PRIOR AUTHORIZATION POLICY

POLICY: Vesicular Monoamine Transporter Type 2 Inhibitors – Austedo Prior Authorization Policy
- Austedo® (deutetrabenazine tablets – Teva)

REVIEW DATE: 06/10/2020; selected revision 01/20/2021

OVERVIEW

Austedo, a vesicular monoamine transporter type 2 (VMAT2) inhibitor, is indicated for the treatment of:[1]
- **Chorea associated with Huntington's disease** in adults.
- **Tardive dyskinesia** in adults.

Guidelines

According to the American Academy of Neurology (AAN) guidelines on the treatment of chorea of Huntington's disease (2012), if Huntington's disease 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.[2] Austedo is not addressed in the guidelines.

The AAN published an evidence-based guideline for the treatment of tardive syndromes (TDS) [2013].[3] The authors found that tetrabenazine possibly reduces TDS symptoms (based on two consistent Class III studies). Therefore, tetrabenazine may be considered in treating TDS (Level C). 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 the duration noted below.

Documentation: Documentation is required for the use of Austedo as noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, prescription claims records, prescription receipts, and/or other information.

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.** Approve for 1 year if the patient meets the following criteria (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has been diagnosed with chorea associated with Huntington's disease **[documentation required]**; AND

C) Diagnosis of Huntington's disease is confirmed by genetic testing (for example, an expanded HTT CAG repeat sequence of at least 36); AND
D) The medication is prescribed by or in consultation with a neurologist.

2. Tardive dyskinesia. Approve for 1 year if the patient meets the following criteria (A and B):
A) Patient is ≥ 18 years of age; AND
B) The medication is prescribed by or in consultation with a neurologist or psychiatrist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Austedo is not recommended in the following situations:

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 2019.
2. 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.
3. 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.