

Commercial/Healthcare Exchange PA Criteria

Effective: May, 2017

Prior Authorization: Austedo

Products Affected: Austedo (deutetrabenazine)

Medication Description:

Austedo (deutetrabenazine) is a monoamine depletor for oral administration indicated for the treatment of chorea associated with Huntington's disease. Huntington disease (HD) is an incurable, adult-onset, autosomal dominant inherited disorder associated with cell loss within a specific subset of neurons in the basal ganglia and cortex. Huntington's disease is a progressive disorder characterized by changes in mood, cognition, chorea, rigidity, and functional capacity over time. Chorea is characterized as jerky, irregular, relatively rapid, involuntary movements that can affect the face or limbs. The exact mechanism by which deutetrabenazine exerts its anti-chorea effects 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. Deutetrabenazine reversibly inhibits the human vesicular monoamine transporter type 2 (VMAT2) resulting in decreased uptake of monoamines into synaptic vesicles and depletion of monoamine stores.

Deutetrabenazine was granted orphan drug designation by the FDA; a drug is granted orphan status if it addresses a population of fewer than 200,000 patients or if it treats conditions that affect more than 200,000 patients but where there is no reasonable expectation of profit being recovered for the drug. About 30,000 people in the United States have Huntington's disease and another 200,000 are at risk of developing the disease, the FDA statement notes.

Covered Uses:

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

Exclusion Criteria: N/A

Required Medical Information:

- Diagnosis
- History of previous therapy tried/failed

Age Restrictions: 18 years of age or older

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

Coverage Duration: 12 months

Other Criteria:

Chorea associated with Huntington's disease

Approve Austedo if the patient meets ALL of the following criteria:

1. The patient is aged ≥ 18 years; **AND**
2. The patient has a diagnosis of Chorea associated with Huntington's disease; **AND**
3. The patient has documented trial, failure or contraindication to tetrabenazine; **AND**
4. Austedo is prescribed by, or in consultation with, a neurologist or psychologist

Tardive Dyskinesia

Approve Austedo 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 psychologist; **AND**
4. One of the following:
 - i. Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication
 - OR
 - ii. Patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication

References:

1. Austedo [package insert]. North Wales, PA; Teva; April 2017.
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	Updated to new template & adopted EmblemHealth criteria	All	4/27/2020