Clinical Policy: Deutetrabenazine (Austedo)

Reference Number: PA.CP.PHAR.341
Effective Date: 01/18
Last Review Date: 14/180 Revision Log

Description
Deutetrabenazine (Austedo™) is a vesicular monoamine transporter 2 (VMAT2) inhibitor.

FDA Approved Indication(s)
Austedo is indicated for the treatment of:

- Chorea associated with Huntington's disease
- Tardive dyskinesia in adults

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

It is the policy of PA Health and Wellness® that Austedo is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Huntington's Disease (must meet all)**:**

1. Diagnosis of chorea associated with Huntington's disease;
2. Prescribed by or in consultation with a neurologist;
3. Age ≥ 18 years;
4. Failure of tetrabenazine at up to 100mg/day, unless contraindicated or clinically significant adverse effects are experienced;
5. At the time of request, tetrabenazine or valbenazine is not prescribed concomitantly;
6. Dose does not exceed 48 mg/day;

Approval duration: 6 months

B. **Tardive Dyskinesia** (must meet all)**:**

1. Diagnosis of tardive dyskinesia secondary to a centrally acting dopamine receptor blocking agent (DRBA);
2. Prescribed by or in consultation with a psychiatrist or neurologist;
3. Age ≥ 18 years;
4. At the time of request, tetrabenazine or valbenazine is not prescribed concurrently;
5. Dose does not exceed 48 mg/day.

Approval duration:
Medicaid - 6 months

C. Other diagnoses/indications

1. Refer to PA.CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. **All Indications in Section I** (must meet all)**:**

1. Currently receiving medication via PA Health and Wellnessbenefit or member has previously met all initial approval criteria or the Continuity of Care Policy PA.LTSS.PHAR.01 applies;
2. Member has had improvement in in chorea or tardive dyskinesia symptoms while on Austedo;
3. Austedo is not prescribed concurrently with tetrabenazine or valbenazine;
4. Prescribed dose of Austedo does not exceed 48 mg per day.

Approval duration: 12 months

A. Other diagnoses/indications (1 or 2):

1. Currently receiving medication via PA Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care Policy, PA.LTSS.PHAR.01, applies.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to PA.CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

Appendices/General Information

Appendix A: Abbreviation Key

MAOI: monoamine oxidase inhibitors
VMAT: vesicular monoamine transporter
EM: extensive metabolizer
PM: poor metabolizer
PO: by mouth
IM: immediate metabolizer

III. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Huntington's Chorea	6 mg PO four times daily, titrated to a dose that reduces chorea; patients requiring doses above 48 mg/day should be genotyped for the drug metabolizing enzyme CYP2D6 to determine if the patient is a poor metabolizer (PM) or an extensive metabolizer (EM). twice daily	48 mg dose /day For EMs and IMs: 18 mg/day, 36 mg/dose

IV. Product Availability

Tablets: 6mg, 9mg, 12mg

V. References

1. Austedo Prescribing Information. North Wales, PA. Teva Pharmaceuticals USA, Inc; April 2017. Available at: www.Austedo.com. Accessed April 3, 2017.

2. Frank S, et al. Effect of deutetrabenazine on chorea among patients with Huntington disease. JAMA. July 2016; 316(1):40-50.
3. O Classen D, et al. Indirect tolerability comparison of deutetrabenazine and tetrabenazine for Huntington disease. J Clin Mov Disord.2107;4(3):1-11.
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; 31: 463-469.
5. Medication-induced movement disorders and other adverse effects of medication. Diagnostic and statistical manual of mental disorders, 5th Ed. American Psychiatric Association.
6. Waln O, Jankovic J. An update on tardive dyskinesia: From phenomenology to treatment. *Tremor Other Hyperkinet Mov (N Y).* July 12, 2013; 3. pii: tre-03-161-4138-1. doi: 10.7916/D88P5Z71. Print 2013.
7. Meyer TA, Belson TE, McAllister R. Tardive dyskinesia: A distressing drug-induced movement disorder. *US Pharm*. 2014; 39(1): HS13-HS16.
8. Lerner PP, Miodownik C, Lerner V. Tardive dyskinesia (syndrome): Current concept and modern approaches to its management. *Psychiatry Clin Neurosci.* June 2015; 69(6): 321-34.
9. Smith HS, Cox LR, Smith BR. Dopamine receptor antagonists. *Annals of Palliative Medicine*. July 2012; 1(2). DOI: 10.3978/j.issn.2224-5820.2012.07.09.
10. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. Available at www.clinicalpharmacology.com. Accessed February 5, 2018.

Reviews, Revisions, and Approvals	Date	Approval Date
2Q 2018 annual review: Tardive dyskinesia: Added criteria and corresponding appendices. Huntington's chorea: Added age requirement per prescribing information. Added preferencing for tetrabenazine per SDC. Both indications: Added requirement for no concomitant use of xenazine or valbenazine for both initial and re-auth requests; references reviewed and updated.	02.05.18	