

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. 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 the treatment of tardive dyskinesia when all of the following criteria is met:

- i. Must be prescribed by or in consultation with a neurologist or psychiatrist.
- ii. Documented diagnosis of tardive dyskinesia secondary to a centrally acting dopamine receptor-blocking agent (DRBA).
- iii. The 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.

III. CONTINUATION OF THERAPY

A. Tardive dyskinesia

Authorization of 6 months may be granted for treatment of tardive dyskinesia when the member has written documentation of a positive clinical response as evidenced by disease stability or disease improvement.

B. Other indications

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

IV. QUANTITY LIMIT

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

V. 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.; March 2025.