

Clinical Pharmacy Program Guidelines for Xenazine

Program	Prior Authorization
Medication	Xenazine
Issue Date	12/2009
Pharmacy and Therapeutics Approval Date	10/2017
Effective Date	11/2017

1. Background:

Xenazine is indicated for the treatment of chorea associated with Huntington’s disease.

Off Label Uses: Xenazine has shown effectiveness in the treatment of hyperkinetic movement disorders (hyperkinesias) characterized by abnormal involuntary movements such as tics (eye blink, shouting obscenities or profanities, etc.) in Tourette’s syndrome (TS) and stereotypies in tardive dyskinesia (TD).

2. Coverage Criteria:

<p>A. <u>Chorea associated with Huntington’s disease</u></p> <p>1. <u>Authorization</u></p> <p>a. Diagnosis of chorea in patients with Huntington’s disease</p> <p>Authorization will be issued for 12 months.</p> <p>B. <u>Tardive dyskinesia (off-label)</u></p> <p>1. <u>Initial Authorization</u></p> <p>a. Patient has stereotypies associated with tardive dyskinesia</p> <p align="center">-AND-</p> <p>b. Patient is greater than or equal to 18 years of age</p> <p align="center">-AND-</p>
--

c. Prescribed by or in consultation with one of the following:

- Neurologist
- Psychiatrist

Authorization will be issued for 12 months.

2. Reauthorization

a. Documentation of positive clinical response to therapy

Authorization will be issued for 12 months.

C. Tourette's syndrome (off-label)

1. Initial Authorization

a. Patient has tics associated with Tourette's syndrome

-AND-

b. History of failure, contraindication, or intolerance to Haldol (haloperidol)

-AND-

c. Prescribed by or in consultation with one of the following:

- Neurologist
- Psychiatrist

Authorization will be issued for 12 months.

2. Reauthorization

a. Documentation of positive clinical response to therapy

Authorization will be issued for 12 months.

3. References:

1. Xenazine Prescribing Information, Biovail Laboratories International. June 2015.
Confidential and Proprietary, © 2017 UnitedHealthcare Services Inc.

2. Bonelli RM, Hofmann P. A systemic review of the treatment studies in Huntington's disease since 1990. *Expert Opin. Pharmacother.* 2007;8(2):141-153.
3. Bonelli RM, Wenning GK. Pharmacological management of Huntington's disease: an evidence-based review. *Curr Pharm Des.* 2006;12:2701-2720.
4. Huntington Study Group. An open-label study of tetrabenazine as anti-chorea therapy in Huntington disease. In preparation (unpublished study 007).
5. DRUGDEX System [Internet database]. Greenwood Village, Colo: Thomson Micromedex. Updated periodically. Accessed October 27, 2015.
6. Kenney C, Jankovic J. Tetrabenazine in the treatment of hyperkinetic movement disorders. *Expert Rev. Neurotherapeutics.* 2006;6(1):7-17.
7. Jankovic J. Treatment of hyperkinetic movement disorder with tetrabenazine: a double-blind crossover study. *Ann Neurol.* 1982;11:41-47.
8. Marsden CD. Involuntary movements other than Parkinsonism. *Proc Roy Soc Med.* 1973;66:27-29.
9. Ondo WG, Hanna PA, Jankovic J. Treatment of Tardive Dyskinesia: assessment by randomized videotapes protocol. *Am J Psychiatry.* 1999;156:1279-1281.
10. Jankovic J, Orman J. Examine therapy of dystonia, chorea, tics, and other dyskinesias. *Neurology.* 1988;38:391-394.
11. Asher SW, Aminoff MJ. Tetrabenazine and movement disorders. *Neurology.* 1981;31:1051-1054.
12. Kingston D. Tetrabenazine for involuntary movement disorders. *Med J Aust.* 1979;1628-630.
13. Sweet RD, Brauun R, Shapiro E, Shapiro AK. Presynaptic catecholamine antagonists as treatment for Tourette syndrome. Effects of alpha methyl para tyrosine and tetrabenazine. *Arch Gen Psych.* 1974;31:857-861.
14. Pakkenberg H, Fog R. Spontaneous oral dyskinesia: results of treatment with tetrabenazine, pimozide, or both. *Arch Neurol.* 1974;31:352-353.
15. Kazamatsuri H, Chien C-P, Cole J. Treatment of Tardive Dyskinesia: clinical efficacy of a dopamine-depleting agent, tetrabenazine. *Arch Gen Psychiat.* 1972;27:95-99.
16. Ondo WG, Jong D, Davis A. Comparison of weight gain in treatments for Tourette syndrome: tetrabenazine vs. neuroleptic drug. *J Child Neurol.* 2008.23:435-437.
17. 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 Jul 18. [Epub ahead of print]

Program	Prior Authorization –Xenazine (tetrabenazine)
Change Control	
Date	Change
Dec 2009	Criteria taken from previously approved AmeriChoice policy. Re-authorization criteria added to ensure that patients are re-evaluated for clinical benefit. Policy was reformatted.
Dec 2010	Annual Review

Dec 2011	Annual Review
Dec 2012	Annual Review
March 2015	<p>Template updated</p> <p>Huntington disease initial criteria: changed initial authorization duration from 1 year to 3 months.</p> <p>Huntington disease reauthorization criteria: removed requirement that “patient’s chorea has not progressed to rigidity and bradykinesia” and replaced with “documentation of clinical response and benefit from therapy”.</p> <p>Added off label criteria for Tardive dyskinesia and Tourette’s syndrome.</p>
November 2016	Annual review, updated policy template
March 2017	Updated policy template. Changed initial authorization duration to 12 months for all indications.
September 2017	Removed prescriber check and reauthorization criteria for HD to allow for Dx to Rx implementation