riluzole (Rilutek®, Teglutik®, Exervan®)

EOCCO POLICY

Policy Type: PA/SP Pharmacy Coverage Policy: EOCCO214

Description

Riluzole (Rilutek®, Teglutik®, Exervan®) is an orally administered benzothiazole for the treatment of patients with amyotrophic lateral sclerosis (ALS).

Length of Authorization

- Initial: 12 months
- Renewal: 12 months

Quantity Limits

Product Name	Dosage Form	Indication	Quantity Limit
riluzole (Rilutek) *	50 mg tablet	Amyotrophic lateral sclerosis (ALS)	60 tablets/30 days
riluzole (Teglutik)	50 mg/10 mL (5 mg/mL) oral suspension		600 ml/30 days
riluzole (Exervan)	50 mg film		60 films/30 days

**Generic riluzole* is a formulary agent and does not require prior authorization

Initial Evaluation

I. Riluzole (Rilutek, Teglutik, Exervan) may be considered medically necessary when the following criteria are met:
   A. Member is 18 years of age or older; **AND**
   B. Medication is prescribed by, or in consultation with, a neurologist; **AND**
   C. A diagnosis of **Amyotrophic lateral sclerosis (ALS); AND**
   D. Treatment with generic riluzole tablet has been ineffective, contraindicated, or not tolerated.

II. Riluzole (Rilutek, Teglutik, Exervan) are considered investigational when used for all other conditions, including but not limited to:
   A. Treatment-resistant depression
   B. Chorea in Huntington's disease

Renewal Evaluation

I. Member has received a previous prior authorization approval for this agent through this health plan; **AND**
II. Member is not continuing therapy based off being established on therapy through samples, manufacturer coupons, or otherwise.; **AND**
III. Documentation of clinical benefit, including stabilization of disease and absence of unacceptable toxicity from the drug [e.g. hepatic injury, severe neutropenia, interstitial lung disease]; **AND**
IV. Treatment with generic riluzole tablet has been ineffective, contraindicated, or not tolerated

Supporting Evidence

I. According to the American Academy of Neurology (AAN) two randomized controlled clinical trials and one cross-sectional study, show that multidisciplinary clinics specializing in ALS care are likely effective in several ways, which include improved quality of life and lengthened survival. The AAN guidelines recommend that specialized multidisciplinary clinical referral should be considered for patients with ALS to optimize health care delivery and prolong survival and may be linked to enhanced quality of life.
II. The safety and efficacy of riluzole (Rilutek®) in pediatric patients with amyotrophic lateral sclerosis (ALS) has not been established.
III. According to the American Academy of Neurology (AAN) practice parameter for the care of patients with ALS, riluzole is safe and effective for slowing disease progression to a modest degree in ALS. They therefore recommend that riluzole should be offered to slow disease progression in patients with ALS.

Investigational or Not Medically Necessary Uses

I. In a randomized, double-blind, placebo-controlled sequential trial that evaluated the efficacy and safety of adjunctive riluzole for treatment-resistant major depressive disorder (MDD), 104 participants were randomized in a 2:3:3 ratio to receive riluzole/riluzole, placebo/placebo and placebo/riluzole. The trial had two phases of 4 weeks each, and the primary endpoint was change in depression severity as assessed by the Montgomery-Åsberg Depression Rating Scale (MADRS), which did not show a statistically significant difference between riluzole and placebo.
II. Chorea is a hallmark of Huntington Disease (HD), along with cognitive decline and psychiatric impairment. The AAN guidelines for pharmacologic treatment of HD, notes two randomized controlled trials evaluating riluzole for chorea for HD using different doses (100 mg or 200 mg) and durations (8 weeks and 3 years). The first study (n=63) showed a statistically significant reduction in unified huntington's disease rating scale (UHDRS) in patients who received riluzole

200 mg/day (-2.2 ± 3.3, p 0.01); however, statistical significance was observed in those who received riluzole 100 mg/day [-0.2 ± 2.9; vs placebo (± 0.7 ± 3.4)]. In the second study (n=537), no statistically significant difference in UHDRS chorea scores at 3 years was observed between participants who received riluzole 50 mg twice daily and placebo. Although the guidelines recommend riluzole 200 mg/day with level B of evidence for HD chorea, there is modest evidence on the efficacy and safety of riluzole for chorea in HD.

References

1. Riluzole (Teglutik®) [Prescribing information]. Berwyn, PA: ITF Pharma, Inc. March 2020.
2. Riluzole (Rilutek®) [Prescribing Information]. Switzerland: Covis Pharma. March 2020.
3. Miller RG, Jackson CE, Kasarkis EJ, et al. Practice Parameter update: The care of the patient with
4. amyotrophic lateral sclerosis: Multidisciplinary care, symptom management, and cognitive/behavioral impairment (an evidence-based review). Neurology® 2009;73:1227–1233.
5. 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.
6. Mathew SJ, Gueorguieva R, Brandt C, et al. A Randomized, Double-Blind, Placebo-Controlled, Sequential Parallel Comparison Design Trial of Adjunctive Riluzole for Treatment-Resistant Major Depressive Disorder. Neuropsychopharmacology (2017) 42, 2567–2574.
7. Armstrong MJ, Miyasaki JM. Evidence-based guideline: Pharmacologic treatment of chorea in Huntington disease. Neurology® 2012;79:597–603.
8. Riluzole (Exervan®) [Prescribing information]. Jersey City, NJ: Mitsubishi Tanabe Pharma America, September 2021.

Policy Implementation/Update:

Action and Summary of Changes	Date
Added Exervan to policy	09/2021
Criteria changed to policy format, added age requirement, specialist referral/prescription, step through generic riluzole tablet and renewal evaluation.	12/2020
Criteria created	07/2013