Deutetrabenazine

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Medical Necessity Criteria

Deutetrabenazine (Austedo™) is considered medically necessary when ALL of the following criteria are met:

- Individual is 18 years of age or older
- Treatment of ONE of the following:
  - Documented diagnosis of Huntington's disease when BOTH of the following criteria are met:
    - Confirmed by genetic testing (for example, an expanded HTT CAG repeat sequence of at least 36)
    - Presence of chorea
  - Diagnosis of tardive dyskinesia when BOTH of the following criteria are met:
    - Prescribed by or in consultation with a neurologist or a psychiatrist
    - Individual has a history of treatment with a dopamine receptor blocking agent (for example, antipsychotics, metoclopramide, prochlorperazine)

Initial authorization is up to 12 months.

Deutetrabenazine (Austedo) is considered medically necessary for continued use when ALL of the following are met:

- Individual continues to meet the initial criteria
• Attestation of beneficial clinical response

Reauthorization for up to 12 months.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Deutetrabenazine (Austedo) is considered experimental, investigational or unproven for ANY other use.

Note: Receipt of sample product does not satisfy any criteria requirements for coverage.

FDA Approved Indications

FDA Approved Indication
Austedo is a vesicular monoamine transporter 2 (VMAT2) inhibitor indicated for the treatment of:
• Chorea associated with Huntington’s disease
• Tardive dyskinesia in adults

Recommended Dosing

FDA Recommended Dosing
The dose of Austedo is determined individually for each patient based on reduction of chorea or tardive dyskinesia and tolerability. When first prescribed to patients who are not being switched from tetrabenazine (a related VMAT2 inhibitor), the recommended starting dose of Austedo is 6 mg administered orally once daily for patients with Huntington’s disease and 12 mg per day (6 mg twice daily) for patients with tardive dyskinesia.
• The dose of Austedo may be increased at weekly intervals in increments of 6 mg per day to a maximum recommended daily dosage of 48 mg.
• Administer total daily dosages of 12 mg or above in two divided doses.
• Administer Austedo with food.
• Swallow Austedo whole. Do not chew, crush, or break tablets.
• For patients at risk for QT prolongation, assess the QT interval before and after increasing total Austedo dosage above 24 mg per day

Switching Patients from Tetrabenazine (Xenazine) to Austedo
Discontinue tetrabenazine (Xenazine) and initiate Austedo the following day. The recommended initial dosing regimen of Austedo in patients switching from tetrabenazine (Xenazine) to Austedo is shown in the table below.

Recommended Initial Dosing Regimen when Switching from Tetrabenazine (Xenazine) to Austedo

<table>
<thead>
<tr>
<th>Current tetrabenazine daily dosage</th>
<th>Initial regimen of Austedo</th>
</tr>
</thead>
<tbody>
<tr>
<td>12.5 mg</td>
<td>6 mg once daily</td>
</tr>
<tr>
<td>25 mg</td>
<td>6 mg twice daily</td>
</tr>
<tr>
<td>37.5 mg</td>
<td>9 mg twice daily</td>
</tr>
<tr>
<td>50 mg</td>
<td>12 mg twice daily</td>
</tr>
<tr>
<td>62.5 mg</td>
<td>15 mg twice daily</td>
</tr>
<tr>
<td>75 mg</td>
<td>18 mg twice daily</td>
</tr>
<tr>
<td>87.5 mg</td>
<td>21 mg twice daily</td>
</tr>
<tr>
<td>100 mg</td>
<td>24 mg twice daily</td>
</tr>
</tbody>
</table>

Drug Availability
Austedo is available as 6 mg, 9 mg and 12 mg tablets.
Background

Professional Societies/Organizations

American Academy of Neurology (AAN) guidelines for the pharmacologic treatment of chorea in Huntington’s disease recommend tetrabenazine, amantadine, or riluzole when Huntington disease chorea requires treatment. The AAN states data are insufficient to make recommendations regarding the use of neuroleptics or donepezil for Huntington disease chorea treatment. This guideline has not updated since the approval of Austedo. (Armstrong, 2012)

American Academy of Neurology (AAN) guidelines for the treatment of tardive syndromes were updated in 2018 and recommend valbenazine and deutetrabenazine, as first-line treatment options. The updated guideline also states tetrabenazine should be used only if valbenazine and deutetrabenazine are unavailable and second-line agents, such as gingko biloba or clonazepam, do not provide adequate relief. (Bhidayasiri, 2013 and 2018)

Off Label Uses
AHFS Drug Information 2019 Edition does not support any off-label uses of Austedo.

Comparative Studies
There are no clinical studies comparing Austedo with other therapeutic alternatives.

References


