

Comments in Support: Senate Bill 448

From Chris Bouneff, Executive Director, NAMI Oregon March 13, 2025 Senate Health Care Committee

NAMI Oregon wishes to express our support for Senate Bill 448, which would direct the Oregon Health Authority to study the impacts of tardive dyskinesia. Tardive dyskinesia is a serious movement disorder that individuals living with mental illness can experience as a side effect of medications that effectively treat symptoms of major conditions such as schizophrenia and bipolar disorder.

This is an important issue for NAMI Oregon, which is the state chapter of the National Alliance on Mental Illness. We are a grassroots, membership-governed organization of individuals and families who live with mental health conditions. Access to effective medications that treat the symptoms of mental health conditions is among our top priorities, which is why we conclude that SB 448 is worthy of our support.

Tardive dyskinesia is a very serious side effect of taking medications that treat the symptoms of serious mental illnesses, and it's a side effect that can become a permanent condition. This puts many patients in an untenable situation — to continue with medications that effectively ameliorate their symptoms but create uncomfortable or disabling involuntary movements or to discontinue their medications for less effective alternatives. The problem being that those alternatives introduce other side effects, such as obesity and heart disease. We are left in a quandary of what is the least harmful side effect.

Today, we have medications that effectively mitigate tardive dyskinesia, meaning people have greater choices when making an informed decision about mental health medications. However, access is a challenge. These medications are not included under Oregon's mental health medication carveout. They are subject to prior authorization and other access criteria, which is an understandable restriction. But with 16 different coordinated care organizations (CCOs), it becomes a web of confusion because there are 16 different sets of hoops to jump through to access a helpful medication.

NAMI's hope is that legislation such as SB 448 leads to a single set of criteria that address the hoops through which both prescribers and patients must jump to access an important classification of medications. We already have national standards established by the American Psychiatric Association. Oregon's Mental Health Clinical Advisory Group (MHCAG), an advisory body with robust expertise that's charged with setting best-practice medication and treatment algorithms, has also established standards for the Oregon Health Authority. Why must each CCO then add even more hoops that veer from national and state standards?

We include with our testimony an analysis that NAMI commissioned last fall that compares CCO criteria to both national and MHCAG criteria. When so much is known about a medication that helps people with serious mental illness stay on medications that address their mental health symptoms, to create even more arbitrary hurdles to access seems imprudent. This lack of uniformity is inefficient and needless and compromises patient care and long-term positive outcomes.

NAMI hopes that legislation such as SB 448 gets Oregon closer to quality uniform criteria so that access isn't arbitrarily based on the location in which an individual lives. We encourage your support for SB 448.

Overview of Oregon Managed Medicaid

Coordinated Care Organizations (CCOs)

VMAT2-Inhibitor Prior Authorization Criteria for Tardive Dyskinesia

November 2024

Links to Resources Used:

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- Oregon Health Authority (OHA) Prior Authorization Criteria for VMAT2-inhibitors (last updated November 2023):
 - https://www.orpdl.org/durm/PA Docs/vesicularmonoaminetransporter2.pdf
- OHA Mental Health Clinical Advisory Group Clinical Guidelines on Movement Disorders (April 2024)
 - https://www.oregon.gov/oha/HPA/DSI-Pharmacy/MHCAGDocs/Recognition-and-Management-of-Antipsychotic-induced-Movement-Disorders_4-04-24.pdf
 - Tardive Dyskinesia starts on page 3
- American Psychiatric Association Guideline for the Treatment of Patients with Schizophrenia (last updated Sept 2020):
 - https://psychiatryonline.org/doi/epdf/10.1176/appi.books.9780890424841
 - Section 14 on VMAT2 medications for Tardive Dyskinesia starts on page 126 of 312

OHA = Oregon Health Authority TD = Tardive Dyskinesia HCP = Healthcare Provider MHCAG = Mental Health Clinical Advisory Group APA = American Psychiatric Association PA = Prior Authorization PMHNP = Psychiatric Mental Health Nurse Practitioner

CAREOREGON (Includes Columbia Pacific, Jackson Care Connect CCOs)

Criteria Type	CareOregon ¹ (Last updated Oct 1, 2024)	OHA PA Criteria for VMAT2- inhibitors ^{2,3}	Oregon Mental Health Clinical Advisory Group ⁴	American Psychiatric Association Guidelines ⁵
Prescriber Specialty	Treatment has been initiated by or is currently supervised by appropriate specialist (PMHNP and other mid- level excluded)	Prescriber specialty criterion was removed per OHA Oct 2023 P&T meeting ³ "The Committee recommended revising the proposed clinical PA criteria to remove the requirement of a specialist for initial approval" ³	"Regularly assess symptoms using validated tools like the Abnormal Involuntary Movement Scale (AIMS) which can be performed by any clinician with appropriate training" No specialist requirements mentioned.	No specialist requirements mentioned. In addition, newer VMAT2-inhibitors are generally well tolerated: "Studies of deutetrabenazine and valbenazine are consistent in showing negligible side effects as compared with placebo."
Trial and Failure Requirements	For valbenazine, trial and failure, or contraindication to, tetrabenazine	Does not require use of tetrabenazine before valbenazine or deutetrabenazine	"A VMAT2-inhibitor valbenazine or deutetrabenazine is suggested in individuals with moderate, severe, or disabling TD" Tetrabenazine is not listed in guidance	"In general, deutetrabenazine and valbenazine are preferred over tetrabenazine because of the greater evidence base supporting their use" "In initial studies of tetrabenazine for Huntington's disease, significant rates of depression and concerns about suicidal ideations were noted. However, in studies of deutetrabenazine and valbenazine in patients with TD, there were no apparent increases in depression or suicidal ideas"
TD Severity	Clear documentation that the TD meets one of the following: • Causing significant functional impairment	Requires diagnosis of moderate to severe TD	"A VMAT2-inhibitor valbenazine or deutetrabenazine is suggested in individuals with	"Patients who have moderate to severe or disabling tardive dyskinesia associated with antipsychotic therapy should be

Change in Anti- Dopaminergic Therapy	 Progression of TD symptoms worsening over time Causing significant distress to the member Therapy modification of the dopamine receptor blocker satisfying one of the following: Medication(s) precipitating the TD has been discontinued, but TD persists 	Consideration of change in antipsychotic therapy not required within criteria.	moderate, severe, or disabling TD" "Evidence for reducing symptoms of tardive dyskinesia by lowering the antipsychotic dose or switching to another	treated with a VMAT2." "Treatment with a VMAT2 inhibitor can also be considered for patients with mild TD on the basis of such factors as patient preference, associated impairment, or effect on psychosocial functioning" "Dyskinetic movements may begin or increase in the context of an antipsychotic dose reduction. A lower dose of antipsychotic medication can be
	 At least 8 weeks trial of each of 2 other agents within the same therapeutic category at a clinically effective and maximum tolerated dose for the member's primary neuropsychiatric diagnoses Documentation that therapy change of the medication(s) precipitating the TD could cause harm or is otherwise inappropriate 		antipsychotic is insufficient." TD "symptoms may be irreversible despite reducing the dose or discontinuing the antipsychotic medication."	considered, although evidence for this approach is minimal, and the potential for benefit must be weighed against the possibility of recurrent symptoms or relapse."
AIMS Score	Documented baseline AIMS score	Requires AIMS score	"Regularly assess symptoms using validated tools like the AIMS, which can be performed by any clinician with appropriate training."	"When using scales such as the AIMS or the DISCUS, it should be noted that there is no specific score threshold that suggests a need for intervention."
Renewal Criteria	 Requires documentation of BOTH of the following: Follow-up AIMS assessment showing improvement from baseline Documented improvement in 	"Documented evidence of clinical improvement by a reduction in AIMS dyskinesia score from baseline"	"Discontinue if no clinically meaningful improvement is documented (for example, at least a 2-point reduction)"	No threshold for AIMS score improvement mentioned

ability to perform	
ADLs, reduction in falls, and increase in quality of life	

- 1. Vesicular Monoamine Transporter 2 Inhibitors. CareOregon. Updated October 1, 2024. Accessed October 20, 2024. Available at: <u>https://www.careoregon.org/docs/default-source/providers/pharmacy-resources/pa-criteria/vesicular-monoamine-transporter-2-inhibitors.pdf</u>
- 2. Vesicular Monoamine Transporter 2 (VMAT2) Inhibitors. Oregon Health Authority. November 1, 2023. Accessed October 20, 2024. Available at: https://www.orpdl.org/durm/PA_Docs/vesicularmonoaminetransporter2.pdf
- Oregon Health Authority Director's Decision on Pharmacy and Therapeutics (P&T) Committee Recommendations Dated October 5, 2023. Oregon Health Authority. October 19, 2023. Accessed October 20, 2024. Available at: <u>https://www.oregon.gov/oha/HPA/DSI-Pharmacy/PT%20Meeting%20Materials/23_1019_October%20203%20PT%20Recommendations_101923_final.pdf</u>.
- Recognition and Management of Antipsychotic-induced Movement Disorders. Oregon Health Authority. Accessed October 20, 2024. Available at: <u>https://www.oregon.gov/oha/HPA/DSI-Pharmacy/MHCAGDocs/Recognition-and-Management-of-Antipsychotic-induced-Movement-Disorders_4-04-24.pdf</u>

The American Psychiatric Association Practice Guideline for the Treatment of Patients with Schizophrenia. 3rd ed. Washington, DC: APA; 2021. Accessed October 20, 2024. Available at: <u>https://psychiatryonline.org/doi/book/10.1176/appi.books.9780890424841</u>.

ALLCARE CCO

Criteria Type	AllCare ¹ (Last updated March 16, 2019)	OHA PA Criteria for VMAT2-inhibitors ^{2,3}	Oregon Mental Health Clinical Advisory Group ⁴	American Psychiatric Association Guidelines ⁵
TD Diagnosis	 Must have ALL of the following: Diagnosis of schizophrenia, schizoaffective disorder, or mood disorder according to DSM-IV criteria DSM diagnosis of moderate to severe dopamine blocker-induced TD 	Requires diagnosis of moderate to severe TD. No specific underlying behavioral health diagnoses required.	"A VMAT2-inhibitor valbenazine or deutetrabenazine is suggested in individuals with moderate, severe, or disabling TD" "Symptoms may be irreversible despite reducing the dose or discontinuing the antipsychotic medication."	"Patients who have moderate to severe or disabling tardive dyskinesia associated with antipsychotic therapy should be treated with a VMAT2." "Treatment with a VMAT2 inhibitor can also be considered for patients with mild TD on the basis of such factors as patient preference, associated impairment, or effect on psychosocial functioning"
TD Severity	TD is causing significant distress to the patient that impacts their activities of daily living (i.e. inability to feed oneself, frequent falls, missing school or work, impaired social interactions, etc)	Diagnosis of moderate to severe TD	"A VMAT2-inhibitor valbenazine or deutetrabenazine is suggested in individuals with moderate, severe, or disabling TD"	"Treatment with a VMAT2 inhibitor can also be considered for patients with mild TD on the basis of such factors as patient preference, associated impairment, or effect on psychosocial functioning"
Prescriber Type	Request is from an appropriate specialist (i.e. psychiatrist or neurologist)	Prescriber specialty criterion was removed per OHA Oct 2023 P&T meeting ³	"Regularly assess symptoms using validated tools like the Abnormal Involuntary Movement Scale (AIMS) which can	No specialist requirements mentioned to initiate treatment. In addition, newer VMAT2-inhibitors

		"The Committee recommended revising the proposed clinical PA criteria to remove the requirement of a specialist for initial approval" ³	be performed by any clinician with appropriate training" No specialist requirements mentioned.	are generally safe and well tolerated: "Studies of deutetrabenazine and valbenazine are consistent in showing negligible side effects as compared with placebo."
Exclusionary Criteria	For renewal: It has been determined that the mental status of the patient is stable and there is no indication of uncontrolled depression or risk of violent or suicidal behavior	Depression/suicidali ty contraindication question set applies to Huntington's disease indication only, and not for Tardive Dyskinesia	"Evidence does not suggest that the risk for depression and suicidality, possibly associated with VMAT-2 inhibitors in people with Huntington's disease, is observed in people with tardive dyskinesia."	"In studies of deutetrabenazine and valbenazine in patients with TD, there were no apparent increases in depression or suicidal ideas either in the randomized portions of the clinical trials or in longer open-label extension periods."
AIMS Score	Documented baseline AIMS score	Requires AIMS score	"Regularly assess symptoms using validated tools like the AIMS, which can be performed by any clinician with appropriate training."	"When using scales such as the AIMS or the DISCUS, it should be noted that there is no specific score threshold that suggests a need for intervention."
Other Plan Criteria	Member does not have "clinical features that were excluded from the drug study"	Not addressed	Not addressed	Not addressed

 Vesicular Monoamine Transporter 2 Inhibitors. AllCare CCO Prior Authorization Criteria Summary. March 2019. Accessed October 1, 2024. Available at: <u>https://www.allcarehealth.com/media/zgvohjst/umccomed0431-vmat2-inhibitors-web.pdf</u>.

2. Vesicular Monoamine Transporter 2 (VMAT2) Inhibitors. Oregon Health Authority. November 1, 2023. Accessed October 20, 2024. Available at: https://www.orpdl.org/durm/PA_Docs/vesicularmonoaminetransporter2.pdf.

 Oregon Health Authority Director's Decision on Pharmacy and Therapeutics (P&T) Committee Recommendations Dated October 5, 2023. Oregon Health Authority. October 19, 2023. Accessed October 20, 2024. Available at: <u>https://www.oregon.gov/oha/HPA/DSI-Pharmacy/PT%20Meeting%20Materials/23</u> 1019 October%202023%20PT%20Recommendations 101923 final.pdf.

4. Recognition and Management of Antipsychotic-induced Movement Disorders. Oregon Health Authority. Accessed October 20, 2024. Available at: https://www.oregon.gov/oha/HPA/DSI-Pharmacy/MHCAGDocs/Recognition-and-Management-of-Antipsychotic-induced-Movement-Disorders_4-04-24.pdf

- The American Psychiatric Association Practice Guideline for the Treatment of Patients with Schizophrenia. 3rd ed. Washington, DC: APA; 2021. Accessed June 2022. Available at: <u>https://psychiatryonline.org/doi/book/10.1176/appi.books.9780890424841</u>.
- 6. Austedo and Austedo XR [Prescribing Information]. Parsippany, NJ: Teva Neurosciences, Inc. July 2024.

Ingrezza [Prescribing Information]. San Diego, CA: Neurocrine Biosciences, Inc. August 2024.

EASTERN OREGON CCO (EOCCO)

Criteria Type	EOCCO ¹ (Last updated July 2024)	OHA PA Criteria for VMAT2-inhibitors ^{2,3}	Oregon Mental Health Clinical Advisory Group ⁴	American Psychiatric Association Guidelines ⁵
Prescriber Specialty	Medication is prescribed by, or in consultation with, a neurologist or psychiatrist	Prescriber specialty criterion was removed per OHA Oct 2023 P&T meeting ³ "The Committee recommended revising the proposed clinical PA criteria to remove the requirement of a specialist for initial approval" ³	"Regularly assess symptoms using validated tools like the Abnormal Involuntary Movement Scale (AIMS) which can be performed by any clinician with appropriate training" No specialist requirements mentioned.	No specialist requirements mentioned. In addition, newer VMAT2-inhibitors are generally well tolerated: "Studies of deutetrabenazine and valbenazine are consistent in showing negligible side effects as compared with placebo."
Change in Anti- Dopaminergic Therapy	Member has failed to respond to a change, or is unable to switch current antidopaminergic therapy	Consideration of change in antipsychotic therapy not required within criteria.	"Evidence for reducing symptoms of tardive dyskinesia by lowering the antipsychotic dose or switching to another antipsychotic is insufficient ." TD "symptoms may be irreversible despite reducing the dose or discontinuing the antipsychotic medication."	"Dyskinetic movements may begin or increase in the context of an antipsychotic dose reduction. A lower dose of antipsychotic medication can be considered, although evidence for this approach is minimal , and the potential for benefit must be weighed against the possibility of recurrent symptoms or relapse."
Exclusionary Criteria	Member does not have uncontrolled symptoms of depression, agitation, psychosis, or increased risk of suicidality, OR that the potential benefit of treatment with VMAT2 outweighs	Depression/suicidality contraindication question set applies to Huntington's disease indication only, and not for Tardive Dyskinesia	"Evidence does not suggest that the risk for depression and suicidality, possibly associated with VMAT-2 inhibitors in people with Huntington's disease, is	"In studies of deutetrabenazine and valbenazine in patients with TD, there were no apparent increases in depression or suicidal ideas either in the randomized portions of the clinical trials or in

the risk of	observed in	longer open-label
depression or	people with	extension
suicidality	tardive	periods."
	dyskinesia."	

- Pharmacy Coverage Policy EOCCO157. Eastern Oregon Coordinated Care Organization. Updated July 2024. Accessed September 10, 2024. Available at: <u>https://www.eocco.com/-/media/EOCCO/PDFs/Formulary/tetrabenazine-Xenazine-deutetrabenazine-Austedo-valbenazine-Ingrezza.pdf</u>.
- 2. Vesicular Monoamine Transporter 2 (VMAT2) Inhibitors. Oregon Health Authority. November 1, 2023. Accessed October 20, 2024. Available at: https://www.orpdl.org/durm/PA_Docs/vesicularmonoaminetransporter2.pdf.
- Oregon Health Authority Director's Decision on Pharmacy and Therapeutics (P&T) Committee Recommendations Dated October 5, 2023. Oregon Health Authority. October 19, 2023. Accessed October 20, 2024. Available at: <u>https://www.oregon.gov/oha/HPA/DSI-Pharmacy/PT%20Meeting%20Materials/23_1019_October%20203%20PT%20Recommendations_101923_final.pdf</u>.
- Recognition and Management of Antipsychotic-induced Movement Disorders. Oregon Health Authority. Accessed October 20, 2024. Available at: <u>https://www.oregon.gov/oha/HPA/DSI-Pharmacy/MHCAGDocs/Recognition-and-Management-of-Antipsychotic-induced-Movement-Disorders_4-04-24.pdf</u>
- 5. The American Psychiatric Association Practice Guideline for the Treatment of Patients with Schizophrenia. 3rd ed. Washington, DC: APA; 2021. Accessed June 2022. Available at: https://psychiatryonline.org/doi/book/10.1176/appi.books.9780890424841.
- 6. Austedo and Austedo XR [Prescribing Information]. Parsippany, NJ: Teva Neurosciences, Inc. July 2024.

Ingrezza [Prescribing Information]. San Diego, CA: Neurocrine Biosciences, Inc. August 2024.

INTERCOMMUNITY HEALTH NETWORK CCO (Samaritan Health

Services)

Criteria Type	Intercommunity Health Network ¹	OHA PA Criteria for VMAT2- inhibitors ^{2,3}	Oregon Mental Health Clinical Advisory Group ⁴	American Psychiatric Association
	(Last updated July 2023)			Guidelines⁵
Trial and Failure Requirements	Trial and failure to clonazepam and amantadine	Does not require trial and failure of off-label drugs for Tardive Dyskinesia	"Amantadine and benzodiazepines are not helpful , and use should be avoided for treatment of TD"	"Data [] are insufficient to support use of amantadine for treatment of TD. Other studies of treatments for TD have been discussed in systematic reviews, as summarized in Table C–2. On the basis of these findings, there is insufficient evidence to support a guideline statement on use of these treatments in individuals with TD." (Note: Table C-2 in the guidelines includes anticholinergics,
				benzodiazepines, and changing of antipsychotic to clozapine)
Prescriber Specialty	Neurologist or Psychiatrist	Prescriber specialty criterion was removed per OHA Oct 2023 P&T meeting ³ "The Committee recommended revising the proposed clinical PA criteria to remove the requirement of a specialist for initial approval" ³	"Regularly assess symptoms using validated tools like the Abnormal Involuntary Movement Scale (AIMS) which can be performed by any clinician with appropriate training" No specialist requirements mentioned.	No specialist requirements mentioned. In addition, newer VMAT2-inhibitors are generally well tolerated: "Studies of deutetrabenazine and valbenazine are consistent in showing negligible side effects as compared with placebo."

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TD Diagnosis	Clinical documentation of TD required, including all of the following: At least 1 month of past or current exposure to a dopamine receptor blocker Dyskinetic or dystonic involuntary movements Exclusion of other causes of abnormal movements AND Clear documentation that TD causes functional impairment	Requires diagnosis of moderate to severe TD. No specific underlying behavioral health diagnoses required.	"A VMAT2-inhibitor valbenazine or deutetrabenazine is suggested in individuals with moderate, severe, or disabling TD" "Symptoms may be irreversible despite reducing the dose or discontinuing the antipsychotic medication."	"Patients who have moderate to severe or disabling tardive dyskinesia associated with antipsychotic therapy should be treated with a VMAT2." "Treatment with a VMAT2 inhibitor can also be considered for patients with mild TD on the basis of such factors as patient preference, associated impairment, or effect on psychosocial functioning"
Change in Anti- Dopaminergic Therapy	 Requires documentation of one of the following: Discontinuation of medication precipitating TD Trial and failure of an 8-week trial of at least 2 other agents within the same therapeutic category at a clinically effective and maximally tolerated dose Evidence the medications precipitating TD are medically necessary 	Consideration of change in antipsychotic therapy not required within criteria.	"Evidence for reducing symptoms of tardive dyskinesia by lowering the antipsychotic dose or switching to another antipsychotic is insufficient ." TD "symptoms may be irreversible despite reducing the dose or discontinuing the antipsychotic medication."	"Dyskinetic movements may begin or increase in the context of an antipsychotic dose reduction. A lower dose of antipsychotic medication can be considered, although evidence for this approach is minimal , and the potential for benefit must be weighed against the possibility of recurrent symptoms or relapse."
AIMS Score	Documentation of AIMS scale as baseline	Requires AIMS score	"Regularly assess symptoms using validated tools like the AIMS, which can be performed by any clinician with appropriate training."	"When using scales such as the AIMS or the DISCUS, it should be noted that there is no specific score threshold that suggests a need for intervention."
Renewal Criteria	Requires BOTH of the following:	"Documented evidence of	"Discontinue if no clinically	No threshold for AIMS score

 Follow-up AIMS assessment showing improvement from baseline Documented improvement in functioning such as ability to perform ADLs, reduction in falls, and increase in quality of life 	clinical improvement by a reduction in AIMS dyskinesia score from baseline"	meaningful improvement is documented (for example, at least a 2-point reduction)"	improvement mentioned
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 Prior Authorization Criteria. InterCommunity Health Network. July 1, 2023. Accessed October 20, 2024. Available at: <u>https://fm.formularynavigator.com/FormularyNavigator/DocumentManager/Download?clientDocumentId=FDiFSTfCTEGaMAdmanWGKA</u>.

- 2. Vesicular Monoamine Transporter 2 (VMAT2) Inhibitors. Oregon Health Authority. November 1, 2023. Accessed October 20, 2024. Available at: https://www.orpdl.org/durm/PA_Docs/vesicularmonoaminetransporter2.pdf.
- Oregon Health Authority Director's Decision on Pharmacy and Therapeutics (P&T) Committee Recommendations Dated October 5, 2023. Oregon Health Authority. October 19, 2023. Accessed October 20, 2024. Available at: <u>https://www.oregon.gov/oha/HPA/DSI-Pharmacy/PT%20Meeting%20Materials/23</u> 1019 October%202023%20PT%20Recommendations 101923 final.pdf.
- Recognition and Management of Antipsychotic-induced Movement Disorders. Oregon Health Authority. Accessed October 20, 2024. Available at: <u>https://www.oregon.gov/oha/HPA/DSI-Pharmacy/MHCAGDocs/Recognition-and-Management-of-Antipsychotic-induced-Movement-</u> Disorders 4-04-24.pdf

The American Psychiatric Association Practice Guideline for the Treatment of Patients with Schizophrenia. 3rd ed. Washington, DC: APA; 2021. Accessed June 2022. Available at: https://psychiatryonline.org/doi/book/10.1176/appi.books.9780890424841.

PACIFICSOURCE COMMUNITY SOLUTIONS

Criteria Type	PacificSource ¹	OHA PA Criteria	Oregon Mental Health Clinical	American
	(Last updated October 2024)	for VMAT2- inhibitors ^{2,3}	Advisory Group ⁴	Psychiatric Association Guidelines ⁵
Prescriber Specialty	Prescribed by, or in consultation with, a neurologist or psychiatrist	Prescriber specialty criterion was removed per OHA Oct 2023 P&T meeting ³ "The Committee recommended revising the proposed clinical PA criteria to remove the requirement of a specialist for initial approval" ³	"Regularly assess symptoms using validated tools like the Abnormal Involuntary Movement Scale (AIMS) which can be performed by any clinician with appropriate training" No specialist requirements mentioned.	No specialist requirements mentioned. In addition, newer VMAT2-inhibitors are generally well tolerated: "Studies of deutetrabenazine and valbenazine are consistent in showing negligible side effects as compared with placebo."
TD Diagnosis	 Diagnosis of moderate to severe TD including ALL of the following: A history of at least one month of ongoing or previous dopamine receptor- blocking agent exposure Presence of dyskinetic or dystonic involuntary movements that developed either while exposed to a dopamine receptor- blocking agent, or within 4 weeks of discontinuation from an oral agent (8 weeks from a depot formulation) Other causes of abnormal movements have been excluded 	Requires diagnosis of moderate to severe TD.	"A VMAT2- inhibitor valbenazine or deutetrabenazine is suggested in individuals with moderate, severe, or disabling TD" "Symptoms may be irreversible despite reducing the dose or discontinuing the antipsychotic medication."	"Patients who have moderate to severe or disabling tardive dyskinesia associated with antipsychotic therapy should be treated with a VMAT2." "Treatment with a VMAT2 inhibitor can also be considered for patients with mild TD on the basis of such factors as patient preference, associated impairment, or effect on psychosocial functioning"
Change in Anti- Dopaminergic Therapy	Requires one of the following: • Persistent dyskinesia despite dose reduction	Consideration of change in antipsychotic therapy not	"Evidence for reducing symptoms of tardive dyskinesia by lowering the	"Dyskinetic movements may begin or increase in the context of an antipsychotic

	or discontinuation of the offending agent • Documented clinical inability to reduce dose or discontinue the offending agent	required within criteria.	antipsychotic dose or switching to another antipsychotic is insufficient ." TD "symptoms may be irreversible despite reducing the dose or discontinuing the antipsychotic medication."	dose reduction. A lower dose of antipsychotic medication can be considered, although evidence for this approach is minimal, and the potential for benefit must be weighed against the possibility of recurrent symptoms or relapse."
AIMS Score	 Baseline evaluation of the condition using one of the following: Abnormal Involuntary Movement Scale (AIMS) Extrapyramidal Symptom Rating Scale (ESRS) 	Requires AIMS score	"Regularly assess symptoms using validated tools like the AIMS, which can be performed by any clinician with appropriate training."	"When using scales such as the AIMS or the DISCUS, it should be noted that there is no specific score threshold that suggests a need for intervention."
Renewal Criteria	Must include improvement in AIMS or ESRS score from baseline	"Documented evidence of clinical improvement by a reduction in AIMS dyskinesia score from baseline"	"Discontinue if no clinically meaningful improvement is documented (for example, at least a 2-point reduction)"	No threshold for AIMS score improvement mentioned

1. 2024 Prior Authorization Criteria. PacificSource. October 15, 2024. Accessed October 20, 2024. Available at: https://pacificsource.com/sites/default/files/2024-06/2023-Medicaid-Preapproval-Criteria-05152023.pdf.

- 2. Vesicular Monoamine Transporter 2 (VMAT2) Inhibitors. Oregon Health Authority. November 1, 2023. Accessed October 20, 2024. Available at: https://www.orpdl.org/durm/PA_Docs/vesicularmonoaminetransporter2.pdf.
- Oregon Health Authority Director's Decision on Pharmacy and Therapeutics (P&T) Committee Recommendations Dated October 5, 2023. Oregon Health Authority. October 19, 2023. Accessed October 20, 2024. Available at: <u>https://www.oregon.gov/oha/HPA/DSI-Pharmacy/PT%20Meeting%20Materials/23_1019_October%20203%20PT%20Recommendations_101923_final.pdf</u>.
- Recognition and Management of Antipsychotic-induced Movement Disorders. Oregon Health Authority. Accessed October 20, 2024. Available at: <u>https://www.oregon.gov/oha/HPA/DSI-Pharmacy/MHCAGDocs/Recognition-and-Management-of-Antipsychotic-induced-Movement-Disorders</u> 4-04-24.pdf

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PROVIDENCE HEALTH PLAN (also applies to YAMHILL CCO)

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Criteria Type	Providence and Yamhill ^{1,2} (Last updated October 2024)	OHA PA Criteria for VMAT2-inhibitors ^{3,4}	Oregon Mental Health Clinical Advisory Group⁵	American Psychiatric Association Guidelines ⁶
Trial and Failure Requirements	For deutetrabenazine and valbenazine, trial (of at least eight weeks) and failure of, or intolerance to, tetrabenazine	Does not require use of tetrabenazine before valbenazine or deutetrabenazine	"A VMAT2-inhibitor valbenazine or deutetrabenazine is suggested in individuals with moderate, severe, or disabling TD" Tetrabenazine is not listed in guidance	"In general, deutetrabenazine and valbenazine are preferred over tetrabenazine because of the greater evidence base supporting their use" "In initial studies of tetrabenazine for Huntington's disease, significant rates of depression and concerns about suicidal ideations were noted. However, in studies of deutetrabenazine and valbenazine in patients with TD, there were no apparent increases in depression or suicidal ideas"
Prescriber Specialty	Must be prescribed by, or in consultation with, a neurologist or psychiatrist	Prescriber specialty criterion was removed per OHA Oct 2023 P&T meeting ⁴ "The Committee recommended revising the proposed clinical PA criteria to remove the requirement of a specialist for initial approval" ⁴	"Regularly assess symptoms using validated tools like the Abnormal Involuntary Movement Scale (AIMS) which can be performed by any clinician with appropriate training" No specialist requirements mentioned.	No specialist requirements mentioned. In addition, newer VMAT2-inhibitors are generally well tolerated: "Studies of deutetrabenazine and valbenazine are consistent in showing negligible side effects as compared with placebo."
TD Diagnosis and Severity	Requires BOTH of the following: Diagnosis of TD secondary to therapy with a	Requires diagnosis of moderate to severe TD.	"A VMAT2-inhibitor valbenazine or deutetrabenazine is suggested in	"When using scales such as the AIMS or the DISCUS, it should be noted

dopamine-	No minimum AIMS	individuals with	that there is no
receptor	threshold required for	moderate, severe,	specific score
blocking agent	treatment.	or disabling TD"	threshold that
 Documentation of moderation to severe TD that is 		No minimum AIMS threshold required for treatment.	suggests a need for intervention." "Patients who have
causing		for treatment.	moderate to severe
functional			or disabling tardive
impairment,			dyskinesia
defined as AIMS			associated with
score of 3 or 4			antipsychotic
on any one of			therapy should be
items 1-9, OR TD that is			treated with a
interfering with			VMAT2."
activities of daily			"Treatment with a
living			VMAT2 inhibitor
			can also be
			considered for
			patients with mild
			TD on the basis of
			such factors as
			patient preference,
			associated
			impairment, or
			effect on
			psychosocial
			functioning"

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TRILLIUM COMMUNITY HEALTH PLAN

Criteria Type	Trillium ¹	OHA PA Criteria for VMAT2-inhibitors ^{2,3}	Oregon Mental Health Clinical	American
	(Last updated May 2024)	VIVIAI 2-INITIDITOIS"	Advisory Group ⁴	Psychiatric Association Guidelines ⁵
Prescriber Specialty	Prescribed by, or in consultation with, a psychiatrist or neurologist	Prescriber specialty restriction was removed per OHA Oct 2023 P&T meeting ³ "The Committee recommended revising the proposed clinical PA criteria to remove the requirement of a specialist for initial approval" ³	"Regularly assess symptoms using validated tools like the Abnormal Involuntary Movement Scale (AIMS) which can be performed by any clinician with appropriate training" No specialist requirements mentioned.	No specialist requirements mentioned to initiate treatment. In addition, newer VMAT2-inhibitors are generally safe and well tolerated: "Studies of deutetrabenazine and valbenazine are consistent in showing negligible side effects as compared with placebo."
AIMS Score	Evidence of moderate to severe TD supported by AIMS score of 3 or 4 on any one of items 1-9	No minimum AIMS score threshold is required to initiate therapy.	"Regularly assess symptoms using validated tools like the AIMS, which can be performed by any clinician with appropriate training."	"When using scales such as the AIMS or the DISCUS, it should be noted that there is no specific score threshold that suggests a need for intervention. In addition, the same total score can be associated with significantly different clinical manifestations and varying impacts on the patient" "Treatment with a VMAT2 inhibitor can also be considered for patients with mild TD on the basis of such factors as patient preference, associated

				effect on psychosocial functioning"
Trial and Failure Requirements	For deutetrabenazine or valbenazine, member has failed treatment with tetrabenazine at up to 200 mg per day (unless contraindicated or clinically significant AEs are experienced)	Does not require use of tetrabenazine before valbenazine or deutetrabenazine	"A VMAT2- inhibitor valbenazine or deutetrabenazine is suggested in individuals with moderate, severe, or disabling TD" Tetrabenazine is not listed in guidance	functioning" "In general, deutetrabenazine and valbenazine are preferred over tetrabenazine because of the greater evidence base supporting their use" In initial studies of tetrabenazine for Huntington's disease, significant rates of depression and concerns about suicidal ideations were noted. However, in studies of deutetrabenazine and valbenazine in patients with TD, there were no apparent increases in depression or suicidal ideas"
Renewal Criteria	Evidence of improvement by a reduction in AIMS dyskinesia score (items 1-7) by at least 50%	"Documented evidence of clinical improvement by a reduction in AIMS dyskinesia score from baseline" Previously, OHA PA criteria required ≥50% AIMS reduction from baseline for renewal but Committee decided to remove the 50% improvement requirement, as is not evidence-based, and may lead to increased difficulty for more severe patients starting with higher baseline to continue treatment (from Oct 5, 2023 P&T Committee meeting) ³	"Discontinue if no clinically meaningful improvement is documented (e.g. at least a 2-point reduction)"	No threshold for AIMS score improvement mentioned
	Mental status of the patient is	Depression/suicidality contraindication	"Evidence does not suggest that	"In studies of deutetrabenazine

stable and there is	question set applies to	the risk for	and valbenazine
no risk of	Huntington's disease	depression and	in patients with
uncontrolled	indication only, and not	suicidality,	TD, there were no
depression or risk	for Tardive Dyskinesia	possibly	apparent
of violent or		associated with	increases in
suicidal behavior		VMAT-2 inhibitors	depression or
		in people with	suicidal ideas
		Huntington's	either in the
		disease, is	randomized
		observed in	portions of the
		people with	clinical trials or in
		tardive	longer open-label
		dyskinesia."	extension
			periods."

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UMPQUA HEALTH

Criteria Type	Umpqua ¹ (Last updated Feb	OHA PA Criteria for VMAT2- inhibitors ^{2,3}	Oregon Mental Health Clinical Advisory Group ⁴	American Psychiatric Association
AIMS Score	2024) Documented baseline "Abnormal Voluntary Movement Scale (AIMS)" score of 10 or greater on a scale of 0-20	No minimum AIMS score threshold required to initiate treatment	"Regularly assess symptoms using validated tools like the AIMS, which can be performed by any clinician with appropriate training."	Guidelines ⁵ "When using scales such as the AIMS or the DISCUS, it should be noted that there is no specific score threshold that suggests a need for intervention. "In addition, the same total score can be associated with significantly different clinical manifestations and varying impacts on the patient." "Treatment with a VMAT2-inhibitor can also be considered for patients with mild TD on the basis of such factors as patient preference, associated impairment, or effect on psychosocial
Renewal Criteria	Documented evidence of improvement in AIMS score by at least 50% from baseline	"Documented evidence of clinical improvement by a reduction in AIMS dyskinesia score from baseline" Previously, OHA PA criteria required ≥50% AIMS reduction from baseline for renewal but Committee decided to remove the 50%	"Discontinue if no clinically meaningful improvement is documented (e.g. at least a 2-point reduction)"	functioning." No threshold for AIMS score improvement mentioned

		improvement		
		requirement , as		
		is not evidence-		
		based, and may		
		lead to increased		
		difficulty for		
		more severe		
		patients starting		
		with higher		
		baseline to		
		continue		
		treatment (from		
		Oct 5, 2023 P&T		
		Committee		
		meeting) ³		
Prescriber	Prescribed by, or in	Prescriber	"Regularly assess	No specialist
Specialty	consultation with, a	specialty	symptoms using	requirements
	neurologist or	restriction was	validated tools like	mentioned to
	psychiatrist	removed per	the Abnormal	initiate treatment.
		OHA Oct 2023	Involuntary	
		P&T meeting ³	Movement Scale	In addition, newer
			(AIMS) which can	VMAT2-inhibitors
		"The Committee	be performed by	are generally safe
		recommended	any clinician with	and well tolerated:
		revising the	appropriate	"Studies of
		proposed clinical	training"	deutetrabenazine
		PA criteria to		and valbenazine are
		remove the	No specialist	consistent in
		requirement of a	requirements	showing negligible
		specialist for	mentioned.	side effects as
		initial approval" ³		compared with
				placebo."
Discontinuation of	Requires persistent	Consideration of	"Evidence for	"Dyskinetic
the Anti-	dyskinesia despite	change in	reducing symptoms	movements may
Dopaminergic	cessation of	antipsychotic	of tardive	begin or increase in
Therapy	offending agent, or	therapy not	dyskinesia by	the context of an
	documented	required within	lowering the	antipsychotic dose
	inability to	criteria.	antipsychotic dose	reduction. A lower
	discontinue		or switching to	dose of
	offending agent		another	antipsychotic
			antipsychotic is	medication can be
			insufficient."	considered,
				although evidence
				for this approach is
				minimal, and the
				potential for
				benefit must be
				weighed against
				the possibility of
				recurrent
				symptoms or
				relapse."
Other Plan Criteria	and the second sec	Not in required	Not addressed in	Not addressed in
	Patient does not			
	have localized form	criteria	Tardive Dyskinesia	Tardive Dyskinesia

failed or has a			
contraindication to			
botulinum toxin			
injections			
Provider has	Not in required	Not a	Not a
performed a urine	criteria	recommendation	recommendation
drug screen to rule			
out non-prescribed			
drug causes of TD			
(appropriate results			
would include the			
absence of THC,			
cocaine,			
benzodiazepines,			
opiates, or other			
non-prescribed			
substances)	Not in required	Nota	Neta
Patient recently been evaluated and	Not in required	Not a	Not a recommendation
	criteria	recommendation	
determined not to			
be at risk for a			
prolonged QT			
interval			
Request is for the	Not in required	Not addressed	Not addressed
least costly VMAT2	criteria		
inhibitor approved	criteria		
	criteria		
inhibitor approved	criteria		
inhibitor approved	criteria		
inhibitor approved for the indication	criteria		
inhibitor approved for the indication	criteria		
inhibitor approved for the indication OR	criteria		
inhibitor approved for the indication OR Member has had an	criteria		
inhibitor approved for the indication OR Member has had an adequate trial and	criteria		
inhibitor approved for the indication OR Member has had an adequate trial and failure of,	criteria		
inhibitor approved for the indication OR Member has had an adequate trial and failure of, contraindication to, or intolerance to	criteria		
inhibitor approved for the indication OR Member has had an adequate trial and failure of, contraindication to, or intolerance to the less costly	criteria		
inhibitor approved for the indication OR Member has had an adequate trial and failure of, contraindication to, or intolerance to the less costly alternative agent	criteria		
inhibitor approved for the indication OR Member has had an adequate trial and failure of, contraindication to, or intolerance to the less costly alternative agent (adequate trial is	criteria		
inhibitor approved for the indication OR Member has had an adequate trial and failure of, contraindication to, or intolerance to the less costly alternative agent (adequate trial is defined as adherent	criteria		
inhibitor approved for the indication OR Member has had an adequate trial and failure of, contraindication to, or intolerance to the less costly alternative agent (adequate trial is defined as adherent to therapy for at	criteria		
inhibitor approved for the indication OR Member has had an adequate trial and failure of, contraindication to, or intolerance to the less costly alternative agent (adequate trial is defined as adherent to therapy for at least 3 consecutive	criteria		
inhibitor approved for the indication OR Member has had an adequate trial and failure of, contraindication to, or intolerance to the less costly alternative agent (adequate trial is defined as adherent to therapy for at least 3 consecutive months, MPR	criteria		
inhibitor approved for the indication OR Member has had an adequate trial and failure of, contraindication to, or intolerance to the less costly alternative agent (adequate trial is defined as adherent to therapy for at least 3 consecutive months, MPR greater than or	criteria		
inhibitor approved for the indication OR Member has had an adequate trial and failure of, contraindication to, or intolerance to the less costly alternative agent (adequate trial is defined as adherent to therapy for at least 3 consecutive months, MPR greater than or equal to 80% or no	criteria		
inhibitor approved for the indication OR Member has had an adequate trial and failure of, contraindication to, or intolerance to the less costly alternative agent (adequate trial is defined as adherent to therapy for at least 3 consecutive months, MPR greater than or	criteria		

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Additional CCOs

Plan Name	Notes
Advanced Health CCO	No VMAT2-specific PA criteria found within posted list
	(last updated March 25, 2024)
	Per Advanced Health website, "OHA Fee For Service Drug
	Use Criteria will be used for coverage determinations for
	which Advanced Health criteria is not available"
Cascade Health Alliance CCO	Unable to find criteria online