Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: N/A**
Policy Number: PHW.PDL.703	**Effective Date: 01/01/2020** **Revision Date: 07/2020**
Policy Name: VMAT2 Inhibitors	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ☐ **Revised Policy***
- ✓ **Annual Review - No Revisions**
- ✓ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

Q3 2020 annual review: no changes.

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:**

Clinical Policy: VMAT2 Inhibitors

Reference Number: PHW.PDL.703
Effective Date: 01/01/2020
Last Review Date: 07/2020

Revision Log

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 health plans affiliated with PA Health and 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 beneficiary:

1. Is being prescribed a VMAT2 Inhibitor by, or in consultation with, a neurologist or a psychiatrist

AND

2. Is age-appropriate according to FDA-approved package labeling, compendia, or peer-reviewed medical literature

AND

3. Has documentation of a diagnosis that is:

   a. Indicated in the FDA-approved package labeling, **OR**

   b. Listed in nationally recognized compendia for the determination of medically-accepted indications for off-label uses for the prescribed VMAT2 Inhibitor

AND

4. Does not have a contraindication to the prescribed VMAT2 Inhibitor

AND

5. Was evaluated within the previous 6 months and treated by a psychiatrist if the beneficiary has a history of a prior suicide attempt, bipolar disorder, or major depressive disorder

OR

6. For all others, had a mental health evaluation performed

AND

7. If being treated for a diagnosis of tardive dyskinesia:

   a. Was assessed for and determined to have no other causes of involuntary movement

   AND

   b. Was evaluated for appropriateness of dose decrease of dopamine receptor blocking agents or use of alternative therapies for tardive dyskinesia

   AND

   c. Has documentation of tardive dyskinesia severity using a validated scale or assessment of impact on daily function

AND

8. Is being prescribed a dose consistent with FDA-approved package labeling for known CYP2D6 metabolizer status, medical conditions and concomitant medications

AND

9. For a request for Ingrezza (valbenazine), is not taking a strong CYP3A4 inducer(s)

AND

10. For a request for a non-preferred VMAT2 Inhibitor, whether the beneficiary has documented therapeutic failure or intolerance to the preferred VMAT2 Inhibitors.

11. In addition, if a prescription for a VMAT2 inhibitor is in 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: As described in Section C, if the beneficiary does not meet the clinical review guidelines and/or the quantity limit guidelines listed above, but in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRESCRIPTIONS FOR VMAT2 Inhibitors: The determination of medical necessity of requests for prior authorization of renewals of prescriptions for VMAT2 Inhibitors that were previously approved will take into account whether the beneficiary:

1. For a diagnosis of chorea, experienced a clinical benefit from the prescribed VMAT2 inhibitor based on the prescriber's clinical judgment

   OR

2. For a diagnosis of tardive dyskinesia, experienced an improvement in tardive dyskinesia severity documented by a validated scale or improvement in daily function

   AND

3. Does not have a contraindication to the prescribed VMAT2 Inhibitor

   AND

4. 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

5. Is being prescribed a dose consistent with FDA-approved package labeling for known CYP2D6 metabolizer status, medical conditions and concomitant medications

   AND

6. For a request for Ingrezza (valbenazine), is not taking a strong CYP3A4 inducer(s).

7. In addition, if a prescription for a VMAT2 Inhibitor is in 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: As described in Section C, if the beneficiary does not meet the clinical review guidelines and/or the quantity limit guidelines listed above, but in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, 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 beneficiary.

D. **Approval Duration:**

Deutetrabenazine (Austedo)	**New request**: 6 months **Renewal request**: 12 months
Tetrabenazine (Xenazine)	**New request**: 6 months **Renewal request**: 12 months
Valbenazine (Ingrezza)	**New request:** 6 months **Renewal request**: 6 months

E. References

1. Austedo prescribing information. Teva Pharmaceuticals. April 2017.
2. Ingrezza prescribing information. Neurocrine Biosciences, Inc. April 2017.
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. Tardive dyskinesia: Clinical features and diagnosis. Up To Date, accessed August 28, 2017.
6. Tardive dyskinesia: Etiology and epidemiology. Up To Date, accessed August 28, 2017.
7. 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.
8. 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.
9. 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