ALASKA MEDICAID Prior Authorization Criteria

Vesicular Monoamine **Transporter 2 Inhibitors** (VMAT2)

FDA INDICATIONS AND USAGE^{1,2,3}

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

INGREZZA® (valbenzine) is a vesicular monoamine transporter 2 inhibitor indicated for the treatment of adults with tardive dyskinesia.

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

APPROVAL CRITERIA^{1,2,3}

- A. For AUSTEDO® 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 **AND**;
 - 3) Trial of at least one other medication used to treat TD for at least 30 days.
- 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. 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 **AND**;
 - 3) Trial of at least one other medication used to treat TD for at least 30 days.
- 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 tetrabenzine.

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DENIAL CRITERIA^{1,2,3}

- 1. Patient is receiving concomitant VMAT2 drugs, monoamine oxidase inhibitors, or reserpine **OR**;
- 2. Patient has significant hepatic impairment **OR**;
- 3. Patient is suicidal or has untreated/inadequately treated depression.

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

- Initial 3 months
- Reauthorization 6 months with documentation the patient has shown marked improvement of functional impairment from the baseline of at least 3 points.

OUANTITY LIMITS

Brand/Generic	Ouantity Per Day
AUSTEDO® (dutetrabenzine)	
6 mg tablet	2 tablets
9 mg tablet	4 tablets
12 mg tablet	4 tablets
INGREZZA® (valbenzine)	
40 mg	<u>1 capsule</u>
<u>80 mg</u>	<u>1 capsule</u>
XENAZINE® (tetrabenzine)	
<u>12.5 mg</u>	4 tablets
<u>25 mg</u>	4 tablets

Quantity limit – 34 days supply

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REFERENCES / FOOTNOTES:

- 1. Austedo prescribing information. Teva. August 2017.
- 2. Ingrezza prescribing information. Neurocrine Biosciences, Inc. October 2017.
- 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. Draft Background and Scope. May 8, 2017.

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