Pharmacy and Therapeutics (P&T) Committee Meeting Record

Date: April 15, 2011 **Time:** 9:00 a.m. – 4:00 p.m. **Location:** Idaho Medicaid, 3232 Elder Street, Conference Room D

Moderator: Phil Petersen, M.D.

Committee Members Present: Phil Petersen, M.D.-Chair; Perry Brown, M.D.; William Woodhouse, M.D.; Dennis Tofteland, RPh; John Mahan, M.D.; Catherine Hitt, PharmD; Mark Johnston, RPh; Tami Eide, PharmD ; Mark Turner, M.D.
Others Present: Steve Liles, PharmD; Mark England, PharmD; Bill Milne, RPh; Jane Gennrich, PharmD; Cody Scrivner; Rachel Strutton
Committee Members Absent: Elaine Ladd, PharmD; Scott Malm, PA-C

AGENDA ITEMS	PRESENTER	OUTCOME/ACTIONS
CALL TO ORDER	Phil Petersen, M.D.	Dr. Petersen called the meeting to order.
Committee Business		
➢ *Roll Call*	Phil Petersen, M.D.	Dr. Petersen completed the roll call, welcomed the P&T Committee members and called the meeting to order.
➢ *Reading of Mission Statement*	Phil Petersen, M.D.	Dr. Petersen read the Mission Statement.
➢ *Approval of Minutes from August 27, 2010 Meeting*	Phil Petersen, M.D.	There were no corrections. The August 27, 2010 meeting minutes were accepted as proposed.
➢ *DERP Update and Key Questions*	Tami E. PharmD	Dr. Eide presented the following Drug Effectiveness Review Project (DERP) Key Questions: <u>Newer Antiplatelets</u> – in draft form now, duration of therapy was added, Pletal was added <u>Pharmacologic Treatments for ADHD</u> – non-stimulant drugs (clonidine, guanfacine) have been added, distinctions made between immediate release vs intermediate release vs long acting <u>Long-Acting Opioid Analgesics</u> – added Exalgo, Butrans, Embeda; removed acute non-surgical back pain <u>Targeted Immune Modulators</u> – include patients with co-morbidities as a sub-group; added Stelara and Actemra; removed avoidance of surgery as an effectiveness outcome
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➢ *Update on Atypical Antipsychotics by Diagnosis*	Tami E. PharmD	Dr. Eide provided an oral update on prescribing of Atypical Antipsychotics by Diagnosis: Due to problems with the MMIS data warehouse and reporting software, diagnosis codes needed to analyze the

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<td>new criteria discussed in the August 2010 meeting are not yet accessible. There is hope these diagnosis codes will be available soon.</td>
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<td>Public Comment Period</td>
<td>Phil Petersen, M.D.
Cody Scrivner</td>
<td>Public Comment Period

One person signed up to speak during the public comment period. Public testimony was received from the following speaker:

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<tr><th>Speaker</th><th>Representing</th><th>Agent</th><th>Class</th></tr>
<tr><td>Kara Taggart
MD - urologist</td><td>Self</td><td>Toviaz</td><td>Bladder Relaxant Preparations</td></tr>
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See attached transcription record.</td>
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<td>Proposed changes to
Public Comment guidelines</td>
<td>Phil Petersen, M.D.</td>
<td>Dr. Petersen proposed changing the current public testimony guidelines. The goal of these proposed changes is to have the best data available for review by the P&T Committee members.

Dr. Woodhouse moved to let the industry representatives have the ability to provide a statement of additional evidence only when that data was not available in either the DERP or Provider Synergies reports. The DERP and Provider Synergies reviews are posted on the Idaho Medicaid website prior to the P&T Committee meetings. This statement must be sent to Idaho Medicaid 15 days in advance of the P&T Committee meeting. The statement should be limited to 250 words or less and must specifically point out the information to be considered. Information that will be considered includes new studies released since the last review, excluding placebo studies, and new products or new indications that are not included in the information posted on the website.

There should also be an avenue for industry representatives to dispute any omission and/or misunderstanding of the provided information on the part of the committee. It was recommended to provide an opportunity for the industry representatives to provide their arguments to the Chair, in writing, for consideration by the P&T Committee members.

The Committee decided to hold the May 20, 2011, P&T meeting under the current public comment guidelines. The Committee also requested the Department to draft up the newly proposed guidelines to be reviewed and voted on during the May 2011 meeting. At that time the Committee will review, revise if necessary and vote to accept or reject these new proposed guidelines.

Public comment guidelines for non industry representatives (e.g. healthcare practitioners and Idaho Medicaid participants) will remain the same.</td>
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Drug Class Reviews and Committee Recommendations		Drug Class Reviews and Committee Recommendations
Newer Diabetes Medications, TZDs and Combinations	Roberta (Candy) Wines, MPH - RTI-UNC EPC (audiotape)	Newer Diabetes Medications, TZDs and Combinations This presentation by DERP was a recorded audiotape. The presentation included comparative efficacy and effectiveness and harms for pramlintide, sitagliptin, saxagliptan, exenatide, liraglutide, rosiglitazone and pioglitazone. The fixed dose combination products Avandamet, Avandaryl, Actoplus Met, Duetact and Janumet were also included in the evaluation. The Committee members were informed that if they had any questions for this speaker, Dr. Eide would forward them to DERP for a response. There were no questions. **Committee Recommendations** The Committee concluded that the evidence did not support differences in safety or effectiveness between Byetta and Victoza or Januvia and Onglyza or their combinations with metformin. The committee recommended continuing the current therapeutic criteria for all agents.
Thiozolidinedione Safety DUR Report	Mark England, PharmD Magellan Medicaid	Thiozolidinedione Safety DUR Report The current FDA safety concerns were reviewed. There are still a number of Idaho Medicaid participants receiving Avandia. REMS (Risk Evaluation and Mitigation Strategies) will shortly be mandated by the FDA. Prescribers for Idaho Medicaid participants currently receiving Avandia were recently mailed this information. **Committee Recommendations** The Committee recommended switching Avandia to non-preferred status and implementing therapeutic criteria that match the FDA recommendations. Actos should only be approved after failure of metformin and/or a sulfonylurea or contraindication to their use.
Hypoglycemics, Insulin	Steve Liles, PharmD Provider Synergies	Hypoglycemics, Insulin There was no new clinical data on insulins. **Committee Recommendations** The Committee had no specific recommendations for change. They felt that there was no clinical reason to have Apidra (insulin glulisine) as preferred or non-preferred, but it should remain non-preferred if it was less cost effective than similar insulins.
Hypoglycemics, Meglitinides	Steve Liles, PharmD Provider Synergies	Hypoglycemics, Meglitinides Utilization is very low for this class of medications.

		Committee Recommendations The Committee recommended removing this class of drugs from the PDL due to very low utilization.
Angiotensin Modulators/Angiotensin Modulator Combinations	Steve Liles, PharmD Provider Synergies	<u>Angiotensin Modulators/Angiotensin Modulator Combinations</u> **Angiotensin Modulators**: Dr. Liles provided a review on Angiotensin Receptor Blockers (ARBs). Cozaar is now available generically. **Angiotensin Modulator Combinations:** Dr. Liles provided a review of three new products (Tekamlo –aliskerin + amlodipine), Amturnide (aliskerin + amlodeipine + HCTZ) and Tribenzor (olmesartan + amlodipine + HCTZ). He also provided results of one Meta-Analysis. Hyzaar (losartan-hydrochlorothiazide) is now available generically. **Committee Recommendations** **Angiotensin Modulators:** The Committee felt there were no evidence based differences to support preference of one agent over another in the ARB, ACE inhibitor or their diuretic combinations classes. **Angiotensin Modulator Combinations:** The Committee felt there were no evidence based differences in this class. They felt there was no convincing evidence that the angiotensin modulators plus calcium channel blockers improved outcomes and that they should not be used first line. **Direct Renin Inhibitors and Combination Products:** The Committee concluded that the evidence did not support differences in efficacy or effectiveness or harms and these these agents should not be used first line.
Beta Blockers	Steve Liles, PharmD Provider Synergies	<u>Beta Blockers</u> There was no new clinical data to share with the Committee. **Committee Recommendations** The Committee felt there was no new evidence to support clinically preferring any agent over another.
Calcium Channel Blockers	Steve Liles, PharmD Provider Synergies	<u>Calcium Channel Blockers</u> There are no longer cost differences between diltiazem ER (extended release) and diltiazem LA (long acting) so these products will be combined. **Committee Recommendations** The Committee felt there were no evidence based differences to support any changes to this class

Lipotropics, Other	Steve Liles, PharmD Provider Synergies	Lipotropics, Other Dr. Liles provided a review of the ACCORD (NHLBI) study and one clinical trial for Lovaza, plus one meta-analysis. **Committee Recommendations** The Committee felt there were no evidence based differences to support any changes to this class, but felt gemfibrozil should remain as preferred. The Committee felt that there were no clinically significant differences between the various fenofibrate medications.
Lipotropics, Statins	Steve Liles, PharmD Provider Synergies	Lipotropics, Statins Dr. Liles provided a review of the new product Livalo (pitavastatin) with one clinical trial for this new drug and the new indications for rosuvastatin. He provided a review of the Stroke (AHA/ASA 2010) guidelines, FDA warning for simvastatin, the Heart Protection Study #2 and FDA review of cancer risk with ezetinibe. Also provided were the MESA, SHARP and SEARCH clinical trials, a post hoc analysis and one meta analysis. **Committee Recommendations** The Committee felt there were no evidence based differences to support preferring agents in this class. The Committee stated that the new agent Livalo does not need to be preferred. No specific recommendations were made for the combination products.
Anticoagulants	Steve Liles, PharmD Provider Synergies	Anticoagulants Dr. Liles provided review of the new product dabigatran (Pradaxa), the RELY clinical trial and the AHA/ASA (2011) Stroke Prevention guidelines. **Committee Recommendations** The Committee did not see evidence to support differences in the injectable anticoagulants. The Committee recommended that both warfarin and Pradaxa be preferred , but that Pradaxa have therapeutic criteria for its FDA approved indication for stroke prophylaxis in patients with atrial fibrillation
Platelet Aggregation Inhibitors	Steve Liles, PharmD Provider Synergies	Platelet Aggregation Inhibitors Dr. Liles provided a review of the FDA warnings on concomitant PPI use with Plavix, and the ACC/AHA statement on the warning. He also provided a review of two clinical trials on clopidogrel dosing. There was some discussion on Effient, but there is no new clinical evidence for review. **Committee Recommendations** The committee recommended that Ticlid and Effient remain non-preferred due to safety concerns.

PAH Agents	Steve Liles, PharmD Provider Synergies	<u>PAH Agents</u> There was no new clinical data to share with the Committee. **Committee Recommendations** The Committee felt that there was no evidence based differences to support differences in agents in this class. They felt the criteria should remain for Revatio and Adcirca.
Topical Androgenic Agents	Steve Liles, PharmD Provider Synergies	<u>Topical Androgenic Agents</u> There was no significant new clinical data to share with the Committee. **Committee Recommendations** The Committee recommended adding therapeutic criteria of a documented decreased testosterone level. The Committee stated that there were no clinical differences between the various products. The Committee did recommend having a minimum of one patch and one gel as preferred agents.
BPH Treatments	Steve Liles, PharmD Provider Synergies	<u>BPH Treatments</u> Dr. Liles provided a review of a new drug - Jalyn (dutasteride/tamsulosin). Flomax is now available generically as tamsulosin. **Committee Recommendations** The Committee felt that the evidence did not support differences in efficacy, effectiveness or safety. They concluded that Jalyn had not been shown to be superior in clinical studies and should only be preferred if cost effective.
Bladder Relaxant Preparations	Steve Liles, PharmD Provider Synergies	<u>Bladder Relaxant Preparations</u> There was no new significant clinical data to share with the Committee. **Committee Recommendations** The Committee felt that there was no evidence to place one agent over another. The Committee recommended that oxybutynin ER be preferred and not require a PA for children age 5-18 years. They felt that a variety of agents needed to be available due to differences in tolerance.

Bone Resorption Suppression and Related Agents	Steve Liles, PharmD Provider Synergies	<u>Bone Resorption Suppression and Related Agents</u> Dr. Liles provided a review of two new products - Atelvia (risedronate delayed release) and Prolia (densoumab). He also presented data from the AACE (2010) guidelines and two new clinical trials. **Committee Recommendations** The Committee felt there were no evidence based differences in safety and that the Foreteo clinical criteria should remain. They felt effectiveness differences could be better interpreted when > 5 year therapy outcomes were available.
Phosphate Binders	Steve Liles, PharmD Provider Synergies	<u>Phosphate Binders</u> Dr. Liles provided review of one new clinical trial. **Committee Recommendations** The Committee felt there were no evidence based differences to recommend one agent over another. The Committee recommended preferring either Renagel or Renvela, whichever is more cost effective.
Growth Hormone	Steve Liles, PharmD Provider Synergies & Jane Gennrich, PharmD Medicaid	<u>Growth Hormone</u> Dr. Liles provided a review of the new indications for Omnitrope – Idiopathic Short Stature (ISS), Prader-Willi Syndrome (PWS), Small for Gestational Age (SGA) and a new device of Nutropin AQ – NuSpin prefilled cartridge. There was no other new clinical data to share with the Committee. Dr. Gennrich provided a review of the proposed changes to the therapeutic criteria for growth hormone. **Committee Recommendations** The Committee considers these agents therapeutically interchangeable and felt there were no evidence based differences to preferring one agent over another. They felt that device data was not a consideration for the committee. **Committee recommendations for changes to therapeutic criteria changes** Chronic renal impairment – add criteria on parathyroid levels, phosphorus levels, rickets, and slipped capital femoral epiphysis. Growth hormone deficiency – add treatment for hypothyroidism, if present, will be initiated. Prader-Willi Syndrome – add baseline and annual monitoring for obstructive sleep apnea and scoliosis. HIV Cachexia – add initial approval will be for 12 weeks with extension of therapy on a case-by-case basis. Growth Hormone Stimulation testing – define growth hormone deficiency as peak levels < 10ng/ml. Medical Necessity Documentation for Growth – add that height 2 standard deviations below mean or less than 3rd percentile of normal for age/sex is for initial approval only, delete requirement for height velocity at 10th percentile of normal for age/sex tracked over at least one year, and add that radiology report on bone age should include standard deviation and/or confidence intervals. Dr. Gennrich will incorporate these recommendations and have Dr. Perry Brown and Dr. Mark Turner review the final therapeutic criteria.

Erythropoiesis Stimulating Proteins	Steve Liles, PharmD Provider Synergies	<u>Erythropoiesis Stimulating Proteins</u> There was no new clinical data to share with the Committee. **Committee Recommendations** The Committee felt there were no evidence based differences for the agents in this class.
Hepatitis C Agents	Steve Liles, PharmD Provider Synergies	<u>Hepatitis C Agents</u> Dr. Liles provided a review of two new clinical trials and one systematic review. **Committee Recommendations** The Committee felt that his is a drug class that is best left to the decision of specialists and that there should be no restrictions as most prescribers are following protocols.
Pancreatic Enzymes	Steve Liles, PharmD Provider Synergies	<u>Pancreatic Enzymes</u> Dr. Liles provided a review of one new product - Pancreaze. There is no comparative data between the various pancreatic enzyme products currently available. **Committee Recommendations** The Committee concluded that there was no comparative evidence, but that the FDA has now standardized products. They recommended open access to all FDA approved agents.
Proton Pump Inhibitors	Steve Liles, PharmD Provider Synergies	<u>Proton Pump Inhibitors</u> Dr. Liles provided a review of the FDA warnings about long-term usage of PPIs – increased fracture risk, hypomagnesaemia, pneumonia. The data on Plavix and PPIs was reviewed. **Committee Recommendations** The Committee recommended that patients on Plavix should be able to receive pantoprazole and that patients on Plavix should be automatically denied for omeprazole. As it can be easier to use Prevacid capsules (can be opened and contents sprinkled on food) in children than the ODT dosage form, the Committee recommended that both lansoprazole capsules and ODT be preferred in children < 10 years old.

Pharmacy and Therapeutics Committee
Public Comment
April 15, 2011

Kara Taggart, M.D.
Good morning, I am Dr. Kara Taggart, a urologist in town, here to speak on Toviaz for overactive bladder drugs. I am asking, more like begging, to please keep Toviaz on your formulary. Toviaz is the only drug out there with proven superiority. There are now at least two head-to-head studies powered for superiority showing this is the most efficacious drug on the market. There is another study out there that is only powered for non-inferiority against the market leader, when these are compared head-to-head, so we know that the drug works the best. The pharmacokinetics is what is key for me in prescribing the drug for two reasons., one is how it is broken down to the active metabolite with esterases that are widely available by everyone, so the dosage doesn't have to be modified for race, age, gender, etc. The other key element in the pharmacokinetics is how it is broken down, one renal route and two hepatic routes. They aren't cytochrome P-450 routes, it can be used in people with mild renal insufficiency, moderate insufficiency and mild hepatic insufficiency, so the drug can be used by a lot more people because of that. Those two things are really important to me. Especially with my Medicaid patients as they tend to be on a lot more drugs and so by having these various pathways to break it down, I think that personally, is a main factor in choosing this drug. But the bottom line is the patient and their quality of life. These are patients that are vastly crippled. They are stuck at home; they are embarrassed to go out, smelling bad in pads. Now they can sit through a movie for the first time in 10 years, they can go out to dinner; they can get out in society. So their quality of life improvements that I have seen in the past year, because I have been able to use this drug with my Medicaid patients, has been really dramatic. Again I not only plead, but I beg for you to allow me to continue to use this drug. Thank you.

Committee Question
My experience with all these medicines, as a class, is they have been fairly questionable as far as efficacy and side effect profiles. I remember when we spoke about this drug class in our last meeting we looked at the increased efficacy which had a cost in increases in side effects too. It was the irritating stuff, the dry mouth and constipation and the like. I would like your comments on the side effects as well.

Kara Taggart, M.D.
Well, I don't think they are any different. Of course the dry mouth and the constipation are the biggest ones. As I look at dose escalation, I base it on side effects. If the patient is not having dry mouth or constipation at the starting dose, and I feel I can go up on efficacy, then I will go up to the higher dose. I find if I have those who are complaining of dry mouth take the medication at bed time, once they are at a steady state on the 24 hour drug, then they still have the efficacy during the day, but they are significantly less bothered by the dry mouth because the peak plasma levels are going to be while they are sleeping. I have found this to be very helpful. There is individual variation and there is no known reason why this drug may have a little less side effects than that one in a given individual, but my experience across the board is they are the same type of side effects. I am not finding it is the dry eyes at all with the Toviaz, it is the dry mouth. Again, by changing the dosing, in those people who are having the issues, to the night time, they are not discontinuing the drug because of the side effects.