



Tetrabenazine (Xenazine®)
Effective 04/17/19

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|------------------------------|---|---------------------|--|
| Plan | <input checked="" type="checkbox"/> MassHealth <input checked="" type="checkbox"/> Commercial/Exchange | Program Type | <input checked="" type="checkbox"/> Prior Authorization |
| Benefit | <input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX) | | <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy |
| 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 FDA approved for the treatment of chorea associated with Huntington disease (HD).

Coverage Guidelines

Authorizations may be granted when the following criteria are met:

- 1. Member is a new AllWays Health Partners member and has already been stabilized on tetrabenazine for the treatment of chorea associated with Huntington’s disease
OR
- 1. Member has a diagnosis of chorea associated with Huntington disease
AND
- 2. The prescribing physician is a Neurologist

All other indications will be evaluated on a case-by case basis

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; may be issued for 120 tablets* per month up to 36 months when provider had submitted clinical documentation of member’s improvement in overall disease activity
- 3. The following quantity limits apply:

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|---------------|------------------------|
| Tetrabenazine | 120 tablets* per month |
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* Note: If a dose of 37.5 mg to 50 mg per day is needed it should be dosed in a three times per day regimen. Patients who require dosing above 50 mg per day should be genotyped for CYP2D6.

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.

Black Box Warning:

| Depression and suicidality |
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| <p>Tetrabenazine can increase the risk of depression and suicidal thoughts and behavior (suicidality) in patients with HD. Anyone considering the use of tetrabenazine must balance the risks of depression and suicidality with the clinical need for control of choreiform movements. Closely observe patients for the emergence or worsening of depression, suicidality, or unusual changes in behavior. Inform patients, caregivers, and families of the risk of depression and suicidality, and instruct them to report behaviors of concern promptly to the treating health care provider. Exercise particular caution in treating patients with a history of depression or prior suicide attempts or ideation, which are increased in frequency in HD. Tetrabenazine is contraindicated in patients who are actively suicidal, and in patients with untreated or inadequately treated depression.</p> |

References

1. Xenazine (tetrabenazine) tablets [prescribing information]. Deerfield, IL: Lundbeck; September 2018
2. Tetrabenazine (Xenazine) for Huntington's chorea. The Medical Letter. 2009;51(1304):7-8.
3. Guay DR. Tetrabenazine, a monoamine-depleting drug used in the treatment of hyperkinetic movement disorders. Am J Geriatr Pharmacother 2010; 8:331.
4. 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
5. University of Iowa Hospitals and Clinics. Physicians Guide to the Management of Huntington's Disease: Movement Disorder [webpage on the Internet]. Iowa City (IA): 2003 [cited 2009 April 9]. Available from: <http://www.uihealthcare.com/topics/medicaldepartments/neurology/huntingtonsdisease/movementdisorder.html>
6. Suchowersku O. Huntington disease: Management. In: Basow DS (Ed). UpToDate. Waltham (MA): UpToDate; 2014 [cited: 23 May 2014]. Available at: <http://www.uptodate.com/index/utd.do>.



7. 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>
8. 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

Disclaimer

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