### **CLINICAL POLICY**

Antiemetics/Antivertigo Agents



# Clinical Policy: Antiemetics/Antivertigo Agents

Reference Number: PHW.PDL.085

Effective Date: 01/01/2020 Last Review Date: 07/2023

**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 PA Health and Wellness<sup>®</sup> that Antiemetics/Antivertigo Agents are **medically necessary** when the following criteria are met:

#### I. Requirements for Prior Authorization of Antiemetics/Antivertigo Agents

### A. Prescriptions That Require Prior Authorization

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

- 1. A non-preferred Antiemetics/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 Antiemetics/Antivertigo Agent with a prescribed quantity that exceeds the quantity limit.
- 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,
- 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 Antiemetics/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 PA.CP.PMN.59 Quantity Limit Override.

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

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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 Antiemetics/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.

#### D. Approval Duration: 6 months

#### E. References

- 1. Alhashimi D, Al-Hashimi H, Fedorowicz Z. Antiemetics 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-theCounter Cough and Cold Medicines in Children October 2008. Available at <a href="http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2008/ucm116">http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2008/ucm116</a> 964. htm (cited 03/11)
- 3. Information for Healthcare Professionals Promethazine (market as Phenergan and generic products) April 2006. Available at <a href="http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatients">http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatients</a> andProv iders/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).
- 8. Promethazine HCl and Codeine Phosphate Oral Solution November 2008. Detailed View: Safety Labeling Changes Approved By FDA Center for Drug Evaluation and Research (CDER). Available at: http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyRelatedDrugLabelingChang es/ucm121083.htm (cited 03/11).
- 9. Starke P, Weaver J, Chowdhury B. Boxed warning added to promethazine

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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

 $http://www.ashp.org/import/news/HealthSystemPharmacyNews/newsarticle.aspx?id=2168 \ (cited \ 03/11).$ 

Reviews, Revisions, and Approvals	Date
Policy created	01/2020
Q3 2020 annual review: no changes.	07/2020
Q1 2021 annual review: no changes.	01/2021
Q1 2022 annual review: no changes.	11/2021
Q1 2023 annual review: no changes.	11/2022
Q3 2023: policy revised according to DHS revisions effective 07/10/2023.	07/2023