Effective Date: 04/2024
Last Approval/Version: 04/2024
Next Review Due By: 04/2025
Policy Number: C25216-A

Austedo - IL Medicaid Only

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.

A. TARDIVE DYSKINESIA (TD):
   1. Documented diagnosis of moderate to severe tardive dyskinesia.
      AND
   2. Prescriber attests (or the clinical reviewer has found) that Austedo (deutetrabenazine) will not be used concurrently with ANY of the following contraindicated products: tetrabenazine (Xenazine), valbenazine (Ingrezza), MAOI (monoamine oxidase inhibitors) [e.g., selegiline (Emsam), isocarboxazid (Marplan), phenelzine (Nardil), tranylcypromine (Parnate)].
      AND
   3. Prescriber attests (or the clinical reviewer has found) that the member does not have any

FDA labeled contraindications that haven't been addressed within the documentation submitted for review.
OR

B. CHOREA ASSOCIATED WITH HUNTINGTON'S DISEASE (HD):
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. Prescriber attests (or the clinical reviewer has found) that the member does not have serious untreated or undertreated psychiatric illness, such as depression, and is not suicidal.
AND
3. Prescriber attests (or the clinical reviewer has found) that the member does not have any FDA labeled contraindications that haven't been addressed within the documentation submitted for review.
AND
4. Prescriber attests (or the clinical reviewer has found) that Austedo (deutetrabenazine) will not be used concurrently with ANY of the following contraindicated products: tetrabenazine (Xenazine), valbenazine (Ingrezza), MAOI (monoamine oxidase inhibitors) [e.g., selegiline (Emsam), isocarboxazid (Marplan), phenelzine (Nardil), tranylcypromine (Parnate)].
AND
5. Documentation of baseline evaluation and 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 for continuation of therapy.

CONTINUATION OF THERAPY:

A. FOR TARDIVE DYSKINESIA:
1. Adherence to therapy at least 85% of the time as verified by prescriber and/or member's medication fill history (review Rx history for compliance).
AND
2. Prescriber attests (or clinical reviewer has found) that the member's condition has stabilized or improved based on provider's assessment while on therapy.
AND
3. Prescriber attests to (or clinical reviewer has found) no evidence of intolerable adverse effects or drug toxicity.
OR

B. FOR CHOREA ASSOCIATED WITH HUNTINGTON'S DISEASE:
1. Adherence to therapy at least 85% of the time as verified by prescriber and/or member's medication fill history (review Rx history for compliance).
AND
2. Documentation showing that the member's condition has stabilized or improved based on provider's assessment while on therapy, as evidenced by improvement from baseline in Total Maximal Chorea Scores OR chorea symptoms. [DOCUMENTATION REQUIRED]
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
See Other Special Considerations for recommended dosing

QUANTITY:
Maximum dosage: 48 mg/day

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 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:
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

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	

NOTE: Step thru tetrabenazine is not required for approval, per Illinois Healthcare and Family Services (HFS).

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.

NOTE: AIMS score is not required for approval, per Illinois Healthcare and Family Services (HFS).

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:
<u>Chorea associated with Huntington's Disease</u>
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

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

HCPCS 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

REFERENCES

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SUMMARY OF REVIEW/REVISIONS	DATE
ANNUAL REVIEW COMPLETED- Notable revisions: Required Medical Information Appendix References	04/2024
Established tracking in new format	Q2/2023