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PHARMACY POLICY STATEMENT
Kentucky Medicaid

DRUG NAME	Austedo (deutetrabenazine)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Preferred Product) QUANTITY LIMIT— up to 48 mg per day
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Austedo (deutetrabenazine) is a **preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

CHOREA ASSOCIATED WITH HUNTINGTON'S DISEASE

For **initial** authorization:

1. Member must be at least 18 years and older and medication is prescribed by neurologist or psychiatrist or nurse practitioner within a psychiatric or neurologic practice; AND
2. Member must have diagnosis of Huntington's disease with chorea symptoms; AND
3. Documented consultation on risks of suicidal ideation or behavior while on Austedo is submitted with member's chart notes (Austedo is contraindicated in patients who are suicidal, and in patients with untreated or inadequately treated depression); AND
4. Member's baseline Total Maximal Chorea Score (of the Unified Huntington's Disease Rating Scale (UHDRS)) is submitted with chart notes.
5. **Dosage allowed:** Starting dose of 6 mg once daily with weekly titration by 6 mg per day up to maximum dosage of 48 mg (24 mg twice daily).

If member meets all the requirements listed above, the medication will be approved for 3 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Member must have documentation of improvement of Total Maximal Chorea Scores after week 12.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

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TARDIVE DYSKINESIA (TD)

For **initial** authorization:

1. Member is 18 years of age and older and medication is prescribed by neurologist or psychiatrist or nurse practitioner within a psychiatric or neurologic practice; AND
2. Member has clinical diagnosis of Tardive Dyskinesia documented in chart notes; AND
3. Member must try and fail at least 1 other guideline recommended treatments first (e.g., clonazepam, ginkgo biloba, etc.); AND
4. Chart notes confirming that member does **not** have risk for suicidal or violent behavior and has stable psychiatric symptoms; AND
5. If member has a history of substance use disorder, chart notes confirming that member is in remission for **at least** 3 months must be provided; AND
6. Member's The Abnormal Involuntary Movement Scale (AIMS) score is documented in chart notes; AND
7. Member does **not** have ANY of the following:
   a) History of hepatic impairment;
   b) History of renal impairment;
   c) Allergy, hypersensitivity, or intolerance to tetrabenazine.
8. **Dosage allowed:** Starting dose of 12 mg once daily with weekly titration by 6 mg per day up to maximum dosage of 48 mg (24 mg twice daily).

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Member must have documentation of improvement of AIMS score.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Austedo (deutetrabenazine) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
06/16/2017	New policy for Austedo created.
11/01/2017	New diagnosis of Tardive Dyskinesia was added.
02/08/2018	Criterion requirement of clinical diagnoses of Tardive Dyskinesia for at least 3 months was removed. Length of initial authorization increased to 3 months. Criterion on guidelines recommended treatment was revised. Substance use disorder remission length requirement changed. New provider's specialty was added for both diagnosis.
05/06/2019	The guideline recommended treatment criterion changed from two to one medication to try as a trial.

References:

1. Austedo [package insert]. North Wales, PA; Teva Pharmaceuticals, Inc. August, 2017.
2. Huntington Study group. Effect of deutetrabenazine on chorea among patients with huntington disease: a randomized clinical trial. JAMA. 2016; 316(1):40-50. doi: 10.1001/jama.2016.8655.
3. Claassen DO, Carroll B, De Boer LM, et al. Indirect tolerability comparison of deutetrabenazine and tetrabenazine for huntington disease. J Clin Mov Dis 2017(4):3. doi: 10.1186/s40734-017-0051-5.

4. ClinicalTrials.gov. Bethesda (MD): National Library of Medicine (US). 2017. Identifier NCT02291861, Addressing Involuntary Movements in Tardive Dyskinesia (AIM-TD); 2017 [cited 2017 Nov 1]. Available from: https://clinicaltrials.gov/ct2/show/NCT02291861?term=deutetrabenazine&recrs=e&rank=5.
5. ClinicalTrials.gov. Bethesda (MD): National Library of Medicine (US). 2017. Identifier NCT02195700, Aim to Reduce Movements in Tardive Dyskinesia (ARM-TD); 2017 [cited 2017 Nov 1]. Available from: https://clinicaltrials.gov/ct2/show/NCT02195700?term=deutetrabenazine&recrs=e&rank=2.

Effective date: 07/01/2019
Revised date: 05/06/2019