

**New York State Medicaid
Pharmacy and Therapeutics Committee
Meeting Summary
April 19, 2012**

Agenda and Introduction

The Medicaid Pharmacy & Therapeutics Committee met on Thursday, April 19, 2012 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. Patel, Vik, PharmD, Managed Care Liaison II, Vertex Pharmaceuticals, Trumbull, CT
2. Goldman, Donna E, MD, Senior Medical Science Liaison, Medical Affairs, Genentech, A Member of the Roche Group, San Francisco, CA
3. Moorjani, Harish , MD, Clinical Asst. Professor of Medicine, NY Medical College, Briarcliff Manor, NY
4. Star, Vicki, MD, Merck Senior Medical Director, Merck, West Point, PA
5. Dugandic, Maria, PharmD, Associate Director Healthcare, Quality, & Outcomes, Boehringer Ingelheim, Ridgefield, CT
6. Mintz, Guy L, MD, FACP, FACC, Medical Director, NY Preventative Cardiology Institute, Great Neck, NY
7. Khan, Arsalan, PharmD, MBA, Principal Liaison in Health Economics & Outcomes Research, Janssen Scientific Affairs, Piscataway, NJ
8. Wexelman, Warren, MD, Private Practice, Brooklyn, NY
9. Dadourian, Daniel, MD, FACC, Medical Director of Medical Affairs Strategic Development, AstraZeneca Pharmaceuticals, Wilmington, DE
10. Wunej, Jawad, PharmD, Consultant Outcomes Liaison. Eli Lilly & Company, Indianapolis, IN
11. Berman, Gail, MD, Senior Medical Director, Novartis Pharmaceuticals, East Hanover, NJ
12. Self, Rachel, PhD, Neuroscience Medical Science Liaison, Bristol-Myers Squibb, Plainsboro, NJ
13. Pratts, Michael, MD, Attending Psychiatrist, St. Joseph's Hospital, Syracuse, NY
14. Crandall, David, PhD, Sr. Area Medical Specialist - NY, Sunovion, Marlborough, MA
15. Renna, John, PharmD, Medical Science Liaison, Shire Pharmaceutical, Wayne, PA
16. Iacobellis, Don, PharmD, Global Health Outcomes Liaison, Eli Lilly & Company, Indianapolis, IN
17. Blau, Alan, PhD, Forest Research, NY, NY
18. Malberg, Jessica, PhD, Forest Research, NY, NY
19. Williams, James, MD, Senior Medical Director, Respiratory, Novartis Pharmaceuticals, East Hanover, NJ

20. Coleman, Amber, PharmD, BCPS, Health Outcomes Liaison, GlaxoSmithKline, Columbia, MD
21. Kanczweski, Gerard, RPh, MS, Regency Therapeutics Division of Luitpold Pharmaceuticals, Shirley, NY

C. Key issues raised by interested parties during the public comment period:

Hepatitis C Agents

The Committee was asked to consider:

- Information on telaprevir regarding indication, mechanism of action, dosing and administration, adverse effect profile, contraindications and warnings. A summary of telaprevir use in combination therapy was also given noting efficacy and sustained virologic response (SVR).
- Updated information on Pegasys and ribavirin included in the prescribing information and American Association of Liver Diseases (AASLD) guidelines.
- Information on the new protease inhibitors boceprevir and telaprevir, used for treating Hepatitis C, which were FDA approved in May 2011. The speaker provided their experience with using these drugs and an increase in cure rates observed.
- Information on boceprevir regarding indication, mechanism of action, dosing and administration, adverse effect profile, and clinical trials regarding its use.
- Information on PegIntron regarding indication, response rates, and weight-based dosing.

Anticoagulants

The Committee was asked to consider:

- Information on dabigatran regarding indications, dosing and administration, precautions, and adverse effect profile as well as clinical efficacy and safety primary endpoints observed in the RE-LY trial.
- Information on the side effect profile of rivaroxaban and convenience of rivaroxaban in relation to warfarin. The Rocket-AF trial was noted as it pertained to rivaroxaban safety and efficacy in the atrial fibrillation population.
- Information on rivaroxaban regarding indication, mechanism of action, precautions, REMS program, and pivotal clinical studies including the Rocket-AF trial.

Antiplatelets

The Committee was asked to consider:

- Information on ticagrelor for its use in acute coronary syndrome (ACS) populations. The speaker provided experiences with the drug for this diagnosis noting that additional pharmacy budget spend should not be a factor considering reduced events and event related costs.
- Information on ticagrelor regarding indications, adverse effects and boxed warnings. The PLATO trial was presented which compared ticagrelor to clopidogrel. It was noted that ticagrelor had a 16% relative risk reduction in the primary endpoint of cardiovascular vascular (CV) death, myocardial infarction (MI) or stroke compared to clopidogrel.
- Information on prasugrel regarding indications, dosage and administration, mechanism of action, efficacy, precautions, safety information, and adverse effect profile.

HMG-CoA Reductase Inhibitors (Statins):

The Committee was asked to consider:

- Information regarding pitavastatin including indication, dosage and administration, mechanism of action, efficacy, safety, precautions, and adverse effect profile.

Direct Renin Inhibitors

The Committee was asked to consider;

- Information on aliskiren regarding new clinical information from the ALTITUDE trial. Safety information was also presented from a Dear Healthcare Professional letter in reference to information observed in the ALTITUDE trial.

Second Generation Antipsychotics

The Committee was asked to consider:

- Information on aripiprazole regarding indications, pharmacoeconomics, and safety data.
- Information on asenapine regarding indications and dosage, administration and safety. The drug's metabolic profile was also mentioned.
- Increasing the access to these medications in the pediatric population and to consider increasing the amount of preferred medications in this therapeutic class.
- Information on lurasidone regarding new clinical data which was recently published.

Central Nervous System Stimulants

The Committee was asked to consider:

- Information on lisdexamfetamine regarding FDA approval for maintenance therapy in adults with attention deficit hyperactivity disorder (ADHD) and additional labeling update which included boxed warnings, maintenance/extended treatment, contraindications, and post marketing experience.

Serotonin-Norepinephrine Reuptake Inhibitors (SNRIs)

The Committee was asked to consider:

- Information on duloxetine regarding indications, dosage and administration, safety, and adverse effect profile. The Committee was also asked to consider efficacy data for the new indication of chronic low back pain (CLBP).

Selective Serotonin Reuptake Inhibitors (SSRIs)

The Committee was asked to consider;

- Information on vilazodone including indication, mechanism of action, efficacy, precautions, dosing and administration, and adverse effect profile.

Inhaled Anticholinergics

The Committee was asked to consider;

- Information on roflumilast regarding indication, mechanism of action, efficacy, precautions, dosing and administration, and adverse effect profile.

Long Acting Beta-Agonists (LABAs):

The Committee was asked to consider;

- Information on indacaterol regarding indications, dosage and administration including device, efficacy, safety, and adverse effect profile.

Inhaled Corticosteroid/LABA Combinations

The Committee was asked to consider:

- Information on fluticasone/salmeterol regarding recently published comparative studies on clinical efficacy with inhaled corticosteroids (ICS), including higher

doses of ICS and other combination products. The speaker informed the Committee of abstracts of published clinical, health outcome and pharmacoeconomic studies since the class was last reviewed and highlighted that one of the studies was in a Medicaid population.

- Information regarding mometasone/formoterol including indication, dosage and administration, safety, and adverse effect profile.

Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

The Committee was asked to consider:

- Information on ketorolac nasal spray regarding its clinical and economic benefits in comparison to opioids. The speaker provided additional information on ketorolac nasal spray such as limitations of use and safety.

D. Pharmacy and Therapeutics Committee Comments during public comment period:

- A Committee member commented on concerns about dabigatran due to the fact that there is no antidote to reverse bleeding potential. They also noted personally observing two cases of fatal bleeding with patients on dabigatran therapy and safety concerns with use in the elderly and renally impaired.
- A Committee member asked a speaker to clarify that the rivaroxaban product had no side effects and to explain the interaction between rivaroxaban and prednisone. Speaker clarified the statements.
- A Committee member asked the speaker to comment on the pharmacokinetics and reversibility of rivaroxaban.
- A Committee member asked what degree of renal insufficiency would affect the clearance of rivaroxaban.
- A Committee member reiterated the irreversibility of rivaroxaban and asked the speaker to clarify the half-life of the product as well as the effect renal insufficiency has on the medication.
- A Committee member stated that a speaker for ticagrelor presented a commercialized testimony with no factual evidence supporting his case. The speaker responded by mentioning the PLATO trial and how ticagrelor plus aspirin was shown superior to clopidogrel plus aspirin.
- A Committee member asked if there was an interaction between ticagrelor and PPIs. Speaker stated ticagrelor has no interactions with PPIs unlike clopidogrel.
- A Committee member asked a speaker how prasugrel had no interactions even though it is heavily metabolized by liver enzymes. Speaker clarified the statement regarding the potential for prasugrel interactions.
- A Committee member asked why pitavastatin was not compared to a more potent statin than pravastatin. Speaker stated that it was compared to atorvastatin and simvastatin in non-inferiority trials.
- A Committee member asked about references for pharmacoeconomic data provided on aripiprazole.
- A Committee member asked speaker what percentage of his patients were on Medicaid. The speaker responded that 80% were.
- A Committee member asked speaker if vilazodone was a congener of nefazodone. The Speaker responded no.
- A Committee member asked the speaker to clarify if patients in the roflumilast trial were allowed to be on tiotropium concurrently.
- A Committee member asked why fluticasone/salmeterol came in two devices utilizing different techniques with multiple strengths. They also commented that this was confusing

and could affect adherence and outcomes. Speaker stated this allowed for more options for patients.

E. Clinical Presentation and Discussion

Eileen Zimmer, Pharm D, MBA, Magellan Medicaid Administration

Robert Correia, Pharm D, New York State Department of Health, Office of Health Insurance Programs

Preferred Drug Program: Initial Review

1. Hepatitis C Agents – Oral

Dr. Zimmer provided background information on Hepatitis C and gave an overview of oral protease inhibitors and ribavirins. She provided indications, mechanisms of action, contraindications, warnings, drug interactions, adverse effects, dosage and administration for all the products being reviewed. Dr Zimmer also provided a summary of the clinical trials SPRINT-2, ADVANCE, and REALIZE and provided an update of practice guidelines in the treatment of Genotype 1 HCV infection.

Dr Correia commented that there is a lack of comparative evidence between the ribavirins to suggest that any of the products are clinically superior. He also noted that the two protease inhibitors offer alternatives in adverse effects, as well as therapeutic regimens, including length of therapy, interim testing, etc. He concluded that the updated 2011 guidelines from the AASLD do not indicate a preference between the protease inhibitors in their recommendations for optimum genotype-1 triple therapy along with ribavirin and pegylated interferon alfa.

2. Anticoagulants – Oral

Dr. Zimmer provided background information on the class and gave an overview of the products including indications, pharmacology, and use in special populations, dosage and administration. Dr. Zimmer also presented an overview of thrombosis as well as the clinical trials RE-LY and ROCKET. Dr. Zimmer concluded with a brief update of the Antithrombic Therapy and Prevention of Thrombosis guidelines from the American College of Chest physicians (ACCP).

Dr. Correia noted that this drug class is in a tremendous state of progress with new pharmacological alternatives. He commented that there are now three major mechanisms of action available, vitamin K antagonism, direct thrombin inhibition, and factor Xa inhibition. Dr. Correia stated that the new anticoagulants offer the advantage of not requiring monitoring of anticoagulation effect, while at the same time having the disadvantage of having no antidote. Dr. Correia concluded by commenting on the new ACCP guidelines which were released in February 2012. The new 9th edition focuses on evidence-based recommendations, and includes assessment of the quality or strength of that evidence as well. It is specifically noted that there is inadequate evidence in most cases for the newer agents. When included in recommendations along with or instead of alternatives such as warfarin, they are usually accompanied by qualifying statements, and the recommendations are lower strength.

Preferred Drug Program: Re-review

1. Hepatitis C Agents – Injectable

Dr. Zimmer briefly discussed information regarding the Hepatitis C injectable agents which were previously reviewed in September of 2009. Dr. Zimmer then presented new clinical information related to the Pegylated Interferons regarding new indications, formulations, label revisions, and the release of the products from the REMS program.

Dr. Correia provided context for the addition of the new/expanded indications. This included the new labeling in terms of their pediatric indications as well as additional labeling identifying both products as appropriate in Chronic Hepatitis C including various severities of renal failure. Dr. Correia discussed the updated guidelines from the AASLD and mentioned that there is no differentiation between the two pegylated interferon alphas as part of optimum genotype-1 triple therapy along with ribavirin and a hepatitis C protease inhibitor.

2. Platelet Inhibitors

Dr. Zimmer discussed a new product in the class Brilinta (ticagrelor) including indication, pharmacology, pharmacokinetics, use in special populations, contraindications and dosing and administration. She also discussed new clinical information regarding Effient (prasugrel) and Plavix (clopidogrel). Dr. Zimmer also presented information from the PLATO trial and recommendations from the ACCP regarding antithrombotic therapy.

Dr. Correia highlighted the three primary mechanisms of the various platelet inhibitors. He also addressed the new ACCP anticoagulation guidelines and mentioned how evidence for clopidogrel or clopidogrel plus aspirin remains strong. Recommendations for the newer agents are low-level as evidence is weak, with specific mention of lack of evidence for long-term effectiveness and safety. Dr. Correia commented that each medication in this class has its advantages and disadvantages and that the entire body of clinical evidence for this class demonstrates the risk versus benefit balance between effectiveness of platelet inhibition and the risk for adverse events primarily due to an increased risk of bleeding.

3. HMG-CoA Reductase Inhibitors (Statins)

Dr. Zimmer discussed new clinical information regarding updated practice guidelines from the National Heart, Lung and Blood Institute (NHLBI) as well as safety concerns regarding high-dose simvastatin. Label revisions regarding ezetimibe, simvastatin, lovastatin and pitavastatin were also discussed. Dr. Zimmer presented clinical trial updates of the SATURN and LUNAR studies as well as information about new generics available in the class, atorvastatin and atorvastatin/amlodipine.

Dr. Correia elaborated on the label changes relevant to the entire drug class. In particular, he mentioned the increase in blood sugar and hemoglobin A1C which the FDA mandated to be included on all statin labels except for pravastatin. He noted the reason they have provided for this exception was based on the results of the West of Scotland Coronary Prevention Study (WOSCOPS) which reported a 30% decrease in the incidence of diabetes in pravastatin-exposed patients vs. unexposed patients.

4. Triglyceride Lowering Agents

Dr. Zimmer presented information regarding triglyceride lowering agents which included FDA safety communication and release of REMS requirement for Trilipix. Dr. Zimmer discussed of how Trilipix may not lower a patient's risk of having a heart attack or stroke after results were completed from the ACCORD trial.

Dr. Correia stated that clinical trials indicate that the omega-3 fatty acid product is significantly less effective at lowering triglyceride levels than fibrates, and also does not have the capacity to elevate HDL levels. He further noted both types of fibric acid derivatives, the fibrates and gemfibrozil, have comparable effects in lowering triglycerides and raising HDL. Dr. Correia concluded with additional information in regards to the new FDA safety information and spoke of how all the fenofibrates and fenofibric acids were not shown to reduce coronary heart disease morbidity and mortality in patients with Type 2 Diabetes. He noted only gemfibrozil has evidence of actual clinical outcomes, including cardiovascular and all-cause mortality, and is FDA-approved for reducing coronary heart disease risk.

5. Direct Renin Inhibitors

Dr. Zimmer provided information on the revised indication language and boxed warning of fetal toxicity as a class effect of Direct Renin Inhibitors. Warning/precautions of the class were also discussed as well as drug interactions with NSAIDs (including Cox-2 inhibitors), statins, and amlodipine. Dr. Zimmer also presented information on the termination of the ALTITUDE study including manufacturer recommendations and next steps.

Dr. Correia concluded there is still only one direct renin inhibitor in this class, aliskiren, available either alone or in combination products.

6. Second Generation Antipsychotics

Dr. Zimmer presented information on Symbyax (olanzapine/fluoxetine) including its indication, pharmacology, pharmacokinetics, use in special populations, contraindications and dosing and administration. Symbyax clinical trial information was also presented. FDA safety information was also presented for Fanapt (iloperidone), clozapine, Saphris (asenapine), and Risperdal (risperidone). Dr. Zimmer concluded by stating that Zyprexa/Zyprexa Zydis (olanzapine) were removed from REMS requirements.

Dr. Correia concluded that this is a class where a significant part of the clinical consideration is balancing efficacy and risk of adverse outcomes between the drugs. He noted all of the drugs in this class are approved for treatment of schizophrenia, most are also approved for treatment of bipolar disorder and some additionally for different specific features or episodes of the disease as well as additional indications or evidence to support use as adjunctive therapy in depressive disorders, autistic disorders, or pediatrics. Dr. Correia also spoke to the major side effects which are most significant in drug selection including weight gain, risk of diabetes, cardiac conduction abnormalities, extrapyramidal symptoms and tardive dyskinesia.

7. Central Nervous System (CNS) Stimulants

Dr. Zimmer presented clinical information regarding new generics methylphenidate ER tablets/capsules, new formulations of Focalin XR (dexmethylphenidate), a new indication of ADHD in adults for Vyvanse (lisdexamfetamine) and a REMS update. Dr. Zimmer also spoke of the cardiovascular risk associated with ADHD medications, label revisions as well as updated practice guidelines from the American Academy of Pediatrics (AAP).

Dr Correia noted the AAP/ADHD guidelines primarily address general use of the overall class of drugs. Dr. Correia concluded that there is a lack of evidence to demonstrate an overall advantage for any drug with shared indications in the class, and it would be preferable to have drugs in the short, intermediate, and long acting ranges represented among the preferred drugs.

8. Serotonin/Norepinephrine Reuptake Inhibitors (SNRIs)

Dr. Zimmer provided FDA safety communications regarding duloxetine and the possibility of severe skin reactions such as Stevens-Johnson Syndrome. Dr. Zimmer also spoke of the interaction between linezolid/methylene blue and SNRIs which may lead to Serotonin Syndrome.

Dr. Correia briefly mentioned that overall, the available evidence, including systematic review by the U.S. Department of Health and Human Services' Agency for Healthcare Research and Quality, is that these drugs are very comparable in efficacy and effectiveness.

9. Selective Serotonin Reuptake Inhibitors (SSRIs)

Dr. Zimmer presented an overview on the new medication Viibryd (vilazodone) including its indication, pharmacology, pharmacokinetics, use in special populations, contraindications and dosing and administration. Clinical trial information was also presented on vilazodone as well as its release from REMS requirements. New clinical information on FDA safety communications was presented regarding citalopram in regards to QT prolongation. The SSRI/linezolid class interaction was presented in regards to the risk of Serotonin Syndrome and the risk of persistent pulmonary hypertension of the newborn (PPHN) with SSRI's.

Dr. Correia commented on the new drug vilazodone which is lacking comparative evidence versus other drugs within the class. Dr. Correia commented on the products mechanism of actions clarifying that all the drugs inhibit neuronal serotonin reuptake and 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 serotonergic or cholinergic receptors, which is theorized to impact subtle differences in adverse effect profiles. Dr. Correia concluded that 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.

10. Inhaled Anticholinergics/COPD Agents

Dr. Zimmer presented information associated with the new medication Daliresp (roflumilast) including its indication, pharmacology, pharmacokinetics, use in special populations, contraindications and dosing and administration. Dr. Zimmer also provided updated practice guidelines from the ACP regarding diagnosis and management of COPD as well as the guidelines from the Global Initiative for Chronic Obstructive Lung Disease (GOLD).

Dr. Correia commented on the new medication roflumilast which has weak evidence for long-term benefits or adverse effects. He summarized the guidelines to include specific points noting that long-acting formulations are preferred over short-acting formulations and that the oral drug roflumilast came out too recently to be included in the 2011 ACP guidelines. Dr. Correia concluded the new global GOLD guidelines do include roflumilast, and indicate that inhaled bronchodilators are preferred over oral bronchodilators and there is only Level B

evidence to support use for patients with more severe COPD and experiencing exacerbations which is consistent with FDA labeling as well.

11. Inhaled Beta-2 Adrenergic Agents – Long Acting

Dr. Zimmer presented an overview on the new medication Arcapta (indacaterol) Neohaler including indication, pharmacology, pharmacokinetics, use in special populations, contraindications and dosing and administration. She noted that the FDA is requiring the LABA manufacturers to conduct clinical trials to further evaluate the safety of LABA's when used alone, or when used in combination with an ICS in comparison to ICS alone, with results due to the FDA in 2017. Updated practice guidelines were also provided.

Dr. Correia commented that there is a new long-acting beta-2 agonist indacaterol, available via hand-held inhaler, approved only for COPD. He concluded that no new comparative information has been found to indicate any of these products demonstrates overall clinical advantage in terms of either efficacy or safety.

12. Inhaled Beta-2 Adrenergic Agents – Short Acting

Dr. Zimmer discussed updated practice guidelines.

Dr. Correia commented that the new information pertains to the guidelines and doesn't change the comparative review of the drugs in this class.

13. Inhaled Corticosteroids/Long Acting Beta-2 Adrenergic Agents

Dr. Zimmer discussed updated practice guidelines and the request of new safety information by the FDA regarding the use of LABAs with ICS for the treatment of asthma. The label revision of Dulera (mometasone/formoterol) was also presented regarding the risk of anaphylactic reactions.

Dr. Correia commented that the new guidelines don't differentiate between these combination products and that there is no new evidence since the last review to justify giving any medication in this class preferential availability.

14. Leukotriene Modifiers

Dr. Zimmer discussed the label revision of the medication Accolate (zafirlukast) including a precaution associated with this medication because of patients presenting with systemic eosinophilia or eosinophilic pneumonia and a contraindication with this medication for patients with hepatic impairment. Dr. Zimmer also discussed the label revision for Singulair (montelukast) noting it is now approved for patients 6 years of age and older and provided EIB dosing.

Dr. Correia concurred with Dr. Zimmer and commented that no new comparative evidence was found within this class.

15. Proton Pump Inhibitors (PPIs)

Dr. Zimmer discussed new safety information with regards to this class of medications being associated with clostridium difficile-associated diarrhea. Updated practice guidelines were also discussed which included recommendations against the use of PPIs greater than once

daily and esophageal pH monitoring in the management of Barrett's esophagus. Label revisions were also discussed for Dexilant (dexlansoprazole), Protonix (pantoprazole), omeprazole, and Nexium (esomeprazole).

Dr. Correia commented that none of the new clinical information reviewed would change previous conclusions regarding this class of medications. He also mentioned that there is no clinical basis to differentially recommend any particular product within this class.

16. Prescription Non-Steroidal Anti-Inflammatory Agents

Dr. Zimmer presented information on the new medications Sprix (ketorolac) nasal spray and Duexis (ibuprofen/famotidine) including their indications, pharmacology, pharmacokinetics, use in special populations, contraindications, dosing and administration studies conducted. Dr. Zimmer also discussed label revisions to Mobic (meloxicam), Vimovo (naproxen/esomeprazole), and Celebrex (celecoxib) and REMS removal for some products in the class.

Dr. Correia commented on the new dosage form of ketorolac as a nasal spray. He noted all forms of ketorolac are limited to very short-term use, including this form to 5 days, relevant to evidence of a rapid increase in all adverse effects for all forms of ketorolac beyond this duration of use, with particular concerns for serious GI ulceration and bleeding. Clinical evidence for the intranasal form is currently limited to inpatient studies and only in comparison to placebo; comparative evidence to other NSAIDs is lacking. He concluded by stating the wide array of available NSAIDs include multiple dosage forms, routes of administration, and pathways for metabolism and elimination, as well as overlapping indications and dosing frequencies. All the NSAIDs including oral, topical, and nasal forms, share a common set of Black Box warnings, as well as an additional set of common warnings and precautions as previously presented.

F. Executive Session:

The Committee recessed the public session at 11:55 AM to go into executive session for review of financial information relating to the Committee's recommendations of preferred drugs in the following classes: Hepatitis C Agents, Oral Anticoagulants, Platelet Inhibitors, HMG-CoA Reductase Inhibitors/Statins, Triglyceride Lowering Agents, Direct Renin Inhibitors, Proton Pump Inhibitors and Non-Steroidal Anti-Inflammatory Agents. No official action was taken in the executive session. The executive session was recessed at 1:15 PM.

The Committee recessed the public session at 2:20 PM to go into executive session for review of financial information relating to the recommendation of preferred drugs in the following classes: Second Generation Antipsychotics, Selective Serotonin Reuptake Inhibitors, Serotonin/Norepinephrine Reuptake Inhibitors, CNS Stimulants, Inhaled Anticholinergics/COPD Agents, Inhaled Beta-2 Adrenergic Agents – Long Acting, Inhaled Beta-2 Adrenergic Agents – Short Acting, Inhaled Corticosteroids/Long Acting Beta-2 Adrenergic Agents and Leukotriene Modifiers. No official action was taken in the executive session. The executive session was recessed at 3:00 PM.

G. 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
<p>Hepatitis C – Protease Inhibitors</p> <p>Preferred Drugs Incivek, Victrelis</p> <p>Non-preferred Drugs None</p>	<p>Approved as Recommended</p>
<p>Hepatitis C – Ribavirins</p> <p>Preferred Drugs ribavirin tablet and capsule</p> <p>Non-preferred Drugs Copegus, Rebetol, Ribapak, Ribasphere</p>	<p>Approved as Recommended</p>
<p>Hepatitis C - Injectables</p> <p>Preferred Drugs Pegasys, PegIntron</p> <p>Non-preferred Drugs None</p>	<p>Approved as Recommended</p>
<p>Anticoagulants – Oral</p> <p>Preferred Drugs Coumadin, Jantoven, Pradaxa, warfarin</p> <p>Non-preferred Drugs Xarelto</p>	<p>Approved as Recommended</p>
<p>Antiplatelets</p> <p>Preferred Drugs Aggrenox, dipyridamole, Effient, Plavix</p> <p>Non-preferred Drugs Brilinta, Persantine, ticlopidine</p>	<p>Approved as Recommended</p>
<p>Statins</p> <p>Preferred Drugs atorvastatin, lovastatin, pravastatin, Simcor, simvastatin</p> <p>Non-preferred Drugs Advicor, Altoprev, atorvastatin/amlodipine, Caduet, Crestor, Lescol, Lescol XL, Lipitor, Livalo, Mevacor, Pravachol, Vytorin, Zocor</p>	<p>Approved as Recommended</p>

<p>Triglyceride Lowering Agents</p> <p>Preferred Drugs gemfibrozil, Tricor, Trilipix</p> <p>Non-preferred Drugs Antara, fenofibrate, fenofibric acid, Fibricor, Lipofen, Lofibra, Lopid, Lovaza, Triglide</p>	<p>Approved as Recommended</p>
<p>Direct Renin Inhibitors</p> <p>Motion was made to alter the DOH recommendation. The Committee voted in favor of altering the DOH recommendation as follows (vote of 9 to 0):</p> <p>Preferred Drugs Tekturna, Tekturna HCT</p> <p>Non-preferred Drugs Amturnide, Tekamlo, Valturna</p>	<p>Approved as Recommended</p>
<p>Proton Pump Inhibitors</p> <p>Preferred Drugs omeprazole Rx, pantoprazole, Prilosec OTC</p> <p>Non-preferred Drugs Aciphex, Dexilant, lansoprazole Rx, Nexium, omeprazole/sodium bicarbonate Rx, omeprazole OTC, Prevacid OTC, Prevacid Rx, Prilosec Rx, Protonix</p>	<p>Approved as Recommended</p>
<p>NSAIDs</p> <p>Preferred Drugs diclofenac potassium, diclofenac sodium, diclofenac sodium XR, etodolac, flurbiprofen, ibuprofen, indomethacin, indomethacin SR, ketoprofen, ketorolac, meloxicam, nabumetone, naproxen, naproxen sodium, naproxen EC, oxaprozin, piroxicam, sulindac, Voltaren Gel</p> <p>Non-preferred Drugs Anaprox, Arthrotec, Cambia, Celebrex, Cataflam, Clinoril, Daypro, diflunisal, Duexis, etodolac SA, Feldene, fenoprofen, Flector, ketoprofen SA, meclofenamate, Mobic, mefenamic acid, Nalfon, Naprelan, Naprosyn, Naprosyn EC, Pennsaid, Ponstel, Sprix, tolmetin, Vimovo, Voltaren XR, Zipsor</p> <p>For Celebrex (celecoxib) the Committee recommended the following criteria for systematic by-pass editing:</p> <ul style="list-style-type: none"> • <i>Over the age of 65</i> • <i>Concurrent use of an anticoagulant</i> • <i>History of GI Bleed/Ulcer or Peptic Ulcer Disease</i> 	<p>Approved as Recommended</p>

<p>Second Generation Antipsychotics</p> <p>Motion was made to alter the DOH recommendation. The Committee voted in favor of altering the DOH recommendation as follows (vote of 7 to 2):</p> <p>Preferred Drugs Abilify, clozapine, Fanapt, Geodon, risperidone, quetiapine, Saphris, Seroquel XR</p> <p>Non-preferred Drugs Clozaril, Fazaclo, Invega, Latuda, olanzapine, Risperdal, Seroquel, ziprasidone, Zyprexa</p>	<p>The Committee's recommendation is modified as follows:</p> <p>Abilify to remain non-preferred. Prior authorization for Abilify will not be required when prescribed for patients with bipolar disorder or schizophrenia as verified through Medicaid claims information.</p>
<p>SSRIs</p> <p>Preferred Drugs citalopram, fluoxetine, fluvoxamine, paroxetine, sertraline</p> <p>Non-preferred Drugs Celexa, escitalopram, fluoxetine 60mg, fluoxetine weekly, Lexapro, Luvox CR, paroxetine CR, Paxil, Paxil CR, Pexeva, Prozac, Sarafem, Viibryd, Zoloft</p>	<p>Approved as Recommended</p>
<p>SNRIs</p> <p>Preferred Drugs Cymbalta, venlafaxine IR, venlafaxine ER (capsule)</p> <p>Non-preferred Drugs Effexor XR, Pristiq, Savella, venlafaxine ER (tablet)</p>	<p>Approved as Recommended</p>
<p>CNS Stimulants</p> <p>Preferred Drugs Adderall XR, amphetamine salt combo IR, Concerta, dexamethylphenidate, dextroamphetamine, Focalin XR, Metadate ER, Methylin, Methylin ER, methylphenidate, methylphenidate SR (tablet), Vyvanse</p> <p>Non-preferred Drugs Adderall, amphetamine salt combo ER, Daytrana, Desoxyn, Dexedrine Spansule, dextroamphetamine SR, Focalin, Metadate CD, methamphetamine, methylphenidate ER (18, 27, 36, 54 mg), methylphenidate ER (capsule), Nuvigil, Procentra, Provigil, Ritalin, Ritalin LA, Ritalin SR</p>	<p>Approved as Recommended</p>
<p>Inhaled Anticholinergics/COPD Agents</p> <p>Preferred Drugs Atrovent HFA, Combivent, ipratropium, ipratropium/albuterol, Spiriva</p> <p>Non-preferred Drugs Daliresp, Duoneb</p>	<p>Approved as Recommended</p>

<p>LABAs</p> <p>Preferred Drugs Foradil, Serevent Diskus</p> <p>Non-preferred Drugs Arcapta, Brovana, Perforomist</p>	<p>Approved as Recommended</p>
<p>SABAs</p> <p>Preferred Drugs albuterol (solution), Maxair Autohaler, ProAir HFA, Proventil HFA</p> <p>Non-preferred Drugs Accuneb, levalbuterol (solution), Xopenex (solution), Xopenex HFA, Ventolin HFA</p>	<p>Approved as Recommended</p>
<p>Inhaled ICS/LABA Combinations</p> <p>Preferred Drugs Advair, Symbicort, Dulera</p> <p>Non-preferred Drugs None</p>	<p>Approved as Recommended</p>
<p>Leukotriene Modifiers</p> <p>Preferred Drugs Accolate, Singulair, zafirlukast</p> <p>Non-preferred Drugs None</p>	<p>Approved as Recommended</p>

The meeting adjourned at 3:30 PM

Meeting Summary Posted 5/14/2012

H. 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 G.

Preferred drugs will not require prior authorization within the PDP.

- PDP drugs may still be subject to utilization management programs as noted on the preferred drug list.

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 when utilizing preferred products. Prescribers, or their agents, will need to initiate the prior authorization process when ordering non-preferred products.

3. State Health Program:

- Annual gross savings associated with these therapeutic classes under the PDP are estimated at \$39M. 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 6/21/2012

Updated 10/30/2012