Austedo (deutetrabenazine)
Austedo XR (deutetrabenazine extended release)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Austedo (deutetrabenazine)/Austedo XR (deutetrabenazine extended release) policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

A. Treatment of chorea associated with Huntington’s disease in adults
B. Treatment of tardive dyskinesia in adults

POLICY

Required Documentation

Submission of the following information is necessary for both initial approval and continuation of therapy prior authorization reviews (where applicable): Documentation of score of items 1 to 7 of the Abnormal Involuntary Movement Scale (AIMS).

Criteria for Initial Approval

A. Tardive dyskinesia

Authorization of 6 months may be granted for treatment of tardive dyskinesia when the baseline AIMS score for items 1 to 7 is obtained.

B. Chorea associated with Huntington's disease
Authorization of 6 months may be granted for treatment of chorea associated with Huntington's disease when both of the following criteria are met:
1. Member demonstrates characteristic motor examination features
2. Member meets one of the following conditions:
   i. Laboratory results indicate an expanded *HTT* CAG repeat sequence of at least 36
   ii. Member has a positive family history for Huntington's disease

Continuation of Therapy

A. Tardive dyskinesia
Authorization of 12 months may be granted for treatment of tardive dyskinesia when the member's tardive dyskinesia symptoms have improved as indicated by a decreased AIMS score (items 1 to 7) from baseline.

B. Chorea associated with Huntington's disease
Authorization of 12 months may be granted for treatment of chorea associated with Huntington's disease when the disease has improved or stabilized.

Austedo (deutetrabenazine) and Austedo XR are considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

Medication	Standard Limit	FDA-recommended dosing
Austedo 6 mg tablet	60 tablets per 30 days	12 mg orally per day (one 6 mg tablet twice daily) The dose may increase at weekly intervals in increments of 6 mg per day to a maximum recommended daily dosage of 48 mg Switching from tetrabenazine dosing regimen: 6 mg orally once daily to 24 mg orally twice daily depending on current tetrabenazine daily dosage
Austedo 9 mg tablet	120 tablets per 30 days	
Austedo 12 mg tablet	120 tablets per 30 days	
Austedo XR 6 mg tablet	90 tablets per 30 days	12 mg orally per day The dose may increase at weekly intervals in increments of 6 mg per day to a maximum recommended daily dosage of 48 mg Switching from tetrabenazine dosing regimen: 6 mg orally once daily to 48 mg orally once daily depending on current tetrabenazine daily dosage
Austedo XR 12 mg tablet	120 tablets per 30 days	
Austedo XR 24 mg tablet	60 tablets per 30 days	
Austedo XR Titration Kit (6 mg, 12 mg, and 24 mg tablets)	42 tablets per 28 days	Titration Dosing: • Week 1: one 12 mg tablet orally per day

Medication	Standard Limit	FDA-recommended dosing
		• Week 2: one 6 mg and one 12 mg tablet orally per day • Week 3: one 24 mg tablet orally per day • Week 4: one 6 mg and one 24 mg tablet orally per day

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- N/A

REFERENCES

- Austedo [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc. September 2023.
- Frank S, Testa CM, Stamler D, et al. Effect of deutetrabenazine on chorea among patients with Huntington disease: A randomized clinical trial. Huntington Study Group. *JAMA.* 2016;316(1):40-50.
- Fernandez HH, Factor SA, Hauser RA, et al. Randomized controlled trial of deutetrabenazine for tardive dyskinesia: The ARM-TD study. *Neurology.* 2017;88:2003-10.
- Anderson KE, Stamler D, Davis MD, et al. Deutetrabenazine for treatment of involuntary movements in patients with tardive dyskinesia (AIM-TD): a double-blind, randomized, placebo-controlled, phase 3 trial. *Lancet Psychiatry.* 2017;4: 595-604.
- American Psychiatric Association. (2021). *Practice Guideline for the Treatment of Patients With Schizophrenia, third edition.* https://doi.org/10.1176/appi.books.9780890424841

POLICY HISTORY

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