# New York State Medicaid Pharmacy and Therapeutics Committee Meeting Summary June 15, 2012

# **Agenda and Introduction**

The Medicaid Pharmacy & Therapeutics Committee met on Friday June 15, 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, Bharat, PharmD, Medical Science Liaison, GlaxoSmithKline, Malvern, PA
- 2. Vazquez, Julio E., MS, PharmD, Outcomes Liaison Puerto Rico, Global Health Outcomes, Eli Lilly and Co., Indianapolis, IN
- 3. Thomson, Heather, MBA, MS, Senior Field Scientist, Health Outcomes and Pharmacoeconomics, Endo Pharmaceuticals, Inc., Chadds Ford, PA
- 4. Arsever, Christiane, MD, Senior Medical Director, Merck & Co., Inc., North Wales, NY
- 5. Ferraro, Natalie, DPM, RN, Medical Science Liaison Metabolism, Bristol-Myers Squibb, Plainsboro, NJ
- 6. Dugandzic, Maria, PharmD, Associate Director, Healthcare Quality & Outcomes, Boehringer-Ingelheim Pharmaceuticals, Inc., Brooklyn, NY
- 7. Gerety, Gregg, MD, Head Section of Endocrinology, St Peter's Hospital, Albany, NY
- 8. Bennett, Jr., Leonard, PharmD, Senior Medical Liaison, Managed Markets, Novo Nordisk, Inc., Princeton, NJ
- 9. Lemley, Craig, Associate Director, Regional Accounts, Amylin Pharmaceuticals, San Diego, CA
- 10. Heise, Jamie, PharmD, Senior Medical Science Liaison, Clinical Developments & Medical Affairs, Shire Pharmaceuticals, Wayne, PA
- 11. Phalen, Timothy J., PhD, Immunology Medical Science Liaison, UCB Inc., Smyrna, GA
- 12. Posta, Linda M., RPh, MBA, PharmD, Scientific Manager, Managed Markets, Astellas Pharma US, Northbrook, IL
- 13. Russell, David J., MD, FACS, Senior Medical Director, Pfizer, Inc., New York, NY
- 14. Schmitt, Laurie, PharmD, BCPS, Therapeutic Specialist- Cardiovascular, Forest Research Institute, Jersey City, NJ

# C. Key issues raised by interested parties and Committee members during the public comment period:

#### Alpha Reductase Inhibitors (for BPH)

The Committee was asked to consider efficacy and safety of Avodart and Jalyn including results of the CombaT trial and the REDUCE trial.

A Committee member asked if there were head to head trials between the alphaadrenergic blockers and the alpha reductase inhibitors. The speaker noted there was none.

# Anabolic Steroids - Topical

The Committee was asked to consider efficacy and safety and indicated that testosterone is categorized as pregnancy category X and a schedule III controlled substance.

A Committee member asked to clarify the mechanism to which the side effect of gynecomastia occurs. Another Committee member asked what the incidence of secondary exposure was. The speaker noted this is based on post marketing reporting and explained how to reduce exposure risk.

# Long Acting Opioids

The Committee was asked to consider the new formulation of Opana ER which is designed to be crush resistant and indicated that there are no significant changes to the prescribing information to reflect this technology.

#### Dipeptidyl Peptidase-4 (DPP-4) Inhibitors

The Committee was asked to consider:

- Indications, limitations of use, dosage and administration and clinical studies for Januvia. Janumet. and Juvisvnc.
- New clinical information for Onglyza including safety and efficacy data and warnings and precautions.
- Indications, safety, efficacy, warnings, precautions and drug interactions for Tradjenta.

A Committee member commented that the reduction of HbA1c was similar to that of metformin alone. Weight loss was also questioned. The speaker responded there was some weight loss as compared to TZDs but it was minimal. A Committee member also asked for clarification on how linagliptin had a better safety profile based on dosing and cautioned regarding statements indicating the drug has no adverse drug interactions.

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

The Committee was asked to consider:

- 52 week data regarding the efficacy and safety of Victoza vs. sitagliptan and 26 week data associated with adding on Levemir to Victoza and metformin.
- Byetta and Bydureon cost effectiveness including a combined ADA-EASD position statement listing GLP-1 agents as a second option (after diet, exercise and metformin) in the treatment of diabetes.

A Committee member asked for further information on pancreatitis and about this drug class being diverted for weight loss. Another Committee member also inquired about head to head trials in this class. The speaker spoke to the Lead-6 and Duration-6 trials between

Byetta and Bydureon. A Committee member also questioned information provided about Bydureon being competitively priced and how they arrived at that.

#### Sulfasalazine Derivative

The Committee was asked to consider indications and usage, dosage and administration, adverse reactions, safety information and a clinical study in the maintenance of ulcerative colitis remission for Lialda.

#### Immunomodulators - injectable

The Committee was asked to consider asked to consider indications and usage, dosage and administration, adverse reactions, safety information and clinical trials (PRECiSE1/PRECiSE 2 and RAPID 1/ RAPID 2) for Cimzia.

#### Phosphate Binder/Regulators

The Committee was asked to consider updated information for Fosrenol including dosage and administration, contraindications, warning and precautions, adverse events, pharmacodynamics and safety information.

A Committee member expressed concern about diabetic patients and GI slow motility in this patient population. The Committee member questioned the mechanism of action of Fosrenol. The speaker commented that risk factors should be considered and patient education on administration be conducted with this product.

#### **Urinary Tract Antispasmodics**

The Committee was asked to consider:

- The effectiveness of Vesicare including the comparative effectiveness report prepared for the Agency for Healthcare Research and Quality (AHRQ) by the Minnesota Evidence Based Practice Center.
- The product Toviaz including an evaluation of cognitive function in healthy older adults treated with fesoterodine.

#### Beta Blockers

The Committee was asked to consider the updated indication for the product Bystolic.

#### **Cholesterol Absorption Inhibitors**

The Committee was asked to consider indications, mechanism of action, selected clinical studies and cautionary information for Zetia.

A Committee member asked if rhabdomyolysis was seen less with Zetia vs. statins in post marketing surveillance. Another Committee member noted constipation issues when trying to utilize this class of drugs with his patients. It was noted that Welchol may cause less constipation than the other drugs in the class.

#### Ophthalmic Prostaglandin Agonists

The Committee was asked to consider the new product Zioptan including dosage and administration, warning and precautions, mechanism of action clinical studies and tolerability information.

#### D. 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. Alpha Reductase Inhibitors (for BPH)

Dr. Zimmer provided a general background Benign Prostatic Hyperplasia (BPH) including the American Urological Association (AUA) 2010 Guidelines on the Management of BPH. Regarding the products in the therapeutic class information presented included indications, dosage and administration, warnings, adverse effects and drug interactions. Dr. Zimmer presented two clinical trials: Enlarged Prostate International Comparator Study (EPICS) and CombaT study.

Dr. Correia stated that there is little good comparative evidence between dutasteride and finasteride. Findings of an increased incidence of high-grade prostate cancer precipitated a warning for both drugs by the FDA in 2011. This therapeutic class and area of therapy, like many others, seem to identify a trade—off between effectiveness and adverse effect profile.

A Committee member questioned if the class was extensively metabolized by CYP3A4 or just dutasteride.

#### 2. Anabolic Steroids – topical

Dr. Zimmer provided a general background on male hypogonadism and testosterone supplementation. Regarding the products in the therapeutic class, information presented included indications, dosage and administration, warnings, adverse effects and drug interactions. Also noted is that long term studies that evaluate topical treatment options for hypogonadism at lacking.

Dr. Correia stated that the products in the class contain the same active ingredient and there is no evidence of any significant difference in efficacy.

A Committee member noted that topical application may lead to possible unintended exposure to the drug.

#### 3. Ophthalmic Antibiotics and Antibiotic/Steroid Combinations

Dr. Zimmer provided a general background on bacterial conjunctivitis. Regarding the products in the therapeutic class information presented included indications, dosage and administration, warnings, adverse effects and drug interactions. Also noted is that there is very little quality comparative data published for products in this therapeutic class.

Dr. Correia stated that there is little comparative evidence between products in these classes. Product selection is largely empirical and consideration should be made for coverage of both gram positive and gram negative organisms and fungi, as well as different antibiotic classes. Product selection for preferred status should also be inclusive of liquid drops and ointments.

A Committee member questioned the use of a steroid in treating eye infections. Another member commented that with sensitization of the eye a steroid may mute the immune system response.

# Preferred Drug Program: Re-review

#### 1. Long Acting Opioids

Dr. Zimmer provided an overview of new information since the previous review of the therapeutic class. The overview included:

- New Products Nucynta ER, Conzip and tramadol ER 150mg capsule
- New Generics oxymorphone ER and tramadol ER 300mg
- New Formulations Opana ER
- Label Revision for Oxycontin

Dr. Correia stated that comparative evidence for the class is limited. Some key comparative review points were provided including adverse events, pediatric indications and comparative metabolism of the different drugs and impact on drug interactions. There is little new comparative clinical evidence since the last review and none to indicate any of the drugs offer an overall advantage within the class.

A Committee member commented that abuse of these products is epidemic and they should not be used to treat low back pain. Another member commented on recent legislation for opioids. A committee member also provided insight to how she handles pain therapy requests in her practice.

#### 2. Short Acting Opioids

Dr. Zimmer provided an overview of new information since the previous review of the therapeutic class. The overview included:

- New Product Oxecta
- Notation of removal of the Risk Evaluation and Mitigation Strategies (REMS) requirement for morphine sulfate oral solution

Dr. Correia stated that there is a wide array of products with some having alternative dosage forms and the aim would be to represent a good cross section of drugs as preferred.

#### 3. DPP-4 Inhibitors

Dr. Zimmer provided an overview of new information since the previous review of the therapeutic class. The overview included:

- New Products Jentadueto, Janumet XR and Juvisync
- Label revisions for Onglyza, Kombiglyze, Januvia and Janumet

Dr. Correia stated that there is little, if any, comparative evidence for effectiveness across the three DPP-4 inhibitors or combination products. Indirect evidence seems to indicate that they are clinically comparable in efficacy. Each drug may introduce specific concerns for patients with certain comorbidities or concurrent therapies, with none offering an overall advantage.

#### 4. GLP-1 Agents

Dr. Zimmer provided an overview of new information since the previous review of the therapeutic class. The overview included:

- New Product Bydureon
- Label revision new indication for Byetta
- Updated Practice Guidelines: American Diabetes Association Standards of Medical Care in Diabetes Position Statement
- Notation of removal of the REMS requirement for Byetta
- Revisions to the Victoza REMS

Dr. Correia stated that there are now three GLP-1s in the marketplace each with a different dosing regimen. For all three, there is a significant concern about the development of pancreatitis. Comparative effectiveness for efficacy or effectiveness between the products is quite limited. In terms of actual clinical relevance and applicability, the comparative evidence between the three products is marginal. Any of the products may have specific characteristics which may represent potential advantage or risks for certain patient with none being superior overall.

A Committee member questioned why Byetta does not include the same warnings for thyroid C- cell tumors and asked if the studies were done in humans. Dr. Correia noted the warning currently only applied to the longer acting products.

# 5. Pancreatic Enzymes

Dr. Zimmer provided an overview of new information since the previous review of the therapeutic class. The overview included:

- New Formulations Creon and Zenpep
- Notation of removal of the REMS requirement for Creon, Pancreaze, and Zenpep

Dr Correia stated that all three products contain the same three enzymes but may not be interchangeable because of slight differences in dosage or delayed release technology. Comparative evidence between the products in the class is lacking and therefore none can be classified as superior overall.

#### 6. Anti-Emetics

Dr. Zimmer provided an overview of new information since the previous review of the therapeutic class. The overview included:

- Updated Practice Guidelines: National Comprehensive Cancer Network (NCCN)
- Updated treatment recommendations
- FDA safety communications

Dr. Correia stated that no new comparative information is available since the previous review of the class.

A Committee member speculated if QT prolongation was related to high doses of the products.

#### 7. Sulfasalazine Derivatives

Dr. Zimmer provided an overview of new information since the previous review of the therapeutic class. The overview included:

New indication for Lialda

Dr Correia stated that the only new information is a new maintenance indication for Lialda for remission of ulcerative colitis (UC). Lialda now joins Asacol and sulfasalazine DR/ER as delayed release products indicated for both UC treatment and maintenance. As discussed in previous reviews these products can be categorized by indication of active disease versus maintenance treatment or by the mechanism used to deliver the active drug for the site of action. Consideration of preferred and non-preferred status should include prodrug and delayed release mechanisms as well as active and maintenance treatment indications.

#### 8. Immunomodulators - injectable

Dr. Zimmer provided an overview of new information since the previous review of the therapeutic class. The overview included:

- New Formulation Orencia
- Updated Treatment Guidelines
- FDA Safety Communication
- Label Revisions for Humira and Cimzia
- Notation of removal of the REMS requirement for Cimzia, Enbrel, Humira and Simponi

Dr. Correia stated that in general, reviews and guidelines in this clinical area consider two major subgroups of biologic drugs, Tumor Necrosis Factor (TNF) inhibitors and non-TNF biologics. The Oregon Drug Effectiveness Review Project comparative effectiveness report relevant to these drugs was updated in March of this year and findings reviewed. Evidence and current guideline indicate that TNF inhibitors seem to have better efficacy than the non-TNF biologics. However, new and previous evidence seems to indicate that anti-TNF products are associated with more serious adverse effects then the non-TNF biologics.

A Committee member commented on how the Tumor Necrosis Factor (TNF) inhibitors work better but have more side effects.

# 9. Phosphate Binders/Regulators

Dr. Zimmer provided an overview of new information since the previous review of the therapeutic class. The overview included:

- New Product Phoslyra
- New Generic calcium acetate 677mg
- Label revisions for Fosrenol and Renvela

Dr. Correia stated that there is no new comparative information between the drugs in the class to alter the previous comparative evaluation. Marginal differences are claimed for each product, efficacy versus tolerability, with none of the products demonstrating an overall advantage.

A Committee member commented on the expense of non-calcium based products and expressed concern with lanthanum use.

#### 10. Urinary Tract Antispasmodics

Dr. Zimmer provided an overview of new information since the previous review of the therapeutic class. The overview included:

- New Formulation Gelnique 3% gel
- Label revisions related to adverse events

Dr. Correia stated that there was one more additional warning added to the labeling for Vesicare regarding reported somnolence. As discussed in previous reviews of the class, clinical trials demonstrate similar efficacy and adverse effect profiles with marginal detectable differences between some selected indicators. Any of the products provide comparable modest symptomatic relief with none demonstrating an overall advantage.

#### 11. Anti-Virals – oral

Dr. Zimmer provided an overview of new information since the previous review of the therapeutic class. The overview included:

Label revisions for Famvir

Dr. Correia stated that all three drugs are effective and any may have a particular advantage for a specific use or patient population but none are superior overall.

#### 12. Beta Blockers

Dr. Zimmer provided an overview of new information since the previous review of the therapeutic class. The overview included:

- New Product Dutoprol
- Label revisions associated with adverse events and administration guidelines prior to surgery

Dr. Correia stated that good new comparative clinical information is lacking and no new evidence of overall clinical superiority to justify preferential availability of any one product in the class.

#### 13. Cholesterol Absorption Inhibitors

Dr. Zimmer provided initial review information for the bile acid sequestrants including prescribing information and clinical trials and an overview of new information since the previous review of drugs in the therapeutic class. The review also included:

- · Background on digestive process related to bile acid
- Mechanism of action, indications, adverse effects and drug interactions for bile acid sequestrants
- Clinical trials for cholestyramine
- · Label revisions for Zetia

Dr. Correia stated that these products reduce LDL cholesterol in the range of 10% to 20%; with none having any impact on HDL cholesterol. Colesevelam may be better tolerated than cholestyramine and colestipol. The cholesterol absorption inhibitors are not considered primary therapy for hyperlipidemia and should be generally used secondary to Statins.

#### 14. Fluoroquinolones - oral

Dr. Zimmer provided an overview of new information since the previous review of the therapeutic class. The overview included:

- New Generics levofloxacin 250mg, 500mg, 750mg tablets and 25mg/mL solution
- New indication for Levaquin
- Notation of removal of the REMS requirement for the majority of the products in the class
- Label revisions regarding warnings and precautions

Dr. Correia stated, as in previous reviews of the class, the oral fluoroquinolones are generally categorized into second and third generation products with second generation having good gram negative activity and third generation having better gram positive activity. As currently the case, it would be best to have both generations represented as preferred products.

#### 15. Ophthalmic Prostaglandin Agonists

Dr. Zimmer provided an overview of new information since the previous review of the therapeutic class. The overview included:

- New Product Zioptan
- New Generic latanoprost 0.005% solution

Dr. Correia stated that there was no new comparative information between the drugs in this class. Marginal differences are claimed for each product continues to balance between slight study variations in change in intraocular pressure and tolerability with none demonstrating an overall advantage.

#### 16. Ophthalmic Antihistamines

- Dr. Zimmer provided an overview of new information since the previous review of the therapeutic class. The overview included:
  - New Generic epinastine 0.05% solution

Dr. Correia stated, as in previous reviews of this class, any of the products are effective for the treatment of allergic conjunctivitis, with none demonstrating an overall advantage.

# 17. Topical Steroids - Medium Potency and Very High Potency

Dr. Zimmer noted that there was no information identified since the previous review of the therapeutic class.

Dr. Correia stated that no new clinical information is known to exist since the previous review of these classes. The goal would be to continue to provide a broad selection of products types within each potency category.

#### 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 and non-preferred products with each of the therapeutic classes under review. No official action was taken in the executive session. The executive session was recessed at 2:00 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
Alpha Reductase Inhibitors (for BPH)  Preferred Avodart, finasteride  Non-preferred Jalyn, Proscar	Approved as Recommended
Anabolic Steriods - topical  Preferred Androderm, Androgel, Testim  Non-preferred Axiron, Fortesta	Approved as Recommended
Preferred bacitracin/polymixin B, erythromycin, gentamicin, Natacyn, neomycin/gramicidin/polymyxin, polymixin/trimethoprim, sulfacetamide (solution), tobramycin  Non-preferred Azasite, bacitracin, Bleph-10, Garamycin, Ilotycin, neomycin/bacitracin/polymixin, Neosporin, Polytrim, sulfacetamide (ointment), Tobrex	Approved as Recommended
Ophthalmic Antibiotic/Steroid Combinations  Preferred Blephamide, Maxitrol (ointment), neomycin/polymixin/dexamethasone, sulfacetamide/prednisolone, Tobradex (ointment, suspension)  Non-preferred Maxitrol (suspension), neomycin/bacitracin/polymixin/HC, neomycin/polymixin/HC, Pred-G, tobramycin/dexamethasone, TobradexST, Zylet	Approved as Recommended

Long Acting Opioids	
Long Adming Opiolas	
Preferred fentanyl patch, Kadian, morphine sulfate SR (tablet)	Approved as
Non-preferred Avinza, Butrans, Conzip, Duragesic, Exalgo, morphine sulfate ER (capsule), MS Contin, Nucynta ER, Opana ER, Oramorph SR, oxycodone HCL CR, oxymorphone ER, Oxycontin, Ryzolt, tramadol ER, Ultram ER	Recommended
Short Acting Opioids	
Preferred butalbital/APAP/codeine, codeine, codeine/APAP, hydrocodone/APAP, hydrocodone/ibuprofen, morphine IR, oxycodone/APAP,tramadol	
Non-preferred butalbital compound/codeine, butorphanol NS, Cocet/Cocet Plus, Demerol, dihydrocodeine/APAP/caffeine, Dilaudid, Endocet, Endodan, Fioricet w/codeine, Fiorinal w/codeine, Hycet, hydromorphone, Ibudone, levorphanol, Lorcet/Lorcet Plus, Lortab, Magnacet, Maxidone, Meperidine, Norco, Nucynta, Opana, Oxecta, oxycodone IR, oxycodone/ASA, oxycodone/ibuprofen, oxymorphone, pentazocine/APAP, pentazocine/naloxone, Percocet, Percodan, Primalev, 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
Preferred Janumet, Janumet XR, Januvia, Jentadueto, Kombiglyze XR, Onglyza, Tradjenta  Non-preferred Junisync	Approved as Recommended
Preferred Byetta  Non-preferred Bydureon, Victoza	Approved as Recommended
Pancreatic Enzymes	
Preferred Creon, pancrelipase, Zenpep	Approved as Recommended
Non-preferred Pancreaze	

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Anti-Emetics	
Preferred	
ondansetron	Approved as
	Recommended
Non-preferred	
Anzemet, granisetron, Sancuso, Zofran, Zuplenz	
Sulfasalazine Derivatives	
Preferred	
Apriso, Asacol, Dipentum, sulfasalazine, sulfasalazine ER	Approved as
	Recommended
Non-preferred  Acadel HD, Azulfidino, Azulfidino Entab, balcalazido, Lialda, Bontaca	
Asacol HD, Azulfidine, Azulfidine Entab, balsalazide, Lialda, Pentasa	
Immunomodulators - injectable	
Preferred	
Enbrel, Humira	Approved as
	Recommended
Non-preferred	
Cimzia, Kineret, Orencia (subcutaneous), Simponi	
Phosphate Binders/Regulators	
Preferred	
calcium acetate, Eliphos, Fosrenol, Renagel, Renvela (tablet)	Approved as
	Recommended
Non-preferred	
Phoslo, Phoslyra, Renvela (powder)	
Urinary Tract Antispasmodics	
Preferred	
oxybutynin, Oxytrol, Sanctura XR, Toviaz, Vesicare	A
	Approved as Recommended
Non-preferred	Necommended
Detrol, Detrol LA, Ditropan XL, Enablex, Gelnique, oxybutynin ER,	
Sanctura, trospium	
Anti-Virals - oral	
Preferred	
acyclovir, Valtrex	Approved as
Non-preferred	Recommended
famciclovir, Famvir, valacyclovir, Zovirax	
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Data Black and	
Beta Blockers	
Preferred atenolol, atenolol/chlorthalidone, bisoprolol/HCTZ, cavedilol, labetalol, metoprolol tartrate, propranolol, propranolol/HCTZ  Non-preferred acebutolol, betaxolol, bisoprolol, Bystolic, Coreg, Coreg CR, Corgard, Corzide, Dutoprol, Inderal LA, Innopran XL, Kerlone, Levatol, Lopressor, Lopressor HCT, metoprolol succinate XL, metoprolol tartrate/HCTZ, nadolol, nadolol/bendroflumethiazide, pindolol, propranolol SA/ER, Sectral,	Approved as Recommended
Tenoretic, Tenormin, Torpol XL, timolol, Trandate, Zebeta, Ziac	
Cholesterol Absorption Inhibitors	
Preferred     colestipol (tablet), Colestid (tablet), cholestryamine, cholestryamine light,     Prevalite  Non-preferred     colestipol (granules), colestid (granules), Questran, Questran Light,     Welchol, Zetia	Approved as Recommended
Fluoroquinolones – oral	
Preferred ciprofloxacin (tablet), Cipro (suspension), levofloxacin (tablet)  Non-preferred Avelox, Cipro (tablet), ciprofloxacin ER, Factive, Levaquin, levofloxacin (solution), Noroxin, ofloxacin	Approved as Recommended
Ophthalmic Prostaglandin Agonists	
Preferred latanoprost  Non-preferred Lumigan, Travatan Z, Xalatan, Zioptan	Approved as Recommended
Ophthalmic Antihistamines	
Preferred Pataday  Non-preferred azelastine, Bepreve, Elestat, Emadine, epinastine, Lastacaft, Optivar, Patanol	Approved as Recommended

Topical Steroids – medium potency	
Preferred hydrocortisone butyrate (ointment, solution), hydrocortisone valerate, mometasone furoate	Approved as Recommended
Non-preferred Cloderm, Codran, Cutivate, Dermatop, Elocon, fluocinolone, fluticasone, hydrocortisone butyrate (cream), Luxiq, Pandel, prednicarbate	rxesommended
opical Steroids – very high potency	
Preferred     clobetasol (cream, gel, ointment, solution), halobetasol  Non-preferred     clobetasol (foam, lotion), Clobex, Cormax, Olux, Olux-E, Temovate,	Approved as Recommended
Temovate-È, Ultravate	

The meeting adjourned at 2:30 PM

Meeting Summary Posted 7/10/2012

#### 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 within the PDP. PDP drugs may still be subject to utilization management programs as noted on the preferred drug list (PDL).

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 \$8.8M. 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 8/13/2012