PRIOR AUTHORIZATION POLICY

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

- Xenazine® (tetrabenazine tablets – Lundbeck, generic)

REVIEW DATE: 06/08/2022

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 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 one of the following criteria:

FDA-Approved Indication

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

1. Xenazine® tablets [prescribing information]. Deerfield, IL: Lundbeck; September 2017.
2. 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.
3. 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.
4. 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.
5. Kenney C, Jankovic J. Tetrabenazine in the treatment of hyperkinetic movement disorders. *Expert Rev Neurotherapeutics.* 2006;6:7-17.
6. IBM Micromedex®. IBM Corporation. Available at: https://www.micromedexsolutions.com/. Accessed on June 2, 2022. Search terms: tetrabenazine.
7. Jankovic J, Orman J. Tetrabenazine therapy of dystonia, chorea, tics, and other dyskinesias. *Neurology.* 1988;38:391-394.

8. Kenney C, Hunter C, Jankovic J. Long-term tolerability of tetrabenazine in the treatment of hyperkinetic movement disorders. *Mov Disord.* 2007;22:193-197.
9. Jankovic J, Beach J. Long-term effects of tetrabenazine in hyperkinetic movement disorders. *Neurology.* 1997;48:358-362.
10. Paleacu D, Giladi N, Moore O, et al. Tetrabenazine treatment in movement disorders. *Clin Neuropharmacol.* 2004;27:230-233.
11. Ondo WG, Hanna PA, Jankovic J. Tetrabenazine treatment for tardive dyskinesia: assessment by randomized videotape protocol. *Am J Psychiatry*. 1999;156:1279-1281.
12. Jankovic J. Treatment of hyperkinetic movement disorders with tetrabenazine: a double-blind crossover study. *Ann Neurol*. 1982;11(1):41-47.
13. Asher SW, Aminoff MJ. Tetrabenazine and movement disorders. *Neurology*. 1981;31(8):1051-1053.
14. Kingston D. Tetrabenazine for involuntary movement disorders. *Med J Aust*. 1979;1(13):628-630.
15. Kazamatsuri H, Chien C, Cole JO. Treatment of tardive dyskinesia: clinical efficacy of a dopamine-depleting agent, tetrabenazine. *Arch Gen Psychiat*. 1972;27:95-99.
16. Jain S, Greene PE, Frucht SJ. Tetrabenazine therapy of pediatric hyperkinetic movement disorders. *Mov Disord.* 2006;21:1966-1972.
17. Ondo WG, Jong D, Davis A. Comparison of weight gain in treatments for Tourette syndrome: tetrabenazine versus neuroleptic drugs. *J Child Neurol.* 2008;23:435-437.
18. Quezada J, Coffman KA. Current Approaches and New Developments in the Pharmacological Management of Tourette Syndrome. *CNS Drugs*. 2018; 32(1):33–45.
19. Swash M, Roberts AH, Zakko H, Heathfield KWG. Treatment of involuntary movement disorders with tetrabenazine. *J Neurol Neurosurg Psychiatry*. 1972;35(2):186-191.
20. Pakkenberg H, Fog R. Spontaneous oral dyskinesia. Results of treatment with tetrabenazine, pimozide, or both. *Arch Neurol.* 1974;31(5):352-353.
21. Guay DR. Tetrabenazine, a monoamine-depleting drug used in the treatment of hyperkinetic movement disorders. *Am J Geriatr Pharmacother*. 2010;8(4):331-373.
22. Dressler D. Nonprimary dystonias. *Handb Clin Neurol*. 2011;100:513-538.