Vesicular Monoamine Transporter 2 Inhibitors (VMAT2)

FDA INDICATIONS AND USAGE[1,2,3]

AUSTEDO® and AUSTEDO XR® (deutetrabenazine) are vesicular monoamine transporter 2 inhibitors indicated for the treatment of chorea associated with Huntington's disease and tardive dyskinesia in adults.

INGREZZA® (valbenazine) is a vesicular monoamine transporter 2 inhibitor indicated for the treatment of adults with tardive dyskinesia and chorea associated with Huntington's disease.

XENAZINE® (tetrabenazine) is vesicular monoamine transporter 2 inhibitor indicated for the treatment of chorea associated with Huntington's disease.

APPROVAL CRITERIA[4]

A. For AUSTEDO® and AUSTEDO XR® authorization:
   a. Patient is 18 years of age or older **AND;**
   b. Prescribed by or in consultation with a psychiatrist or neurologist **AND;**
   c. A patient must have the diagnosis of chorea associated with Huntington's disease **OR;**
   d. Diagnosis of moderate to severe tardive dyskinesia (TD) and all the following:
      1) The provider has reduced or discontinued medications known to cause tardive dyskinesia or provides clinical rational as to why dose reduction or discontinuation is not possible **AND;**
      2) The provider has documented the baseline Abnormal Involuntary Movement Scale (AIMS) score which must be ≥ 8 **AND**;
      3) One or more of the criteria composing lines 1 through 7 of the standard AIMS score sheet must be moderate or severe, defined as a line item score of ≥3.

B. For INGREZZA® authorization:
   a. Patient is 18 years of age or older **AND;**
   b. Prescribed by or in consultation with a psychiatrist or neurologist **AND;**
   c. A patient must have the diagnosis of chorea associated with Huntington's disease **OR;**
   d. Diagnosis of moderate to severe tardive dyskinesia (TD) and all the following:
      1) The provider has reduced or discontinued medications known to cause tardive dyskinesia or provides clinical rational as to why dose reduction or discontinuation is not possible **AND;**
      2) The provider has documented the baseline Abnormal Involuntary Movement Scale (AIMS) score which must be ≥ 8 **AND**;
      3) One or more of the criteria composing lines 1 through 7 of the standard AIMS score sheet must be moderate or severe, defined as a line item score of ≥3.

C. For XENAZINE® authorization:
   a. Patient is 18 years of age or older **AND;**

b. Prescribed by or in consultation with a neurologist **AND;**
c. A patient must have the diagnosis of chorea associated with Huntington's disease **AND;**
d. Patient must have tried and failed at least two manufactures of generic tetrabenazine.

DENIAL CRITERIA[1,2,3]

1. Patient is receiving concomitant VMAT2 drugs, monoamine oxidase inhibitors, or reserpine **OR;**
2. Patient is suicidal or has untreated/inadequately treated depression in patients with the diagnosis of Huntington's disease **OR;**
3. Patient has significant hepatic impairment.
    - deutetrabenazine and tetrabenazine only

CAUTIONS[1,2,3]

- Restlessness, agitation, akathisia and Parkinsonism: Reduce dose or discontinue if occurs.
- Sedation/Somnolence: May impair patient's ability to drive or operate machinery.
- QTc prolongation: Not recommended in combination with other drugs that prolong QTc.

DURATION OF APPROVAL[5]

- Initial: 3 months
- Reauthorization: 12 months with documentation the patient has shown marked improvement of functional impairment; defined as a reduction from the baseline of at least 2 points on one or more criteria comprising lines 1 through 7 of the standard AIMS score sheet with a baseline score ≥3.

QUANTITY LIMITS

Quantity limit – 34 days supply

AUSTEDO® (deutetrabenazine)

- 6 mg tablet: 2 tablets per day
- 9 mg tablet: 4 tablets per day
- 12 mg tablet: 4 tablets per day

AUSTEDO XR®

- 6 mg tablet: 1 tablet per day
- 12 mg tablet: 1 tablet per day

- 18 mg tablet: 1 tablet per day
- 24 mg tablet: 2 tablets per day
- 30 mg tablet: 1 tablet per day
- 36mg tablet: 1 tablet per day
- 42mg tablet: 1 tablet per day
- 48mg tablet: 1 tablet per day

INGREZZA® (valbenazine)

- 40 mg: 1 capsule per day
- 60 mg: 1 capsule per day
- 80 mg: 1 capsule per day

XENAZINE® (tetrabenazine)

- 12.5 mg: 4 tablets per day
- 25 mg: 4 tablets per day

REFERENCES / FOOTNOTES:

[1] Austedo/Austedo XR prescribing information. Teva. February 2025.
[2] Ingrezza prescribing information. Neurocrine Biosciences, Inc. February 2025.
[3] Xenazine Prescribing Information. Lundbeck/Valeant. September 2017.
[4] Institute for Clinical and Economic Review (ICER). Vesicular Monoamine Transporter 2 Inhibitors for Tardive Dyskinesia: Effectiveness and Value. Final Evidence Report. December 22, 2017.
[5] Stacy M, Sajatovic M, Kane JM, et al. Abnormal involuntary movement scale in tardive dyskinesia: minimal clinically important difference. Mov Disord. 2019; 34(8):1203-1209.