Effective Date: 6/2018
Reviewed Date: 6/2019, 7/2020, 5/2021, 4/2022, 3/2023, 3/2024 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.

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.