

Pharmacy and Therapeutics Committee Meeting Summary

April 15, 2011

Agenda and Introduction

The Medicaid Pharmacy & Therapeutics Committee met on Friday, April 15, 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 comment to the committee:

1. Davis, William, RPh, JD, National Clinical Account Manager - Medical Affairs, AstraZeneca Pharmaceuticals, Wilmington, DE
2. Odabashian, Harry C, MD, Albany, NY, on behalf of Merck, North Wales, PA
3. Riaz, Faisal, MD, Senior Manager Clinical Sciences and Outcomes, Takeda Pharmaceuticals, Kennesaw, GA
4. D'Ambrosio, Beth, PharmD, Regional Scientific Associate Director, Novartis Pharmaceuticals, Pittsford, NY
5. Winther, Marisa, PharmD, Regional Scientific Manager, AstraZeneca Pharmaceuticals, Wilmington, DE
6. Boykin, Shawn, PhD, Health Outcomes Consultant, Eli Lilly & Co, Indianapolis, IN
7. Trainer, JoAnn B, PharmD, Sr Director, Regional Medical and Research Specialist, Pfizer, Yardley, PA
8. Racine, Alison, PharmD, Sr Regional Medical Scientist, GlaxoSmithKline, Whitehouse Station, NJ
9. Renna, John, PharmD, Medical Science Liaison, Shire Pharmaceutical, Wayne, PA
10. Sees, Karen L, DO, on behalf of Noven Therapeutics, NY, NY
11. Owens, Mark, DO, on behalf of Noven Therapeutics, NY, NY
12. Higgins, Emilie, Advocacy and Programs Coordinator, National MS Society, Albany, NY
13. Maxwell, Rae Ann, RPh, PhD, Managed Markets Scientific & Outcomes Liaison, Biogen Idec, Westin, MA
14. Durrence, Heith, PhD, Scientific Director, Somaxon Pharmaceuticals, San Diego, CA
15. Elmore, Erin, MD, Essex Neurological Associates, on behalf of Merck, North Wales, PA
16. Whiten, Steve, Sr National Director, Integrated Healthcare, Taro Pharmaceuticals USA, Hawthorne, NY
17. Pardo, Dennis P, OD, MPH, FAAO, Medical Affairs Manager, ISTA Pharmaceuticals, Irvine, CA
18. Perrotta, Vincent G, RPh, Sr Area Manager, Allergan, Irvine, CA
19. Russell, David J, MD, Senior Medical Director, Pfizer, Albany, NY
20. Posta, Linda M, RPh, MBA, Scientific Manager, Managed Markets, Astellas Pharma US, Milford, CT

C. Key issues raised by interested parties and the Pharmacy and Therapeutics Committee pertaining to the clinical review of the following therapeutic classes/drugs:

Public comments:

Prescription Non-Steroidal Anti-Inflammatory Agents (NSAID):

- The Committee was asked to consider information regarding indications, safety, dosing and administration and black box warnings. The Committee was also asked to consider a non-inferiority trial comparing a combination NSAID, naproxen and esomeprazole, to celecoxib, a Cyclooxygenase II (COX II) inhibitor, for the treatment of osteoarthritis of the knee.

Angiotensin Receptor Blockers (ARBs)

- The Committee was asked to consider information regarding clinical trials of a new ARB with active comparators as well as indications, dosing and administration, safety, warnings and precautions and black box warnings.

Direct Renin Inhibitors

- The Committee was asked to consider information regarding two fixed dose direct renin inhibitor combination products. The Committee was also asked to consider indications, dosing and administration, efficacy, adverse event profile, safety information and black box warnings.

HMG-CoA Reductase Inhibitors/Statins

- The Committee was asked to consider a non-inferiority trial comparing the efficacy of a new statin product with an active comparator. The Committee was also asked to consider indications, dosing and administration, mechanism of action, drug interactions, safety and contraindications of this new statin. Several clinical trials were noted, including ENHANCE, JUPITOR, IDEAL and PLANET I & II. The Committee was asked to consider additional new post-hoc, sub-group analysis from these trials. The Committee was also asked to consider the availability of generic atorvastatin in November of this year as it relates to Medicaid pharmacy benefits being transitioned to Managed Care and maintaining consistency in patients' drug therapy. One of the presenters also expressed that the combination product ezetimibe/simvastatin would enhance compliance to achieve cholesterol goals.

Triglyceride Lowering Agents

- The Committee was asked to consider a study on the prevention of recurrent symptomatic atrial fibrillation/atrial flutter with omega-3 fatty acids which provided no increased benefit. The Committee was also asked to consider that omega-3 fatty acids have less drug interactions and adverse events as noted in the updated product information.

Central Nervous System Stimulants

- The Committee was asked to consider trials regarding the expanded labeled indications for the methylphenidate patch and lisdexamfetamine. The Committee was also asked to consider the flexibility of dosing with the methylphenidate patch.

Multiple Sclerosis Agents

- The Committee was asked to consider information on fingolimod, the first oral product available in this class, and the clinical trials TRANSFORMS and FREEDOMS related to this product. The Committee was also asked to consider dosing and administration for the product as well as mechanism of action, adverse event profile and warnings and precautions. Reference was made to the National Multiple Sclerosis Society's Disease Management Consensus Statement for Committee consideration. Also noted were potential risks and benefits for all the drugs in this class and that careful deliberation should be used in the choice of treatment based on the patient. The Committee was also asked to consider retrospective data, for interferon beta-1a, measuring safety, adherence and persistence as well as other markers.

Sedative Hypnotics/Sleep Agents

- The Committee was asked to consider information on doxepin, a new drug to the class that is not a controlled substance. It was also stated that the product has no abuse potential and a favorable safety profile.

Serotonin Receptor Agonists (Triptans)

- The Committee was asked to consider ease of use and compliance issues, generic versus brand choice and effective targeting of symptoms in addition to the pain that can be associated with migraine syndrome.

Topical Agents for Psoriasis

- The Committee was asked to consider generic calcipotriene ointment, which is AB-rated to Dovonex ointment (discontinued in April 2007). The presenter indicated a need from NYS dermatologists for this drug which is again available in this vehicle.

Ophthalmic Antihistamines

- The Committee was asked to consider studies with bepotastine reviewing mechanism of action, H1 selectivity and in vitro animal studies.

Non-Steroidal Anti-Inflammatory – Ophthalmic

- The Committee was asked to consider clinical trials with bromfenac including indications, administration and dosing (including course of therapy), and safety and efficacy with relation to lowest effective dose and exposure to preservatives.

Ophthalmic Prostaglandin Agonists

- The Committee was asked to consider information on a new formulation of bimatoprost. Clinical trial information was presented as well as information on preservative concentrations, discontinuation rates, and discomfort.

Urinary Tract Antispasmodics

- The Committee was asked to consider a comparative trial between fesoterodine and tolterodine LA and the primary and secondary endpoints achieved. The Committee was also asked to consider new analysis of previous studies which measured changes in urgency, flexibility of dose, quality of life scores and tolerability and safety.

Pharmacy and Therapeutics Committee Comments:

- A Committee member asked the presenter if there was any real world evidence that the combination naproxen and esomeprazole product is any better than the individual components.
- A Committee member and presenter discussed use of rosuvastatin in the Asian population with regards to lower dosing. Another Committee member also asked why patients ≥ 70 years of age didn't achieve as high a reduction in relative risk as the other population analyses.
- A Committee member asked a presenter to comment on why patients may be more adherent to the new statin as suggested in their testimony due to less drug interactions. The presenter commented that this has not been established in trials.
- A Committee member asked the presenter if atorvastatin is on most managed care formularies.
- A Committee member asked the presenter if they knew if any statins were going OTC.
- A Committee member asked the presenter if there was going to be a follow up to a study discussed about using omega-3 fatty acids for prevention of recurrent symptomatic atrial fibrillation/atrial flutter.
- A Committee member and presenter discussed skin irritation with the methylphenidate patch. The presenter stated most erythema resolved after 24-36 hours and that patients should alter administration sites. The committee member also asked if there were head to head trials with other products. The presenter clarified that there were but that the trials were not powered to see a difference between the two.
- A Committee member asked the presenter to comment on fatalities or increased risk of infection with fingolimod. The presenter noted that the two fatalities reported were on an unmarketed dose and there was not an increased risk of urinary tract or respiratory infections to her knowledge.
- A Committee member asked the presenter to comment on side effects for doxepin doses greater than 10mg and if there was data comparing the 6mg to 10 mg dose. The presenter commented on next day effects including grogginess and anticholinergic effects. Another Committee member mentioned that she prescribes it for itching and uses the liquid because it is less costly.
- A Committee member asked if there were any head to head studies in humans with regards to bepotastine ophthalmic solution.
- A Committee member asked for clarification if one bottle per patient is equivalent to a course of treatment for bromfenac ophthalmic solution.

D. Clinical Presentation and Discussion

Barbara Rogler, PharmD, MS, Magellan Medicaid Administration and Robert Correia, PharmD, NYS Department of Health, Office of Health Insurance Programs (DOH/OHIP).

Preferred Drug Program: Initial Review

1. Proposal to identify preferred drugs in the therapeutic class of Tetracyclines

Dr. Rogler provided background information on the class and gave an overview of the products including indications, mechanisms of action, pharmacokinetics, contraindications and warnings, drug interactions, use in special populations, compendia uses and dosage and administration.

Dr Correia summarized commonalities of the drugs in the class and highlighted the differences in indications, pharmacokinetics, indications and interactions. He concluded most significant differences

among the products in this class are between the types of tetracycline, rather than individual products and even then there is no evidence of any overall superiority.

Preferred Drug Program: Re-review

1. Prescription Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

Dr. Correia and Dr. Rogler noted a new product in this class, diclofenac potassium powder. They discussed its unique indication and dosing and administration. Dr. Rogler also provided the Committee with a summary of FDA approved dosing and administration for all the oral and topical products in the class. Dr. Correia concluded that diclofenac is available in multiple strengths and dosage forms, including immediate and delayed release oral, powder for oral solution, liquid filled capsules and topical dosage forms many which are available generically.

A Committee member commented on the history of the "fenacs" class in general and on the dissolvable form of diclofenac in particular, taking into consideration the drug's potential to cause liver toxicity.

2. Angiotensin Receptor Blockers (ARBs), ARB/Diuretic Combinations

Dr. Rogler noted two new generic products in the class, losartan and losartan/hctz, as well as a new ARB, azilsartan. She presented an overview of azilsartan which included indication, dosage, administration, strengths available and black box warning. She also presented a comparative study between azilsartan, olmesartan and valsartan. Dr. Rogler discussed a labeling revision for valsartan/hctz as well as a FDA Safety Alert for olmesartan in which the FDA announced after reviewing the results of the ROADMAP and ORIENT trials, that the benefits of olmesartan continue to outweigh the potential risks when used for the treatment of patients with high blood pressure according to the drug label. She also discussed another FDA Safety Alert based on a meta-analysis evaluating ARBs and adverse events of death from CV cause compared to taking placebo. Dr. Rogler noted the FDA believes the benefits of ARBs continue to outweigh their potential risks.

Dr. Correia presented a synopsis of studies done in this class and their relation to diabetes and cardiovascular outcomes. Dr. Correia concluded that there is a body of evidence of improved outcomes in cardiovascular disease as well as diabetes with the use drugs in the angiotensin converting enzyme inhibitor (ACEI) class. These have been attributed to the various impacts ACEIs have on the entire renin-angiotensin system. He reminded the Committee that ACEIs are generally preferred due to evidence of positive outcomes in multiple areas including cardiovascular and diabetes and that ARBs are generally reserved for cases where the ACEIs are not tolerated for some reason.

3. ARB/Calcium Channel Blocker Combinations

Dr. Rogler discussed a new fixed-dose combination product in the class, olmesartan/amlodipine/hctz. She presented an overview of the product which included indication, dosage, administration, and strengths available. Dr. Correia mentioned that now there is a choice of two different ARBs available in a triple combination but both use the same calcium channel blocker and diuretic.

4. Direct Renin Inhibitors

Dr. Rogler discussed two new combination products in the class, aliskiren/amlodipine and aliskiren/amlodipine/hctz. She presented an overview of their indications, dosages, administration, and strengths available. Dr. Rogler also discussed an FDA Safety Alert for aliskiren/hctz relating to angioedema of the face, extremities, lips, tongue, glottis and/or larynx which has necessitated the need for hospitalization and intubation. She also discussed labeling revisions for aliskiren, aliskiren/hctz and aliskiren/valsartan regarding hypersensitivity reactions and drug interaction with verapamil.

Dr. Correia concluded there is still only one direct renin inhibitor in this class, aliskiren, available either alone or in combination products. He also reiterated safety warnings related to angioedema and hypersensitivity.

A Committee member commented on the place in therapy of this drug class.

5. HMG-CoA Reductase Inhibitors/Statins

Dr. Rogler discussed new labeling revisions for simvastatin and ezetimibe/simvastatin, new strengths available for simvastatin/niacin ER and the addition of a new drug to the class, pitavastatin. She provided an overview of the new product including indication, dosage, administration, strengths available, contraindications, limitations of use and pharmacokinetics as well as an overview of all of the products in the class with regards to indications and drug interactions. Dr. Rogler also presented a comparative study between pitavastatin and atorvastatin in which pitavastatin was shown to be non-inferior. Dr. Rogler updated the Committee on the FDA's preliminary analyses of the SEARCH trial and the increased risk of muscle injury in patients taking simvastatin 80mg.

Dr. Correia also commented on the side effect profile for the drugs in the class focusing on drug interactions and special populations. He also commented that a significant portion of information available or presented was additional post-hoc, sub-group analysis of data existing from older trials.

6. Triglyceride Lowering Agents

Dr. Rogler gave a brief overview of the drugs in the class and their indications. She also discussed a label revision for gemfibrozil.

Dr. Correia commented on a new study for the use of the omega-3 fatty acid product for atrial fibrillation which showed no benefit for this use. He also commented that the omega-3 fatty acid product is only indicated when triglyceride levels exceed 500 mg/dL. He concluded 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.

7. Anti-Fungals

Dr. Rogler and Dr. Correia discussed a new warning for griseofulvin ultramicrosized tablets related to serious skin reactions and hepatic toxicities.

A Committee member asked about the number of cases reported and the relative increase in incidence.

8. Central Nervous System Stimulants

Dr. Rogler and Dr. Correia discussed expanded indications for methylphenidate transdermal patch and lisdexamfetamine in adolescents 13-17 years of age for the treatment of ADHD. They also addressed numerous label revisions in the class. Dr. Correia also noted the methylphenidate patch dosage form that was presented as providing dosage flexibility also provided vulnerability to misuse. Dr. Correia concluded that there is a lack of evidence to demonstrate an overall advantage for any drug with shared indications in the drug class, and it would be preferable to have drugs in the short, intermediate, and long acting ranges represented among the preferred drugs.

9. Multiple Sclerosis Agents

Dr. Rogler provided an overview of products in the class including indications, dosage and administration. She also discussed a new product in the class, fingolimod, and provided additional information on the products warnings and precautions, mechanism of action and pharmacokinetics. Dr. Rogler presented the TRANSFORMS trial focusing on primary and secondary endpoints as well as adverse events.

Dr. Correia concluded that fingolimod may offer a significant advantage in terms of route of administration, has good efficacy, but this is also balanced by some significant serious and different adverse effects from the other agents in the class.

A Committee member commented on side effects for other drugs in the class and relapse rates. Another member commented on the difficulties to conduct trials on drugs for this disease.

10. Sedative Hypnotics/Sleep Agents

Dr. Rogler discussed label revisions for zolpidem and ramelteon, a new generic product, zolpidem ER and two new products to the class, doxepin tablets and zolpidem oral spray. She provided information on the new products which included indications, dosage and administration, pharmacology, pharmacokinetics, contraindications, drug interactions and use in special populations.

Dr. Correia concluded that comparative evidence to other drugs in this class is lacking. He stated that pivotal trials with doxepin were statistically better than placebo, but clinically the effects were modest when also considering the patient criteria for exclusion from these studies. Dr. Correia stated that the resulting study populations may not be significantly representative of actual patient populations in the Medicaid program.

11. Serotonin Receptor Agonists (Triptans)

Dr. Rogler and Dr. Correia both noted a new generic in the class, naratriptan, since the previous review. Dr. Rogler also discussed a label revision for all products in the class strengthening the warning regarding serotonin syndrome. Dr. Correia concluded it would be preferable to include as many dosage forms as feasible in this class as preferred products.

12. Topical Anti-Virals

Dr. Rogler and Dr. Correia both discussed a new product to the class acyclovir/hydrocortisone cream. Dr. Rogler also discussed the products indication, dosage, administration and packaging. Dr. Correia concluded that these products are primarily used to marginally shorten the course of a spontaneously resolving condition, with the exception of acyclovir ointment, which is indicated for genital herpes.

A Committee member commented on the usefulness of hydrocortisone. Another member commented on the effectiveness of a plain emollient for symptom relief.

13. Topical Agents for Psoriasis

Dr. Rogler and Dr. Correia discussed a new generic as well as a new branded formulation for calcipotriene 0.005% ointment since the previous review. Dr. Correia stated that there is not an actual new drug in this class, only a new manufacturer of a product that was previously available.

Several Committee members discussed the difference between ointments and creams.

14. Ophthalmic Antihistamines

Dr. Rogler presented information on alcaftadine, a new drug in the class since the previous review, with regards to indication, dosage, administration, warnings and precautions. Dr. Rogler also provided a comparison of indications, approved age range and dosing and administration for all the products in the class.

Dr. Correia commented on the studies submitted for bepotastine. He stated that most were based on theoretical relationships to clinical practice such as comparison of a single dose or drop of drug, comparison in animal models or tissues and with response to alternative sensitizing agents. Dr. Correia concluded that relief of symptoms based on antihistamine and mast cell stabilization seem to be class effects and that all of the drugs reviewed in this class have both of these properties, with the exception of emedastine which has only antihistamine effect.

A Committee member commented on the affects of normal saline in providing symptom relief. Another member commented on obtaining both ocular and nasal relief from a product.

15. Ophthalmic Fluoroquinolones

Dr. Rogler presented information a levofloxacin 0.5% (a new generic) and moxifloxacin 0.5% and gatifloxacin 0.5%, both of which are new drugs to the class since the previous review. Dr. Rogler provided a comparison of their indications, dosing and administration as well as all the products in the class in regard to indications and approved age ranges.

Dr. Correia discussed these products in terms of how they are classified by generation and spectrum of activity. He concluded since there is an overall differential spectrum of activity between second generation fluoroquinolones compared with the later generations, it would be recommended to have both of these groups represented on the preferred drug list.

Several Committee members commented that ophthalmic fluoroquinolones should not be used as first line agents for the treatment of bacterial conjunctivitis. They also discussed Drug Utilization Review (DUR) initiatives as well as provider education for this class of drugs.

16. Non-Steroidal Anti-Inflammatory- Ophthalmic

Dr. Rogler and Dr. Correia presented information on bromfenac 0.09% ophthalmic solution, a new drug to the class since the previous review. Dr. Rogler provided information on the product including indication, dosing and administration. She also provided a comparison of indications and dosing for all of the products in the class. Dr. Correia concluded a review of the clinical evidence available, including limited comparative evidence, did not reveal any overall clinical superiority for any drug in this class.

A committee member inquired about corneal melting with generic products. Dr. Rogler clarified that this has occurred with generic as well as branded products in the class.

17. Ophthalmic Prostaglandin Agonists

Dr. Rogler and Dr. Correia presented information on the new generic, latanoprost, and new strength of bimatoprost 0.01%, available since the previous review. Dr. Rogler discussed a clinical study measuring intraocular pressure (IOP) with the new strength of bimatoprost 0.01%. Dr. Correia concluded marginal differences are claimed for each drug or product, but continue to tend to balance between slight study variations in change in Intraocular Pressure (IOP) and tolerability due to adverse effects with none demonstrating an overall advantage.

18. Antihistamines – Second Generation

Dr. Rogler and Dr. Correia presented information on the new generic levocetirizine and the availability of fexofenadine OTC since the previous review. Dr. Correia concluded there was no significant new clinical evidence demonstrating overall superiority for any drugs in this class since the last review date.

A committee member asked if leukotriene modulators are more widely used now with all the OTC products recently available in this class. Several members commented on the degree of sedation for products within the class and also in comparison to other products available.

19. Urinary Tract Antispasmodics

Dr. Rogler presented new labeling revisions regarding angioedema for several products in the class.

Dr. Correia stated every product in this class now has labeling which includes experience with angioedema. Dr. Correia presented new evidence that was submitted concerning a second clinical trial comparing fesoterodine with tolterodine ER. Results of this trial are consistent with the clinical information reviewed last year which showed a similar benefit for both treatments in patients with over-active bladder (OAB), with fesoterodine doing statistically better at some specific defined endpoint outcomes, but also demonstrating higher incidence of adverse effects and discontinuation rates. Dr. Correia concluded any of these drugs provide comparable, modest, symptomatic relief, with none demonstrating an overall advantage.

A Committee member commented on OAB in the MS community.

E. Executive Session:

The Committee recessed the public session at 12:30 PM to go into executive session for review of financial information relating to the Committee's recommendations of preferred drugs in the following classes: Tetracyclines, Prescription NSAIDs, Angiotensin Receptor Blockers (ARBs), ARB/Diuretic Combinations, ARB/Calcium Channel Blocker Combinations, Direct Renin Inhibitors, Statins, Triglyceride Lowering Agents, Anti-Fungals and Central Nervous System Stimulants. 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 3:10 PM to go into executive session for review of financial information relating to the recommendation of preferred drugs in the following classes: Multiple Sclerosis Agents, Sedative Hypnotics/Sleep Agents, Triptans, Topical Anti-Virals, Topical Agents for Psoriasis, Ophthalmic Antihistamines, Ophthalmic Fluoroquinolones, Non-Steroidal Anti-Inflammatory- Ophthalmic, Ophthalmic Prostaglandin Agonists, Antihistamines – Second Generation and Urinary Tract Antispasmodics. No official action was taken in the executive session. The executive session was recessed at 3:50 PM.

F. Recommendations of the Pharmacy and Therapeutics 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>The standard clinical questions be used in the prior authorization review process for non-preferred drugs:</p> <p>Q: Has your patient experienced treatment failure with preferred drugs in the class?</p> <p>Q: Has your patient experienced an adverse drug reaction with preferred drugs in the class?</p> <p>Q: Is there a documented history of successful therapeutic control with a non-preferred drug and transition to a preferred drug is medically contraindicated?</p>	<p>Approved as Recommended</p>
<p>Tetracyclines</p> <p>Preferred Drugs demeclocycline, doxycycline hyclate 50mg and 100mg, doxycycline monohydrate, minocycline, tetracycline</p> <p>Non-preferred Drugs Adoxa (doxycycline monohydrate), Doryx (doxycycline hyclate DR), doxycycline hyclate 20mg, doxycycline hyclate DR, Dynacin (minocycline HCL), minocycline ER, Oracea (doxycycline monohydrate), Periostat (doxycycline hyclate), Solodyn ER (minocycline ER), Vibramycin (doxycycline hyclate), Vibra-tabs (doxycycline hyclate)</p>	<p>Approved as Recommended</p>
<p>Prescription Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)</p> <p>Preferred Drugs diclofenac potassium, diclofenac sodium, diclofenac sodium XR, diflunisal, etodolac, etodolac SA, fenoprofen, flurbiprofen, ibuprofen, indomethacin, indomethacin SR, ketoprofen, ketoprofen SA, ketorolac, meclofenamate, mefenamic acid, meloxicam, nabumetone, naproxen, naproxen sodium, naproxen EC, oxaprozin, piroxicam, sulindac, tolmetin, Voltaren Gel (diclofenac sodium)</p> <p>Non-preferred Drugs Anaprox (naproxen sodium), Anaprox DS (naproxen sodium DS), Arthrotec (diclofenac sodium/misoprostol), Cambia (diclofenac potassium), Cataflam (diclofenac potassium), Clinoril (sulindac), Daypro (oxaprozin), Feldene (piroxicam), Flector (diclofenac epolamine), Indocin (indomethacin), Mobic (meloxicam), Nalfon (fenoprofen), Naprelan (naproxen sodium CR), Naprosyn (naproxen), Naprosyn EC (naproxen EC), Pennsaid (diclofenac sodium topical solution), Ponstel (mefenamic acid), Vimovo (naproxen and esomeprazole magnesium), Voltaren (diclofenac sodium), Voltaren XR (diclofenac sodium DR), Zipsor (diclofenac potassium)</p>	<p>Approved as Recommended</p>

<p>Angiotensin Receptor Blockers (ARBs)</p> <p>Preferred Drugs Diovan (valsartan), losartan</p> <p>Non-preferred Drugs Atacand (candesartan cilexetil), Avapro (irbesartan), Benicar (olmesartan medoxomil), Cozaar (losartan), Edarbi (azilsartan medoxomil), Micardis (telmisartan), Teveten (eprosartan mesylate)</p>	<p>Approved as Recommended</p>
<p>ARB/Calcium Channel Blockers</p> <p>Preferred Drugs Exforge (valsartan/amlodipine besylate), Exforge HCT (valsartan/amlodipine/hctz)</p> <p>Non-preferred Drugs Azor (olmesartan medoxomil/amlodipine besylate), Tribenzor (olmesartan/amlodipine/hctz), Twynsta (telmisartan/amlodipine)</p>	<p>Approved as Recommended</p>
<p>ARB/Diuretic Combinations</p> <p>Preferred Drugs Diovan HCT (valsartan/hctz), losartan/hctz</p> <p>Non-preferred Drugs Atacand HCT (candesartan cilexetil/hctz), Avalide (irbesartan/hctz), Benicar HCT (olmesartan medoxomil/hctz), Hyzaar (losartan/hctz), Micardis HCT (telmisartan/hctz), Teveten HCT (eprosartan/hctz)</p>	<p>Approved as Recommended</p>
<p>Direct Renin Inhibitors</p> <p>Preferred Drugs Tekturna (aliskiren), Tekturna HCT (aliskiren/hctz), Valturna (valsartan/aliskiren)</p> <p>Non-preferred Drugs Amturnide (aliskiren/amlodipine/hctz), Tekamlo (aliskiren/amlodipine)</p>	<p>Approved as Recommended</p>
<p>HMG-CoA Reductase Inhibitors/Statins</p> <p>Preferred Drugs Crestor (rosuvastatin), Lipitor (atorvastatin), lovastatin, pravastatin, Simcor (simvastatin/niacin extended-release), simvastatin</p> <p>Non-preferred Drugs Advicor (lovastatin/niacin extended-release), Altoprev (lovastatin extended-release), Caduet (atorvastatin/amlodipine), Lescol (fluvastatin), Lescol XL (fluvastatin XL), Livalo (pitavastatin), Mevacor (lovastatin), Pravachol (pravastatin), Vytorin (simvastatin/ezetimibe), Zocor (simvastatin)</p>	<p>Approved as Recommended</p>
<p>Triglyceride Lowering Agents</p> <p>Preferred Drugs gemfibrozil, Tricor (fenofibrate), Trilipix (fenofibric acid)</p> <p>Non-preferred Drugs Antara (fenofibrate), fenofibrate, fenofibric acid, Fenoglide (fenofibrate), Fibricor (fenofibric acid), Lipofen (fenofibrate), Lofibra (fenofibrate), Lopid (gemfibrozil), Lovaza (omega-3 acid ethyl esters), Triglide (fenofibrate)</p>	<p>Approved as Recommended</p>

<p>Anti-Fungals</p> <p>Preferred Drugs Gris-PEG (griseofulvin), griseofulvin suspension, terbinafine</p> <p>Non-preferred Drugs Grifulvin V tablet (griseofulvin), itraconazole, Lamisil (terbinafine), Sporanox (itraconazole)</p>	<p>Approved as Recommended</p>
<p>Central Nervous System Stimulants</p> <p>Preferred Drugs Adderall XR (amphetamine salt combo XR), amphetamine salt combo, Concerta (methylphenidate), dexamethylphenidate, dextroamphetamine sulfate, dextroamphetamine sulfate SA, Focalin (dexamethylphenidate), Focalin XR (dexamethylphenidate XR), Metadate ER (methylphenidate ER), Methylin (methylphenidate), Methylin ER (methylphenidate ER), methylphenidate, methylphenidate ER/SR, Vyvanse (lisdexamfetamine dimesylate)</p> <p>Non-preferred Drugs Adderall (amphetamine salt combo), amphetamine salt combo ER, Daytrana (methylphenidate), Desoxyn (methamphetamine), Dexedrine Spansule (dextroamphetamine), Metadate CD (methylphenidate CD), methamphetamine, Nuvigil (armodafinil), Procentra (dextroamphetamine sulfate), Provigil (modafinil), Ritalin (methylphenidate), Ritalin SR (methylphenidate SR), Ritalin LA (methylphenidate LA)</p> <p>Continue to use the one additional clinical prior authorization question for specific product indications:</p> <p>Q: Is the patient being treated for excessive sleepiness associated with shift work sleep disorder or as an adjunct to standard treatment for obstructive sleep apnea?</p>	<p>Approved as Recommended</p>
<p>Multiple Sclerosis Agents The Committee recommended the following (by a vote of 10 to 1):</p> <p>Preferred Drugs Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Copaxone (glatiramer acetate), Rebif (interferon beta-1a)</p> <p>Non-preferred Drugs Extavia (interferon beta-1b), Gilenya (fingolimod)</p>	<p>Approved as Recommended</p>
<p>Sedative Hypnotics/Sleep Agents</p> <p>Preferred Drugs chloral hydrate syrup, estazolam, flurazepam, temazepam 15mg, temazepam 30mg, zolpidem</p> <p>Non-preferred Drugs Ambien (zolpidem), Ambien CR (zolpidem CR), Doral (quazepam), Edluar (zolpidem sublingual tablet), Halcion (triazolam), Lunesta (eszopiclone), Restoril (temazepam), Rozerem (ramelteon), Silenor (doxepin), Somnote (chloral hydrate), Sonata (zaleplon), temazepam 7.5mg, temazepam 22.5mg, triazolam, zaleplon, zolpidem ER, Zolpimist (zolpidem oral spray)</p>	<p>Approved as Recommended</p>
<p>Serotonin Receptor Agonists (Triptans)</p> <p>Preferred Drugs</p>	<p>Approved as</p>

<p>Maxalt MLT (rizatriptan), sumatriptan</p> <p>Non-preferred Drugs Amerge (naratriptan), Axert (almotriptan), Frova (frovatriptan), Imitrex (sumatriptan), Maxalt tablet (rizatriptan), naratriptan, Relpax (eletriptan), Treximet (sumatriptan/naproxen), Zomig (zolmitriptan)</p>	Recommended
<p>Topical Anti-Virals</p> <p>Preferred Drugs Abreva (docosanol), Zovirax (acyclovir) ointment</p> <p>Non-preferred Drugs Denavir (penciclovir), Xerese (acyclovir/hydrocortisone), Zovirax (acyclovir) cream</p>	Approved as Recommended
<p>Topical Agents for Psoriasis The Committee recommended the following (by a vote of 6 to 5):</p> <p>Preferred Drugs calcipotriene ointment, calcipotriene scalp solution, Dovonex (calcipotriene) cream</p> <p>Non-preferred Drugs Calcitrene (calcipotriene), Dovonex (calcipotriene) scalp solution, Taclonex (calcipotriene/betamethasone dipropionate), Vectical (calcitriol)</p>	Approved as Recommended
<p>Ophthalmic Antihistamines</p> <p>Preferred Drugs Patanol (olopatadine), Pataday (olopatadine)</p> <p>Non-preferred Drugs azelastine, Bepreve (bepotastine), Elestat (epinastine), Emadine (emedastine), Lastacaft (alcaftadine), Optivar (azelastine)</p>	Approved as Recommended
<p>Ophthalmic Fluoroquinolones</p> <p>Preferred Drugs ciprofloxacin, ofloxacin, Vigamox (moxifloxacin)</p> <p>Non-preferred Drugs Besivance (besifloxacin), Ciloxan (ciprofloxacin), IQIIX (levofloxacin), levofloxacin, Moxeza (moxifloxacin), Ocuflax (ofloxacin), Quixin (levofloxacin), Zymar (gatifloxacin), Zymaxid (gatifloxacin)</p>	Approved as Recommended
<p>Non-Steroidal Anti-Inflammatory – Ophthalmic</p> <p>Preferred Drugs diclofenac, flurbiprofen, ketorolac</p> <p>Non-preferred Drugs Acular (ketorolac), Acular LS (ketorolac), Acuvail (ketorolac tromethamine), Bromday (bromfenac), Nevanac (nepafenac), Ocufer (flurbiprofen), Voltaren (diclofenac), Xibrom (bromfenac)</p>	Approved as Recommended
<p>Ophthalmic Prostaglandin Agonists</p> <p>Preferred Drugs latanoprost, Travatan (travoprost), Travatan Z (travoprost)</p> <p>Non-preferred Drugs</p>	Approved as Recommended

Lumigan (bimatoprost), Xalatan (latanoprost)	
<p>Antihistamines – Second Generation</p> <p>Preferred Drugs cetirizine OTC tablet and syrup, loratadine OTC tablet and syrup</p> <p>Non-preferred Drugs Allegra/Allegra-D (fexofenadine/fexofenadine PSE), cetirizine-D OTC, Clarinex/Clarinex-D (desloratadine/desloratadine PSE), fexofenadine/fexofenadine-D, levocetirizine, loratadine-D OTC, Semprex-D (acrivastine/PSE), Xyzal (levocetirizine)</p> <p>Continue to use the one additional clinical prior authorization question for specific product indications: Q: Is the patient under twenty-four (24) months of age?</p>	Approved as Recommended
<p>Urinary Tract Antispasmodics</p> <p>Preferred Drugs oxybutynin, Oxytrol (oxybutynin), Sanctura XR (trospium), Vesicare (solifenacin), Toviaz (fesoterodine fumarate)</p> <p>Non-preferred Drugs Detrol (tolterodine), Detrol LA (tolterodine LA), Ditropan (oxybutynin), Ditropan XL (oxybutynin XL), Enablex (darifenacin), Gelnique (oxybutynin gel), oxybutynin ER, Sanctura (trospium), trospium</p>	Approved as Recommended

G. Additional Discussion:

Janet Zachary-Elkind, Assistant Division Director, DOH/OHIP/DFPP, presented an overview of 2011-2012 Budget Initiatives. She also expressed appreciation to Dr. Martin and the Committee for their service and dedication.

Several committee members had questions regarding the Budget initiatives surrounding Managed Care Organizations (MCO) formularies and changes to the current prior authorization processes.

Jason Helgerson, NYS Medicaid Director, introduced himself to the Committee and commented on the need to continue to appropriately manage our fee-for-service population amidst the changes in this year's Budget. He also expressed the importance of this Committee to make cost-effective clinically-sound decisions.

Dr. Martin, Chairperson, expressed his appreciation to serve as the Chair of the Committee and is looking forward to continuing to work with this Committee in a different capacity.

Marla Eglowstein, Committee member, announced that she is taking a leave of absence and hopes to resume her role on the Committee at a later date.

The meeting adjourned at 4:15 PM

Meeting Summary Posted 05/12/2011

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 F.

Preferred Drugs will not require prior authorization

The impact of this final determination is as follows:

a. 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.

b. 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.

c. State Health Program:

- Annual gross savings associated with these therapeutic classes under the PDP are estimated at \$88M. The savings are achieved through changes in utilization to equally effective and less expensive products including the receipt of supplemental rebates from pharmaceutical manufacturers.

Meeting Summary with Final Determinations Posted 05/24/2011