

## SPECIALTY GUIDELINE MANAGEMENT

### XENAZINE (tetrabenazine) tetrabenazine (generic)

#### POLICY

##### I. 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.

- A. FDA-Approved Indication  
Treatment of chorea associated with Huntington's disease
- B. Compendial Uses
  - 1. Tic disorders
  - 2. Tardive dyskinesia
  - 3. Hemiballismus
  - 4. Chorea not associated with Huntington's disease

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

##### II. DOCUMENTATION

Submission of the following information is necessary for both initial approval and continuation of therapy prior authorization reviews (where applicable): Documentation of score of items 1 to 7 of the Abnormal Involuntary Movement Scale (AIMS).

##### III. CRITERIA FOR INITIAL APPROVAL

- A. **Chorea associated with Huntington's disease**  
Authorization of 6 months may be granted for treatment of chorea associated with Huntington's disease when both of the following criteria are met:
  - 1. Member demonstrates characteristic motor examination features
  - 2. Member meets one of the following conditions:
    - i. Laboratory results indicate an expanded *HTT* CAG repeat sequence of at least 36
    - ii. Member has a positive family history for Huntington's disease
- B. **Chorea not associated with Huntington's disease**  
Authorization of 6 months may be granted for treatment of chorea not associated with Huntington's disease.
- C. **Tic disorders**  
Authorization of 6 months may be granted for treatment of tic disorders.

<b>Reference number(s)</b>
2266-A

**D. Tardive dyskinesia**

Authorization of 6 months may be granted for the treatment of tardive dyskinesia when the baseline AIMS score for items 1 to 7 is obtained.

**E. Hemiballismus**

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

**IV. CONTINUATION OF THERAPY**

**A. Tardive dyskinesia**

Authorization of 12 months may be granted for treatment of tardive dyskinesia when the member's tardive dyskinesia symptoms have improved as indicated by a decreased AIMS score (items 1 to 7) from baseline.

**B. Other indications**

Authorization of 12 months may be granted for treatment of all other indications listed in Section III when the member has experienced improvement or stabilization.

**V. REFERENCES**

1. Xenazine [package insert]. Deerfield, IL: Lundbeck Inc.; November 2019.
2. Micromedex® (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: <http://www.micromedexsolutions.com>. Accessed March 7, 2023.
3. AHFS Drug Information. <http://online.lexi.com/lco>. Accessed March 7, 2023.
4. Guay DR. Tetrabenazine, a monoamine-depleting drug used in the treatment of hyperkinetic movement disorders. *Am J Geriatr Pharmacother*. 2010; 8:331-373.
5. Armstrong MJ, 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(6):597-603.
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. Tetrabenazine [package insert]. Weston, FL: Apotex Corp.; October 2021.
8. American Psychiatric Association. (2021). *Practice Guideline for the Treatment of Patients With Schizophrenia, third edition*. <https://doi.org/10.1176/appi.books.9780890424841>