Pharmacy and Therapeutics (P&T) Committee Meeting Record

Date: Friday, October 11, 2013 Time**:** 9:00 a.m. – 3:00 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; Elaine Ladd, PharmD; David Calley, PharmD; Tami Eide, PharmD; Kevin Ellis, PharmD; Mark Turner, M.D.; Troy Geyman, M.D.; Jeffrey Johnson, PA-C, PharmD; Greg Thompson, M.D; Leigh Morse, M.D., Berk Fraser, RPh (for Mark Johnston, RPh)

Others Present: Paula Townsend, PharmD, Magellan Health Services; Jane Gennrich, PharmD, Division of Medicaid; Chris Johnson, PharmD, Division of Medicaid; Emily Perez, Division of Medicaid; Teresa Martin, Division of Medicaid

AGENDA ITEMS	PRESENTER	OUTCOME/ACTIONS
CALL TO ORDER	Perry Brown, M.D.	Dr. Brown called the meeting to order.
Committee Business		
➢ *Roll Call*	*Perry Brown, M.D.*	Dr. Brown completed the roll call.
➢ *Reading of Mission Statement*	*Perry Brown, M.D.*	Dr. Brown read the Mission Statement.
➢ *Approval of Minutes from May 10, 2013 Meeting*	*Perry Brown, M.D.*	The May 10, 2013 meeting minutes were reviewed. Dr. Mark Turner moved to accept the minutes, Dr. Jeffrey Johnson seconded and the Motion passed. The minutes were accepted as written.
➢ *DERP Update*	*Tami Eide, PharmD*	Dr. Eide provided an update from DERP (Drug Effectiveness Review Project). She talked about the various drug classes to be reviewed including an updated Second Generation Antipsychotic review. Tennessee and North Carolina are now participating in DERP, bringing the total number of states participating in the governance to 11.
➢ *Clinician Administered Drugs*	*Jane Gennrich, PharmD*	Dr. Jane Gennrich gave an update regarding clinician administered drugs billed as medical claims

		and pharmacy oversight. Reasons for pharmacist involvement include consistency as the same criteria is used regardless of whether billed as a medical claim or as a pharmacy prescription; pharmacist expertise with extensive drug knowledge, evidence evaluation experience and access to both medical and drug history; and the potential for supplemental rebates. All new J-codes for medications billed as medical claims are evaluated by a DHW pharmacist for indication, place in therapy, and potential utilization (both for FDA approved indications and potential off-label use). Existing J-codes are systematically being reviewed for current and potential utilization and indications. For drugs where a prior authorization is not needed, quantity limits or age restrictions may be added or the drug may be placed on a quarterly watch list and paid claims evaluated quarterly. Dr. Gennrich explained that communications to providers includes announcing drugs requiring PA in the Medicaide Newsletter and posting of prior authorization status on the Molina website. Dr. Gennrich then reviewed the prior authorization process. Two examples demonstrating the value of oversight of clinician administered drugs were provided – immunoglobulin and botulinumtoxin. The P&T Committee asked about the prior authorization approval and denial process. Dr. Gennrich explained Idaho Medicaid's PA process. She explained the turnaround time in the Pharmacy is within 24 hours. For approvals, a fax is sent to the prescriber's office. For denials, a fax is also sent to the prescriber's office as well as a letter, mailed to both the prescriber and the Idaho Medicaid participant.
➢ *Update on Board of Pharmacy Activities Surrounding Opioid Abuse and Diversion*	*Berk Fraser, RPh, Deputy Executive Director, Idaho Board of Pharmacy*	Mr. Fraser gave an update from the Idaho Board of Pharmacy on activities regarding opioid abuse and diversion. He talked about the different statutory authorities that created the Prescription Monitoring Program (PMP), which was started in 1997 by the Idaho Legislature. This was the nation's second PMP. This authority indicates that the Board shall create, operate, and maintain a controlled substances (CS) prescription database and that the Board shall maintain a program to track and provide information to patients, practitioners and pharmacists to assist in avoiding inappropriate use of controlled substances. In fiscal year 2013 there were 2,795,356 controlled substance prescriptions reported and collated into patient and prescriber profiles. By rule, the PMP database is only available to licensing boards, peace officers, Health and Welfare, prescribers, pharmacists, patients (may obtain their own information only) and by order of a court and prosecuting attorney. Mr. Fraser reviewed the advancements made since the PMP went on-line in 2008. He explained that each month, the Board sends a cover letter and a patient history to each prescriber who prescribed to a patient that was also prescribed controlled substances by five (5) or more

		prescribers that month. In 2013, the average number of letters sent per month was 377. He explained that 38% of prescribers are currently registered to use the on-line PMP. Further information indicates that 90% of the controlled substances dispensed are issued by 16% of the prescribers in Idaho. Signage (window clings) are currently distributed to practitioners and pharmacies to announce PMP participation to the public. Mr. Fraser stated that a new PMP is being rolled out with a target date of 12/4/13. This new database will have the capability of interstate data sharing with other participating states, of which there are currently 17. This new system will be capable of daily PMP data submissions and other enhancements. Potential future legislation includes mandatory PMP on-line registration with each controlled substance registration, reduced allowable expiration dates of certain controlled substances and a requirement that a controlled substance prescription is filled within 72 hours of the date that the prescription is written. Mr. Fraser explained that in 2010 the Board started requiring monthly reports of controlled substance distributions by wholesalers to prescribers and that this is unique to Idaho. The Board's investigator identifies suspicious distributions and investigates. Over the past 3 years, due to diversion there have been 20 prescriber controlled substance registration revocations, 21 prescriber controlled substance registrations restricted and 3 prescriber controlled substance registrations suspended. Eighteen pharmacists have had licenses revoked, restricted or suspended due to diversion.
Public Comment Period	Perry Brown, M.D. Chris Johnson, PharmD	**<u>Public Comment Period</u>** One (1) person signed up to speak during the public comment period. Public testimony was received from the following speaker:

Speaker	Representing	Agent	Class
Dr. Julian De Bruyn Kops	Self	Tudorza, Daliresp	COPD Agents

Drug Class Reviews and Committee Recommendations		Drug Class Reviews and Committee Recommendations
➢ Immunomodulators, Atopic Dermatitis	Paula Townsend, PharmD Magellan Health Services	**<u>Immunomodulators, Atopic Dermatitis</u>** Dr. Townsend announced no new significant clinical information is available for drugs in this class. New national guidelines for atopic dermatitis treatment are expected in 2014. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ Bronchodilators, Beta Agonists (short-acting, long-acting, oral)	Paula Townsend, PharmD	**<u>Bronchodilators, Beta Agonists</u>** Dr. Townsend gave an update on the FDA actions related to products in the class. Foradil (formoterol) and Arcapta (indacaterol) have been released from their respective REMS requirements. Levalbuterol inhalation solution and HFA (Xopenex) have had dysphonia and GERD added as adverse events based on postmarketing review. Dr. Townsend also reported on a new Cochrane systematic review comparing tiotropium to long-acting beta agonists. Tiopropium was more effective than LABAs overall in preventing exacerbations and disease-related hospitalizations. There were no differences between groups in mortality, symptom improvement or changes in lung function as measured by FEV1. Patients on tiotropium had fewer serious adverse drug reactions and withdrawals from the study. **Committee Recommendations** The committee concluded that there were no evidence-based differences in effectiveness or safety to support preferring any agent over another in the sub-categories of long-acting, short acting, or oral. The Committee recommended that all single entity long-acting beta agonists be non-preferred as asthmatic patients should only use long-acting agents with concomitant corticosteroids.

➢ Leukotriene Modifiers	Paula Townsend, PharmD	**Leukotriene Modifiers** Dr. Townsend announced that no new significant clinical information is available for drugs in this class. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ Glucocorticoids, Inhaled	Paula Townsend, PharmD	**Glucocorticoids, Inhaled** Dr. Townsend reviewed two new Cochrane systematic reviews for this drug class. Study one compared inhaled corticosteroids (ICS) to placebo. ICS decrease the mean rate of exacerbations and slowed the rate of decline in quality of life. Long-term rate of pneumonia was increased with ICS. There was no significant effect on mortality and no major effect on fractures and bone mineral density over three years. Study two compared ICS/LABA combination products to LABA alone. Exacerbations were lower with the combination, but pneumonia was more common. There were no differences in mortality risk, hospitalizations due to exacerbations or adverse drug events. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ COPD Agents	Paula Townsend, PharmD	**COPD Agents** Dr. Townsend announced that Combivent MDI was discontinued in 7/2013 – supplies are exhausted and Combivent Respimat is now the only formulation available. Tudorza (acidinium bromide inhalation powder) is a new drug approved 9/2013. It is a long-acting anticholinergic indicated for long-term maintenance treatment of bronchospasm associated with COPD. Dr. Townsend reviewed results of three randomized placebo controlled trials. There is no comparator data. There was an FDA action for Daliresp (roflumilast) which added detail to warnings of psychiatric events and post-marketing reports of angioedema, urticaria and rash.

		Committee Recommendations The committee did not feel Tudorza offered any advantage over current agents and recommended Tudorza be non-preferred. They asked the department to consider approving for patients with documented dexterity issues without having to first try and fail Spiriva. The Committee expressed concern with the Daliresp safety issues. They recommended tightening up the PA criteria including defining severe COPD per GOLD Guidelines.
➢ Intranasal Rhinitis Agents	Paula Townsend, PharmD	**Intranasal Rhinitis Agents** Dr. Townsend announced that the FDA had approved OTC sales of Nasacort AQ and it is expected to be available in December. Astepro is now is approved down to age 6 years (previously ≥ 12 years) for treatment of seasonal and perennial allergic rhinitis. She reviewed a new study for azelastine vs. fluticasone propionate which showed fluticasone superior in relieving rhinorrhea, but not in other nasal and ocular symptoms. Azelastine reduced ocular symptoms faster by ≥ three days. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. If OTC fluticasone is more cost-effective than the legend products, the committee recommended that it be placed on the list of reimbursable over-the-counter medications.
➢ Antihistamines, minimally sedating	Paula Townsend, PharmD	**Antihistamines, minimally sedating** Dr. Townsend announced that levocetirizine (Xyzal) now has a post marketing warning for urinary retention. There are two new generics, desloratadine ODT (for Clarinex ODT) and fexofenadine ODT OTC (for Allegra ODT). There is no new clinical data. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ Cough and Cold	Paula Townsend, PharmD	**Cough and Cold** Dr. Townsend announced that there was no new significant clinical information in this class. Many cough and cold products may undergo minor reformulations due to the new 2014 acetaminophen allowance guidelines.

		Committee Recommendations The committee concluded that there were no evidence based differences to support preferring any agent over another in this class.
➢ Otic Anti-infectives and Anesthetics	Paula Townsend, PharmD	**Otic Anti-infectives and Anesthetics** Dr. Townsend announced that there is no new significant clinical information in this class. **Committee Recommendations** The committee concluded that there were no evidence based differences to support preferring any agent over another in this class.
➢ Otic Antibiotics	Paula Townsend, PharmD	**Otic Antibiotics** Dr. Townsend reviewed the 2013 American Academy of Pediatrics acute otitis media (AOM) guidelines. Oral amoxicillin continues to be recommended as first-line except when there is a history of its use within the past 30 days, the patient has a penicillin allergy or the patient has concurrent purulent conjunctivitis. Topical agents are only recommended as treatment options for recurrent AOM in patients with tympanostomy tubes or perforation. **Committee Recommendations** The committee concluded that there were no evidence based differences to support preferring any agent over another in this class
➢ Ophthalmic Antibiotics	Paula Townsend, PharmD	**Ophthalmic Antibiotics** Dr. Townsend announced that there is no new significant clinical information in this class. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ Ophthalmic Antibiotic/Steroid Combinations	Paula Townsend, PharmD	**Ophthalmic Antibiotic/Steroid Combinations** Dr. Townsend announced that Poly-Pred Ophthalmic Suspension (prednisolone acetate/neomycin sulfate/polymyxin B sulfate) was discontinued by the manufacturer Allergan in the spring of 2013. The pediatric use section of the Zylet (loteprednol/tobramycin) PI was revised to include results from a blepharoconjunctivitis trial in pediatric patients ages 0-6 years in which Zylet was not shown to be more efficacious or safer than vehicle, loteprednol ophthalmic suspension, or tobramycin ophthalmic solution.

		Committee Recommendations The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. The committee requested utilization data for pediatric use vs. adult use for this drug class be brought back to the committee.
➢ Ophthalmics, Anti-inflammatories	Paula Townsend, PharmD	**<u>Ophthalmics, Anti-inflammatories</u>** Dr. Townsend announced three new drugs in this class: Lotemax (loteprednol) gel; Prolensa (bromfenac) ophthalmic solution indicated for the treatment of post-operative inflammation and the reduction of ocular pain post cataract extraction; and Llevro (nepafenac) ophthalmic solution indicated for treatment and inflammation associated with cataract surgery. Keterolac has had warnings added to its label for risk of bronchospasm or exacerbation of asthma in patients with known hypersensitivity to ASA/NSAID or past history of asthma and also a warning that NSAID's may cause increased bleeding of ocular tissue in conjunction with ocular surgery. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ Ophthalmics for Allergic Conjunctivitis	Paula Townsend, PharmD	**<u>Ophthalmics for Allergic Conjunctivitis</u>** Dr. Townsend announced no new significant clinical information for drugs in this class. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ Ophthalmics, Glaucoma Drugs	Paula Townsend, PharmD	**<u>Ophthalmics, Glaucoma Drugs</u>** Dr. Townsend announced a new drug Simbrinza, which is indicated for the reduction in elevated intraocular pressure in ocular hypertension and open-angle glaucoma. A second new drug, Rescula (unoprostone) a prostaglandin analog, previously marketed was also reviewed. It is also indicated for reduction of elevated intraocular pressure in ocular hypertension and open angle glaucoma . Travoprost (for Travatan) is a new generic. It does contain benylkonium chloride. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.

➢ Other Committee Business	Tami Eide, PharmD	**<u>Other Committee Business</u>** Our next P&T Committee meeting is scheduled for November 15, 2013. There was no other committee business. The meeting adjourned at 3:00 p.m.

Julian De Bruyn Kops, MD

Good morning. I'm here as a private practitioner. I'm in Idaho Falls. I have a large family practice and I treat a large amount of pulmonary patients. I'm here to talk very briefly about differences in inhalers that may not be available to you, that might not be obvious to you, for those who don't treat patients face to face and try to get them to use their inhalers. I want to talk about a very common kind of patient with COPD who is in the advanced stages of their disease. Typically, they are older, typically they are hypoxic and not thinking well, and many of them can't see well, and many of them have arthritis. We have two drugs in this class of long-acting muscarinic drugs: We have a drug called Spiriva, and Spiriva is a wonderful drug, and I use it all the time, but for the kind of patient I just discussed to you, it is cumbersome. I'd like to just point out the things that make it cumbersome and difficult to use. It comes packaged like this. You have to pull it apart and, more difficult, you have to try to open it and pull the pill out. This is not easy. I have a long fingernail, but if you have arthritis, it's not all that easy to do, and then you have to manually put it in the inhaler, and then you have to remember to spear it. In someone who is in a hurry and who has hypoxia, they may not remember that. Then you put it together, and you breathe in, and you know that people who have COPD, it's like breathing in a small straw, so their inspiratory effort is compromised, and that's crucial with this delivery mechanism, because it develops a vortex in here where the pill is spun. If you have a restricted effort, you may not get the full benefit of the dose, because you didn't develop enough vortex to rotate it fast enough. And you've got no way to know if you got the dose. If you didn't breathe in hard enough, but you've done everything else all right, then how would you know that you got the dose? You'd have to open it up, take the pill out, and shake it to see if I got it. This works if you are young and nimble and can see. Tudorza, which is a competitor; there are no AB comparisons that say that Tudorza is any better efficacy-wise, they both work, but they are the only two drugs, long-acting muscarinic drugs that are approved. The recent guidelines are very specific in what they recommend to treat COPD. They say long-acting beta agonists and long-acting muscarinics. In my experience, this delivery system, the Tudorza delivery system is easier for more advanced COPD patients to use. All you do is push, there's a green flag on this to tell the patient that it's ready to use, and when you breathe it in, you have tactile feedback. There's a device in here that goes "clank" that rattles it slightly, and this little flag turns from green to red, indicating to the patient "You got your dose". I'll just breathe in on it next to the microphone. I hope you heard it go "clank". You can feel it and the flag turns red. That's easier for them to use, and gives them feedback that "I got my dose. I got all of it." These are things that are not readily available using a Spiriva inhaler. I, in no way, want to badmouth Spiriva. It's a wonderful drug, but in senior people with advanced COPD and hypoxia and reduced dexterity, it is difficult. I have one other drug; Daliresp is a niche drug for COPD, whose sole function is designed to reduce chronic exacerbations. These are what kill these patients. When they get sick, infected, and can't manage their respiratory on their own, they're going to have to be in the hospital with IVs and an intense pulmonary toilet, sometimes intubation. But in my experience, exacerbations are what kill these people as time goes on. Daliresp is for that kind of advanced COPD patient. It's specifically approved by the FDA to reduce the frequency of chronic exacerbations. It's not a bronchodilator itself and has a different mechanism of action. But I did want to mention those two things and this issue of the differences in these two very good drugs matters. Does anyone have any questions?

Committee

Is the inspiratory effort actually necessary for the full dose differ between those products? I know you can tell you've gotten one dose or not, but is the inspiratory effort different for the two inhalers?

Julian De Bruyn Kops, MD

I think it requires more for this. There is a spring action in here that seems to be less, and there is still a pill in here. I hope you can hear this. This is the Spiriva, and it makes a very characteristic noise when you've done it right, a "vrrrrr" like that. Now I'm going to breathe in on it. [demonstration] That's a pretty good inspiratory effort that I can develop. I'll try to mimic someone with COPD. [demonstration]. It doesn't make as much noise, but it doesn't tell you qualitatively, "Well did you spin it fast enough to get all the powder out?" With my own experience, demonstrating these and having patients try it themselves in the office, because I usually try to do that. Show them, "This is what you need to do to use that". You know, we take it out, I show them what happens, and I say "There, your puncture moved", but there's unused powder in there. It's been my impression they can't do it, not everyone, but some with advanced COPD can't do that, and I have no such necessity with this drug, because this drug, with this inhaler, when you use it, you're there, and they know it because they've heard it clank and they've had that. So I think what I'm asking you is that they're both very good drugs and they work, but give us an option, that you can use this or this. Yes ma'am?

Committee
Doctor, you mention that most of the COPD patients have some dexterity [issues], arthritis, they're elderly. What patient population are you familiar with and that you see that are Medicaid covered patients?

Julian De Bruyn Kops, MD
The older ones.

Committee
Do you know approximately the percentage? I'm just trying to get a feel for, I mean elderly patients are not Medicaid covered, they'd be Medicare, correct? I'm just wondering if we know.

Julian De Bruyn Kops, MD
I don't have a feeling for that.

Committee
And then, have you wanted to prescribe the Tudorza and the patient was unable to get it?

Julian De Bruyn Kops, MD
Yes.

Committee
For Medicaid?

Julian De Bruyn Kops, MD
For Medicaid.

Committee
Okay.

Thanks for that. I wasn't aware of that. I'm impressed with your advocacy for your patient and for going the extra mile for educating a new person how to use this. It's beyond what most providers do, it's also beyond what I do, so I'm impressed with this.

Julian De Bruyn Kops, MD
Thank you. I am not representing or being paid for my testimony. I do speak for several pharmaceutical firms. I speak for the firm that makes the one that I talked about. I do not speak for Spiriva, but I do speak from a lot of personal experience using these particular inhalers.

Committee
Thank you.