

ISSUE DATE June 29, 2023	EFFECTIVE DATE July 10, 2023	NUMBER *See below
SUBJECT Prior Authorization of Antiemetic/Antivertigo Agents – Pharmacy Services		BY  Sally A. Kozak, Deputy Secretary 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 Antiemetic/Antivertigo Agents 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 Antiemetic/Antivertigo Agents will be utilized in the fee-for-service and managed care delivery systems. Providers rendering services to MA beneficiaries in the managed care delivery system should address any questions related to the prior authorization of Antiemetic/Antivertigo Agents to the appropriate managed care organization.

BACKGROUND:

*01-23-12	09-23-12	27-23-06	33-23-12
02-23-05	11-23-05	30-23-09	
03-23-05	14-23-05	31-23-13	
08-23-16	24-23-11	32-23-05	

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) Drug Utilization Review (DUR) Board meets to review provider prescribing and dispensing practices for efficacy, safety, and quality and to recommend interventions for prescribers and pharmacists through the Department's Prospective DUR and Retrospective DUR programs.

DISCUSSION:

During the April 26, 2023, meeting, the DUR Board recommended revising the guidelines to determine medical necessity of prescriptions for Antiemetic/Antivertigo Agents to specify that requests for a non-preferred Antiemetic/Antivertigo Agent will consider the mechanism of action and route of administration of the requested non-preferred agent.

The revisions to the guidelines to determine medical necessity of prescriptions for Antiemetic/Antivertigo Agents submitted for prior authorization, as recommended by the DUR Board, 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 Antiemetic/Antivertigo Agents 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 Antiemetic/Antivertigo Agents) 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 and products 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>

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

I. Requirements for Prior Authorization of Antiemetic/Antivertigo Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Antiemetic/Antivertigo Agents that meet the following conditions must be prior authorized:

1. A non-preferred Antiemetic/Antivertigo Agent. See the Preferred Drug List (PDL) for the list of preferred Antiemetic/Antivertigo Agents at: <https://papdl.com/preferred-drug-list>.
2. An Antiemetic/Antivertigo Agent with a prescribed quantity that exceeds the quantity limit. 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>.
3. A prescription for promethazine for a child under 6 years of age.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antiemetic/Antivertigo Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is being prescribed the Antiemetic/Antivertigo Agent for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**
2. For a non-preferred Antiemetic/Antivertigo Agent, **one** of the following:
 - a. For a non-preferred oral serotonin receptor antagonist, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred oral serotonin receptor antagonists,
 - b. For a non-preferred non-oral serotonin receptor antagonist, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred non-oral serotonin receptor antagonists,
 - c. For a non-preferred oral neurokinin-1 receptor antagonist, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred oral neurokinin-1 receptor antagonists,
 - d. For a non-preferred non-oral neurokinin-1 receptor antagonist, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred non-oral neurokinin-1 receptor antagonists,

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- e. For all other non-preferred Antiemetic/Antivertigo Agents, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Antiemetic/Antivertigo Agents approved or medically accepted for the beneficiary's diagnosis;

AND

- 3. For promethazine for a child under 6 years of age, **all** of the following:
 - a. Is experiencing acute episodes of nausea and/or vomiting,
 - b. Is at risk for emergency department/hospital admission for dehydration,
 - c. Has demonstrated therapeutic failure of or a contraindication or an intolerance to oral rehydration therapy,
 - d. Has demonstrated therapeutic failure of or a contraindication or an intolerance to alternative pharmacologic treatments, such as ondansetron,
 - e. Will not be taking promethazine concomitantly with a medication with respiratory depressant effects, including cough and cold medications,
 - f. Has a documented evaluation for causes of persistent nausea and/or vomiting if symptoms have been present for more than one week,
 - g. Does not have a history of a contraindication to the prescribed medication;

AND

- 4. If a prescription for an Antiemetic/Antivertigo Agent 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.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement 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 an Antiemetic/Antivertigo Agent. 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.

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D. 5-Day Supply

In response to health and safety concerns, the Department will not cover a 5-day supply of an Antiemetic/Antivertigo Agent that contains promethazine pending approval of a request for prior authorization when prescribed for a beneficiary under 6 years of age.

E. References

1. Alhashimi D, Al-Hashimi H, Fedorowicz Z. Antiemetic for reducing vomiting related to acute gastroenteritis in children and adolescents [abstract]. Cochrane Database Syst Rev 2009 Apr 15(2):CD005506.
2. FDA Statement Following CHPA's Announcement on Nonprescription Over-the-Counter Cough and Cold Medicines in Children October 2008. Available at [http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2008/ucm116964](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2008/ucm116964.htm). htm (cited 03/11).
3. Information for Healthcare Professionals – Promethazine (market as Phenergan and generic products) April 2006. Available at <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm126465.htm> (cited 03/11).
4. Leung AK, Robson WL. Acute gastroenteritis in children: role of anti-emetic medication for gastroenteritis-related vomiting [abstract]. Paediatr Drugs 2007;9(3):175-84.
5. Managing Acute Gastroenteritis Among Children: Oral Rehydration, Maintenance, and Nutritional Therapy. Centers for Disease Control and Prevention MMWR 2003;52(RR-16):1-16.
6. Managing Acute Gastroenteritis Among Children: Oral Rehydration, Maintenance, and Nutritional Therapy. American Academy of Pediatrics [Statement of Endorsement] 2004;114(2):507.
7. Ondansetron (Sept 2010). In Drug Summary Information. Thomson Reuters (Healthcare) Inc. Available at <http://www.thomsonhc.com> (accessed 03/02/11).
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9. Starke P, Weaver J, Chowdhury B. Boxed warning added to promethazine labeling for pediatric use. N Eng JMed 2005;352(25):2653.
10. Traynor K. Promethazine Contraindicated in Young Children, FDA Warns April 2006. Available at <http://www.ashp.org/import/news/HealthSystemPharmacyNews/newsarticle.aspx?id=2168> (cited 03/11).