

Clinical Pharmacy Program Guidelines for Xenazine

Program	Prior Authorization
Medication	Xenazine (tetrabenazine)
Markets in Scope	Arizona, California, Hawaii, Nevada, Maryland, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	12/2009
Pharmacy and Therapeutics Approval Date	10/2020
Effective Date	12/2020

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 seen in tardive dyskinesia (TD) or issues such as tics (eye blink, shouting obscenities or profanities, etc.) in Tourette’s syndrome (TS).

Xenazine has black box warnings for suicidal ideation and depression. Please see full prescribing information for additional details.

2. Coverage Criteria:

<p>A. <u>Chorea associated with Huntington’s disease</u></p> <p>1. <u>Authorization</u></p> <p style="padding-left: 40px;">a. Diagnosis of chorea in patients with Huntington’s disease</p> <p style="text-align: center;">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 style="padding-left: 40px;">a. Diagnosis of tardive dyskinesia</p> <p style="text-align: center;">-AND-</p>
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b. **One** of the following:

(1) Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication

-OR-

(2) Patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication

-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.

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 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. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4. References:

1. Xenazine [package insert]. Deerfield, IL: Lundbeck Pharmaceuticals LLC; November 2019.
2. Pringsheim T, et al. Neurology. 2019; 92(19): 896-906.
3. Jankovic J. Tourette syndrome. Nordli, DR (Ed). UpToDate. Waltham, MA: UpToDate Inc. <http://www.uptodate.com> (Accessed on August 28, 2019).
4. Tarsy D. Tardive dyskinesia: Prevention, prognosis, and treatment. Hurtig, H (Ed). UpToDate. Waltham, MA: UpToDate Inc. <http://www.uptodate.com> (Accessed on August 28, 2019).
5. Micromedex 2.0 [database online]. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: <http://www.micromedexsolutions.com>. Accessed September 10, 2020.

Program	Prior Authorization –Xenazine (tetrabenazine)
Change Control	
Date	Change
12/2009	Criteria taken from previously approved AmeriChoice policy. Re-authorization criteria added to ensure that patients are re-evaluated for clinical benefit. Policy was reformatted.
12/2010	Annual Review
12/2011	Annual Review
12/2012	Annual Review

3/2015	<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>
11/2016	Annual review, updated policy template
3/2017	Updated policy template. Changed initial authorization duration to 12 months for all indications.
9/2017	Removed prescriber check and reauthorization criteria for HD to allow for Dx to Rx implementation
10/2018	Revised tardive dyskinesia (TD) section to align with criteria for other TD programs. Removed age edit since there is not an age edit coded. Updated references.
10/2019	Annual review. Minor revisions to background. Updated references.
10/2020	Annual review. Updated references. Added Additional Clinical Rules section.