Commercial PA Criteria

Effective: August 16, 2017

Prior Authorization: Austedo

Products Affected: Austedo (deutetrabenazine), Austedo XR (deutetrabenazine extended-release tablets)

Medication Description:
Deutetrabenazine is a monoamine depletor for oral administration indicated for the treatment of chorea associated with Huntington's disease. The precise mechanism by which deutetrabenazine exerts its effects in the treatment of tardive dyskinesia and chorea in patients with Huntington's disease is unknown but is believed to be related to its effect as a reversible depletor of monoamines (such as dopamine, serotonin, norepinephrine, and histamine) from nerve terminals. The major circulating metabolites (α-dihydrotetrabenazine [HTBZ] and β-HTBZ) of deutetrabenazine, are reversible inhibitors of VMAT2, resulting in decreased uptake of monoamines into synaptic vesicles and depletion of monoamine stores.

Covered Uses:

1. Chorea associated with Huntington's disease
2. Tardive Dyskinesia in adults

Exclusion Criteria:

1. None

Required Medical Information:

1. Diagnosis
2. History of previous therapy tried/failed

Age Restrictions: 18 years of age or older

Prescriber Restrictions: Prescribed by, or in consultation with, a neurologist or psychiatrist.

Coverage Duration: 12 months

Other Criteria:

Initial Approval Criteria

1. Chorea associated with Huntington's disease

Approve if the patient meets ALL of the following criteria:

A. The patient is aged ≥ 18 years; **AND**
B. The patient has a diagnosis Huntington's disease confirmed by genetic testing (for example, an expanded HTT CAG repeat sequence of at least 36); **AND**
C. Medication is prescribed by, or in consultation with a neurologist.

2. Tardive Dyskinesia

Approve if the patient meets ALL of the following criteria:

1. The patient is aged ≥ 18 years; **AND**

2. The patient has a diagnosis of tardive dyskinesia; **AND**
3. Austedo is prescribed by, or in consultation with, a neurologist or psychiatrist.

References:

1. Austedo® tablets/Austedo® XR extended-release tablets [prescribing information]. North Wales, PA: Teva; September 2023.
2. Frank S, Testa CM, Stamlet D, et al. Effect of deutetrabenazine on chorea among patients with Huntington Disease: A Randomized Clinical Trial. JAMA; 2016: 316(1):40-50.
3. American Academy of Neurology. Evidence-based guideline: Pharmacologic treatment of chorea in Huntington's disease. Available at: http://www.neurology.org/content/79/6/597.full.pdf+html. Accessed July 3, 2017.
4. American Academy of Neurology. Pharmacologic treatment of chorea in Huntington's disease. Available at: https://www.aan.com/Guidelines/Home/GetGuidelineContent/559. Accessed July 3, 2017.
5. Fernandez HH, Factor SA, Hauser RA, et al. Randomized controlled trial of deutetrabenazine for tardive dyskinesia: The ARM-TD study. Neurology. 2017 Apr 26. [Epub ahead of print] Available at: http://www.neurology.org/content/early/2017/04/26/WNL.0000000000003960.long. Accessed July 3, 2017.
6. Jankovic J, Jimenez-Shahed J, Budman C, et al. Deutetrabenazine in Tics Associated with Tourette Syndrome. Tremor Other Hyperkinet Mov (NY). 2016; 6: 422. Published online 2016 Nov 7. doi: 10.7916/D8M32W3H. Accessed July 3, 2017.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	7/11/17
2	Update	Added diagnosis of TD to match FDA Label; added criteria for TD; added option of psychologist for both dx.	Covered Uses, Other Criteria	7/29/2019
3	Update	Addition of Austedo XR Removal of: The patient has documented trial, failure or contraindication to tetrabenazine (from Chorea Associated with Huntington's Disease) Addition of "confirmed by genetic testing (for example, an expanded HTT CAG repeat sequence of at least 36" to diagnosis confirmation of Huntington's Removal from Tardive dyskinesia criteria: "One of the following: Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication **OR** Patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication"	Products affected Other Criteria	7/2/2024
4	Update	Moved to combined EH-CCI template	All	7/9/2024