Effective Date: 06/01/2021
Reviewed: 03/2021, 4/2022, 6/2023, 5/2024 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. DOCUMENTATION

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

III. INITIAL CRITERIA

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

A. Patient will not use Austedo or Austedo XR concomitantly with monoamine oxidase inhibitors (MAOIs), reserpine or tetrabenazine.
B. Patient 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. The patient 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 when 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. Diagnosis of tardive dyskinesia secondary to a centrally acting dopamine receptor-blocking agent (DRBA).
iii. Baseline documentation of score of items 1 to 7 of the Abnormal Involuntary Movement Scale (AIMS) with a total score of ≥ 6.

IV. 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. Patient is tolerating treatment
C. Patient will not use Austedo or Austedo XR concomitantly with monoamine oxidase inhibitors (MAOIs), reserpine or tetrabenazine
D. Patient is not using an additional vesicular monoamine transporter 2 (VMAT2) while taking Austedo or Austedo XR
E. Patient 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 patient 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 patient has written documentation of a positive clinical response by a decrease of at least 3 points in total AIMS score (items 1 to 7) compared to baseline score for tardive dyskinesia.

V. QUANTITY LIMIT

- Austedo 6mg and 9mg tablets: 2 tablets/day
- Austedo 12mg tablets: 4 tablets/day
- Austedo XR 6mg and 12mg tablets: 1 tablet/day
- Austedo XR 24mg tablets: 2 tablets/day

VI. 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