pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
November 16, 2021	January 3, 2022	*See below

SUBJECT

Prior Authorization of VMAT2 Inhibitors – Pharmacy Services

BY

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Office of Medical Assistance Programs

IMPORTANT REMINDER: All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISe to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at: https://www.dhs.pa.gov/providers/Providers/Pages/PROMISe-Enrollment.aspx.

PURPOSE:

The purpose of this bulletin is to issue updated handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for VMAT2 Inhibitors submitted for prior authorization.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program. The guidelines to determine the medical necessity of VMAT2 Inhibitors will be utilized in the fee-for-service delivery system and by the MA managed care organizations (MCOs) in Physical Health HealthChoices and Community HealthChoices. Providers rendering services in the MA managed care delivery system should address any questions related to the prior authorization of VMAT2 Inhibitors to the appropriate MCO.

BACKGROUND:

*01-21-43	09-21-42	27-21-34	33-21-42
02-21-30	11-21-32	30-21-37	
03-21-30	14-21-33	31-21-45	
08-21-45	24-21-40	32-21-30	

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

The appropriate toll-free number for your provider type.

Visit the Office of Medical Assistance Programs website at https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx.

The Department of Human Services' (Department) Pharmacy and Therapeutics (P&T) Committee reviews published peer-reviewed medical literature and recommends the following:

- Preferred or non-preferred status for new drugs in therapeutic classes already included in the Preferred Drug List (PDL);
- Changes in the status of drugs on the PDL from preferred to non-preferred and non-preferred to preferred;
- New quantity limits;
- Classes of drugs to be added to or deleted from the PDL; and
- New guidelines or revisions to existing guidelines to evaluate the medical necessity of prescriptions submitted for prior authorization.

DISCUSSION:

During the September 15, 2021, meeting, the P&T Committee recommended the following revisions to the guidelines to determine medical necessity of VMAT2 Inhibitors:

- Removal of the language regarding use of alternative therapies for the treatment of tardive dyskinesia;
- Removal of the guideline that the beneficiary is prescribed a dose consistent with FDA-approved package labeling for known CYP2D6 metabolizer status, medical conditions, and concomitant medications;
- Addition of a guideline the beneficiary is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature;
- Removal of the guideline for Ingrezza (valbenazine) that the beneficiary is not taking a strong CYP3A4 inducer;
- Specification that requests for a non-preferred VMAT2 Inhibitor will take into account the beneficiary's diagnosis; and
- Addition of a guideline to the requests for renewal of prior authorization that the VMAT2 Inhibitor is prescribed by or in consultation with a neurologist or psychiatrist.

The revisions to the guidelines to determine medical necessity of prescriptions for VMAT2 Inhibitors submitted for prior authorization, as recommended by the P&T Committee, were subject to public review and comment and subsequently approved for implementation by the Department.

PROCEDURE:

The procedures for prescribers to request prior authorization of VMAT2 Inhibitors are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapter related to VMAT2 Inhibitors) when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs that require prior authorization.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

RESOURCES:

Prior Authorization of Pharmaceutical Services Handbook – SECTION I
Pharmacy Prior Authorization General Requirements
https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Pharmacy-Prior-Authorization-General-Requirements.aspx

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines
https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Clinical-Guidelines.aspx

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 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 beneficiary 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 beneficiary'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 the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

   NOTE: If the beneficiary 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 beneficiary, 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 beneficiary:

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 the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at:

https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

NOTE: If the beneficiary 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 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. 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.
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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.