MEDICAL MUTUAL®

Drug Policy

Policy:	**Austedo (deutetrabenazine tablets)** **Austedo XR (deutetrabenazine extended-release tablets)**	**Annual Review Date: 02/20/2025** **Last Revised Date: 02/20/2025**

OVERVIEW

Austedo is indicated for the treatment of chorea associated with Huntington's disease (HD) and Tardive Dyskinesia in adults. Austedo reversibly depletes monoamines (such as dopamine, serotonin, norepinephrine, and histamine) from nerve terminals. Austedo and its major circulating metabolites (α-dihydrotetrabenazine [HTBZ] and β-HTBZ) reversibly inhibit vesicular monoamine transporter type 2 (VMAT2), resulting in decreased uptake of monoamines (e.g., dopamine) into synaptic vesicles and depletion of monoamine stores. Austedo has also been evaluated for use in one small, Phase Ib study in adolescents with moderate-to-severe tics associated with Tourette syndrome.

POLICY STATEMENT

This policy involves the use of Austedo and Austedo XR. Prior authorization is recommended for pharmacy benefit coverage of Austedo and Austedo XR. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Austedo or Austedo XR as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Austedo or Austedo XR be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Austedo or Austedo XR is recommended in those who meet the following criteria:

Food and Drug Administration (FDA)-Approved Indications

1) **Chorea Associated with Huntington's Disease (HD).** Approve for 1 year if the patient meets the following criteria (a, b, c, d, e and f):
   - **a)** Patient has been diagnosed with chorea associated with HD confirmed by genetic testing (for example, an expanded HTT CAG repeat sequence of at least 36)* ; AND
   - **b)** Patient is ≥ 18 years of age; AND
   - **c)** Austedo is prescribed by or in consultation with a neurologist; AND

d) To the best of the prescribing physician's knowledge, the patient is not suicidal, and does not have untreated or inadequately treated depression; AND
e) The patient does not have contraindications such as: hepatic impairment, taking reserpine concomitantly and/or has a history of congenital long QT syndrome or cardiac arrhythmias; AND
f) The patient has previously tried generic tetrabenazine tablets according to the prescribing physician*
   i) (NOTE: An exception to the requirement for a trial of generic tetrabenazine can be made if the patient has already tried and cannot take brand Xenazine according to the prescribing physician*. These patients who have already tried brand Xenazine are not required to "step back" and try generic tetrabenazine.)

2) Tardive Dyskinesia (TD) Approve for 1 year if the patient meets the following criteria (a, b, c, d, e, f, and g):
a) Austedo is prescribed by or in consultation with a neurologist or psychiatrist; AND
b) Patient has an Abnormal Involuntary Movement Scale (AIMS) score of 6 or greater; AND
c) Patient is ≥18 years of age; AND
d) Patient has been clinically diagnosed with TD according to the DSM V Criteria (i, ii, and iii)*****
   i) Involuntary athetoid or choreiform movements; AND
   ii) History of treatment with a neuroleptic agent (i.e. antipsychotic); AND
   iii) Symptoms lasting longer than 4-8 weeks
e) The patient does not have contraindications such as: hepatic impairment, taking reserpine concomitantly and/or has a history of congenital long QT syndrome or cardiac arrhythmias; AND
f) Adjustments to possible offending medication such as dose reduction or discontinuation were attempted but ineffective in resolving Tardive Dyskinesia symptoms or patient is not a candidate for dose reduction or discontinuation of the offending medication; AND
g) If a patient is using the offending medication for a behavioral health indication, the use of a second generation (atypical) antipsychotic has been attempted unless contraindicated.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year (365 days)
B) *Extended Approval:* 1 year (365 days)

***Documentation Required:** When documentation is required, the prescriber must provide written documentation supporting the trials of other agents or the requested medical information, noted in the criteria as *. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation

supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Austedo™ tablets [prescribing information]. Teva Pharmaceuticals USA, Inc.; December 2020.
2. US National Institutes of Health. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2017 April 14]. Available from: https://www.clinicaltrials.gov/. Accessed on April 14, 2017. Search term: deutetrabenazine.
3. Jankovic J, Jimenez-Shahed J, Budman C, et al. Deutetrabenazine in tics associated with Tourette Syndrome. Tremor Other Hyperkinet Mov (N Y). 2016 Nov 7;6:422. eCollection 2016.
4. Xenazine® tablets [prescribing information]. Deerfield, IL: Lundbeck; June 2015.
5. 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(5):463-469.

OTHER REFERENCES UTILIZED

- 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.