MEDICAL MUTUAL®

Drug Policy

Policy:	**Exservan (riluzole) oral film** **Tiglutik Kit (riluzole) oral suspension** **Rilutek (riluzole) oral tablets**	**Annual Review Date: 01/18/2024** **Last Revised Date: 01/18/2024**

OVERVIEW

Exservan and Tiglutik Kit are alternative formulations of riluzole, which is indicated for the treatment of amyotrophic lateral sclerosis (ALS). Exservan and Tiglutik are members of the benzothiazole class, but the specific mechanism of action in patients with ALS is unknown. Exservan and Tiglutik can cause liver injury and patients should be monitored for signs and symptoms of hepatic injury every month for the first three months of treatment and periodically thereafter. The use of Exservan or Tiglutik is not recommended if patients develop hepatic transaminases levels greater than 5 times the upper limit of normal and should be discontinued if evidence of liver dysfunction (eg. elevated bilirubin) is seen.

POLICY STATEMENT

This policy involves the use of Rilutek, Exservan and Tiglutik Kit. Prior authorization is recommended for pharmacy benefit coverage of Rilutek, Exservan and Tiglutik Kit. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Rilutek, Exservan and Tiglutik Kit, as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Rilutek, Exservan and Tiglutik Kit be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Rilutek, Exservan and Tiglutik Kit is recommended in those who meet the following criteria:

1. **Amyotrophic Lateral Sclerosis (ALS) Initial Therapy**
   Criteria. *Approve if the patient meets the following criteria: (a, b, c, d, AND e)*
   a) Patient is 18 years of age or older; AND
   b) Baseline ALS Functional Rating Scale-Revised (ALSFRS-R) score measured; AND
   c) Patient has normal respiratory function (defined as percent-predicted forced vital capacity values of [%FVC] greater than or equal to 60 %); AND

d) Prescribed by or in consultation with a neurologist or physician who specializes in the treatment of ALS; AND
e) Patient must have previously tried therapy with generic riluzole oral tablets;

2. Amyotrophic Lateral Sclerosis (ALS) Continuation Therapy
Criteria. *Approve if the patient meets the following criteria: (a, b, c, d, AND e):*

a) Patient is 18 years of age or older; AND
b) Baseline ALS Functional Rating Scale-Revised (ALSFRS-R) score measured ; AND
c) Prescribed by or in consultation with a neurologist or physician who specializes in the treatment of ALS; AND
d) Patient must have previously tried therapy with generic riluzole oral tablets.

Initial Approval/ Extended Approval.
A) *Initial Approval: 6 months*
B) *Extended Approval: 1 year*

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Exservan has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Exservan™ [prescribing information]. Warren, NJ: Aquestive Therapeutics; November 2019.
2. Tiglutik Kit™ [prescribing information]. Berwyn, PA: IFT Pharma ; Accessed January 2020.