

Effective Date: 6/2018
Reviewed Date: 6/2019, 7/2020, 5/2021, 4/2022, 3/2023
Scope: Medicaid

SPECIALTY GUIDELINE MANAGEMENT

Tetrabenazine

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 to initiate the prior authorization review: Documentation of score of items 1 to 7 of the Abnormal Involuntary Movement Scale (AIMS) for tardive dyskinesia

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.

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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 6 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 6 months may be granted for treatment of all other indications listed in Section III when the member has experienced improvement or stabilization.

V. QUANTITY LIMIT

- a. Tetrabenazine 12.5mg tablet: 8 tablets/day
- b. Tetrabenazine 25mg 4 tablets/day

VI. REFERENCES

1. Micromedex® (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: <http://www.micromedexsolutions.com>. Accessed August 06, 2019.
2. AHFS Drug Information. <http://online.lexi.com/lco>. Accessed August 06, 2019.
3. Guay DR. Tetrabenazine, a monoamine-depleting drug used in the treatment of hyperkinetic movement disorders. *Am J Geriatr Pharmacother*. 2010; 8:331-373.
4. 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.
5. 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.
6. Tetrabenazine [package insert]. Baltimore, MD: Lupin Pharmaceuticals Inc.; November 2021.