

Effective Date: 06/01/2021
Reviewed: 03/2021, 4/2022, 6/2023
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

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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  $\geq 6$ .

## **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