

October 8, 2008

Dear Healthcare Practitioner:

The Pharmacy and Therapeutics Committee (P&T Committee) of Presbyterian Health Plan and Presbyterian Insurance Company, Inc. (Presbyterian) met on September 17, 2008 to promote appropriate use of drugs in maintaining our 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, as well as on 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

Tamiflu (oseltamivir) and Relenza (zanamivir): Tamiflu and Relenza are oral neuraminidase inhibitors that are indicated for the treatment and prophylaxis of uncomplicated acute illness due to the influenza infection. The committee voted to add Tamiflu and Relenza to all the formularies for members aged ≤ 18 years and ≥ 65 years for treatment or prophylaxis with the following quantity limits:

Tamiflu capsules – 10 capsules per 180 days
Tamiflu suspension – 10 day course per 180 days
Relenza diskhaler – 10 doses (1 diskhaler) per 180 days

For members aged 19 to 64 years the committee voted to have Tamiflu and Relenza available by Prior Authorization for the treatment of influenza with the following criteria:

1. The member has a positive influenza test or documented symptoms of influenza.
2. The request is made within 48 hours of the first influenza symptoms.
3. The member has a documented immunocompromised medical condition.

Influenza vaccine products: Listed below are three injectable influenza vaccine products available for the 2008-2009 season:

Fluarix® (GlaxoSmithKline Biologicals)
Fluvirin® (Diagnostics Limited)
Fluzone® (Sanofi Pasteur Inc.)

Per the FDA, they are designed to protect against A/Brisbane/59/2007 (H1N1)-like virus, A/Brisbane/10/2007 (H3N2)-like virus, and a B/Florida/4/2006-like virus. For more information on the prevention and control of influenza, visit the CDC/ACIP immunization recommendations for 2008

at www.cdc.gov.

If a member cannot tolerate the injectable form of the vaccine then FluMist is an option.

FluMist® (influenza virus vaccine live, intranasal): FluMist is a vaccine indicated for the active immunization of individuals **2 to 49 years of age** against the influenza disease caused by influenza virus subtypes A and type B. A health care provider must administer it intra-nasally.

FluMist should not be administered to any individuals with asthma. FluMist should not be administered to children aged <5 years of age with recurrent wheezing because of the potential for increased risk of wheezing post vaccination unless the potential benefits outweigh the risks. Do not administer FluMist to children less than 2 years of age because of increased risk of hospitalization and wheezing observed in clinical trials. FluMist is a live vaccine and careful consideration of the potential benefits and risks should be considered before administration to immunocompromised persons.

To locate retail pharmacies that will be carrying FluMist for the 2008-2009 influenza season, please visit www.FluMist.com.

Rituxan® (rituximab) Injection: Rituxan is a genetically engineered anti-CD20 monoclonal antibody currently approved for the treatment of B-cell non-Hodgkin's lymphoma (NHL) and for the treatment of moderate to severe Rheumatoid Arthritis (RA). Rituxan selectively depletes CD20 B cells, which plays a role in the autoimmune response and in the chronic synovitis, associated with RA. Rituxan will require a Prior Authorization for use. The formulary criteria for Rituxan were approved by the committee and are listed below. Ongoing input from both national organizations and local experts will be received and adjustments will be made as needed.

Approved Formulary Criteria for Prior Authorization for Rituxan Injection

Approved Indications:

1. Non-Hodgkin's Lymphoma (NHL)

- Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell NHL as a single agent.
- Previously untreated follicular, CD20-positive, B-cell NHL in combination with CVP (cyclophosphamide, vincristine, and prednisone) chemotherapy.
- Non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL, as a single agent, after first-line chemotherapy.
- Previously untreated diffuse large B-cell, CD20-positive NHL in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, and prednisolone) or other anthracycline-based chemotherapy regimens.

2. Rheumatoid Arthritis (RA)

- Criteria for approval:
 1. Must be prescribed by a rheumatologist.

2. Patient is 18 years or older.
 3. Documented presence of moderate to severe rheumatoid arthritis.
 4. Documented trial and failure to at least one TNF inhibiting drug or has been intolerant to treatment with at least three TNF-inhibiting drugs such as Enbrel® (*etanercept*), Humira® (*adalimumab*), and Remicade® (*infliximab*).
 5. Must be given in conjunction with methotrexate (MTX).
 6. Will not be approved for use in combination with a TNF-inhibiting drug such as Enbrel®, Humira®, and Remicade® or with Orencia® (*abatacept*).
- Dosing criteria: The recommended dose for the treatment of RA is two 1000mg IV infusions separated by 14 days.
 - Retreatment criteria: Continued use will require Prior Authorization and will only be approved after 6 months have passed from the last course of treatment, and only if retreatment is necessary to control symptoms.

The following indications listed below will be considered for approval for treatment with Rituxan if the dosing and length of therapy are supported by, and are consistent with published medical evidence. Continuation of treatment or retreatment with Rituxan for the following indications listed below will only be approved if medically necessary, if clinical improvement has been demonstrated, and if supported by published medical evidence.

- Chronic inflammatory polyneuropathy/IgM-associated polyneuropathy.
- Corticosteroid refractory pemphigus vulgaris or pemphigus foliaceus.
- Graft versus host disease.
- Multicentric Castleman's disease (angiofollicular lymph node hyperplasia).
- Multiple Sclerosis (MS).
- Myasthenia Gravis.
- Neuromyelitis optica.
- Post-transplant lymphoproliferative disorder (PTLD).
- Prophylaxis of rejection in sensitized kidney transplant recipients with donor specific antibodies.
- Refractory autoimmune hemolytic anemia (AIHA).
- Refractory immune or idiopathic thrombocytopenic purpura (ITP).
- Relapsed or refractory hairy cell leukemia (HCL) in persons who have failed at multiple (two or more) courses of cladribine.
- Second-line treatment of persons with relapsed or refractory CD20 positive chronic lymphocytic leukemia (CLL).
- Symptomatic persons with stage III-IV nodular lymphocyte-predominate Hodgkin's disease (LNPHD) who are refractory or intolerant to standard chemotherapy.
- Systemic lupus erythematosus (SLE).
- Waldenstrom's macroglobulinemia (WM).
- Wegener's granulomatosis.

Any other medical conditions or exceptions to the above conditions of coverage for Rituxan will be considered through the pharmacy exception process. Clinical, peer-reviewed, published evidence will be required for any diagnosis not otherwise listed.

Botox® (Botulinum Toxin Type A): Botox is a neurotoxin complex that inhibits neuromuscular transmission and produces a temporary localized reduction in muscle activity. Botox will require a Prior Authorization for use. The formulary criteria were approved by the committee and are listed below. We will continue to receive ongoing input from both national organizations and local experts, and adjustments will be made as needed.

Approval Formulary Criteria for Prior Authorization for Botox

Approved indications:

- 1. Blepharospasm** (doses of 100 units or less).
- 2. Cervical Dystonia** (doses of 300 units or less).
- 3. Severe primary axillary hyperhidrosis** (doses of 100 units or less) that meets the following criteria:
 - Documented trials and failures of anticholinergics and drying agents such as topical aluminum chloride (DrySol®, Xerac AC®, and Hypercare®).
- 4. Strabismus** (doses of 100 units or less).
- 5. Cerebral Palsy** (doses of 400 units or less).
- 6. Facial Nerve Disorder/Hemi-facial Spasm** (doses of 100 units or less).
- 7. Laryngeal Dystonia** (doses of 100 units or less).
- 8. Limb Dystonia** (doses of 100 units or less).
- 9. Migraines** (doses of 100 units or less) that meets the following criteria:
 - Documented trials and failures with conventional and prophylactic therapies **AND**
 - Must be written by a neurologist.
- 10. Severe palmar hyperhidrosis** (doses of 100 units or less) that meets the following criteria:
 - Documented trials and failures of anticholinergics and drying agents such as topical aluminum chloride (DrySol, Xerac AC, and Hypercare).
- 11. Spasmodic Torticollis** (doses of 300 units or less).
- 12. Spasticity resulting from an acquired or congenital brain disorder** (doses of 400 units or less).

Any exceptions to the above conditions of coverage for Botox will be considered through the pharmacy exception process. Clinical, peer-reviewed, published evidence will be required for any diagnosis not otherwise listed.

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

Drug Name (all strengths available are included)	Salud, SCI, NMRx	Commercial	Medicare/Senior
Cleocin Pediatric 75mg/5ml powder for solution (Clindamycin)	Formulary	Tier 2	Tier 2
Tamiflu capsules and suspension (oseltamivir)	Formulary if aged ≤18 or ≥65 years. PA* required if aged 19-64 years. QL** - #10/180 days	Tier 3 if aged ≤18 or ≥65 years. PA required if aged 19-64 years. QL - #10/180 days	Tier 3 if aged ≤18 or ≥65 years. PA required if aged 19-64 years. QL - #10/180 days
Relenza diskhaler (zanamivir)	Formulary if aged ≤18 or ≥65 years. PA required if aged 19-64 years. QL - #1 inh/180days	Tier 3 if aged ≤18 or ≥65 years. PA required if aged 19-64 years. QL- #1 inh/180 days	Tier 3 if aged ≤18 or ≥65 years. PA required if aged 19-64 years. QL - #1 inh/180 days
FluMist (Influenza Virus Vaccine Live nasal spray)	Formulary	Tier 2	Non-Formulary Covered under Medicare Part B for members under the age of 49. Not covered under Medicare Part D.
Rituxan (rituximab)	PA required	PA required	PA required
Botox (Botulinum toxin type A)	PA required	PA required	PA required

*PA – Prior Authorization

**QL – Quantity Limit

The following medications were added to the formularies because they met the Presbyterian Health Plan P&T Committee formulary inclusion criteria for combination medications.

Drug Name (all strengths available are included)	Salud, SCI, NMRx	Commercial	Medicare/Senior
Avandamet® tablets (Avandia®/metformin)	Formulary Step Edit required*	Tier 2 Step Edit required	Tier 2 Step Edit required
ACTOPlus met® tablets (Actos®/metformin)	Formulary Step Edit required	Tier 2 Step Edit required	Tier 2 Step Edit required
Duetact® tablets (Actos/glimepiride)	Formulary Step Edit required	Tier 2 Step Edit required	Tier 2 Step Edit required
glyburide/metformin tablets (generic for Glucovance®)	Formulary Step Edit required	Tier 1 Step Edit required	Tier 1 Step Edit required
glipizide/metformin tablets (generic for Metaglip®)	Formulary Step Edit required	Tier 1 Step Edit required	Tier 1 Step Edit required
Advicor® tablets (Niaspan® & lovastatin)	Formulary Step Edit required	Tier 2 Step Edit required	Tier 3
Simcor® tablets (Niaspan & simvastatin)	Formulary Step Edit required	Tier 2 Step Edit required	Tier 2 Step Edit required
Janumet® tablets (Januvia® & metformin)	Non-Formulary PA** required	Tier 3 PA required	Tier 3 PA required

*Step Edit requirement is prior to prescription use in the previous 120 days of one medication in the combination product. Once the Step Edit requirement is met then the combination medication will process at the pharmacy without a Prior Authorization. If the Step Edit requirement is not met then a Prior Authorization will be required.

**PA – Prior Authorization

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>

Byetta (Exenatide): As of August 18, 2008, the FDA (Food and Drug Administration) is working with Amylin Pharmaceuticals to add stronger and more prominent warnings in the product label for Byetta about the risk of acute hemorrhagic or necrotizing pancreatitis. The FDA has received reports of 6 cases of hemorrhagic or necrotizing pancreatitis in patients taking Byetta. Byetta and other potentially suspect drugs should be promptly discontinued if pancreatitis is suspected.

Vytorin® (ezetimibe/simvastatin): As of September 3, 2008, the FDA is investigating a report from the SEAS trial (Simvastatin and Ezetimibe in Aortic Stenosis) of a possible association between the use of Vytorin and a potentially increased incidence of cancer. The FDA though has determined that, to date, these findings in the SEAS trial plus interim data from ongoing trials should not prompt patients to stop taking Vytorin or any other cholesterol lowering drugs.

Simvastatin and amiodarone: As of August 8, 2008, the FDA is notifying the public of the risk of rhabdomyolysis when simvastatin is used with amiodarone. The risk is dose related and increases when simvastatin doses greater than 20mg per day are given with amiodarone. Per the FDA prescribers should avoid doses of simvastatin greater than 20mg per day in patients taking amiodarone.

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 or by phone at (505) 923-5530. He can be reached Monday through Friday from 8:00 a.m. to 5:00 p.m. As always, thank you for partnering with us to improve the health of individuals, families and communities

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 Prior Authorizations. Please visit the Provider page online at www.phs.org for more information.

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

Sincerely,



Larry Georgopoulos, B.S.Pharm. R.Ph.
Pharmacy Director
Presbyterian Health Plan
(505) 923-5530
lgeorgop@phs.org



Julie DiTucci-Reiter, R.Ph.
Clinical Pharmacist
Presbyterian Health Plan
(505) 923-5404
jditucci@phs.org

**Pharmacy Authorization Review Process Form
For TAMIFLU® or RELENZA®**

Please complete all the below sections for this request to be considered for approval.

*****ONE DRUG PER FORM*****

<p align="center">Patient Information</p> <p>ID Number: _____</p> <p>Social Security Number: _____ - _____ - _____</p> <p>Member Name: _____</p> <p>Date of Birth: _____</p>	<p>Drug: <input type="checkbox"/> Tamiflu 75mg <input type="checkbox"/> Tamiflu 12 mg/ml</p> <p> <input type="checkbox"/> Tamiflu 30mg</p> <p> <input type="checkbox"/> Tamiflu 45mg <input type="checkbox"/> Relenza 10mg</p> <p>Dosing: _____</p> <p>Length of Therapy: _____</p> <p>Diagnosis: _____</p> <p>Requesting Physician: _____</p> <p>Physician Signature: _____</p> <p>Specialty: _____ Requestor: _____</p> <p>Physician Phone Number: _____</p> <p>Physician Fax Number: _____</p>
---	---

Criteria for approval:

1. **For members aged ≤18 or ≥65 years:** Prior Authorization **IS NOT REQUIRED**.
 - Treatment or prophylaxis will be covered once per 180 days with the following quantity limits:
 - ♦ 10 capsules of Tamiflu or a 10-day course of Tamiflu suspension.
 - ♦ 10 doses (1 diskhaler) of Relenza.

2. **For members aged 19 to 64 years:** Prior Authorization **IS REQUIRED** using this Form.
 - One course of **treatment** per 180 days will be approved if all of the following criteria are met:
 1. The member is immunocompromised - please list medical conditions below: _____.

AND

- A. Positive influenza test within 48 hours of the first influenza symptoms.
When was test conducted? Date____ Time____AM/PM

OR

- B. Documented influenza symptoms within 48 hours from this request.
When did first influenza symptoms start? Date____ Time____AM/PM

Please return completed Form to: (505) 923-5540 (fax). For assistance with this Form, please call (505) 923-5757 or 1-888-923-5757 and select option 3 for Pharmacy Services Department.

Pharmacy Services Use Only		
PA NUMBER: _____ <input type="checkbox"/> APPROVED _____ <input type="checkbox"/> DENIED _____ RPh. Review: _____ Date: _____ Medical Director: _____ Date: _____ _____ _____	ASO _____ COMM _____ PIC _____ MCAID _____ SRCARE _____	