PHARMACY POLICY STATEMENT
Georgia Medicaid

DRUG NAME	Austedo (deutetrabenazine)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Austedo, approved by the FDA in 2017, 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. An extended-release formulation was approved in 2023.
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 (HD)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication is prescribed by or in consultation with a neurologist; AND
3. Member has a documented diagnosis of Huntington's Disease, confirmed by family history or genetic testing (expanded CAG repeat in the HTT gene); AND
4. Member is experiencing bothersome symptoms of chorea associated with Huntington's Disease; AND
5. 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
6. Member's baseline Total Maximal Chorea Score (of the Unified Huntington's Disease Rating Scale (UHDRS)) is submitted with chart notes.
7. **Dosage allowed/Quantity limit:**
   Austedo: Starting dose of 6 mg twice daily (12 mg/day). May be titrated weekly by 6 mg per day up to max dose of 48 mg/day (24 mg twice daily). QL: 120 tablets/30 days
   Austedo XR: Starting dose of 12 mg once daily. May be titrated weekly by 6 mg per day up to max dose of 48 mg once daily. QL: 60 tablets/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 (TMC) 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 at least 18 years of age; 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.
7. **Dosage allowed/Quantity limit:**
   Austedo: Starting dose of 6 mg twice daily (12 mg/day). May be titrated weekly by 6 mg per day up to max dose of 48 mg/day (24 mg twice daily). QL: 120 tablets/30 days
   Austedo XR: Starting dose of 12 mg once daily. May be titrated weekly by 6 mg per day up to max dose of 48 mg once daily. QL: 60 tablets/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 compared to baseline.

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." 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. HD: For reauth, changed "after week 12" to "compared to baseline." Removed psych as specialist.
03/15/2023	Added dosing and quantity limits for new XR formulation. Adjusted dose and quantity for IR formulation per prescribing information. TD: Removed psychiatric and substance abuse parts of criteria. Clarified that improvement is compared to baseline.
11/14/2023	Added diagnostic confirmation for Huntington's; added 2 references.

References:

1. Austedo [package insert]. North Wales, PA; Teva Pharmaceuticals, Inc. 2023.
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, Jitkritsadakul 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
13. Bachoud-Lévi AC, Ferreira J, Massart R, et al. International Guidelines for the Treatment of Huntington's Disease. Front Neurol. 2019;10:710. Published 2019 Jul 3. doi:10.3389/fneur.2019.00710
14. Ferreira JJ, Rodrigues FB, Duarte GS, et al. An MDS Evidence-Based Review on Treatments for Huntington's Disease. Mov Disord. 2022;37(1):25-35. doi:10.1002/mds.28855

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