Xenazine

Description

Xenazine (tetrabenazine)

Background

Xenazine is the first FDA approved medication for treatment of chorea associated with Huntington's disease (HD).¹

HD affects an estimated 30,000 Americans, and is a devastating neurodegenerative disease that causes progressive movement disorders, cognitive dysfunction, behavioral changes, and is ultimately fatal. Chorea is the most common symptom, affecting approximately 90% of HD patients, and is characterized by excessive, involuntary and repetitive movements, which are the most visible and dangerous manifestations of HD and interfere with patients' abilities to perform activities of daily living, including dressing, bathing and caring for themselves.²

Concurrent use of reserpine and xenazine may result in elevated catecholamine levels. When switching a patient from reserpine to xenazine, wait for chorea to re-emerge and at least 20 days after stopping reserpine before initiating tetrabenazine to avoid overdose and significant depletion of norepinephrine and serotonin in the CNS.

Xenazine is available as 12.5 and 25 mg oral tablets. The dose should be titrated slowly and individualized for each patient.

The recommended initial dose is 12.5 mg once daily in the morning. After one week, the dose may be increased to 12.5 mg twice daily. The dose may be increased by 12.5 mg per week until a well-tolerated dose that controls chorea symptoms is identified.
Xenazine

The maximum recommended single dose is 25 mg. Total daily doses of 37.5 mg or greater should be divided into a three times daily regimen. Total daily doses above 100 mg are not recommended.¹

**Regulatory Status**

*FDA-approved indication: Xenazine is a vesicular monoamine transporter 2 (VMAT) inhibitor indicated for the treatment of chorea associated with Huntington’s disease.*¹⁰

Xenazine can increase the risk of depression and suicidal thoughts and behavior (suicidality) in patients with Huntington disease. For this reason the FDA has given the drug a black box warning: Anyone considering the use of Xenazine must balance the risks of depression and suicidality with the clinical need for control of choreiform movements. Xenazine is contraindicated in patients who are actively suicidal, and in patients with untreated or inadequately treated depression.¹

**Related policies**

**Policy**

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Xenazine may be considered **medically necessary** for the conditions listed below. Xenazine may be considered **investigational** for all other indications.

**Prior-Approval Requirements**

- Patient must have ONE of the following:
  - Tourette's disorder
  - Huntington's Chorea
  - Other Chorea
  - Acute Dystonia Due to Drugs
  - Orofacial Dyskinesia
  - Subacute Dyskinesia Due to Drugs
  - Dystonia

AND

- Not actively suicidal
No untreated or inadequately treated depression, concomitant use of a MAOI (monoamine oxidase inhibitor), concomitant use of reserpine (must be >20 days post discontinuing therapy), or severe hepatic impairment.

**Prior – Approval Renewal Requirements**

Same as above

**Policy Guidelines**

**Pre - PA Allowance**

*None*

**Prior - Approval Limits**

<table>
<thead>
<tr>
<th>Quantity</th>
<th>12.5mg - 720 tablets per 90 days</th>
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<td>25 mg – 360 tablets per 90 days</td>
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<tr>
<th>Duration</th>
<th>12 months</th>
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**Prior – Approval Renewal Limits**

Same as above

**Rationale**

**Summary**

HD affects an estimated 30,000 Americans, and is a devastating neurodegenerative disease that causes progressive movement disorders, cognitive dysfunction, behavioral changes, and is ultimately fatal. Xenazine is the first FDA approved medication for treatment of chorea associated with Huntington's disease (HD). Xenazine can increase the risk of depression and suicidal thoughts and behavior (suicidality) in patients with Huntington disease.

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Xenazine while maintaining optimal therapeutic outcomes.

**References**

2. http://www.drugs.com/newdrugs/xenazine-tetrabenazine-approved-fda-patients-chorea-
The use of Xenazine to treat dyskinetic movement disorders has been demonstrated to be safe and effective. The clinical literature supports the use of Xenazine in tardive dyskinesia, chorea not associated with HD, orofacial dyskinesia and Tourette’s syndrome. 4, 5, 6, 7, 8, 9 Practicing neurologists consulted also report the use of Xenazine for these indications as generally accepted medical practice.

### Keywords

- Xenazine
- Tardive dyskinesia
- Chorea
- Hyperkinetic movement disorders
- Tetrabenazine
- Dystonia
- Chorea
- Tic
- Dyskinesia
- Tourette’s syndrome
- Neurology
- Mov Disord
- Clin Neuropharmacol
- Clin Drug Investig