

Pharmacy and Therapeutics (P&T) Committee Meeting Record

Date: July 17, 2009 **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.; Catherine Hitt PharmD; Tim Rambur, PharmD; Dennis Tofteland, RPh; Michelle Miles, PA-C; John Mahan, M.D.; Tami Eide, PharmD

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

Committee Members Absent: Mark Johnston, RPh; Mark Turner, M.D.

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. John Mahan and welcomed him to the P&T Committee.
➤ <i>Reading of Confidentiality Statement</i>	Phil Petersen, M.D.	Dr. Petersen read the Confidentiality Statement.
➤ <i>Approval of Minutes from February 20, 2009 Meeting</i>	Phil Petersen, M.D.	There were no corrections. The February 20, 2009 meeting minutes were accepted as proposed.
➤ <i>Introduction of P&T Public Comment revisions</i>	Phil Petersen, M.D.	Dr. Petersen presented the new changes to the P&T Committee public comment process. Public comment will be limited to clinical and social comments. Testimony regarding pricing, cost, or other financial information is not permitted. Dr. Petersen noted that the information stated above regarding the

<p>➤ <i>Key Questions</i></p>	<p>Tami E. PharmD</p>	<p>P&T public comment changes were made available to the audience members as a hand out at the beginning of this meeting.</p> <p>There was discussion regarding not allowing comments related to cost. Members of the Committee felt it important to allow the public to speak on cost effectiveness. The statement “Testimony regarding pricing, cost, or other financial information is not permitted”, will be reviewed to insure the statement’s intent is met.</p> <p>Dr. Eide provided an update on the Drug Effectiveness Review Project (DERP). The DERP project is beginning into its 3rd stage of review and there are now thirteen (13) states involved in the project. She then extended an invitation to the Committee to submit any topics they would like to see covered by DERP 3. All participating organizations are nominating topics and voting on new topics will happen October 2009.</p> <p>Dr. Eide presented the following Key Questions: <u>Targeted Immune Modulators</u> <u>Pharmacological Treatment in ADHD</u> <u>Direct Renin Inhibitors, Angiotensin Converting Enzyme Inhibitors and Angiotensin II Receptor Blockers</u></p> <p>Dr. Eide then provided decision updates on reviews scanned by DERP: Will Update -Atypical Antipsychotics -Antihistamines</p> <p>Will Not Update -Drugs for Neuropathic Pain -Combo Drugs for Diabetes and Hyperlipidemia -Hormone Therapy -Calcium Channel Blockers -Oral Hypoglycemics -Skeletal Muscle Relaxants -Antiplatelets -Alzheimer’s Agents</p> <p>Hormone therapy will be nominated for coverage by AHRQ’s Effective Health Care Program.</p>
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<p>Public Comment Period</p>	<p>Phil Petersen, M.D. Bob Faller, Medical Program Specialist</p>	<p>Thirteen (13) people signed up to speak during the public comment period. Public testimony was received from the following speakers:</p> <table border="1" data-bbox="871 342 1902 1065"> <thead> <tr> <th>Speaker</th> <th>Representing</th> <th>Agent</th> <th>Class</th> </tr> </thead> <tbody> <tr> <td>Dr. Peter Dobles</td> <td>self</td> <td></td> <td>Controller Medications for Asthma; PA process</td> </tr> <tr> <td>George Tomas, PA</td> <td>Idaho Pulmonary Association</td> <td>Advair</td> <td>Glucocorticoid/Bronchodialator combination; PA process</td> </tr> <tr> <td>Dr. Kara McGee</td> <td>self</td> <td>Nasonex</td> <td>Intranasal Rhinitis Agents</td> </tr> <tr> <td>Dr. James Quinn</td> <td>self</td> <td>Avelox</td> <td>Fluoroquinilones</td> </tr> <tr> <td>Deb Criss</td> <td>Merck</td> <td>Singulair</td> <td>Leukotriene Modifiers</td> </tr> <tr> <td>Csilla Csoboth</td> <td>Boehringer Ingleheim</td> <td>Spiriva</td> <td>Bronchodialators, Anticholinergic</td> </tr> <tr> <td>Kathy Alkire NP</td> <td>Clinic at Eagle</td> <td>Valtrex</td> <td>Antivirals, Oral</td> </tr> <tr> <td>Kathy Alkire NP</td> <td>Clinic at Eagle</td> <td>Asthmanex</td> <td>Inhaled Glucocorticoids</td> </tr> <tr> <td>Gilda Harrison</td> <td>Astellas</td> <td>Protopic Ointment</td> <td>Topical Calcinerurin Inhibitors (Atopic Dermatitis Agents)</td> </tr> <tr> <td>Meredith Zarling</td> <td>GlaxoSmithKline</td> <td>Advair discus</td> <td>Glucocorticoid/Bronchodialator combination</td> </tr> <tr> <td>Adam Shprecher</td> <td>Schering Plough</td> <td>Avelox</td> <td>Fluoroquinolones</td> </tr> <tr> <td>Laura Litzenberger</td> <td>OMJPL</td> <td>Levaquin</td> <td>Fluoroquinolones</td> </tr> <tr> <td>Randy Legg</td> <td>Astra Zenica</td> <td>Symbicort</td> <td>Glucocorticoid/Bronchodialator combination</td> </tr> <tr> <td>Dan Manning</td> <td>Shering Plough</td> <td>Nasonex</td> <td>Intranasal Rhinitis Agents</td> </tr> <tr> <td>Dan Manning</td> <td>Shering Plough</td> <td>Asmanex</td> <td>Inhaled Glucocorticoids</td> </tr> </tbody> </table>	Speaker	Representing	Agent	Class	Dr. Peter Dobles	self		Controller Medications for Asthma; PA process	George Tomas, PA	Idaho Pulmonary Association	Advair	Glucocorticoid/Bronchodialator combination; PA process	Dr. Kara McGee	self	Nasonex	Intranasal Rhinitis Agents	Dr. James Quinn	self	Avelox	Fluoroquinilones	Deb Criss	Merck	Singulair	Leukotriene Modifiers	Csilla Csoboth	Boehringer Ingleheim	Spiriva	Bronchodialators, Anticholinergic	Kathy Alkire NP	Clinic at Eagle	Valtrex	Antivirals, Oral	Kathy Alkire NP	Clinic at Eagle	Asthmanex	Inhaled Glucocorticoids	Gilda Harrison	Astellas	Protopic Ointment	Topical Calcinerurin Inhibitors (Atopic Dermatitis Agents)	Meredith Zarling	GlaxoSmithKline	Advair discus	Glucocorticoid/Bronchodialator combination	Adam Shprecher	Schering Plough	Avelox	Fluoroquinolones	Laura Litzenberger	OMJPL	Levaquin	Fluoroquinolones	Randy Legg	Astra Zenica	Symbicort	Glucocorticoid/Bronchodialator combination	Dan Manning	Shering Plough	Nasonex	Intranasal Rhinitis Agents	Dan Manning	Shering Plough	Asmanex	Inhaled Glucocorticoids
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<p>➤ Ophthalmics for Allergic Conjunctivitis</p>	<p>Steve Liles, PharmD Provider Synergies</p>	<p><u>Ophthalmics for Allergic Conjunctivitis</u> This drug class was last reviewed July 2008. Dr. Liles reviewed one (1) double blind, randomized controlled clinical trial of Optivar, Elestat, and Zaditor with the Committee.</p> <p>Committee Recommendations The Committee felt there were no evidence based differences to make any changes to this class.</p>
<p>➤ Topical Calcineurin Inhibitors</p>	<p>Nancy Lee, PharmD, Fellow OHSU EPC</p>	<p><u>Topical Calcineurin Inhibitors</u> Dr. Lee reviewed the evidence from this class review that was completed in October 2008. The review concluded that tacrolimus 0.03% ointment is as effective as pimecrolimus 1% cream in treating atopic dermatitis and in improving pruritis in patients with mild to moderate disease and probably for moderate to severe disease (indirect evidence). Results are conflicting on whether tacrolimus 0.1% is more effective than pimecrolimas 1%. Total withdrawal rate due to adverse events were not significantly different between both strengths of tacrolimus and pimecrolimus.</p> <p>Committee Recommendations The Committee did not see evidence to favor one (1) agent over the other. They did have concerns on the place in therapy for these agents and asked that as evaluation be done on which physician specialties were prescribing and ensuring they were used second line after topical steroids. They suggested targeted education on appropriate use.</p>
<p>➤ Antihyperuricemics, Oral</p>	<p>Steve Liles, PharmD</p>	<p><u>Antihyperuricemics, Oral</u> This is the first review of this drug class. Dr. Liles reviewed the products in this drug class and their indications, as well as the mechanism of action and a comparison of febexustate vs. allopurinol. Dr. Liles also reviewed two (2) double blind, randomized controlled clinical trials with the Committee.</p> <p>Committee Recommendations The Committee felt there were evidence-based differences between allupurinol and febuxostat (Uloric). They felt there were safety issues without a demonstrated better efficacy with Uloric. The Committee recommended that allupurinol be preferred and that Uloric be reserved for patients who are continuing to have gout attacks after three (3) months of allupurinol therapy and are either intolerant or fail to achieve serum urate levels < six (6) mg/dl.</p>

<p>➤ Fluoroquinolones, Oral</p>	<p>Steve Liles, PharmD</p>	<p><u>Fluoroquinolones, Oral</u> This drug class was last reviewed July 2008. Dr. Liles reviewed the GOLD guidelines for treatment of acute exacerbation of chronic bronchitis, quinolone resistance patterns and black boxed warnings. The Committee also reviewed one (1) clinical trial of UTI/pylonephritis and one Meta-Analysis of pneumonia treatment.</p> <p>Committee Recommendations The Committee felt there were no evidence based differences to make any changes to this drug class. They felt it was important to have a respiratory quinolone and that Cipro suspension could be considered for preferred status based on utilization patterns.</p>
<p>➤ Cephalosporins & Related Antibiotics</p>	<p>Steve Liles, PharmD</p>	<p><u>Cephalosporins & Related Antibiotics</u> This drug class was last review July 2008. Dr. Liles reviewed the warnings related to hypersensitivity reactions in Penicillin/Beta agonist combinations.</p> <p>Committee Recommendations The Committee recommended cefadroxil and cefprozil as preferred agents in this drug class, if found to be cost effective. The Committee also recommended cefaclor be removed as a preferred agent due to clinical safety issues.</p>
<p>➤ Macrolides/Ketolides</p>	<p>Steve Liles, PharmD</p>	<p><u>Macrolides/Ketolides</u> This drug class was last reviewed July 2008. Dr. Liles reviewed the guidelines for treatment of Mycobaterium avium complex in HIV patients with the Committee.</p> <p>Committee Recommendations The Committee felt there were no evidence based differences to make any changes to this drug class and Ketex should keep the same clinical criteria.</p>
<p>➤ Antivirals, Oral</p>	<p>Steve Liles, PharmD</p>	<p><u>Antivirals, Oral</u> This drug class was last reviewed July 2008. Dr. Liles reviewed Influenza A resistance of this drug class with the Committee.</p> <p>Committee Recommendations The Committee felt there were no evidence based differences to make any changes to this drug class.</p>
<p>➤ Antivirals, Topical</p>	<p>Steve Liles, PharmD</p>	<p><u>Antivirals, Topical</u> This drug class was last reviewed July 2008. There was no new significant clinical information available</p>

<p>➤ Antiparasitics, Topical</p>	<p>Steve Liles, PharmD</p>	<p>for this drug class.</p> <p>Committee Recommendations The Committee felt there were no evidence based differences to make any changes to this drug class at this time.</p> <p><u>Antiparasitics, Topical</u> This drug class was last reviewed July 2008. Dr. Liles reviewed one (1) new drug: benzyl alcohol 5% lotion and the two (2) clinical trials for that agent.</p> <p>Committee Recommendations The Committee recommended making the new drug benzyl alcohol 5% lotion a preferred agent, as long as it is cost effective. If it is found to be non cost effective, the Committee recommended placing benzyl alcohol 5% lotion as non preferred with a PA criteria of documented failure of a preferred agent.</p>
<p>➤ Vaginal Antibiotics</p>	<p>Steve Liles, PharmD</p>	<p><u>Vaginal Antibiotics</u> This drug class was last reviewed July 2008. There is no new significant clinical data for this drug class.</p> <p>Committee Recommendations The Committee recommended that both clindamycin and metronidazole products be available.</p>
<p>➤ Antifungals, Oral</p>	<p>Steve Liles, PharmD</p>	<p><u>Antifungals, Oral</u> This drug class was last reviewed July 2008. Dr. Liles reviewed the IDSA 2009 Oropharyngeal Candidiasis guidelines for this drug class with the Committee, as well as guidelines for symptomatic candida cystitis and vulvovaginal candidiasis. The Committee reviewed a clinical trial for tinea capitis and a Meta-Analysis of griseofulvin in tinea capitis</p> <p>Committee Recommendations If found to be cost effective, the Committee recommended griseofulvin products, itraconazole and terbinafine be considered for preferred status.</p>
<p>➤ Antifungals, Topical</p>	<p>Steve Liles, PharmD</p>	<p><u>Antifungals, Topical</u> This drug class was last reviewed July 2008. There was no new significant clinical data for this drug class.</p> <p>Committee Recommendations The Committee recommended that econazole remain preferred if status changes to OTC . They recommended the DUR Board do a utilization review of indications for the antifungals/steroid combinations and that they survey dermatologists for the place in therapy for these agents.</p>

Rachel Strutton

**Pharmacy and Therapeutics Committee
Public Comment
July 17, 2009**

Committee

I will call your attention to the sign-in sheet, that we have it divided into three sections:

The first section is for medical practitioners, and then the second section for private citizens, and then a section for the drug industry. So when you're signing in, if you could follow those guidelines, that would be helpful.

Do we have any physicians here today to speak? Any practitioners? Okay. Yes sir, go ahead. Are you signed in?

Answer

Yes.

Committee

Okay, go ahead.

Dr. Peter Doble

Dr. Peterson, Faller and members of the Committee. I'm Peter Doble, I'm an ENT physician from Twin Falls, and I'd like to speak to you today about considering redesigning the approach to preauthorization for asthma inhalers. For the sake of clarity and brevity, I made some notes and I'm going to refer to them, and of course my new program makes it sideways, so I have to figure out how to make that work.

Committee

If I could just interrupt you for a minute. Do you have any affiliation?

Dr. Peter Doble

I have no affiliation and I have not been paid. I'm not on the speaker parade. I do research that's funded by the NIH. Your current policy, our current policy, place prior authorization for inhaled steroids and combined medications, and the decision tree that we deal with as a physician requires us to move through a series of decisions, and while this is a wonderfully thought out process, it is not in sync at present time with what's been available by the NIH and the Pulmonary Academy, and the direction now is fairly clearly delineated at moving to combined therapy as quickly as possible, to the most effective drugs as quickly as possible, tend to limit and make more cost effective situations and discount, decrease hospitalizations. I would speak to the cost versus cost effectiveness that was mentioned before. We can use more inexpensive medications more frequently and have more illnesses and have a higher cost in the end than if we are using a more effective medication early on and hopefully proceed to a better level of care sooner. The current situation also with the choices that are available with inhaled therapy forces physicians who are going to treat patients under the age of twelve to use medications in their off-label fashion. Now, while each individual physician has this as part of his or her prescription prerogative, there has been an outcry in the public as to off-label uses and I know for certain that the FDA is looking at off-label uses, so I know that there are medications that have indications to a much lower age and it would be a reasonable thing to consider, I feel as a practitioner, it would be a reasonable thing to consider using those. Lastly, the economic burden that I face as a physician for filling out and having staff fill out the prior authorizations is, I look at it as an unfunded mandate

Rachel Strutton

by the State to make your formulary more cost effective for you, but it makes my work load considerably more expensive, and I had to lay people off, due to these economic times, so every time I get a preauthorization for certain medications, you know, obviously I'm going to be compliant with those that I feel are reasonable. Could a patient use an over-the-counter anti-allergy medication as opposed to Singulair, for example. I think that makes sense and it causes one to reflect, but if we're going to be moving toward more effective application of medical practice, treating something that requires high hospitalization rates like asthma, I think it makes sense to consider modifying the preauthorization practice. Thank you for your time. How'd I do for time?

Committee

Very good.

Any other practitioners? Yes sir?

George Tomas, PA

Good morning. My name is George Tomas. By training, I'm a PA, I graduated from the University of Utah in 1977. I currently serve at Idaho Pulmonary Associates as their Clinical Director. What I would like to do is come to you this morning and give you a perspective perhaps that wasn't considered in much detail previous, regarding the also, preauthorization process and how it impacts Idaho Pulmonary Associates. For those of you who don't know who we are, we are a pulmonary group. We also do critical medicine, as well as sleep disorders. We have 14 physicians and three mid-level practitioners. We have approximately 21,000 registered patients as of yesterday. We take in 300 new patient referrals per month, so the demand is quite high in the Treasure Valley and Northwest, and it's hard to keep up with such demands. What I'm here to say to you, is I would like to give you some perspective on how it really affects us in regards to the cost in regards the process of getting preauthorizations for drugs, such as Advair. The way it affects us, is that I took some reports and this is the numbers that I, surprised me, that I'm going to present to you today. From early 2007 to present, we prescribed approximately 2,583 new prescriptions, not refills, but brand new prescriptions for the long-acting beta agonist combined with the inhaled corticosteroids. 2,583. Of those, we have one-third that required preauthorizations. These were divided into three different brands: Flovent, Advair and Symbicort. Those were the three major players in our prescriptions. To give you some perspective as to how the pulmonologists prescribe, of the 2,583 prescriptions, 1,800 were Advair, 79 were Symbicort, and the remaining, Flovent. The cost of preauthorizations is thus: We pay approximately \$15 per hour for the labor cost to do preauthorizations. That doesn't include benefits, taxes, etc., that is just pure labor cost. We also pay \$25 per preauthorization for overhead that includes leases, utilities, all the things required that accounts for overhead. In addition, about \$2.50 per preauthorization for supplies, paper, toner, faxing, telephone and faxing, approximately \$9.00, for a total of \$51.50 per prescription that requires preauthorization. If you multiply that times the number of preauthorizations we have had to do, which is 861, that comes out to \$44,340.00; not chump change as far as IPA is concerned. Now, not only that, but what's it cost Health & Welfare, Department of Medicaid, to process the preauthorizations? I don't really know the exact number, but from what I gathered, at least in the State of Washington, it is about \$40-45 per prescription for the preauthorization process. I don't know how accurate that is, or if it's germane to Idaho, but I assume that it's probably similar. In addition, what does it cost to retail pharmacists when there is a preauthorization to do, interrupt their normal flow of filling prescriptions, they have to call the physician's office to go through the preauthorization process. That, I don't really know for sure either. Finally, patient cost. What does it cost them in gas, wear and tear on their vehicles, to go to the pharmacy multiple times versus a single visit to pick up their prescription, due to preauthorization? In addition, what does it cost them to get time away from work? Also the inconvenience and frustration, and finally, what's the cost of improvement in quality of life? As they say in the commercials, it's priceless. In conclusion, I believe the preauthorization has merit, it has much value, if you're trying to stratify medications and costly procedures, I wholeheartedly advocate that, however I want to plead with this committee today to consider the effects that I presented in terms of cost to a single physician group. The elimination of the preauthorization requirement for those drugs, particularly Advair, Symbicort, Flovent, can actually contribute to the de-escalation of the cost of health care, if you look at it in global terms. The preauthorization requirement for these drugs, in our opinion, Idaho Pulmonary Associates, is not cost effective, nor is efficient, particularly if you consider that the authorization rate for those drugs in our practice is virtually 100%. Thank you.

Committee

Any other practitioners?

Rachel Strutton

Kara McGee, PA

Hi, my name is Kara McGee, I'm a PA, went to Idaho State University and I've been practicing for approximately 11 years, and I am here to request that Nasonex remain on the formulary. I think it's a very good nasal steroid spray that's very well tolerated by a lot of my patients, indicated down to age 2, so it's, I hope, a wide range of patients that I can give it to, and it's very well tolerated. I'll keep this very short and to the point, because I know that's what you want. I just think it's just a very good medication for treating allergic rhinitis and non-allergic rhinitis. So that's what I have to say. Thank you very much.

Committee

Thanks. Any other practitioners?

Dr. James Quinn

Good morning, my name is James Quinn. I'm a physician in Boise in Urgent Care at this time. I have no connection with the company that I'm going to speak on, no reimbursement, in fact I even had to borrow coffee from your container this morning. I have been a doctor for 41 years, and I found out that if I pick the medicine that works the best for me, satisfies me and satisfies my patient, I tend to stay with it, and Avelox has been doing that. It's nice to be able to give it to a patient who has a terrible sinusitis, a bronchial pneumonia, or just a regular, community-acquired pneumonia, and it's not very exciting to give testimony of people's sinusitis, unless you're the one who has the sinusitis. Then everybody wants to talk about how miserable they are, but it's refreshing to be able to give somebody the medication and tell them that "You will be better in 5-8 days." and I feel better because the number of complications that I have had have been very, very small. I think by giving the medication, I keep people out of the hospital, and I'm not saying it to besmirch any other medication, except that I'm trying to do what's best for my patient and what makes me feel comfortable. In deference to Dr. Peterson's admonishment, I'll try to keep this as brief as possible, and I thank you for your time.

Committee

Can I get you to sign in here, because don't believe I have you on.

Dr. James Quinn

Is this for the coffee? <laughter>

Committee

No, we're going to have to bill you for that. <laughter> Thanks. Okay, any other practitioners? Okay. Deb Criss?

Deb Criss

Good morning, it's nice to see some familiar faces. I'm Deb Criss, I'm an employee of Merck Human Health, I have been so for the past 21 years, my current position is Health Science Consultant in the Respiratory Division, and I'm here today in support of Singulair for the prevention and treatment of asthma. Again, in keeping with your new guidelines, I want to say that I have no new data at this time to share with you, except for a comment. After reviewing the data that you will be reviewing on the leukotriene receptor antagonist class later this morning, that Singulair, just a reminder that Singulair is indicated for the prevention of exercise-induced bronchoconstriction in patients that are 15 years of age and older. That would be a 10 mg tablet that should be dosed at least two hours prior to exercise. I did want to make myself available, should you have any questions about the medication. All right, thank you for the opportunity today.

Csilla Csoboth

Good morning and thank you for trying to pronounce my name. My name is Csilla Csoboth and I'm the National Medical Scientist at Boehringer-Ingelheim, and I'm here to support Spiriva. As you know, COPD is the leading cause of disability and is the fourth leading cause of death in the United States, and the GOLD Guidelines recommend a stepwise approach where long-acting bronchodilators are recommended for moderate to severe COPD patients in addition to pulmonary rehabilitation. I'd also like to be compliant with your new guidelines; we have no new information regarding the efficacy of Spiriva. As you know, it is indicated for the long-term maintenance therapy, once-daily use for COPD, emphysema and chronic bronchitis, and it improves pulmonary function and exercise endurance time. I'd like to bring

Rachel Strutton

your attention to our safety data. Spiriva has an established safety profile, and the latest pooled analysis of thirty clinical trials that are placebo-controlled, double-blind, randomized trials, with the data from more than 19,000 COPD patients, more than 10,000 patients use tiotropim that was conducted by Boehringer-Ingelheim, demonstrated that there is no increased risk of death or cause, or cardiovascular death, and no increased risk of stroke in patients who are taking Spiriva. I'd like to thank you for your attention, and if you have any questions, I'm here to answer them. Thank you very much and have a good day.

Kathy Alkire, NP

I apologize for being late. I'm here to speak about Valtrex and Asmanex and I'd like to start with Valtrex. As a provider, I'd like to just let you know that Valtrex works far superior to acyclovir in helping HSV-2 patients. It's the only once-a-day medication on the market, which makes its compliance better over the other option which is, in fact, cheaper, but it is a much better drug, and there are some anecdotal data now that will come forward soon about oral herpes lesions that, if it is used preventatively or early in an oral herpes outbreak, it will work very well in preventing further infection. I'd also like to just speak on Asmanex. Asmanex, I use in my practice as a prevention drug for asthma. It's a once-a-day inhaled glucocorticoid drug. It has an indication down to age 4, and is very well tolerated. It is a bit cheaper than Flovent. All the drugs in this class are quite expensive, but this one works very, very well, since it's a once-a-day, and thank you for allowing me up here late.

Committee

I'm sorry, I missed where you work?

Kathy Alkire, NP

I'm sorry, I work at the Clinic At Eagle. I'm a nurse practitioner, and it's a small medical clinic in downtown Eagle. We see patients across the spectrum from infancy through 80s, so we use both of these drugs quite a bit. Thank you.

Gilda Harrison

Good morning. I'm the Scientific Affairs Manager with Astellas Pharma and in view of your new guidelines, I would like to give you a very quick overview for Protopic ointment which you already have on your PDL, and we are requesting that you consider maintaining that drug on it. As you may know, Protopic ointment is recommended for adults and children 2-15 years of age. It is not recommended for children below age 2. This is actually for a second-line therapy for the short-term and noncontinuous, chronic treatment of moderate to severe atopic dermatitis. This is for non-immunocompromised patients, who have failed to respond adequately to other prescribed prescription treatments. It does have a black box warning, which I'm sure you're all aware about, but there has been no causal relationship established, and although this has not been established, there have been very rare cases of malignancy that have been reported in patients who have been treated with this class of drugs. To date, long-term Protopic ointment in pediatric and adult atopic dermatitis patients have now demonstrated an increased incidence of malignancy, including lymphoma. In regard to comparative trials, adults with moderate AD at baseline using Protopic have shown significantly better improvement than pimecrolimus treated patients, including EASI scores of 59% versus 43% for a portion of patients with improvement by 1+ grade in the Investigator's Global Assessment score was also higher with 79% versus 62%, and there were fewer discontinuations due to lack of efficacy with this product. In regards to safety, the most common adverse events reported with Protopic were skin burning, pruritus, flu-like symptoms and headache, with no difference in the overall incidence of non-application site events and infection compared to vehicle. So, in summary, Protopic ointment is an important, safe, and effective treatment option for patients with AD when used according to label.

Meredith Zarling

Good morning and thank you for the opportunity to speak to you today about Advair Diskus and Advair HFA. My name is Meredith Zarling and I'm a Clinical Pharmacist and a Regional Medical Scientist with GlaxoSmithKline. I'd like to present information in support of Advair in the Idaho Preferred Drug List, and very quickly I want to highlight five points: Number one, the National Heart, Lung & Blood Institute panel of experts, after careful review of the literature, issued very clearly defined guidelines on the management of asthma. According to the guidelines, patients not on a controller already should be assessed to severity of disease and then managed appropriately based on that severity. For patients greater than 12, with a severity class of mild, persistent asthma, the preferred treatment is low-dose inhaled corticosteroids. However, for patients who meet the criteria for moderate asthma, such as a patient who is using albuterol daily, it's recommended that the patients initiate therapy at step-3, which preferred therapies are low-dose inhaled corticosteroid plus long-acting beta agonist combination, or medium-dose inhaled

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corticosteroid. For patients with severe asthma, these patients should initiate therapy at step-4 or -5, in which the preferred therapy is medium- or high-dose combination therapy with an inhaled corticosteroid and long-acting beta agonist. NIH guidelines are aligned with how physicians currently manage their moderate to severe asthmatics and are aligned with Advair prescribing information. Second point is, in a study by Murray published by Annals of Allergy, Asthma & Immunology, they found Advair to significantly improve overall asthma control and improve lung function and decrease use of albuterol when compared to fluticasone alone. These were patients with moderate to severe asthma and were symptomatic on albuterol alone. Third, a validated model of a corticosteroid potential to reduce growth velocity in children was developed from data and 32 published studies. The results showed that Flovent powder, 200 mcg q.d., had the lowest potential to reduce growth velocity in children compared to other inhaled corticosteroids in the study, including budesonide. Fourth, Advair 250/50 mcg is the only combination product approved for the reduction of exacerbations in COPD. Last year, a COPD study published by Ferguson in Respiratory Medicine showed a 30% decrease in COPD exacerbations with Advair when compared to Serevent. The number needed to treat to prevent one exacerbation was 2, so for every two patients treated with Advair instead of Serevent, one exacerbation was prevented. These results led to the FDA expanding the indication from COPD to adding the reduction of COPD exacerbations, and no other COPD medication can make this claim. Finally, unlike other combination products, Advair is indicated down to the age of 4 years for the treatment of asthma. It's available in two different devices; a metered-dose inhaler and an easy to use disk device, and is available in three strengths. In conclusion, based on the data and the recommendations and national guidelines, Medicaid patients in the State of Idaho are best served if Advair Diskus and HFA are placed on the formulary without restriction. And then, very quickly, I would like to talk about Veramyst. Veramyst is indicated for the treatment of symptoms of both seasonal and perennial allergic rhinitis down to the age of 2, which is one of only a couple of products on the market that are indicated down to the age of 2. Veramyst has two times the binding affinity to the human glucocorticoid receptor, more than twice that of fluticasone propionate. It's the only nasal steroid proven to relieve not only four nasal symptoms, but also ocular symptoms. We have five out of five replicated studies which show treatment of significant improvement in nasal symptoms, as well as ocular symptoms, and no other steroid on the market has been shown to have data that shows consistent ocular effects. Third, the device is a very unique attribute of the product. It's innovative in its design based on feedback from patients and physicians. It has a side actuator, which releases a low volume of mist, half that of Flonase, and this decreases the amount of product running down the back of the throat. It also has a very short nozzle, which assists in the ease of administration in pediatric patients. So based on these advantages, I would like to ask the Committee to retain Veramyst as a branded nasal corticosteroid available for Medicaid patients in the State of Idaho. Do you have any questions at all?

Question

I have one. You mentioned a study about growth retardation. Was that an outcomes study that measured growth as such? It was kind of, I didn't quite catch what you were saying.

Meredith Zarling

It was a compilation, almost a meta-analysis of 32 studies that looked at equivalent, not, they didn't look at the dose equivalencies, they looked at cortisol equivalency, so that it made sure that they were on a level playing field with all the different steroids, so you can't go this to this, for all different potencies, so it was a meta-analysis looking at growth studies, randomized, placebo-controlled trials, between all the steroids that were available on the market at the time. Okay, thanks.

Adam Shprecher

Hi, my name is Adam Shprecher and I'm a Clinical Pharmacist working with Schering Plough Medical Affairs. Thank you for considering Avelox (moxifloxacin) for continued coverage under the Idaho Medicaid system. Moxifloxacin, available both IV and p.o., is indicated for sinusitis, bronchitis, community-acquired pneumonia including multi-drug-resistant Strep, uncomplicated and complicated skin and skin structure infections, and is the only fluoroquinolone indicated as a monotherapy for complicated intra-abdominal infections. All of these indications are for patients greater than 18 years of age and are all at a 400 mg once-daily dose. In the CAPRI trial, moxifloxacin was associated with a faster clinical recovery than Levaquin therapy and moxifloxacin demonstrated a comfortable cardiac rhythm safety profile to Levaquin amongst other similarities among the safety profile as well, and the package inserts for both moxifloxacin and levofloxacin were recently harmonized to reflect similar language pertaining to safety data involving QT prolongation, risk of C. difficile colitis, and hepatic reactions due to hypersensitivity. Recent data published comparing Avelox to high-dose Levaquin therapy by Torres and colleagues, was a randomized, double blind, non-inferiority study looking at high-dose levofloxacin, levofloxacin given at 500 mg twice daily, 1000 mg a day, including IV ceftriaxone given 2 gm once daily in combination therapy as compared to moxifloxacin as a once-daily, 400 mg monotherapy in patients with required hospitalization for community-acquired pneumonia. Moxifloxacin was found to be non-

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inferior to treatment with ceftriaxone plus levofloxacin 1000 mg a day therapy in divided doses. Moxifloxacin is not approved for the treatment of urinary tract infections, or for infections due to Pseudomonas, and when a fluoroquinolone is used for these infections, generic ciprofloxacin is available and covers the same pathogens as levofloxacin, with comparable efficacy data. If you have any questions, please feel free. Thank you.

Laura Litzenberger

My name is Laura Litzenberger, and I am a Medical Science Liaison with Ortho-McNeil Pharmaceutical, and I'm here to ask the Committee to maintain Levaquin on the PDL. Levaquin's been available in the United States since 1996. I'd like to update the Committee on the resistance data that has been produced for the last twelve years through the Tracking Resistance in the United States Today (TRUST) study. This is looking specifically at Strep pneumoniae resistance during the respiratory period of each previous year, and what we've found is that Levaquin maintains greater than 99% susceptibility to Strep pneumoniae across the nation, however this year in Idaho, both Levaquin and moxifloxacin resistance has decreased to between 97% and 98%. Those data are available if you want to look on the Levaquin.com website and it will talk about the methodology of the study and the exact resistance patterns. I would like to remind the Committee that Levaquin is recommended at a dose of 750 mg once a day. The previous speaker spoke of 1000 mg and that's not a labeled indication. 750 mg once a day is the approved dose for the treatment of community-acquired pneumonia at a five-day interval. Also sinusitis 750 mg once a day at a five-day interval. The five days of drug exposure will perhaps decrease the resistance that's associated with antibiotic therapy, also may increase patient compliance, and will decrease collateral damage, so there's less drug exposure over those five days. I would like to remind the Committee that there's a difference in the excretion pattern of a fluoroquinolone, that Levaquin is excreted and changed in the bowel at 4% compared to moxifloxacin at 25%, so there is a potential for a change in the GI flora. Levaquin has never been associated with cases of vancomycin-resistant Enterococcus, and that's an important point. If there's any additional information I'm open for questions.

Randy Legg

Can you hear me okay? My name is Randy Legg, I'm a PharmD, Medical Liaison for AstraZeneca, I live in Spokane, and I'm going to hold my comments brief on Symbicort in accordance with the new format. Symbicort currently is on the PDL for Idaho Medicaid and we hope that it maintains that as well going forward. Symbicort is a combination product of budesonide and formoterol. It's available in two strengths, the first strength is 80 mcg of budesonide with 4.5 mcg of formoterol. The second is a 160/4.5 mcg. As of February 22, Symbicort did get approval for COPD, and is now approved in the maintenance and treatment of air flow obstruction in patients with chronic obstructive pulmonary disease, including chronic bronchitis and emphysema. This approval was based on two studies, and I'll give you the results of the studies here. [Illegible] significantly improved lung function as early as day-1 and was sustained after twelve months. It's the only ICS/LABA combination maintenance medication for COPD with an onset of bronchodilatation within five minutes, reduce overall daily COPD exacerbations in 35% versus formoterol, reduced total daily rescue medication use by 56%, and the safety profile was comparable to the profiles mild components and placebo, and instance of pneumonia was similar to placebo as well. That's it, unless you have questions for me. Thanks.

Dan Manning

Good morning, my name is Dan Manning, I'm a PharmD with Schering Plough's Global Medical Affairs, and in light of the new rules, I'm going to keep this short also in regards to Nasonex and Asmanex. I do want to mention that Asmanex now does come in a 1/10 dose and is also indicated down to four years of age. I have a little device here which has a dose counter on it for the patients, and every time you load a dose, it clicks down and takes a dose down by one. Once it hits down to zero, it locks out and the patient knows they're out of this medication. The other thing I want to talk about is Nasonex. It has one of the broadest range of indications for patients using nasal inhaled steroids. It's indicated down to two years of age, and it is the only nasal steroid approved for the prophylaxis of seasonal allergic rhinitis, and it's the only nasal steroid approved for nasal polyps. Schering Plough would like the board to recommend maintaining those two products on the formulary. Any questions? Thank you.

Committee

Do we have any other speakers? No other speakers?