

February 13, 2009

Dear Healthcare Practitioner:

Presbyterian Health Plan and Presbyterian Insurance Company, Inc. (Presbyterian) Pharmacy and Therapeutics Committee (P&T Committee) met on January 21, 2009 to promote appropriate use of drugs in maintaining the formularies. We are dedicated to supporting our network of practitioners and would like to share with you the decisions made at that meeting that affect our formularies and pharmacy benefits. Please note that online versions of all Presbyterian formularies are available on our website at [www.phs.org/pharmacy/index.htm](http://www.phs.org/pharmacy/index.htm), as well as on [www.nm-formulary.com](http://www.nm-formulary.com). All formularies are downloadable onto your handheld Palm device through the **Epocrates Rx** software.

## P&T COMMITTEE DECISIONS

### Additions/Changes to the Presbyterian Formularies/PDLs

**Astepro™ nasal spray (azelastine):** Astepro nasal spray has recently been approved by the FDA (Food and Drug Administration) and is a new formulation of Astelin nasal spray. Astepro nasal spray is indicated for the treatment of seasonal allergic rhinitis. The committee voted and approved adding Astepro nasal spray to the Presbyterian formularies except for the Salud/NMRx/SCI formularies. The generic version of Atrovent® nasal spray (ipratropium) is available on all the Presbyterian formularies.

**Calcitonin-salmon nasal spray:** There is now an AB rated generic available for Miacalcin® nasal spray. Calcitonin-salmon nasal spray is available on all the Presbyterian formularies.

**Combigan® ophthalmic solution (brimonidine/timolol):** Combigan is a combination of an alpha-blocker and a beta blocker that is indicated for the treatment of glaucoma. It is available on all the Presbyterian formularies except for the Salud/SCI/NMRx formularies. There are many other alternatives available that are covered on the Salud/SCI/NMRx formularies.

**Elestat® ophthalmic solution (epinastine):** Elestat is an antihistamine indicated for the treatment of allergic rhinitis. It is available on all the Presbyterian formularies except for the Salud/SCI/NMRx formularies. There are many other alternatives that are covered on the Salud/SCI/NMRx formularies.

**Levetiracetam tablets and oral solution:** There is now an AB rated generic available for Keppra® tablets and oral solution. Levetiracetam tablets and oral solution are available on all the Presbyterian formularies.

**Sumatriptan tablets and injectable solution:** There is now an AB rated generic product available for Imitrex® tablet and injectable solution. Sumatriptan tablets and injectable solution are available on all the Presbyterian formularies with a quantity limit of #18 tablets per 30 days or #4 injections per 30 days.

**Venlafaxine Extended Release (ER) Tablets:** This is a new product that was approved by the FDA. It is not a generic therapeutic equivalent (AB rated) to Effexor XR® capsules; therefore they cannot be interchanged at the pharmacy level without the prescriber's consent. Venlafaxine ER tablets are indicated

for the treatment of major depressive disorder and social anxiety disorder. The committee voted and approved adding venlafaxine ER tablets to the Presbyterian formularies with a Step Edit requirement and a quantity limit. The Step Edit will require a prescription claim in the past 180 days of a 30 day trial of at least two generic antidepressant agents. If the Step Edit requirement is not met, then a Pharmacy Exception is required. The quantity limit is 30 tablets per 30 days.

**Vyvanse® (lisdexamfetamine) capsules:** Vyvanse is a new stimulant that has been approved by the FDA for the treatment of attention deficit hyperactivity disorder in adults and in pediatric patients aged 6 to 12 years. The committee voted and approved adding Vyvanse to all the Presbyterian formularies with a quantity limit. For the Salud/SCI/NMRx formularies, Vyvanse was added with a Step Edit requirement and a quantity limit. The Step Edit will require a prescription claim in the past 180 days of a 30 day trial of one cerebral stimulant such as dextroamphetamine, amphetamine/dextroamphetamine salt combination (generic for Adderall), methylphenidate, or Adderall XR®\*. If the Step Edit requirement is not met then a Pharmacy Exception is required. The quantity limit is 30 tablets per 30 days.

\*Adderall XR currently requires either Step Edit or Pharmacy Exception for coverage on the Salud/NMRx/SCI formularies.

### **Formulary Pharmacy Exception Criteria Additions**

**Orencia® injectable infusion (abatacept):** The committee voted to approve the following Pharmacy Exception criteria for Orencia.

#### **Indications for Approval:**

1. Rheumatoid Arthritis (RA)
2. Juvenile Idiopathic Arthritis (JIA)

#### **Criteria for Approval (must meet all of the following for approval):**

- a. The patient has disease activity with active synovitis in at least 3 sets of joints – ex. Bilateral proximal interphalangeal (PIP) joint involvement = 1 set, or bilateral knee involvement = 1 set.
- b. The patient must have had an adequate trial (3 months or more) of methotrexate to a maximum tolerated dose (weight adjusted dose for children). If the patient has a contraindication to methotrexate, then an adequate trial (3 months or more) of one of the following other (DMARDs) must have been tried:
  1. Leflunomide (generic for Arava).
  2. Hydroxychloroquine (generic for Plaquenil).
  3. Sulfasalazine (generic for Azulfidine).
  4. Cellcept (mycophenolate mofetil).
  5. Azathioprine (generic for Imuran).
- c. The patient must have had an adequate trial and failure of at least two TNF (Tumor Necrosis Factor) inhibiting drugs such as Enbrel (etanercept), Humira (adalimumab), or Remicade (infliximab).
- d. The patient must have a current PPD (tuberculosis) negative skin test or negative QuantiFERON-TB Gold test prior to initiation of therapy.
- e. The patient should have documentation of having received a pneumococcal immunization (Pneumovax 23®, Pnu-Immune 23®, or Prevnar®) prior to initiation of therapy.

## Formulary Pharmacy Exception Criteria Revisions

Only a summary of the revisions are included below. To see the complete Presbyterian formulary Pharmacy Exception criteria document online, please access:

<http://www.phs.org/wcm/groups/public/@phs/@php/documents/phscontent/wcmdev1001476.pdf>

**Androgel®, Androderm®, and Testim® (topical testosterone products):** The committee voted to approve the following criteria revisions to the Pharmacy Exception criteria for Androgel, Androderm, and Testim.

**Indications for Approval:** Hypogonadism (primary and secondary).

**Criteria for Approval:** The patient must have one of the following documented by laboratory confirmation:

- At least two low total testosterone levels. (Two blood draws required on separate days.)
- At least two low free testosterone levels. (Two blood draws required on separate days.)
- One low free testosterone level with an elevated LH and FSH.
- One low total testosterone level with an elevated LH and FSH.

Notes: Testosterone replacement therapy is not covered for the treatment of sexual dysfunction. If there is conflict in the results of the total testosterone and free testosterone lab tests, then the free testosterone results will be used to evaluate the request.

**Enbrel® (etanercept), Humira® (adalimumab), and Remicade® ( infliximab) injectable solutions:**

The committee voted to approve the following criteria revisions to the existing Pharmacy Exception criteria for Enbrel, Humira, and Remicade for the indications of rheumatoid arthritis (RA), juvenile rheumatoid arthritis (for Enbrel and Remicade only), psoriatic arthritis, and ankylosing spondylitis unless otherwise specified.

- QuantiFERON®-TB Gold test (QFT-G) was added as an alternative along with the tuberculin skin test (PPD) as an option for testing for tuberculosis infection for all FDA approved indications.
- For ankylosing spondylitis only, patients with axial disease and a documented trial and failure, or a contraindication, to NSAIDs (Non-Steroidal Anti-Inflammatory Drugs) can be started on Enbrel, Humira, or Remicade without a trial of a DMARD (Disease Modifying Anti-Rheumatic Drug) first.
- The following criteria were changed from 6 months to 3 months and #4 and #5 were added:  
“The patient must have had an adequate trial (3 months or more) of methotrexate to a maximum tolerated dose (weight adjusted dose for children). If the patient has a contraindication to methotrexate, then an adequate trial (3 months or more) of one of the following other (DMARDs) must have been tried:”
  1. Leflunomide (generic for Arava®).
  2. Hydroxychloroquine (generic for Plaquenil®).
  3. Sulfasalazine (generic for Azulfidine®).
  4. Cellcept® (mycophenolate mofetil).
  5. Azathioprine (generic for Imuran®).

**Rituxan® injectable infusion (rituximab):** The committee voted to approve the following criteria revisions to the existing Pharmacy Exception criteria for Rituxan, for the indication of rheumatoid arthritis only.

- Leflunomide was added as an option instead of methotrexate for those patients intolerant to methotrexate. Rituxan must be given in conjunction with either leflunomide or methotrexate.
- Under dosing criteria, the recommended dose for approval was changed from 1000mg to 500-1000mg.
- The following criteria were changed by adding in the term “Frequency:”  
“The following indications listed below will be considered for approval for treatment with Rituxan if the dosing, frequency, and length of therapy are supported by, and are consistent with published medical literature.”
- Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) was removed from the list of covered indications because it is considered investigational at this time and will not be covered.

**Formulary Coverage Comparison of the ADHD extended release medications**

<b>Drug Name</b>	<b>Salud/SCI/NMRx</b>	<b>Commercial</b>	<b>Medicare/Senior</b>
<b>Methylin ER®</b> (methylphenidate ER tablets)	<b>Formulary QL* of #30/30 days</b>	<b>Tier 1</b>	<b>Tier 1</b>
<b>Metadate CD®</b> (methylphenidate ER capsules)	<b>Formulary QL* of #30/30 days</b>	<b>Tier 2 QL* of #30/30 days</b>	<b>Tier 2 QL* of #30/30 days</b>
<b>Concerta®</b> (methylphenidate ER tablets)	<b>Step Edit required QL* of #30/30 days</b>	<b>Tier 2 QL* of #30/30 days</b>	<b>Tier 2 QL* of #30/30 days</b>
<b>Adderall XR</b> (dextroamphetamine & amphetamine salts ER capsules)	<b>Step Edit required QL* of #30/30 days</b>	<b>Tier 2 QL* of #30/30 days</b>	<b>Tier 2 QL* of #30/30 days</b>
<b>Vyvanse</b> (lisdexamfetamine capsules)	<b>Step Edit required QL* of #30/30 days</b>	<b>Tier 3 QL* of #30/30 days</b>	<b>Tier 3 QL* of #30/30 days</b>

\*QL – Quantity Limit

**Summary of P&T Committee Decisions  
(Additions/Revisions)**

<b>Drug Name</b> (all strengths available are included)	<b>Salud, SCI, NMRx</b>	<b>Commercial</b>	<b>Medicare/Senior</b>
<b>Astepro nasal spray</b> (azelastine)	<b>Not Covered</b>	<b>Tier 2</b>	<b>Tier 2</b>
<b>Calcitonin-Salmon nasal spray</b> (generic for Miacalcin)	<b>Covered</b>	<b>Tier 1</b>	<b>Tier 1</b>
<b>Combigan ophthalmic solution</b> (brimonidine/timolol)	<b>Not Covered</b>	<b>Tier 3</b>	<b>Tier 3</b>
<b>Elestat ophthalmic solution</b> (epinastine)	<b>Not Covered</b>	<b>Tier 2</b>	<b>Tier 2</b>
<b>Levetiracetam tablets and oral solution</b> (generic for Keppra)	<b>Covered</b>	<b>Tier 1</b>	<b>Tier 1</b>
<b>Sumatriptan succinate tablets</b> (generic for Imitrex)	<b>Covered</b> <b>QL* of #18/30 days</b>	<b>Tier 1</b> <b>QL* of #18/30 days</b>	<b>Tier 1</b> <b>QL* of #18/30days</b>
<b>Sumatriptan succinate injectable solution</b> (generic for Imitrex)	<b>Covered</b> <b>QL* of #4/30 days</b>	<b>Tier 1</b> <b>QL* of #4/30 days</b>	<b>Tier 1</b> <b>QL* of #4/30 days</b>
<b>Venlafaxine ER tablets</b>	<b>Step Edit required</b> <b>QL* of #30/30 days</b>	<b>Step Edit required</b> <b>Tier 2</b> <b>QL* of #30/30 days</b>	<b>Step Edit required</b> <b>Tier 3</b> <b>QL* of #30/30 days</b>
<b>Vyvanse</b> (lisdexamfetamine)	<b>Step Edit required</b> <b>QL* of #30/30 days</b>	<b>Tier 3</b> <b>QL* of #30/30 days</b>	<b>Tier 3</b> <b>QL* of #30/30 days</b>

\*QL – Quantity Limit

## SUMMARY OF P&T SAFETY ISSUES

For complete information, please go to the following website:  
<http://www.fda.gov/medwatch/safety/2008/safety08.htm#chronological>

**Bisphosphonates:** On November 12, 2008, the FDA notified health professionals of their follow-up review of the data based on a previous FDA alert from October 1, 2007 on possible safety concerns with the bisphosphonates. Data available to the FDA at that time, including data from the NDA approval of Reclast for osteoporosis, showed an increased risk of serious atrial fibrillation and this risk was reflected in the Reclast labeling. After the FDA's review, their recommendation is that healthcare professionals should not alter their prescribing patterns for the bisphosphonates and patients should continue taking their bisphosphonate medication. In addition, the FDA is continuing to monitor post-market reports of atrial fibrillation in patients who have taken bisphosphonates.

**Ethex Corporation:** On December 23, 2008, the Ethex Corporation and the FDA notified healthcare professionals of a voluntary recall to the consumer level of a single production lot of hydromorphone 2mg tablets due to the possibility that it may contain oversized tablets. For more information on the specific lot numbers affected by this recall, see the manufacturer's recall notice on the FDA website listed above.

The changes to the formularies, as outlined above, are based on requests from our practitioners and the recommendations of the P&T Committee. We value your input. If you have any concerns, please contact Larry Georgopoulos, R.Ph, by e-mail at [lgeorgop@phs.org](mailto:lgeorgop@phs.org) or by phone at (505) 923-5530, Monday through Friday from 8:00 a.m. to 5:00 p.m.

In addition to the formulary changes, we would like to remind you that our phone numbers have changed. The new numbers are (505) 923-5757 (in the Albuquerque area) or 1-888-923-5757 (outside the Albuquerque area). Pharmacy Department hours are Monday through Friday from 8:00 a.m. to 5:00 p.m. Pres Online is also available for you to verify eligibility and submit Pharmacy Exceptions. Please visit the Provider page of [www.phs.org](http://www.phs.org) for more information.

Thank you for partnering with us to improve the health of individuals, families, and communities.

Sincerely,



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