ConnectiCare

# Commercial/Healthcare Exchange PA Criteria

***Effective: March 8th, 2019***

***Prior Authorization:*** Tiglutik

***Products Affected:*** Tiglutik (riluzole) oral suspension

***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. Tiglutik addresses an unmet need to provide a formulation that would be easier to swallow or could be administered in a G-tube. The recommended dose of Tiglutik is 50mg (10ml) taken orally twice daily. It should be taken at least 1 hour before or 2 hours after a meal.

***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

***References:***
1. Tiglutik [package insert]. Berwyn, PA; ITF Pharma; September 2018.

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***Policy Revision history:***

| Rev # | Type of Change | Summary of Change | Sections Affected | Date |
|---|---|---|---|---|
| 1 | New Policy | New Policy | All | 03/08/2019 |