

**Pharmacy and Therapeutics (P&T) Committee Meeting Record**

**Date:** April 20, 2012     **Time:** 9:00 a.m. – 3:30 p.m.     **Location:** Idaho Medicaid, 3232 Elder Street, Boise, Idaho, Conference Room D

**Moderator:** Perry Brown, M.D.

**Committee Members Present:** Perry Brown, M.D.-Chair; Dennis Tofteland, RPh; Catherine Hitt-Piechowski, PharmD; Elaine Ladd, PharmD; Tami Eide, PharmD; Mark Turner, M.D.; John Mahan, M.D.; Mark Johnston, RPh; Troy Geyman, M.D; Jeffrey Johnson, PA-C, PharmD

**Others Present:** Paula Townsend, PharmD, Magellan Health Services ; Mark England PharmD, Magellan Medicaid Administration; Jane Gennrich, PharmD.; Wendy Golaszewski, Rachel Strutton, Teresa Martin, Division of Medicaid

<b>AGENDA ITEMS</b>	<b>PRESENTER</b>	<b>OUTCOME/ACTIONS</b>
CALL TO ORDER	Perry Brown, M.D.	Dr. Brown called the meeting to order.
<b>Committee Business</b>		
➤ <i>Roll Call</i>	Perry Brown, M.D.	Dr. Brown completed the roll call, welcomed the P&T Committee members and called the meeting to order. He introduced new committee member Troy Geyman, MD, and Paula Townsend, PharmD from Magellan Health Services and new Medicaid staff Wendy Golaszewski and Teresa Martin.
➤ <i>Reading of Mission Statement</i>	Perry Brown, M.D.	Dr. Brown read the Mission Statement.
➤ <i>Approval of Minutes from November 18, 2011 Meeting</i>	Perry Brown, M.D.	The November 18, 2011 meeting minutes were accepted as proposed.
➤ <i>DERP Update</i>	Tami Eide, PharmD	<b><u>DERP Update</u></b> Dr. Eide provided an overview on the focus for DERP (Drug Effectiveness Review Project) Phase IV. Since there will be fewer participants (Medicaid States and Canada) than DERP III and the cost of research has gone up, the project will focus on high impact drugs. These drugs are new, costly and have a heightened potential for inappropriate or inefficient use. The prioritized drug classes will be anticoagulants, antiplatelets, diabetes agents, MS Drugs, Hepatitis

<p>➤ Update on Atypical Antipsychotics by Diagnosis</p>	<p>Tami Eide, PharmD</p>	<p>C Drugs, atypical antipsychotics and asthma controller/COPD drugs. All of these drug classes have had recent new drug approvals or have agents in the drug development pipeline.</p> <p><b><u>Update on Atypical Antipsychotics by Diagnosis</u></b>  Dr. Eide provide a brief update stating that the diagnosis codes in participants’ electronic profiles necessary for the Division of Medicaid to provide utilization data to both the P&amp;T Committee and the DUR Board are now available. Preliminary reviews have begun. Dr. Eide also noted that Idaho Medicaid is part of a statewide group, which includes Child Welfare. The group is currently developing best practices and policies on the usage of psychotropic drugs in foster children. This is part of a nationwide directive and will tie into the atypical antipsychotics by diagnosis project.</p>												
<p>➤ DUR Board Update Androgenic Utilization and PA Criteria</p>	<p>Mark England, Pharm. D. Jane Gennrich, Pharm.D.</p>	<p><b><u>DUR Board Updates</u></b>  <b><u>Androgenic Utilization and PA Criteria</u></b>  Dr. England provided a review of the Transdermal Testosterone Drug Utilization Review including the rationale for the DUR project as well as the criteria for patient selection for review. He reviewed the product selection, potential cost savings, and diagnosis of androgen deficiency in men. Dr. Gennrich then provided a review of the DUR recommendations which included initial therapeutic criteria for transdermal testosterone and contacting prescribers of current patients receiving transdermal testosterone. Dr. Gennrich also provided a copy of the new PA form to be used for Androgenic Drugs, Topical as well as the educational information document that was mailed to current prescribers.</p>												
<p><b>Public Comment Period</b></p>	<p>Perry Brown, M.D. Wendy Golaszewski</p>	<p><b><u>Public Comment Period</u></b>  Four (4) people signed up to speak during the public comment period. Public testimony was received from the following speakers:</p> <table border="1" data-bbox="926 1138 1950 1351"> <thead> <tr> <th>Speaker</th> <th>Representing</th> <th>Agent</th> <th>Class</th> </tr> </thead> <tbody> <tr> <td>W.E. Watkins, MD</td> <td>Self</td> <td>Toviaz</td> <td>Bladder Relaxant Preparations</td> </tr> <tr> <td>Tracy Young, NP</td> <td>Self</td> <td>All Hepatitis C Agents with special interest in Ribapack</td> <td>Hepatitis C Agents</td> </tr> </tbody> </table>	Speaker	Representing	Agent	Class	W.E. Watkins, MD	Self	Toviaz	Bladder Relaxant Preparations	Tracy Young, NP	Self	All Hepatitis C Agents with special interest in Ribapack	Hepatitis C Agents
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<p>➤ Angiotensin Modulators</p>	<p>Paula Townsend, PharmD Magellan Health Services</p>	<p>Committee was concerned about the black box warning for Xarelto and asked that education be provided to providers concerning starting adequate anticoagulation with overlap prior to discontinuing rivaroxaban for non-bleeding reasons in patients with atrial fibrillation.</p> <p><b><u>Angiotensin Modulators</u></b> Dr. Townsend provided a review of new drugs Edarbi (azilsartan medoxomil) and Edarbyclor (azilsartan/chlorthalidone). She announced that eprosartan (Teveten) and irbesartan (Avapro) had recently become available generically and valsartan (Diovan) would be available generically in Fall of 2012. She also reviewed the ALTITUDE clinical trial. ALTITUDE was a Phase III study examining the addition of aliskiren to ARB or ACEI therapy in patients with Type II diabetes and renal impairment. The study was terminated early in December 2011 because there was no benefit to adding aliskiren and there was an increased incidence of nonfatal stroke, renal complications, hyperkalemia and hypotension. Based on this there have been recent FDA Safety Communications and more are expected.</p>
<p>➤ Angiotensin Modulator Combinations</p>	<p>Paula Townsend, PharmD Magellan Health Services</p>	<p><b><u>Angiotensin Modulator Combinations</u></b> There was no new clinical data to share with the committee.</p> <p><b>Committee Recommendations</b> <b><i>Ace Inhibitors and Ace Inhibitor/Diuretic Combinations:</i></b> The committee concluded that there were no evidence based differences to support preferring any agent over another within this drug class. <b><i>Angiotensin Receptor Blockers and Angiotensin Receptor Blockers /Diuretic Combinations:</i></b> The Committee concluded that Edarbi and Edarbyclor had no clinical advantage to other agents and should only be preferred if more cost effective than other agents in the class. The committee concluded that there were no evidence based differences to support preferring any agent over another within this drug class. <b><i>Angiotensin Receptor Blocker/Calcium Channel Blocker Combinations:</i></b> The committee concluded that there were no evidence based differences to support preferring any agent over another within this drug class. <b><i>Direct Renin Inhibitors and Direct Renin Inhibitor Combinations :</i></b> The committee recommended excluding Valtorna (aliskiren/valsartan) from Idaho Medicaid coverage as it will be removed from the market by July 2012 due to safety concerns. The committee recommended that all other aliskiren products remain non-preferred and that educational information on not using them with an ACEI or ARB in patients with diabetes or renal disease be added to the prior authorization form.</p>

<p>➤ Beta Blockers</p>	<p>Paula Townsend, PharmD Magellan Health Services</p>	<p><b><u>Beta Blockers</u></b> Dr. Townsend provided a review of one new product Dutoprol (25, 50 or 100 mg metoprolol succinate/HCTZ 12.5) and one newly published clinical trial comparing the tolerability of carvedilol and bisoprolol. There were no significant differences in overall tolerability with the two agents. Bisoprolol had a greater reduction in heart rate and a significantly higher incidence of dose-limiting bradycardia. Carvedilol had a greater reduction in FEV1 and significantly more pulmonary adverse drug reactions.</p> <p><b>Committee Recommendations</b> The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents and that preferred status should be based on cost-effectiveness.</p>
<p>➤ Calcium Channel Blockers</p>	<p>Paula Townsend, PharmD Magellan Health Services</p>	<p><b><u>Calcium Channel Blockers</u></b> Dr. Townsend provided a review of the FDA labeling changes for Procardia XL, nifedipine and amlodipine due to safety issues.</p> <p><b>Committee Recommendations</b> The committee concluded that there were no evidence based differences to support preferring any agent over another in this class and preferred status should be based on cost-effectiveness.</p>
<p>➤ Lipotropics, Other</p>	<p>Paula Townsend, PharmD Magellan Health Services</p>	<p><b><u>Lipotropics, Other</u></b> Dr. Townsend provided a review of the ACCORD (NHLBI) Trial and the November 2011 FDA safety announcement that fenofibric acid may not lower the risk of MI or stroke.</p> <p><b>Committee Recommendations</b> The committee concluded that there were no evidence based differences to support preferring any agent over another in this class.</p>
<p>➤ Lipotropics, Statins</p>	<p>Paula Townsend, PharmD Magellan Health Services</p>	<p><b><u>Lipotropics, Statins</u></b> Dr. Townsend announced that there were two new generics: atorvastatin (for Lipitor) and amlodipine / atorvastatin ( for Caduet). She provided a summary of recent FDA actions. The FDA has removed recommendations for routine monitoring of liver enzymes for all statins. They have also required labeling changes for simvastatin, lovastatin, and atorvastatin contraindicating use with CYP3A4 inhibitors to reduce the risk of rhabdomyolysis. In June 2011, the FDA also placed restrictions on the use of the simvastatin 80 mg dose.</p>

<p>➤ Hypoglycemics, Insulin</p>	<p>Paula Townsend, PharmD Magellan Health Services</p>	<p><b>Committee Recommendations</b> The committee concluded that there were no evidence based differences to support preferring any agent over another in this class.</p> <p><b><u>Hypoglycemics, Insulin</u></b> There was no new significant clinical data to share with the committee.</p> <p><b>Committee Recommendations</b> The committee concluded that there were no evidence based differences to support preferring any agent over another in this class.</p>
<p>➤ Hypoglycemics, Incretin Mimetics/Enhancers</p>	<p>Paula Townsend, PharmD Magellan Health Services</p>	<p><b><u>Hypoglycemics, Incretin Mimetics/Enhancers</u></b> Dr. Townsend provided a review of the new DPP-4 enzyme inhibitor drug linagliptin (Tradjenta) which is also available in combination with metformin (Jentadueto). Other new products include sitagliptin + metformin (Janumet XR), sitagliptin + metformin + simvastatin (Juvissync) and exenatide extended-release, once-weekly (Bydureon).</p> <p><b>Committee Recommendations</b> The committee concluded that there were no evidence based differences to support preferring any agent over another in this class. They did not feel that the new combination drugs provided any significant advantages.</p>
<p>➤ Hypoglycemics, TZD</p>	<p>Paula Townsend, PharmD Magellan Health Services</p>	<p><b><u>Hypoglycemics, TZD</u></b> There was no new significant clinical data to share with the committee.</p> <p><b>Committee Recommendations</b> The committee concluded that there were no evidence based differences to support preferring any agent over another in this class.</p>
<p>➤ Proton Pump Inhibitors</p>	<p>Paula Townsend, PharmD Magellan Health Services</p>	<p><b><u>Proton Pump Inhibitors</u></b> Dr. Townsend announced the availability of a new generic, lansoprazole 15 mg OTC (for Prevacid OTC). Dr. Townsend also reviewed the FDA safety communication of February 2012 which discussed the increased chance of developing clostridium difficile-associated diarrhea in patients with prolonged use of proton pump inhibitors especially at higher dosages.</p>

<p>➤ Pulmonary Arterial Hypertension (PAH) Agents, Oral</p>	<p>Paula Townsend, PharmD Magellan Health Services</p>	<p><b>Committee Recommendations</b> The committee concluded that there were no evidence based differences to support preferring any agent over another in this class.</p> <p><b><u>PAH Agents, Oral</u></b> Dr. Townsend announced that Revatio was expected to be generically available later this year. She provided a review of one new meta-analysis of monotherapy vs. combination therapy published in the American Journal of Cardiology. The analysis concluded that there were no significant differences between monotherapy and combination therapy in mortality risk, hospital admissions for worsening PAH, escalation of therapy or improvement in NYHA functional class.</p> <p><b>Committee Recommendations</b> The committee concluded that there were no evidence based differences to support preferring any agent over another in this class.</p>
<p>➤ Topical Androgenic Agents</p>	<p>Paula Townsend, PharmD Magellan Health Services</p>	<p><b><u>Topical Androgenic Agents</u></b> Dr. Townsend discussed three new products for this class: AndroGel 1.62% (new concentration), Androderm transdermal 2mg and 4mg (replaces the previously available 2.5mg and 5mg patches) and Axiron, a topical androgen gel applied to the axilla. All new products have the same FDA approved indication.</p> <p><b>Committee Recommendations</b> The committee concluded that there were no evidence based differences to support preferring any agent over another in this class.</p>
<p>➤ BPH Treatments</p>	<p>Paula Townsend, PharmD Magellan Health Services</p>	<p><b><u>BPH Treatments</u></b> Dr. Townsend provided a review of one new clinical trial , EPICS or the Enlarged Prostate International Comparator Study. The study compared duasteride 0.5 mg to finasteride 5 mg and demonstrated similar prostate volume reduction with both drugs.</p> <p><b>Committee Recommendations</b> The committee concluded that there were no evidence based differences to support preferring any agent over another in this class.</p>

<p>➤ Bladder Relaxant Preparations</p>	<p>Paula Townsend, PharmD Magellan Health Services</p>	<p><b><u>Bladder Relaxant Preparations</u></b> There was no new significant clinical data to share with the committee.</p> <p><b>Committee Recommendations</b> The Committee felt that were side effect differences between the different agents. They recommended that oxybutinin ER be designated preferred solely for the purpose of less frequent dosing if this change is cost effective. The Committee also recommended that Toviaz and Vesicare remain as preferred agents based on utilization patterns and input from current prescribers.</p>
<p>➤ Bone Resorption Suppression and Related Agents</p>	<p>Paula Townsend, PharmD Magellan Health Services</p>	<p><b><u>Bone Resorption Suppression and Related Agents</u></b> There was no new significant clinical data to share with the committee. Dr. Townsend announced that monthly Boviva recently went generic, but that multiple lawsuits have been filed by the brand name manufacturer against the generic companies. A correction was made to the Power Point presentation. Mialcalcin (calcitonin) is currently a non-preferred agent and calcitonin is currently a preferred agent.</p> <p><b>Committee Recommendations</b> The committee concluded that there were no evidence based differences to support preferring any agent over another in this class.</p>
<p>➤ Phosphate Binders</p>	<p>Paula Townsend, PharmD Magellan Health Services</p>	<p><b><u>Phosphate Binders</u></b> Dr. Townsend provided a review of one new product Phoslyra, a calcium acetate 667mg/5 mL solution. Renagel will be removed from the market eventually, but no date has been announced yet.</p> <p><b>Committee Recommendations</b> The committee concluded that there were no evidence based differences to support preferring any agent over another in this class.</p>
<p>➤ Growth Hormone</p>	<p>Paula Townsend, PharmD Magellan Health Services</p>	<p><b><u>Growth Hormone/Growth Factors</u></b> Dr. Townsend announced the introduction to the market of one new device, Norditropin FlexPro prefilled pens: 5, 10, 30 mg . She also announced that Omnitrope now has an indication for treatment of pediatric patients with growth failure associated with Turner’s Syndrome. Dr.</p>



<p>➤ Pancreatic Enzymes</p>	<p>Paula Townsend, PharmD Magellan Health Services</p>	<p><b><u>Pancreatic Enzymes</u></b> Dr. Townsend announced that three new formulations for this drug class are available: Creon 3,000; Zenpep 3,000; and Zenpep 25,000 were now available. Two other agents, Viokace and Ultresa have been approved by the FDA, but are not yet available.</p> <p><b><u>Committee Recommendations</u></b> The committee concluded that there were no evidence based differences to support preferring any agent over another in this class.</p> <p><b><u>Other Committee Business</u></b> Dr. Eide reminded the committee that the next meeting is scheduled for May 11, 2012.</p> <p>The meeting adjourned at 1:30 PM.</p>
<p>➤ Other Committee Business</p>		

**Pharmacy and Therapeutics Committee  
Public Comment  
April 20, 2012**

Wilfred Watkins, MD

Good morning, I'm Bill Watkins, I'm from Nampa. I've practiced urology there for 44 years, a little more than that, and usually when I testify, I'm at the front of the room, but, as a urologist, I speak to people's backs quite often, so I'm comfortable with that. By way of disclosure, I have not received, nor have I any promise of any reimbursement from Pfizer, and I found out when we were doing our taxes, that my wife had sold our stock, so I won't get anything in that respect. I do get money from a lithotripter, which has nothing to do with this, but it is disclosure. I receive money from the Department of Defense; I see patients at the VA Hospital once a week in Boise and once a month in Caldwell. I get Social Security, and my wife gets it too, of course. I'm here to ask you not to take Toviaz off the formulary, because I find in my treatment of patients with overactive bladder, that there are some patients who cannot tolerate the side effects, which usually are manifested by dry mouth and constipation, and unless you can reduce those side effects, they won't take the medication, nor could they tolerate taking the medication. There are other people who don't get the full response, so they don't actually get dry. That's what we're after with patients with

overactive bladder; what we're trying to do is get them dry. It also helps if we reduce their frequency and urgency and those kinds of things. In my experience, Toviaz does a very good job of decreasing the side effects and increasing the efficacy. Are there any questions? Thank you Mr. Chairman.

Tracy Young, NP

Good morning everyone. I'm a nurse practitioner and I work at Digestive Health. I've been in practice as a nurse practitioner for 12 years, and the last seven have been strictly GI. A big portion of my job is to treat patients with hepatitis-C. I would really like to thank all of you, because for the last year, that has really been fun. Genotype-1, which we see the most of in the United States, has always been traditionally very difficult to treat and, with your generosity, in the last year, I have been able to use triple therapy and have gone from a success rate of about 40% to running about 80% right now. I would very much like you to allow me to continue with my choice of medication. I use all the interferons on the market, I use all the ribavirins on the market, and there are two protease inhibitors that were approved by the FDA in May of last year, that have dramatically contributed to my success. I would very much like you to allow me to continue treating my patients that way, giving them a second chance at life. So, to be very specific, we're talking about telaprevir and boceprevir, the protease inhibitors, as well as interferon alpha-2a, interferon alpha-2b, and all the ribavirins. I would like to put in a plug for RibaPak, because with the protease inhibitors, the pill burden just for those medications, for boceprevir, is twelve pills per day, for telaprevir it's six pills a day on top of the interferon and whatever other medications they're on, so being able to use the RibaPak, which would only be one pill twice a day as opposed to 5-6-7 pills would be very helpful. Any questions? Thank you, I'll see you next year.

Mandy Hosford, MD

Thank you, whoever set up the microphone for making sure it was appropriate for my stature. I'm here to speak for Brilinta today. Brilinta has not been reviewed as part of the platelet aggregation inhibitor class by this committee as you are all well aware, and when the DERP Report was issued, or its most recent report was issued in June of 2011, Brilinta had not yet been approved. So, in a couple of minutes, I will just go over the very high level basics of Brilinta and then ask you all what questions you have. So primarily, Brilinta is indicated to treat acute coronary syndromes, so with regards to the Medicaid population, I would suspect this is not a substantial proportion of the Medicaid demographic. It has been studied in acute coronary syndromes across NSTEMI, STEMI or unstable angina, so essentially, the spectrum of ACS. It has been studied in combination with aspirin and it has been shown that its efficacy is attenuated versus clopidogrel. It has only been studied versus clopidogrel at this time, Plavix. Its efficacy is attenuated with higher doses of aspirin, so it actually contains a box warning that requests patients who are taking Brilinta only take it with aspirin doses of less than 100 mg a day, and, as we all know, that's 81 mg here in the U.S. It has been indicated in ACS to reduce the risk of cardiovascular death, heart attack, but not stroke. Its large study was the PLATO study, and that looked at a combined endpoint of cardiovascular death, heart attack and stroke, and the efficacy result of a 16% relative risk reduction compared to Plavix was driven largely by the difference in cardiovascular death and MI (heart attack). Additionally, in patients who were managed invasively, treatment with PCI reduced the rate of stent thrombosis overall, of the 23% relative risk reduction. Furthermore, contraindications include patients that we did not study in the PLATO trial, so these are patients that have active bleeding disorders at present, or currently actively, pathologically bleeding, so a peptic ulcer disease, we did not study those patients, and they would be contraindicated. Additionally, patients with severe hepatic impairment, we did not include them, because they tend to be more predisposed to bleeding regardless, as well as patients with a history of intracranial hemorrhage, so those would be the three patient groups that are contraindicated. The difference in how Brilinta is different from Plavix or prasugrel is that it is orally active and requires no hepatic metabolism for activation. That does not mean it's not metabolized. The drug is metabolized to be eliminated, and that is done by the 3A4 system. So, you will see in the prescribing information, patients who take Brilinta should not be on very, very strong 3A4 modifiers, inhibitors or inducers, and this includes simvastatin 80 mg and lovastatin 80 mg. Additionally, with regards to inhibition of platelet aggregation, so how does it work? Essentially, the PLATO trial is a proof of concept trial, that when we look at how these drugs inhibit platelet aggregation, does that impact events, we see with Brilinta, after a loading dose of 180 mg (that's two tablets) versus a clopidogrel loading

dose of 300 mg or 600 mg, that the inhibition of platelet aggregation is reached maximally for Brilinta at two hours, and at every time point over an 8-hour period is higher than that for clopidogrel, about by twofold. But again, we can't correlate IPA or inhibition of platelet aggregation with outcomes; hence the indication is based on the outcomes we observed in the PLATO trial. I just want to leave a minute for questions; I have about a minute left. The thing I really want to point out is the reason for the aspirin dosing. We did observe in the overall PLATO trial, that in North America (this was a global study in over 18,000 patients) the results for Brilinta were numerically inferior to those for clopidogrel, and we looked at this as "Could it be study conduct management issues in the US?", "Is it just the result of how we in North America are different?", "Is it a play of chance from statistical findings?", but what we ultimately identified in the next three seconds, is that we can relate this to the high aspirin that a lot of the patients that we had in North America were on; a lot of them were discharged on 325 mg q.d. and when we look at lower aspirin doses, they get better results. Thanks for using iPhone, [which has the time limit set on it] because you don't have to cut me off. What questions do you have in the -4 seconds I have left? Thank you for considering to include it. I appreciate it very much.

Ellen Hunter, MD

Good morning, my name is Dr. Ellen Hunter, and I'm a gastroenterology and hepatologist in Boise. I do treat a large number of patients with hepatitis-C, including Medicaid patients. I spoke at this committee in November, 2011, and I just thought I'd make a brief statement today, that we do have excellent treatment for Hepatitis C and, in particular, a major breakthrough occurred last year with the addition of protease inhibitors boceprevir and telaprevir, and with this addition, there has been a major breakthrough in the treatment of Hepatitis C. In the past, we have had about a 50% chance of clearing the virus and now, with the addition of the oral protease inhibitors, we have an approximately 80% chance of clearing Hepatitis C. As you may know, Hepatitis C is a significant problem in the nation, as well as in the world. In the US, there are approximately four million persons with Hepatitis C that are at risk for developing cirrhosis or scarring of the liver and complications of cirrhosis, including liver failure and liver cancer. So I am using these treatments for Hepatitis C with success, and I recommend that the P&T Committee continue to have both protease inhibitors available for Idaho patients with chronic Hepatitis C. I would be happy to take any questions.