

Reference number(s) 2266-A

Specialty Guideline Management tetrabenazine-Xenazine

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Xenazine	tetrabenazine

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications^{1,2}

Treatment of chorea associated with Huntington's disease.

Compendial Uses

- Chorea not associated with Huntington's disease^{4,5}
- Hemiballismus^{4,5}
- Tardive dyskinesia^{3,4,7}
- Tic disorders³⁻⁶

All other indications are considered experimental/investigational and not medically necessary.

tetrabenazine-Xenazine SGM 2266-A P2025.docx

© 2025 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

Documentation

Submission of the following information is necessary to initiate the prior authorization review for initial requests:

- Chorea associated with Huntington's disease: Chart notes or medical record documentation of characteristic motor examination features.
- Tardive dyskinesia: Chart notes or medical record documentation of clinical manifestations of disease.

Coverage Criteria

Chorea associated with Huntington's disease^{1,2}

Authorization of 6 months may be granted for treatment of chorea associated with Huntington's disease when both of the following criteria are met:

- Member demonstrates characteristic motor examination features.
- Member meets one of the following conditions:
 - Laboratory results indicate an expanded HTT CAG repeat sequence of at least 36
 - Member has a positive family history for Huntington's disease

Chorea not associated with Huntington's disease^{4,5}

Authorization of 6 months may be granted for treatment of chorea not associated with Huntington's disease.

Hemiballismus^{4,5}

Authorization of 6 months may be granted for the treatment of hemiballismus.

Tardive dyskinesia^{3,4,7}

Authorization of 6 months may be granted for treatment of tardive dyskinesia when both of the following criteria are met:

- Member exhibits clinical manifestations of disease.
- Member's tardive dyskinesia has been assessed through clinical examination or with a structured evaluative tool (e.g., Abnormal Involuntary Movement Scale [AIMS], Dyskinesia Identification System: Condensed User Scale [DISCUS]).

tetrabenazine-Xenazine SGM 2266-A P2025.docx

© 2025 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

Tic disorders³⁻⁶

Authorization of 6 months may be granted for treatment of tic disorders.

Continuation of Therapy

Authorization of 12 months may be granted for members with an indication listed in the coverage criteria section who are experiencing benefit from therapy as evidenced by disease stability or disease improvement.

References

- 1. Xenazine [package insert]. Deerfield, IL: Lundbeck Inc.; November 2019.
- 2. Tetrabenazine [package insert]. Weston, FL: Apotex Corp.; October 2021.
- 3. Micromedex® (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: http://www.micromedexsolutions.com. Accessed March 6, 2025.
- 4. AHFS DI (Adult and Pediatric). Lexicomp. Last updated March 11, 2024. Accessed March 6, 2025. http://online.lexi.com/lco
- 5. Guay DRP. Tetrabenazine, a monoamine-depleting drug used in the treatment of hyperkinetic movement disorders. Am J Geriatr Pharmacother. 2010;8:331-373.
- 6. Kenney C, Hunter C, Jankovic J. Long-term tolerability of tetrabenazine in the treatment of hyperkinetic movement disorders. Movement Disorders. 2007;22(2):193-7.
- 7. American Psychiatric Association. (2021). Practice Guideline for the Treatment of Patients With Schizophrenia, third edition. https://doi.org/10.1176/appi.books.9780890424841