ALASKA MEDICAID
Prior Authorization Criteria

Vesicular Monoamine Transporter 2 Inhibitors (VMAT2)

FDA INDICATIONS AND USAGE1,2,3

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 CRITERIA1,2,3

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.
DENIAL CRITERIA

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

• 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.

QUANTITY LIMITS

<table>
<thead>
<tr>
<th>Brand/Generic</th>
<th>Quantity Per Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>AUSTEDO® (dutetrabenzine)</td>
<td></td>
</tr>
<tr>
<td>6 mg tablet</td>
<td>2 tablets</td>
</tr>
<tr>
<td>9 mg tablet</td>
<td>4 tablets</td>
</tr>
<tr>
<td>12 mg tablet</td>
<td>4 tablets</td>
</tr>
<tr>
<td>INGREZZA® (valbenzine)</td>
<td></td>
</tr>
<tr>
<td>40 mg</td>
<td>1 capsule</td>
</tr>
<tr>
<td>80 mg</td>
<td>1 capsule</td>
</tr>
<tr>
<td>XENAZINE® (tetrabenzine)</td>
<td></td>
</tr>
<tr>
<td>12.5 mg</td>
<td>4 tablets</td>
</tr>
<tr>
<td>25 mg</td>
<td>4 tablets</td>
</tr>
</tbody>
</table>

Quantity limit – 34 days supply
REFERENCES / FOOTNOTES: