the patient with amyotrophic lateral sclerosis: Drug, nutritional, and respiratory therapies (an evidence-based review): Report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology* 2009;73:1218–1226.
3. Miller RG, Jackson CE, Kasarskis EJ, et al. Practice Parameter update: The care of the patient with amyotrophic lateral sclerosis: Multidisciplinary care, symptom management, and cognitive/behavioral impairment (an evidence-based review): Report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology* 2009;73:1227–1233.
4. Rilutek prescribing information. Sanofi-Aventis U.S. LLC. November 2012.