Effective Date: 06/01/2021
Reviewed: 03/2021, 4/2022, 6/2023, 5/2024, 2/2025, 2/2026 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 are met for all indications and the requested indication:

All Indications

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

A. For use in Huntington's disease, Austedo or Austedo XR must be prescribed by or in consultation with a neurologist.
B. 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).
C. Documentation that member demonstrates characteristic motor examination features
D. Documentation that 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

Tardive Dyskinesia

A. For use in tardive dyskinesia, Austedo or Austedo XR must be prescribed by or in consultation with a neurologist or psychiatrist.
B. Documented diagnosis of tardive dyskinesia secondary to a centrally acting dopamine receptor-blocking agent (DRBA).
C. Documentation that member exhibits clinical manifestations of tardive dyskinesia

D. 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

Austedo or Austedo XR will continue to pay after the initial approval if there is at least one paid claim of at least a 28-day supply within the last 365 days for Austedo or Austedo XR.

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 12 mg & 18 mg & 24 mg & 30 mg tablets: 1 tablet/day

V. REFERENCES

1. Austedo [package insert]. Parsippany, NJ: Teva Neuroscience, Inc. February 2025.
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.