

Xenazine (tetrabenazine)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications	Quantity Limit
Xenazine (tetrabenazine)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Xenazine (tetrabenazine) may be approved for individuals who meet the following criteria:

Documentation is provided that individual has a diagnosis of chorea associated with Huntington's Disease; **OR**

- I. Individual requires symptomatic management of other hyperkinetic movement disorders (hyperkinesias) including (AHFS):
 - A. Hemiballismus; **OR**
 - B. Senile chorea; **OR**
 - C. Tic Disorder; **OR**
 - D. Tourette's syndrome (Gilles de la Tourette's syndrome); **OR**
 - E. Tardive Dyskinesia.

Requests for Xenazine (tetrabenazine) may not be approved for individuals who meet the following criteria:

- I. Individual is suicidal or has untreated/inadequately treated depression; **OR**
- II. Individual has hepatic impairment; **OR**
- III. Individual is currently utilizing monoamine oxidase inhibitors (MAOIs), reserpine, deutetrabenazine or valbenazine; **OR**
- IV. Individual has congenital long QT syndrome or arrhythmia associated with a prolonged QT interval.

Requests for **brand** Xenazine must also meet the following criteria, in addition to the above Prior Authorization criteria:

- I. Individual has failed an adequate trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of one chemically equivalent generic tetrabenazine agent;
AND
 - A. Generic tetrabenazine had inadequate response; **OR**
 - B. Generic tetrabenazine caused adverse outcome; **OR**

- C. The individual has a genuine allergic reaction to an inactive ingredient in generic agent. Allergic reaction(s) must be clearly documented in the individual's medical record.

Note:

Xenazine (tetrabenazine) has black box warnings for depression and suicidality. Xenazine can increase the risk of depression and suicidal thoughts and behavior. This risk must be balanced with the clinical need. Individuals should be closely monitored for emergence or worsening of depression, suicidality, or unusual behavior changes. Particular caution should be exercised in treating individuals with a history of depression or prior suicide attempts or ideation. Xenazine is contraindicated in individuals who are actively suicidal, and in individuals with untreated or inadequately treated depression.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2021. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: June 29, 2021.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.
5. American Psychiatric Association. (2013). Diagnostic and statistical manual of mental disorders: DSM-5. Washington, D.C: American Psychiatric Association.
6. Bhidayasiri R, Fahn S, Weiner WJ, et al. Evidence-based guideline: treatment of tardive syndromes: report of the guideline development subcommittee of the American Academy of Neurology. *Neurology*. 2013;81:463-9. Available at <https://www.aan.com/Guidelines/>.
7. Bhidayasiri R, Jikritsadakul O, Friedman JH, Fahn S. Updating the recommendations for treatment of tardive syndromes: A systematic review of new evidence and practical treatment algorithm. *J Neurol Sci*. 2018 Jun 15; 389:67-75.
8. 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; 79:597-603.
9. Huntington Study Group. Effect of deutetabenazine on chorea among patients with Huntington disease: A randomized clinical trial. *JAMA*. 2016; 316(1):40-50.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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