Pharmacy and Therapeutics (P&T) Committee Meeting Record

Date: Friday, April 15, 2016

Time: 9:00 a.m. – 3:10 p.m. **Location:** Idaho Medicaid, 3232 Elder Street, Boise, Idaho, Conference Room D

Moderator: Phil Petersen, M.D.

Committee Members Present: Phil Petersen, MD-Chair; Tami Eide, PharmD; Brian Crownover, MD; Cali Bradberry, PA; Christopher Streeter, MD; David Calley, PharmD; Kevin Ellis, PharmD; Leigh Morse, MD; Mark Turner, M.D.; Stephen Carlson, PharmD

Committee Members Absent: Perry Brown, MD; Alex Adams, PharmD

Others Present: Richard Pope, PharmD, Magellan Health Services; Mark England, PharmD, Magellan Medicaid Administration; Chris Johnson, PharmD, Division of Medicaid; Jane Gennrich, PharmD, Division of Medicaid; Wendy Estrellado, Division of Medicaid; Olga Coply, Division of Medicaid

AGENDA ITEMS	PRESENTER	OUTCOME/ACTIONS
CALL TO ORDER	*Phil Petersen, MD*	*Dr. Petersen called the meeting to order.*
Committee Business		
➢ *Roll Call*	*Phil Petersen, MD*	Dr. Petersen completed the roll call and welcomed the P&T Committee members.
➢ *Reading of Confidentiality and Mission Statements*	*Phil Petersen, MD*	Dr. Petersen read the Confidentiality and Mission Statements.
➢ *Approval of Minutes from November 20, 2015 Meeting*	*Phil Petersen, MD*	The November 20, 2015 meeting minutes were reviewed. The minutes were approved as proposed.
➢ *DERP Update*	*Tami Eide, PharmD*	The Drug Effectiveness Review Project (DERP) is a collaborative of Medicaid and public pharmacy

		programs dedicated to producing comparative, evidence-based research to evaluate efficacy, effectiveness, and safety of drugs to help improve patient safety and quality of care while helping government programs to contain costs for new therapies. Dr. Eide reported that DERP is now in its fifth cycle, and new topics for review have not yet been determined. Drug updates will be completed for Multiple Sclerosis drugs on May 5 and Oral Anticoagulants on May 12; this information will be included for review at the next P & T Meeting on May 20, 2016. A review of the Targeted Immune Modulators will be available in June along with a COPD update. An update on the Newer Diabetes drugs will be provided in July. A review of second generation antipsychotic medications, which is a very large update, will occur in October and will be included for discussion at the P & T Meeting on November 18, 2016.

➢ *Update on Idaho Medicaid Hepatitis C Antiviral Utilization*	*Christopher Johnson, PharmD*	**<u>Update on Idaho Medicaid Hepatitis C Antiviral Utilization</u>**
		Dr. Johnson provided an update on prior authorization requests for Hepatitis-C agents for the time period 1/1/2016 to 3/31/2016. He reported on the outcomes of the requests, the approved agent/genotypes, as well as approval and denial rates. The Department has received 36 requests during this time period with the following outcomes:
		• 16 (43%) approved
		• 17 (46%) denied
		  ○ 13 did not meet fibrosis score criteria
		  ○ 3 had active substance abuse
		  ○ 1 was Medicare patient
		• 3 (1%) were pending review at the time of report
		Chris discussed the appeals process for denial. Of the appeals that proceeded to hearing, 27 denials were affirmed (denial sustained by hearing officer) or defaulted (patient did not attend hearing); seven appeals were requested from providers, but a provider cannot request appeal for a patient without authorization; four appeals were submitted late (>28 days); and three appeals are currently pending fair hearing.
		Current treatment criteria requires a patient to have a liver biopsy with Metavir stage F3-F4, adhere to counseling, and have a negative urine toxicology screen within one month of the request. Chris stated that the information most typically seen which results in a denial relates to urine toxicity screening. The committee inquired on standardized criteria related to toxicology screening and how long a person must remain drug and alcohol free to be able to receive Hepatitis C treatment. Dr. Johnson reported that there were no identified standard requirements, but the majority of states we have been in contact with require at least six months of negative toxicology screens for patients.

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<td>Public Comment Period</td>
<td>Phil Petersen, MD
Pharmacy Staff</td>
<td><u>Public Comment Period</u>
One person signed up to speak during the public comment period. Public testimony was received from the following speaker:
<table>
<tr><th>Speaker</th><th>Representing</th><th>Agent</th><th>Class</th></tr>
<tr><td>Daniel Flynn, MD</td><td>St. Luke’s CEC</td><td>Nordotropin</td><td>Growth Hormone</td></tr>
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<td>➢ Direct-Acting Antiviral Agents for Hepatitis C Infection</td>
<td>Shelly Selph, MD
Pacific Northwest Evidence-based Practice Center</td>
<td><u>Direct-Acting Antiviral Agents for Hepatitis C Infection</u>
Dr. Selph presented the systematic evidence review for a report regarding the Direct-Acting Antiviral Agents (DAA) for Hepatitis C Infection (HCV). Dr. Selph reported that 25 new randomized trials were reviewed. Two trials compared sofosbuvir/velpatasvir versus sofosbuvir/ribavirin. These trials provided direct evidence pertaining to treatment with and without ribavirin, different DDA doses, and different durations of treatment. Indirect evidence from the Canadian Agency for Drugs and Technologies in Health (CADTH) was also reviewed.

Dr. Selph reported on the major findings by treatment group and genotype. The take home points to this review were summarized as follows:
• Treatment with sofosbuvir/velpatasvir resulted in increased SVR than longer duration with sofosbuvir/ribavirin in mixed treatment history and genotype 2 or 3 patients (Strength of evidence (SOE): Low to Moderate for SVR).
• Sofosbuvir/velpatasvir for 12 weeks increased SVR compared with 8 weeks in treatment-naïve patients with genotype 1.
• Simeprevir/sofosbuvir for 8 weeks increased the risk of viral relapse compared with 12 weeks in treatment-naïve patients with HCV genotype 1.
• In treatment-experienced patients, two DDAs increased SVR over sofosbuvir/ribavirin.
• In treatment-naïve patients, ledipasvir/sofosbuvir and the 3D regimen/ribavirin increased SVR over sofosbuvir/ribavirin.
• Inclusion of ribavirin to the 3D regimen improved SVR rates with 12 weeks of treatment in treatment-naïve patients with genotype 1a.
• Simeprevir/sofosbuvir for 12 weeks increased SVR compared with 8 week in treatment-experienced Egyptians with HCV genotype 4, but the trial was small.
• Addition of ribavirin may or may not improve SVR or relapse rates, but often increases harms.
• Eight weeks may not be adequate treatment for some DAA regimens in certain populations. Overall, SVR 12 appears to correlate well with SVR 24.
• There are few trials of the newest DAAs.</td>
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Drug Class Reviews and Committee Recommendations		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?
➢ *Drug Class Review – Hepatitis C Agents*	*Richard Pope, PharmD Magellan Health Services*	**<u>Drug Class Review – Hepatitis C Agents</u>** Dr. Pope reported on three new products: Daklinza (declatasvir), Technivie (ombitasvir, paritaprevir, ritonavir), and Zepatier (grazoprevir/elbasvir). He reviewed indications, contradictions, dosage, warnings and drug interactions. He reported on the clinical trials done for approval of these drugs. There are no comparative data available for these medications. He reported that Olysio is now indicated for Genotype 4 in combination with Sovaldi and that Harvoni now indicated for treatment of genotypes 4, 5, and 6 and in patients co-infected with HIV. The Viekira Pak warning for use in Child-Pugh Class B patients has been updated to a contraindication for Class B. The American Association for the Study of Liver Diseases and Infectious Diseases Society of America (AASLD/IDSA) Hepatitis C Treatment Guidelines have been updated to reflect recent FDA approvals. Class I, Level A recommendations (the strongest) generally follow the use of the available products as described by their package insert.
➢ *Hepatitis C Therapeutic Criteria for Prior Authorization*	*Christopher Johnson, PharmD*	**<u>Hepatitis C Therapeutic Criteria for Prior Authorization</u>** Dr. Johnson reviewed the draft Idaho Medicaid Therapeutic criteria for this drug class. This draft is based on the most current evidence and will continue to be updated. The criteria were approved by the Committee. **Committee Recommendations** The Committee recommended that interferons be non-preferred. The Committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the DDA agents for their usage per indications and guidelines. The Committee reaffirmed the ability of the Department to make temporary coverage decisions between cycles for new agents that could provide advantages. These will be communicated to the Committee and validated and be approved or denied at the next scheduled meeting.

➢ *Angiotensin Modulators/ Angiotensin Modulator Combinations*	*Richard Pope, PharmD*	**Angiotensin Modulators** Dr. Pope discussed one new product, Entresto (sacubitral/valsartan) which is indicated for patients with chronic heart failure (NYHA Class II-IV). He reviewed the PARADIGM-AF study which showed Entresto superior in reducing the risk of cardiovascular death or hospitalization for CHF versus enalapril. He reviewed contraindications, dosage, warnings and drug interactions. Dr. Pope further reported that the FDA has completed its safety review on Benicar and found no clear evidence of a higher rate of cardiovascular risk in type 2 diabetics compared to placebo. **Angiotensin Modulator Combinations** Dr. Pope discussed one new product. Prestalia (perindopril/amlodipine). He reviewed indications, contradictions, dosage, warnings and drug interactions. There are no comparative clinical data available. **Committee Recommendations** The Committee recommended that Entresto be available within the guidelines of the study criteria and the indications. The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents in the ACE Inhibitors, ACE Inhibitor/Diuretic Combination, Angiotensin Receptor Blockers, Angiotensin Receptor Blocker/Diuretic Combination, Direct Renin Inhibitor, Direct Renin Inhibitor Combination or Neprilysin Inhibitor Combination drug classes.
➢ *Beta Blockers*	*Richard Pope, PharmD*	**Beta Blockers** There was no new clinically significant information in this class to discuss. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ *Calcium Channel Blockers*	*Richard Pope, PharmD*	**Calcium Channel Blockers** There was no new clinically significant information in this class to discuss. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.

➢ *Antihypertensives, Sympatholytic*	*Richard Pope, PharmD*	**Antihypertensives, Sympatholytic** There was no new clinically significant information in this class to discuss. It was noted that the majority of use for clonidine and guanfacine is not for the treatment of hypertension, but for ADHD. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ *PAH Agents, Oral and Inhaled*	*Richard Pope, PharmD*	**PAH Agents, Oral and Inhaled** Dr. Pope discussed one new product, Uptravi (selexipag). He reported on contradictions, dosage, warnings and drug interactions. There are no data available in pregnant women and no comparative clinical data available. He also reported that Letairis is now indicated in combination with Adcirca for the treatment of PAH. Previously it was only indicated as monotherapy. He also announced that PDE-5 inhibitors are now contraindicated for concomitant use with a guanylate cyclase stimulator such as Adempas due to potentiation of their hypotensive effects. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ *Vasodilators, Coronary*	*Richard Pope, PharmD*	**Vasodilators, Coronary** There was no new clinically significant information for drugs in this class. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. The committee recommended continuing to have at least on product available in each dosage form (sublingual spray, ointment, patch, oral capsule/tablet) as preferred
➢ *Lipotropics, Statins*	*Richard Pope, PharmD*	**Lipotropics, Statins** Dr. Pope provided the following product updates • Liptruzet has been discontinued by the manufacturer • Lescol XL is now available generically • Advicor and Simcor production was discontinued in 2015 • Crestor is now indicated for the treatment of heterozygous familial hypercholesterolemia in patient 8 to 17 years old. Previous recommendations only went down to 10 years old. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or

		safety between the agents. They recommended that a high potency of atorvastatin or Crestor be available as preferred. They recommended a review of the PA criteria for Vytorin to evaluate the need for failure of two preferred agents.
➢ *Lipotropics, Other*	*Richard Pope, PharmD*	**Lipotropics, Other** Dr. Pope discussed the PCSK9 Inhibitors which are new to this drug class. He discussed indications, warnings, dosing, drug interactions and adverse effects of the two new products, Praluent and Repatha. There is no comparative clinical data available. He reported that although they are very effective in lowering LDL, the PCSK9 inhibitor outcome trials are not scheduled to be completed before 2nd quarter 2016. Dr. Pope provided product guidelines including the removal of Niaspan and Trilipix indication for combined use with statins. Fenoglide is now available as a generic. He reviewed the American Heart Association scientific statement on familial hypercholesterolemia. He also reviewed the IMPROVE-IT study which despite results did not result in the FDA advisory committee recommending the use of Zetia/Vytorin for the reduction of risk of myocardial infarction and stroke in patients with acute coronary syndrome. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the non-PCSK9 Inhibitor agents. They recommended that guidelines and criteria for PCSK9 be according to label and include recommendations for no smoking, dietary management and prescribing by a cardiology or endocrinology specialist.
➢ *Bladder Relaxant Preparations*	*Richard Pope, PharmD*	**Bladder Relaxant Preparations** Dr. Pope announce that Actavis has discontinued the production of Gelnique and Enablex is now available generically. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.

➢ *BPH Treatments*	*Richard Pope, PharmD*	**BPH Treatments** Dr. Pope announced that Avodart and Jalyn are now available generically. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ *Growth Hormone Criteria*	*Jane Gennrich, Pharm.D.*	**Growth Hormone Criteria** Dr. Gennrich provided a review of Idaho Medicaid's current therapeutic criteria for growth hormone therapy, dated May 2015. The committee approved the criteria as is for the next year.
➢ *Growth Hormone*	*Richard Pope, PharmD*	**Growth Hormone** Dr. Pope announced that Genentech is discontinuing production of the Nutropin AQ line of products. The NuSpin products will remain on the market. He also announced that Tev-Tropin had a name change to Zomacton . **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ *Topical Androgenic Agents*	*Richard Pope, PharmD*	**Androgenic Agents** Dr. Pope reviewed one new product: Natesto (testosterone). This is the first nasal testosterone available on the market. He reviewed the indications, contraindications, warnings, adverse effects, and drug interactions of the product. No comparative data is available. He also reported that the American Association of Clinical Endocrinologists had issued a position statement noting that testosterone replacement therapy in men with cardiovascular risk factors can be beneficial, despite recent concerns to the contrary. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. They did not feel Natesto should be a preferred agent and that age-related criteria be incorporated for all agents.

➢ *Hypoglycemics, Metformins*	*Richard Pope, PharmD*	**Hypoglycemics, Metformins** Dr. Pope announced that Glumetza (metformin ER) is now available as a generic. The 2016 American Diabetes Association recommendations regarding this class of drugs for glycemic treatment approaches is largely unchanged from 2015. There is no comparative data available between the extended release and rapid release medications. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy or effectiveness between the different dosage forms of metformin. They did feel that the ER had a better safety profile in regards to diarrhea and that both IR and ER forms needed to be available on the preferred list.
➢ *Hypoglycemics, Incretin Mimetics/Enhancers*	*Richard Pope, PharmD*	**Hypoglycemics, Incretin Mimetics/Enhancers** Dr. Pope noted that the FDA had issued a warning for DPP-4 inhibitors regarding severe and disabling joint pain. This will be reflected in prescribing information for each drug. He announced that the FDA is requiring additional data before approving the Onglyza/Farxiga combination. He reviewed updates to the American Academy of Clinical Endocrinologists treatment guidelines which revised the management algorithm to recommend this class of drugs for initial treatment for HbA1c <7.5%. For HbA1c >7.5%, metformin remains the top option. There were no changes to the 2016 American Diabetes Association guidelines from the 2015 guidelines with respect to this drug class. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy or effectiveness between agents in this class. The committee recommended that at least one weekly incretin mimetic agent be preferred. It was also recommended that Victoza be considered for addition to the preferred drug list for this class of drugs.
➢ *Hypoglycemics, SGLT2*	*Richard Pope, PharmD*	**Hypoglycemics, SGLT2** Dr. Pope reported on one new product: Synjardy (empagliflozin/metformin). He reported on its indications for treatment, contradictions, dosage and warnings and clinical trials. He reported that nvokana labeling now contains a warning regarding the increased risk of bone fractures and decrease bone mineral density. He reported on the recently published EMPA-REG Outcome study that concluded that Type II patients taking Jardiance (empagliflozin) had a lower rate of the primary composite cardiovascular outcome and of death from any cause compared to placebo. He announced that the FDA has added ketoacidosis, urosepsis, and pyelonephritis to all SCLT2 inhibitor labels. He reviewed updates to the American Academy of Clinical Endocrinologists treatment guidelines which revised the management algorithm to recommend this class of drugs for initial treatment for HbA1c

		<7.5%. For HbA1c >7.5%, metformin remains the top option. The 2016 American Diabetes Association guidelines recommendations are largely unchanged from 2015. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy and effectiveness between the agents.
➢ *Hypoglycemics, TZD*	*Richard Pope, PharmD*	**Hypoglycemics, TZD** Dr. Pope reported that the FDA has removed REMS requirements for rosiglitazone-containing products. He also reported that the 2016 American Diabetes Association recommendations regarding the TZD class of drugs is largely unchanged from the 2015 guidelines. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness, or safety
➢ *Hypoglycemics, Insulin*	*Richard Pope, PharmD*	**Hypoglycemics, Insulin** Dr. Pope reported on one new product, Tresiba (insulin degludec). He reviewed dosing, contraindications, warnings and adverse effects. There is no comparative data available. The 2016 American Diabetes Association recommendations for insulins remain the same as the 2015 edition. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy and effectiveness between the agents. They felt there was some safety differences in use of the inhaled insulin and it should be non-preferred. They felt that Truejo and Tresiba should be second line to the other intermediate, long-acting agents.
➢ *Pancreatic Enzymes*	*Richard Pope, PharmD*	**Pancreatic Enzymes** Dr. Pope announced that the authorized generic for Zenpep 5,000 units has been discontinued. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. They did request that stable patients not be forced to switch agents.

➢ *Proton Pump Inhibitors*	*Richard Pope, PharmD*	**Proton Pump Inhibitors** Dr. Pope reported that the age for Prilosec suspension had been lowered to 1 month of age for erosive esophagitis. He reported on recently published population-based studies that had reported an increased incidence of chronic kidney disease in patients receiving long-term proton pump therapy. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ *H. Pylori Treatments*	*Richard Pope, PharmD*	**H. Pylori Treatments** There was no new clinically significant information in this class to discuss. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. They directed the Department to evaluate whether the combination products or individual agents were more cost effective in making their decisions.
➢ *Ulcerative Colitis*	*Richard Pope, PharmD*	**Ulcerative Colitis** Dr. Pope announce the oral agent Delzicol is now indicated for treatment of mild to moderately active ulcerative colitis for patients five years and older (previously only indicated for 12 years and older).. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ *Gastrointestinal (GI) Mobility Agents, Chronic*	*Richard Pope, PharmD*	**GI Mobility Agents, Chronic** Dr. Pope reported on one new product, Viberzi (eluxadoline). He discussed the indications, contraindications, warnings, drug interactions, dosing and adverse effects. He reviewed two placebo controlled trials for this agent. There is no comparative clinical study data available. He announced that Lotronex is now available generically. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents for their designated indications.

➢ *Bone Resorption Suppression and Related Agents*	*Richard Pope, PharmD*	**Bone Resorption Suppression and Related Agents** Dr. Pope reported Actonel (risendronate) is now available generically in all strengths and that Atelvia is also available generically. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents
➢ *Phosphate Binders*	*Richard Pope, PharmD*	**Phosphate Binders** Dr. Pope announced that Fosrenol is now available as a powder pack. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
Other Committee Business	*Phil Petersen, MD* *Tami Eide, PharmD*	**Other Committee Business** The next P&T Committee meeting is scheduled for May 20, 2016. Dr.Peterson asked that the CDC Narcotic guidelines be sent to the members and reviewed for the next meeting. There was no other committee business. The meeting adjourned at 3:10 p.m.

Pharmacy and Therapeutics Committee
Public Comment
April 15, 2016

Daniel Flynn, MD

Hi everyone, I'm Daniel Flynn, I'm a pediatric endocrinologist and physician. My practice site is St. Luke's downtown, with the Children's Endocrinology Clinic. We're speaking in reference to Novo Nordisk and their product, Norditropin. I'm not being compensated for speaking today. In the past, I have received speaker's fees for doing growth hormone-related talks. We're a primary prescriber of growth hormone-related products in the area, and there's a few things about somatropin in general, like it's better if you take it regularly, the benefits aren't just for height, it's good for cardiovascular outcome, it's good for skeletal health, and it's good for life span. We care more as endocrinologists about the bone health and the heart health than the height outcomes, and I think those things are why it's covered by Medicaid than the stature. It really does good to have full compliance with the medication. With Norditropin, the reason we like that as endocrinologists, is that it's more likely to be taken reliably. There are a few products that are associated with local site pain, but most people are able to get through with that, but it's the only one where you can continue to use the product if you leave it out of the refrigerator overnight, so we see, both myself and Dr. Taylor, the other endocrine doc in our clinic, see that there's better compliance with Norditropin and subsequently better, measurable outcomes in terms of effect. There's more of a predictable increase in height, which tells us that there are better things going on internally, such as skeletal density and protection of cardiovascular health. All the medications work the same. Somatropin is the actual recombinant growth hormone. It works whether it's coming from any of the, I think, seven different drug manufacturers, but one of the things that we like about Norditropin is that there is better compliance and less wasted products, and then it's the least painful out of all of the different preparations. I still think there should be multiple agents kind of in the go-to formulary, particularly because we have a lot of kids under two years old who are diagnosed and there's only, to my knowledge at this time, two approved products for treating kids less than two years old. My recommendation would be to have two different products approved, at least one of those being one of those two products that is shown to be safe and effective for children less than two. Norditropin is not one of those two products, but there are other options. That's where we're coming from as pediatric endocrinologists, in terms of efficacy, compliance, and overall effect. Thank you.

Committee

Any questions for our speaker?

Question
Yeah, Dr. Flynn, two questions. First is, so as the formulary stands now, are you currently opposed to it, and then second, are you currently opposed to [inaudible] not on that list?

Daniel Flynn, MD
I agree that, right now, it works pretty well. We have two endocrine nurses at our clinic who, most of their day is spent with working with prior authorizations and, in speaking with them, it does well. I think the criteria are appropriate. Most of the time, we do see significantly delayed skeletal maturation, but that's not a diagnostic criteria for the Pediatric Endocrine Society, so I wouldn't feel as though that needed to be a limitation imposed on the use of growth hormone. Plus, if you've ever looked at a bone age or read a report, there is a great deal of subjectivity associated with those, so it does kind of make it more difficult when that's a hurdle that has to be overcome for gaining use of product. But I think things are appropriate now and in line with the criteria for diagnosis.