

**Tetrabenazine (Xenazine®)**  
**Effective 08/01/2020**

<b>Plan</b>	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit		
<b>Specialty Limitations</b>	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
<b>Contact Information</b>	<b>Medical and Specialty Medications</b>		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
<b>Exceptions</b>	<b>Non-Specialty Medications</b>		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
<b>Exceptions</b>	N/A		

### Overview

Tetrabenazine is a vesicular monoamine transporter 2 (VMAT) inhibitor indicated for the treatment of chorea associated with Huntington's disease.

### Coverage Guidelines

Authorization may be granted for members who are currently receiving treatment with tetrabenazine, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

### Or

Authorizations may be granted when both of the following criteria are met:

1. Member has a diagnosis of chorea associated with Huntington disease
2. The prescriber is a neurologist or in consultation with a neurologist

### Continuation of Therapy

Reauthorization requires physician documentation of improvement of member's improvement in overall disease activity

### Limitations

1. Initial approvals will be for 12 months
2. Reauthorizations will be for 36 months
3. The following quantity limits apply:

Tetrabenazine 12.5mg	120 tablets per 30 days
Tetrabenazine 25mg	60 tablets per 30 days
Maximum total daily dose is 100 mg	

### Appendix

#### Recommended Dosing

- Initiation: 12.5 mg per day given once in the morning.

- **Titration:** After 1 week, dose can be increased to 25 mg per day given as 12.5 mg twice a day. Continue to titrate slowly at weekly intervals of 12.5 mg, to allow identification of the dose that reduces chorea and is well tolerated.
- **Maximum single dose:** is generally recommended to be 25 mg, including poor CYP2D6 metabolizers; however, a max single dose of 37.5 mg is recommended in extensive and intermediate CYP2D6 metabolizers.
- **Maximum daily dose\*:** Total daily dose is 100 mg. In CYP2D6 poor metabolizers, maximum daily dose of 50 mg is recommended. In intermediate and extensive CYP2D6 metabolizers, a maximum daily dose of 100 mg is also recommended.

## References

1. Xenazine (tetrabenazine) tablets [prescribing information]. Deerfield, IL: Lundbeck; September 2018
2. Guay DR. Tetrabenazine, a monoamine-depleting drug used in the treatment of hyperkinetic movement disorders. *Am J Geriatr Pharmacother* 2010; 8:331.
3. National Institute of Neurological Disorders and Stroke. Huntington's Disease: Hope Through Research [on the Internet]. Bethesda (MD): NIH; 2014 [updated Apr 2014; cited 23 May 2014]. Available from: [http://www.ninds.nih.gov/disorders/huntington/detail\\_huntington.htm](http://www.ninds.nih.gov/disorders/huntington/detail_huntington.htm)
4. Suchowersku O. Huntington disease: Management. In: Basow DS (Ed). *UpToDate*. Waltham (MA): UpToDate; 2014 [cited: 23 May 2014]. Available at: <http://www.utdol.com/index/utd.do>.
5. Xenazine® (tetrabenazine) tablets risk evaluation and mitigation strategy (REMS). U.S. Food and Drug Administration (FDA). U.S. Department of Health & Human Services. Silver Spring (MD): 2013. Available at: <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111350.htm>
6. Armstrong MJ and Miyasaki JM. Evidence-based guideline: Pharmacologic treatment of chorea in Huntington disease: Report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology*. 2012;79:597-603.

## Review History

06/15/09 - Reviewed

08/03/09 - Implemented

06/21/10 - Reviewed

06/27/11 - Updated

06/25/12 - Reviewed

06/24/13 - Reviewed

06/23/14 - Reviewed

06/22/15 - Reviewed

06/27/16 - Reviewed

09/18/17 - Reviewed

04/17/19 – Reviewed

05/20/2020 – Reviewed and Updated May P&T Mtg; removed black box warning from criteria; references updated; added QL to criteria; added started and stabilized statement. Effective 8/1/20.

