New 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 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 Xenazine (tetrabenazine) for prior authorization.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance Program and providing services in the fee-for-service delivery system, including pharmacy services to residents of long-term care facilities.

BACKGROUND:

The DHS Drug Utilization Review (DUR) Board meets semi-annually to review provider prescribing and dispensing practices for efficacy, safety, and quality and to recommend interventions for prescribers and pharmacists through the Department of Human Services (DHS) Prospective Drug Use Review and Retrospective Drug Use Review programs.

*01-17-45  09-17-44  27-17-42
02-17-40  11-17-40  30-17-41
03-17-40  14-17-41  31-17-46
08-17-47  24-17-41  32-17-40  33-17-45

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
DISCUSSION:

During the September 20, 2017 DUR Board meeting, the DUR Board recommended that DHS update the guidelines to ensure safe and appropriate utilization of Xenazine (tetrabenazine) in response to warnings of depression and suicidality in patients with Huntington’s disease in the Food and Drug Administration approved package labeling. The DUR Board recommended guidelines to determine medical necessity of Xenazine (tetrabenazine) which were subject to public review and comment, and subsequently approved for implementation by DHS.

PROCEDURE:

The procedures for prescribers to request prior authorization of Xenazine (tetrabenazine) 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 Xenazine (tetrabenazine)) 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
Xenazine (tetrabenazine)
1. Requirements for Prior Authorization of Xenazine (tetrabenazine)

   A. Prescriptions That Require Prior Authorization

   All prescriptions for Xenazine (tetrabenazine) must be prior authorized.

   B. Review of Documentation for Medical Necessity

   In evaluating a request for prior authorization of a prescription for Xenazine (tetrabenazine), the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

   1. Is being prescribed Xenazine (tetrabenazine) 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. A diagnosis of chorea associated with Huntington Disease

      OR

      b. A diagnosis other than chorea associated with Huntington Disease that is:

         i. Listed in nationally recognized compendia for the determination of medically accepted indications for off-label uses

         OR

         ii. Supported by peer reviewed medical literature provided by the prescriber

      AND

   4. Does not have a contraindication to Xenazine (tetrabenazine)
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. Has a dosage adjustment of 50%, if taking a medication that is a strong CYP2D6 inhibitor

AND

9. Meets the following for dosing above 50 milligrams (mg) per day:
   a. A demonstrated therapeutic failure at a dose of 50 mg or less per day
   
   AND
   
   b. Documentation of CYP450 2D6 genotyping that shows intermediate or extensive metabolism

OR

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(Replacing December 9, 2014)
10. Does not meet the clinical review guideline listed above, but in the professional judgment of the physician reviewer, the service is medically necessary to meet the medical needs of the beneficiary.

In addition, if a prescription for Xenazine (tetrabenazine) 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.

FOR RENEWALS OF PRESCRIPTIONS FOR XENAZINE (TETRABENAZINE): The determination of medical necessity of requests for prior authorization of renewals of prescriptions for Xenazine (tetrabenazine) that were previously approved will take into account whether the beneficiary:

1. For a diagnosis of chorea, experienced a clinical benefit from Xenazine (tetrabenazine) 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 Xenazine (tetrabenazine)

   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 Xenazine (tetrabenazine)

   AND

5. Has a dosage adjustment of 50%, if taking a medication that is a strong CYP2D6 inhibitor

   AND

6. Meets the following for dosing above 50 milligrams (mg) per day:
a. A demonstrated therapeutic failure at a dose of 50 mg or less per day

AND

b. Documentation of CYP450 2D6 genotyping that shows intermediate or extensive metabolism

OR

7. Does not meet the clinical review guideline listed above, but in the professional judgment of the physician reviewer, the service is medically necessary to meet the medical needs of the beneficiary.

In addition, if a prescription for Xenazine (tetrabenazine) 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.

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 the request for a prescription for Xenazine (tetrabenazine). 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. Dose and Duration of Therapy

Approvals of requests for prior authorization of prescriptions of Xenazine (tetrabenazine) will be limited as follows:

1. The initial prescription will be approved for a period of up to 6 months

2. Renewals of prescriptions that were previously approved will be approved for a period of up to 12 months

E. References


January 8, 2018
(Replacing December 9, 2014)
MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES


