Xenazine® (tetrabenazine)
Prior Authorization Criteria

FDA APPROVED INDICATIONS AND DOSAGE

FDA Indication¹: For the treatment of chorea associated with Huntington’s disease.

Dosing¹: Starting dose is 12.5 mg once daily. Titrate up after one week to 12.5 mg twice daily. Titrate by 12.5 mg weekly based on tolerability and effect. If dose of 37.5 mg to 50 mg daily is needed, administer as three doses. Daily dose greater than 50 mg requires genotyping for CYP2D6. Maximum recommended daily dose is 100 mg.

CLINICAL RATIONALE
Xenazine (tetrabenazine) is the first treatment FDA approved for the treatment of chorea in persons with Huntington’s disease (HD).¹ The efficacy of tetrabenazine was evaluated in a randomized, double-blind, placebo-controlled, multicenter trial.² Patients were treated with tetrabenazine or placebo for 12 weeks. The primary end point was change in total chorea score, which rates chorea on a scale from 0 (no chorea) to 4 for 7 different parts of the body (total scale, 0–28).² Patients treated with tetrabenazine demonstrated an estimated decrease in total chorea score of 5.0 units during maintenance therapy versus an estimated decrease of 1.5 units in placebo-treated patients (treatment effect, −3.5 units; P<.05).² Tetrabenazine is contraindicated in patients who are actively suicidal or with untreated or inadequately treated depression, in patients with impaired hepatic function and in patients taking monoamine oxidase inhibitors or reserpine; reserpine should be discontinued at least 20 days before starting tetrabenazine.¹ Tetrabenazine has been approved with a required Risk Evaluation and Mitigation Strategy (REMS) to ensure that the drug’s benefits outweigh its risks.¹ Tetrabenazine acts by depleting monoamines (dopamine, serotonin, and norepinephrine) from nerve terminals. Tetrabenazine is being studied in the treatment of schizophrenia and movement disorders but it is not approved for these uses.³

For additional clinical information see Prime Therapeutics Monograph on Xenazine (tetrabenazine).

REFERENCES

Document History
Original Prime Standard criteria approved by P&T UM Committee 05/2009
Annual Review Prime Standard criteria, criteria maintained, approved by P&T UM Committee 05/0210
Initial Client Review Client Specific criteria, approved by HCSC Corporate Clinical Committee 07/2010
Xenazine® (tetrabenazine) Prior Authorization

OBJECTIVE
The intent of the Xenazine (tetrabenazine) Prior Authorization (PA) Criteria is to appropriately select patients for therapy according to product labeling and/or clinical guidelines and/or clinical studies and according to dosing recommended in product labeling. The PA criteria will direct its use to the FDA approved indication for the treatment of chorea associated with Huntington’s disease. Criteria require that patients do not have any listed contraindications for Xenazine (inadequately treated depression, suicidality, impaired hepatic function, or concurrent use of reserpine or MAOIs). Criteria will limit approved dose to at or below the maximum FDA-labeled dose and the quantity of each tablet strength to 4 tablets per day.

TARGET DRUGS
Xenazine® (tetrabenazine)

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL
Xenazine will be approved when ALL of the following are met:
1. The patient has a diagnosis of chorea associated with Huntington’s disease
   AND
2. The patient is being treated for depression if patient has diagnosis of depression or suicidal ideation
   AND
3. The patient is not receiving a monoamine oxidase inhibitor (MAOI)
   AND
4. The patient is not receiving reserpine or patient’s reserpine will be discontinue at least 20 days before starting Xenazine therapy
   AND
5. The patient does not have impaired hepatic function
   AND
6. The requested dose is at or below the FDA-labeled maximum dose of 100 mg/day and the requested quantity is at or below the program quantity limit

Length of Approval: 12 months
Xenazine® (tetrabenazine) Prior Authorization

ELECTRONIC EDIT
The overall process for a prior authorization will not allow the targeted drugs to adjudicate through the claims system. When a patient requests a targeted drug the system will reject the claim with the message indicating that prior authorization is necessary.

<table>
<thead>
<tr>
<th>Brand (generic)</th>
<th>GPI</th>
<th>Multisource Code</th>
<th>Quantity per Day Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Xenazine® (tetrabenazine)</td>
<td>62380070000310</td>
<td>M, N, O, or Y</td>
<td>4 tablets</td>
</tr>
<tr>
<td>12.5mg tablet</td>
<td>62380070000320</td>
<td>M, N, O, or Y</td>
<td>4 tablets</td>
</tr>
</tbody>
</table>

PRIOR AUTHORIZATION CRITERIA QUESTION SET
Initial and Renewal Evaluation
1. Does the patient have a diagnosis of chorea associated with Huntington’s disease? If yes, continue to 2. If no, deny.
2. Does the patient have a current diagnosis of depression or suicidal ideation and behavior (suicidality) or a history of depression or suicidality? If yes, continue to 3. If no, continue to 4.
3. Is the patient being treated for depression? If yes, continue to 4. If no, deny.
4. Is the patient currently taking a monoamine oxidase inhibitors (MAOIs, including Marplan/isocarboxazid, Nardil/phenelzine, and Parnate/tranylcypromine)? If yes, deny. If no, continue to 5.
5. Is the patient currently taking reserpine? If yes, continue to 6. If no, continue to 7.
6. Will the reserpine be discontinued at least 20 days before starting Xenazine (tetrabenazine)? If yes, continue to 7. If no, deny.
7. Does the patient have impaired hepatic function? If yes, deny. If no, continue to 8.
8. Is the requested dose at or below the FDA-labeled maximum dose of 100 mg/day and the requested quantity at or below the program quantity limit? If yes, approve for 12 months. If no, deny.