

Commercial/Healthcare Exchange PA Criteria *Effective: March 8th, 2019*

Prior Authorization: Tiglutik

Products Affected: Tiglutik oral suspension, Exservan oral film

Medication Description:

Riluzole is the only known drug to have any impact on survival in amyotrophic lateral sclerosis (ALS). The exact mechanism is not known but is thought to have activity by reducing glutamate-induced excitotoxicity.

Covered Uses: Treatment of amyotrophic lateral sclerosis (ALS).

Exclusion Criteria:

1. Patients with a history of severe hypersensitivity reactions to riluzole or to any of its components (anaphylaxis has occurred)

Required Medical Information:

1. Diagnosis
2. Medical history

Age Restrictions: 18 years of age and older

Prescriber Restrictions: Prescribed by, or in consultation with, a neurologist.

Coverage Duration: 12 months

Other Criteria:

- A. The patient has a diagnosis of Amyotrophic lateral sclerosis (ALS); **AND**
- B. The patient is unable to ingest a solid dosage form (e.g., riluzole oral tablet) due to one of the following:
 - a. Oral/motor difficulties; OR
 - b. Dysphagia

Quantity Limits:

Exservan- 60 films for 30 days

References:

1. Tiglutik [package insert]. Berwyn, PA; ITF Pharma; September 2018.
2. Exservan (riluzole) [prescribing information]. Warren, NJ: Aquestive Therapeutics; April 2021.

Policy Revision history:

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	03/08/2019
2	Annual Review	N/A	N/A	3/20/2020
3	Update	Addition of Exservan oral film Updated criteria to include quantity limit for Exservan	Products Affected Other Criteria	9/14/2021