

**DATE** JULY 2010  
**ISSUE** 3

### HELPFUL NUMBERS FOR PROVIDERS

Passport Health Plan

PerformRx: (800) 578-0898

Bin: 600428

Processor control: 02920000

Passport Advantage

PerformRx: (866) 533-5490

Bin: 012353

Processor control: 03650000

Injectables: (866) 533-5490,  
options 2,2,5

### HELPFUL NUMBERS FOR MEMBERS

Passport Health Plan

1-800-578-0603, option #2

Passport Advantage

1-800-578-0603, option #1

### WEBSITE

[www.passporthealthplan.com](http://www.passporthealthplan.com)

### NEW IN THIS ISSUE

- Medicare (Part D) Exclusions and Part B Drugs
- Allergic Rhinitis: Review of Treatment Options
- Pharmacy Tips & Reminders:
  - Shortage of Fluticasone Nasal Inhaler
  - High Risk Medication Use in the Elderly
- Formulary Updates
- Recent FDA Advisories
- P&T Committee Review

## Medicare (Part D) Exclusions and Part B Drugs

Passport Health Plan (Medicaid) may provide additional coverage for some drugs or classes of drugs excluded from Medicare Part D (i.e. over-the-counter drugs [OTCs], benzodiazepines, and barbiturates and cost-sharing for Part B drugs and supplies such as diabetic strips and lancets).

If you submit a claim to Passport Advantage and receive the error message “#211 CMS Excluded Part D drug,” please submit a secondary claim to Passport Health Plan using the member’s Passport Health Plan information (such as member ID number, PerformRx/Argus BIN #, and Processor Control #).

### Billing Questions?

If you receive edits or alerts while attempting to process the secondary claim to Passport Health Plan, call the PerformRx HelpDesk at (866) 533-5490 immediately for assistance with the claim.

## Allergic Rhinitis: Review of Treatment Options

Allergic rhinitis (AR) affects 10 to 30 percent of adults and up to 40 percent of children in the United States. If left untreated, AR may exacerbate asthma, sinusitis, otitis, sleep deprivation, and other disorders. Pharmacologic treatment options include nasal corticosteroids, oral antihistamines, decongestants, leukotriene receptor antagonists (LTRA), and nasal cromolyn.

**Oral antihistamines** are considered a mainstay of therapy. Second-generation agents such as loratadine (Claritin®), fexofenadine (Allegra®), and cetirizine (Zyrtec®) are recommended as initial therapy because of

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*All medications may be subject to edits to limit quantities dispensed, day's supply, and drug-drug interactions at the point of service. Appropriate diagnosis, drug therapy length and approved indications will be used in determining medical necessity.*

*Committee decisions are based upon relevant medical literature that is evidence based, peer reviewed, and English language based, using appropriate study designs.*

*Price(s) listed are AWP from First Data Bank as of 01-20-2006. These are displayed as a reference only and intended to be a learning tool for providers for the costs of therapy prescribed for a one-month period unless otherwise indicated. Prices are calculated from AWP using the lower dose strengths applicable to therapy for 30-day supply calculated.*

their favorable risk-benefit profile and lack of sedative effects. Oral antihistamines are less effective for nasal congestion than other symptoms. Continuous use is most effective but PRN use is appropriate because of the relatively rapid onset of action.

**Intranasal corticosteroids** are considered the most effective medications for treating AR. They are effective for all symptoms of AR (including nasal congestion) and are more effective than the combination of oral antihistamines and LTRA. The onset of action is slower than oral antihistamines. PRN use is effective but continuous use may be more effective.

The **leukotriene receptor antagonist (LTRA)** montelukast (Singulair®) has been approved for the treatment of seasonal and perennial AR. However, there is no significant difference in efficacy between LTRAs and antihistamines. Concomitant use with antihistamines can have an additive effect but is less effective than administering intranasal corticosteroids as monotherapy.

**Intranasal cromolyn** is effective for the treatment and prevention of symptoms. The onset of action may take 4 to 7 days and full benefits may take weeks. It is less effective than nasal corticosteroids and comparative studies with LTRAs and antihistamines are lacking.

A short course (5-7 days) of **oral corticosteroids** may be appropriate for very severe nasal symptoms. Oral use is preferred over single or recurrent administration of intramuscular corticosteroids.

**Reference:** *The Diagnosis and Management of Rhinitis: an updated practice parameter. J Allergy Clin Immunol 2008 Aug;122(2 Suppl):S1-84.*

The following chart contains some of the PHP preferred agents for the treatment of allergic rhinitis. For a complete listing of preferred treatment options, please refer to the PHP online searchable formulary at [www.passporthealthplan.com](http://www.passporthealthplan.com).

| Medication Name  | Strength/Dose form                              | Formulary Status            | Criteria for Approval |
|--|---|-----------------------------|-----------------------|
| <b>Second Generation Antihistamines</b>  |   |                             |                       |
| Loratadine (generic)<br>(OTC availability)   | Tablet: 10mg<br>RediTab: 10mg<br>Syrup: 5mg/5mL | Preferred (will pay at POS) |                       |
| Loratadine/<br>pseudoephedrine 12<br>hour, 24 hour (generic)<br>(OTC availability) | Tablet: 5mg/120mg<br>Tablet: 10mg/240mg         |                             |                       |
| Cetirizine (generic)<br>(OTC availability)   | Tablet: 5mg, 10mg Syrup:<br>5mg/5mL             | Preferred (will pay at POS) |                       |
| Cetirizine/<br>pseudoephedrine 12<br>hour (generic) (OTC<br>availability)          | Tablet: 5mg/120mg                               | Preferred (will pay at POS) |                       |

|   |   |  |   |
|---|---|--|---|
| Fexofenadine (generic)                                      | Tablet: 30mg, 60mg, 180mg   | Preferred with step therapy  | Documented trial with a minimum of 4 weeks of therapy with two preferred (first line) agents.   |
| Allegra (fexofenadine)                                      | Tablet: 30mg, 60mg, 180mg<br>ODT: 30mg<br>Oral Suspension: 30mg/5mL | Non-preferred, requires prior authorization<br><b>(Third Line)</b> | 1. Documented trial with a minimum of 4 weeks of therapy with two preferred ( <b>first line</b> ) agents.<br><br>2. Documented trial with a minimum of 4 weeks of therapy with generic fexofenadine ( <b>second line</b> ) agent. |
| Allegra-d 12 hour, 24 hour (fexofenadine/pseudoephedrine)   | Tablet: 60mg/120mg<br>Tablet: 180mg/240mg                           |  |   |
| Clarinet (desloratadine)                                    | Tablet: 5mg<br>RediTab: 2.5mg, 5mg<br>Syrup: 2.5mg/5mL              |  |   |
| Clarinet-d 12 hour, 24 hour (desloratadine/pseudoephedrine) | Tablet: 2.5mg/120mg Tablet:<br>5mg/240mg                            |  |   |
| Xyzal (levocetirizine)                                      | Tablet: 5mg   |  |   |
| <b>Leukotriene-Receptor Antagonist</b>                      |   |  |   |
| Singulair (montelukast)                                     | Tablets: 10mg Chewable<br>Tablets: 4mg, 5mg<br>Granules: 4mg        | Preferred (will pay at POS)  |   |
| <b>Intranasal Corticosteroids</b>                           |   |  |   |
| Fluticasone (generic)                                       | Spray: 50 mcg/actuation   | Preferred (will pay at POS)  |   |
| Nasonex (Mometasone)  | Spray: 50 mcg/actuation   |  |   |
| Rhinacort AQ (budesonide)                                   | Spray: 32 mcg/actuation   | Preferred with step therapy  | Trial of fluticasone or Nasonex in the last 6 months OR member is currently pregnant or nursing.  |
| Nasacort AQ (triamcinolone)                                 | Spray: 55 mcg/actuation   | Non-preferred, requires PA   |   |

## Pharmacy Tips and Reminders

- Shortage of Fluticasone Nasal Inhaler**  
 Several manufacturers are experiencing shortages of generic fluticasone. Until the shortage has resolved, brand name Flonase will also pay at point-of-sale for Passport Health Plan/Passport Advantage members.
- High Risk Medication Use in the Elderly**  
 Among ambulatory people  $\geq 65$  years, adverse drug effects occur at a rate of about 50 events per 1,000 person-years. Hospitalization rates due to adverse drug effects are four times higher in elderly patients than in younger patients.

Some drug categories (eg., analgesics, antihistamines, hypoglycemic drugs, psychoactive drugs) pose special risks for elderly patients. The Beers Criteria are most commonly used to identify drug categories of concern in the elderly.

Here are some suggestions to assist you with reducing the risk of drug-related problems with our elderly members:

**Providers:**

- Choose the safest possible alternative
- Check for potential drug-disease and drug-drug interactions
- Start with a low dose
- Use the fewest drugs necessary

**Pharmacist:**

Pharmacists are in an ideal position to reduce the risk of adverse drug reactions in the elderly by identifying all medications (OTC and prescription) the individual is taking and intervening with the prescriber when you receive a prescription for a high risk medication.

*Reference: Merck Manual/Drug Categories of Concern in the Elderly.*

## Formulary Updates

- **Passport Health Plan (PHP):**  
PHP formulary updates may be found at [www.passporthealthplan.com/pharmacy](http://www.passporthealthplan.com/pharmacy).
  - **Iron liquid drops 15mg/1ml now preferred for PHP.**
  - **Effective September 1, 2010, Zyrtec/cetirizine chewable tablets will change to non-preferred status.**  
PHP members receiving brand or generic Zyrtec chewable tablets will not be grandfathered and should transition to another preferred alternative. Cetirizine solution and loratadine ODT are formulary alternatives for members who require an alternative to a tablet formulation.
  - **Effective September 1, 2010, Tagamet (cimetidine) will change to non-preferred status.**  
PHP members who received cimetidine in the last 60 days will be grandfathered. New prescriptions for cimetidine or nizatidine will require prior authorization.
  - **Reminder: Axid (nizatidine) non-preferred for Passport Health Plan members.**
  - **Generic Drug Additions**  
The following generic drugs have been added to the PHP Preferred Drug List:
    - Tamsulosin (generic Flomax)
    - Imiquimod (generic Aldara)
    - Epinephrine Auto-Injector (generic Adrenallick) 0.3mg and 0.15mg
    - Diltiazem 24 hr ER (Cardizem LA)
    - Apraclonidine 0.5% drops (Iopidine)
- **Passport Advantage (PAD):**  
PAD formulary updates may be found at [www.passportadvantage.org/pharmacy](http://www.passportadvantage.org/pharmacy).
- **Over-the-Counter (OTC) Listing:**  
The recently-updated PHP OTC listing may be found at [www.passporthealthplan.com/pharmacy](http://www.passporthealthplan.com/pharmacy).

# Recent Federal Drug Administration (FDA) Advisories Affecting Network Pharmacies and Providers

The FDA recently issued the following advisories:

## **June 24, 2010 – P&G 4-Hour Decongestant Nasal Spray Recalled**

Proctor & Gamble announced a voluntary recall of its VapoSpray 4-Hour Nasal Spray by Sinex after finding the product formulation may not meet the expiration dates on the package.

## **June 21, 2010 Mylotarg (gemtuzumab ozogamicin) Withdrawn from Market**

The FDA notified healthcare professionals that results from a recent clinical trial raised new concerns about the product's safety. The drug failed to demonstrate clinical benefit to patients enrolled in trials. Mylotarg will not be commercially available to new patients. Patients who are currently receiving the drug may complete their therapy following consultation with their health care professional.

## **June 17, 2010 Fraudulent Tamiflu Sold on Internet is Dangerous to Patients Allergic to Penicillin**

The FDA notified consumers and healthcare professionals about a potentially harmful product represented as "Generic Tamiflu" sold over the Internet. FDA tests revealed that the fraudulent product does not contain Tamiflu's active ingredient, oseltamivir, but cloxacillin, an ingredient in the same class of antibiotics as penicillin.

## **June 15, 2010 – Some OTC Products Recalled**

In consultation with the FDA, McNeil Consumer Healthcare, Division of McNEIL-PPC, Inc., is recalling five product lots inadvertently omitted from the list of products included in the company's January 15, 2010 product recall. The additional lots involved are four product lots of Benadryl® Allergy Ultratab™ tablets (100 count), and one product lot of Extra Strength Tylenol® Rapid Release Gels (50 count), all produced before January 15, 2010. A further analysis of the presence of 2,4,6-tribromoanisole (TBA) has confirmed that the risk of serious adverse medical events is remote.

## **June 15, 2010 Vitamin D Supplement Products: Medication Use Error**

Some liquid Vitamin D supplement products are sold with droppers that could allow parents to accidentally give harmful amounts of Vitamin D to their infant. The easiest way to insure infants do not get more than the recommended dose is to use a product supplied with a dropper that gives no more than 400 IU per dose.

## **June 11, 2010 Benicar (olmesartan): Ongoing Safety Review**

The FDA is evaluating data from two clinical trials in which patients with type 2 diabetes taking the blood pressure medication, Benicar (olmesartan), an angiotensin II receptor blocker, had a higher rate of death from a cardiovascular cause compared to patients taking a placebo.

## **May 29, 2010 PediaCare Children's Products [Blacksmith Brand]: Recall of four products**

Blacksmith Brands and the FDA notified healthcare professionals and patients about a nationwide recall of all lots of four PediaCare children's products. These products are sold exclusively in the United States and were manufactured by McNeil Consumer Healthcare at McNeil's Fort Washington, PA plant.

## **May 29, 2010 Intravenous Medications Manufactured by Claris: Recalled**

The FDA notified healthcare professionals not to use the intravenous medications, metronidazole, ciprofloxacin and ondansetron manufactured by Claris Lifesciences due to contamination. The FDA received reports of floating matter in intravenous bags of metronidazole and ondansetron.

**May 25, 2010 Proton Pump Inhibitors (PPI): Class Labeling Change**

The FDA notified healthcare professionals and patients of revisions to the prescription and over-the-counter [OTC] labels for proton pump inhibitors, which work by reducing the amount of acid in the stomach, to include new safety information about a possible increased risk of fractures of the hip, wrist, and spine with the use of these medications.

**May 16, 2010 – Rotarix Vaccine Safety Update**

The FDA determined it is appropriate for clinicians and health care professionals to resume the use of Rotarix and continue the use of RotaTeq vaccine. Based on a careful evaluation, the FDA determined the vaccine's benefits outweigh the risk of porcine circovirus (PCV1 and PCV2), which has not been proven to pose a safety risk in humans.

**May 12, 2010 – Promacta in Study of Patients With Chronic Liver Disease**

Health care professionals are reminded that Promacta is indicated for the treatment of thrombocytopenia in adult patients with chronic immune (idiopathic) thrombocytopenic purpura (ITP) and is not indicated for the treatment of thrombocytopenia in patients with chronic liver disease. Treatment with Promacta should be aimed at increasing the platelet count to a level that reduces the risk of bleeding; Promacta should not be used in an attempt to normalize the platelet count. Use caution when administering Promacta to patients with known risk factors for thromboembolism. Exercise caution when administering Promacta to patients with hepatic disease. Use a lower starting dose (25mg once daily) of Promacta in patients with moderate to severe hepatic disease and monitor closely.

**May 3, 2010 – Safety Review of GnRH Agonists Drug Class Used to Treat Prostate Cancer**

The FDA notified health care professionals and patients of its review suggesting an increase in the risk of diabetes and certain cardiovascular diseases in men treated with GnRH agonists. Health care professionals and patients should carefully weigh the benefits and risks of GnRH agonists when determining treatment choices. The FDA recommends that patients receiving GnRH agonists should be monitored for development of diabetes and cardiovascular disease.

**April 30, 2010 - McNeil Consumer Health care OTC Infants' and Children's Products Recalled**

McNeil Consumer Healthcare and the FDA notified health care professionals of a voluntary recall of certain OTC Children's and Infants' liquid products manufactured in the United States, including Tylenol, Motrin, Zyrtec, and Benadryl products. Some of these products may not meet required quality standards. This recall is not being undertaken on the basis of adverse medical events. However, as a precautionary measure, parents and caregivers should not administer these products to their children.

Please visit <http://www.fda.gov/opacom/7alerts.html> for more information.

## The Passport Health Plan Pharmacy and Therapeutics Committee Reviewed the Following Medications on April 20, 2010

| Brand Name | Generic Name   | Indication  | Preferred Drug List Alternatives  | Passport Health Plan Drug Status  | Cost Per 30 Day Supply (Or Per Unit)                            |
|------------|--|---|---|---|---|
| Ulesfia    | benzyl alcohol                                       | The topical treatment of head lice in patients 6 months of age and older.   | <p>Permethrin<br/>\$6.88-\$11.75<br/>(59-120 mL)</p> <p>Pyrethrins/<br/>piperonyl butoxide<br/>\$4.28-\$8.62<br/>(60-120 mL)</p> <p>Lindane (with step therapy)<br/>\$141.00 (60 mL)</p> <p>Malathion<br/>(with step therapy<br/>\$153.00 (59 mL)</p> | Add to Preferred Drug List with step therapy with either a permethrin or pyrethrins/piperonyl butoxide product. | \$25.93-\$155.59<br>(227-1362 grams - 1 to 6 bottles)           |
| Vagifem    | 10mcg Vaginal Tablets                                | Treatment of atrophic vaginitis.  | <p>Estrace® Cream<br/>\$113.46<br/>(42.5g tube)</p> <p>Premarin® Cream<br/>\$114.13<br/>(42.5g tube)</p>  | Add to Preferred Drug List.   | <p>\$47.99<br/>(8 tablets)</p> <p>\$107.94<br/>(18 tablets)</p> |
| Exalgo     | Hydromorphone hydrochloride extended release tablets | Management of moderate to severe pain in opioid-tolerant patients requiring continuous, around-the-clock opioid analgesia for an extended period of time. | Morphine Sulfate ER<br>Kadian Oxycodone ER with prior authorization.  | Remain non-preferred.   | \$8.85 - 8mg<br>\$13.28 - 12mg<br>\$17.71 - 15mg                |
| Victoza    | liraglutide injection, 0.6mg                         | Adjunct to diet and exercise for adults with type 2 diabetes.   | <p>Insulin (various) Levemir, Humulin, etc.</p> <p>(Note: Byetta is available through the prior authorization process – \$235 per pen)</p>  | Remain non-preferred.   | \$255.01 - 6ml  |
| Biothrax   | anthrax vaccine injection, 0.5ml                     | Prevention of anthrax infection in adults at high risk of exposure to anthrax.  | N/A   | Remain non-preferred.   | \$79.43 - 0.5ml   |

| Brand Name           | Generic Name                                       | Indication   | Preferred Drug List Alternatives   | Passport Health Plan Drug Status | Cost Per 30 Day Supply (Or Per Unit)                 |
|----------------------|--|--|--|----------------------------------|--|
| Zyram                | Hydrocortisone Acetate & Pramoxine Cream: 2.35%-1% | Topical relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.  | Analpram-HC (cream with applicator only)<br>\$41.03-\$128.38 (30-120 g)<br><br>Epifoam<br>\$33.42 (10 g)<br><br>Pramosone (cream only)<br>\$69.13-\$94.71 (28.4g, 57 g)<br><br>Pramosone-E<br>\$65.94-\$90.20 (28.4-57 g)<br><br>ProctoFoam-HC<br>\$62.92 (10 g) | Add to Preferred Drug List.      | \$35.10 per 30gm                                     |
| Pevnar 13            | Pneumococcal 13-valent conjugate vaccine           | The prevention of invasive pneumococcal disease /otitis media in infants and young children 6 weeks to 5 years of age. Also extends protection against six additional serotypes of the bacterium <i>Streptococcus pneumoniae</i> .   | Vaccines for members less than 19 years old are covered through the Vaccines For Children program (VFC).   | Remain non-preferred.            | \$114.75   |
| Zyclara              | Imiquimod 3.75%                                    | Treatment of clinically typical, nonhyperkeratotic, nonhyptrophic, visible, or palpable actinic keratoses on the face/balding scalp in immunocompetent adults. Indicated for daily use on an accelerated 6-week dosing cycle consisting of 2 weeks of daily treatment, 2 weeks of nontreatment, and then another 2 weeks of daily treatment. | Imiquimod (generic Aldara5%)<br>\$532.74 (24 packets)  | Remain non-preferred.            | \$605<br>28 packets                                  |
| Differin 0.1% Lotion | adapalene  | Treatment of acne.   | Tretinoin cream 0.1% (various strengths)<br>45 gram<br>\$67.75<br>Tretinoin gel 0.01% 15gm, 45 gram (various strengths)<br>\$28.04 -\$76-65<br>Differin 0.1% gel 45 grams<br>\$193.37<br>Differin 0.3% gel 45 grams<br>\$187.00                                  | Remain non-preferred.            | \$187.00<br>59 ml                                    |
| Mirapex ER           | Pramipexole ER tablets                             | Once daily treatment for signs and symptoms of early idiopathic Parkinson's disease.   | Pramipexole (generic Mirapex)<br>90 tablets (30-day supply)<br>\$78.77   | Remain non-preferred.            | \$261.00 (30-day supply)                             |
| Norvir               | Ritonavir 100mg tablet                             | HIV Protease inhibitor- used in combination with other HIV medications. New formulation is heat resistant with no refrigeration required.  | Norvir Softgel Capsules<br>\$3300 (30-day supply max dose: 600 mg twice daily)   | Add to Preferred Drug List.      | \$3,300 (30-day supply max dose: 600 mg twice daily) |