

## Clinical Policy: VMAT2 Inhibitors

Reference Number: PHW.PDL.703

Effective Date: 01/01/2020

Last Review Date: 11/2024

### 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 PA Health & Wellness® that VMAT2 Inhibitors is **medically necessary** when the following criteria are met:

### I. Requirements for Prior Authorization of VMAT2 Inhibitors

#### A. Prescriptions That Require Prior Authorization

All prescriptions for VMAT2 Inhibitors must be prior authorized.

#### B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a VMAT2 Inhibitor, the determination of whether the requested prescription is medically necessary will take into account whether the member:

1. Is prescribed the VMAT2 Inhibitor for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**
2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
4. Is being prescribed the VMAT2 Inhibitor by or in consultation with a neurologist or a psychiatrist; **AND**
5. Does not have a contraindication to the prescribed medication; **AND**
6. **One** of the following:
  - a. For a member with a history of a prior suicide attempt, bipolar disorder, or major depressive disorder, was evaluated within the previous 6 months and treated by a psychiatrist
  - b. For all others, had a mental health evaluation performed;

**AND**

7. If being treated for a diagnosis of tardive dyskinesia, **all** of the following:
  - a. Was assessed for and determined to have no other causes of involuntary movement,
  - b. Was evaluated for appropriateness of dose decrease of dopamine receptor blocking agents,
  - c. Has documentation of tardive dyskinesia severity using a validated scale or assessment of impact on daily function;

**AND**

8. For a non-preferred VMAT2 Inhibitor, has a documented therapeutic failure or intolerance to the preferred VMAT2 Inhibitors approved or medically accepted for the member's diagnosis. See the Preferred Drug List (PDL) for the list of preferred VMAT2 Inhibitors at: <https://papdl.com/preferred-drug-list>; **AND**
9. If a prescription for a VMAT2 inhibitor is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override.

NOTE: If the member does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the member, the request for prior authorization will be approved.

**FOR RENEWALS OF PRIOR AUTHORIZATION FOR VMAT2 Inhibitors:** The determination of medical necessity of a request for renewal of a prior authorization for a VMAT2 Inhibitor that was previously approved will take into account whether the member:

1. **One** of the following:
  - a. For a diagnosis of chorea, experienced a clinical benefit from the prescribed VMAT2 inhibitor based on the prescriber's clinical judgment
  - b. For a diagnosis of tardive dyskinesia, experienced an improvement in tardive dyskinesia severity documented by a validated scale or improvement in daily function;

**AND**

2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. Is being prescribed the VMAT2 Inhibitor by or in consultation with a neurologist or a psychiatrist; **AND**
4. Does not have a contraindication to the prescribed medication; **AND**
5. Was re-evaluated and treated for new onset or worsening symptoms of depression and determined to continue to be a candidate for treatment with the prescribed VMAT2 Inhibitor; **AND**
6. If a prescription for a VMAT2 Inhibitor is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override.

NOTE: If the member does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the member, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a VMAT2 Inhibitor. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the member.

D. Approval Duration:

|                                   |   |
|-----------------------------------|---|
| <b>Deutetrabenazine (Austedo)</b> | <b>New request:</b> 6 months<br><b>Renewal request:</b> 12 months |
| <b>Tetrabenazine (Xenazine)</b>   | <b>New request:</b> 6 months<br><b>Renewal request:</b> 12 months |
| <b>Valbenazine (Ingrezza)</b>     | <b>New request:</b> 6 months<br><b>Renewal request:</b> 6 months  |

E. References

1. Austedo prescribing information. Teva Pharmaceuticals. June 2021.
2. Ingrezza prescribing information. Neurocrine Biosciences, Inc. April 2021.

3. Xenazine prescribing information. Valeant Pharmaceuticals North America LLC. September 2017.
4. Cloud LJ, Zutshi D, Factor SA. Tardive dyskinesia: therapeutic options for an increasingly common disorder. *Neurotherapeutics*. 2014;11(1):166-176.
5. Bashir HH, Jankovic J. Treatment of Tardive Dyskinesia. *Neurologic Clinics*. 2020 May;38(2):379-396.
6. Tardive dyskinesia: Clinical features and diagnosis. Up To Date, accessed July 12, 2021.
7. Tardive dyskinesia: Etiology and epidemiology. Up To Date, accessed July 12, 2021.
8. Tardive dyskinesia: Prevention, treatment, and prognosis. Up To Date, accessed July 12, 2021.
9. Armstrong MJ, Miyasaki JM. Evidence-based guideline: Pharmacologic treatment of chorea in Huntington disease – Report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology* 2012;79:597–603. Reaffirmed July 18, 2015.
10. Nance M, Paulsen JS, Rosenblatt A, Wheelock V. A physician's guide to the management of Huntington's disease, 3rd Ed, Huntington's Disease Society of America, 2011.
11. Suchowersky O. Huntington disease: Management. UpToDate. Accessed August 25, 2017.

| Reviews, Revisions, and Approvals                                | Date       |
|--|------------|
| Policy created   | 01/01/2020 |
| Q3 2020 annual review: no changes.                               | 07/2020    |
| Q1 2021 annual review: no changes.                               | 01/2021    |
| Q1 2022: revised according to DHS revisions effective 01/03/2022 | 10/2021    |
| Q1 2023 annual review: no changes.                               | 11/2022    |
| Q1 2024 annual review: no changes.                               | 11/2023    |
| Q1 2025 annual review: no changes.                               | 11/2024    |