Pharmacy and Therapeutics (P&T) Committee Meeting Record

Date: October 19, 2012 **Time:** 9:00 a.m. – 4:00 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.; Mark Johnston, RPh; Troy Geyman, M.D; Jeffrey Johnson, PA-C, PharmD; Leigh Morse, M.D.
Others Present: Paula Townsend, PharmD, Magellan Health Services; Mark England PharmD, Magellan Medicaid Administration; Jane Gennrich, PharmD., Division of Medicaid; Cody Scrivner, Division of Medicaid; Teresa Martin, Division of Medicaid; Chris Johnson, PharmD, 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, welcomed the P&T Committee members and called the meeting to order. He introduced new committee members Dr. Lucinda (Leigh) Morse, Dr. Kevin Ellis and Dr. David Calley.
➢ *Reading of Mission Statement*	Perry Brown, M.D.	Dr. Brown read the Mission Statement.
➢ *Approval of Minutes from May 20, 2012 Meeting*	Perry Brown, M.D.	The May 20, 2012 meeting minutes were accepted as proposed.
➢ *DERP Update*	Tami Eide, PharmD	**DERP Update** Dr. Eide provided an overview on the focus for DERP (Drug Effectiveness Review Project) Phase IV. The work plan includes Reports, Horizon Scans, P&T Briefs and Academic Detailing materials. There are currently 8 other states involved in DERP IV. Dr. Eide reviewed Key Questions for an upcoming Oral Factor Xa Inhibitors review as well as adding linagliptin to an existing diabetes review. The Committee had no additional input for the proposed reviews.

➢ Update on Foster Children and Psychotropic Drugs	Tami Eide, PharmD	**<u>Update on Foster Children and Psychotropic Drugs</u>** Dr. Eide provided an overview of the GAO (General Accounting Office) study on psychotropic medications prescribed for foster and non-foster children in 5 states in 2008. The study concluded that these drugs are being prescribed significantly more often for foster children. Idaho compared its prescribing patterns to the 5 study states (Florida, Massachusetts, Michigan, Oregon and Texas) in 2008 as well as in 2011. Idaho had a higher percentage of psychotropic prescribing in both foster and non-foster children than the other 5 states. A multidisciplinary work group with representation from Idaho Department of Health and Welfare, Child Protection Program, physicians, and social workers has been assembled to work on this issue. Idaho Medicaid's Pharmacy Unit is involved to provide baseline data, interventions, monitoring, and education. Dr. Eide provided information as to the type of drugs used, the types of practitioners prescribing these drugs, the regional prescriber variation and the age distribution. Dr. Eide gave the results from information gathered from Idaho's DUR studies on five or more psychotropic medications and two or more antidepressants. Dr. Eide, Dave Simnitt and four other Idaho representatives attended a conference held in Washington D.C. in August 2012 that was sponsored by three national groups and it was found that Idaho is ahead on several items. The purpose of this conference was to enhance cross-system efforts, showcase collaborative projects and initiatives, encourage strategies for addressing mental health and trauma related needs and to facilitate development and implementation of each State's oversight plan that was due on June 30, 2012.
➢ DUR Board Update Atopic Dermatitis	Mark England, Pharm. D. .	**DUR Board Updates** **<u>Atopic Dermatitis</u>** Dr. England provided a review of Atopic Dermatitis (AD). This study was done at the request of the P&T Committee and included the patterns of use, presence or absence of step up therapy from steroids, specialty of prescribers and geographic regional differences of prescribing patterns. The cause of AD appears to be a result of interactions between genetics, environment, skin barrier defects and the immune system. Treatments include emollients and topical corticosteroids. Oral sedating antihistamines are useful for patients who have sleep disturbances and antibiotics should be reserved for patients with acutely infected lesions. Topical calcineurin inhibitors (Elidel and Protopic) should be second-line treatment for flare-ups and maintenance. In March 2010, the FDA issued a public health advisory about the potential for cancer risk associated with the use of Elidel (pimecrolimus) and Protopic (tacrolimus) and restricted its use in children less than 2 years of age. Information presented included data comprising of a regional map, claims data from 2011

		and claim levels according to products. The DUR board found that the use of Elidel and Protopic was appropriate. The P&T Committee members recommended that the DUR board repeat the study at a future date and look at cases where there is no treatment history of a corticosteroid and/or refill history greater than three months in a given year.
➢ Narcotic Analgesic Update	Tami Eide, PharmD	**Narcotic Analgesic Update** Dr. Eide provided a review of Narcotic Patterns of Use in Chronic Non-Malignant Pain in Medicaid patients. She explained that the report included the top 150 recipients by total narcotic claim count from the recipients who had at least one narcotic claim in each of the 24 months ending December 2011. Results included length of time for continuous opioid use, number of different opioids, daily morphine equivalents and the diagnosis and indications for the participants. Dr. Eide reviewed Idaho's current management practices. Idaho is in the process of implementing a manual prior authorization review for fentanyl transdermal patches as well as adding additional prior authorization requirements for oxycodone and Butrans patches. Dr. Eide reviewed what other states are doing for dispensing restrictions and management strategies. Also reviewed were key points of Washington's new state law which includes required elements for a patient evaluation, a dosing threshold trigger for consultation with a pain specialist, criteria to be considered a pain specialist, periodic review of a patient's course of treatment, guidance for episodic care practitioners, consultation exemptions for special circumstances and continuing education requirements for prescribers. The committee then discussed the Idaho Medicaid's current Lock-In program where participants can be "locked in" to a specific prescriber and/or to a specific pharmacy. The suggestion was made to have more information available to prescribers on the lock-in program. Mark Johnston, Executive Director for the Board of Pharmacy, talked about an inter-state data sharing system and upcoming statute changes. He discussed e-med prescriptions and the e-prescribing systems available.
Public Comment Period	Perry Brown, M.D. Cody Scrivner	**Public Comment Period** One (1) person signed up to speak during the public comment period. Public testimony was received from the following speaker:

Speaker	Representing	Agent	Class
Barbara Felt, PharmD	GlaxoSmithKline	Veramyst	Intranasal Rhinitis Agents
Barbara Felt, PharmD	GlaxoSmithKline	Advair	Combination Inhaled

				Glucocorticoids and Bronchodilators
	Barbara Felt, PharmD	GlaxoSmithKline	Flovent	Inhaled Glucocorticoids

Drug Class Reviews and Committee Recommendations		**Drug Class Reviews and Committee Recommendations**
➢ Immunomodulators, Atopic Dermatitis	Paula Townsend, PharmD Magellan Health Services	**Immunomodulators, Atopic Dermatitis** Dr. Townsend indicated that there was no new clinical data to share with the committee. **Committee Recommendations** The committee concluded that there were no evidence based differences to support preferring any agent over another in this class.
➢ Respiratory Drugs Overview	Paula Townsend, PharmD	**Respiratory Drugs Overview** Dr. Townsend provided a review of the Global Initiative for Asthma - Management Approach for Adults and children >5years as well as for children < 5 years. For children < 5 years, inhaled corticosteroids have been shown to be superior to leukotriene receptor antagonists. She also reviewed the new GOLD Clinical Guidelines which include pharmacologic therapies for stable COPD.
➢ Bronchodilators, Beta Agonists Short-Acting	Paula Townsend, PharmD	**Bronchodilators, Beta Agonists Short-Acting (Oral and Inhaled)** No new clinical data on specific agents was shared with the committee. It was discussed that Ventolin currently has a dose-counter; ProAir is going to be coming out with a dose counter with an anticipated date of December 2012. The committee has some concerns with inapparopriate use of oral albuterol. **Committee Recommendations** The committee recommends instituting prior authorization for oral albuterol. For inhaled short-acting beta-agonists, while the committee recognized the usefulness of a dose counter, it concluded that that there were no evidence based differences to support preferring any agent over another in this class.

➢ Bronchodilators, Beta Agonists Long-Acting	Paula Townsend, PharmD	**<u>Bronchodilators, Beta Agonists Long-Acting</u>** In August 2012, an FDA Action released Brovana (arformoterol) and Serevent (salmeterol) the REMS requirements. Foradil (formoterol) and Arcapta (indacaterol) have not been released from their respective REMS at this time. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents and that preferred status should be based on cost-effectiveness.
➢ Leukotriene Modifiers	Paula Townsend, PharmD	**<u>Leukotriene Modifiers</u>** Dr. Townsend announced the Singulair is now available generically as montelukast, which comes in a tablet, chew tablet and granules. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents and that preferred status should be based on cost-effectiveness.
➢ Glucocorticoids, Inhaled and Combination Inhalers	Paula Townsend, PharmD	**<u>Glucocorticoids, Inhaled</u>** Dr. Townsend announced that Symbicort and Advair have been released from their REMS requirement. She reviewed highlights of a 2011 Cochrane Meta-Analysis which compared the relative effects of inhaled corticosteroids (ICS) to long-acting beta agonists (LABA) on clinic outcomes in patients with stable COPD. Conclusions supported LABAs as first line and ICS as adjuctive therapy in those with frequent exacerbations. **Committee Recommendations** The committee concluded that there were no evidence based differences to support preferring any agent over another in this class and preferred status should be based on cost-effectiveness.
➢ COPD Agents	Paula Townsend, PharmD	**<u>COPD Agents</u>** Dr. Townsend provided a review of one new product in this class. Combivent Respimat is a CFC-free formulation and addition to the Combivent line. Combivent MDI will be discontinued in May of 2013 and once supplies are exhausted the Respimat form will be the only version available.

		Committee Recommendations The committee concluded that there were no evidence based differences to support preferring any agent over another in this class.
➢ Intranasal Rhinitis Agents	Paula Townsend, PharmD	**<u>Intranasal Rhinitis Agents</u>** Dr. Townsend announced that there are three new products to the market. QNASL (beclomethasone), Zetonna (ciclesonide) and Dymista (azelastine/fluticasone propionate). She reviewed the clinical studies of QNASL and Zetonna and for Dymista for which there were three trials comparing the combination therapy vs. its individual components. **Committee Recommendations** The committee concluded that there were no evidence based differences to support preferring any agent over another in this class. The committee felt that Dymsta as a combination agent had an advantage for patient care and should be made available if it was cost equivalent to the other agents. The committee requested to put a hard stop on the non-preferred agents and that they be evaluated through the prior authorization process for reason for failure and adequate treatment trial.
➢ Antihistamines, minimally sedating	Paula Townsend, PharmD	**<u>Antihistamines, minimally sedating</u>** Dr. Townsend announced that Xyzal is now available generically as levocetirizine. Cetirizine is available as an orally disintegrating tablet for patients $\geq$ 6 years olds. There is a new liquid gel cap formulation of loratadine available also. She discussed an FDA Action which indicates that Allegra allergy oral suspension is now only available OTC, but requires a physician evaluation in children less than 6 years old when used for chronic idiopathic urticaria (CIU). **Committee Recommendations** The committee concluded that there were no evidence based differences to support preferring any agent over another in this class.
➢ Cough and Cold	Paula Townsend, PharmD	**<u>Cough and Cold</u>** There was no new significant clinical data to share with the committee. **Committee Recommendations**

		The committee recommended preferring a short list of FDA approved cough and cold products and to enforce the quantity limits of two fills of 120ml per 6 months for liquid products. The committee recommended including benzonatate capsules as a preferred agent.
➢ Otic Anti-infectives and Anesthetics	Paula Townsend, PharmD	**Otic Anti-infectives and Anesthetics** There was no new significant clinical data to share with the committee. **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 announced the availability of a new generic ciprofloxacin 2% otic solution. **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 provided a review of a new clinical study which was a randomized open-label controlled trial to determine concentrations of besifloxacin, moxifloxacin and gatifloxacin in aqueous humor following single doses preoperatively. **Committee Recommendations** The committee concluded that there were no evidence based differences to support preferring any agent over another in this class and preferred status should be based on cost-effectiveness.
➢ Ophthalmic Antibiotic/Steroid Combinations	Paula Townsend, PharmD	**Ophthalmic Antibiotic/Steroid Combinations** Dr. Townsend announced that there is no new significant clinical data to share with the committee. **Committee Recommendations** The committee concluded that there were no evidence based differences to support preferring any agent over another in this class.

➢ Ophthalmics, Anti-inflammatories	Paula Townsend, PharmD	**Ophthalmics, Anti-inflammatories** Dr. Townsend provided a review of a new indication for Durezol - treatment of anterior uveitis. **Committee Recommendations** The committee concluded that there were no evidence based differences to support preferring any agent over another in this class and preferred status should be based on cost-effectiveness.
➢ Ophthalmics for Allergic Conjunctivitis	Paula Townsend, PharmD	**Ophthalmics for Allergic Conjunctivitis** There was no new significant clinical data to share with the committee. **Committee Recommendations** The committee concluded that there were no evidence based differences to support preferring any agent over another in this class.
➢ Ophthalmics, Glaucoma Drugs	Paula Townsend, PharmD	**Ophthalmics, Glaucoma Drugs** Dr. Townsend reviewed one new drug, Zioptan (tafluprost). There was one 24 month non-inferiority study vs. latanoprost. Other trial studies were vs. vehicle and timolol (non-inferior). **Committee Recommendations** The committee concluded that there were no evidence based differences to support preferring any agent over another in this class and preferred status should be based on cost-effectiveness.
➢ Other Committee Business	Tami Eide PharmD	**Other Committee Business** Dr. Eide reviewed the dates for the upcoming 2013 year. The committee decided to change the dates for the May meeting to the 10th and for the October meeting to the 11th. The other meeting dates are April 19th and November 15th. Dr. Eide reminded the committee that the next meeting is scheduled for November 16, 2012 The meeting adjourned at 2:00 p.m.

Pharmacy and Therapeutics Committee
Public Comment
October 19, 2012

Barbara Felt, PharmD

Hello, my name is Barbara Felt. I'm a PharmD and a medical science liaison, I work for GlaxoSmithKline, and I was invited by Jane and probably the State Committee to chat with you a little bit today. The topic is the effect of Veramyst on growth in children, so I want to thank you for that opportunity. The information that I'm going to talk about today is actually based on a Phase-4 commitment from the FDA when Veramyst was approved. The data collection was completed in March of 2011, and the analysis was completed last August; so it was not quite ready for your meeting last year. The purpose of the study was to evaluate the effect of Veramyst on growth in pediatric children over a one-year period of time. The patients that were eligible for enrollment in this trial were prepubescent children; males from age 5 to 8.5 and females 5 to 7.5 years of age, and they had to have a diagnosis and history of perennial allergic rhinitis, and they may or may not have also had seasonal allergic rhinitis and non-allergic rhinitis. This study, like a few growth studies that you'll see, had a very long baseline period, where patients were actually evaluated and made sure that the growth in those patients was actually normal before they were randomized into the two treatment arms. The two treatment arms were Veramyst in the 110 mcg dose a day (that's the higher dose for kids) and a placebo group, so there were about 474 patients in the study; 237 patients in each one of the treatment arms, and there were no differences in baseline growth rates at baseline. The primary endpoint of the study was the mean difference in growth velocity over 52 weeks as determined by stadiometry. At end point, the placebo patients grew 5.46 cm per year, and the Veramyst were at 5.19 cm per year. That's a difference of 0.27 cm per year, which was statistically significant. In terms of secondary endpoints, there were no clinically relevant differences seen there. The items that were measured were 24-hour urinary cortisol excretion, nasal examinations, routine chemistries, that sort of thing. In terms of adverse events, they were similar between groups. The most commonly reported, drug related adverse event was epistaxis; 7% in the Veramyst group and 6% in the placebo group. So, in conclusion, patients taking Veramyst had a 0.27 cm per year decrease in the growth velocity versus placebo patients. This information was added to the package insert earlier this year, and I think Magellan is actually going to go over that. So, the recommendation is that when pediatric patients are put on Veramyst, that the physicians or their practitioners actually monitor their growth, and it is recommended that patients actually start at the 55 mcg dose and then only go to the higher dose if they need it to control their symptoms, and once their symptoms are under control, then go back down to the lower dose. I'm happy to answer any questions if you have them.

Question
You said it was looked at over a 52-week period, but you also stated that it was a long-term study, so is that...

Barbara Felt, PharmD
Well with the nasal growth studies, that's pretty long term, yeah.

Question
I was going to ask: Are you aware of any data in the more rapid growers in early adolescence?

Barbara Felt, PharmD
I'm not aware of that, no.

Question
Okay, I was just curious. Thank you.

Barbara Felt, PharmD
Okay I have another one. I think I'm the only one here that's testifying today. Are you Jane? I knew I recognized you. I was invited also to talk about three studies in your corticosteroid group and, so, of course, we submitted the Advair and Flovent studies. There are three of them, as I said. The first one is actually a study comparing Advair to Dulera, and so I'm going to use brand names, if that's okay. It was a head-to-head trial published in 2011, and it was actually a study that was sponsored by Merck, so I don't know any more about it, other than what was actually in the publication. The purpose of the study was to determine whether Dulera was non-inferior to Advair in terms of lung function over 12 weeks, and the doses that were used in the study of Dulera were the 200/10 dose and of the Advair Diskus, it was the 250/50 dose. The patient population that was studied were patients 12 years of age and older, who had uncontrolled asthma, despite taking medium doses of inhaled steroids with or without a long-acting beta agonist. There were 722 patients that were randomized in the 1:1 fashion to receive either Dulera or Advair. Baseline characteristics and demographics were similar between the two treatment groups, and important to note is the discontinuation rates in the study, were 42% for Dulera and 41% for Advair, and the primary reason stated in the paper was "Administrative Reasons", so I don't know any more than that. Only 2% of the patients actually, in each treatment group, were withdrawn due to adverse events. Also, the other important point to know is the patients were not blinded in this study, because there were not placebo diskus devices available. The primary endpoint was changed from baseline to week 12 in area under the curve (FEV1) and there were no significant differences in that outcome parameter, which was 3.43 liters versus 3.24 liters. Those were the parameters, with the Dulera group having the higher number. Secondary endpoints with one exception: There were no significant differences in any of the secondary outcome parameters, which included other lung function assessments, asthma control, asthma symptoms, quality of life, and those sorts of measures. The one exception was Onset of Action. It was evaluated on day-1 and there was a faster onset of action in the Dulera group with the formoterol component versus the Advair group. Drug related adverse events were

similar between the groups, and the most common treatment related adverse events were dysphonia, headache, oropharyngeal pain, and candidiasis. The second study is a study from the Care Network. Are you familiar with the Care Network? The care network is a group of primary physicians, allergists and pulmonologists. They receive funding from the NIH to do research on pediatric asthma topics. There was an article called the Peak article that was published a few years ago in the New England Journal of Medicine looking at steroids versus placebo, and the effect of early intervention on pediatric patients; so, within the 2-4-year-old age group. Not their primary, but one of the outcome parameters that they looked at was growth, and they had two years' on treatment and one year off treatment in that study, and in the two years on treatment, they found with fluticasone (which was the steroid that they used, the low dose), they found a 1.1 cm reduction in growth over the two years, but in the one year off treatment, there were no differences in growth between the two groups. So this study that was published over the last year was a little deeper evaluation into those differences in growth, and what they found was, they looked at two years off treatment, and there was no significant difference in linear growth between the fluticasone group and the placebo groups when they looked at the cohort overall. There were 285 children in the original cohort. Post hoc analysis actually did look at patients who were two years old and they were less than 15 kg, and they did see that the patients who were on fluticasone had less linear growth than the patients treated with placebo. So, as a reminder, this was an off-label study, as it was studied in patients 2-4 years old. Fluticasone is indicated for patients four and above and patients who have asthma, so this study actually looked at patients who were at risk for developing asthma. So we do have the growth warning in the study, we have recommendations on monitoring it, and using the lowest effective dose, so those warnings are already in the label.

The third article was published earlier this year. It was a cross sectional safety study, looking at long-term effects of fluticasone on osteocalcin, cortisol levels, and bone mineral density in prepubescent children that have asthma in Turkey. So there were 230 children in each group, age 6-11. They had to have a documented diagnosis of mild or moderate asthma, and they were using fluticasone intermittently for five or more years. There was a control group that was set up that also had newly diagnosed asthma, and they were age matched to the treatment group. On average, patients were nine years old and they were taking about 180 mg of the inhaled steroid a day. The results were that between the study and control groups, there were no significant differences observed in the parameters that were evaluated, and also, as a reminder, in the Flovent package insert, it does carry a warning that decreases in bone mineral density have been observed with long-term treatment with inhaled steroids. So that is all I have for your inhaled steroid portion. Any questions? I'd be happy to answer them. Thank you.