Clinical Policy: Vesicular Monoamine Transporter 2 (VMAT2) Inhibitors

Reference Number: OR.CP.PHAR.1004
Effective Date: 07.01.22
Last Review Date: 05.24
Line of Business: Medicaid – Oregon Health Plan Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
The following agents contain a vesicular monoamine transporter 2 (VMAT2) inhibitor and require prior authorization: deutetrabenazine (Austedo, Austedo XR), tetrabenazine (Xenazine), valbenazine (Ingrezza).

Goal(s):
- Promote safe use of VMAT2 inhibitors in adult patients.
- Promote use that is consistent with medical evidence and product labeling.

Length of Authorization:
- Initial: Up to 3 months
- Renewal: Up to 12 months

Requires PA:
- All VMAT2 inhibitors

Covered Alternatives:
- Current Trillium Preferred Drug List listed at:
  - https://www.trilliumohp.com/providers/pharmacy.html

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Trillium Community Health Plan that deutetrabenazine, tetrabenazine or valbenazine are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Chorea Associated with Huntington's Disease (must meet all)**:**

1. Diagnosis of chorea associated with Huntington's disease;
2. Prescribed by or in consultation with a psychiatrist or neurologist;
3. Baseline total maximal chorea score of 8 or higher as assessed by the Unified Huntington's disease Rating Scale–Total Chorea Movement subscore (UHDRS-TCS) (*see Appendix D*);
4. Age ≥ 18 years;

5. Member is determined to not have uncontrolled depression or be at risk of violent or suicidal behavior;
6. Request is for one of the following (a or b):
   a. Request is for tetrabenazine;
   b. Request is for deutetrabenazine or valbenazine and member has failed treatment with tetrabenazine (e.g., no improvement on any one of UHDRS chorea items 1 through 7) at up to 100 mg per day, unless contraindicated or clinically significant adverse effects are experienced;
7. If request is for Xenazine, member must use generic tetrabenazine, unless contraindicated or clinically significant adverse effects are experienced;
8. Multiple VMAT2 inhibitors (tetrabenazine, deutetrabenazine, valbenazine) are not prescribed concomitantly;
9. Dose does not exceed the FDA-approved maximum recommended dose.

Approval duration: 3 months

B. Tardive Dyskinesia (must meet all)**:**

1. Diagnosis of moderate to severe tardive dyskinesia secondary to a centrally acting dopamine receptor blocking agent (DRBA) (*see Appendix F*);
2. Prescribed by or in consultation with a psychiatrist or neurologist;
3. Age ≥ 18 years;
4. Evidence of moderate to severe TD is supported by an Abnormal Involuntary Movement Scale (AIMS) score of 3 or 4 on any one of items 1 through 9 (*see Appendix G*);
5. Request is for one of the following (a or b):
   a. Request is for tetrabenazine;
   b. Request is for deutetrabenazine or valbenazine and member has failed treatment with tetrabenazine (e.g., no improvement on any one of AIMS items 1 through 9) at up to 200 mg per day, unless contraindicated or clinically significant adverse effects are experienced;
6. If request is for Xenazine, member must use generic tetrabenazine, unless contraindicated or clinically significant adverse effects are experienced;
7. Multiple VMAT2 inhibitors (tetrabenazine, deutetrabenazine, valbenazine) are not prescribed concomitantly;
8. Dose does not exceed the maximum recommended dose.

Approval duration: 3 months

C. Tourette Syndrome (must meet all):

1. Diagnosis of tics associated with Tourette syndrome;
2. Prescribed by or in consultation with a psychiatrist or neurologist;
3. Failure of at least two guideline directed medications each from different therapeutic classes, unless clinically significant adverse effects are experienced or all are contraindicated (a, b, or c):
   a. Alpha-2 Adrenergic Agonist (clonidine or guanfacine);
   b. Anticonvulsant (topiramate);
   c. Antipsychotic (pimozide, aripiprazole or risperidone);
4. Request is for tetrabenazine;

5. Dose does not exceed the maximum recommended dose.

Approval duration: 3 months

D. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the PDL the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the PDL the non-formulary policy for the relevant line of business: OR.CP.PMN.1001 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Huntington's Disease (must meet all):

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);
2. Patient is responding positively to therapy as documented by evidence of improvement in total maximal chorea score of at least 2 points from baseline;
3. Metal status of the patient is stable and there is no risk of uncontrolled depression or risk of violent or suicidal behavior;
4. If request is for a dose increase, new dose does not exceed the FDA-approved maximum recommended dose.

Approval duration: up to 12 months

B. Tardive Dyskinesia (must meet all):

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);
2. Patient is responding positively to therapy as documented by evidence of improvement by a reduction in AIMS dyskinesia score (Items 1-7) by at least 50%;
3. Metal status of the patient is stable and there is no risk of uncontrolled depression or risk of violent or suicidal behavior;
4. If request is for a dose increase, new dose does not exceed the FDA-approved maximum recommended dose.

Approval duration: up to 12 months

C. Tourette Syndrome (must meet all):
1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);
2. Member been taking tetrabenazine for >2 months (if ≤2 months then use Initial Approval Criteria to determine medical necessity of request);
3. Member is responding positively to therapy as documented by reduced tic severity from baseline as assessed by the Yale Global Tic Severity Score (YGTSS) Total Tic Score (range 0-50);
4. If request is for a dose increase, new dose does not exceed the maximum recommended dose.

Approval duration: up to 12 months

D. Other diagnoses/indications (must meet 1 or 2):
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the PDL the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the PDL the non-formulary policy for the relevant line of business: OR.CP.PMN.1001 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information:

Appendix A: Abbreviation/Acronym Key

AAN: American Academy of Neurology
AIMS: Abnormal Involuntary Movement Scale
APA: American Psychiatric Association
CAG: cytosine-adenine-guanine
DRBA: dopamine receptor blocking agent
DSM V: Diagnostic and Statistical Manual, Version 5
FDA: Food and Drug Administration
HTT: huntingtin
MAOI: monoamine oxidase inhibitors
TD: tardive dyskinesia
UHDRS: Unified Huntington Disease Rating Scale
VMAT2: vesicular monoamine transporter

Appendix B: General Information:

- The 2020 American Psychiatric Association (APA) Practice guideline for the treatment of patients with schizophrenia recommends that patients who have moderate to severe or disabling TD be treated with a reversible VMAT2 inhibitor (i.e., deutetrabenazine, tetrabenazine, and valbenazine); the guideline notes that the AIMS tool can be instrumental in such decision-making.
  - Per the 2020 APA Guideline, tetrabenazine typical dosing range is 25-75 mg per day with the following additional comments: Give in divided doses - increase from initial dose of 25-50 mg/day by 12.5 mg/week to maximum of 150-200 mg/day. Retitrate dose for treatment interruptions of more than 5 days. Test for CYP2D6 metabolizer status before giving doses > 50 mg/day. Do not exceed 50 mg/day in poor metabolizers or in patients treated with a strong inhibitor of CYP2D6.
- Medication-induced movement disorders, including tardive dyskinesia, are organized in the DSM V as follows: neuroleptic-induced parkinsonism/other medication-induced parkinsonism, neuroleptic malignant syndrome, medication-induced acute dystonia, medication-induced acute akathisia, tardive dyskinesia, tardive dystonia/tardive akathisia, medication-induced postural tremor, other medication-induced movement disorder, antidepressant discontinuation syndrome, and other adverse effects of medication.[5]
- Tardive dyskinesia is a type of movement disorder that occurs secondary to therapy with *centrally acting* DRBAs (*see Appendix E*). (DSM V)
- Typical therapeutic drug classes containing DRBAs include first- and second-generation antipsychotics, antiemetics, and tri-cyclic antidepressants (*see Appendix F*). (DSM V)
- Other therapeutic drug classes containing agents that have been variously associated with movement disorders are listed below: (Waln 2013, Meyer 2014, Lerner 2015)
  - Antiarrhythmics
  - Antibiotics
  - Anticholinergics
  - Antidepressants
  - Antiepileptics
  - Antihistamines
  - Antimanics
  - Bronchodilators
  - Calcium channel blockers
  - Central nervous system stimulants
  - Dopamine agonists
  - Dopamine depleting agents
  - Dopaminergics
  - Glucocorticoids
  - Immunosuppressants
  - Mood stabilizers
  - Muscle relaxants
  - Oral contraceptives

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Known hypersensitivity to the requested drug product
  - Suicidal or untreated/inadequately treated depression (*deutetrabenazine, tetrabenazine*)
  - Hepatic impairment (*deutetrabenazine, tetrabenazine*)
  - Taking reserpine or MAOIs (*deutetrabenazine, tetrabenazine*)
  - Taking another VMAT2 inhibitor
- Boxed warning(s):
  - Depression and suicidality

Appendix D: The Unified Huntington Disease Rating Scale (UHDRS)

- The UHDRS encompasses motor, behavioral, cognitive, and functional components for use in evaluating patients with Huntington disease and is commonly used in both research and clinical practice.
- The American Academy of Neurology (AAN) guidelines evaluating pharmacologic therapies for chorea associated with Huntington disease describe the chorea subscore of the UHDRS motor component as a rating of 7 body regions (facial, bucco-oral-lingual, trunk, extremities) on a five-point scale from 0 to 4 with 0 representing no chorea.
- See Huntington Study Group 1996 and Mestre et al. 2018 for additional information about the UHDRS.

(AAN Guidelines 2012, Huntington Study Group 1996, Mestre 2018)

Appendix E: Tardive Dyskinesia: DSM-V Definition

Tardive Dyskinesia *(ICD-9 333.85/ICD-10 G24.01)*
• Involuntary athetoid or choreiform movements (lasting at least a few weeks) generally of the tongue, lower face and jaw, and extremities (but sometimes involving the pharyngeal, diaphragmatic, or trunk muscles) developing in association with the use of a neuroleptic medication for at least a few months. • Symptoms may develop after a shorter period of medication use in older persons. In some patients, movements of this type may appear after discontinuation, or after change or reduction in dosage, of neuroleptic medications, in which case the condition is called neuroleptic withdrawal emergent dyskinesia. Because withdrawal emergent dyskinesia is usually time limited, lasting less than 4-8 weeks, dyskinesia that persists beyond this window is considered to be tardive dyskinesia.

Appendix F: Tardive Dyskinesia: Centrally Acting Dopamine Receptor Blocking Agents (Neuroleptics)

Pharmacologic Class	**Therapeutic Class**		
	First-generation (typical) antipsychotics	**Antiemetic agents**	**Tri-cyclic antidepressants**
Phenothiazine	Chlorpromazine Fluphenazine Perphenazine Thioridazine Thiothixene Trifluoperazine	Chlorpromazine Perphenazine Prochlorperazine Promethazine* Thiethylperazine	Amoxapine†
Butryophenone	Haloperidol	Droperidol Haloperidol**	
Substituted benzamide		Metoclopramide Trimethobenzamide	
Dibenzazepine	Loxapine		
Diphenylbutylpiperidine	Pimozide		
Pharmacologic Class	**Second-generation (atypical) antipsychotics**		
Quinolone	Aripiprazole, brexpiprazole		

Pharmacologic Class	Therapeutic Class		
	First-generation (typical) antipsychotics	Antiemetic agents	Tri-cyclic antidepressants
Dibenzazepine	Asenapine		
Piperazine	Cariprazine		
Dibenzodiazephine	Clozapine, quetiapine		
Benzisoxazole	Iloperidone		
Benzisothiazole	Lurasidone, ziprasidone		
Thienobenzodiazepine	Olanzapine		
Pyrimidinone	Paliperidone, risperidone		

(DSM V, Meyer 2014, Smith 2010, Clinical Pharmacology, Lexicomp)
**First generation H1 antagonist*
***Off-label use*
†A dibenzoxapine that shares properties with phenothiazines

Appendix G: Tardive Dyskinesia: The Abnormal Involuntary Movement Scale (AIMS)

- The AIMS is a clinician-rated 12-item assessment tool developed by the National Institute of Mental Health to evaluate severity of involuntary movements in multiple movement disorders including TD. The AIMS is commonly used in both research and clinical practice.
- AIMS items 1-10 are rated on a 5-point scale (0 - none; 1 - minimal; 2 - mild; 3 - moderate; 4 - severe). Items 1-7 assess dyskinesia severity by body region (items 1-4 orofacial; items 5-7 extremity and trunk). Items 8-10 assess overall severity, incapacitation, and patient awareness respectively - item 8 uses the highest score of any one of items 1-7. Items 11 (dental) and 12 (dentures) are yes/no questions which help characterize lip, jaw, and tongue movements.
- See Munetz 1988 for additional information about the AIMS.

Appendix H: Dosage and Administration

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
deutetrabenazine (Austedo, Austedo XR)	**Huntington's Chorea & TD** When not switching from tetrabenazine: Recommended starting dose • Austedo XR: 12 mg PO QD • Austedo: 6 mg PO BID Titrate at weekly intervals by 6 mg/day based on reduction of chorea or tardive dyskinesia, and tolerability, up to a maximum recommended daily dosage of 48 mg. When switching between Austedo and Austedo XR, switch to the same total daily dosage.	48 mg/day (36 mg/day in poor CYP2D6 metabolizers or with strong CYP2D6 metabolizers)

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	When switching from tetrabenazine: see Prescribing Information dosage chart	
tetrabenazine (Xenazine)	**Huntington's Chorea** 12.5 mg PO QD for 1 week, then 12.5 mg BID, then titrated by 12.5 mg weekly to a tolerated dose up to maximum of 50 mg/day (100 mg/day for CYP2D6 intermediate or extensive metabolizers)	50 mg/day (max single dose of 25 mg) Extensive or intermediate CYP2D6 metabolizer: 100 mg/day (max single dose of 37.5 mg)
	Tardive Dyskinesia *(off-label)** Typical dosing range (mg/day): 25-75 Comments: Give in divided doses: increase from initial dose of 25-50 mg/day by 12.5 mg/week to maximum of 150-200 mg/day. Retitrate dose for treatment interruptions of more than 5 days. Test for CYP2D6 metabolizer status before giving doses > 50 mg/day. Do not exceed 50 mg/day in poor metabolizers or in patients treated with a strong inhibitor of CYP2D6. *The American Psychiatric Association practice guideline for the treatment of patients with schizophrenia. 2020. Third Ed.*	200 mg/day in divided doses
	Tourette Syndrome *(off-label)* Increase from initial dose of 25 mg/day, with increases by 25 mg daily until 100 mg daily reached or adverse effects intervene; then subsequently titrate based on response (maximal daily dose, 37.5 to 150 mg daily)	150 mg/day
Valbenazine (Ingrezza)	**Huntington's Chorea** 40 mg PO once daily; increase the dose in 20 mg increments every two weeks to the recommended dose of 80 mg once daily. A dosage of 40 mg or 60 mg once daily may be considered depending on response and tolerability.	80 mg/day
	Tardive Dyskinesia 40 mg PO once daily; after a week, increase to the recommended dose of 80 mg once daily. A dosage of 40 mg or 60 mg once daily may be considered depending on response and tolerability.	80 mg/day

**Off-label dose supported by the 2020 American Psychiatric Association (APA) Practice Guideline for the Treatment of Patients With Schizophrenia. See additional dosing comments in Appendix B.*

Appendix I: Product Availability:

Medication	Formulation and Strength
deutetrabenazine	Immediate-release tablets: 6 mg, 9 mg, 12 mg
	Extended-release tablets: 6 mg, 12 mg, 24 mg
tetrabenazine	Tablets: 12.5 mg, 25 mg
valbenazine	Capsules: 40 mg, 60 mg, 80 mg

V. References

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created; adapted from previously approved policy TCHP.PHAR.181 Vesicular Monoamine Transporter 2 (VMAT2) Inhibitors	03.17.22	04.07.22
2Q 2023 annual review: no significant changes; template changes applied to other diagnoses/indications and continued therapy section; references reviewed and updated.	03.13.23	04.06.23
2Q 2024 annual review. Updated criteria to match FFS updates: initial approval duration extended to 3 months for all indications; removed QT prolongation contraindication from Chorea initial approval criteria; added tetrabenazine as preferred agent for TD; Tourette syndrome indication added; cleaned up and standardized Appendixes; references reviewed and updated.	04.17.24	05.21.24

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.