

April 14, 2009

Dear Healthcare Practitioner:

Presbyterian Health Plan and Presbyterian Insurance Company, Inc. (Presbyterian) Pharmacy and Therapeutics Committee (P&T Committee) met on March 18, 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, 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

Uloric® tablets (febuxostat). The Food and Drug Administration (FDA) have recently approved Uloric tablets. Uloric is a xanthine oxidase inhibitor indicated for the chronic management of hyperuricemia in patients with gout. The committee voted and approved adding Uloric tablets to the Presbyterian formularies with the following Pharmacy Exception criteria:

Indications for approval:

1. Gout Prophylaxis

AND

2. One of the following criteria must be met:

- a. Documented failure at maximal therapeutic doses (600mg/day) of allopurinol (generic for Zyloprim®). A documented failure is considered as non-resolution of tophi or at least 4 gout attacks (joint flares) per year with demonstrated medication compliance.

OR

- b. Documented intolerance to allopurinol. Examples of intolerance include skin reactions or cytopenias.

OR

- c. Treatment failure of allopurinol due to documented renal insufficiency.
Example: $\text{CrCl} \leq 10\text{ml/min}$.

Euflexxa™ and Synvisc-One® (Hyaluronic acid) injections. Euflexxa and Synvisc-One are intra-articular viscosupplement injections that are indicated for the treatment of pain due to osteoarthritis of the knee. This treatment is for patients who have failed to adequately respond to conservative non-pharmacologic therapy and simple analgesics such as acetaminophen. The committee voted and approved adding Euflexxa and Synvisc-One to the Presbyterian formularies.

Formulary Pharmacy Exception Criteria Revisions

Cymbalta® (duloxetine) capsules. The FDA has recently approved Cymbalta for the treatment of fibromyalgia. The committee voted to approve the revision to the Pharmacy Exception criteria for Cymbalta capsules.

Indications for approval:

1. Depression – the patient must have a documented failure at therapeutic doses on two antidepressants, which include Selective Serotonin Reuptake Inhibitors (SSRIs), Serotonin-Norepinephrine Reuptake Inhibitors (SNRIs), or bupropion (generic for Wellbutrin®).
2. Neuropathic pain – the patient must have a documented failure at therapeutic doses of all of the following:
 - a. Gabapentin (generic for Neurontin®).
 - b. One of the following alternatives:
 - A tricyclic antidepressant such as amitriptyline (generic for Elavil®), desipramine (generic for Norpramin®), or nortriptyline (generic for Pamelor®).
 - Lamotrigine (generic for Lamictal®)
 - Divalproex (generic for Depakote®)
 - Carbamazepine (generic for Tegretol®)
3. Fibromyalgia – the patient must have a documented failure of all of the following:
 - a. A daily low-impact exercise program.
 - b. A tricyclic antidepressant at therapeutic doses such as amitriptyline, desipramine, or nortriptyline.
 - c. Gabapentin at a therapeutic dose (1,200 to 2,400 mg/day).

Quantity limits:

20mg and 30mg capsules – 60 capsules for 30 days

60mg capsules – 30 capsules for 30 days

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

Drug Name (all strengths available are included)	Salud, SCI, NMRx	Commercial	Medicare/Senior
Divalproex sodium extended release tablets and capsules (generic for Depakote® and Depakote Sprinkles®)	Covered	Tier 1	Tier 1
Uloric tablets (Febuxostat)	PE* required QL** of #30/30 days	3rd tier PE required QL of #30/30 days	3rd tier PE required QL of #30/30 days
Euflexxa (Hyaluronic acid)	Covered under Medical Benefit	Covered under Medical Benefit	Covered under Medical Benefit

*PE – Pharmacy Exception

**QL – Quantity Limit

SUMMARY OF P&T SAFETY ISSUES

For complete information, please go to the following website:

<http://www.fda.gov/medwatch/safety/2009/safety09.htm>

Ethex Corporation. On January 28, 2009, the Ethex Corporation and the FDA issued a nationwide voluntary recall of certain products and their lot numbers to a wholesale or a retail level. This recall was issued as a precautionary measure because they may have been manufactured under conditions that did not sufficiently comply with current Good Manufacturing Practices. Some of these products have had specific lots recalled earlier due to defects found, including oversized tablets that may deliver higher than labeled doses. Products recalled to the retail level include: *Hydromorphone tablets, Metoprolol Succinate extended release tablets, Isosorbide Mononitrate extended release tablets, Propafenone tablets, and Morphine Sulfate extended release tablets.* Presbyterian Health Plan has identified those members who were taking the above medications manufactured by Ethex Corporation and has informed them of the recall by a mailed letter. The mailed letter instructed those members to call their dispensing pharmacy for more for specific information.

Raptiva®. On February 19, 2009, the FDA issued a public health advisory concerning three confirmed reports, and one other possible report of progressive multifocal leukoencephalopathy (PML), a rare brain infection, in patients using the psoriasis drug efalizumab (Raptiva). Of those patients, three have died. All four patients were treated with the drug for more than three years. Efalizumab is a once a week injection that is approved for adults with moderate to severe plaque psoriasis and who are candidates for systemic therapy.

Metoclopramide (generic for Reglan®). On February 26, 2009, the FDA mandated that manufacturers of metoclopramide add a black box to the product labeling that warns about the fact that chronic use has been linked to tardive dyskinesia, even after the drug is no longer being taken. The FDA wants patients and healthcare professionals to know about this risk so that they can make an informed decision about treatment, and that the chronic use of metoclopramide therapy should be avoided in all but rare cases where the benefit is believed to outweigh the risk.

Zonisamide (generic for Zonegran®). On February 23, 2009, after reviewing updated clinical data, the FDA has determined that zonisamide can cause metabolic acidosis in some patients. The FDA is working with the manufacturers of zonisamide to revise the product labeling to reflect this new safety information.

Plavix® (clopidogrel) and Proton Pump Inhibitors (PPIs). On January 26, 2009, the FDA announced that they are aware of published reports that clopidogrel is less effective in some patients than it is in others. The FDA has notified healthcare professionals about the fact that the makers of Plavix have agreed to work with the FDA to conduct studies. These studies are to obtain additional information that will allow a better understanding and characterization of the effects of generic factors and other drugs (especially PPIs) on the effectiveness of clopidogrel. Until further information is available the FDA recommends the following:

- Healthcare providers should continue to prescribe. Patients should continue to take clopidogrel as directed because clopidogrel has demonstrated benefits in preventing blood clots that could lead to a heart attack or stroke.

- Healthcare providers should re-evaluate the need for starting or continuing treatment with a PPI, including Prilosec OTC, in patients taking clopidogrel.
- Patients taking clopidogrel should consult with their healthcare provider if they are currently taking or considering taking a PPI.

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, 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 for more information.

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

Sincerely,



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