

## PHARMACY POLICY STATEMENT

### Marketplace

|                         |                                   |
|-------------------------|-----------------------------------|
| <b>DRUG NAME</b>        | <b>Austedo (deutetrabenazine)</b> |
| BILLING CODE            | Must use valid NDC                |
| BENEFIT TYPE            | Pharmacy                          |
| SITE OF SERVICE ALLOWED | Home                              |
| STATUS                  | Prior Authorization Required      |

Austedo is a vesicular monoamine transporter 2 (VMAT2) inhibitor indicated in adults for the treatment of chorea associated with Huntington’s disease and for the treatment of tardive dyskinesia.

Tardive dyskinesia (TD) is the most common type of tardive syndrome, which primarily involves abnormal, involuntary movements of the face. It is caused by antipsychotic medications or other drugs that block dopamine receptors. Severity of TD is assessed using the Abnormal Involuntary Movement Scale (AIMS), a 12-item scale with a total score range of 0 to 28, with a higher score translating to increased severity.

Huntington’s disease is a hereditary, progressive, neurodegenerative disease characterized by involuntary movements, cognitive dysfunction, and psychiatric symptoms. A prominent Huntington disease symptom is chorea, an involuntary, sudden movement that can affect any muscle and flow randomly across body regions.

Austedo (deutetrabenazine) will be considered for coverage when the following criteria are met:

#### Huntington’s Disease

For **initial** authorization:

1. Member is 18 years of age or older; AND
2. Medication is prescribed by or in consultation with a neurologist; AND
3. Member has a documented diagnosis of chorea that is associated with Huntington’s Disease; AND
4. Documented consultation on risks of suicidal ideation or behavior while on Austedo is submitted with member’s chart notes (Austedo is contraindicated in patients who are suicidal, and in patients with untreated or inadequately treated depression); AND
5. Member’s baseline Total Maximal Chorea Score (of the Unified Huntington’s Disease Rating Scale (UHDRS)) is submitted with chart notes.
6. **Dosage allowed/Quantity limit:** Starting dose of 6 mg once daily with weekly titration by 6 mg per day up to maximum dosage of 48 mg (24 mg twice daily).  
(60 tablets per 30 days)

***If all the above requirements are met, the medication will be approved for 3 months.***

For **reauthorization**:

1. Member must have documentation of improved Total Maximal Chorea Score compared to baseline.

***If all the above requirements are met, the medication will be approved for an additional 12 months.***

#### Tardive Dyskinesia (TD)

For **initial** authorization:

1. Member is 18 years of age or older; AND
2. Medication is prescribed by or in consultation with a neurologist or psychiatrist; AND
3. Member has a documented diagnosis of tardive dyskinesia; AND
4. Symptoms have been present at least 3 months and impede daily activities or quality of life; AND
5. Documentation of Abnormal Involuntary Movement Scale (AIMS) score must be in chart notes; AND
6. One or more of the following approaches has been attempted with inadequate symptom control:
  - a) The drug causing TD symptoms has been stopped and a different drug has been tried and/or
  - b) The member is clinically stable on the offending drug and the lowest effective dose is being used; AND
7. Chart notes confirm the member does not have increased risk for suicidal or violent behavior and has stable psychiatric symptoms; AND
8. If member has a history of substance use disorder, chart notes confirm the member is in remission.
9. **Dosage allowed/Quantity limit:** Starting dose of 12 mg per day (6 mg twice daily) with weekly titration by 6 mg per day up to maximum dosage of 48 mg (24 mg twice daily). (60 tablets per 30 days)

***If all the above requirements are met, the medication will be approved for 3 months.***

For **reauthorization**:

1. Member must have documentation of improvement of AIMS score.

***If all the above requirements are met, the medication will be approved for an additional 12 months.***

**CareSource considers Austedo (deutetrabenazine) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.**

| DATE       | ACTION/DESCRIPTION   |
|------------|--|
| 06/16/2017 | New policy for Austedo created.  |
| 11/01/2017 | New diagnosis of Tardive Dyskinesia was added.   |
| 02/08/2018 | Criterion requirement of clinical diagnoses of Tardive Dyskinesia for at least 3 months was removed. Length of initial authorization increased to 3 months. Criterion on guidelines recommended treatment was revised. Substance use disorder remission length requirement changed. New provider's specialty was added for both diagnosis.   |
| 05/06/2019 | The guideline recommended treatment criterion changed from two to one medication to try as a trial.  |
| 04/07/2022 | Transferred to new template. Updated and added references. Removed NPs from specialist and added generalized "or in consultation with."<br>TD: Removed trial of clonazepam or ginkgo. Removed list of exclusions. Removed duration from substance use disorder remission. Corrected dosing to say twice daily instead of once. Added that TD must be present for at least 3 months and with impeding symptoms. Reduced initial auth duration from 6 mo to 3 mo.<br>HD: For reauth, changed "after week 12" to "compared to baseline." Removed psych as specialist. |

References:

1. Austedo [package insert]. North Wales, PA; Teva Pharmaceuticals, Inc. 2021.
2. Huntington Study group. Effect of deutetrabenazine on chorea among patients with huntington disease: a randomized clinical trial. JAMA. 2016; 316(1):40-50. doi: 10.1001/jama.2016.8655.

3. Claassen DO, Carroll B, De Boer LM, et al. Indirect tolerability comparison of deutetrabenazine and tetrabenazine for huntington disease. *J Clin Mov Dis* 2017(4):3. doi: 10.1186/s40734-017-0051-5.
4. Anderson KE, Stamler D, Davis MD, et al. Deutetrabenazine for treatment of involuntary movements in patients with tardive dyskinesia (AIM-TD): a double-blind, randomised, placebo-controlled, phase 3 trial. *Lancet Psychiatry*. 2017;4(8):595-604. doi:10.1016/S2215-0366(17)30236-5
5. Fernandez HH, Factor SA, Hauser RA, et al. Randomized controlled trial of deutetrabenazine for tardive dyskinesia: The ARM-TD study. *Neurology*. 2017;88(21):2003-2010. doi:10.1212/WNL.0000000000003960
6. Fernandez HH, Stamler D, Davis MD, et al. Long-term safety and efficacy of deutetrabenazine for the treatment of tardive dyskinesia. *J Neurol Neurosurg Psychiatry*. 2019;90(12):1317-1323. doi:10.1136/jnnp-2018-319918
7. Hauser RA, Barkay H, Fernandez HH, et al. Long-Term Deutetrabenazine Treatment for Tardive Dyskinesia Is Associated With Sustained Benefits and Safety: A 3-Year, Open-Label Extension Study. *Front Neurol*. 2022;13:773999. Published 2022 Feb 23. doi:10.3389/fneur.2022.773999
8. Bhidayasiri R, Jitkrisadukul O, Friedman JH, Fahn S. Updating the recommendations for treatment of tardive syndromes: A systematic review of new evidence and practical treatment algorithm. *J Neurol Sci*. 2018;389:67-75. doi:10.1016/j.jns.2018.02.010
9. Solmi M, Pigato G, Kane JM, Correll CU. Treatment of tardive dyskinesia with VMAT-2 inhibitors: a systematic review and meta-analysis of randomized controlled trials. *Drug Des Devel Ther*. 2018;12:1215-1238. Published 2018 May 14. doi:10.2147/DDDT.S133205
10. Armstrong MJ, Miyasaki JM; American Academy of Neurology. Evidence-based guideline: pharmacologic treatment of chorea in Huntington disease: report of the guideline development subcommittee of the American Academy of Neurology. *Neurology*. 2012;79(6):597-603. doi:10.1212/WNL.0b013e318263c443
11. Reilmann R. Pharmacological treatment of chorea in Huntington's disease-good clinical practice versus evidence-based guideline. *Mov Disord*. 2013;28(8):1030-1033. doi:10.1002/mds.25500
12. Dean M, Sung VW. Review of deutetrabenazine: a novel treatment for chorea associated with Huntington's disease. *Drug Des Devel Ther*. 2018;12:313-319. Published 2018 Feb 15. doi:10.2147/DDDT.S138828

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