MEDICATION POLICY

Generic Name: Tetrabenazine

Therapeutic Class or Brand Name: Xenazine®

Applicable Drugs (if Therapeutic Class)**:**

Preferred: Tetrabenazine tablets (generic)

Non-Preferred: Xenazine® tablets

Date of Origin: 2/1/13 **Date Last Reviewed/Revised:** 12/13/17

GPI Code: 6238007000

Prior Authorization Criteria (may be considered medically necessary when criteria I through V are met):

I. Documented diagnosis of chorea associated with Huntington's disease.

II. Documented chart notes that the patient is being monitored for symptoms of depression and that depression is being addressed if it is present.

III. Minimum age requirement: 18 years old.

IV. Prescriber is a neurologist.

V. Non-preferred products (i.e. Xenazine® tablets) require a documented clinical reason containing details as to why generic tetrabenazine is not appropriate or is contraindicated.

Exclusion Criteria:

- Patients who are actively suicidal, or who have depression which is untreated or undertreated.
- Patients with impaired hepatic function.
- Patients taking monoamine oxidase inhibitors (MAOIs) or reserpine.
- Patients taking deutetrabenazine or valbenazine.

Other Criteria:

- N/A

Quantity/Days Supply Restrictions:

- Authorized in quantities of up to 50 mg per day.

Disclaimer: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgment in providing the most appropriate care for their patients.

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- Quantities up to 100 mg per day may be considered medically necessary when there is documentation of both a AND b:
  - **a.** Tetrabenazine 50 mg per day has not provided an adequate response.
  - **b.** CYP2D6 genotyping shows that the patient is an extensive (EM) or intermediate metabolizer (IM) of CYP2D6.
- The quantity is limited to a maximum of a 30 day supply per fill.

Approval Length:

- **Authorization:** 3 months.
- **Re-Authorization:** 6 months. An updated letter or progress notes showing that (1) chorea symptoms have improved or stabilized AND (2) patient is being monitored for symptoms of depression and that depression is being addressed if it is present.

Appendix:

N/A

References:

1. http://blue.regence.com/trgmedpol/drugs/dru176.pdf.
2. Medi-Span.
3. http://www.lundbeck.com/upload/us/files/pdf/Products/Xenazine_PI_US_EN.pdf.

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Historical Tracking Of Changes Made To Policy	
12/13/2017	1. **Added** "Patients taking deutetrabenazine or valbenazine" **under Exclusion Criteria**.
10/6/2016	1. **Changed** "N/A" **to** "Preferred: Tetrabenazine tablets (generic); Non-Preferred: Xenazine® tablets" **following Applicable Drugs**. 2. **Added** "V. Non-preferred products (i.e. Xenazine® tablets) require a documented clinical reason containing details as to why generic tetrabenazine is not appropriate or is contraindicated" **under Prior Authorization Criteria**. 3. **Changed** "Xenazine®…" **to** "Tetrabenazine…" **under Quantity/Days Supply Restrictions**.
4/21/2015	1. **Changed** "Documented diagnosis of Huntington's disease with the presence of chorea symptoms as confirmed by a neurologist" **to** "Documented diagnosis of chorea associated with Huntington's disease" **and** "Prescriber is a neurologist" **under Prior Authorization Criteria**. 2. **Changed** "Quantities up to 100 mg per day may be considered medically necessary when there is documentation showing that Xenazine® 50 mg daily has not provided adequate response" **to** "Quantities up to 100 mg per day may be considered medically necessary when there is documentation of both a AND b: a. Xenazine® 50 mg per day has not provided an adequate response; b. CYP2D6 genotyping shows that the patient is an extensive (EM) or intermediate metabolizer (IM) of CYP2D6" **under Quantity/Days Supply Restrictions**. 3. **Added** "The quantity is limited to a maximum of a 30 day supply per fill" **under Quantity/Days Supply Restrictions**.
12/5/2013	1. **Adapted policy to new format.** 2. **Added GPI Code**. 3. **Added** "Minimum age requirement: 18 years old" **to Prior Authorization Criteria**. 4. **Added** "Patients who are actively suicidal, or who have depression which is untreated or undertreated; Patients with impaired hepatic function; Patients taking monoamine oxidase inhibitors (MAOIs) or reserpine" **to Exclusion Criteria**. 5. **Updated references** to include Medi-Span and Xenazine package insert.

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