

PRIOR AUTHORIZATION POLICY

POLICY: Vesicular Monoamine Transporter Type 2 Inhibitors – Tetrabenazine Prior Authorization Policy

- Xenazine® (tetrabenazine tablets – Lundbeck, generic)

REVIEW DATE: 04/10/2024

OVERVIEW

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

Clinical Efficacy

There are several published studies which have assessed the efficacy and safety of tetrabenazine for the treatment of other hyperkinetic movement disorders (e.g., tics in Tourette syndrome and tardive dyskinesia).²⁻⁴ 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.⁵

Guidelines

The American Academy of Neurology (AAN) evidence-based guidelines on pharmacologic treatment of chorea in Huntington's disease (2012) state that if chorea in Huntington's disease requires treatment, clinicians should prescribe tetrabenazine, amantadine, or Rilutek® (riluzole tablets) [Level B].⁶

The AAN published an evidence-based guideline for the treatment of tardive syndromes (2013).⁷ The authors found that tetrabenazine possibly reduces tardive syndrome symptoms (based on two consistent Class III studies). Therefore, tetrabenazine may be considered in treating tardive syndromes (Level C).

The AAN published practice guideline recommendations for the treatment of tics in patients with Tourette syndrome and chronic tic disorders (2019).⁸ The guidelines state that the dopamine depleters, tetrabenazine, deutetabenazine, 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. All approvals are provided for the duration noted below. 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.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indication

1. **Chorea Associated with Huntington's Disease.** Approve for 1 year if the patient meets ALL of the following (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 BOTH of the following (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 BOTH of the following (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 BOTH of the following (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

1. Xenazine® tablets [prescribing information]. Deerfield, IL: Lundbeck; November 2019.
2. Merative Micromedex®. Merative US. Available at: <https://www.micromedexsolutions.com/>. Accessed on April 3, 2024. Search terms: tetrabenazine.
3. Chen JJ, Ondo WG, Dashtipour K, et al. Tetrabenazine for the treatment of hyperkinetic movement disorders: a review of the literature. *Clin Ther*. 2012;34(7):1487-504.
4. Guay DR. Tetrabenazine, a monoamine-depleting drug used in the treatment of hyperkinetic movement disorders. *Am J Geriatr Pharmacother*. 2010;8(4):331-373.
5. Quezada J, Coffman KA. Current Approaches and New Developments in the Pharmacological Management of Tourette Syndrome. *CNS Drugs*. 2018; 32(1):33-45.
6. Armstrong MJ, Miyasaki JM. Evidence-based guideline: pharmacologic treatment of chorea in Huntington disease: report of the guideline development subcommittee of the American Academy of Neurology. *Neurology*. 2012;79:597-603.
7. Bhidayasiri R, Fahn S, Weiner WJ, et al. Evidence-based guideline: treatment of tardive syndromes: report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology*. 2013;81(5):463-469.
8. Pringsheim T, Okun MS, Müller-Vahl K, et al. Practice guideline recommendations summary: treatment of tics in people with Tourette syndrome and chronic tic disorders. *Neurology*. 2019;92:896-906.

