



## Prior Authorization Approval Criteria

### Xenazine (tetrabenazine)

<b>Generic name:</b>	Tetrabenazine (TBZ)
<b>Brand name:</b>	Xenazine
<b>Medication class:</b>	Central monoaminergic depletor
<b>FDA-approved uses:</b>	Treatment of chorea associated with Huntington's disease
<b>Available dosage forms:</b>	12.5mg and 25mg tablets
<b>Usual dose:</b>	Starting dose of 12.5mg/day. After one week may be increased up to 25mg/day given as 12.5mg bid. If a dose of 37.5mg to 50mg/day is needed, it should be given tid. The maximum recommended single dose is 25mg. -Patients who appear to require doses greater than 50mg/day should be genotyped for CYP2D6, and special dosing recommendations apply. Doses greater than 100mg/day are not recommended for anyone.
<b>Approximate monthly cost:</b> (based on AWP 2009)	\$2,055.00/month for 25mg/day
<b>Duration of therapy:</b>	Indefinite

**Criteria for use** (*bullet points below are all inclusive unless otherwise noted*):

- Confirmed diagnosis of chorea associated with Huntington's disease.
- Required information is needed to complete review which includes clinical notes from the patient's medical records including any applicable labs and/or tests, supporting the diagnosis.
- Must have tried and failed at least two of the following: amantadine, an antipsychotic (fluphenazine, haloperidol, risperidone, ziprasidone, quetiapine or olanzapine), riluzole, or a benzodiazepine.
- Must be prescribed by a neurologist that treats Huntington's Disease.
- For doses greater than 50 mg/day, CYP2D6 genotyping is required.
- Must be enrolled in the Risk Evaluation and Mitigation Strategy (REMS)\* program
- If approved, Xenazine will be approved for 3 months at a time.
- Prescribing doctor must speak with a medical director.

**Criteria for continuation of therapy:**

- Signs and symptoms of chorea must be decreased.
- Patient must not show signs of worsening depression.

**Caution:**

- Black box warning: Worsening depression and an increased risk of suicide. Patients prone to depression and those with a history of psychiatric illness should be monitored closely when taking TBZ.

**Monitoring:**

- Mood, cognition, rigidity and functional capacity must be monitored since these were

shown to cause slight worsening.

**Contraindication:**

- Patients who are actively suicidal, or in patients with untreated or inadequately treated depression
- Impaired hepatic function
- Patients who are taking MAO inhibitors
- Patients who are on reserpine or have taken reserpine within 20 days of TBZ

**Not approved if:**

- Patient does not meet the above stated criteria.
- Patient has any contraindications to the use of TBZ.
- Patient has untreated or inadequately treated depression.

**Special considerations:**

- Standard treatments for chorea include benzodiazepines, amantadine (Symmetrel), haloperidol, risperidone, ziprasidone (Geodon), quetiapine (Seroquel), and riluzole.
- TBZ has been shown to decrease the chorea of HD, it was also shown to cause slight worsening in mood, cognition, rigidity, and functional capacity and prescribers should periodically re-evaluate the need for therapy.

*\* Xenazine will be marketed under an FDA-approved Risk Evaluation and Mitigation Strategy (REMS) to decrease the risk of depression and suicidal ideation that may be associated with the drug, and are often pre-existing conditions in Huntington's disease patients. The REMS includes educational materials for prescribers, pharmacists and patients (and their caregivers) to help minimize adverse effects associated with Xenazine. It also includes a Medication Guide, which informs patients and their caregivers about the risks of depression, suicidal thoughts and actions, and other side effects. The FDA requires that the Medication Guide be handed out with every prescription for the drug dispensed.*

FCHP Pharmacy and Therapeutics Committee approval: \_\_\_\_\_

Date: \_\_\_\_\_

Adopted: 3/11/2009