Austedo (deutetrabenazine), Austedo XR (deutetrabenazine extended-release)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Initial approval: 3 months Subsequent approval: 1 year

Medications	Quantity Limit
Austedo (deutetrabenazine) Austedo XR (deutetrabenazine extended-release)	May be subject to quantity limit

APPROVAL CRITERIA

Initial requests for Austedo (deutetrabenazine) or Austedo XR (deutetrabenazine extended-release) may be approved for individuals who meet the following criteria:

I. Individual is 18 years of age or older;

AND

II. Documentation is provided that individual has a diagnosis of chorea associated with Huntington's disease;

OR

III. Individual has a diagnosis of tardive dyskinesia (TD) confirmed by the following (DSM-5):
   A. Documentation is provided showing at least 60 days of stable (drug, dose) medication exposure (either typical or first generation antipsychotic agents [such as, chlorpromazine, haloperidol, fluphenazine], atypical or second-generation antipsychotic agents [such as, clozapine, risperidone, olanzapine, quetiapine, aripiprazole], or certain dopamine receptor-blocking drugs used in treatment of nausea and gastroparesis [such as, prochlorperazine, promethazine, metoclopramide]); **AND**
   B. Presence of involuntary athetoid or choreiform movements lasting at least 30 days.

Requests for continuation of therapy for Austedo (deutetrabenazine) or Austedo XR (deutetrabenazine extended-release) may be approved for individuals who meet the following criteria:

I. Documentation is provided that individual has experienced an improvement in symptoms deemed to be clinically significant by the provider based on stabilization or improvement in Abnormal Involuntary Movement Scale (AIMS) score (for TD) or total maximal chorea score (for Huntington's disease).

Requests for Austedo (deutetrabenazine) or Austedo XR (deutetrabenazine extended-release) 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, tetrabenazine, or valbenazine; **OR**
IV. Individual has congenital long QT syndrome or arrhythmia associated with a prolonged QT interval.

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 deutetrabenazine 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 polices may take precedence over the application of this clinical criteria.