Pharmacy and Therapeutics (P&T) Committee Meeting Record

Date: October 19, 2018

Time: 9:00 a.m. – 1:40 p.m. **Location:** Idaho Medicaid, 3232 Elder Street, Boise, Idaho, Conference Room D

Moderator: Christine Hahn, M.D.

Committee Members Present: Christine Hahn, MD, Chair; Tami Eide, PharmD; Andrei Rudyi, PharmD; Alex Adams, PharmD, MPH, Board of Pharmacy; Christopher Streeter, MD; Paul Driver, PharmD; David Calley, PharmD; Joseph Weatherly, DO; Jeffery Johnson, PA, PharmD; Brian Crownover, MD.

Committee Members Absent: Perry Brown, Jr., MD.

Others Present: Matthew Lennertz, PharmD, Magellan Health Services; Chris Johnson, PharmD, Division of Medicaid; Jane Gennrich, PharmD, Division of Medicaid; Suzanne Fox, Division of Medicaid; Clay Lord, Division of Medicaid; Mark England, PharmD, Magellan Medicaid Administration.

AGENDA ITEMS	PRESENTER	OUTCOME/ACTIONS
CALL TO ORDER	*Christine Hahn, MD*	*Dr. Hahn called the meeting to order.*
Committee Business ➢ *Roll Call*	*Christine Hahn, MD*	Dr. Hahn completed the roll call and welcomed the P&T Committee members.
➢ *Reading of Mission and Confidentiality Statements*	*Christine Hahn, MD*	Dr. Hahn read the Mission and Confidentiality Statements.
➢ *Approval of Minutes from May 18, 2018 Meeting*	*Christine Hahn, MD*	The May 18, 2018 minutes were reviewed. The minutes were approved without any changes.
Update of Idaho Opioid Equivalent Dosing Project	*Mark England, PharmD Magellan Medicaid Administration*	**Update of Idaho Opioid Equivalent Dosing Project** Dr. England reviewed IDHW's Pharmacy Program's approach for managing Opioid utilization which includes: • Quantity Limits on all drugs • PA on specific State Drug Classes

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Profile review and educational outreach
MME (Morphine Milligram Equivalents) of 90 mg cumulative daily dose from all opioids

He reported that an edit went into production on July 19, 2017 to stop payment on participants receiving over 90 mg MME daily without an approved prior authorization. Temporary prior authorizations were entered into to the system for 3,669 members that were on more than 90 mme for a limited time period of 7/19/17-7/19/18 to allow prescribers time to taper doses and/or change therapy.
Prior Authorizations from 7/19/17-9/30/18 were processed for 1,370 requests with 246 denials and 1,124 approvals.
Dr. England reviewed the following:

Participants with at least one opioid prescription by number of prescribers and pharmacies used with breakdown of those receiving > 90 daily MME.
Top 20 specific opioids prescribed
Top 20 pharmacies dispensing opioids
Top 20 participants (de-identified) with highest daily MME

Range from 1,016 MME daily to 5,760 MME daily

He reported on results of opioid prescribing interventions from 7/1/18 – 9/30/18

26% decrease in Members on Opioids from 1Q2017 to 3Q2018
28% decrease in Opioid Members on > 90 MME from 1Q2017 to 3Q2018

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<td>Public Comment Period</td>
<td>Christine Hahn, MD
Chris Johnson, PharmD</td>
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<u>Public Comment Period</u>
Public testimony was received from the following speakers:
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<tr><th>Speaker</th><th>Representing</th><th>Agent</th><th>Class</th></tr>
<tr><td>W. Patrick Knibbe, MD</td><td>St. Luke’s Rheumatology</td><td>Humira, citrate-free</td><td>Cytokine/CAM Agents</td></tr>
<tr><td>Mark Jensen</td><td>Pfizer</td><td>Xeljanz</td><td>Cytokine/CAM Agents</td></tr>
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Biological Drugs to Treat Asthma and Chronic Spontaneous Urticaria	*Brittany Lazur, MPH* *Center for Evidence-based Policy, OHSU*	**<u>Biological Drugs to Treat Asthma and Chronic Spontaneous Urticaria</u>** Ms. Lazur reviewed the Drug Effectiveness Review Project report on Biologic Drugs to treat Asthma and Chronic Spontaneous Urticaria completed by the Pacific Northwest Evidence-based Practice Center completed in April 2018. This report included four injectable biologics, none of which are considered first-line therapies and are reserved for patients with treatment refractory asthma or chronic spontaneous urticaria. Benralizumab (Fasenra), Reslizumab (Cinqair), and Mepolizumab (Nucala) are Anti-interleukin-5 monoclonal antibodies approved to treat severe asthma in patients with an eosinophilic phenotype. Omalizumab (Xolair) is an anti-IgE monoclonal antibody approved to treat uncontrolled allergic asthma and chronic spontaneous urticaria resistant to antihistamines. The evidence review identified 5 systematic reviews, 15 placebo-controlled trials and 2 non-randomized studies. There were no trials directly comparing biologic drugs. Agents were added to preexisting therapy and compared with placebo. **Summary of Findings:** Benralizumab, reslizumab, and mepolizumab all significantly reduced exacerbations requiring steroids. Benralizumab and mepolizumab also significantly reduced exacerbations requiring emergency or hospital admission as well as significant decreases in oral steroid dosages needed. Omalizumab reduced exacerbations requiring oral steroids or emergency or hospital admission. for allergic asthma. Exacerbations were significantly reduced in moderate to severe asthma, but not severe asthma. Omalizumab showed significant improvement in response and complete response for chronic spontaneous urticaria. Quality of life improved significantly across drugs and indications, but was not clinically meaningful, except for mepolizumab. Lower rates of serious adverse events were seen with benralizumab and omalizumab in asthma. There were no differences for other drugs or in patients

		with Chronic Spontaneous Urticaria.
Drug Class Reviews and Committee Recommendations	*Matthew Lennertz, PharmD* *Magellan Health Services*	**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 comparative evidence to support clinically significant differences in efficacy or effectiveness between agents? If yes, what are the differences? 2. Is there comparative evidence to support clinically significant differences in safety between agents? If yes, what are the differences? 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?
➢ *Immunomodulators, Asthma*	*Matthew Lennertz, PharmD* *Magellan Health Services*	**<u>Immunomodulators, Asthma</u>** Dr. Lennertz reported one new product in the class: Fasenra (benralizumab). Fasenra (benralizumab) is a new IL-5 receptor monoclonal antibody approved as add-on maintenance treatment for patients with severe asthma 12 years or older with an eosinophilic phenotype, but not to treat other eosinophilic conditions or to relieve acute bronchospasm or status asthmaticus. He reviewed the dosing, warnings and adverse reactions. He reported that there was no comparative clinic data available. Dr. Lennertz also reported that Nucala is now approved for the treatment of adults with eosinophilic granulomatosis with polyangiitis (EGPA), previously known as Churg-Stauss syndrome. **Committee Recommendations** The committee concluded that mepolizumab and benrazlizumab had better clinical effectiveness data and that mepolizumab had better evidence for quality of life. They felt that the evidence for reslizumab was less compelling and it should be a second-tier agent. They would like specific criteria listed on the PDL document with subclasses for IL-5 antagonists and Anti-IgE antibodies.
➢ *Anti-Allergens, Oral*	*Matthew Lennertz, PharmD*	**<u>Anti-Allergens, Oral</u>** Dr. Lennertz reported on one new products in this class. Odactra (House Dust Mite Allergen Extract) for immunotherapy in adults with House Dust Mite-induced allergic rhinitis. Dr. Lennertz reviewed a focused update on sublingual allergen therapy (SLIT) published by the American Academy of Allergy, Asthma and Immunology (AAAAI) and the American

		College of Allergy, Asthma, and Immunology (ACAAI). Per the review SLIT should only be used for FDA-approved uses and may not be suitable for all patients. They noted that dosing equivalence between products should not be assumed and stressed the importance of administration of initial doses in the presence of a health care professional. They recommended that all patients receive a prescription for self-injectable epinephrine. **Committee Recommendations** The committee concluded since each agent is indicated for specific allergens, no comparisons can be done between agents. They stated that criteria should remain the same as currently stated on the PDL document.
➢ *Antihistamines, Minimally Sedating*	*Matthew Lennertz, PharmD*	**Antihistamines, Minimally Sedating** Dr. Lennertz reported that there is no recent information of significance in this class. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ *Immunomodulators, Atopic Dermatitis*	*Matthew Lennertz, PharmD*	**Immunomodulators, Atopic Dermatitis** Dr. Lennertz reported no new products in this class and there is no recent information of significance in this class. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy or effectiveness between the agents. The committee recommended that Eucrisa (crisaborole) be considered for preferred status as it does not have black box warning for rare cases of malignancy that is present in the package inserts for the calcineurin inhibitors, tacrolimus and pimecrolimus.
➢ *Epinephrine, Self-Injected*	*Matthew Lennertz, PharmD*	**Epinephrine, Self-Injected** Dr. Lennertz reported that the FDA had approved a new Auvi-Q 0.1 mg strength for infants and children weighing 7.5 to 15 kg for the treatment of life-threatening allergic reactions, including anaphylaxis who are at risk for or have a history of serious allergic reactions (previously approved in those 15 kg or greater only). The FDA also approved a generic version of Epipen and Epipen Jr. manufactured by Teva. A launch date has not been established but is anticipated for Fall 2018. He reported on product shortages of Epipen due to significant violations of current good manufacturing practice. It was also noted that Auvi-Q remains federally non-rebatable and cannot be paid for by Idaho Medicaid.

		Product shortages were discussed, and it was reported that Idaho Medicaid's Pharmacy Unit is working with dispensing pharmacies to ensure that patients have access to self-injected epinephrine during product shortages. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ *Intranasal Rhinitis*	*Matthew Lennertz, PharmD*	**Intranasal Rhinitis** Dr. Lennertz reported three new products in this class: Xhance (fluticasone propionate), Fluticare (fluticasone propionate), and Sinuva (mometasone furoate). Xhance is approved to treat nasal polyps in adults. Dr. Lennertz reviewed indications, dosing, contraindications, warnings and adverse effects of these agents as well as clinical trials available. Sinuva is a new agent that is approved for treatment of nasal polyps. It is a corticosteroid eluting implant placed in the ethmoid sinus under endoscopic visualization. It is therefore not an outpatient drug and will not be listed on the preferred drug list document. Dr. Lennertz also reviewed The American College of Allergy, Asthma, and Immunology (ACAAI) updated guidelines on the treatment of seasonal allergic rhinitis (SAR). Key recommendations for patient ≥ 12 years of age include: routine prescribing of intranasal corticosteroid monotherapy over combination therapy; use of an intranasal corticosteroid over a leukotriene receptor antagonist in patients ≥ 15 years of age and combination of an intranasal corticosteroid plus an intranasal antihistamine for patients with moderate to severe symptoms. **Committee Recommendations** The committee concluded that there was not comparative evidence to support clinically significant differences in efficacy, effectiveness, or safety between the agents. They recommended considering the addition of a combination agent as preferred if feasible.
➢ *Glucocorticoids, Inhaled*	*Matthew Lennertz, PharmD*	**Glucocorticoids, Inhaled** Dr. Lennertz reported two new products in this class: QVAR Redihaler (beclomethasone dipropionate HFA) and Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol). He reviewed indications, dosing, contraindications, warnings and adverse reactions of these agents. He reviewed clinical trials used for approval of Trelegy Ellipta. Trelegy Ellipta is the first approved single-device triple inhaler. It is a fixed dose combination of an inhaled corticosteroid, anticholinergic, and a long-acting beta 2-adrenergic agonist (LABA). He

		reported that now that QVAR Redihaler is available that Teva has discontinued the manufacturing of QVAR metered-dose inhaler.
		
		Dr. Lennertz reported on the following product updates:
		• Trelegy Ellipta is now approved for the maintenance treatment of airflow obstruction in patients with COPD and to reduce exacerbations of COPD. This new indication no longer specifies current use of fluticasone furoate/vilanterol (Breo Ellipta) in patients who require additional bronchodilation or the current use of umeclidinium (Incruse Ellipta) and Breo Ellipta.
		• Arnuity Ellipta (fluticasone furoate) is now approved for the maintenance treatment of asthma in patients 5 years of age and older.
		  o Previously approved for patients 12 years of age and older.
		  o A 50mcg strength was also approved, and the recommended dose for patients 5 to 11 years of age is 50mcg.
		
		Dr. Lennertz also reviewed updated safety data on use of the combination treatment for asthma with long-acting beta agonists and inhaled corticosteroids. Based on 4 large clinical safety trials, the FDA determined that treatment of asthma with long-acting beta agonists in combination with inhaled corticosteroids does not lead to significantly more serious asthma-related adverse effects than treatment with an inhaled corticosteroid alone. These trials have been added to labeling and information for combination products and the boxed warning for asthma-related death has been removed. The boxed warning for increased risk of asthma-related death with use of LABAs alone will remain in labels for single component LABAs.
		
		Committee Recommendations
		The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. They recommended that a two-component combination be tried prior to approval of Trelegy. Revisions were requested to the PA form used for agents in this class.

➢ *Bronchodilators, Beta Agonist, Short-Acting*	*Matthew Lennertz, PharmD*	**<u>Bronchodilators, Beta Agonists, Short-Acting</u>** Dr. Lennertz reported no new products and no recent information of significance in this class. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.

➢ *Bronchodilators, Beta Agonists, Long-Acting*		**<u>Bronchodilators, Beta Agonists, Long-Acting</u>** Dr. Lennertz reported no new products in this class. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. The committee recommended that one long-acting nebulized bronchodilator be preferred.
➢ *Leukotriene Modifiers*	*Matthew Lennertz, PharmD*	**<u>Leukotriene Modifiers</u>** Dr. Lennertz reported no new products and no recent clinical information of significance in this class. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ *COPD Agents*	*Matthew Lennertz, PharmD*	**<u>COPD Agents</u>** Dr. Lennertz reported one new product in this class: Lonhala Magnair (glycopyrrolate inhaled). It is approved for the long-term maintenance treatment of COPD and is the first nebulized long-acting muscarinic antagonist. He reviewed dosing, place in therapy, warnings and adverse reactions. He reported that there is no comparative clinical data available. Dr. Lennertz reported on FDA approval of the SmartTouch monitoring device application for use with Symbicort inhalers. He also reported that a new 250mcg strength of Daliresp (roflumilast) was approved. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ *Smoking Cessation*	*Matthew Lennertz, PharmD*	**<u>Smoking Cessation</u>** Dr. Lennertz reported no new products and no recent clinical information of significance in this class. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.

➢ *Immune Globulins*	*Matthew Lennertz, PharmD*	**Immune Globulins** Dr. Lennertz reported three new products in this class: Panzyga, HyperRab, and Kedrab. Panzyga is an immune globulin intravenous (human-ifas) 10% liquid approved for the treatment of primary humoral immunodeficiency in patients 2 years of age and older and for chronic immune thrombocytopenia in adults. Dosing, contraindications, warnings and adverse reactions were reviewed. There is no comparative clinical data available. Hyper Rab and Kedrab are indicated for the treatment of rabies. Dr. Lennertz reported also that Hizentra is now approved for the treatment of adults with chronic inflammatory demyelinating polyneuropathy (CIDP) as maintenance therapy to prevent relapse of neuromuscular disability and impairment. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between non-specific immune globulin products. It was noted that HyperRab's higher concentration is advantageous in treating children who have been exposed to Rabies.
➢ *Botulinum Toxins*	*Matthew Lennertz, PharmD*	**Botulinum Toxins** Dr. Lennertz reported no new products in this class. He reported that Botox Cosmetic is now approved for temporary improvement in the appearance of moderate to severe forehead lines associated with frontalis muscle activity. As drugs for cosmetic use are not covered by Idaho Medicaid, this indication will not be covered by Idaho Medicaid. Dr. Lennertz also noted that Xeomin is now indicated for the treatment of chronic sialorrhea (excessive drooling) in adults. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. PA requirements will be updated to include sialorrhea.
➢ *Cytokine/CAM Agents*	*Matthew Lennertz, PharmD*	**Cytokine/CAM Agents** Dr. Lennertz reviewed the utilization patterns of this class. He clarified that utilization statistics for citrate-free formulations of agents (e.g., Humira) are rolled up into the stats for the agent as a whole and are not broken out into separate agents for utilization tracking

		purposes. Dr. Lennertz reported two new products in this class: Ilumya (tildrakizumab-asmn) and Olumiant (baricitinib). Ilumya is a new interleukin-23 antagonist selective to the p19 subunit approved for treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. Olumiant is a new Janus kinase (JAK) inhibitor, indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies. He reviewed dosing, contraindications, warnings, adverse events and clinical evaluations completed for market approval of these agents. Dr. Lennertz reported on an international multidisciplinary task force consensus-based recommendation on the use of biosimilars for rheumatologic diseases. The task force states that biosimilars are not considered superior or inferior to the originator product, should be considered safe and effective for all the originator product's approved indications and decisions to substitute a biosimilar product for a reference drug should be made by the prescriber. In product updates Dr. Lennertz noted: • Stelara is now approved for moderate to severe plaque psoriasis to include treatment of adolescent patients aged 12 to 17 years who are candidates for phototherapy or systemic therapy. • Simponi Aria has been approved for the treatment of adults with active ankylosing spondylitis (AS) or active psoriatic arthritis (PsA). • Taltz is approved for the treatment of adults with active psoriatic arthritis. • Xeljanz/Xeljanz XR are now indicated for the treatment of adults with active psoriatic arthritis who have had an inadequate response or intolerance to methotrexate or other disease-modifying antirheumatic drugs (DMARDs). • Xeljanz is now approved for the treatment of patients with moderately to severely active ulcerative colitis. • Kevzara is approved as 150 mg/1.14 mL and 200 mg/1.14 mL solution in single-dose prefilled pens. • Cimzia is approved for use in adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. • Actemra is approved for subcutaneous dosing in pediatric patients 2 years of age and older with systemic juvenile idiopathic arthritis. • Humira is now available in a citrate free formulation.

		Committee Recommendations The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents for their respective indications. They recommended making Humira citrate free preferred if the cost is comparable to that of the original formulation. The committee recommended that at least one drug be preferred for each of the most common diagnoses.
➢ *Ophthalmic Antibiotics*	*Matthew Lennertz, PharmD*	**<u>Ophthalmic Antibiotics</u>** Dr. Lennertz reported no new products in this class. He reported that Vigamox safety and efficacy has been established in all pediatric ages and that Vigamox is now available generically. **Committee Recommendations:** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ *Ophthalmic Antibiotic/Steroid Combinations*	*Matthew Lennertz, PharmD*	**<u>Ophthalmic Antibiotic/Steroid Combinations</u>** Dr. Lennertz reported no new products and no recent clinical information of significance in this class. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ *Ophthalmic Anti-Inflammatories, Immunomodulators*	*Matthew Lennertz, PharmD* *Magellan Health Services*	**<u>Ophthalmic Anti-Inflammatories, Immunomodulators</u>** There were no new products in this class. Dr. Lennertz reported that a multi-dose, preservative-free preparation of Restasis is now available. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. The committee agreed that the criteria for Restasis should include trial and failure of OTC lubricant agents and recommended development and implementation of a new PA form for agents in this class.
➢ *Ophthalmics for Allergic Conjunctivitis*	*Matthew Lennertz, PharmD* *Magellan Health Services*	**<u>Ophthalmics for Allergic Conjunctivitis</u>** Dr. Lennertz reported no new products and no recent clinical information of significance in this class.

		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 meeting adjourned at 1:40 p.m. Next meeting is scheduled for November 16, 2018.

Pharmacy and Therapeutics Committee Meeting
Public Comment

W. Patrick Knibbe, St. Luke's

I'm W. Patrick Knibbe. I'm Director of Children's Rheumatology for St. Luke's. I take care of itty-bitties with Juvenile Idiopathic Arthritis. I appreciate seeing some familiar names, we've traded electronic records. My reason for coming today is pretty simple, but now that I have the floor, I'll probably add some other things.

We take care of kids with debilitating polyarticular and extended oligoarticular arthritis. Many of those kids end up on a biologic agent, of which only two TNF inhibitors are approved for Juvenile Idiopathic Arthritis, Enbrel and Humira. Humira has typically been not a favorite of our children, because it hurts like crazy.

Recently, after five years of prodding from rheumatologists all over the country, they have changed the formulation so that it is now citrate-free, has a smaller needle, and doesn't hurt. Illustrative of that, Lucas, my patient from Idaho Falls, who's been on Humira for two and a half years, had to be chased around the house, pinned down by his mother while his father gave him the Humira—until last week, when he came in and proudly announced to me that he'd given his own injection with the new formula.

Medicaid has not approved the new formulation. I have dozens of kids who are needing this medication, and the switch to the more comfortable preparation seems like a no-brainer to me. It's not any different in terms of cost, access, everything else, and I was told by…, when I called a few times this past month inquiring about the reason, it was that there is no rebate program from AbbVie on this particular medication. How many people have children—their tender little…, that's all the preparation really does, it doesn't hurt as much, seems like a no-brainer to be approved. I hope that will take place soon so that we can take care of kids without having them scream and yell. That's my primary mission to come here today, but I also wanted to—since we're the only pediatric rheumatology practice in the state, and we take care of the majority of the kids with juvenile arthritis, and certainly the majority of kids on Medicaid who have Juvenile Idiopathic Arthritis —the preapproval process for simple things like non-steroidal anti-inflammatory medications, often proves onerous, with several letters and inquiries and such. And I know some of my colleagues around the country have been able to negotiate with providers to have sort of a bit of a free pass in terms of preapproval. For example, the only Medicaid formulary anti-inflammatory medications are ibuprofen and naproxen. Naproxen causes a sun-sensitive rash, and every summer cute little blonde kids get a permanent scarring rash on their cheeks from naproxen. I don't use naproxen, everyone has tried ibuprofen, and when I tried to prescribe another anti-inflammatory medication, pharmacies rejected, had to go through preapproval. We know which anti-inflammatories work for which types of arthritis, and it would really be helpful if that simple sort of thing, to give pediatric

rheumatologists a bit of a pass on this. It would reduce the amount of paperwork for a simple medication like piroxicam, meloxicam.

Anyway, appreciate the time, and it's great to meet some folks that I've had interaction with, and I would be delighted to take questions on any topic in pediatric rheumatology.

Committee
So even meloxicam you've had trouble with…

W. Patrick Knibbe
Yes. We typically get a rejection for any anti-inflammatory other than ibuprofen and naproxen.

Committee
Is that based on FDA age-approval range?

W. Patrick Knibbe
There is only one FDA-approved anti-inflammatory, and that's naproxen for juvenile idiopathic arthritis. But we use all of the anti-inflammatory medications. It doesn't work in spondylopathies, in situs-related arthritis, it's just not successful, and we always use another anti-inflammatory like diclofenac or piroxicam or meloxicam in those kids. And it delays their treatment by two to three weeks at least, because they get a rejection, there has to be a letter generated, the pharmacy has to write one, I have to write one—it just delays treatment.

Committee
And you're seeing an absolute difference in benefit above and beyond what naproxen or ibuprofen allows…

W. Patrick Knibbe
Yes, absolutely. That's only based on 30 years of experience, but… I know in huge controlled studies there's probably not a difference, but that's my individual… that's probably eminence-based medicine instead of evidence-based medicine, but...

Committee
Outside the field of rheumatology, I get the same issues pop up in my practice as well for things… the 18-year-old versus a 17-year-old, and the 17-year-old gets blocked by the FDA age indications, so I certainly can understand…

W. Patrick Knibbe
The famous FDA gap… kids up to 16, and adults start at 18, so what do we do with those kids from 16 to 18? You write letters. Of course, there is sudden adult syndrome, Mary is already in jail, convicted, those kids are already adults at 16. Anyway, appreciate your comments.

Committee
I've got a question just from a pharmacy standpoint. A couple of years ago, I started using Cover My Meds, which is supposed to simplify the paperwork aspect of PAs. Do you have much experience as providers with it?

W. Patrick Knibbe
Yes, we have, but Medicaid won't play with Cover My Meds. It bogs down, and doesn't work, and my staff and myself, dig on the PDL, fax it in, to the Medicaid office because Cover My Meds doesn't work.

Committee
We get a lot of PAs through Cover My Meds.

W. Patrick Knibbe
And while I have the floor again, rheumatologists have data that when special patients are referred to rheumatologists and they have special needs, we provide more efficient care. We know which medications work for which conditions, we have data and experience in different medications, and having to justify using a different TNF inhibitor for Uveitis, or an IL-17 inhibitor. We know these medications well, it really delays the process of treatment when there's an argument about which TNF inhibitor is covered by both pediatric and adult medications. I would want to be available to advise about those medications so that process can be smooth. We know how to deliver appropriate care, even though sometimes the original medication may be more expensive. We know that it eliminates the downstream health effects, such as total hip replacement, total knee replacement, other kinds of procedures that become terribly expensive. And if we were given that kind of leeway, that kind of collaboration, I think we could save the system money long term.

Any other questions for me?

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Mark Jensen, Pfizer

Good morning. I'm Mark Jensen. I'm a pharmacist and an employee of Pfizer. I'm here today to ask you to add Xeljanz to the Preferred Drug List. Xeljanz is an oral drug indicated for adult patients with rheumatoid arthritis, psoriatic arthritis, and, most recently, ulcerative colitis. The dose for ulcerative colitis is 10mg BID for at least eight weeks, then maintained with 5 or 10mg BID. Clinicians should discontinue after 16 weeks at 10mg BID if an adequate therapeutic benefit is not achieved. Clinicians should use the lowest effective dose to maintain response. And I should tell you that Xeljanz XR—which is our extended release product—is not indicated for treatment of ulcerative colitis at this time. For further prescribing information, I refer you to the PI.

But I'd like to quickly review the data behind the new ulcerative colitis indication. Phase 3 of the ulcerative colitis program consisted

of three multinational studies. The studies included patients who were either TNF inhibitor non-responders, or failures, or TNF inhibitor-naïve patients, about 50/50.

The first two studies were identical eight-week induction studies where tofacitinib 10mg BID was compared with placebo in inducing remission. The primary endpoint was achieved in both studies, and a statistically significantly greater percentage of patients on tofacitinib achieved remission compared to placebo. Secondary endpoints, such as the proportion of patients showing improvement in the endoscopic appearance of mucosa, were also significantly improved compared with placebo. A postdoc analysis was conducted, using pooled data, patient data, for both of the induction trials. Statistically significant differences in rectal bleeding scores and stool frequency scores between 10mg tofacitinib and placebo were observed as early as day 3. Adverse reaction rates, as well as those for serious infections, across the treatment groups. There were five cases of non-serious herpes zoster in the tofacitinib group and one case in the placebo group for the eight-week induction study. Clinical responders from that induction program were re-randomized to receive tofacitinib at 10mg BID, 5mg BID, or placebo for one year. All patients enrolled in the maintenance study were required to taper their steroids. Again, the primary endpoint of remission was achieved in this longer, 52-week study. All key secondary endpoints including the proportion of tofacitinib patients with improvement of endoscopic appearance and normalization of endoscopic appearance of the mucosa were achieved. Keeping in mind that these people on <***unintelligible***> steroids entering the maintenance study were required to discontinue that therapy, an important endpoint being sustained steroid-free remission was confirmed at both weeks 26 and 52 were significantly greater in the tofacitinib groups both 5 and 10 at 35 and 47% than placebo-treated patients, which was 5% of the patients. The safety profile in the patients with active ulcerative colitis was consistent with the safety profile observed in rheumatoid arthritis patients, which as a reminder included nine and a half years of clinical trials experience and 23,000 patient years of clinical trial experience. Adverse reactions reported in up to 5% of subjects in the UC trials program included nasal pharyngitis, elevated cholesterol levels, headache, URIs, increased CPK, rash, diarrhea, and herpes zoster. Across the entire 12 <***unintelligible***> program, dose-dependent adverse reactions were seen in patients treated with Xeljanz 10mg BID compared to 5mg BID, including herpes zoster, infections, serious infections, and non-melanoma skin cancer.

In conclusion, in addition to the RA and psoriatic arthritis indication, Xeljanz is now indicated for the treatment of adults with active ulcerative colitis. Xeljanz is a useful option to have available on the PDL as a preferred agent due to its unique mechanism of action, established safety and efficacy, and availability as an oral dosage form. Thanks for your time, and I'd be happy to answer any questions you might have.

There were no questions for Dr. Jensen.