envolve Pharmacy Solutions

Clinical Policy: Deutetrabenazine (Austedo)
Reference Number: ERX.SPA.150
Effective Date: 09.01.17
Last Review Date: 08.17
Line of Business: Commercial [Prescription Drug Plan] Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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

FDA approved indication
Austedo is indicated for the treatment of chorea associated with Huntington's disease.

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 health plans affiliated with Envolve Pharmacy Solutions™ that Austedo is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Huntington's Chorea (must meet all):
1. Diagnosis of chorea associated with Huntington's disease;
2. Prescribed by or in consultation with a neurologist;
3. Dose does not exceed 48 mg/day.

Approval duration: Length of Benefit

B. Other diagnoses/indications
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

II. Continued Therapy

A. Huntington's Chorea (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 48 mg/day.

Approval duration: Length of Benefit

B. Other diagnoses/indications (must meet 1 or 2):
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

Drug	Dosing Regimen	Dose Limit/ Maximum Dose
Xenazine® (tetrabenazine)	12.5 mg PO for 1 week then 12.5 mg twice daily. Dose can be titrated by 12.5 mg weekly up to maximum dose of 50 mg/day. Patients who require doses more than 50 mg per day should be genotyped for CYP2D6 expression.	100 mg/day PO in patients who are CYP2D6 intermediate or extensive metabolizers; 50 mg/day PO in patients who are poor metabolizers of CYP2D6.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Huntington's chorea	6 mg/day titrated weekly by increments of 6 mg/day to a maximum total daily dose of 48 mg.	48 mg/day (18 mg/dose PO and 36 mg/day PO in poor CYP2D6 metabolizers).

VI. Product Availability
Tablets: 6 mg, 9 mg, 12 mg

VII. 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. Clinical Pharmacology. Austedo Drug Monograph. Accessed May 2017 at http://www.clinicalpharmacology-ip.com.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	05/17	08/17

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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