TETRABENAZINE

Generic	Brand	HICL	GCN	Exception/Other
TETRABENAZINE	XENAZINE	07350		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Is the request for a tetrabenazine dosage that exceeds 50mg?

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient have a diagnosis of chorea (involuntary movements) associated with Huntington's disease and meets the following criteria?
   - The prescription has been prescribed or recommended by a neurologist
   - The patient has been genotyped for CYP2D6 and is identified as an extensive metabolizer (EM) or intermediate metabolizer (IM) of CYP2D6

   If yes, **approve for 12 months by GPID with the following quantity limits:**
   - **12.5mg tablet: #3 tablets per day**
   - **25mg tablet: #4 tablets per day**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have a diagnosis of chorea (involuntary movements) associated with Huntington's disease and meets the following criteria?
   - The prescription has been prescribed or recommended by a neurologist

   If yes, **approve for 12 months by GPID with the following quantity limits:**
   - **12.5mg tablet: #3 tablets per day**
   - **25mg tablet: #2 tablets per day**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   DENIAL TEXT: Our guideline for **TETRABENAZINE (Xenazine)** requires a diagnosis of chorea (involuntary movements) associated with Huntington's disease and that the medication has been prescribed or recommended by a neurologist. Request for a tetrabenazine dosage that exceeds 50mg requires that the patient has been genotyped for CYP2D6 and is identified as an extensive (EM) or intermediate metabolizer (IM) of CYP2D6.

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RATIONALE
Ensure appropriate diagnostic, utilization and safety criteria are used for tetrabenazine management.

FDA APPROVED INDICATION
Xenazine is indicated for the treatment of chorea associated with Huntington's disease.

DOSAGE
The dose of Xenazine should be individualized.

Dosing Recommendations Up to 50 mg per day
The starting dose should be 12.5 mg per day given once in the morning. After one week, the dose should be increased to 25 mg per day given as 12.5 mg twice a day. Xenazine should be titrated up slowly at weekly intervals by 12.5 mg daily, to allow the identification of a tolerated dose that reduces chorea. If a dose of 37.5 to 50 mg per day is needed, it should be given in a three times a day regimen. The maximum recommended single dose is 25 mg. If adverse reactions such as akathisia, restlessness, parkinsonism, depression, insomnia, anxiety or sedation occur, titration should be stopped and the dose should be reduced. If the adverse reaction does not resolve, consideration should be given to withdrawing Xenazine treatment or initiating other specific treatment.

Dosing Recommendations Above 50 mg per day
Patients who require doses of Xenazine greater than 50 mg per day should be first tested and genotyped to determine if they are poor metabolizers (PMs) or extensive metabolizers (EMs) by their ability to express the drug metabolizing enzyme, CYP2D6. The dose of Xenazine should then be individualized accordingly to their status as PMs or EMs.

- Extensive and Intermediate CYP2D6 Metabolizers

Genotyped patients who are identified as extensive (EMs) or intermediate metabolizers (IMs) of CYP2D6, who need doses of Xenazine above 50 mg per day, should be titrated up slowly at weekly intervals by 12.5 mg daily, to allow the identification of a tolerated dose that reduces chorea. Doses above 50 mg per day should be given in a three times a day regimen. The maximum recommended daily dose is 100 mg and the maximum recommended single dose is 37.5 mg. If adverse reactions such as akathisia, parkinsonism, depression, insomnia, anxiety or sedation occur, titration should be stopped and the dose should be reduced. If the adverse reaction does not resolve, consideration should be given to withdrawing Xenazine treatment or initiating other specific treatment (e.g., antidepressants).

- Poor CYP2D6 Metabolizers

In PMs, the initial dose and titration is similar to EMs except that the recommended maximum single dose is 25 mg, and the recommended daily dose should not exceed a maximum of 50 mg.

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REFERENCES

- Lundbeck Pharmaceuticals, Inc. Xenazine package insert. Deerfield, IL. June, 2015.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 06/01/16
Created: 02/09
Client Approval: 05/16
P&T Approval: 11/15