



Provider Update

From Presbyterian Health Plan and Presbyterian Insurance Company Inc. (Presbyterian)

January/February 2010

Dear Healthcare Practitioner:

The P&T Committee meets every month to promote the appropriate use of drugs, maintain the formularies, and to support our network of practitioners. The P&T Committee met on **January 20, 2010** and we would like to share with you the decisions made at that meeting that affect our formularies and pharmacy benefits.

❖ Summary of P&T Committee Decisions (effective February 1, 2010)

Drug Name (all strengths available are included unless indicated)	Salud/SCI/NMRx	Commercial	Senior Care and Medicare PPO (pending CMS approval)
azelastine ophthalmic solution (generic for Optivar®)	Covered	Tier 1	Tier 1
tramadol ER tablets 100mg, 200mg (generic for Ultram® ER)	Not Covered	Tier 1 QL of #30/30 days	Tier 1 QL of #30/30 days
ciclopirox shampoo (generic for Loprox®)	Not Covered	Tier 1	Tier 1
fluoxetine tablets and capsules (generic for Prozac®)	Covered	Tier 1	Tier 1
naltrexone tablets (generic for ReVia®)	Covered	Tier 1	Tier 1
Valcyte® (valganciclovir) tablets	PA required QL of #60/30 days	Tier 4 QL of #60/30 days	Tier 4 QL of #60/30 days
Campral® (acamprosate) tablets	PA required QL of #180/30 days	Tier 3, PA required QL of #180/30 days	Tier 3, PA required QL of #180/30 days
Vivitrol® (naltrexone) injection	PA required QL of #1 vial/30 days	Tier 3, PA required QL of #1 vial/30 days	Part B, PA required QL of #1 vial/30 days

QL = Quantity Limits/PA = Prior Authorization
CMS = Centers for Medicare and Medicaid Services

U. S. Food and Drug Administration (FDA) safety alerts from November 2009 to January 2010

For complete information, please go to the following website: www.fda.gov/medwatch/ /2009/safety09.htm

- **Clopidogrel (Plavix®) and omeprazole (Prilosec®).** Safety information has been released regarding an interaction between clopidogrel and omeprazole which shows that when taken together the effectiveness of clopidogrel is reduced.
- **Sibutramine (Meridia®).** A new contraindication has been added to the prescribing information which states that is not to be used in patients with a history of cardiovascular disease.
- **Valproic acid and divalproex sodium.** Studies have shown an increased risk of neural tube defects and other major birth defects in babies exposed to valproate and related products during pregnancy.
- **Diclofenac sodium topical gel (Voltaren Gel®).** Revisions to the Hepatic Effects section of the prescribing information include warnings about the potential for elevations in liver function tests during treatment with all products containing diclofenac.
- **Desipramine (Norpramin®).** Changes to the Warnings and Overdosage sections of the prescribing information state that extreme caution should be used when given to patients with a family history of sudden death or cardiac dysrhythmias.

❖ **Formulary Criteria Additions/Revisions**

To see the complete Presbyterian Formulary Exception Criteria document online, please access:

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

➤ **Valcyte (valganciclovir) tablets**

Indications for approval:

- Treatment of CMV retinitis in adult AIDS patients.
- Prevention of CMV disease in kidney, heart, and kidney-pancreas transplant adults patients at high risk.
- Prevention of CMV disease in kidney and heart pediatric transplant patients at high risk.

Quantity Limit: 60 tablets for 30 days.

➤ **Campral (acamprosate) tablets**

Indications for approval: Alcohol dependence that meets the following criteria:

- A documented trial and failure with either naltrexone tablets or disulfiram. **OR**
- Severely impaired liver function (Liver function tests that are more than 3 times normal values). **AND**
- Patient is engaged in a comprehensive management program that includes a psychosocial component of the therapy (i.e. psychosocial behavioral interventions* focused on relapse prevention) during the entire course of therapy.

Quantity Limit: 180 tablets for 30 days.

➤ **Vivitrol (naltrexone) Injection**

Indications for approval: Alcohol dependence that meets the following criteria:

- A documented trial and failure of oral naltrexone tablets plus one other oral deterrent agent such as disulfiram or acamprosate (Campral). **AND**
- The patient is engaged in a comprehensive management program that includes a psychosocial component of the therapy (i.e. psychosocial behavioral interventions* focused on relapse prevention) during the entire course of therapy.

Quantity Limit: One vial per month.

*Intervention examples include, but are not limited to; an intensive outpatient program, individual or group counseling for substance abuse and dependence, or regular attendance at Alcoholics Anonymous. (AA).

➤ **Reclast® (zoledronic acid) injection**

Indications for approval (5 indications total):

- Osteoporosis: A hip, spine, or radius T-score ≤ -2.5 .
- Osteopenia (low bone mass): A hip, spine, or radius T-score between -1.0 and -2.5.
- Glucocorticoid-induced osteoporosis: Patients expected to be on glucocorticoids for at least 12 months.
- The patient does not meet criteria for any of the above indications but does have a 10-year hip fracture probability $\geq 3\%$ or a 10-year major osteoporosis-related fracture probability $\geq 20\%$ based on the US-adapted WHO absolute fracture risk model, FRAX®, available online at <http://www.shef.ac.uk/FRAX>.

AND ALL OF THE ABOVE INDICATIONS MUST MEET ONE OF THE FOLLOWING:

- a) Gastrointestinal (GI) intolerance to one oral bisphosphonate. **OR**
- b) GI contraindication to one oral bisphosphonate. **OR**
- c) A non-responder to at least one oral bisphosphonate.

- Paget's disease:

Criteria for continuation of therapy:

- For osteoporosis, must demonstrate no decrease or an increase in BMD after 12 months of therapy.
- For osteoporosis, patients already receiving Reclast who's T-scores have since improved to a low bone mass range (between -1.0 to -2.5); future approvals will be based on the original osteoporosis qualifying criteria.

Quantity Limit:

For osteoporosis or Paget's disease:

One 5mg infusion per 12 months.

Osteopenia: One 5mg infusion per 24 months.

All of the Presbyterian formularies are available online at

www.phs.org/PHS/programs/pharmacy/index.htm

They are also downloadable onto most hand-held devices with the Epocrates Rx software

The changes to the formularies, as outlined above, are based on requests from our practitioners and by the recommendations of the P&T Committee. We value your input. If you have any concerns, please contact the Pharmacy Director, Larry Georgopoulos, PharmD at lgeorgop@phs.org or at (505) 923-5530. You can also contact the author of this newsletter, Julie DiTucci-Reiter, PharmD at jditucci@phs.org or at (505) 923-5404, Monday through Friday from 8:00 a.m. to 5:00 p.m.

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