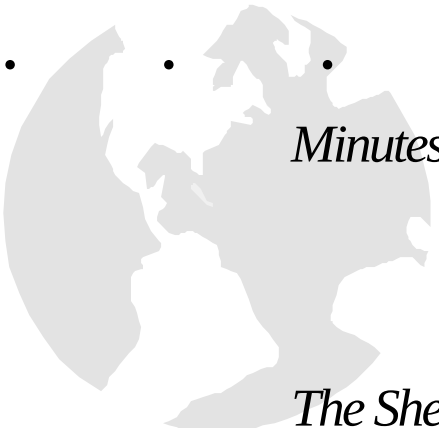
Maryland Pharmacy Program
PDL P&T Meeting



Minutes from May 24, 2011

The Sheppard Pratt Conference Center

Maryland Pharmacy Program
PDL P& T Meeting

Minutes- May 24, 2011

Attendees:

P&T Committee

Marie Mackowick (Chairperson); Lisa Hadley (Vice Chairperson); Brian Pinto; Helen Anderson; Donald Yee; Winston Wong; Mary Ellen Moran; Steven Daviss; Renee Riddix-Hilliard; Jenel Steele-Wyatt; Robert Lyles; Sharon Baucom

DHMH Staff

Athos Alexandrou (Maryland Pharmacy Program Director); Dixit Shah (Maryland Pharmacy Program Deputy Director); Alex Taylor (Division Chief, Clinical Pharmacy Services); Paul Holly (Consultant Pharmacist to Maryland Pharmacy Program)

ACS

Karriem Farrakhan; Iris Ivey

Provider Synergies/Magellan Medicaid Administration (PS/MMA)

Gina McKnight-Smith

Proceedings:

The public meeting of the PDL P&T Committee was called to order by the Chairperson, Dr. Mackowick, at 9:05 a.m. The meeting began with brief introductions of all the representatives including the P&T Committee members, DHMH, ACS, and PS/MMA. Two new physician members were introduced, Dr. Jenel Steele-Wyatt and Dr. Sharon Baucom. They serve as replacements for two retiring members, Dr. Vijay Reddy and Dr. Wallace Johnson. The Committee then approved the minutes from the previous P&T Committee meeting held on August 19, 2010 with one modification for an insertion that increases clarity (see page 5 of those minutes).

Dr. Mackowick then asked Mr. Taylor to provide a status update on the Medicaid Pharmacy Program by first offering a welcome to the two new P&T members: Dr. Sharon Baucom and Dr. Jenel Steele-Wyatt. Mr. Taylor re-stated the importance of the

Medicaid PDL which has continued to save millions of dollars on prescription drugs thus allowing the State to manage costs without reducing covered services. The failing economy continues to significantly reduce Maryland's revenues and has increased the Medicaid Program enrollments simultaneously. Unlike prior years when the funds from the American Recovery and Reinvestment Act (ARRA) were readily available to Maryland, those funds will not be available for the next fiscal year leaving the anticipated shortfall for State Fiscal Year 2012 (SFY2012) at about $1.16 billion.

Mr. Taylor emphasized that every Marylander must do their part including the various State agencies like the Maryland Medicaid Pharmacy Program and its advisory committees like the P&T Committee, Medicaid prescribers, Medicaid providers and Medicaid recipients. The P&T Committee should work collectively to make recommendations that are safe, clinically appropriate and fiscally responsible. The goal is to cast the widest net for healthcare services and pharmacy benefits to the greatest number of Medicaid recipients.

Mr. Taylor re-stated the Department's commitment to refining the PDL and P&T process. He encouraged the use of the rotation for service as an opportunity to continue to attract world-class P&T members and influx new ideas into the process. The two members who rotated off (Dr. Reddy and Dr. Johnson) will receive certificates of appreciation under the signature of the Secretary of Health, Dr. Joshua Sharfstein.

Mr. Taylor re-iterated the mechanisms to obtain a PDL prior authorization through a phone call or a fax. The pharmacy hotline remains active averaging about 1061 calls each month with about 23% of them relating to the PDL.

Dr. Mackowick acknowledged that it was time for the public presentation period to begin. As customary, there is no question/answer period, pre-selected speakers have 5 minutes with a timer.

Name	Affiliation	Class/Drug of Interest
Elizabeth Carpacio, PharmD, MD	AstraZeneca	Crestor
Ali Toumadj, PharmD	Gilead	Letairis, Cayston
Barry Tucker, PharmD	Amgen	Neulasta, Aranesp, Prolia
Steven Cavalier, MD	EMD Serono	Rebif
Sharon Hoffman, PharmD	Abbott	Androgel, Creon, Niaspan, Simcor, Trilipix, Tricor
Olga Pratt and Maurice Cuffee, MD	Bristol Myers Squibb	Onglyza, Kombiglyze, Plavix

Name	Affiliation	Class/Drug of Interest
Scott Aaronson, MD	Sunovion	Latuda
Joseph Martinez, RPh, PDE	Amylin	Byetta
Marsha Walkup, PharmD	Shire	Lialda
Tanner Odom, PharmD	Novartis	Gilenya
Joan Zhang, CRNNP, MSN, MBA	United Therapeutics	Adcirca
Dana Evans, MD	Genentech/Roche	Nutropin, Nutropin AQ, Pegasys
Carolyn Jones, PhD	Acorda Therapeutics	Ampyra
Melissa Slizewski	Consumer – National MS Society	MS Drugs

Dr. Mackowick thanked the presenters for all their input. A presentation from ACS, the claims processor, was delivered by Mrs. Iris Ivey. After providing a report to the Committee members, she pointed out in a chart the 640 PDL PA requests for non-preferred drugs in the prior quarter (4th quarter 2010). She also stated that the chart of the first page showed the rank order of the Top Ten PDL classes for number of PA requests during the fourth quarter of 2010. The numbers were consistent with those given in the last reporting period (2nd quarter 2010). There were no questions related to the ACS reports.

Mr. Taylor addressed two matters of Old Business from the previous P&T meeting. He did follow-up on issues raised by two P&T members and they appear to be resolved to the satisfaction of the Department. The second matter related to the P&T committee's suggestion for extension of the look-back period for grandfathering and use of second tier antipsychotics from 120 days to two years. After considerable discussion and consultation with the DUR Board who voted 6 to 2 in favor of maintaining the existing look back period of 120 days, the Department decided to maintain the look back period of 120 days.

Dr. Daviss raised a concern related to the presentation to the DUR Board by the Department of the underlying reasons for the P&T recommendation. He suggested that the rationale was not clearly stated to the DUR Board and the fact that the recommendation was a unanimous vote by the P&T. Dr. Daviss raised concerns related to 'poor' communication between the P&T Committee and the DUR Board. He suggested use of detailed reasons from the P&T Committee to pass on to the DUR Board. Mr. Taylor agreed to a summary level document being re-presented to the DUR Board at their next meeting provided a P&T member compose such a document. Dr. Daviss agreed to

compose the rationale in the form of a letter for the P&T recommendation to extend the look back period from 120 days to two years. This letter would then be submitted to the DUR Board. Mr. Alexandrou felt this was a serious concern related to the Department's transparency so he agreed to take this matter to the DUR Board himself on behalf of the P&T Committee.

Mr. Alexandrou, Director of the Maryland Pharmacy Program also addressed Old Business related to an internal analysis completed in collaboration with the Director of Mental Hygiene Administration (MHA), Dr. Brian Hepburn. The analysis evaluated the impact over an eight month period of the antipsychotic edits (Tier 2 and Non-Preferred). Of nearly 10,000 recipients whose claims triggered the edit (denial), the vast majority of recipients (9,697) had outcomes whereby the prescriber either obtained the necessary prior authorization for the Tier 2 or Non-Preferred drug, the prescriber switched the recipient to one of the Tier 1 Preferred drugs, or the pharmacist provided a 30 day emergency supply pending contact and/or prior authorization from the prescriber. There were 303 individuals who did not have record of receiving any kind of antipsychotic medications. These individuals were the focus of the analysis.

Dr. Hepburn and his vendor, Value Options, researched these 303 recipients to determine if not receiving any antipsychotic medication due to the edits placed on the drugs (Tier 2 or Non-Preferred) resulted in a subsequent hospitalization or other untoward effect. After analyzing the data, MHA determined that about 17 of the 303 recipients were hospitalized. However, some of the hospitalizations were several months after the claim denial took place and the investigators conducting the analysis did not conclude the hospitalization to be relevant to the edits placed on the claim.

A repeat analysis was done for the time period of July 1, 2010 through February 28, 2011. During this period, there were about 8,000 recipients whose claims triggered the edit with about 316 recipients who did not receive any antipsychotic medication. The data proved consistency between the two time periods and demonstrated again that nearly 96 percent of the recipients were able to successfully receive some form of antipsychotic therapy.

Several P&T Committee members offered feedback and questions related to the aforementioned informal analysis/study. Mr. Alexandrou stated that he is pleased with the results of this limited study and if anyone has any specific recipients that they are aware of who were hospitalized as a direct result of not receiving their antipsychotic medication due to the claims edits, then their information including Medicaid ID should be passed on to him for further evaluation. Dr. Daviss requested one additional piece of information be forwarded to the P&T Committees related to the actual number of 30 day emergency supplies from the original analysis.

Dr. Mackowick then introduced the start of the therapeutic class reviews. She stated that there were 23 classes that had no recommended changes from the existing PDL. Dr. Daviss asked why there appeared to be changes noted in RED on the slides. Dr. McKnight-Smith stated that those modifications relate to the State's Maximum Allowable Cost (SMAC) program edits on multi-source, brand-name drugs where new generics have emerged since the last review. DHMH monitors the generic price closely

and makes any necessary modifications related to PDL status of any multi-source drug and its generic at its discretion. Dr. Pinto wanted to examine the Platelet Aggregation Inhibitors related to further consideration of Effient. After making a motion with a proper second to give Effient preferred status, the vote was tied. The Chair broke the tie and the motion was defeated. The Committee agreed to leave the remaining categories unchanged as well.

Immediately following were review of nine classes with single drug reviews and 23 classes with modified recommendations from the existing PDL The following table reflects the voting results for each of the affected therapeutic categories:

Class	**Voting Result**
Analgesics, Narcotics (Long-Acting)	**Maintain current Preferred agents:** fentanyl transdermal, methadone, morphine ER, Kadian
Androgenic Agents	**Maintain current Preferred agents:** Androderm, Androgel
Angiotensin Modulator Combinations	**Maintain current preferred agents**: amlodipine/benazepril, Azor/Tribenzor, Exforge/Exforge HCT, Valturna
Antibiotics, GI	**Maintain current preferred agents**: metronidazole, neomycin, Alinia, Tindamax, Vancocin
Antibiotics, Inhaled	**Maintain current preferred products**: TOBI
Antifungals, Oral	**Maintain current Preferred agents**: fluconazole, ketoconazole, nystatin, terbinafine, GrisPeg
Antivirals, Oral	**Maintain current Preferred agents**: acyclovir, amantadine, rimantadine, Valtrex (Brand only)
Beta Blockers	**Maintain current Preferred agents:** acebutolol, atenolol, atenolol/chlorthalidone, bisoprolol, bisoprolol/HCTZ, carvedilol, labetalol, metoprolol tartrate, metoprolol tartrate/HCTZ, metoprol succinate, nadolol, nadolol/bendroflumethiazide, pindolol, propranolol, propranolol LA, sotalol/sotalol AF, timolol, Innopran XL, Levatol
BPH Agents	**Maintain current Preferred agents:** doxazosin, finasteride, tamsulosin, terazosin, Uroxatral

Class	Voting Result
Calcium Channel Blockers	**Maintain current Preferred agents**: amlodipine, diltiazem, diltiazem SR, diltiazem ER, felodipine, isradipine, nicardipine, nifedipine SR, verapamil, verapamil ER, verapamil SR
Cephalosporins and Related Agents	**Maintain current Preferred agents:** amoxicillin/clavulanate, cefaclor, cefadroxil, cefdinir, cefuroxime, cefprozil, cephalexin, Suprax
Erythropoietins	**Maintain current Preferred agents**: Aranesp, Procrit
Growth Hormones	**Maintain current Preferred agents**: Genotropin, Norditropin, Nutropin/Nutropin AQ
Hepatitis C Agents	**Maintain current Preferred agents**: ribavirin, Pegasys
Hypoglycemics, Insulins and Related Agents	**Maintain current Preferred agents**: Humalog, Humalog Mix, Humulin, Lantus, Novolin, NovoLog, NovoLog Mix
Hypoglycemics, Meglitinides	**Maintain current Preferred agents:** nateglinide, Prandin
Lipotropics, Statins	**Maintain current Preferred agents:** lovastatin, pravastatin, simvastatin, Crestor, Lescol/Lescol XL, Lipitor, Simcor
Macrolides/Ketolides	**Maintain current Preferred agents:** azithromycin, erythromycin
Pancreatic Enzymes	**Maintain current Preferred agents:** pancrelipase, Creon, Pancreaze, Zenpep
Platelet Aggregation Inhibitors	**Maintain current Preferred agents:** dipyridamole, ticlopidine, Aggrenox, Plavix
Proton Pump Inhibitors	**Maintain current Preferred agents:** lansoprazole, lansoprazole solutab, omeprazole, omeprazole OTC

Class	Voting Result
Skeletal Muscle Relaxants	**Maintain current Preferred agents:** baclofen, carisoprodol, carisoprodol compound, chlorzoxazone, cyclobenzaprine, dantrolene, methocarbamol, orphenadrine, orphenadrine compound, tizanidine tablets
Tetracyclines	**Maintain current Preferred agents:** doxycycline, doxycycline DR, doxycycline monohydrate, minocycline, tetracycline
Single Drug Reviews	**Voting Result**
Antidepressants, Other	**DO NOT ADD:** Oleptro
Antihistamines, Minimally Sedating	**DO NOT ADD:** Claritin LiquiGel
Antipsychotics	**DO NOT ADD:** Latuda *(Initially, there was a tie-vote to add this as a preferred drug by the P&T Committee. However, Dr. Daviss withdrew his motion to add this pending full class review at the next meeting.)*
Glucocorticoids, Inhaled	**DO NOT ADD:** Dulera
Ophthalmic Antibiotics	**DO NOT ADD:** Moxeza **DO NOT ADD**: Zymaxid
Ophthalmics for Allergic Conjunctivitis	**DO NOT ADD:** Lastacaft
Ophthalmics, Anti-Inflammatories	**DO NOT ADD:** Bromday
Sedative Hypnotics	**DO NOT ADD:** Silenor **DO NOT ADD**: Zolpimist
Stimulants and Related Agents	**DO NOT ADD:** Kapvay

Class	Voting Result
Acne Agents, Topical	**REMOVE:** Nuox, Clinac BPO **DO NOT ADD:** benzoyl peroxide OTC, Veltin **Other Preferred Agents**: benzoyl peroxide, clindamycin topical, erythromycin, sulfacetamide-sulfur, tretinoin, Azelex, BenzaClin, Differin (Brand only), Epiduo, Retin-A Micro
Analgesics, Narcotics, Short-Acting	**REMOVE:** Reprexain, Ibudone **DO NOT ADD:** Abstral, Zolvit **Other Preferred Agents**: APAP with codeine, ASA with codeine, butalbital/APAP/codeine/caffeine, butalbital/APAP/codeine, codeine, dihydrocodeine/ASA/caffeine, dihydrocodeine/APAP/caffeine, hydrocodone/APAP, hydrocodone/ibuprofen, hydromorphone, morphine sulfate, oxycodone, oxycodone/APAP, oxycodone/ASA, pentazocine/APAP, pentazocine/naloxone, tramadol, tramadol/APAP
Angiotensin Modulators	**ADD:** Benicar/Benicar HCT **REMOVE:** Micardis/Micardis HCT **Other Preferred Agents**: benazepril/benazepril HCT, captopril/captopril HCTZ, enalapril/enalapril HCTZ, fosinopril/fosinopril HCTZ, lisinopril/lisinopril HCTZ, losartan, losartan/HCTZ, quinapril, quinaretic, ramipril
Antibiotics, Topical (formerly Topical Impetigo Agents)	**ADD:** gentamicin, bacitracin OTC, bacitracin/polymyxin OTC **Other Preferred Agents:** mupirocin
Antibiotics, Vaginal	**REMOVE** – Clindesse Vaginal **Other Preferred agents:** clindamycin vaginal, metronidazole vaginal, Cleocin Ovules, Vandazole Vaginal

Class	Voting Result
Anticoagulants (formerly Anticoagulants, Injectable)	**ADD –** warfarin, Lovenox (Brand only) **DO NOT ADD –** Pradaxa **REMOVE** – enoxaparin (generic only), Arixtra **Other Preferred agents:** Fragmin
Antifungals, Topical	**DO NOT ADD –** Nuzole, Pediaderm AF, Ketocon Plus **REMOVE** – Naftin, Lamisil Solution **Other Preferred agents:** clotrimazole OTC, clotrimazole Rx, clotrimazole/betamethasone, econazole, ketoconazole, miconazole OTC, nystatin, nystatin/triamcinolone, terbinafine OTC, tolnaftate OTC
Antiemetic/Antivertigo Agents (formerly Antiemetics, Oral)	**DO NOT ADD –** granisetron IV, trimethobenzamide IM and oral, Emend IV, Aloxi IV, Zuplenz **ADD –** Emend oral **Other Preferred agents**: dimenhydrinate, meclizine, metoclopramide oral and inj, ondansetron, ondansetron ODT, prochlorperazine (all forms), promethazine (all forms), Marinol (Brand only), Metozolv ODT, Scopace, TransDerm Scop
Antimigraine Agents	**DO NOT ADD –** Cambia **REMOVE –** Maxalt, Maxalt MLT **Other Preferred agents –** sumatriptan, Relpax
Antiparasitics, Topical	**REMOVE -** Ulesfia **DO NOT ADD –** Natroba **Other Preferred agents:** permethrin OTC, permethrin Rx, Eurax, Ovide (Brand only)

Class	Voting Result
Antivirals, Topical	**ADD –** Abreva, Zovirax Ointment **DO NOT ADD –** Xerese **Other Preferred agents**: Denavir
Bladder Relaxants	**DO NOT ADD –** trospium immediate-release **REMOVE –** Enablex, Gelnique **Other Preferred agents**: oxybutynin, Toviaz, Vesicare
Bone Resorption Suppression Agents	**REMOVE**– Actonel, Actonel with Calcium **DO NOT ADD** – Atelvia, Prolia **Other preferred products**: alendronate, Miacalcin (Brand only)
Colony Stimulating Factors	**REMOVE** –Leukine **Other Preferred products**: Neupogen
Fluoroquinolones, Oral	**ADD –** Levaquin **REMOVE** - Avelox **Other Preferred products:** ciprofloxacin
Hypoglycemics, Incretin Mimetics/Enhancers	**ADD –** Kombiglyze XR **REMOVE –** Januvia, Janumet **Other Preferred products:** Byetta, Onglyza, Symlin
Hypoglycemics, TZDs	**REMOVE–** ActoPlusMet, ActoPluxMet XR, Avandamet, Avandaryl, Duetact **Other Preferred products:** Actos, Avandia
Immunosuppressives, Oral	**REMOVE** – cyclosporine modified (*State later modified the status of this multi-source product prior to July 1, 2011 PDL implementation*) **Other Preferred agents**: azathioprine, cyclosporine modified, mycophenolate mofetil, Prograf (Brand only), Rapamune, Sandimmune

Class	Voting Result
Lipotropics, Other	**REMOVE –** colestipol, Antara **Other Preferred agents –** cholestyramine, gemfibrozil, Niacor, Niaspan, Tricor, Trilipix
MS Agents	**ADD –** Ampyra (*Added by recommendation of P&T Committee*), Avonex **DO NOTADD –** Gilenya **REMOVE –** Rebif **Other Preferred agents:** Betaseron, Copaxone
PAH Agents, Oral	**ADD** – Adcirca **Other Preferred agents**: Letairis, Revatio, Tracleer, Ventavis
Phosphate Binders	**REMOVE –** Fosrenol **Other Preferred agents:** PhosLo, Renagel
UC Agents	**ADD –** Apriso **REMOVE** – Asacol HD **Other Preferred agents:** balsalazide, sulfasalazine, Asacol, Canasa

~ 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.).

After the conclusion of the review of the therapeutic classes, Dr. Mackowick addressed two remaining items of business: the selection of a new Vice-Chair for the P&T Committee and confirmation of the next meeting date. Two physicians volunteered to serve as the Vice-Chair: Dr. Hadley and Dr. Daviss. A ballot was generated for the voting P&T members. As the votes were being cast pending the return of one P&T member who had stepped out of the room for moment, Dr. Mackowick addressed the next meeting date. The Committee confirmed Thursday, November 3, 2011 as their next meeting date to be held at the usual location, Sheppard Pratt Conference Center. The voting resulted in the selection of Dr. Lisa Hadley as the Vice Chairman.

Dr. Daviss asked Dr. McKnight-Smith how many States were participating in the TOP$ multi-state pool. Dr. McKnight-Smith confirmed there are eight participating states. He mentioned that all of the States have posted minutes from their P&T meetings except Maryland. Mr. Taylor stated that not all states are congruent in how they administer their PDLs or the administrative policies that govern the posting of information. Dr. Daviss asked to make a motion to have the minutes posted, but Mr. Alexandrou stated that is a Departmental matter that is being reviewed by the legal advisors at this time. Dr. Daviss asked for a report at the next P&T meeting that states the guidance from the Attorney General's office on this matter. Mr. Alexandrou agreed to address that for the next meeting.

Another issue was raised related to the size of the binders and the possibility of going green through the use of disc. Dr. Mackowick did a brief poll to determine if any P&T member objected to receiving a disc instead of a binder. There were no objections raised so the Committee members will receive discs going forward.

With no further business, the meeting adjourned at 12:30 pm.

M E M O R A N D U M
TO: DUR COMMITTEE MEMBERS
FROM: STEVEN DAVISS, ON BEHALF OF P&T COMMITTEE MEMBERS
DATE: 5/31/2011

Last August the P&T Committee voted unanimously to extend the look-back period to two years for determining whether a patient prescribed an antipsychotic medication was deemed to be "drug-naive." The P&T Committee deliberated for some time on a number of reasons, pro and con, before all members voted to extend the look-back period.

We later heard that the DUR Board voted 6-2 against our proposal. We also heard that all the points we made were not transmitted to the committee, nor was the fact that the P&T vote was unanimous.

At our meeting last week, we discussed this again and decided to write a memo to DUR explaining this in more detail. We feel that if the reasons were made more clear, the DUR members would hopefully vote to support the P&T members on this issue. Below is the background on this issue.

In 2009, MMPP began a tiering system within the PDL such that patients requiring antipsychotics but never having been treated with antipsychotics in the past would be required to go through step therapy, thus using a Tier 1 drug for at least 6 weeks before being allowed to use a Tier 2 drug without having to obtain a prior authorization. Those patients who *have* in the past received Tier 1 antipsychotics *could* be prescribed Tier 2 antipsychotics without a prior authorization. Unfortunately, the vote for this tiering system came at the end of a long session, members had to leave because it was after noon, and there was not much time for discussion. As a result, the definition of “in the past”, also called the “look-back period,” came to be 90 days, later extended to 120 days by DUR in 2009.

Last year, we discussed making the look-back period forever, so that if the patient had ever been on a Tier 1 agent, they would qualify for Tier 2. As a concession to MMPP, we decided to request that the look-back period be changed to two years, rather than forever. Here are the reasons in support of extending the look-back:

- Patients do not become “drug-naive” just because more than four months has elapsed since their last antipsychotic was filled.
- Patients would not have to repeat a Tier 1 drug that in the past had resulted in inefficacy, adverse effects, or intolerance.
- P&T members felt it made no clinical sense to ignore prescription data beyond an arbitrarily chosen 90 or 120 days.
- One P&T member from Kaiser commented that within their large system, they look-back to all the data available, which can be 5 years or more.
- Another member noted that a two-year look-back is consistent with what the Maryland Health Information Exchange and SureScripts are doing.
- ACS has confirmed that they could make this change in their programming with ease

and without any required changes to their contract with the state.

On behalf of the members of the P&T Committee, we ask the members of the DUR Board to consider making this change in the look-back period to at least two years.

Thank you.