

Effective Date: 06/01/2021
Reviewed: 03/2021, 4/2022, 6/2023, 5/2024, 2/2025
Scope: Medicaid

Austedo (deutetrabenazine) Austedo XR (deutetrabenazine extended release)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. Treatment of chorea associated with Huntington's disease
2. Treatment of tardive dyskinesia in adults

All other indications are considered experimental/investigational and not medically necessary.

II. INITIAL CRITERIA

Authorization of 6 months may be granted when all of the following criteria is met:

- A. Documentation that the member will not use Austedo or Austedo XR concomitantly with monoamine oxidase inhibitors (MAOIs), reserpine or tetrabenazine.
- B. Documentation that the member is not using an additional vesicular monoamine transporter 2 (VMAT2) while taking Austedo or Austedo XR.
- C. Dose does not exceed 48mg/day.

Huntington's Disease

- i. For use in Huntington's disease, Austedo or Austedo XR must be prescribed by or in consultation with a neurologist.
- ii. Documentation that the member is not suicidal or has untreated/inadequately treated depression (a score of greater than or equal to 11 on the depression subscale of the Hospital Anxiety and Depression scale (HADS)).
- iii. Authorization may be granted for treatment of chorea associated with Huntington's disease with documentation that both of the following criteria are met:
 1. Member demonstrates characteristic motor examination features
 2. Member meets one of the following conditions:
 - a. Laboratory results indicate an expanded *HTT* CAG repeat sequence of at least 36
 - b. Member has a positive family history for Huntington's disease; OR

Tardive Dyskinesia

- i. For use in tardive dyskinesia, Austedo or Austedo XR must be prescribed by or in consultation with a neurologist or psychiatrist.
- ii. Documented diagnosis of tardive dyskinesia secondary to a centrally acting dopamine receptor-blocking agent (DRBA).

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- iii. The member’s tardive dyskinesia has been assessed through clinical examination or with a structured evaluative tool (e.g., Abnormal Involuntary Movement Scale {AIMS}, Dyskinesia Identification System : Condensed User Scale [DISCUS])

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted when all of the following criteria is met:

- A. If member has not been approved for this drug by Neighborhood in the past, clinician must submit documentation that initial criteria is met.
- B. Documentation that the member is tolerating treatment
- C. Member will not use Austedo or Austedo XR concomitantly with monoamine oxidase inhibitors (MAOIs), reserpine or tetrabenazine
- D. Member is not using an additional vesicular monoamine transporter 2 (VMAT2) while taking Austedo or Austedo XR
- E. Documentation that the member meets either the following criteria:
 - i. For the treatment of chorea associated with Huntington’s disease, the chorea symptoms have improved or stabilized from baseline and member is not suicidal, or has untreated/inadequately treated depression (a score of greater than or equal to 11 on the depression subscale of the Hospital Anxiety and Depression scale (HADS); OR
 - ii. For the treatment of tardive dyskinesia, the member has written documentation of a positive clinical response as evidenced by disease stability or disease improvement.

IV. QUANTITY LIMIT

- Austedo 6 mg and 9 mg tablets: 2 tablets/day
- Austedo 12 mg tablets: 4 tablets/day
- Austedo XR 6 mg, 12 mg, 18 mg, 24 mg, 30 mg, 36 mg, 42 mg, and 48 mg tablets: 1 tablet/day
- Austedo XR titration kit 6 mg & 12 mg & 24 mg tablets: 1.5 tablets/day
- Austedo XR titration kit 12 mg & 18 mg & 24 mg & 30 mg tablets: 1 tablet/day

V. REFERENCES

1. Austedo [package insert]. Parsippany, NJ: Teva Neuroscience, Inc. September 2023.
2. 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.
3. 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.
4. 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.
5. American Psychiatric Association. (2021). *Practice Guideline for the Treatment of Patients With Schizophrenia, third edition*. <https://doi.org/10.1176/appi.books.9780890424841>