New York State Medicaid
Pharmacy and Therapeutics Committee
Meeting Summary
June 16, 2011

Agenda and Introduction

The Medicaid Pharmacy & Therapeutics Committee met on Thursday, June 16, 2011 from 8:45 AM to 4:30 PM in Meeting Room 6, Concourse, Empire State Plaza, Albany, New York.

A. Background Materials Provided:

The Committee was provided copies of written materials submitted by interested parties in advance of the meeting.

B. Public Comment Period:

The following speakers provided public comment to the Committee:

1. McDonald, Eric, Director of Sales, Taro Pharmaceuticals, Hawthorne, NY
2. Cannito, Maria, PharmD, MS, Director, Medical Outcomes Specialists, Pfizer, Pittsford, NY
3. Szabo, Erika, MPH, Global Health Outcomes Liaison, Eli Lilly, Indianapolis, IN
4. Schwartz, Kenneth, MD, Saratoga Family Physicians, Saratoga Springs, NY
5. Eren, Devrim, PhD, Medical Science Liaison, Aptalis Pharma, Yardley, PA
6. Schroeder, Scott, MD, Section Head, Division of Pulmonary & Critical Care, AMC Pediatric Pulmonary Group, Albany Medical Center, Albany, NY
7. Hoffman, Sharon, Regional Clinical Executive, Abbott Laboratories, Abbott Park, IL
8. Gann, Kathryn L, PhD, Senior Medical Science Liaison, Amylin Pharmaceuticals, San Diego, CA
9. Servera, Soraly, MD, Medical Affairs, Novo Nordisk, Princeton, NJ
10. Fruiterman, Mark L, MD, The Endocrine Group, Albany, NY
11. Braden, Wesley, PhD, Medical Science Liaison, United Therapeutics, Durham, NC
12. Kowalski, Maribeth, PharmD, MBA, Medical Liaison, Purdue Pharma, Stamford, CT
13. Khan, Arsalan, Principal Liaison, Johnson and Johnson/Janssen, Piscataway, NJ
14. Strouss, Lisa, PharmD, Senior Area Medical Specialist, Sunovion Pharmaceuticals, Marlborough, MA
15. Owens, Mark, DO, Medical Director, The League Treatment Center, Brooklyn, NY
16. Roberts, Holly, MD, Director RMRS, Pfizer, NY, NY
17. Self, Rachel L, PhD, Neuroscience Medical Science Liaison, Bristol-Myers Squibb, Liverpool, NY
18. Dinh, Quinn, MD, Senior Director, Medical Affairs, Azur Pharma, Philadelphia, PA
19. Morris, Adrian, MD, Attending Psychiatrist, Glens Falls Hospital, Glens Falls, NY
20. Shapiro, Matthew, Development and Events Coordinator, National Alliance on Mental

Illness, Albany, NY

21. Rosenthal, Harvey, Executive Director of the New York Association of Psychiatric Rehabilitation Services, Albany**,** NY
22. Liebman, Glenn, CEO, Mental Health Association in NYS, Albany, NY
23. Amyot, Edmond, MD, NYS Psychiatric Association, Saratoga Hospital, Saratoga Springs, NY
24. Cheema, Sohail, MD, Westbury Therapeutic Medical Services, Westbury, NY
25. Baran, Daniel, MD, Region Medical Director, Merck, Upper Gwynedd, PA
26. Beeman, David R, PharmD, National Clinical Account manager, Astra Zeneca Pharmaceuticals, Roseville, CA
27. Caminis, John, MD, Vice President, Clinical Development, Warner Chilcott, Rockaway, NJ
28. Heslin, Eugene P, MD, Bridge Street Family Medicine, Saugerties, NY
29. Thomas, Susan, MD, Associate Director, National Medicine-Diabetes, Boehringer Ingelheim Pharmaceuticals, Ridgefield, CT
30. Dalsania, Amy, PharmD, Medical Science Liaison, Bristol-Myers Squibb, Plainsboro, NJ
31. Prior, Cheryl, PharmD, Medical Liaison-Managed Markets, Norvo Nordisk, Princeton, NJ
32. Lazala, Carmen, MD, Pediatric Endocrinology, Director of Briggs Family Pediatrics, Bronx, NY
33. Racicot, Diane, MBA, RD, National Account Manager, Strativa Pharmaceuticals, Division of Par, Woodcliff Lake, NJ
34. Weiner, Jonathan, Medical Science Liaison, Shire, Wayne, PA

C. Key issues raised by interested parties pertaining to the following therapeutic classes:

Public comments:

Short Acting Opioids

- The Committee was asked to consider information on tapentadol regarding indication, dual mechanism of action, dosing and administration and adverse reaction profile. The Committee was also asked to consider non-inferiority comparative studies with oxycodone IR in the reduction of pain relief and incidence of nausea and/or vomiting.

Topical Steroids

- The Committee was asked to consider information on desoximetasone, as a class structure C corticosteroid, which is regarded as hypoallergenic by the North American Contact Dermatitis Group.

Serotonin/Norepinephrine Reuptake Inhibitors (SNRIs)

- The Committee was asked to consider information regarding major depressive disorder (MDD) and the American Psychiatric Association recommendations for first line treatment. The Committee was also asked to consider the clinical efficacy, safety and pharmacokinetic profile of desvenlafaxine.
- The Committee was asked to consider information on duloxetine including indications, safety, adherence and persistence. The Committee was also asked to consider placebo controlled trials measuring pain reduction in patients with chronic musculoskeletal pain.

- The Committee was asked to consider information on milnacipran for the treatment of fibromyalgia.

Helicobacter pylori Agents

- The Committee was asked to consider information regarding the epidemiology of H. pylori and the primary causes of treatment failure. The Committee was also asked to consider the efficacy of bismuth, metronidazole, and tetracycline (a 3-in-1 capsule) that is taken with omeprazole and the eradication rates achieved with this quadruple therapy.

Pancreatic Enzymes

- The Committee was asked to consider information on exocrine pancreatic insufficiency (EPI). The Committee was also asked to consider clinical studies evaluating the safety and efficacy of pancrealipase in both children and adults with cystic fibrosis (CF).
- The Committee was asked to consider information on CF, the importance of nutrition in these patients and prevention of malnutrition as the primary goal. The Committee was also asked to consider the addition of enzyme supplements to help restore the delicate balance in the human body for patients suffering from CF, chronic pancreatitis and pancreatectomy. Additionally, information on clinical efficacy and safety were also presented.

Glucagon-like-Peptide-1 (GLP-1) Agents

- The Committee was asked to consider information on exenatide including its place in treatment algorithms for both the American Association of Clinical Endocrinologists (AACE) and the American Diabetes Association (ADA). The Committee was also asked to consider efficacy as well as data published in the Journal of Medical Economics comparing medical costs of patients taking insulin glargine versus exenatide.
- The Committee was asked to consider efficacy information on liraglutide including the LEAD-6 trial and its extension. The Committee was also asked to consider liraglutide with regards to indication and once a day dosing.

Phosphodiesterase type-5 inhibitors (for PAH)

- The Committee was asked to consider information on pulmonary arterial hypertension (PAH) including the 2008 World health Organization (WHO) guidelines and the 2009 American Heart Association (AHA)/American College of Cardiology (ACC) consensus document. The Committee was also asked to consider information on tadalafil including indication, dosing and administration, mechanism of action and dose dependent efficacy in clinical trials.

Long Acting Opioids

- The Committee was asked to consider information regarding transdermal buprenorphine including indication, dosing and administration and box warning.

Atypical Antipsychotics

- The Committee was asked to consider information on olanzapine including safety and cost effectiveness of olanzapine versus aripiprazole.
- The Committee was asked to consider information on lurasidone including indication, dosing and administration, efficacy and safety profile.
- The Committee was asked to consider information on paliperidone including indications, dosing and administration, adverse reactions and metabolism. The Committee was also

asked to consider information on head to head trials with quetiapine and olanzapine as well as meta analyses with other oral atypical antipsychotics.

- The Committee was asked to consider information on ziprasidone including indications, metabolic and tolerability profile. The Committee was also asked to consider information on head to head trials with olanzapine and risperidone as well as the CATIE trial.
- The Committee was asked to consider information on aripiprazole including a new indication and safety data in the pediatric population.
- The Committee was asked to consider information on clozapine orally disintegrating tablets (ODT) with regards to the formulation and availability of new strengths.
- The Committee was asked to consider information on asenapine including a new indication, efficacy data, sublingual formulation and safety and metabolic profile. A presenter indicated that generic products were inferior in the acutely psychotic or manic patient.
- The Committee was asked to consider open access for all atypical antipsychotics. The Committee was also asked to consider expanding and strengthening the PSYCKES program.
- The Committee was asked to consider information on quetiapine including studies done in children and adolescents evaluating safety, efficacy and tolerability.

Bisphosphonates – Oral

- The Committee was asked to consider the reduced risk of fractures with risedronate as well as dosing and administration for risedronate DR.

Dipeptidyl Peptidase-4 (DPP-4) Inhibitors

- The Committee was asked to consider information on sitagliptin and sitagliptin/metformin including indications, adverse reactions and comparative data with sulfonylureas as well as add on data with other oral antihyperglycemic agents. The Committee was also asked to consider diabetes as the underlying disease as well as comorbidity.
- The Committee was asked to consider information on linagliptin including indications, dosing and administration, efficacy (as well as a non inferiority trial between glimepiride and metformin), contraindications, warnings, adverse reactions and drug interactions.
- The Committee was asked to consider information on saxagliptin including indications, dosing and administration, clinical trial efficacy and safety.

Growth Hormones

- The Committee was asked to consider information on buffers and preservatives used in somatropin (Norditropin) as well as a new device for the product. The Committee was also asked to consider dosing accuracy, ease of use and adherence in relation to the new device.

Anti-Emetics

- The Committee was asked to consider information on ondansetron oral soluble film including indications, dosing and administration, and safety.

Sulfasalazine Derivatives

- The Committee was asked to consider information on mesalamine once-daily (Lialda) and delayed-release (Asacol HD) including indications, dosing and administration, efficacy, adverse reactions and safety. The Committee was also asked to consider differences in

drug delivery systems, extension trials, healing rates (ASCEND I and II) and recurrence of ulcerative colitis (S.I.M.P.L.E. study).

Pharmacy and Therapeutics Committee Comments:

- A Committee member commented that the treatment of choice for contact dermatitis is not topical corticosteroids.
- A Committee member asked the presenter if there were any head to head trials with venlafaxine ER.
- A Committee member asked a presenter if there were any studies with duloxetine versus a tricyclic antidepressant in the treatment of fibromyalgia.
- A Committee member asked a presenter what percent of their patients were on Medicaid. The presenter indicated approximately 10-15%.
- A Committee member commented on resistance rates with metronidazole and clarithromycin and also mentioned that adherence is a problem and may be exacerbated by having to obtain a proton pump inhibitor separately.
- A Committee member asked a presenter for an update on the risk of pancreatitis with exenatide. The presenter clarified the black box warnings.
- A Committee member asked a presenter for an update on the risk of pancreatitis with liraglutide. The presenter commented there were 8 cases in over 4,000 patients and that it is difficult to relate dosing or duration to the increased incidence of pancreatitis. If there is any risk of pancreatitis, the physician should reconsider GLP-1 therapy.
- A Committee member asked a presenter if they have seen any abuse of liraglutide in obese patients for weight reduction. The presenter answered that they have not seen it and added that a 3mg dose is being tested now for an obesity indication.
- A Committee member asked a presenter about protections against extraction and addiction potential with the buprenorphine patch. A Committee member also commented on QTc prolongation. A Committee member asked for clarification on why this product would not be a good candidate for step therapy. The presenter clarified only in opioid experienced patients the buprenorphine patch may not provide adequate analgesia.
- A Committee member commented on tapentadol and that the product is a CII and has abuse potential.
- A Committee member asked a presenter about head to head studies with paliperidone and other products in the class. The presenter clarified there was a six week trial with risperidone in 2010.
- A Committee member commented on a study measuring cost effectiveness of aripiprazole versus olanzapine and wanted to know if the increase in weight gain with olanzapine attributed to other health problems and actually increased health care costs. Another Committee member asked how they determined total cost effectiveness.
- A Committee member commented on QTc prolongation with lurasidone and how that was assessed in the studies.
- A Committee member asked a presenter if they had enough experience with lurasidone to really determine if it had a better side effect profile since it has only been on the market for a short time. The presenter commented that 10-15% of his patients are using lurasidone.
- A Committee member commented on aripiprazole's indication for use as adjunctive therapy to antidepressants and expressed concern that aripiprazole was being used concomitantly with an antidepressant before an inadequate response was seen. Another Committee member asked about metabolic implications versus other antipsychotics in the class. The presenter cited a Swedish study which showed a favorable metabolic profile.

- A Committee member asked a presenter to comment on open access for primary care physicians versus psychiatrists. The presenter commented that a psychiatrist has more experience and should have open access. A Committee member also asked how the presenter selected an antipsychotic for a naïve patient. The presenter commented that he uses his experience to tailor therapy to each patient. Another Committee member commented that more than half of the prescriptions in this class are written by primary care physicians according to the Office of Mental Health but it is difficult to discern whether a psychiatrist was consulted first. Another Committee member commented on the use of this class of drugs off-label.
- A Committee member asked a presenter to comment on whether NAMI has an official stance on open access for atypical antipsychotics for primary care physicians versus psychiatrists. A presenter commented that it is a challenge just to obtain treatment for these patients at all.
- A Committee member asked a presenter to comment on whether there should be open access for all medications. The presenter commented that he focuses on his community and if the patients are prescribed what they need they will cost less.
- A Committee member clarified that in Medicaid fee-for-service the provider still prevails which does not apply to managed care organizations.
- A Committee member asked a presenter to comment about other States with more stringent rules/criteria around mental health drugs and if there was evidence that there were better outcomes than in NY.
- A Committee member cautioned a presenter about their comments on generic products and stated that bioequivalence data on generic products is robust. A Department of Health (DOH) staff member commented that the Pharmacist can aide in educating patients on brand to generic recognition.
- A Committee member asked a presenter to clarify that quetiapine is not an antidepressant.
- A Committee member asked a presenter about follow up drug surveillance data regarding adverse reactions (swollen tongue and angioedema) with asenapine. The presenter commented that there were no post marketing reports and that the adverse reactions were probably due to the anesthetic properties of the drug.
- A Committee member commented that metformin does not cause renal deterioration.
- A Committee member asked a presenter if sitagliptin slows gastric emptying time. The presenter clarified that oral DPP-4 inhibitors do not.
- A Committee member asked a presenter if there was any comparative data with ondansetron oral soluble film and other products in the class. The presenter clarified that it has only been compared to ondansetron.

D. Clinical Presentation and Discussion

Candi Wines, MPH, University of North Carolina at Chapel Hill Evidence based Practice Center
Barbara Rogler, Pharm D, MS, Magellan Medicaid Administration
Robert Correia, Pharm D, New York State Department of Health, Office of Health Insurance Programs

Preferred Drug Program: Initial Review

1. Proposal to identify preferred drugs in the therapeutic class of Short Acting Opioids

Dr. Rogler provided background information on the class and gave an overview of the products including indications, mechanisms of action, contraindications, warnings, drug interactions, adverse reactions, dosage and administration. Dr. Rogler also presented information from January 2011, by the Food and Drug Administration (FDA), requiring drug manufacturers to limit the strength of acetaminophen in prescription drug products to 325mg.

Dr Correia concluded that this class of drugs can all be calculated for equianalgesic dosages, although some will reach a ceiling effect or upper limit before others.

A Committee member commented that tapentadol could be more addictive when used for longer periods of time.

2. Proposal to identify preferred drugs in the therapeutic class of Topical Anti-Fungals

   Drs. Correia and Rogler provided background information on the class and gave an overview of the products including indications, pharmacology, use in special populations, dosage and administration. They also presented information on the types of infections treated by this class of drug as well as an explanation of the different vehicles used to deliver the medications, noting advantages and disadvantages for each.

   Dr. Correia noted that this drug class was previously researched by the University of Buffalo and presented at the February 2010 DUR Board meeting. He reiterated the results of their literature review pertinent to effectiveness of agents for various indications. Dr. Correia noted tremendous overlap of indications for these products.

3. Proposal to identify preferred drugs in the therapeutic class of Topical Steroids

   Dr. Rogler provided background information on the class and gave an overview of the products including indications, pharmacology, contraindications and warnings, drug interactions, adverse effects, use in special populations and dosage and administration. Dr. Rogler also presented information on the grouping of categories in this class based on their potency (low, medium, high, very high) and that the concentration of drug and vehicle used may affect the level of potency.

   Dr. Correia concluded that the relevant issues are to assure there are products available in each of the potency classifications, and to provide as broad a selection of product types as possible within those potency classes.

4. Proposal to identify preferred drugs in the therapeutic class of SNRIs

   Dr. Rogler provided background information on the class and gave an overview of the products including indications, pharmacokinetics, contraindications and warnings, drug interactions, adverse effects, use in special populations and dosage and administration. Dr. Rogler also presented information fibromyalgia and diabetic peripheral neuropathic (DPN) pain and the drugs approved to treat those conditions.

   Dr. Correia commented that the Oregon Drug Effectiveness Review Project comparative effectiveness report for the second generation antidepressants and another report covering drugs in this class used for fibromyalgia was just released this year. Dr. Correia also reiterated the products indications and provided information from the 2011 American Academy of Neurology guidelines that recommended for painful diabetic neuropathy, Level A evidence indicates that pregabalin be offered first rather than an SNRI. He also commented that for fibromyalgia pain, an indirect meta-analysis indicated that duloxetine was better than

milnacipran in short-term trials of 8 to 15 weeks, but no difference existed between the drugs at 28 weeks. Dr. Correia concluded that overall, in evaluating the available evidence, including a systematic review by the U.S. Department of Health and Human Services' Agency for Healthcare Research and Quality, these drugs are very comparable in efficacy and effectiveness.

A Committee member inquired about classifications for antidepressants. They commented on tricyclic antidepressants and how they are still valuable for use in fibromyalgia. They also mentioned how SNRIs are used if there is a failure to a SSRI in clinical practice.

5. Proposal to identify preferred drugs in the therapeutic class of SSRIs

   Dr. Rogler provided background information on the class and gave an overview of the products including indications, pharmacology, pharmacokinetics, drug interactions, contraindications and warnings, adverse effects, use in special populations and dosage and administration. Dr. Rogler concluded that SSRIs are considered first-line treatment for their FDA approved indications and despite the differences in pharmacokinetic properties of each agent, the full response time for all of the SSRIs typically takes four to six weeks.

   Dr. Correia commented all the drugs inhibit neuronal serotonin reuptake and that various drugs within the class are also suggested to have a minor impact on reuptake of other neurotransmitters such as norepinephrine or dopamine, or agonist effects on serotinergic or cholinergic receptors, which is theorized to impact subtle differences in adverse effect profiles. Dr. Correia concluded for the indication shared by the drugs in this class, there is no evidence of overall superiority, and significant evidence of similarity in efficacy and effectiveness.

6. Proposal to identify preferred drugs in the therapeutic class of Helicobacter Pylori Agents

   Dr. Rogler provided background information on the class and gave an overview of the products including indications and dosage and administration. Dr. Rogler also presented information on H. pylori infection and treatment guidelines from the American College of Gastroenterology. She also provided results from a non-inferiority trial comparing a fixed dose combination capsule versus separate triple therapy for H. pylori eradication.

   Dr. Correia reiterated that both of the metronidazole, tetracycline and bismuth combination therapies require an additional H_2 antagonist or omeprazole to be obtained and taken as part of the regimen so these product packages are not 100% complete therapy. Dr. Correia concluded that additionally, there is concern with accelerating development of resistance to metronidazole with more widespread use.

7. Proposal to identify preferred drugs in the therapeutic class of Pancreatic Enzymes

   Dr. Rogler provided background information on the class and gave an overview of the products including indications and dosage and administration. Dr. Rogler explained how each enzyme type exerts its effect on the body as well as the significant effects a deficiency of a particular enzyme may cause.

   Dr. Correia concluded all of these products contain the same three enzymes, amylase, lipase, and protease, in comparable ranges of dosages and all the products in this class have labeling as well as recommendation guidelines for use in infants and children as well as adults.

8. Proposal to identify preferred drugs in the therapeutic class of Glucagon-like Peptide-1 (GLP-1) Agents

   Candi Wines presented the Drug Effectiveness Review Project (DERP) Drug Class Review for Newer Diabetes Medications and Combinations which included a review of the GLP-1 Agents.

   Dr. Rogler provided background information on the class and gave an overview of the products including indications, pharmacokinetics, contraindications and warnings, drug interactions, adverse reactions, use in special populations and dosage and administration. Dr. Rogler also reviewed the LEAD-6 trial which was a non inferiority trial that compared liraglutide and exenatide.

   Dr. Correia commented that GLP-1 agonists are generally not recommended as first-line monotherapy. He also stated that the 2009 guidelines from the American Diabetes Association and the European Association for the Study of Diabetes clinical consensus statement only identify metformin as step-1 therapy, and that the GLP-1 agonists are only step-2 therapy after metformin. Dr. Correia informed the Committee that the FDA sent out a notice that as a requirement of a risk evaluation and mitigation strategy (REMS) for liraglutide, a letter was being sent to healthcare professionals about a potential risk of thyroid C-cell tumors, including medullary thyroid carcinoma (MTC) as well as an increased risk of acute pancreatitis. The FDA labeling states that liraglutide is not indicated as first-line therapy for patients who have inadequate glycemic control on diet and exercise. Dr. Correia concluded that there is significant concern about development of pancreatitis for both liraglutide and exenatide, and labeling indicates to use with caution in patients with a history of pancreatitis.

9. Proposal to identify preferred drugs in the therapeutic class of Phosphodiesterase type-5 (PDE-5) Inhibitors (for PAH)

   Dr. Rogler described pulmonary arterial hypertension (PAH), its affects on the body, how it is diagnosed and the drugs that are used to treat the disease. Dr. Rogler and Dr. Correia provided background information on the class and gave an overview of the products including indications, pharmacokinetics, contraindications and warnings, drug interactions, adverse reactions, use in special populations and dosage and administration. Dr. Correia also stated that differences in dosing as well as metabolism and elimination could affect drug selection for specific patients.

   A Committee member commented on drug interactions with alpha blockers and some limitations associated with older treatments like calcium channel blockers.

Preferred Drug Program: Re-review

1. Proposal to identify preferred drugs in the therapeutic class of Long Acting Opioids

   Dr. Correia and Dr. Rogler discussed the new buprenorphine transdermal system. They focused on indication, pharmacokinetics, drug interactions and use in special populations for the product. Dr. Rogler provided updated information on new REMS plan for long acting opioids.

Dr. Correia stated that there is a new 6th update pending to the OHSU/DERP report on Long-Acting Opioids that he was able to review but concluded that there is no new comparative clinical evidence since the last re-review to indicate any of these drugs offers an overall advantage within the class.

A committee member questioned value of the buprenorphine transdermal system.

2. Proposal to identify preferred drugs in the therapeutic class of Atypical Antipsychotic

   Dr. Rogler discussed a new product in the class lurasidone including indication, pharmacology, pharmacokinetics, use in special populations, contraindications and dosing and administration. She also discussed several new product indications, safety revisions and a labeling update for all products in the class for use during pregnancy and the risk of abnormal muscle movement and withdrawal syndrome.

   Dr. Correia concluded that this is a class of drug where the consideration is balancing efficacy and risk of adverse outcomes between the drugs.

   A Committee member asked about original trials conducted for atypical antipsychotics. Dr. Rogler clarified that they were done in Europe with institutionalized patients. Another Committee member commented on the CATIE trials and questioned side effects with new versus older medications. Dr. Rogler commented that more tardive dyskinesia is seen with the older products but overall adverse effects are more prominent in higher doses across all antipsychotics.

3. Proposal to identify preferred drugs in the therapeutic class of Oral Bisphosphonates

   Dr. Correia and Dr. Rogler discussed a new product to the class, risedronate DR, since the previous review. They provided an updated safety alert for bisphosphonates regarding information previously communicated describing the risk of subtrochanteric and diapyseal femur fractures. Dr. Correia and Dr. Rogler also presented the 2010 American Association of Clinical Endocrinologists (AACE) Guidelines for prevention and treatment of postmenopausal osteoporosis that recommend alendronate and risedronate as first-line and ibandronate as a second-line agent.

4. Proposal to identify preferred drugs in the therapeutic class of Dipeptidyl Peptidase-4 (DPP-4) Inhibitors

   Candi Wines, MPH, UNC at Chapel Hill Evidence based Practice Center presented the Drug Effectiveness Review Project (DERP) Drug Class Review for Newer Diabetes Medications and Combinations which included a review of the DPP-4 Inhibitors.

   Dr. Correia and Dr. Rogler discussed two new products to the class, linagliptin and a combination product, saxagliptin/metformin ER. Dr. Rogler provided additional information on sitagliptin and sitagliptin/metformin with regards labeling additions about acute renal failure, increasing incidence of pancreatitis and other side effects. Dr. Rogler also presented a non-inferiority trial between sitagliptin and saxagliptin versus glipizide. Dr. Correia also discussed impact of difference in metabolism and elimination for the three drugs. Dr. Correia concluded there is little if any comparative information for effectiveness of the three current DPP-4 Inhibitors or the combination products, but indirect evidence seems to indicate that they are clinically comparable in efficacy.

A Committee member commented on proper titration in a trial presented. A Committee member also commented on DPP-4 agents compared to metformin.

5. Proposal to identify preferred drugs in the therapeutic class of Thiazolidinediones (TZDs)

   Candi Wines presented the Drug Effectiveness Review Project (DERP) Drug Class Review for Newer Diabetes Medications and Combinations which included a review of the Thiazolidinediones (TZDs).

   Drs. Correia and Rogler provided updates to the rosiglitazone and pioglitazone labeling. They presented an update on the REMS required for the rosiglitazone, that included a restricted access and distribution program in which clinicians and patients must enroll in to prescribe and receive the product. Additionally, Dr. Correia and Dr. Rogler provided a FDA safety communication from this week informing the public that use of pioglitazone for more than one year may be associated with an increased risk of bladder cancer.

   Dr. Correia concluded that there is still no comparative evidence which demonstrates any advantage of either of these products overall, in terms of efficacy or harms, although the evidence for increased risk of adverse effects for each of these drugs individually or as a class continues to accumulate.

   A Committee member commented on lipid abnormalities with the use of these products.

6. Proposal to identify preferred drugs in the therapeutic class of Growth Hormones

   Dr. Correia and Dr. Rogler presented new indications for somatropin (Omnitrope) and commented on new devices available for somatropin (Norditropin). They provided information on a FDA safety alert stemming from a study in France which stated there was a small increased risk of death when recombinant growth hormone was used to treat certain types of short stature including GH-deficiency, idiopathic, or gestational age. Dr. Correia concluded that the endocrine society has stated there are no observable differences in the results obtained from the different preparations as long as the appropriate regimen is followed and that there is no evidence that clinical outcome differs among the various injection systems.

7. Proposal to identify preferred drugs in the therapeutic class of Anti-Emetics

   Dr. Correia and Dr. Rogler indicated that there is a new drug in the class, ondansetron oral soluble film and provided additional safety revisions for ondansetron and dolasetron. Dr. Correia concluded that available dosage forms now include oral film, oral disintegrating tablets, oral liquid and transdermal patch and that ultimately all products are effective with none of these products demonstrating an overall advantage.

8. Proposal to identify preferred drugs in the therapeutic class of Proton Pump Inhibitors (PPIs)

   Dr. Correia and Dr. Rogler indicated there are two new generics in the class, omeprazole/bicarbonate Rx and lansoprazole ODT. They provided additional FDA safety information on PPIs including the possible increased risk of fractures of the hip, wrist and spine, safety announcement related to low serum magnesium levels due to long term use of PPIs and a reminder warning against concomitant use of clopidogrel and omeprazole.

9. Proposal to identify preferred drugs in the therapeutic class of Sulfasalazine Derivatives

   Dr. Correia and Dr. Rogler presented safety labeling revisions for mesalamine (Asacol/Asacol HD) during pregnancy. Dr. Correia summarized the difference between a prodrug and delayed release formulations as well as active and maintenance treatments for ulcerative colitis.

10. Proposal to identify preferred drugs in the therapeutic class of Intranasal Corticosteroids

    Dr. Correia and Dr. Rogler summarized differences in number of sprays/day, dosing frequency and usage among pediatric patients.

E. Executive Session:

The Committee recessed the public session at 1:00 PM to go into executive session for review of financial information relating to the Committee's recommendations of preferred drugs in the following classes: Glucagon-like Peptide-1 (GLP-1) Inhibitors, Dipeptidyl Peptidase (DPP-4) Inhibitors and Thiazolidinediones (TZDs). No official action was taken in the executive session. The executive session was recessed at 1:45 PM.

The Committee recessed the public session at 4:00 PM to go into executive session for review of financial information relating to the recommendation of preferred drugs in the following classes: Helicobacter Pylori Agents, Proton Pump Inhibitors (PPIs), Bisphosphonates-oral, Growth Hormones, Anti-emetics, Sulfasalazine Derivatives, Intranasal Corticosteroids, Atypical Antipsychotics, SSRIs, SNRIs, Short Acting Opioids, Long Acting Opioids, Topical Steroids, Topical Anti-Fungals, Pancreatic Enzymes and Phospodiesterase type-5 Inhibitors (PDE-5s). No official action was taken in the executive session. The executive session was recessed at 4:50 PM.

F. Recommendations of the P&T Committee submitted to the Commissioner of Health for final determination.

Based on the submitted or presented clinical information and on the financial information provided during the executive session, the Committee unanimously (unless otherwise noted) recommended the following:

Recommendations of Pharmacy and Therapeutics Committee	Commissioner's Final Determination
The standard clinical questions be used in the prior authorization review process for non-preferred drugs: Q: Has your patient experienced treatment failure with preferred drugs in the class? Q: Has your patient experienced an adverse drug reaction with preferred drugs in the class? Q: Is there a documented history of successful therapeutic control with a non-preferred drug and transition to a preferred drug is medically contraindicated?	Approved as Recommended

Short Acting Opioids Motion was made to alter the DOH recommendation**.** The Committee upheld the motion to alter the DOH recommendation as follows: **Preferred Drugs** codeine/APAP, codeine, hydrocodone/APAP, morphine IR, oxycodone/APAP, oxycodone/ibuprofen, tramadol **Non-preferred Drugs** butalbital compound w/codeine, butorphanol NS, Dazidox, Demerol, dihydrocodeine/APAP/caffeine, Dilaudid, Endocet, Endodan, Hycet, hydrocodone/ibuprofen, hydromorphone, Ibudone, levorphanol, Lorcet, Lorcet Plus, Lortab, Magnacet, Margesic H, Maxidone, meperidine, Norco, Nucynta, Opana, oxycodone, oxycodone/ASA, oxymorphone, OxyIR, Panlor SS, pentazocine/APAP, pentazocine/naloxone, Percocet, Percodan, Primalev, Primlev, Reprexain, Roxicet, Roxicodone, Rybix ODT, Synalgos DC, tramadol/APAP, Trezix, Tylenol #3, Tylenol #4, Tylox, Ultracet, Ultram, Vicodin/Vicodin ES/Vicodin HP, Vicoprofen, Xodol, Xolox, Zamicet, Zydone	Approved as Recommended
Topical Anti-Fungals **Preferred Drugs** clotrimazole OTC, miconazole OTC, nystatin cream/ointment, nystatin powder, nystatin/triamcinolone, terbinafine OTC, tolnaftate OTC **Non-preferred Drugs** clotrimazole Rx, clotrimazole/betamethasone, ciclopirox, econazole, Ertaczo, Exelderm, Extina, ketoconazole, Lamisil AT, Loprox, Lotrisone, Mentax, Naftin, Nyamyc, Nystop, Oxistat, Pedi-Dri, Tinactin, Vusion, Xolegel	Approved as Recommended
Topical Steroids **Preferred Drugs** <u>Very High Potency</u> halobetasol, clobetasol <u>High Potency</u> amcinonide, fluocinonide, fluocinonide emollient, fluocinonide E, triamcinolone acetonide <u>Medium Potency</u> fluocinolone, hydrocortisone valerate <u>Low Potency</u> hydrocortisone acetate OTC, hydrocortisone acetate Rx, hydrocortisone/aloe-vera **Non-preferred Drugs** <u>Very High Potency</u> Clobex, Cormax, Olux/Olux-E, Temovate/Temovate-E, Ultravate <u>High Potency</u> Apexicon/Apexicon E, Beta-Val, betamethasone valerate, betamethasone dipropionate, desoximetasone, diflorasone, Diprolene/Diprolene AF, Halog,	Approved as Recommended

Kenalog, Topicort/Topicort LP, Vanos <u>Medium Potency</u> Cloderm, Cordran, Cutivate, Dermatop, Elocon, fluticasone proprionate, hydrocortisone butyrate, Locoid Lipocream, Luxiq, mometasone furoate, Pandel, prednicarbate <u>Low Potency</u> alclometasone, Aclovate, desonide, Desonate, Derma-Smooth/FS, Texacort, Verdeso, Nucort	
SNRIs **Preferred Drugs** Cymbalta, Effexor XR, Savella, venlafaxine **Non-preferred Drugs** Effexor, Pristiq, venlafaxine ER capsules, venlafaxine ER tablets	Approved as Recommended
SSRIs **Preferred Drugs** citalopram, fluoxetine, fluvoxamine, paroxetine, Paxil suspension, sertraline **Non-preferred Drugs** Celexa, fluoxetine weekly, Lexapro, Luvox CR, paroxetine CR, Pexeva, Paxil, Paxil CR, Prozac, Sarafem, Selfemra, Zoloft	Approved as Recommended
Helicobacter Pylori Agents Motion was made to alter the DOH recommendation**.** The Committee upheld the motion to alter the DOH recommendation as follows (vote of 6 to 3): **Preferred Drugs** Helidac, Pylera, Prevpac **Non-preferred Drugs** None	Approved as Recommended
Pancreatic Enzymes **Preferred Drugs** Creon, pancrelipase **Non-preferred Drugs** Pancreaze, Zenpep	Approved as Recommended
Glucogon-like Peptide-1 (GLP-1) Agents **Preferred Drugs** Byetta **Non-preferred Drugs** Victoza	Approved as Recommended

Phosphodiesterase type-5 Inhibitors (for PAH) **Preferred Drugs** Adcirca, Revatio **Non-preferred Drugs** None	Approved as Recommended
Long Acting Opioids **Preferred Drugs** Duragesic, Kadian, morphine sulfate SR, Opana ER, Oramorph SR **Non-preferred Drugs** Avinza, Butrans, Embeda, Exaglo, fentanyl patch, MS Contin, oxycodone CR, Oxycontin, Ryzolt, tramadol ER, Ultram ER	Approved as Recommended
Atypical Antipsychotics **Preferred Drugs** clozapine, Fanapt, FazaClo, Geodon, risperidone, Saphris, Seroquel, Seroquel XR **Non-preferred Drugs** Abilify, Clozaril, Invega, Latuda, Risperdal, Zyprexa Non-preferred drugs will NOT require prior authorization until systems are in place which allows patients stabilized on these products to continue therapy without obtaining prior authorization.	Approved as Recommended
Bisphosphonates – Oral A motion was made to alter the DOH recommendation. The Committee recommended to uphold the DOH recommendation as follows (vote of 6 to 3): **Preferred Drugs** alendronate, Fosamax solution **Non-preferred Drugs** Actonel, Actonel with calcium, Atelvia, Boniva, Fosamax tablets, Fosamax plus D	Approved as Recommended
Dipeptidyl Peptidase-4 (DPP-4) Inhibitors **Preferred Drugs** Janumet, Januvia, Kombiglyze XR, Onglyza **Non-preferred Drugs** Tradjenta	Approved as Recommended
Thiazolidinediones (TZDs) The Committee recommended to uphold the DOH recommendation as follows (1 abstention): **Preferred Drugs** Actos, Actoplus Met, Duetact	Approved as Recommended

Non-preferred Drugs Actoplus Met XR, Avandia, Avandamet, Avandaryl	
Growth Hormones **Preferred Drugs** Genotropin, Nutropin, Nutropin AQ **Non-preferred Drugs** Humatrope, Norditropin, Omnitrope, Saizen, Tev-Tropin, Zorbtive Continue to use the one additional clinical prior authorization question for specific product indications: Are you using the non-preferred product for an FDA approved indication that is not listed for a preferred agent?	Approved as Recommended
Anti-Emetics **Preferred Drugs** ondansetron **Non-preferred Drugs** Anzemet, granisetron, Granisol, Kytril, Sancuso, Zofran, Zuplenz	Approved as Recommended
Proton pump Inhibitors **Preferred Drugs** Nexium, omeprazole OTC, omeprazole Rx, pantoprazole, Prilosec OTC **Non-preferred Drugs** Aciphex, Dexilant, lansoprazole Rx, Nexium Packet, omeprazole/sodium bicarbonate Rx, Prevacid OTC, Prevacid Rx, Prilosec Rx, Protonix	Approved as Recommended
Sulfasalazine Derivatives **Preferred Drugs** Apriso, Asacol, Dipentum, Pentasa, sulfasalazine IR, sulfasalazine DR/ER **Non-preferred Drugs** Asacol HD, Azulfidine, Azulfidine Entab, balsalazide, Colazal, Lialda	Approved as Recommended
Intranasal Corticosteroids **Preferred Drugs** Nasacort AQ **Non-preferred Drugs** Beconase AQ, Flonase, flunisolide, fluticasone, Nasonex, Omnaris, Rhinocort Aqua, Veramyst	Approved as Recommended

The meeting adjourned at 5:15 PM

Meeting Summary Posted 07/08/2011

G. Final Determinations

The Commissioner has determined that the Medicaid program will require prior authorization under the Preferred Drug Program (PDP) for non-preferred products in each of the drug classes as listed in Section F.

Preferred Drugs will not require prior authorization

The impact of this final determination is as follows:

1. State Public Health Population:
    - Minimal effect on Medicaid enrollees, as a large majority of enrollees currently utilize preferred products.
    - Non-preferred products remain available with prior authorization.
2. Program Providers:
    - No impact on prescribers or pharmacies when utilizing preferred products. Prescribers, or their agents, will need to initiate the prior authorization process when ordering non-preferred products. Pharmacies will need to complete the prior authorization process as required.
3. State Health Program:
    - Annual gross savings associated with these therapeutic classes under the PDP are estimated at $31M. The savings are achieved through changes in utilization to equally effective and less expensive products including the receipt of supplemental rebates from pharmaceutical manufacturers.

Final Determinations Posted 7/28/2011