

PRIOR AUTHORIZATION POLICY

POLICY: Vesicular Monoamine Transporter Type 2 Inhibitors – Austedo™ (deutetrabenazine tablets – Teva)

TAC APPROVAL DATE: 05/22/2019

OVERVIEW

Austedo reversibly depletes monoamines (such as dopamine, serotonin, norepinephrine, and histamine) from nerve terminals.¹ Austedo and its major circulating metabolites (α -dihydrotrabenazine [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 is indicated for the treatment of chorea associated with Huntington's disease (HD) and for the treatment of tardive dyskinesia (TD) in adults. Austedo has been evaluated for use in one small, Phase Ib study in adolescents with moderate-to-severe tics associated with Tourette syndrome.² Tetrabenazine (Xenazine®, generics) is also a VMAT2 inhibitor indicated for the treatment of chorea associated with HD.³

Guidelines

According to the American Academy of Neurology (AAN) guidelines on the treatment of chorea of HD (2012), if HD chorea requires treatment, clinicians should prescribe tetrabenazine (≤ 100 mg/day), amantadine (300 to 400 mg/day), or riluzole (200 mg/day) [Level B] for varying degrees of expected benefit.⁵ Austedo is not addressed in the guidelines.

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Austedo. Because of the specialized skills required for evaluation and diagnosis of patients treated with Austedo as well as the monitoring required for adverse events and long-term efficacy, approval requires Austedo to be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals are provided for 1 year in duration.

Documentation: In the Austedo Policy, documentation is required where noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, prescription claims records, prescription receipts and/or laboratory data.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

- 1. Chorea Associated with Huntington's Disease (HD):** Approve for 1 year if the patient meets BOTH of the following criteria (A and B):
 - A) Patient has been diagnosed with chorea associated with Huntington's Disease (HD) **[documentation required]**; AND

B) Austedo is prescribed by or in consultation with a neurologist.

2. Tardive dyskinesia (TD): Approve for 1 year if Austedo is prescribed by or in consultation with a neurologist or psychiatrist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Austedo has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Austedo™ tablets [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; July 2018.
2. Jankovic J, Jimenez-Shahed J, Budman C, et al. Deutetrabenazine in tics associated with Tourette Syndrome. *Tremor Other Hyperkinet Mov.* 2016;6:422.
3. Xenazine® tablets [prescribing information]. Deerfield, IL: Lundbeck; September 2017.
4. 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.

HISTORY

Type of Revision	Summary of Changes*	TAC Approval Date
New policy	--	04/19/2017
Selected revision	Removal of approval criteria requiring patients to try generic tetrabenazine prior to Austedo.	07/19/2017
Selected revision	Addition of tardive dyskinesia as an FDA-approved indication.	09/13/2017
Annual revision	No change to criteria.	04/25/2018
Annual revision	No change to criteria.	05/22/2019

TAC – Therapeutic Assessment Committee; DEU – Drug Evaluation Unit; * For a further summary of criteria changes, refer to respective TAC minutes available at: <http://esidepartments/sites/Dep043/Committees/TAC/Forms/AllItems.aspx>.