Clinical Policy: Deutetrabenazine (Austedo)

Reference Number: CP.PHAR.341
Effective Date: 07/17
Last Review Date: 07/17
Line of Business: Medicaid

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 (VMAT2) inhibitor.

FDA approved indication

Deutetrabenazine (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 Centene Corporation® 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 a neurologist;
3. Failure of tetrabenazine at up to 100mg/day, unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 48 mg/day;
5. At the time of request, member has none of the following contraindications
   a. Suicidal or untreated/inadequately treated depression;
   b. Hepatic impairment;
   c. Will concurrently use MAOIs, reserpine, or tetrabenazine.

Approval duration: 6 months

B. Other diagnoses/indications

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

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Member has had improvement in chorea symptoms while on Austedo;
3. Prescribed dose of Austedo does not exceed 48 mg per day.

Approval duration: 12 months

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

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

2. Refer to CP.PHAR.57 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 – CP.PHAR.57 or evidence of coverage documents

IV. 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

V. 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

VI. Product Availability

Tablets: 6mg, 9mg, 12mg

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. http://www.clinicalpharmacology-ip.com.

Reviews, Revisions, and Approvals	Date	Approval Date
Policy created	06/17	07/17

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.