Clinical Pharmacy Program Guidelines for Xenazine

<table>
<thead>
<tr>
<th>Program</th>
<th>Prior Authorization</th>
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<tr>
<td>Medication</td>
<td>Xenazine</td>
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<tr>
<td>Pharmacy &amp; Therapeutics</td>
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<tr>
<td>Approval Date</td>
<td>11/2016</td>
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<tr>
<td>Effective Date</td>
<td>1/2017</td>
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1. **Background:**

Xenazine is indicated for the treatment of chorea associated with Huntington’s disease.

Off Label Uses: Xenazine has shown effectiveness in the treatment of hyperkinetic movement disorders (hyperkinesias) characterized by abnormal involuntary movements such as tics (eye blink, shouting obscenities or profanities, etc.) in Tourette’s syndrome (TS) and stereotypies in tardive dyskinesia (TD).

2. **Coverage Criteria:**

A. **Chorea associated with Huntington’s disease**

1. **Initial Authorization**
   a. Diagnosis of chorea in patients with Huntington’s disease

   -AND-

   b. Prescribed by or in consultation with a neurologist

   **Authorization will be issued for 12 months.**

2. **Reauthorization**
   a. Documentation of positive clinical response to therapy

   **Authorization will be issued for 12 months.**

B. **Tardive dyskinesia (off-label)**

1. **Initial Authorization**
   a. Patient has stereotypies associated with tardive dyskinesia
b. Patient is greater than or equal to 18 years of age

-AND-

c. Prescribed by or in consultation with one of the following:
   - Neurologist
   - Psychiatrist

Authorization will be issued for 12 months.

2. **Reauthorization**
   a. Documentation of positive clinical response to therapy

Authorization will be issued for 12 months.

C. **Tourette’s syndrome (off-label)**

1. **Initial Authorization**
   a. Patient has tics associated with Tourette’s syndrome

-AND-

b. History of failure, contraindication, or intolerance to Haldol (haloperidol)

-AND-

c. Prescribed by or in consultation with one of the following:
   - Neurologist
   - Psychiatrist

Authorization will be issued for 12 months.

2. **Reauthorization**
   a. Documentation of positive clinical response to therapy

Authorization will be issued for 12 months.
3. References:

<table>
<thead>
<tr>
<th>Date</th>
<th>Change</th>
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<tbody>
<tr>
<td>Dec 2009</td>
<td>Criteria taken from previously approved AmeriChoice policy. Re-authorization criteria added to ensure that patients are re-evaluated for clinical benefit. Policy was reformatted.</td>
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<tr>
<td>Dec 2010</td>
<td>Annual Review</td>
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<td>Dec 2011</td>
<td>Annual Review</td>
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<td>Dec 2012</td>
<td>Annual Review</td>
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<tr>
<td>March 2015</td>
<td>Template updated</td>
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<td></td>
<td>Huntington disease initial criteria: changed initial authorization duration from 1 year to 3 months.</td>
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<tr>
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<td>Huntington disease reauthorization criteria: removed requirement that “patient’s chorea has not progressed to rigidity and bradykinesia” and replaced with “documentation of clinical response and benefit from therapy”.</td>
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<tr>
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<td>Added off label criteria for Tardive dyskinesia and Tourette’s syndrome.</td>
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<tr>
<td>November 2016</td>
<td>Annual review, updated policy template</td>
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