VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Vesicular Monoamine Transporter Type 2 Inhibitors – Tetrabenazine Prior Authorization Policy
- Xenazine® (tetrabenazine tablets – Lundbeck, generic)

REVIEW DATE: 06/16/2021

OVERVIEW

Tetrabenazine, a vesicular monoamine transporter type 2 inhibitor, is indicated for the treatment of **chorea associated with Huntington's disease** in adults.[1]

Beginning in September 2015, tetrabenazine has been available as an AB-rated generic to brand Xenazine. Generic tetrabenazine is FDA-approved and is available in the same tablet dosage form and the same 12.5 mg and 25 mg strengths as brand Xenazine.

Clinical Efficacy

There are multiple controlled and uncontrolled trials conducted with tetrabenazine that included patients with dystonias.[6-10,12,13,16,19,21,22] In retrospective trials, an overall moderate clinical improvement or better was seen in 161 out of 163 patients with dystonia treated with tetrabenazine.[21] A treatment algorithm for secondary dystonias was developed that notes tetrabenazine can be tried following a trial of an anticholinergic in children with severe secondary dystonias.[22] In adults, tetrabenazine can be tried (alone or as combination therapy) following a low-dose trial of anticholinergic.

Tetrabenazine has been studied for the treatment of tardive dyskinesia, either as initial therapy or in patients who have responded poorly to other agents (e.g., reserpine, bromocriptine, clozapine).[5-15]

While most of the data for treatment of Tourette syndrome indicate that antipsychotic medications, both typical and atypical, are most effective, other medications (including tetrabenazine) may be used first to avoid the potential side effects of dopamine blockade.[18]

Guidelines

The American Academy of Neurology (AAN) evidence-based guidelines on pharmacologic treatment of chorea in Huntington's disease (2012) states that if chorea in Huntington's disease requires treatment, clinicians should prescribe tetrabenazine, amantadine, or Rilutek® (riluzole tablets) [Level B].[2]

The AAN published an evidence-based guideline for the treatment of tardive syndromes (TDS) [2013].[3] The authors found that tetrabenazine possibly reduces TDS symptoms (based on two consistent Class III studies). Therefore, tetrabenazine may be considered in treating TDS (Level C).

The AAN published practice guideline recommendations for the treatment of tics in people with Tourette syndrome and chronic tic disorders (2019).[4] The guidelines state that the dopamine depleters, tetrabenazine, deutetrabenazine, and valbenazine, are lacking published, randomized, controlled trials in the treatment of tics but note that these drugs are increasingly used off-label. When appropriately dosed, these drugs are generally well-tolerated but may be associated with drowsiness, depression, and parkinsonism.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of tetrabenazine. Because of the specialized skills required for evaluation and diagnosis of patients treated with tetrabenazine as well as the monitoring required for adverse events and long-term efficacy, approval requires tetrabenazine to be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of tetrabenazine is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Chorea Associated with Huntington's Disease.** Approve for 1 year if the patient meets the following criteria (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Diagnosis of Huntington's disease is confirmed by genetic testing (for example, an expanded HTT CAG repeat sequence of at least 36); AND
   - **C)** The medication is prescribed by or in consultation with a neurologist.

Other Uses with Supportive Evidence

2. **Hyperkinetic Dystonia.** Approve for 1 year if the patient meets the following criteria (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** The medication is prescribed by or in consultation with a neurologist.

3. **Tardive Dyskinesia.** Approve for 1 year if the patient meets the following criteria (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** The medication is prescribed by or in consultation with a neurologist or psychiatrist.

4. **Tourette Syndrome and Related Tic Disorders.** Approve for 1 year if the patient meets the following criteria (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** The medication is prescribed by or in consultation with a neurologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of tetrabenazine is not recommended in the following situations:

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

REFERENCES

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