

Pharmacy and Therapeutics (P&T) Committee Meeting Record

Date: January 15, 2010 **Time:** 9:00 a.m. – 3:30 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.; Mark Johnston, RPh; Elaine Ladd, Pharm.D.; Scott Malm, PA-C; Catherine Hitt Pharm.D.; Tami Eide, Pharm.D.; Mark Turner, M.D.

Others Present: Steve Liles, PharmD.; Bob Faller; Rachel Strutton; Melinda Sater, PharmD

Committee Members Absent:

AGENDA ITEMS	PRESENTER	OUTCOME/ACTIONS
CALL TO ORDER	Phil Petersen, M.D.	Dr. Petersen called the meeting to order.
Committee Business		
➤ <i>Roll Call</i>	Phil Petersen, M.D.	Dr. Petersen completed the roll call, welcomed the P&T Committee members and called the meeting to order.
➤ <i>Introduction of new Committee members</i>	Phil Petersen, M.D.	Dr. Petersen introduced Dr. Ladd and Mr. Malm and welcomed them to the P&T Committee.
➤ <i>Reading of Mission Statement</i>	Phil Petersen, M.D.	Dr. Petersen read the Mission Statement.
➤ <i>August 20, 2010 meeting date discussion</i>	Phil Petersen, M.D.	The meeting date for the August 20, 2010, has been changed to August 27, 2010 due to potential Health and Welfare office closures.
➤ <i>Approval of Minutes from August 21, 2009 Meeting</i>	Phil Petersen, M.D.	There were no corrections. The August 21, 2009 meeting minutes were accepted as proposed.

<p>➤ <i>Introduction of First Health as new Medicaid Pharmacy PBM</i></p>	<p>Tami Eide, PharmD.</p>	<p>Dr. Eide Introduced First Health as new Medicaid Pharmacy Benefit Management (PBM) system and provided a brief background. This new pharmacy system is scheduled to go live January 30, 2010.</p> <p>Q: How will providers throughout the State see this transition happen? A: There have been several workshops and a lot of messaging that has gone out. Medicaid is hoping the transition will be transparent for prescribers. It is likely that physician office staff is aware of these changes. The one change prescribers may notice that the PA forms now ask for the National Provider Identification (NPI) number instead of the state license number.</p> <p>Q: How is the diagnosis going to be added to an electronic prescription? There is not a specified place for this. A: The Idaho Medicaid Pharmacy Unit will look into this.</p> <p>Suggestion: Medicaid to connect with the Idaho Medical Association (IMA) to distribute communications regarding the PBM system and its implementation.</p>
<p>➤ <i>Key Questions</i></p>	<p>Tami E. PharmD</p>	<p><u>Key Questions</u></p> <p>Dr. Eide presented the following Key Questions:</p> <p><u>Multiple Sclerosis</u> <u>New Diabetes Medications and Combinations of Therapy</u> <u>Newer Antihistamines</u> <u>Atypical Antipsychotics</u> <u>Fibromyalgia</u></p>

Public Comment Period

Phil Petersen, M.D.
 Bob Faller, Medical
 Program Specialist

Twelve (12) people signed up to speak during the public comment period. Public testimony was received from the following speakers:

Speaker	Representing	Agent	Class	Disclosures
Dr. Arnold Silva	self	Valturna	Angiotensin Modulators/CCB Combination drugs	Novartis speaker bureau
Dr. Arnold Silva	self	Lipitor	Lipotropics, Statins	
Ben Kuhlman, PA	Boise Kidney and Hypertension Institute	Lovaza and Lipitor	Lipotropics, Other and Lipotropics Statins	
Dr. Antonio Lopez	self	Crestor	Lipotropics, Statins	
Dr. Joe Williams	Idaho Urologic Institute	Avodart	BPH Treatment	
Dr. Richard Radovich		Cymbalta Lyrica Savella	Fibromyalgia Drugs	
Dr. Kara Taggart	Mt. State Urology	Toviaz	Bladder Relaxant Preparations	
Dr. Steven DeNagy		Cymbalta Lyrica Savella	Fibromyalgia Drugs	Pfizer Lilly Forrest
Dr. Robert Lee	self	Lipitor	Lipotropics, Statins	
Dr. David Kemp		Bystolic	Beta Blockers	Forrest
Robert Pearson, PharmD	GlaxoSmithKline	Relisten	Hypoglycemics, TZDa	
Leigh Platte	Astellas Pharma	VESicare	Bladder Relaxant Preparations	
Jennifer Brzana, PharmD	GlaxoSmithKline	Avodart	BPH Treatment	

<p>➤ Erythropoiesis Stimulating Proteins</p>	<p>Steve Liles, PharmD</p>	<p>Committee Recommendations The Committee felt there were no evidence-based differences to support any changes to this class.</p> <p><u>Erythropoiesis Stimulating Proteins</u> Dr. Liles reviewed the NCCN Guidelines (2009) regarding increased mortality and tumor progression associated with these agents with the Committee. There was no other new significant clinical data to share with the Committee.</p> <p>Committee Recommendations The Committee felt Aranesp offered some advantages, but preferred status could be decided based on net cost. The Committee would like to see a DUR review for this drug class to determine what the CVA rate is on these drugs.</p>
<p>➤ Phosphate Binders</p>	<p>Steve Liles, PharmD</p>	<p><u>Phosphate Binders</u> Dr. Liles provided an update on new dosage formulations of 800mg and 2400mg for Renvela. There was no other new significant clinical data in this drug class to share with the Committee.</p> <p>Committee Recommendations The Committee felt there were no evidence based differences to support any changes to this class. They determined Renagel and Renvela were equivalent and the Department could prefer which ever one was more cost-effective during any given time period.</p>
<p>➤ Pulmonary Artery Hypertension (PAH) Agents, Oral</p>	<p>Steve Liles, PharmD</p>	<p><u>Pulmonary Artery Hypertension (PAH) Agents, Oral</u> Dr. Liles provided some updated information on the disease itself and the ACC/AHA Joint PH Expert Consensus and World symposium on Pulmonary Hypertension – PAH Guidelines. He introduced three new products (Ventavis, Tyvaso and Adcirca) to this drug class and their place in therapy. He also reviewed four new clinical trials (two on Ventavis, one on Tyvaso and one on Letairis).</p> <p>Committee Recommendations The Committee recommended making all agents preferred based on lack of evidence of differences clinically between the agents. They recommended the PA criteria for a PAH indication be retained on Revatio and Adcirca.</p>

<p>➤ Lipotropics, Statins and Fixed Dose Combination Products Containing a Statin</p>	<p>Susan Carson, MPH, OHSU EPC</p>	<p><u>Lipotropics, Statins and Fixed Dose Combination Products Containing a Statin</u> Ms. Carson presented an overview of the Final Report Update 5 (December 2009) for this class. This update included 135 new studies. New conclusions:</p> <ol style="list-style-type: none"> 1) High dose rosuvastatin appears to have greater LDL Cholesterol lowering and HDL raising effects than high dose atorvastatin. 2) Ezetimibe-simvastatin fixed-dose combination products has greater LDL Cholesterol lowering than statin monotherapy. 3) No evidence still for equipotent dose of statins or fixed-dosed combination products for health outcomes of primary or secondary prevention. 4) Little comparative effectiveness in subgroups. 5) Niacin ER fixed-dose combination products have greater adverse events, primarily flushing. 6) In children statins have been shown to reduce LDL Cholesterol by 32% with greater reductions with the ezetimibe/simvastatin combination. 7) Studies of statins in children have not been conducted with long enough follow-up to assess for outcomes related to cardiovascular mortality and morbidity. <p>Committee Recommendations The Committee stated that since all studies look at intermediate outcomes rather than final outcomes, they can not conclude the superiority of one agent over another. The Committee recommended a review of the utilization patterns of different doses of the statins to determine the need for a high-potency agent. They recommended Vytorin remain a step 2 agent for patients who could not get adequate control on a statin alone or tolerate dose increases. They concluded that Advicor and Simcor had no particular advantage and could be either preferred or non-preferred based on cost effectiveness.</p>
<p>➤ Lipotropics, Other</p>	<p>Steve Liles, PharmD</p>	<p><u>Lipotropics, Other</u> Dr. Liles introduced two new products (Fibricor and Trilipix). He also noted a new indication for Niaspan for use with simvastatin if monotherapy is inadequate. He reviewed three double blind randomized clinical trials for Trilipix. He provided results from an AHRQ Systematic Review that showed no strong evidence to support that combination therapy improves clinical outcomes that were seen over high dose statin monotherapy.</p> <p>Committee Recommendations The Committee felt there were no evidence based differences to support any changes to this class.</p>

<p>➤ Bladder Relaxant Preparations</p>	<p>Steve Liles, PharmD</p>	<p><u>Bladder Relaxant Preparations</u> Dr. Liles introduced two new products Gelnique (oxybutynin gel) and Toviaz (fesoterodine ER). He reviewed two new clinical trials (one on Gelnique and on Toviaz), and an AHRQ Evidence-Based Review regarding treatment of over active bladder (OAB), urge urinary incontinence and related symptoms in women.</p> <p>Committee Recommendations The Committee felt no agent stood out as clinically superior to any of the others. They recommended having at least one long-acting agent as preferred.</p>
<p>➤ BPH Treatments</p>	<p>Steve Liles, PharmD</p>	<p><u>BPH Treatments</u> Dr. Liles introduced one new product, Rapaflo (sildenafil). He reviewed two clinical trials for Rapaflo. It was noted Flomax is scheduled to go generic in early March 2010.</p> <p>Committee Recommendations The Committee concluded that the evidence did not support differences in safety or efficacy. They requested the preferred agents included at least one non-alpha blocker to avoid orthostasis in susceptible patients.</p>
<p>➤ Cough and Cold Products</p>	<p>Steve Liles, PharmD</p>	<p><u>Cough and Cold Products</u> There was no new significant data in this drug class.</p> <p>Committee Recommendations The Committee felt there were no evidence based differences to support any agent be preferred over another.</p>
<p>➤ Fibromyalgia Drugs (new review)</p>	<p>Steve Liles, PharmD</p>	<p><u>Fibromyalgia Drugs</u> This is the first time these drugs have been grouped in this drug class. Both Lyrica and Cymbalta will continue to be reviewed for their other indications. Dr. Liles provided an overview of Fibromyalgia. He introduced one new product (Savella/milnacipran) and provided a review of the therapeutic options (non pharmacologic and pharmacologic). He provided a review of antidepressants with two meta-analyses. Dr. Liles reviewed eleven clinical trials (four for Cymbalta, two for Savella, four for Lyrica, plus one for the non-indicated agent gabapentin).</p>

<p>➤ Hypoglycemics, Meglitinides</p>	<p>Steve Liles, PharmD</p>	<p>Committee Recommendations The Committee recommended having all three drugs as preferred agents with the clinical criteria of a diagnosis of Fibromyalgia required. A review of dosage differences by indication will be done during the next review of this drug class.</p> <p><u>Hypoglycemics, Meglitinides</u> Dr. Liles introduced one new product PrandiMet (repaglinide + metformin). He noted meglitinides were not included in the three-step algorithm from ADA Type 2 diabetes guidelines.</p> <p>Committee Recommendations The Committee recommended not reviewing this drug class in the future unless utilization becomes an issue. The Committee did not feel evidence supported superiority of either drug.</p>
<p>➤ Hypoglycemics, TZDs</p>	<p>Steve Liles, PharmD</p>	<p><u>Hypoglycemics, TZDs</u> Dr. Liles reviewed the ADA Guideline Update (2009) on Management of Hyperglycemia in Type 2 Diabetes Mellitus. There was no other new significant clinical data to share with the Committee.</p> <p>Committee Recommendations The Committee concluded that there was no evidence to support preferring one agent over another. They recommended combinations be covered only if more cost effective than the individual components.</p>

**Pharmacy and Therapeutics Committee
Public Comment
January 15, 2010**

Arnold Silva, MD

Good morning, I'm Arnold Silva, a nephrologist with Boise Kidney & Hypertension, and I'm on the speaker's bureau for Novartis, who's asked me to speak on Valtorna this morning. I've also been asked by Pfizer to make a few comments on Lipitor, though I'm not on the speaker's bureau for Pfizer. First off, Valtorna is a new combination antihypertensive therapy. It combines a direct renin inhibitor, Tekturna, with an angiotensin receptor blocker, Diovan. This is a combination that we have been looking forward to, in particular in Nephrology, having both of these drugs which have complimentary mechanisms of action; the direct renin inhibitor, which inhibits the renin angiotensin aldosterone system, the RAS system, at its point of initiation is highly effective in blocking the system, and it also suppresses plasma renin activity, which data continues to accumulate on the importance of suppressing plasma renin activity. As most everyone knows, there is a wealth of data on the benefits of angiotensin receptor blockers and, in this case, we now have the benefit of combining both the direct renin inhibitor with an angiotensin receptor blocker in the same agent. For us in Nephrology in particular, that gives us two primary benefits: the first is with chronic kidney disease, in particular patients that have proteinuria, we know from several trials now that by combining two RAS blocking drugs, that we can further reduce proteinuria and proteinuria is associated with disease outcomes; the higher the proteinuria, the worse the patient does, so if we are more effective in reducing proteinuria, we improve outcomes. The second important aspect of this combination is that it gives us another combination therapy, even though there's a number already out on the market as far as RAS-blocking drugs that either hydrochlorothiazide or amlodipine-based products, there are a number of cases where those products are either not tolerated or not appropriate for the particular patient, so the second I think, and most important, benefit of this new combination is that we have another strategy of using two drugs in the same pill. What you'll find is about a 30% additional blood pressure reduction when these two agents are used together as opposed to either agent by themselves, so that's pretty much the summary and what we feel are the benefits. There's a good amount of data already available on this combination and certainly a lot more in the pipeline. So I will stop and see what sort of questions or comments that you have for me. The other thing, secondly I should mention with the case of Lipitor, this is very useful statin therapy for us in Nephrology. We can use high-dose therapy in our patients with chronic kidney disease, we don't have to be as concerned with drug/drug interactions as we are with some of the other statins, and we also don't have to dose adjust this product in our patients with progressive and advanced chronic kidney disease, so this becomes important for us in choosing statin therapies in patients with chronic kidney disease.

Question

When we looked a few years ago at combination with ARB and an ACE inhibitor and a review of the data back then, our impression was that the benefit was there if you were using sub-maximal doses of either agent, but if you went with the max doses, it didn't seem to have a benefit. With the combination of the direct inhibitor is that different than what with the combination of ACEs and ARBS? Is it an effect that we will still see on maximum dosage?

Arnold Silva, MD

Yes, I think it is. When we look at the data we have so far, you can be on maximum blockade of, for example, an angiotensin receptor blocker and the addition of the direct renin inhibitor does give you additional benefit on the order of 25% further reduction in urinary protein excretion which, again, has been shown to be significant, and that's on average. Some patients have as much as a 50% additional reduction.

Rachel Strutton-Draft

Ben Kuhlman, PA

Good morning, my name is Ben Kuhlman. I'm a nephrology PA with Boise Kidney & Hypertension Institute. I actually work with Dr. Silva. I have no affiliation with GSK or Pfizer. I do not speak for either one of these companies. I'm going to be talking today in support of two agents which our clinic has a wealth of experience and is an integral part of treating our patients in general, and those with high cardiovascular risk, which is quite a few of our patients. The first agent I would like to discuss is Lovaza, which has been studied in two areas, one for triglyceride counts greater than 500 mg/dL and also in combination with simvastatin for triglyceride counts to 200-400 mg/dL. Both trials used the 4 gm a day dose, and in clinical experience we've seen about a 44.9% reduction in triglycerides for the high camp and in combination with simvastatin about a 29.5% reduction. In clinical experience, we've found this to be a very effective agent in treating triglycerides, especially for advanced CKD patients. As far as safety and efficacy, as compared to some of the other options that we have to treat triglycerides, we find this to probably be one of the safest agents. Tolerability, GI upset, burping and taste disturbance at times we see, in our experience, have been about with 10% of the patient population. Adjusting a dose, starting at a lower dose and working up can help reduce that. The reason that I really want to speak in support of this today is also in comparison to some of the other available agents for our stage-4 chronic kidney disease patients, we are limited in what we can use. Often, the fibric acids are contraindicated in this patient population and the nicotinic acids tend to have a higher side effect profile, and also for our stage-3 chronic kidney disease patients, where the fibric acids can be used but at a lower dose and also the same limitations for the nicotinic acids, secondary to side effects, so in general, we have found Lovaza to be well tolerated, efficacious, and a very essential treatment modality for our patient, and often times about the only treatment option we have for these patients who are very high at risk for cardiovascular events. Any questions in regards to Lovaza? Okay. The other agent is Lipitor, which Dr. Silva discussed and I agree with him. Lipitor has a wealth of outcomes data, not only in LDL reduction, but also in risk reduction for cardiovascular events, we can dose it from essentially 10-80 mg irregardless of the patient's kidney function and its tolerability stays the same from 10-80 mg, so it's also a very essential component to treating our patients.

Antonio Lopez, MD

Good morning. My name's Antonio Lopez. I'm a preventative cardiologist at Cardiovascular Associates of Idaho, I'm also a clinical lipidologist. I'm formerly the director of the lipid clinic at the University of Iowa, also the director of the lipid clinic at Southern Illinois University, the Prairie Heart Institute, and I'm the Director of Preventative Cardiology at St. Alphonsus Regional Medical Center, as well as Director of Heart Failure at St. Lukes. I'm also a Fellow of the Council of Arteriosclerosis for the American Heart Association, and on the council for the Epidemiology and Prevention for the American Heart Association. I'm here to discuss Crestor (rosuvastatin), and asked by Astrazeneca to present them here. I'm on the speakers bureau for Astrazeneca, as well as other companies, but I'm on the national faculty of other organizations. Basically, as a clinical lipidologist, Crestor is the most effective statin for achieving goals of therapy for LDL cholesterol, non-HDL cholesterol, as well as best statin for HDL cholesterol. In patients particularly with genetic dyslipidemias, familiar, heterozygous hypercholesterolemias, the most effective statin at high doses that are safe for lowering LDL cholesterol. It's a safety record that is excellent, been reviewed, and also has the approval from the FDA for slowing the progression of atherosclerosis in surrogate trials and recent outcomes studies, so I'm here to endorse the use of Crestor as the most effective statin available. I would like to see this agent utilized in patients who have Medicaid in order to achieve further goals of therapy. I think the agents we have available today are not as effective in achieving goals of therapy. I would be happy to address any questions from the panel.

Question

What percentage of your statin use is Crestor, what percentage would you think is Lipitor and do you think simvastatin?

Antonio Lopez, MD

I think about 70% of my use is rosuvastatin. A subset of patients who are able to achieve goals of therapy with simvastatin, a small percentage, but those agents who don't have as much percentage decrease in LDL cholesterol on simvastatin per generic use, and a small subset of patients with Lipitor. Thank you so much.

Joe Williams, MD

My name is Joe Williams, I'm a urologist with the Idaho Urologic Institute. I have no financial ties with GlaxoSmithKline. I've been asked to come and speak in advocacy of Avodart, which is a 5-alpha reductase inhibitor. We use these to treat symptomatic benign prostatic hyperplasia. There are many other uses relating to prostate physiology, including decreasing blood loss around the time of the transurethral resection of the prostate, I find it very useful there. I use this medication in acute settings when patients are suffering from acute urinary retention, both postoperative and post traumatic, and I think it can have an effect there, because it gets into

Rachel Strutton-Draft

the system quickly and has a quick clinical effect. We're also very excited for the future. There are many studies that have looked at the use of 5-alpha reductase inhibitors in prostate cancer risk reduction, and I think we'll be hearing more about that as FDA approval of these indications arise. I use Avodart preferentially because it does attack its clinical effect through two biochemical pathways. What these medications do, is they inhibit the metabolism of testosterone to dihydrotestosterone. Dihydrotestosterone generates benign prostatic hyperplasia over time, but it can halt that process and result in shrinking of the prostate, not acutely, but over several months, but it can have an effect of somewhat loosening that hold on prostate overgrowth in the acute setting and, of course, with decrease in hematuria around the time of an operation. The half life of the Avodart is roughly five weeks and so missing a dose is not a very big, doesn't have a very big clinical impact, so I find Avodart very useful and I speak in favor of it being maintained as preferred.

Question

Do you use any other agents at all?

Joe Williams, MD

I do. I do. It's a generic, and when patients tell me that they have to have a generic, then I write for that, but especially in my inpatient situations, I ask them not to substitute with Avodart. Very good. Thank you.

Richard Radnovich, MD

Good morning. I'm Richard Radnovich. I'm a physician in private practice in sports medicine and pain management at the Injury Care Medical Center in Boise. I'm also a principle investigator and doing clinical trials for pain medications. I'm a consultant and advisor and speaker for many pharmaceutical companies, including Pfizer, Forrest and Lilly. I also see patients in both the sports medicine and the family practice clinics at the Family Practice Residency, and that's the largest, as you know, the largest provider of medical services to Medicaid patients in the state. I'm here today to speak on behalf of my patients with fibromyalgia and my fellow prescribers. The clinicians on the board, I don't think I need to tell any of you how frustrating and challenging treating fibromyalgia patients can be. This is a disease state that's poorly understood and we don't really have very many efficacious treatments. Of the treatments that we have, the medical treatments fall into three categories: we have the tricyclic antidepressants, the serotonin reuptake inhibitors, and the antiepileptic drugs. In these classes of medications, the only drugs that have sought and achieved FDA approval are milnacipran (Savella), duloxetine (Cymbalta), and pregabalin (Lyrica). These medications have earned the FDA indication because they've shown low adverse events, modest but statistically significant improvement that's durable over time. If we look at the most commonly used, non-FDA approved agents, the tricyclic antidepressants, again the clinicians here will agree that those are very poorly tolerated drugs. They have a list of side effects that are very common and tend to show up in our fibromyalgia patients who tend to be chemical sensitive. If you look at the studies that have been demonstrated to show efficacy for the tricyclics in fibromyalgia patients, we see very small cohorts, and we don't see durability over time. The longest study that I'm aware of is 24 weeks. I don't think that there is a study with fibromyalgia patients and tricyclic antidepressants longer than 24 weeks. The other drug that's commonly used for fibromyalgia, gabapentin, has a single, 12-week study. So not durability over time with gabapentin. If we look at the approved drugs for fibromyalgia, pregabalin (Lyrica) presented its year-long safety data at the American Academy of Rheumatology meeting in 2007 I believe. The data for duloxetine (Cymbalta) was published just this summer by Chappell in the Clinical Journal of Pain and milnacipran (Savella)'s data was published in the Arthritis & Rheumatology Journal in a supplement two years ago and was presented at the American Academy of Pain meeting in 2008. So when we look at the drugs to treat fibromyalgia, there are only three that show efficacy, safety and durability. Those are duloxetine (Cymbalta), pregabalin (Lyrica) and milnacipran (Savella). They deserve to stay on the list as first-line agents for the treatment of fibromyalgia. I would be happy to respond to any questions you might have.

Question

When you say 'durability', how long are studies now for efficacy? You mention there is a long study for safety, but for efficacy how long are the studies?

Richard Radnovich, MD

All those were required by the FDA to have year-long data, and I can tell you that they're looking at it longer term.

Rachel Strutton-Draft

Question

How long is the longest data?

Richard Radnovich, MD

52-week, if that's going to be our standard, I think it's going to be hard for us. There are ongoing studies looking at these that are more than twice as long as the nearest competitor's study. Thank you very much.

Kara Taggart, MD

Good morning, I'm Dr. Kara Taggart with St. Lukes Mountain States Urology. I do speak for Pfizer, but I'm here today representing my group with Mountain States Urology for Toviaz for the class of overactive bladder. I first got involved with Toviaz when a patient came to me saying that they had been on the clinical study and that this was the first drug in all of the drugs of the selective class for overactive bladder that actually worked for her. It really intrigued me and I sort of sought Pfizer out to say "How can I get involved in this drug? I want to know what the best drug out there is." and I sought them out before its release in May. What appeals to me about the drug, first of all, a couple of things, first is how it's broken down through its active metabolite, through esterases. Esterases are widely available; men, women, young, old, race, it's widely available, so the drug is actively and rapidly converted to the active metabolite, but more importantly, there are three different routes for metabolizing the drug to clear it, so there's two hepatic and one renal route for breakdown. This drug can be used in patients with renal insufficiency, hepatic insufficiency, it's not a problem for patients with being on other drugs, no interaction with cytochrome P450 drugs, no problem with oral contraception or other hormone drugs. So that's really appealing to me. Certainly as a St. Lukes employee, I see a lot of Medicaid patients. A lot of Medicaid patients are on a lot of other drugs, so the safety was a big issue for me, but when you have a patient who says that for the first time in their life they've sat through a whole movie, that's pretty exciting things for them. The quality of life changes that can come about with this drug. In a very timely fashion, just this week is being released the first head-to-head study in the class of OAB drugs that's been powered to show superiority. There is a prior study that was just powered for non inferiority, so coming this week is just the first study that compared Toviaz to Detrol in the highest doses available of the drugs, which did show superiority in the class as well. So I'd like your consideration for including Toviaz on your core formulary for overactive bladder.

Steven DeNagy, MD

Thank you for the opportunity to address the committee. My name is Steven DeNagy. I'm an internist from Idaho Falls, Idaho. I'm a certified internist and certified in clinical psychopharmacology and teach for Idaho State University continuing education through the Department of Counseling and the College of Health Sciences throughout the state. I am a speaker bureau for several pharmaceutical companies and a variety of classes, including in the past Pfizer, Eli Lilly and Forrest. I'm here to speak to the class of fibromyalgia and particularly for my patients, I suppose because my practice is quite complicated because I have a strong psychiatric population as well as complex internal medicine, I'm hoping for open access to the currently three approved drugs for fibromyalgia which would be Lyrica, Cymbalta, and most recently Savella. As previously mentioned, all three agents have one-year efficacy and safety data, and in particular I don't think any of them are quite alike to each other. You have Cymbalta, which is a bit more serotonergic than, you know, neutral. You have milnacipran which is on the other end, a bit more neurotonergic, so you have quite different drugs. Then you have an antiepileptic drug which can be used in combination as well as monotherapy. These are tough people to treat. The other thing that I do is I'm also a Suboxone provider. I see a lot of opiate-addicted patients and, interestingly, this might seem like a strange tie-in for this, but I really would like to see our patients have their pain treated in non-opioid means. Some of the imaging data that comes with fibromyalgia data set is that these folks have substantial endogenous opiate activity already prior to any treatment. Fascinating finding, which is probably part of the explanation why narcotics don't work in this population. However, since the withdrawal of opioids is, in fact a hyperalgesic allodynic syndrome. It makes it extraordinarily difficult to get fibromyalgia patients off narcotics. You might look at my profile; I have fibromyalgia patients on narcotics because I can't get them off, so I would rather not get them on in the first place. So I really am excited to see a very open formulary for this class, because I would like to see this treated more aggressively. I would also like to see the Department of Health & Welfare explore some novel strategies to improve the fitness of these patients. I know that sounds like a pretty en courant thought, but exercise is the only treatment which has been shown to modify the actual disease course. It's not to trivialize the importance of analgesic management, but if we improve their analgesic function, I think the possibility of exercise is better, but we need a means of encouraging it and if you could incentivize that somehow, I don't know how, you can think about it or we can talk about it, I think that would be a marvelous thing to do. So there's probably much more I could say about this, but I would just like to see access for it. I'm a little concerned about Savella because it's the new one on the block, so that might, there might be a tendency to not approve that. I think they're all very useful drugs

Rachel Strutton-Draft

and I would like to see easy access for all of them. I also, by the way, I'll give you applause because I do like the idea of, even though this is the first time I've heard of your PBM changes, I see the potential for that streamlining our PA process which is not one of the favorite things our staff faces every day, but I really applaud you for trying to do that. Hopefully, that will be very helpful. Thank you. Any questions?

Robert Lee, MD

Good morning everybody. My name is Dr. Robert Lee. I'm with the Boise Heart Clinic and I'm an interventional cardiologist. I am on the speaker's bureau for Pfizer, and I'm here to speak about Lipitor. The thing about Lipitor is that in this day and age, we really do strive to practice evidence-based medicine. I think that Lipitor has the most robust data to support its use. If you look at the studies and some of the recommendations from the NCEP, just for instance, the NCEP has given us these "optional guidelines" for treatment of LDL and total cholesterol of LDL of 70 and total cholesterol level of less than 160. You know, these are relatively difficult goals to meet, and the reason that these goals have been set, or these optional goals have been set, is because of studies that have used Lipitor as the active agent at the 80 mg dose, so if you look at these studies, actually, you know, these studies support the use of high-dose Lipitor. They don't really support the use of high-dose statin. All these studies are based on Lipitor. You know, just for example, just recently, there was a brand new study in the Journal of American College of Cardiology approximately two weeks ago, that supports the use of a loading dose of 80 mg of Lipitor (atorvastatin) within 24 hours of a percutaneous coronary intervention (PCI) showing a reduction of events from something from around 15% to 9% in 600 patients, so these are the studies that support the use of Lipitor. Very robust. Every time that another statin has gone head-to-head with Lipitor, you know, in their own studies, they've come out on the losing end. Pravastatin ran several studies, ran a couple studies, and lost out. Simvastatin ran another study and they were not as efficacious. Finally, I think the other thing to think about is always, you know, we're always concerned about cost, and Lipitor should be going generic quite shortly, so I think it just makes sense to keep Lipitor on the Medicaid formulary. It soon will be very competitive with the other generics.

David Kemp, MD

Good morning. My name's David Kemp. I'm a cardiologist in Twin Falls, Idaho, chairman of Southern Idaho Cardiology and the Director of St. Lukes MVRMC [unintelligible] for cardiac services. I am on the speaker bureau for Forrest and have been asked to speak on behalf of Bystolic. In cardiology, we are in an enviable position right now, because most, if not all, of the medication we've been using for the past decade, have gone generic, so we have statins and beta blockers and ACE inhibitors, all of which have gone generic. Most, if not all, of our patients one time or another are on beta blockers and, while we do have some good choices with generics for beta blockers, unfortunately many of those patients don't tolerate those generic medications, so I would just like to urge you to consider Bystolic because we consider it a good alternative to patients that are intolerant to the metoprolol or the carvedilol. It has some unique properties; it's the most selective beta blocker that we have, so consequently it's probably the first choice for someone who has severe COPD or [unintelligible]. It's also a good alternative to carvedilol which sometimes even at its lowest dose is not tolerated by a lot of patients. It has many properties that a lot of beta blockers don't have in that has afterload reduction properties and, in fact, one of my colleagues doesn't consider it a beta blocker, even though it is the most selective beta blocker because of some of those properties. Certainly, it's been used for many, many years in Europe even before it came to this country and was picked up by Forrest, and has a wealth of robust data to support its benefits, as do many of the other beta blockers. Any questions? Thank you.

Robert Pearson, PharmD

Hi, good morning, my name is Rob Pearson and I'm a pharmacist with the Research & Development Division of GlaxoSmithKline. I'd like to take a moment to thank the committee for this opportunity to briefly share some new information about Avandia that has become available within the past year. There's two important new trials that were presented at the American Diabetes Association last year. These were then subsequently published in the New England Journal and in the Lancet respectively. The first trial, the RECORD trial was a cardiac outcomes trial with over 4,400 patients that were followed for over five years. The results of this trial, the RECORD trial, demonstrated no increase in cardiovascular events with Avandia compared to metformin and the sulfonylureas and, more importantly, this RECORD trial documents Avandia's abilities to sustain glycemic control for over five years, which no other oral antidiabetic medication has done. The second of these two trials, the BARI 2D trial, was sponsored by the National Institutes of Health, and this trial included very high-risk patients with long-term diabetes and also known coronary disease. Again, in this population, Avandia was not only found to be safe, but when used with metformin, it was able to significantly gain a sustained glycemic control compared to the insulin-providing strategies in this trial. Today, with many medications to choose from for the management of diabetes, it is reassuring to know that Avandia is now the most well studied oral anti-diabetic medication ever, with over 1.9 million patient years of clinical trial experience ranging from prediabetic patients

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to patients with late-stage diabetes and even coronary heart disease as well. Avandia is also the only TZD with a cardiac outcomes trial that met its primary end point and only Avandia again has shown the ability to sustain glycemic control for over five years. Recently, the American Association of Clinical Endocrinology published their updated diabetes treatment guidelines which again reaffirmed the use of Avandia as monotherapy and in combination therapy for the treatment of type-2 diabetes, and these guidelines also go on to reference the durability of Avandia for the treatment of diabetic patients. So the bottom line is, of course, diabetes is a leading cause of morbidity and mortality here in the state of Idaho, the clinicians who treat diabetes need the full armamentarium of medications available to effectively treat these patients. Because of its solid efficacy profile, I would like to respectfully request that Avandia remain as a preferred product here for the Medicaid patients in Idaho. Thank you very much. I would be happy to answer any questions that you might have. Thank you.

Leigh Platte

Good morning, my name is Leigh Platte and I'm the Scientific Liaison for Astellas and our compound is VESicare. However, I'm talking today about an independent study that was from Dr. Steven Kaplan in New York. He presented this at the American Urology Association meetings last April in Chicago. It's an eight-week, open label trial of 156 consecutive patients, 87 women and 69 men with overactive bladder. The aim of this study was to ascertain the efficacy, the safety and tolerability of generic substitutes for branded anticholinergic medications. Patients completed a three-day diary at baseline and at eight weeks. Patients had been receiving either Detrol-LA, VESicare, Enblex, or Sanctura-XR. When switched to the generic oxybutynin immediate release, because of their primary care prescriber or their prescription benefit provider, men and women respectively experienced more frequency that was 2.1 more episodes in women and 2.4 in men, more nocturia, 1.2 in women and 1.4 in men, more incontinence, an increase of 40% in men and 46% in females, post void residual urine increased 14.7 ml in women and 19.7 ml in men. In addition, there were increased side effects in both genders, dry mouth increased 14% in men and 23% in women, and constipation increased 32% in women and 34% in men. Switching from VESicare and Detrol-LA to generic oxybutynin resulted in the greatest changes in safety and efficacy. So Dr. Kaplan's conclusion is, in this preliminary analysis, conversion from branded anticholinergic medication to generic oxybutynin resulted in a significant diminution in both efficacy and safety. He also pointed out it could be a wide variability from generic to generic in the oxybutynin immediate release. Thank you, are there any questions? Thank you very much.

Jennifer Brzana, PharmD

Good morning, I'm Jennifer Brzana, a pharmacist with GlaxoSmithKline Research & Development. Thank you for the opportunity to share some new clinical data concerning Avodart or dutasteride with you. The Provider Synergies write up on drugs indicated for BPH treatment includes the two-year interim data from the CombAT trial, which stands for "combination of Avodart and tamsulosin". That trial is now completed and was published in this month's issue of the European Urology. As requested, I'm going to share with you the four-year results from that trial. To review, the CombAT trial is a four-year study that evaluated whether combination therapy including Avodart, a 5-alpha reductase inhibitor, and tamsulosin, an alpha blocker, is more effective than either monotherapy alone for improving symptoms and long-term outcomes of acute urinary retention and prostate related surgery in men greater than 50 years of age with the diagnosis of BPH, experiencing moderate to severe symptoms, with total prostate volumes greater than 30 grams. Symptom baseline scores across all three treatment groups averaged 16.4 on the IPSS scale. At four years, symptoms were decreased or improved by 3.8 points in the tamsulosin 0.4 mg per day monotherapy arm, 5.3 points in the dutasteride 0.5 mg per day monotherapy arm, and 6.3 points in the combination arm. Combination therapy provided superior symptom reduction versus Avodart from month-3 in the trial to completion at four years and versus tamsulosin therapy from month-9 to completion of the trial. After four years, the combined primary endpoint of acute urinary retention and BPH related surgery occurred in significantly fewer men who received combination therapy of Avodart and tamsulosin compared to tamsulosin monotherapy. There was no significant difference between combined therapy and Avodart monotherapy with regards to this endpoint. The most commonly reported drug-related adverse events in this trial were impotence, decreased libido, ejaculation disorders, breast disorders and dizziness. The incidence of drug-related adverse events was significantly higher in the combination group, however discontinuation rates due to adverse events was similar across all three treatment arms, between 4% and 6%. New onset adverse events were most commonly seen in the first year of therapy. Given that the symptoms of BPH are the main reason men with enlarged prostates seek treatment, utilizing Avodart along with an alpha blocker provides these patients with the greatest level of symptom improvement sustained after four years. Avodart also provided the additional benefit of significant reductions in the risk of both acute urinary retention and BPH related surgery. For these reasons, we ask that Avodart be retained on the Idaho State Medicaid formulary. Thank you and I'll take any questions.