pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
July 23, 2018	July 23, 2018	*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:
http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994

PURPOSE:

The purpose of this bulletin is to:

1. Inform providers of the addition of the VMAT2 Inhibitors class of drugs to the Preferred Drug List (PDL); and
2. Issue 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 and providing services in the fee-for-service delivery system. Providers rendering services under the MA managed care delivery system should address any questions related to VMAT2 Inhibitors to the appropriate managed care organization.

*01-18-17	09-18-18	27-18-16	33-18-17
02-18-12	11-18-12	30-18-12	
03-18-12	14-18-13	31-18-18	
08-18-19	24-18-13	32-18-12	

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 Web site at
http://www.dhs.pa.gov/provider/healthcaremedicalassistance/index.htm

BACKGROUND:

The Department of Human Services' (DHS) Pharmacy and Therapeutics (P&T) Committee meets semi-annually to review published peer-reviewed clinical literature and make recommendations relating to the following:

- New drugs in therapeutic classes already included in the 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 the PDL; and
- Guidelines to determine medical necessity.

DISCUSSION:

During the May 16, 2018, meeting, the P&T Committee recommended the addition of the VMAT2 Inhibitors class of drugs to the PDL. The drugs within this class, Austedo (deutetrabenazine), Ingrezza (valbenazine), and Xenazine (tetrabenazine) already require a clinical prior authorization for health and safety reasons based upon recommendations of the DHS Drug Utilization Review (DUR) Board. The handbook pages describing the requirements for prior authorization of VMAT2 Inhibitors, and the guidelines to determine medical necessity represent a merger of the current handbook pages for Austedo (deutetrabenazine), Ingrezza (valbenazine), and Xenazine (tetrabenazine). The requirements for prior authorization and the medical necessity guidelines were subject to public review and comment, and subsequently approved for implementation by DHS.

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. DHS 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

SECTION II
VMAT2 Inhibitors

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 the Quantity Limits Chapter.

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 the Quantity Limits Chapter.

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. 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.