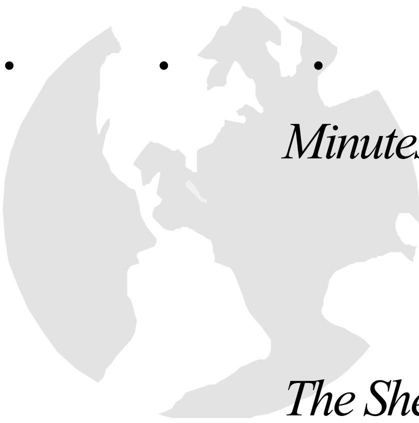
Maryland Pharmacy Program
PDL P&T Meeting



Minutes from August 19, 2010

The Sheppard Pratt Conference Center

Maryland Pharmacy Program
PDL P& T Meeting

Minutes- August 19, 2010

Attendees:

P&T Committee

Vijay Reddy (Chairperson); Marie Mackowick (Vice-Chairman); Donald Yee; Brian Pinto; Robert Lyles; Winston Wong; Mary Ellen Moran; Steven Daviss; Helen Anderson; Lisa Hadley

DHMH Staff

Athos Alexandrou (Maryland Pharmacy Program Director); Dixit Shah (Maryland Pharmacy Program Deputy Director); Alex Taylor (Division Chief, Clinical Pharmacy Services); Paul Holly; Dennis Klein; Megan Shook; Angela Chavis

ACS

Karriem Farrakhan

Provider Synergies

Gina McKnight-Smith; Jonathan Haag (Pharmacy Student Intern)

Proceedings:

The public meeting of the PDL P&T Committee was called to order by the Chairperson, Dr. Reddy, at 9:05 a.m. The meeting began with brief introductions of all the representatives including the P&T Committee members, DHMH, ACS, and Provider Synergies. The Committee then approved the minutes from the previous P&T Committee meeting held on March 3, 2010 and requested that email responses to prior questions be incorporated into the minutes (See Addendum).

Dr. Reddy then asked Mr. Taylor to provide a status update on the Medicaid Pharmacy Program. Mr. Taylor re-introduced two of the newer members to the P&T, Mrs. Helen Anderson and Dr. Lisa Hadley. He also observed a moment of silence for another new member, Dr. Renee Hilliard, who was not present due to the death of her father-in-law. Mr. Taylor re-stated the importance of the Medicaid PDL which has saved millions of

dollars on prescription drugs that have allowed the State to manage costs without reducing covered services. The failing economy has significantly reduced Maryland's revenues and increased the Medicaid Program enrollments simultaneously. He stated that there are approximately 680,000 people in the seven MCOs and about 38,000 in the Fee-for-Service (FFS) population. Mr. Taylor urged the Committee to continue to be fiscally responsible when recommending preferred status to the most cost-efficient and clinically sound therapies within the selected PDL classes.

Mr. Taylor stated that the Patient Protection and Affordable Care Act of 2010 (PPACA) included a section that affects rebates (federal and supplemental). However, the Center for Medicaid and Medicare Services (CMS) has not yet provided the regulations and rules for State Medicaid Programs to follow despite the retroactive effective date of January 1, 2010. Rebate changes include an increase in minimum federal rebate for brand name (15.1 to 23.1 percent), generic drugs (11 to 13 percent) and clotting factors/drugs approved exclusively for pediatric use (15.1 to 17.1 percent). The new legislation requires all of the increase to go to the federal government instead of being shared between the federal and state agencies. CMS has not delivered additional guidance on the status of line extensions which will include extended release formulations, but the State does expect a cost shift to occur with that as well. Lastly, the PPACA allows State Medicaid Programs to gain rebates on the prescriptions for recipients who are part of managed care organizations (MCOs). The State will continue to monitor for CMS guidance and updated information related to this health reform law and its implementation/impact on the State Medicaid Pharmacy Program.

Mr. Taylor re-iterated the minimal complexity associated with the PDL prior authorization process especially when compared to other State Medicaid programs. He also stated that the Maryland Medicaid PDL stands out with more options for preferred drug selections. The PDL is available through Epocrates. The current compliance rate is over 95% which means that most prescribers are able to find a satisfactory option for therapy. The pharmacy hotline remains active averaging about 899 calls each month with about 20% of them relating to the PDL. Mr. Taylor concluded by asking everyone to either place their cell phones on vibrate or mute and that all consumer speakers provide full disclosure prior to giving testimony.

Dr. Reddy acknowledged that it was time for the public presentation period to begin. She also reiterated the rules that the 15 pre-registered speakers must adhere to the five-minute time limit in place.

Name	Affiliation	Class/Drug of Interest
Sangjin Oh, MD	Consumer – practicing neurologist and previous consultant (ViaGen and Teva) and speaker's bureau participant (Pfizer)	MS Agents/Ampyra

Name	Affiliation	Class/Drug of Interest
Jennifer Vido	Consumer - Mid-Atlantic Region of the Arthritis Foundation	Cytokine and CAM Antagonists
Geetha Jayaram, MD	Consumer – Johns Hopkins Hospital, Director of Inpatient Short Stay Service for the Severely and Chronically Mentally Ill	Antipsychotics
Joseph Malcyzn, PharmD	Amgen	Cytokine and CAM Antagonists/Enbrel
Erin Drew, MD	GSK	Glucocorticoids, Inhaled/ Advair Long Acting Beta Agonists/ Serevent
Julie Kivior, BSN	Eli Lilly & Company – Outcomes Liaison	Platelet Aggregation Inhibitors/Effient Hypoglycemics/Insulin/Humulin and Humalog products Antipsychotics/Zyprexa all forms Stimulants and Related Agents/Strattera
Aroon Datta, RPh	Forest	SSRIs/Lexapro
Kelly Reed, PhD	URL Pharma/ARS Scientific	Anti-Hyperuricemics/Colcrys
Rodney Taylor, PharmD	Novartis	Antipsychotics/Fanapt
Anna Tallman, PharmD	Strativa	Oral Antifungals/Oravig
Romy Nocera	Acorda	MS Agents/Ampyra
Larry Ashburn	Sanofi-Aventis	Insulins/Lantus
Carla Donato, PharmD	UCB	Cytokine and CAM Antagonists/Cimzia

Name	Affiliation	Class/Drug of Interest
William Loy Yap, MD Sherwanna Clarke, PharmD	Abbott Labs	Pancreatic Enzymes/Creon Cytokine and CAM Antagonists/Humira
Kenneth Jackson, PharmD	Shionogi	Anti-Parasitics, Topical/Ulesfia

Dr. Reddy thanked the presenters for all their informative input. A presentation by the claims processor, ACS, by Dr. Karriem Farrakhan was given. After providing a handout to the Committee members, he pointed out in a chart the 756 new PDL PA requests for non-preferred drugs in the second quarter of 2010 (April through June). He also stated that the chart of the first page showed the rank order of the Top Ten PDL classes, and the new PDL category called Fibromyalgia Agents topped the list. He stated the only other significant change was the decrease in the number of non-preferred Antipsychotic PA requests. The final pages of the report identify specific drugs within the select PDL classes and the number of related PA requests.

An involved discussion ensued about a statistic related to the number of PA requests for the non-preferred Antipsychotics, the look back period for Tier 2 adjudication, step therapy in the Antipsychotics class, the use of specialist identification for psychiatrist to bypass all edits, and a special analysis being conducted through the Mental Hygiene Administration (MHA) and the Maryland Medicaid Pharmacy Program to evaluate the impact of the tiering (step therapy) and non-preferred status of antipsychotics on hospitalization rates. Mr. Alexandrou weighed in on the analysis being conducted since it is ongoing and appears to only affect about 303 individual recipients over the past eight to nine months who requested a Tier 2 or Non-Preferred antipsychotic and did not get a prior authorization or an alternative Tier 1 antipsychotic. Mr. Alexandrou re-iterated that Dr. Hepburn and MHA are going to cross check these 303 individuals with the hospitalization information to determine if their hospitalizations were related to 'denial of a Tier 2 or non-preferred antipsychotic'. Mr. Alexandrou stated there could have been other reasons for the hospitalization that were non-mental health related.

Dr. Daviss then offered a scenario where a psychiatrist colleague called him related to a denial of Fanapt where he was compelled by the call staff to 'pick something else'. After agreement by Dr. Farrakhan and Mr. Taylor that is not part of the process, Mr. Taylor asked Dr. Daviss to share the contact information for that psychiatrist with him. Dr. Daviss stated that he would provide that information to Mr. Taylor after retrieving it from his office.

Another discussion ensued about access to the 30 day emergency supply of Antipsychotics with an exchange between Dr. Daviss and Dr. Farrakhan. Dr. Daviss requested that the following question be analyzed:

For those who go to the pharmacy to get their medication and are unable to due to the need for a prior authorization and not going through the necessary steps for approval,

how many (what percentage) are actually getting the 30 day emergency supply versus leaving the pharmacy with nothing?

However, Dr. Farrakhan went on to say that data would be very convoluted because not necessarily everyone who did not get an emergency supply went without therapy. According to him, the physician may have changed the drug. Dr. Reddy stated that the pharmacist may also just send the patient away with a message to speak with the prescriber instead of giving the emergency supply. Dr. Daviss agreed with her and stated this is what he is trying to figure out.

Mr. Alexandrou stated that this is the link to the 303 recipients he referred to earlier out of the 10,000 recipients during the 8 to 9 month period of study who did not get an emergency supply or have another drug in their profile. Mr Alexandrou described the following scenarios for presentation to a pharmacy with a Tier 2 or non-preferred antipsychotic prescription:

1) Pharmacist will call prescriber who will be instructed to either call ACS for a prior authorization or switch to a Tier 1 preferred agent.

2) Pharmacist may not be able to reach the prescriber and may dispense a 30 day emergency supply.

3) Pharmacist may incorrectly state that 'Medicaid won't cover this', 'go home' or 'call your doctor'.

Dr. Daviss stated that Scenario 3 is his concern and would be a good number to track to determine how many patients are having trouble getting medication for their illness. Mr. Alexandrou re-stated that the analysis is being conducted right now and will be shared with the same group that had been convened to make some determinations at that time. Mr. Alexandrou also stated that it is premature to recommend tracking this information until we have the results from the original analysis. Once the analysis tool is fine tuned, it may not be too labor intensive to generate a report, but the State must first determine what is feasible.

Lastly, Dr. Daviss suggested that the required phone call by the pharmacist to provide the 30 day emergency supply be waived. He stated this would allow the pharmacist to dispense the medication. However, Mr. Alexandrou stated this phone call is documentation tool to ensure the pharmacist takes action. If it is removed as a requirement, at the end of the 30 days if the physician was not contacted, then there is no additional 30 day emergency supply to access. Dr. Pinto suggested moving on to the PDL Review of Therapeutic Classes since most of these questions surround claims adjudication and processes. Dr. Reddy offered thanks to Dr. Farrakhan.

Dr. Reddy then introduced the start of the therapeutic class reviews. He stated that there were 21 classes that had no recommended changes from the existing PDL. The Committee agreed to leave these categories unchanged. Immediately following were six single drug reviews of SE BPO, Exalgo, Rybix ODT, Zortress, Ampyra and Zegerid OTC. Finally, the review of the remaining 18 cateories (including two new categories)

was conducted. The following table reflects the voting results for each of the therapeutic categories:

Class	Voting Result
Alzheimers Agents	**Maintain current Preferred agents:** Aricept, Aricept ODT, Exelon, Exelon Patch, Namenda
Androgenic Agents	**Maintain current Preferred agents:** Androderm, Androgel
Antibiotics, Vaginal	**Maintain current Preferred agents:** generics (clindamycin and metronidazole vaginal gel), Cleocin, Clindesse, Vandazole
Antidepressants, Other	**Maintain current Preferred agents:** generics (bupropion IR, bupropion SR, bupropion XL, mirtazapine, trazodone, venlafaxine, venlafaxine ER tablets), Parnate (Brand Name only)*, Nardil, Venlafaxine ER Tablets (Brand Name)
Antidepressants, SSRIs	**Maintain current Preferred agents:** generics (citalopram, fluoxetine, fluvoxamine, paroxetine, sertraline), Lexapro
Antiemetics	**Maintain current Preferred agents**: generics (ondansetron, ondansetron ODT), Marinol
Antihyperuricemics	**Maintain current Preferred agents**: allopurinol, colchicine, probenecid, probenecid/colchicine
Antiparasitics, Topical	**Maintain current Preferred agents: –** generic permethrin, OTC permethrin, Eurax, Ovide (Brand Name)*, Ulesfia
Anti-Parkinson's Agents	**Maintain current preferred agents**: benztropine, levodopa/carbidopa IR and ER, ropinirole, selegiline, trihexyphenidyl, Stalevo
Antivirals, Topical	**Maintain current preferred agents**: Denavir
Atopic Dermatitis	**Maintain current preferred products**: Elidel, Protopic

Class	Voting Result
Cephalosporins and Related Agents	**Maintain current Preferred agents:** generics (amoxicillin/clavulanate susp and tab, cefaclor, cefadroxil, cefdinir, cefprozil, cefuroxime, cephalexin), Suprax
Fluoroquinolones, Oral	**Maintain current Preferred agents**: generic ciprofloxacin, Avelox
Glucocorticoids, Inhaled	**Maintain current Preferred agents**: Advair Diskus/Advair HFA, Aerobid, Aerobid-M, Flovent Diskus/Flovent HFA, Qvar, Symbicort
Hypoglycemics, Incretin Mimetics/Enhancers	**Maintain current Preferred agents**: Byetta, Januvia, Janumet, Onglyza, Symlin, Symlin Pens
Hypoglycemics, Insulins	**Maintain current Preferred agents:** Humulin, Humulin Pens, Humalog, Humalog Mix, Humalog Mix Pens, Lantus, Lantus Pens, Novolin, Novolin Pens, Novolog, Novolog Pens, Novolog Mix 70/30, Novolog Mix 70/30 Pens
Leukotriene Modifiers	**Maintain current Preferred agents:** Accolate, Singulair
Macrolides/Ketolides	**Maintain current Preferred agents:** generics (azithromycin and erythromycin)
Platelet Aggregation Inhibitors	**Maintain current Preferred agents**: generics (dipyridamole and ticlopidine), Aggrenox, Plavix
Stimulants and Related Agents	**Maintain current Preferred agents:** generics (amphetamine, amphetamine salt combo ER, dexmethylphenidate, dextroamphetamine, methylphenidate, methylphenidate ER), Concerta, Daytrana, Focalin (Brand Name)*, Focalin XR, Intuniv, Metadate CD, Methylin Chew and Sol, Strattera**, Vyvanse
Tetracyclines	**Maintain current Preferred agents**: doxycycline, minocycline, tetracycline

Single Drug Reviews	Voting Result
Acne Agents, Topical	**DO NOT ADD:** SE BPO
Analgesics, Narcotics (Long-Acting)	**DO NOT ADD:** Exalgo
Analgesics, Narcotics (Short-Acting)	**DO NOT ADD:** Rybix ODT
Immunosuppressives, Oral	**DO NOT ADD:** Zortress
MS Agents	**DO NOT ADD:** Ampyra
Proton Pump Inhibitors	**DO NOT ADD:** Zegerid OTC
Class	**Voting Result**
Analgesics/Anesthetics, Topical	**ADD:** capsaicin OTC **DO NOT ADD:** Pennsaid, Qutenza **Maintain current Preferred agents:** Lidoderm, Voltaren Gel
Antibiotics, Inhaled (NEW)	**ADD:** TOBI **DO NOT ADD:** Cayston
Antifungals, Oral	**DO NOT ADD:** Oravig **REMOVE**: Ancobon **Maintain current preferred products**: generics (fluconazole, ketoconazole, nystatin, terbinafine), GrisPeg

Class	Voting Result
Antifungals, Topical	**DO NOT ADD –** OTC (Butenafine), Bensal HP **REMOVE** – Oxistat **Maintain current Preferred products**: generics (clotrimazole Rx, nystatin-triamcinolone, clotrimazole-betamethasone, nystatin, ketoconazole, ketoconazole shampoo, econazole), OTCs (clotrimazole, miconazole, terbinafine, tolnaftate), Naftin
Antipsychotics (The P&T Committee recommended that a 2 year look back period for grandfathering be considered for this class. The State deferred action on this recommendation until review at upcoming DUR Board meeting.)	**Tier 1** **ADD –** Fanapt, Orap, Risperdal Consta **Maintain current Tier 1 Preferred products:** generics (clozapine, risperidone, amitriptyline/perphenazine, chlorpromazine, fluphenazine, fluphenazine decanoate, haloperidol, haloperidol decanoate, perphenazine, thioridazine, thiothixene, trifluoperazine), Geodon, Geodon IM, Moban, Seroquel **Tier 2** **Maintain current Tier 2 Preferred products**: Abilify, Zyprexa, Zyprexa IM **DO NOT ADD:** Zyprexa Relprevv
Antivirals, Oral	**ADD:** Valtrex (Brand name) **Maintain current Preferred agents**: acyclovir, amantadine, rimantadine, valacyclovir
Bile Salts (NEW)	**ADD:** ursodiol, URSO, URSO Forte **DO NOT ADD**: Chenodal
Bone Resorption Suppression Inhibitors	**REMOVE –** Boniva **Maintain current Preferred products:** generic alendronate, Actonel, Actonel with Calcium, Miacalcin*

Class	Voting Result
Bronchodilators, Anticholinergics	**ADD:** ipratropium/albuterol neb **Maintain current Preferred agents**: ipratropium neb, Atrovent HFA, Combivent, Spiriva
Bronchodilators, Beta Agonists	**ADD** – Proventil HFA **REMOVE** – Foradil, Serevent **Maintain current Preferred agents**: generics (albuterol, albuterol neb, terbutaline), ProAir HFA, Ventolin HFA
Cytokine and CAM Antagonists	**REMOVE –** Kineret **Maintain current Preferred agents:** Cimzia, Enbrel, Humira **DO NOT ADD –** Actemra
Intranasal Rhinitis Agents	**REMOVE –** Nasacort AQ, Nasonex, Veramyst **Maintain current Preferred products:** generics (flunisolide, fluticasone), Astelin, Astepro
NSAIDs/COX II Inhibitor	**ADD –** OTC naproxen, generic nabumetone **DO NOT ADD –** Indocin Rectal, Vimovo **REMOVE** – generic mefenamic acid **Maintain current Preferred agents**: generics (diclofenac, etodolac, fenoprofen, flurbiprofen, ibuprofen Rx, indomethacin, ketoprofen, ketorolac, meclofenamate, meloxicam, naproxen Rx, oxaprozin, piroxicam, sulindac)
Ophthalmics, Antibiotics	**ADD –** generic polymyxin/trimethoprim **Maintain current Preferred Agents –** generics (bacitracin, bacitracin/polymixin, ciprofloxacin solution, erythromycin, gentamicin, neo-poly-gram, ofloxacin, sulfacetamide, tobramycin, triple antibiotic), Tobrex Ointment, Vigamox

Class	Voting Result
Ophthalmics for Allergic Conjunctivitis	**ADD** – generic ketorolac **Maintain current Preferred agents**: generic cromolyn, OTC ketotifen, Alrex, Pataday, Patanol
Ophthalmic Anti-Inflammatories	**ADD** – generic ketorolac LS **Maintain current Preferred agents:** generics (diclofenac, flurbiprofen, fluorometholone, dexamethasone), Flarex, FML Forte, FML SOP, Lotemax, Maxidex, Pred Mild
Ophthalmics, Glaucoma	**REMOVE** – generic brimonidine P **Maintain current Preferred agents:** generics (betaxolol, brimonidine, carteolol, levobunolol, metipranolol, pilocarpine, timolol), Alphagan P (Brand only)*, Azopt, Betimol, Betoptic S, Combigan, Cosopt (Brand Name)*, Istalol, Travatan, Travatan Z, Trusopt (Brand Name)*, Xalatan
Pancreatic Enzymes	**ADD** – Pancreaze, Zenpep **Maintain current Preferred agents**: generic pancrelipase, Creon

* The State will continue to monitor the pricing of generic drug products (both new and existing) and continues to maintain autonomy to modify or adjust the PDL status of multi-source brands and/or generic drugs that may become necessary as a result of fluctuations in market conditions (e.g. changes in Federal rebates, supplemental rebates, etc.). At this time, the noted brand name drugs are part of the State's DAW-6 program.

** The P&T Committee recommended that Strattera be maintained as preferred. There is currently an AGE edit in place that requires trial of a Tier 1 preferred agent prior to adjudication of Strattera claims for patients who are 17 years and younger.

After the clinical presentation of the Antipsychotics class by Dr. Gina McKnight-Smith, Dr. Daviss asked if the State would consider extending the look back period from 120 days (previously approved by the DUR Board) to two years. Dr. Farrakhan confirmed that it is systematically feasible to do a two year look back. Dr. McKnight-Smith asked what additional clinical value is made available by having such a long look back period. Dr. Lyles and Mr. Yee stated that they have experiences where longer look back periods are in use. The Committee voted in favor of recommending an extension of the look back period to two years. Dr. Pinto added after the vote for a point of clarification, "This will be a recommendation to the DUR Board, correct?" Mr. Taylor confirmed that it would be presented to the DUR Board in approximately one and one half weeks.

At the conclusion of the therapeutic class reviews, Dr. Reddy announced the next meeting will be Tuesday, May 24, 2011 at 9am at the Sheppard Pratt Conference Center. With no further business, the meeting adjourned at 12:06 p.m.

Addendum

>>> Alex Taylor 8/13/2010 2:55 PM >>>
To: The Maryland Medicaid P&T Committee Members,

Below you will find the answers to the action items that the P&T Committee members requested from ACS at the last P&T Committee meeting.

Thanks for your service to the Maryland Medicaid patients. See you on Thursday, August 19, 2010 at 8:00 AM.

Alex

Farrakhan, Karriem
To Whom It May Concern:

In response to the questions posed to ACS during the most recent Pharmacy and Therapeutics Committee Meeting on March 2, 2010, I present the following:

During the 4th quarter of 2009, there were 2355 participants whose claims required a Tier 2 prior authorization for either Abilify or Zyprexa and 1286 (55%) of these participants received a tiering override.

Total # of paid Abilify claims for 4Q09: 14237
8% (1174 claims) of this total was tiering overrides for 1005 participants. Less than 3% (408 claims) of this total were paid emergency fills for 393 participants. Not all of the emergency fills were submitted for the full 30 day supply available to them.

Total # of paid Zyprexa claims for 4Q09: 7118
5% (349 claims) of this total was tiering overrides for 281 participants. Less than 2% (135 claims) of this total were paid emergency fills for 117 participants. Not all of the emergency fills were submitted for the full 30 day supply available to them.

Despite formulary changes that occurred from 3Q09 to 4Q09, there was no significant change in the number of claims paid for Antipsychotics from one quarter to the next:

The total # of paid Antipsychotic claims during **3Q09**: 82622

The total # of paid Antipsychotic claims during **4Q09**: 83138

This is a difference of 516 claims; an increase of less than 1%.

Thank you,

Karriem Farrakhan, PharmD, MBA

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