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Last P&T Approval/Version: 04/30/2025
Next Review Due By: 04/2026
Policy Number: C12650-A

Austedo (deutetrabenazine)

PRODUCTS AFFECTED

Austedo (deutetrabenazine), Austedo XR (deutetrabenazine)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Tardive Dyskinesia, Chorea associated with Huntington's Disease

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. TARDIVE DYSKINESIA (TD):
   1. Documented diagnosis of moderate to severe tardive dyskinesia (TD)
      AND
   2. Documentation of baseline evaluation of condition documented by Abnormal Involuntary Movement

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Scale (AIMS) OR Extrapyramidal Symptom Rating Scale (ESRS) score [DOCUMENTATION REQUIRED]
NOTE: Documentation of the member's current AIMS score from items 1-7 (results range from 0 to 28, with higher scores indicating more severe involuntary movements) required OR Extrapyramidal Symptom Rating Scale (ESRS). Reauthorization requires positive response or demonstrated efficacy to therapy. Baseline score reviewed at continuation of therapy.
AND

3. Documentation member has had an inadequate response to at least ONE of the following alternative approaches to treat tardive dyskinesia: (a) Adjustments to possible offending medication(s) known to cause TD (dose reduction or discontinuation) were attempted but ineffective in resolving TD symptoms, OR (b) Switched from a first-generation to a second-generation antipsychotic, OR (c) Switched to an antipsychotic with a different mechanism of action (i.e., xanomeline/trospium) OR (d) Member is not a candidate for a trial of dose reduction, tapering, discontinuation of the offending medication, or switching to an alternative antipsychotic therapy [Appendix] [DOCUMENTATION REQUIRED]
   AND
4. Documentation of a trial (4 weeks) and failure or labeled contraindication to Tetrabenazine at up to 100 mg/day. See Appendix 2 for guideline language.
   MOLINA REVIEWER NOTE: For Nevada Marketplace, please see Appendix.
   AND
5. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Austedo (deutetrabenazine) include: Hepatic impairment, taking MAOIs (e.g., selegiline (Emsam), isocarboxazid (Marplan), phenelzine (Nardil), tranylcypromine (Parnate)), reserpine, valbenazine, or tetrabenazine, avoid use in patients with congenital long QT syndrome or with arrhythmias associated with a prolonged QT interval]

B. CHOREA ASSOCIATED WITH HUNTINGTON'S DISEASE:

1. Diagnosis of Huntington's disease with chorea symptoms confirmed by documentation of ONE of the following [DOCUMENTATION REQUIRED]:
   (a) Huntington Disease Mutation Analysis indicating an expanded CAG repeat (≥ 36) in the Huntington gene (HTT) (also known as HD gene)
   OR
   (b) A positive family history of HD, with autosomal dominant inheritance pattern
   AND
2. Documentation of baseline evaluation and documentation of Total Chorea Score [using the Unified Huntington's Disease Rating Scale (UHDRS)]
   NOTE: *Reauthorization requires positive response or demonstrated efficacy to therapy. Baseline score reviewed at continuation of therapy.*
   AND
3. Documentation of trial and failure, or contraindication to tetrabenazine up to 100mg/day
   MOLINA REVIEWER NOTE: For Nevada Marketplace, please see Appendix.
   AND
4. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Austedo (deutetrabenazine) include: Suicidal, or untreated/inadequately treated depression, Hepatic impairment, taking MAOIs (e.g., selegiline (Emsam), isocarboxazid (Marplan), phenelzine (Nardil), tranylcypromine (Parnate)), reserpine, valbenazine, or tetrabenazine, avoid use in patients with congenital long QT syndrome or with arrhythmias associated with a prolonged QT interval]

CONTINUATION OF THERAPY:

A. TARDIVE DYSKINESIA, CHOREA ASSOCIATED WITH HD:

1. Adherence to therapy at least 85% of the time as verified by Prescriber or member medication fill

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history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
AND

2. Documentation member's condition has stabilized or improved based on Prescriber's assessment while on therapy [DOCUMENTATION REQUIRED]:
   a) TD: Disease stabilization or improvement in TD symptoms as documented by decrease from baseline in AIMS score of at least 2 points OR ESRS score of at least 4 points
   b) Chorea Associated with HD: Disease stabilization or improvement from baseline in Total Maximal Chorea Scores OR chorea symptoms

   AND
3. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity

DURATION OF APPROVAL:
Initial authorization: 12 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:
Tardive Dyskinesia: Prescribed by, or in consultation with, a board-certified psychiatrist or neurologist.
Chorea associated with Huntington's Disease: Prescribed by, or in consultation with, a board-certified neurologist with expertise in HD.
[If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:
18 years of age and older

QUANTITY:
Maximum dosage: 48 mg/day
See Other Special Considerations for recommended dosing

PLACE OF ADMINISTRATION:
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral

DRUG CLASS:
Vesicular Monoamine Transporter 2 (VMAT2) Inhibitor

FDA-APPROVED USES:
Indicated in adults for the treatment of Chorea associated with Huntington's disease and Tardive dyskinesia

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

State Specific Information
State Marketplace

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Nevada (Source: Nevada Legislature)

"Chapter 689A of Nevada Revised Statutes (NRS) is hereby amended by adding thereto a new section to read as follows:

1. A policy of health insurance which provides coverage for prescription drugs must not require an insured to submit to a step therapy protocol before covering a drug approved by the Food and Drug Administration that is prescribed to treat a psychiatric condition of the insured, if:
    a. The drug has been approved by the Food and Drug Administration with indications for the psychiatric condition of the insured or the use of the drug to treat that psychiatric condition is otherwise supported by medical or scientific evidence;
    b. The drug is prescribed by:
        i. A psychiatrist
        ii. A physician assistant under the supervision of a psychiatrist;
        iii. An advanced practice registered nurse who has the psychiatric training and experience prescribed by the State Board of Nursing pursuant to NRS 632.120; or
        iv. A primary care provider that is providing care to an insured in consultation with a practitioner listed in subparagraph (1), (2) or (3), if the closest practitioner listed in subparagraph (1), (2) or (3) who participates in the network plan of the insurer is located 60 miles or more from the residence of the insured; and
    c. The practitioner listed in paragraph (b) who prescribed the drug knows, based on the medical history of the insured, or reasonably expects each alternative drug that is required to be used earlier in the step therapy protocol to be ineffective at treating the psychiatric condition…

3. As used in this section:
    c. *'Step therapy protocol' means a procedure that requires an insured to use a prescription drug or sequence of prescription drugs other than a drug that a practitioner recommends for treatment of a psychiatric condition of the insured before his or her policy of health insurance provides coverage for the recommended drug*."

Molina Reviewer Note: Medical necessity review for a psychiatric condition cannot require trial of other medications first. This is applicable to formulary medications that require prior authorization and non-formulary medications and is not limited to only medications designated 'ST'. If the requested drug is a brand name and the generic is on formulary, request can be reviewed for specific medical reason generic cannot be used.

Appendix 1: Centrally Acting Dopamine Receptor Blocking Agents (Neuroleptics)

Drugs that most commonly cause TD are older antipsychotic agents such as haloperidol, chlorpromazine, and thioridazine; other drugs that may be associated with TD include antidepressants (amitriptyline, fluoxetine, phenelzine, sertraline, and trazodone), anti-Parkinson's drugs (levodopa), epilepsy drugs (phenobarbital and phenytoin), and metoclopramide

Appendix 2:

RESULTS AND RECOMMENDATIONS: New evidence was combined with the existing guideline evidence to inform our recommendations. Deutetrabenazine and valbenazine are established as effective treatments of TD (Level A) and must be recommended as treatment. Clonazepam and Ginkgo biloba probably improve TD (Level B) and should be considered as treatment. Amantadine and tetrabenazine might be considered as TD treatment (Level C). Pallidal deep brain stimulation possibly improves TD and might be considered as a treatment for intractable TD (Level C). There is insufficient evidence to support or refute TS treatment by withdrawing causative agents or switching from typical to atypical DRBA (Level U).

Tardive Dyskinesia: Treatment Update
Current Neurology and Neuroscience Reports (2019)
19: 69https://doi.org/10.1007/s11910-019-0976-1

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Treatment options for TSs/TD		
Managing the DRBAs	Reassessing the need of antipsychotics Reducing or switching the DRBAs to newer generation agent (only if tolerated by the patient)	
Pharmacological agents	Most effective treatment—VMAT2 inhibitors	Valbenazine Deutetrabenazine Tetrabenazine
	Less effective—other agents	GABA-ergic compounds—diazepam, clonazepam, baclofen Antioxidants—vitamin E, *Ginkgo biloba* NMDA receptor antagonist—amantadine
	Insufficient evidence [29, 30]	Bromocriptine, buspirone, levetiracetam, melatonin, r eserpine, selegiline, vit B6, zonisamide, trihexyphenidyl
Chemodenervation treatment	Most evidence is for tardive dystonia	
Surgical therapy	Bilateral Globus pallidus interna DBS stimulation for severe TD/TSs refractory to other treatments	

Appendix 3: Abnormal Involuntary Movement Scale (AIMS) is an assessment tool used to detect and follow the severity of tardive dyskinesia (TD) over time. AIMS is composed of 12 clinician-administered and scored items. This outcome sums items 1 through 7 which cover orofacial movements, as well as extremity and truncal dyskinesia (the total motor AIMS score). Ratings are based on a 5-point scale of severity from 0 (none), 1 (minimal), 2 (mild), 3 (moderate), to 4 (severe) for a total scale of 0-28. A negative change from baseline score indicates improvement.

AIMS: https://qxmd.com/calculate/calculator_601/abnormal-involuntary-movement-scale- aims
https://www.austedohcp.com/tardive-dyskinesia/evaluation-and-assessment

ESRS:
https://www.phenxtoolkit.org/toolkit_content/PDF/PX661601.pdf

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Tardive dyskinesia (TD) is a potentially irreversible, involuntary movement disorder characterized by repetitive, choreiform or athetoid movements, often involving the orofacial region, trunk, and extremities. It typically arises after prolonged exposure to dopamine receptor blocking agents, particularly first- and second-generation antipsychotics. The pathophysiology is thought to involve dopaminergic hypersensitivity in the basal ganglia following chronic receptor blockade. According to guideline-directed management, the primary intervention is dose reduction or discontinuation of the offending agent, when feasible. Pharmacologic treatment includes vesicular monoamine transporter 2 (VMAT2) inhibitors.

Xanomeline/Trospium is a novel muscarinic agonist/antagonist approved to treat schizophrenia in adults. In clinical trials, there were no significant changes in weight, lipid levels, glucose, insulin, or alertness. It is also not expected to cause tardive dyskinesia. The most common adverse reactions with this therapy were nausea, dyspepsia, constipation, vomiting, hypertension, abdominal pain, diarrhea, tachycardia, dizziness, and gastroesophageal reflux disease. The product label does not carry antipsychotic class warnings or precautions, and it does not include a Boxed Warning. It is contraindicated in patients with urinary retention, moderate or severe kidney or liver disease, gastric retention, untreated narrow-angle glaucoma, or hypersensitivity.

Chorea associated with Huntington's disease (HD) is a hallmark hyperkinetic movement disorder characterized by involuntary, irregular, and unpredictable muscle movements, primarily affecting the face, trunk, and limbs. It results from progressive neurodegeneration of the striatum and cortical structures due to a CAG trinucleotide repeat expansion in the *HTT* gene. Management focuses on symptomatic control, as there is currently no disease-modifying therapy. According to current guidelines, pharmacologic treatment includes VMAT2. Alternative or adjunctive therapies may include atypical antipsychotics such as olanzapine or risperidone, particularly when psychiatric symptoms coexist.

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CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Austedo (deutetrabenazine) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications to Austedo (deutetrabenazine) include: Suicidal, or untreated/inadequately treated depression in patients with Huntington's disease, Hepatic impairment, taking MAOIs, reserpine, valbenazine, or tetrabenazine, avoid use in patients with congenital long QT syndrome or with arrhythmias associated with a prolonged QT interval.

Exclusions/Discontinuation:

Do not use concurrently with other VMAT2 inhibitors (tetrabenazine, valbenazine).

OTHER SPECIAL CONSIDERATIONS:

Black Box Warnings: Deutetrabenazine product labeling includes a black boxed warning regarding an increased risk for depression and suicidality. Patients with Huntington disease are at increased risk for depression and suicidal ideation; deutetrabenazine and tetrabenazine may increase the risk. In clinical trials, depression was reported in 4% and suicidal ideation was reported in 2% of patients treated with deutetrabenazine; patients with uncontrolled depression were excluded from the trials.

Recommended Dose:

Chorea associated with Huntington's Disease
Initial Dose: 12 mg/day
Recommended Dose: 6 mg – 48 mg/day
Maximum Dose: 48 mg/day

Tardive Dyskinesia in Adults
Initial Dose: 12 mg/day
Recommended Dose: 12 mg – 48 mg/day
Maximum Dose: 48 mg/day

Concomitant use of strong CYP2D6 inhibitors
Maximum Dose: 36 mg/day

Poor CYP2D6 Metabolizers
Maximum Dose: 36 mg/day

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS

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Drug and Biologic Coverage Criteria

Austedo TABS 6MG
Austedo TABS 9MG
Austedo TABS 12MG
Austedo Patient Titration Kit TBPK 6 & 9 & 12MG
Austedo XR 6MG
Austedo XR 12MG
Austedo XR18MG
Austedo XR 24MG
Austedo XR 30MG
Austedo XR 36MG
Austedo XR 42MG
Austedo XR 48MG
Austedo XR Patient Titration TEPK 6 & 12 & 24MG
Austedo XR Patient Titration TEPK 12 & 18 & 24 & 30MG

REFERENCES

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Background Contraindications/Exclusions/Discontinuation References	Q2 2025

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REVISION- Notable revisions: Coding/Billing Information Template Update Required Medical Information Background	Q1 2025
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Duration of Approval Quantity FDA-Approved Uses Other Special Considerations Available Dosage Forms References	Q2 2024
REVISION- Notable revisions: Products Affected Required Medical Information Continuation of Therapy Duration of Approval Prescriber Requirements FDA Approved Uses Appendix Contraindications/Exclusions/ Discontinuation Other Special Considerations Available Dosage Forms References	Q2 2023
REVISION- Notable revisions: Required Medical Information Appendix	Q2 2022
Q2 2022 Established tracking in new format	Historical changes on file

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