

Tetrabenazine (Xenazine®)
Effective 08/01/2020

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	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
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.

