Pharmacy and Therapeutics (P&T) Committee Meeting Record

Date: April 21, 2017

Time: 9:00 a.m. – 3:30 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; Andrei Rudyi, PharmD; Paul Driver, PharmD; Perry Brown, Jr., MD; Stephen Carlson, PharmD; Cali Bradberry, PA; Brian Crownover, MD; Ryan Heyborne, MD; Berk Fraser, RPh

Others Present: Sarah Martinez, PharmD, Magellan Health Services; Chris Johnson, PharmD, Division of Medicaid; Jane Gennrich, PharmD, Division of Medicaid; Clay Lord, Division of Medicaid; Keshia Schneider, Division of Medicaid; Mark England, PharmD, Magellan Medicaid Administration.

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. Dr. Ryan Heyborne, Interim Medical Director for Idaho Medicaid was introduced.
➢ *Reading of Mission and Confidentiality Statements*	*Phil Petersen, MD*	Dr. Petersen read the Mission and Confidentiality Statements.
➢ *Approval of Minutes from November 18, 2016 Meeting*	*Phil Petersen, MD*	The November 18, 2016 minutes were reviewed and approved.
Drug Utilization Update – Hepatitis C	*Chris Johnson, PharmD*	**Drug Utilization Update – Hepatitis C** Dr. Johnson provided a summary of the 2017 first calendar quarter drug utilization relative to Hepatitis C agents. In all, 44 requests were reviewed, 21 were approved, 17 were denied, and six requests are still awaiting review, pending additional information submission. Dr. Johnson also presented data on approvals and denials, with breakdowns across the following four categories: Drugs, Genotype, Liver Fibrosis Staging, and Cirrhosis presence or absence. Most denials were for not meeting fibrosis staging criteria.

Public Comment Period	*Phil Petersen, MD* *Keshia Schneider*	**Public Comment Period** No industry representatives were pre-approved to provide testimony; in addition, no medical care practitioners or members of the public attending the meeting requested an opportunity to provide testimony.
Drug Class Reviews and Committee Recommendations	*Sarah Martinez, 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?
➢ *Hepatitis C Agents*	*Sarah Martinez, PharmD*	**Hepatitis C Agents** There were no new oral agents in this class for this meeting, but two new agents are in the pipeline for the next scheduled review. Dr. Martinez reported the following product updates: • Boxed warning has been added to all direct-acting antivirals in this class due to the potential for reactivating the hepatitis B virus. • Technivie is now indicated for treatment of chronic hepatitis C genotype 4 with compensated cirrhosis; previously, this agent was approved only in genotype 4 patients without cirrhosis. • Sovaldi (in combination with ribavirin) is now indicated for the treatment of HCV genotypes 2 or 3 in children 12 years of age and older weighing 35 kg or greater without cirrhosis or with mild cirrhosis. • Harvoni is now indicated for the treatment of HCV genotypes 1, 4, 5 or 6 in children 12 years of age and older weighing 35 kg or greater without cirrhosis or with mild cirrhosis. **Committee Recommendations** The committee concluded that all of the agents were highly effective for their specifically indicated genotypes and that there was no comparative evidence for differences in safety between the agents. The committee recommended having more detailed information on the mechanism of Hepatitis B reactivation at a future meeting to review for integration into the current criteria. They recommended including specific monitoring recommendations and a laboratory test to determine HBV infection.

➢ *Anticoagulants*	*Sarah Martinez, PharmD*	**Anticoagulants** Dr. Martinez reported the following class updates: • The 2017 American College of Cardiology (ACC) provided recommendations for patients with Non-valvular atrial fibrillation (NVAF) regarding therapy interruption due to a procedure: o The decision to interrupt therapy should be based on the type of oral anticoagulant, bleeding risk and procedure bleeding risk. o Warfarin should not be interrupted in patients with low risk of bleeding. o Specific guidelines based on INR are provided if warfarin is interrupted. o For interruption of oral direct-acting agents, the number of doses to skip is based on creatinine clearance and bleeding risk during procedure. • Updates to the 2014 AHA/ACC guidelines for patients with valvular heart disease were as follows: o Anticoagulation with a vitamin K antagonist (VKA) is still indicated for patients with atrial fibrillation and rheumatic mitral stenosis. o VKA (INR target of 2.5) is reasonable after surgical bioprosthetic mitral or aortic valve replacement for 3-6 months after surgery and for 3 months after transcatheter aortic valve replacements in patients at low risk for bleeding. o A lower INR target (1.5 to 2) may be reasonable in some patients. **Committee Recommendations** The committee felt outcome data favored direct acting agents over warfarin in outcome and safety data, otherwise there was no comparative evidence for difference between agents.
➢ *Angiotensin Modulators*	*Sarah Martinez, PharmD*	**Angiotensin Modulators** • Dr. Martinez reported on a new product Qbrelis (lisinopril) oral solution which is indicated for the treatment of hypertension in patients six years and older, adjunct therapy for heart failure, and treatment of acute myocardial infarction. Contraindications, warnings, adverse effects, and drug interactions are similar to those for other lisinopril formulations. • She also reported that Epaned is now available as an oral solution and that Benicar and Benicar HCT are now available generically. • Dr. Martinez also reviewed updated 2013 American College of Cardiology / American Heart Association (ACC/AHA) guidelines which now include Entresto. These guidelines recommend that chronic symptomatic patients with reduced ejection fraction and New York Heart Association (NYHA) class II or III who tolerate ACE inhibitor or ARB be switched to Entresto to reduce morbidity and mortality.

		Committee Recommendations ACE Inhibitors and ACE Inhibitor /Diuretic Combinations: The committee concluded that there was no comparative evidence for efficacy, effectiveness or safety to recommend one agent over another. ARB and ARB /Diuretic Combinations: The committee concluded that there was no comparative evidence for efficacy, effectiveness or safety to recommend one agent over another. The Committee also recommended that ACE Inhibitor or ARB fixed dose combinations not be preferred over separate individual agents unless there was a cost advantage. Entresto: The committee recommended that Entresto be approved with prior authorization criteria to include cardiologist recommendation and meeting the characteristics defined in the approval studies. They recommended that it not be included on the ACE inhibitor PA form, but that a specific PA form be developed.
➢ *Angiotensin Modulator Combinations*	*Sarah Martinez, PharmD*	**Angiotensin Modulator Combinations** Dr. Martinez reported that there is one new product, Byvalson (nebivolol/valsartan). It is a once daily agent for hypertension whose contraindications, warnings, adverse effects and drug interaction are similar to those for the separate component drugs. She also reported that Azor and Tribenzor are now available generically and that Lotrel has been discontinued by the manufacturer as of February 2017. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ *Beta Blockers*	*Sarah Martinez, PharmD*	**Beta Blockers** There are no new agents in this class. **Product and Guideline Updates** Dr. Martinez reported that the American College of Cardiology (ACC) has published guidelines for syncope indicating that in the absence of any contraindications, beta blockers are recommended as first-line therapy for long QT syndrome (LQTS) and suspected arrhythmic syncope. Beta blockers that lack intrinsic sympathomimetic activity are recommended for catecholaminergic polymorphic ventricular tachycardia (CPTV). In

		addition, flecainide is a reasonable option for CPVT in patients who continue to experience syncope or ventricular arrhythmia. **Committee Recommendations** The Committee recommended that at least one extended release propranolol preparation be available as well as metoprolol succinate. If cost effective they felt it would be useful to have a carvedilol extended released preparation available.
➢ *Calcium Channel Blockers*	*Sarah Martinez, PharmD*	**Calcium Channel Blockers** Dr. Martinez reported that there were no significant product or clinical updates for agents 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 the pharmacy program review immediate release nifedipine use to validate it was not being used for long-term blood pressure control or in non-pregnant women.
➢ *Antihypertensives, Sympatholytic*	*Sarah Martinez, PharmD*	**Antihypertensives, Sympatholytic** Dr. Martinez reported that there were no significant product updates for agents in this class. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. They would like in the future to review the utilization of methyldopa as there are many other superior agents available for general blood pressure control.
➢ *Pulmonary Arterial Hypertension Agents, Oral and Inhaled*	*Sarah Martinez, PharmD*	**Pulmonary Arterial Hypertension Agents, Oral and Inhaled** There were no new agents in this class to report. **Product Updates** • Adempas is now contraindicated with concomitant use of phosphodiesterase (PDE-5) inhibitors or nitrates, and in patients with pulmonary arterial hypertension associated with idiopathic interstitial pneumonia. • For patients unable to swallow whole tablets, Adempas tablets may be crushed and mixed with water or soft foods immediately before administration. • Opsumit has a new warning for increased risk of fluid retention and related hospitalization, particularly in patients with left ventricular dysfunction.

		Committee Recommendations The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ *Vasodilators, Coronary*	*Sarah Martinez, PharmD*	**<u>Vasodilators, Coronary</u>** Dr. Martinez reported that there were no new significant clinical updates for agents in this class. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ *Lipotropics, Other*	*Sarah Martinez, PharmD*	**<u>Lipotropics, Other</u>** **Product Updates and Guideline Updates** Dr. Martinez reported that Zetia is now available generically. Dr. Martinez reported on the FOURIER (Further Cardiovascular Outcomes research with PCSK9 Inhibition in Subjects with Elevated Risk) study which evaluated the potential cardiovascular benefits of evolocumab. In the study, evolocumab when added to statin therapy, demonstrated a statistically significant reduction in the risk of cardiovascular events compared to placebo. The results were based on a primary endpoint which was a composite of cardiovascular death, myocardial infarction, stroke or hospitalization for unstable angina or coronary revascularization. There was no significant difference in cardiovascular death or all-cause mortality in the study. She also reviewed the EBBINGHAUS (Evaluating PCSK9 Binding antiBody Influence oN cognitive HeAlth in high cardiovascUlar risk Subjects) trial which evaluated cognitive effects of evolocumab when added to statin therapy in a subset of FOURIER enrolled patients. Evolocumab was non-inferior to placebo in measures of executive function, working memory, memory function, and psychomotor speed. Dr. Martinez reported that the American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE) guidance continues to recommend statins as primary therapy and recommends the addition of ezetimibe for additional LDL reduction. The guidelines have added an extreme risk for cardiovascular disease category for more aggressive LDL lowering goals.

		Committee Recommendations The committee concluded that the evidence did not support differences in efficacy or effectiveness between the agents except for PCSK9 inhibitors in indicated patient populations. They noted there was in general a lack of outcome documentation for many of the classes. They concluded that there were differences in safety between the classes of agents. The Committee recommended that the PCSK9 inhibitors be non-preferred. The Committee endorsed the current criteria for the PCSK9 inhibitors and suggested that a trial of pravastatin be suggested for patients experiencing myalgias from statins prior to starting a PCSK9 inhibitor.
➢ *Lipotropics, Statins*	*Sarah Martinez, PharmD*	**Lipotropics, Statins** Dr. Martinez reported that Crestor is now available generically, and is now indicated for the treatment of homozygous familial hypercholesterolemia in patients 7 to 17 years old (previously indicated only for adults). She also reported that the FDA has withdrawn approval for co-administration of niacin ER or fenofibric acid with a statin because decreases in triglycerides and increases in HDL do not result in cardiovascular event risk reductions. **Committee Recommendations** The committee concluded that there were no differences in efficacy or effectiveness of the agents when given in equipotent doses. They did feel that there were drug interaction related adverse reactions with simvastatin that made it a less safe alternative. Based on this the committee recommended making simvastatin a non-preferred agent for new patients. Stable, chronic patients should be grandfathered. There was a request to review the utilization of any pediatric patients less than the 8 years old or older cut-off established by the American Academy of Pediatrics.
➢ *Androgenic Agents*	*Sarah Martinez, PharmD*	**Androgenic Agents** Dr. Martinez reported that the FDA has issued a label change/warning for all testosterone products regarding abuse potential and serious outcomes. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. They made recommendations to the criteria for baseline and renewal CBC and liver function tests as well as testosterone to prevent overshooting the desired level.

➢ *Benign Prostatic Hyperplasia Treatments*	*Sarah Martinez, PharmD*	**Benign Prostatic Hyperplasia Treatments** Dr. Martinez reported that there were no clinically significant updates for this class. **Committee Recommendations** The Committee concluded that there was no comparative evidence for differences in efficacy or effectiveness between the agents. Safety-wise the committee felt that terazosin had a significantly higher incidence of postural hypotension and should be non-preferred. They recommended at least one 5-alpha-reductase inhibitor be preferred.
➢ *Bladder Relaxant Preparations*	*Sarah Martinez, PharmD*	**Bladder Relaxant Preparations** Dr. Martinez reported that Enablex is now available generically. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy or effectiveness, but that Myrbetric had a better side effect profile especially if a patient was receiving other drugs with anticholinergic effects.
➢ *Bone Resorption Suppression and Related Agents*	*Sarah Martinez, PharmD*	**Bone Resorption Suppression and Related Agents** Dr. Martinez reported that Miacalcin production has been discontinued by the manufacturer for business reasons and that the FDA has added risk of multiple vertebral fractures to warnings/precautions for Prolia/Xgeva. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. They did recommend that calcitonin be available for short-term pain relief for vertebral compression fractures.
➢ *Phosphate Binders*	*Sarah Martinez, PharmD*	**Phosphate Binders** Dr. Martinez reported that Renvela is now indicated in children six years and older with chronic kidney disease (previously indicated only for adults). **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
Review of Growth Hormone Guidelines	*Jane Gennrich, PharmD*	**Review of Growth Hormone Guidelines** Dr. Gennrich reviewed the 2016 Guidelines for Growth Hormone and Insulin-like Growth Factor-1 treatment in children and adolescents published by the U.S. Pediatric Endocrine Society. This is the first update on these guidelines for 13 years.

		Dr. Gennrich proposed the following changes to Idaho Medicaid's therapeutic criteria: • For the diagnosis of growth hormone deficiency, specify growth hormone stimulation testing if clinically appropriate per national guidelines • For initial approval, simplify requirements to be height less than the 3rd percentile of normal for age and sex and remove the current reference to standard deviation. • Replace phrasing "medical necessity documentation for growth" with growth failure secondary to various diagnoses such as growth hormone deficiency and Turner Syndrome. **Committee Recommendations** The Committee approved the Growth Hormone Guidelines with the proposed changes.
Drug Class Reviews and Committee Recommendations		
➢ *Growth Hormone*	*Sarah Martinez, PharmD*	**Growth Hormone** Dr. Martinez reported that there were no significant clinical updates for this class. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents as all are preparations of the same hormone.
➢ *GI Motility, Chronic*	*Sarah Martinez, PharmD*	**GI Motility, Chronic** Dr. Martinez reported that there is one new product in this class. Relistor is now available as an oral formulation. She reviewed its indications, administration and adverse effects. She also reported that Viberzi's label has been revised with final Schedule IV controlled substance status and that the FDA has issued a Drug Safety Communication warning of increased risk of pancreatitis with Viberzi use in patients without a gallbladder and that it should not be used in that population. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy or effectiveness between the agents for designated diagnosis indications and did not support differences in safety. The Committee recommended that at least one agent with an indication for inflammatory bowel disease with diarrhea be available as preferred.

➢ *Pancreatic Enzymes*	*Sarah Martinez, PharmD*	**Pancreatic Enzymes** Dr. Martinez 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. They recommended that established patients be grandfathered on their current medications if the preferred agents changed.
➢ *Proton Pump Inhibitors*	*Sarah Martinez, PharmD*	**Proton Pump Inhibitors** Dr. Martinez reported that Dexilant formulations are now indicated for use in patients 12 to 17 years old for the treatment of erosive esophagitis (capsules only), maintenance of healed erosive esophagitis and heartburn relief, and treatment of heartburn associated with symptomatic, non-erosive GERD (previously indicated only in adults). **Committee Recommendations** The Committee concluded that there were no clinically significant differences in efficacy, effectiveness or safety between the agents. The committee recommended that participants be required to fail a preferred suspension prior to being approved for Prevacid (lansoprazole) solutabs. w
➢ *H. Pylori Treatments*	*Sarah Martinez, PharmD*	**H. Pylori Treatments** Dr. Martinez reported that Pylera now has a black box warning for metronidazole carcinogenicity and a contraindication for use during pregnancy. Omeclamox-Pak and Prevpac now contain warnings for risk of developing cutaneous systemic lupus erythematosus (SLE) due to their PPI component. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. The Committee recommended the use of individual components if more cost effective.
➢ *Ulcerative Colitis Agents*	*Sarah Martinez, PharmD*	**Ulcerative Colitis Agents** Dr. Martinez reported that Asacol HD is now available generically. **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>** There was no other committee business. The meeting adjourned at 1:58 p.m. Next meeting will be on May 19, 2017.