Pharmacy and Therapeutics (P&T) Committee Meeting Record

Date: October 16, 2015

Time: 9:00 a.m. – 3:15 p.m. **Location:** Idaho Medicaid, 3232 Elder Street, Boise, Idaho, Conference Room D

Moderator: Perry Brown, M.D.

Committee Members Present: Perry Brown, MD-Chair; Tami Eide, PharmD; David Calley PharmD; Kevin Ellis, PharmD; Mark Turner, MD; Troy Geyman, MD; Jeffrey Johnson, PA-C, PharmD; Stephen Carlson, PharmD; Christopher Streeter, MD; Brian K. Crownover, MD; Leigh Morse, MD

Committee Members Absent: Alex Adams, PharmD

Others Present: Sarah Martinez, PharmD, Magellan Health Services; Chris Johnson, PharmD, Division of Medicaid; Jane Gennrich, PharmD, Division of Medicaid; Tammy Haugland, Division of Medicaid; Wendy Estrellado, Division of Medicaid, Teresa Martin, Division of Medicaid; Mark England, PharmD, Magellan Medicaid Administration

AGENDA ITEMS	PRESENTER	OUTCOME/ACTIONS
CALL TO ORDER	*Perry Brown, MD*	*Dr. Brown called the meeting to order.*
Committee Business		
➢ *Roll Call*	*Perry Brown, MD*	Dr. Brown completed the roll call and welcomed the P&T Committee members.
➢ *Reading of Confidentiality and Mission Statements*	*Perry Brown, MD*	Dr. Brown read the Confidentiality and Mission Statements.
➢ *Approval of Minutes from May 22, 2015 Meeting*	*Perry Brown, MD*	The May 22, 2015 Minutes were reviewed. The minutes were accepted as proposed.

➢ *DERP UPDATE*	*Tami Eide, PharmD*	**DERP Update** Dr. Eide provided an update on the Drug Effectiveness Review Project's (DERP) current activities. She highlighted reports completed since the last P&T meeting, reports in progress and currently nominated topics which will be discussed and at the DERP Governance meeting in November and voted on later that month.
➢ *Methadone Preferred Drug Status*	*Tami Eide, PharmD*	**Methadone Preferred Drug Status** Dr. Eide discussed the PEW Charitable trust report that came out in April of this year which highlighted a national concern on use of methadone and its position as a preferred drug for many (33) Medicaid states. Other organizations, including the FDA, CDC, AAPM (American Academy of Pain Medicine), ASIPP (American Society of Interventional Pain Physicians) have also recommended that states remove methadone from preferred status on their preferred drug lists (PDL). A Senate Letter was sent to CMS in July recommending that State Medicaid agencies investigate methadone overdoes in Medicaid populations and move methadone from preferred drug lists. Nationally methadone represents only 2% of all opiates prescribed, but 30% of overdose deaths. The Committee recommended that methadone be moved from preferred to non-preferred status and require prior authorization. They also recommended a quantity limit of 40 mg per day which is closest to the morphine equivalent dose of 120 mg per day. They also recommended education on use. They asked that the Department consider moving another non-morphine based agent from non-preferred to preferred as a second line agent for patients who have a contraindication to morphine. The Department was asked to bring methadone criteria to the November P&T meeting.
Public Comment Period	*Perry Brown, MD* *Tammy Haugland*	**Public Comment Period** One (1) person signed up to speak during the public comment period. Two manufacturer representatives were pre-approved to provide testimony. Public testimony was received from the following speakers:

Speaker	Representing	Agent	Class
Lucinda Langford, RN	Self	All	Smoking Cessation
John Sandstrom, Pharm.D.	Baxalta	Gammagard, Hyquvia	Immune Globulins
Mary Kemhus, Pharm.D.	Novartis	Cosentyx	Cytokine/CAMS

Drug Class Reviews and Committee Recommendations	*Perry Brown, MD*	**Drug Class Reviews and Committee Recommendations** Committee members were asked to base their recommendations for each drug class on the answers to the following questions: 1. Is there evidence to support clinically significant differences in efficacy or effectiveness between agents? 2. Is there evidence to support clinically significant differences in safety between agents? 3. Are there any agents that the committee feels strongly must be preferred or non-preferred? 4. Are there any recommendations for changes to PA requirements?
➢ *Bronchodilators, Beta Agonists Short-Acting*	*Sarah Martinez, PharmD*	**<u>Bronchodilators, Beta Agonists Short-Acting</u>** Dr. Martinez reported that there is one new product on the market, Proair Respiclick which is indicated for treatment or prevention of bronchospasm or the prevention of exercise induced bronchospasms in patients 12 years and older. Dr. Martinez also reported that the 2015 Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines and the 2015 GINA (Global Initiative for Asthma) guidelines were updated but that there were not any significant changes to recommendations for drug therapy. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. They expressed concern with potential confusion between Proair HFA and Respiclick and also lack of clinical comparative studies.
➢ *Bronchodilators, Beta Agonists Long-Acting*	*Sarah Martinez, PharmD*	The committee asked that a DUR be done to look at rescue inhaler use, separating out children and adults. The objective is to ensure that no more than 200 doses/month are being used as this is a risk factor for asthma exacerbations and asthma-related death. They further recommended that prior authorization be required for more than one inhaler per month. **<u>Bronchodilators, Beta Agonists Long-Acting</u>** There were no new agents and no recent clinically significant information in this class to report on. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.

➢ *Leukotriene Modifiers*	*Sarah Martinez, PharmD*	**<u>Leukotriene Modifiers</u>** There were no new agents and no recent clinically significant information in this class to report on. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ *Glucocorticoids, Inhaled*	*Sarah Martinez, PharmD*	**<u>Glucocorticoids, Inhaled</u>** Dr. Martinez reported that there are two new products on the market in this class, Asmanex HFA (new HFA formulation) and Arnuity Ellipta which are both indicated for once-daily maintenance treatment of asthma in patients 12 years and older. Dr. Martinez also provided a product update for Breo Ellipta which is now indicated for once daily treatment of asthma in adults (previously indicated for COPD only). She reviewed the clinical studies associated with Arnuity Ellipta FDA approval. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents in either the inhaled glucocorticoid class or the combination beta agonist and glucocorticoid class.
➢ *COPD Agents*	*Sarah Martinez, PharmD*	**<u>COPD Agents</u>** Dr. Martinez reported that there were three new products in this class. Incruse Ellipta (umeclidinium) and Stiolto Respimat (tiotropium/olodaterol) are both products indicated for the long term, once daily, maintenance treatment of airflow obstruction in COPD patients. Spiriva Respimat (tiotropium) is indicated for the long-term maintenance treatment of bronchospasm associated with COPD and for reducing COPD exacerbations. She reported on the clinical studies surrounding these agents. Dr. Martinez also provided a product update for Tudorza Pressair which has added a warning about hypersensitivity to atropine or milk proteins. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. The committee recommended that at least one once daily dosing product be included as a preferred agent.

➢ *Intranasal Rhinitis Agents*	*Sarah Martinez, PharmD*	**<u>Intranasal Rhinitis Agents</u>** There were no new agents to report in this class. Dr. Martinez announced that Patanase (olopatadine) is now available generically. Dr. Martinez also provided several product updates. Qnasal is now indicated for use in patients four years and older (previously for 12 years and older only). Flonase is now available over-the-counter sold as "Flonase Allergy Relief". Flonase Rx was discontinued in January 2015. Dymista is now indicated to relieve symptoms of seasonal allergic-rhinitis in patients six years and older (previously 12 years and older). Astepro is now indicated to relieve symptoms in patients two years and older (previously six years and older) and to relieve symptoms of perennial allergic rhinitis in patients six months and older. New clinical guidelines for allergic rhinitis published in May of 2015 from The American Academy of Otolaryngology Head and Neck Surgery now recommend that intranasal steroids and oral antihistamines be used as first-line treatment for most adults and children over two years of age. Intranasal antihistamines may be offered second-line. The guidelines recommend combination therapy in patients who have an inadequate response to monotherapy with the most effective addition to intranasal steroid therapy being an intranasal antihistamine. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ *Cough and Cold*	*Sarah Martinez, PharmD*	**<u>Cough and Cold</u>** There were no new agents and no recent clinically significant information in this class to report on. Dr. Eide asked the committee to consider whether hydrocodone containing products such as Tussionex should remain preferred now that these products have been moved to Schedule 2 status. She reported that utilization reports showed participants getting multiple, sometimes continuous refills years round. The committee discussed the potential for abuse of these agents. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy or effectiveness between the agents. From a safety standpoint it was recommended that both the hydrocodone and codeine combination products be moved to non–preferred status. It was recommended that Promethazine with Codeine be accessible if appropriate through the prior authorization process with one fill allowed.

➢ *Tobacco Cessation*	*Sarah Martinez, PharmD*	**<u>Tobacco Cessation</u>** There were no new agents and no recent clinically significant information in this class to report on**.** The committee reviewed the current prior authorization form and criteria for Chantix. **Committee Recommendations** The committee concluded that there is evidence to support differences in efficacy, effectiveness and safety between the classes of agents (Nicotine replacement therapies and non-nicotine replacement therapies.) It was recommended to move Chantix to preferred status, but to keep quantity limits and require prior-authorization. They recommended removing criteria of trial and failure of nicotine replacement treatment, but requiring documentation of participation in a smoking cessation /counseling program. They also recommended requiring documentation that patients have follow-up within 5-10 days for evaluation of neuropsychiatric symptoms or behaviors.
➢ *Antihistamines, minimally sedating*	*Sarah Martinez, PharmD*	**<u>Antihistamines, minimally sedating</u>** There were no new agents and no recent clinically significant information in this class to report on**.** **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ *Oral Anti-allergens*	*Sarah Martinez, PharmD*	**<u>Oral Anti-allergens</u>** Dr. Martinez reported that there is one new product in this class, Oralair, which is indicated for treatment of moderate to severe seasonal allergic rhinitis. A positive skin test or in vitro testing for pollen specific IgE antibodies for grass pollen extract – cocksfoot, sweet vernal grass, rye grass, meadow grass or Timothy species is necessary. Dr. Martinez reviewed the 2015 guideline update from the American Academy of Otolaryngology Head and Neck Surgery for allergic rhinitis. The guideline recommends that clinicians offer either sublingual immunotherapy (SLIT) or subcutaneous (SCIT) immunotherapy to patients who have had an inadequate response to pharmacologic therapy, with or without environmental controls. Both forms of immunotherapy have been proven effective in reducing symptoms. **Committee Recommendations** The committee concluded that there is evidence to support differences in efficacy, effectiveness or safety between the agents in this class.

➢ *Epinephrine, self-injected*	*Sarah Martinez, PharmD*	**Epinephrine, self-injected** Dr. Martinez reported that there are two products in this class that have not been reviewed previously by this committee, Adrenaclick and generic epinephrine auto-injector. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. They recommended that Auvi-Q be available upon request for administration by caregivers of developmentally impaired patients.
➢ *Hepatitis C Utilization Update*	*Chris Johnson, PharmD*	**Hepatitis C Utilization Update** Dr. Johnson presented an update of Hepatitis C utilization from 1/1/2015 to 9/30/2015. He provided demographics by gender and age. A total of 140 requests were reviewed with 50 approved and 84 denied. The remaining 6 requests were pended for requested additional information. Of the approved requests there were 37 for Harvoni and 13 for Sovoldi, with no approved requests for Viekira. The majority of approved requests were for Genotype 1 with 4 approved requests for Genotype 2 and 8 for Genotype 3. There were no approved requests for Genotype 4. The current criteria for these agents is based on liver fibrosis staging and current approval is for F3 and F4 stages. Of the approved requests, 32 patients were a stage of F3 and 18 were F4. 74% of patients approved had a history of cirrhosis and 26% had no history of cirrhosis. Cirrhosis status is an important indicator for choice of treatment and duration of treatment. The majority of denials were for not meeting required liver staging criteria. Ten requests were denied for substance abuse. Dr. Johnson is currently following sustained viral response (SVR) levels at 12 and 24 weeks for all treated patients. Out of those treated, 24 patients have achieved SVR 12. Of those patients, 10 patients achieved SVR 24. Two deaths were reported before the SVR 12 testing could be obtained and one treatment failure was reported.
➢ *Hepatitis C (New Agents)*	*Sarah Martinez, PharmD*	**Hepatitis C (New Agents)** This was a review of new agents only. The Department had made these agents temporarily preferred pending committee review. The full Hepatitis C class review will be in Spring 2016. Dr. Martinez reported that there are two new products in this class. Daklinza is indicated for the treatment of chronic Hepatitis C, Genotype 3 infections in combination with Sovoldi. Technivie is approved for Genotype 4 infection without cirrhosis in combination with ribavirin. Dr. Martinez reviewed the studies for the approval of these agents and the AASLD/IDSA Guidelines recommendations for Genotypes 3 and 4. **Committee Recommendations** The committee affirmed the Department decision for both Daklinza and Technivie as preferred agents in the appropriate patients.

➢ *Cytokine/CAMS*	*Sarah Martinez, PharmD*	**<u>Cytokine/CAMS</u>** Dr. Martinez reported that there is one new product in this class, Cosentyx, which is indicated for the treatment of moderate to severe plaque psoriasis in adults. Dr. Martinez presented information on indications, administration and adverse effects of Cosentyx as well as clinical information from the FIXTURE study (Cosentyx vs. Enbrel in plaque psoriasis) and from the CLEAR study (Cosentyx vs. Stelara in subjects with moderate to severe plaque psoriasis). Dr. Martinez announced that : 1. Humira is now indicated for Crohn's disease in patients six years and older and polyarticular juvenile idiopathic arthritis in patients two years and older. 2. Enbrel is now approved for use with or without methotrexate 3. Otezia is now indicated for treatment of severe plaque psoriasis. **Committee Recommendations** The committee concluded that there are some differences in efficacy, effectiveness or safety between the agents. They recommended that Cosentyx be a preferred agent or approved for plaque psoriasis without a requirement of failure of another agent if requested by a specialist.
➢ *Immune Globulins*	*Sarah Martinez, PharmD*	**<u>Immune Globulins</u>** Dr. Martinez reported that there is one new product in this class, Hyqvia (immune globulin-human with recombinant human hyaluronidase), which is indicated for the treatment of primary immunodeficiency in adults. She reviewed indications, administration and adverse reactions of Hyqvia. There are no comparative studies available. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ *Botulinum Toxins*	*Sarah Martinez, PharmD*	**<u>Botulinum Toxins</u>** There were no new agents to report in this class. Dr. Martinez reported on a product update for Botox, which is now indicated for the treatment of upper limb spasticity to include thumb flexors. There was also a product update for Dysport which is now indicated for the treatment of upper limb spasticity in adult patients to decrease the severity of increased muscle tone in elbow flexors, wrist flexors and finger flexors.

		Committee Recommendations The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ *Immunomodulators, Atopic Dermatitis*	*Sarah Martinez, PharmD*	**<u>Immunomodulators, Atopic Dermatitis</u>** Dr. Martinez announced that Protopic is now available generically as tacrolimus. She reviewed the 2014 update to the Allergy, Asthma, and Immunology/American Academy of Dermatology Joint Guidelines which maintain that topical corticosteroids and emollients are the standard of care treatment for atopic dermatitis. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ *Hemophilia Agents*	*Sarah Martinez, PharmD*	**<u>Hemophilia Agents</u>** Dr. Martinez reported on three new products in this class. Ixinity (factor IX) is indicated for patients 12 years and older with hemophilia B. Novoeight (turoctocog alfa) is indicated for hemophilia A in children and adults. Obizur (antihemophilic factor, porcine sequence recombinant) is indicated for the treatment of bleeding episodes in adults with acquired hemophilia A. She reviewed indications, administration, and adverse effects of all of these agents. Dr. Martinez reported four product updates. Helixate FS is now indicated for routine prophylactic treatment to prevent or reduce frequency of bleeding episodes in adults with Hemophilia A. Wilate is now indicated for the perioperative management of bleeding in children and adults with Von Willebrand's disease. Novo Seven RT is now indicated for the treatment of Glanzmann's Thrombasthenia with refractoriness to platelet transfusions with or without antibodies. Xyntha is now approved for use in children. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents within the subclasses by Hemophilia type and product source. After discussing the advantages and disadvantages of this class of drugs as part of the preferred drug list, it was concluded that continued current clinical case management by a Department pharmacist is a more effective management mechanism for this drug class. Recommendation is to no longer review this class.

➢ *Ophthalmic Antibiotics*	*Sarah Martinez, PharmD*	**Ophthalmic Antibiotics** There were no new agents and no recent clinically significant information in this class to report on**.** **Committee Recommendations** The committee concluded that there was some evidence for differences in safety between classes but the evidence did not support differences in efficacy or effectiveness.
➢ *Ophthalmic Antibiotic/Steroid Combinations*	*Sarah Martinez, PharmD*	**Ophthalmic Antibiotic/Steroid Combinations** There was no recent clinically significant information to review in this class. **Committee Recommendations:** The committee concluded that the evidence did not support differences in efficacy or effectiveness or safety between the agents. They did feel that there were safety issues with ophthalmic steroids in general. The recommendation was made to make Pred-G non-preferred since it is not readily available and there hasn't been any utilization of this drug. The committee recommended that a DUR be done on these drugs. The study should look at both the combination antibiotic steroid products as well as the ocular steroid products within the pediatric population. The study should be broken out by age (> 18 and < 18) as well as specialty of prescriber.
➢ *Ophthalmics, Anti-inflammatories*	*Sarah Martinez, PharmD*	**Ophthalmic, Anti-inflammatories** There were no new agents and no recent clinically significant information in this class to report on**.** **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ *Ophthalmics for Allergic Conjunctivitis*	*Sarah Martinez, PharmD*	**Opthalmics for Allergic Conjunctivitis** Dr. Martinez reported that there is one new product, Pazeo, which is indicated for ocular itching associated with conjunctivitis. She reviewed administration and reported that contraindications, warning, adverse effects and drug interactions were similar to other olopatidine ophthalmic products. She reviewed the two clinical trials used for drug approval. Dr. Martinez reviewed the updated 2014 American Academy of Ophthalmology treatment guidelines which recommend an OTC antihistamine/vasoconstrictor combination product or the more effective second generation ophthalmic antihistamines for the treatment of mild allergic conjunctivitis.

		Committee Recommendations The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ *Ophthalmics, Glaucoma Drugs*	*Sarah Martinez, PharmD*	**<u>Ophthalmics, Glaucoma Drugs</u>** Dr. Martinez announced that Lumigan 0.03% is now available generically as bimatoprost. **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>** The committee proposed an amendment to the public testimony guidelines. The guidelines currently in place require the following: (3) new studies released since the last review, excluding placebo studies only. The proposed amendment would further clarify the requirement as follows: (3) new study results published since the last review that meet good evidence requirements of randomized double-blind active control studies. Placebo controlled, observational, open label and non-randomized studies are not accepted for consideration. Studies must have been published or accepted for publication in a peer-reviewed journal. Online only publications and poster presentations will not be considered. The committee unanimously voted to approve these changes. The meeting adjourned at 3:15 p.m.

Pharmacy and Therapeutics Committee Meeting
Public Comment

Lucinda Langford, RN

My name is Lucinda Langford. I am a Bachelor's in Nursing; I have a Masters in Biostatistics. I currently work for Saint Alphonsus Medical Group. I'm a population health RN there. I am working in the Patient-Centered Medical Home. Let's see. I'm not representing anybody, other than my patients, and I don't have any financial ties to any pharmaceutical group. So I wanted to just say "thank you" for allowing me these few minutes to kind of talk about some of the stuff that's going on with our patients and providers in our clinics. I started a smoking cessation pilot in my clinic because we have a lot of tobacco smokers just in my clinic, and we have twenty-six clinics, so I'm looking at my group of patients. Our program is open to anybody that failed other programs that couldn't have any smoking cessation medications, or they didn't have access to them, or they were unable to get help online. So we know that approximately 50% of our smokers are going to prematurely die from other diseases, and these findings from several studies suggest that tobacco cessation benefit should include coverage for medications, behavioral treatments, and few barriers to access. So the smoking prevalence in the Medicaid population is 65% greater than in other populations. So I'm here today to request that you remove barriers to all smoking cessation medications. I have had several Medicaid patients in my smoking cessation pilot program that were decreasing their numbers of cigarettes, only to hit a point where they couldn't get past. So then I tried to get another medication for them like varenicline and there were barriers, and it stopped our momentum, and it stopped the roll that these patients were really on, and they were doing well decreasing, and we didn't have a chance to use that. So several times I found the choices providers did have for the Medicaid patient was not compatible with the patients' other medications or the patients had failed these options, or the medication was just unaffordable for the patient. Several times, I have had to enroll patients myself online for the QuitNow program, just to get them free nicotine gum, because they really don't have any extra money at all. So, and then that takes several weeks to process before they even get it. So a further barrier for the patients is the lack of available smoking cessation programs. There currently is not any reimbursement for people like me, who do this work out of the love of patients, and I have been a nurse for over forty years, and I'm going to keep doing it, but we need reimbursement for this. So I did want to throw that tidbit in there. I do it out of care for my patients, and there was no charge to the patient in my program, but I was recently told I couldn't give away the farm. So I understand how important their health is, and I'm also suggesting that the smoking cessation issue reimbursement be addressed somewhere by somebody down the line here please. At Saint Alphonsus, an ACO, and my clinic is an NCQA Patient-Centered Medical Home, we have had matrixes that we must be completing. This data is being collected currently, and tobacco use is one of the meaningful use measures we're addressing with every patient at every visit. So in my smoking cessation program, which I ran for over six months, I put a stop on it, with patients from my clinic only, I had a 62% quit rate. This would have probably been higher, if there had been no barriers for my Medicaid patients in accessing varenicline. If our goal is to reduce the health care costs overall, then what we do proactively now is a win-win, for helping our patients with smoking cessation. The cost is exponential in the patient who is a smoker. We will be paying for greater costs in health care down the line for these folks. I am pleading on behalf of the patients and the providers in my clinic that I work with, to please remove the barriers to all smoking cessation medications. It's really the right thing to do. Thank you.

Committee

Can I ask you a question, and then maybe other people who want to also? From your perspective and experience, how many trials over how long,

represents a reasonable enough trial to say "This isn't going to work" or "This isn't going to be effective".

Lucinda Langford, RN
Are you talking about medications? Okay, so that's okay, because there's a lot of different ways people are doing things. So, there have been quite a few trials of different medications, and there are lots and lots of studies out there, and I've actually looked at a lot of studies on my own, read a lot of white papers, because this is, I'm not a smoker and never have been, but this is really close to my heart. So as far as starting and stopping, we have, and this is from my personal opinion, we have a lower level of education, and a lot of patients don't understand the consequence of stopping something, you know. They just, "Oh I don't think this is working", so they stop. So truly, it's very difficult to answer your question accurately, but I know of several of my patients that we got nicotine gum for. They have many, many other, the three that I can think of right at the moment have many multiple psyche medications also on board, so it becomes an issue of getting them to be compatible and getting them to go to the end, so it's a, I can't really answer your question accurately with stats. I wish I could, so, I am working on it though.

Committee
I have a question. I wanted to publicly thank you for your passion, and these patients are lucky to have you. The question that I have is, do you feel that a psychosocial intervention like enrollment in a group would be helpful to enforce, along with [inaudible]?

Lucinda Langford, RN
So I saw these patients every Thursday, and I saw most of them individually, and I was truly a cheerleader, and we worked to kind of get all sorts of working, so many different ways. Yes, I think that the psychosocial part of it and having group support or individual support is paramount. I have a 62% quit rate in just my patients because they felt like, especially having a one-on-one, they felt like committed to me, and I fostered that, because I want them to quit, so I really let them know, you know, this matters to me, but it really is going to matter to you. So, yes, I think it's integral.

Committee
So in terms of policy for us as a group, should we then also, in your opinion, recommend to providers that in order to get, [inaudible] process, demonstrate current enrollment in either individual or group quitting program?

Lucinda Langford, RN
Personally, I think that's the optimum. We know that behavioral modification with medications has got a greater success, so, you know, that, but having that as a prior authorization and failing, is where it's a problem, because then, they lose momentum and "I tried, it doesn't work for me". So if I had that option to be able to take care of their medications, take care of them, and Saint Alphonsus would like me to be reimbursed, but that would be the ultimate, is if I could do both at the same time. So having what doesn't seem like a big barrier is a really big barrier for those of us that are actually working this, and we really are trying to get smoking cessation as a big rolling program with Saint Alphonsus. So our providers are very, very engaged. Any other questions? Thank you.

Committee
Next up, I have John Sandstrom from Baxalta. And again, if I could have you state name and degree, employer, who you are representing, and if you're receiving compensation for your testimony and any financial ties to pharmaceutical or medical supply companies.

John Sandstrom, PharmD
Thank you everyone on the committee. I'm John Sandstrom. I'm from Baxalta, formerly Baxter Bioscience, which recently changed to Baxalta. I'm a PharmD. I represent the company, I'm paid by the company, and I'm with Medical Affairs. So I thank everyone for making the changes that we identified in the TCR that was recently posted for immunoglobulins. There were about seven pages of errors. Most of the errors were corrected. However, there were some errors with respect to dosing that still need to be corrected. So I just wanted to take the time to correct those. We agree with all the other errors that were corrected, however. So with respect to the table, the pharmacokinetic table on page 8, if we look at page 8, Gammagard is represented as Gammagard-SC, and I think that you could make a mistake if it's represented that way, because Gammagard liquid is actually indicated for subcutaneous use, so there's no Gammagard-SC. There's no product named Gammagard-SC, so I think that's an important correction to make. Baxalta manufactures three different products; Gammagard liquid, which is an IV and subcutaneous formulation, Gammagard-SD, which is only indicated for IV administration, and then HyQvia, which is a subcutaneous formulation that is administered both with a human hyaluronidase, which increases its bioavailability, and allows for 3-4-week dosing intervals at a 1:1 dosing ratio with the IV formulation. I think it's important to note that the mean dose was not included in the pharmacokinetic table. What the TCR indicates is the 95% confidence interval. It's mistakenly posted as the dose, so it says HyQvia's dose is 134-160 mg/kg. The correct mean weekly equivalent is 147, so that's an incorrect dose. And then also the dosing conversion for subcutaneous formulations, so that's talking about the liquid formulation, should be 1.37 or 137% of the IV dose, dosed every 3-4 weeks. In the TCR, it's incorrect, and it's actually, there are a lot of other mistakes with some of the other products in this TCR. The dosing for one of the other products is also mistaken. It's actually the subcutaneous dose is incorrect as well, but I won't go into that because I don't represent that company, but I'll tell you that it's incorrect. So those need to be changed. So that's my public testimony, and I can follow up with the corrections if you'd like.

Committee
Thank you very much. Does anybody have any questions? Next up we have, is it Mary Kemmis? Am I saying that right? Okay good, good, from Novartis.

Mary Kemmis
Okay, I think I know the drill. So, I'm Mary Kemmis, I'm a pharmacist with Novartis Medical Affairs. I'm here representing Cosentyx. I work for Novartis, so that's my tie. So, thanks for allowing me time to speak today. Today, I'd like to discuss secukinamab, or Cosentyx, which I believe is included in your TIMs review. It's indicated for the treatment of moderate to severe plaque psoriasis. It works by a novel mechanism of action; it actually binds to the IL-17A and inhibits its activity with the IL-17 receptor. This pathway is important, because IL-17 is actually found in large concentrations in the psoriatic plaques in the skin. There is currently no other therapy that works via this mechanism. So today I'm going to actually focus my comments on the CLEAR trial, which is not included in the TCR. It was recently published in the Journal of the American Academy of

Dermatology. So CLEAR is a 52-week, head-to-head trial which compares Cosentyx to Stelara, looking at efficacy, long-term safety and tolerability in 679 patients with moderate to severe plaque psoriasis. The primary endpoint was to demonstrate superiority of Cosentyx 300 mg, which is the recommended dose for the FDA labeling, versus Stelara with respect to PASI 90 at week-16. PASI 90 represents clear or almost clear skin, and this is the first trial to evaluate PASI 90 as a primary endpoint for psoriasis. Typically, we see PASI 75 being the primary endpoint in trials, but with the introduction of newer agents, there is now a movement towards looking at a higher bar because patients can actually achieve clearer skin now. The study showed that 79% of patients treated with Cosentyx achieved a PASI 90 at week-16 versus 58% in the Stelara arm, so that's a 21% difference. PASI 100, or absolutely clear skin, was also achieved by significantly more patients treated with Cosentyx versus those treated with Stelara. That difference was 16%. In the CLEAR study, the safety profile of Cosentyx was comparable to Stelara, and consistent with previously reported phase-3 clinical trials, which I'm sure will be discussed today. There is no black box warning for Cosentyx and there were higher rates of candida observed, about 1% higher, versus Stelara, but this is an expected side effect seen with drugs that target IL-17. So I ask you to consider adding Cosentyx to the Idaho Medicaid PDL, as it's the only IL-17A inhibitor for the treatment of moderate to severe plaque psoriasis. It has demonstrated early and sustained skin clearance, comparative data against now two other biologics, as well as a favorable safety profile. Sorry, my voice is a little affected by the smoke today. Any questions? Thanks.

Committee

And then we had one other testimony approved, is Tim Miller, Timothy Miller here? Okay. So that closes the public comment period.