

**Nonformulary Criteria for Use:
Tetrabenazine (Xenazine®),
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VHA Pharmacy Benefits Management Strategic Healthcare Group and the Medical Advisory Panel

The following recommendations are based on current medical evidence. The content of the document is dynamic and will be revised as new clinical data become available. The purpose of this document is to assist practitioners in clinical decision making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. The clinician, however, must make the ultimate judgment regarding the propriety of any course of treatment in light on individual patient situations

For details, refer to the monograph at www.pbm.va.gov or <http://vaww.pbm.va.gov>

Special Handling drug procurement program:

<http://vaww.national.cmop.va.gov/PBM/Special%20Handling%20Drugs/Forms/AllItems.aspx?RootFolder=%2fPBM%2fSpecial%20Handling%20Drugs%2fXENAZINE%20%28Tetrabenazine%29&View=%7b0B1484F5%2d1A23%2d4573%2d9AE6%2d8677021828CB%7d>

EXCLUSION CRITERIA (Include instructions, example: if one is selected, patient is not eligible)

- patient who is actively suicidal
- patient with untreated or inadequately treated depression
- patients receiving MAOI's
- patient receiving reserpine
- patients with hepatic impairment
- patients with abnormal QTc (>450ms for males, >470ms for females)
- patient with liver function test outside the normal range in the previous 6 months

INCLUSION CRITERIA

Huntington's Disease

- Patients with disabling or painful chorea

Hyperkinetic Movement Disorders

Patient with Tardive dyskinesia or dystonia

And

Have an inadequate response to conventional therapy.

Tardive Dyskinesia:

- Removal of offending agent (i.e. antipsychotic) without resolution of hyperkinetic movement after 3 months
- Inability to remove offending agent given underlying psychiatric disease

Dystonia:

- No response or are intolerant to alternative agents (local botulinum toxin injections, anticholinergics therapy and/or benzodiazepenes

And

Has severe, symptomatic dyskinesia that interferes with quality of life, activities of daily living or other measures of disability

Efficacy of therapy should be assessed when stable, at one month and at three months. Patients may be followed with AIMS scores or other clinically appropriate measures. Documentation of response should be kept in the patient chart

ISSUES FOR CONSIDERATION

Following treatment interruption of more than 5 days tetrabenazine therapy should be retitrated when resumed. For short-term treatment interruption of less than 5 days, treatment can be resumed at the previous maintenance dose without titration

Use caution when prescribing a strong CYP2D6 inhibitor (eg, fluoxetine, paroxetine, quinidine) to a patient already receiving a stable dose of tetrabenazine. In patients receiving coadministered strong CYP2D6 inhibitors, the daily dose of tetrabenazine should be halved.