



Original Effective Date: 03/01/2018  
Current Effective Date: 05/31/2024  
Last P&T Approval/Version: 04/24/2024  
Next Review Due By: 04/2025  
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

## Drug and Biologic Coverage Criteria

Movement 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) 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 of 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 that Austedo (deutetrabenazine) will not be used concurrently with ANY of the following: tetrabenazine (Xenazine), valbenazine (Ingrezza), MAOI (monoamine oxidase inhibitors) [e.g., selegiline (Emsam), isocarboxazid (Marplan), phenelzine (Nardil), tranylcypromine (Parnate)]  
AND
6. 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, 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 ( $\geq 36$ ) in the Huntington gene (HTT) (also known as HD gene)  
OR
  - (b) A positive family history of HD, with autosomal dominant inheritance patternAND
2. Prescriber attests that member does not have serious untreated or undertreated psychiatric illness, such as depression, AND is not suicidal.  
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. 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
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: Suicidal, or untreated/inadequately treated depression, Hepatic impairment, taking MAOIs, reserpine,

## Drug and Biologic Coverage Criteria

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. FOR ALL INDICATIONS:

1. Adherence to therapy at least 85% of the time as verified by Prescriber and member's medication fill history (review Rx history for compliance)  
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 symptomsAND
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

Molina Healthcare, Inc. confidential and proprietary © 2024

*This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare.*

## Drug and Biologic Coverage Criteria

### 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

**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).

## Drug and Biologic Coverage Criteria

### Tardive Dyskinesia: Treatment Update

Current Neurology and Neuroscience Reports (2019)

19: 69<https://doi.org/10.1007/s11910-019-0976-1>

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, <i>Ginkgo biloba</i> NMDA receptor antagonist—amantadine
	Insufficient evidence [29, 30]	Bromocriptine, buspirone, levetiracetam, melatonin, r eserpine, selegiline, vit B6, zonisamide, trihexyphenidyl
Chemodeneration 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://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](https://www.phenxtoolkit.org/toolkit_content/PDF/PX661601.pdf)

## BACKGROUND AND OTHER CONSIDERATIONS

### BACKGROUND:

None

### 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, 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.

### OTHER SPECIAL CONSIDERATIONS:

**Black Box Warnings:** Deutetrabenazine product labeling includes a 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

Molina Healthcare, Inc. confidential and proprietary © 2024

This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare.

## Drug and Biologic Coverage Criteria

### 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

*Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement*

HCPDS CODE	DESCRIPTION
NA	

## AVAILABLE DOSAGE FORMS

Austedo TABS 6MG

Austedo TABS 9MG

Austedo TABS 12MG

Austedo Patient Titration Kit TBPk 6 & 9 & 12MG

Austedo XR 6MG

Austedo XR 12MG

Austedo XR 24MG

Austedo XR Patient Titration TEPK 6 & 12 & 24MG

## REFERENCES

1. Austedo (deutetrabenazine) [prescribing information]. North Wales, PA: Teva Pharmaceuticals; September 2023.
2. Medication-induced movement disorders and other adverse effects of medication. Diagnostic and statistical manual of mental disorders, 5th Ed. American Psychiatric Association.
3. Armstrong MJ et al. Evidence-based guideline: pharmacologic treatment of chorea in Huntington disease: report of the guideline development subcommittee of the American Academy of Neurology. *Neurology* 2012; 79:597.
4. Bhidayasiri R, Fahn S, Weiner WJ, et al. Evidence-based guideline: Treatment of tardive syndromes: report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology*. 2013; 81(5):463-469.
5. Bhidayasiri R, et al. Updating the recommendations for treatment of tardive syndromes: A systematic review of new evidence and practical treatment algorithm. *J Neurol Sci* 2018; 389:67.
6. ClinicalTrials.gov. Bethesda (MD): National Library of Medicine (US). 2017. Identifier NCT02291861, Addressing Involuntary Movements in Tardive Dyskinesia (AIM-TD); 2017 [cited 2017 Nov]. Available from: <https://clinicaltrials.gov/ct2/show/NCT02291861?term=deutetrabenazine&recrs=e&rank=5>.
7. ClinicalTrials.gov. Bethesda (MD): National Library of Medicine (US). 2017. Identifier NCT02195700, Aim to Reduce Movements in Tardive Dyskinesia (ARM-TD); 2017 [cited 2017Nov]. Available from:



## Drug and Biologic Coverage Criteria

<https://clinicaltrials.gov/ct2/show/NCT02195700?term=deutetrabenazine&recrs=e&rank=2>

8. Huntington Study Group et al. Effect of deutetrabenazine on chorea among patients with Huntington disease: a randomized clinical trial. *JAMA* 2016; 316:40.
9. Fernandez HH et al. Randomized controlled trial of deutetrabenazine for tardive dyskinesia: the ARM-TD study. *Neurology* 2017; 88:2003.
10. Anderson KE et al. Deutetrabenazine for treatment of involuntary movements in patients with tardive dyskinesia (AIM-TD): a double-blind, randomized, placebo-controlled, phase 3 trial. *Lancet Psychiatry* 2017; 4:595.
11. Arya, D., Khan, T., Margolius, A., & Fernandez, H. (2019). Tardive Dyskinesia: Treatment Update. *Current Neurology and Neuroscience Reports*, 19(9). doi: 10.1007/s11910-019-0976-1

SUMMARY OF REVIEW/REVISIONS	DATE
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