I. Requirements for Prior Authorization of Antiemetics

A. Prescriptions That Require Prior Authorization

Prescriptions for Antiemetics that meet any of the following conditions must be prior authorized:

1. A prescription for a non-preferred Antiemetic, regardless of the quantity prescribed. See Preferred Drug List (PDL) for the list of preferred Antiemetics at: http://www.providersynergies.com/services/documents/PAM_PDL_20101115.pdf

2. A prescription for a preferred Antiemetic with a prescribed quantity that exceeds the quantity limit. See Quantity Limits for the list of drugs with quantity limits at http://www.dpw.state.pa.us/ucmprd/groups/webcontent/documents/document/s_002077.pdf.

3. A prescription for promethazine for a child under 6 years of age.

EMERGENCY SUPPLY: The Department will not approve an emergency supply of promethazine for recipients under 6 years of age in response to health and safety concerns.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a non-preferred Antiemetic, the determination of whether the requested prescription is medically necessary will take into account the following:

1. For Cesamet – Whether the recipient is 18 years of age or older and :

    a. Is receiving highly emetogenic chemotherapy or radiotherapy

    AND

    b. Has a history of therapeutic failure of:
        i. Preferred antiemetics including Marinol OR
        ii. Emend and Zofran combination therapy

    AND

c. Has a documented history of intolerance of or a contraindication to the preferred Antiemetics.

2. For continuation of Cesamet therapy beyond the initial request for prior authorization, whether the recipient:

   a. Is receiving highly emetogenic chemotherapy or radiotherapy

   AND

   b. Has a documented history of success using Cesamet to treat or control nausea and vomiting

3. For promethazine for a child under 6 years of age, whether the child is experiencing acute episodes of nausea and/or vomiting and:

   a. Is at risk for emergency department/hospital admission for dehydration

   AND

   b. Has demonstrated therapeutic failure or intolerance to oral rehydration therapy

   AND

   c. Has demonstrated therapeutic failure, contraindication or intolerance to alternative pharmacologic treatments, such as ondansetron

   AND

   d. Will not be taking promethazine concomitantly with a medication with respiratory depressant effects, including cough and cold medications

   AND

   e. Has a documented evaluation for causes of persistent nausea and/or vomiting if symptoms have been present for more than one week

AND

4. For use of promethazine for more than 7 days, documentation showing that the recipient:

    a. Was evaluated for causes of persistent nausea and/or vomiting

    OR

    b. Is actively receiving chemotherapy

5. For all other non-preferred Antiemetics, whether the recipient has a history of therapeutic failure or intolerance of the preferred Antiemetics.

6. In addition, if a prescription for either a preferred or non-preferred Antiemetic 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 an Antiemetic. 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 recipient.

D. Dose and Duration of Therapy

The Department will limit approval of requests for prior authorization of Antiemetics as follows:

1. Initial requests for prior authorization of Cesamet will be approved for no more than 2 months.

2. Initial requests for prior authorization of promethazine will be approved for up to a maximum of 7 days; requests for more than 7 days will be approved if the guidelines for medical necessity listed in Section B. above are met.

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-the-Counter Cough and Cold Medicines in Children October 2008. Available at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2008/ucm116964.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).
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/Safety-RelatedDrugLabelingChanges/ucm121083.htm (cited 03/11).
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).