

## Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for tetrabenazine under the patient's prescription drug benefit.

## **Description:**

- A. <u>FDA-Approved Indication</u> 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.

## **Applicable Drug List:**

tetrabenazine

# **Policy/Guideline:**

## **Documentation:**

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

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

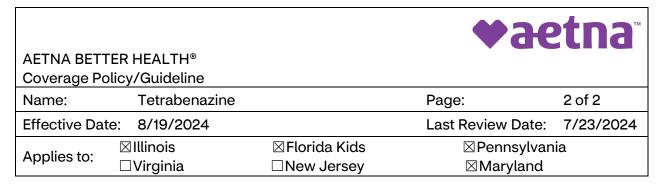
# Criteria for Initial Approval:

# 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.

### D. Tardive dyskinesia

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

- 1. Member exhibits clinical manifestations of disease.
- 2. 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]).

### E. Hemiballismus

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

## Criteria for Continuation of Therapy:

Authorization of 12 months may be granted for members who are experiencing benefit from therapy as evidenced by disease stability or disease improvement.

## **Approval Duration and Quantity Restrictions:**

### **Approval:**

- Initial approval: 6 months
- Renewal approval: 12 months

### **Quantity Level Limit:**

- tetrabenazine 12.5 mg tablet: 120 per 30 days
- tetrabenazine 25 mg tablet: 60 per 30 days

### **References:**

- 1. Xenazine [package insert]. Deerfield, IL: Lundbeck Inc.; November 2019.
- 2. Tetrabenazine [package insert]. Weston, FL: Apotex Corp.; October 2021.
- 3. Micromedex<sup>®</sup> (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: http://www.micromedexsolutions.com. Accessed March 14, 2024.
- 4. AHFS DI (Adult and Pediatric). Lexicomp. Last updated March 11, 2024. Accessed March 14, 2024. 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.* <u>https://doi.org/10.1176/appi.books.9780890424841</u>