Maryland Pharmacy Program
PDL P&T Meeting

Minutes from May 7, 2015

UMBC Research and Technology Park

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Attendees:

P&T Committee

Jenel Steele Wyatt (Chairperson); Zakiya Chambers (Vice Chairperson); John Boronow; Helen Lann; Evelyn White Lloyd; Marie Mackowick; Brian Pinto; Anna Schor; Karen Vleck

Department of Health and Mental Hygiene (DHMH)

Athos Alexandrou (Maryland Pharmacy Program Director); Dixit Shah (Maryland Pharmacy Program Deputy Director); Renee Hilliard (Division Chief, Clinical Pharmacy Services), Mona Gahunia (Chief Medical Officer); Lisa Burgess (Maryland Pharmacy Program Child Psychiatrist); Paul Holly (Consultant Pharmacist to Maryland Pharmacy Program); Dennis Klein (Maryland Pharmacy Program Pharmacist)

Xerox

Karriem Farrakhan, PharmD, MBA

Health Information Designs (HID)

Rachel Boyer, PharmD, BCPS; Naana Osei-Boateng, PharmD

Provider Synergies/Magellan Medicaid Administration (PS/MMA)

Matthew Lennertz, PharmD, MS

Proceedings:

The public meeting of the PDL P&T Committee was called to order by the Chairperson, Dr. Steele Wyatt, at 9:00 a.m. The meeting began with brief introductions of all the representatives including the P&T Committee members, DHMH, and PS/MMA. The Committee then approved the minutes from the previous P&T Committee meeting held on November 6, 2014.

Dr. Steele Wyatt then asked Dr. Hilliard to provide a status update on the Maryland Medicaid Pharmacy Program (MMPP). Dr. Hilliard explained that the PDL is in its twelfth year and has saved over one hundred million dollars on prescription drugs thus allowing the State to manage costs without reducing covered services. The Committee

was reminded that the Program's goal is to provide the safest, clinically sound and most cost effective medications to Maryland Medicaid members.

Dr. Hilliard stated that last meeting she shared that naloxone was carved out of the HealthChoice managed care benefit and covered by Medicaid fee-for-service. She then stated that on January 1st, the remaining substance use disorder medications were also carved out in the same manner as the mental health drugs and antiretrovirals. These drugs include opioid antagonists, opioid partial agonists, alcohol deterrents, and smoking cessation agents. Dr. Hilliard mentioned that the transition to the Medicaid fee-for-service preferred drugs from the HealthChoice formulary drugs went smoothly including the transition of buprenorphine/naloxone tablets to Suboxone film.

Dr. Hilliard explained that the landscape for hepatitis C medications is still changing since the mention of Harvoni at the last meeting with the approval of another interferon free regimen in Viekira Pak. She explained that the committee will determine the status of Harvoni and Viekira Pak in the hepatitis C class today and reminded everyone that DHMH has established clinical criteria to ensure the safe and appropriate use of these medications. The criteria can be used by both the HealthChoice Managed Care Organizations (MCOs) and Medicaid fee-for-service.

Dr. Hilliard stated that during the last two meetings updates were given on MMPP's progress in changing the pharmacy reimbursement methodology to utilize the National Average Drug Acquisition Cost (NADAC). She explained that the NADAC was designed to create a national benchmark that is reflective of the prices paid by retail community pharmacies to acquire medications. She stated that the results of the fiscal impact analysis revealed that utilizing actual acquisition costs with an enhanced dispensing fee would be overall cost neutral to the state. As a result, MMPP conducted a pharmacy stakeholders meeting to present the results with an accompanying comment period that ended on April 20th of 2015. At this time, MMPP is still evaluating the feedback from the stakeholders.

Dr. Hilliard reiterated the mechanism to obtain a PDL prior authorization (PA) is less cumbersome than many other PA processes. Maryland Medicaid's PDL provides more options than many other states and the private sector. The PDL is also accessible through Epocrates. More importantly, prescribers are cooperating with the PDL and current compliance is over 95.5%.

The pharmacy hotline remains active averaging about 2390 calls each month with about 6% of them relating to the PDL. Dr. Hilliard thanked the Committee for their dedication and commitment to serving the citizens of the State of Maryland.

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

Name	Affiliation	Class/Drug of Interest
Olivia Lee, PharmD	AbbVie Inc	Viekira Pak
Craig Sponseller, MD	Kowa Pharmaceuticals America Inc	Livalo
Emily Holmes, MBA	Reckitt Benckiser Pharmaceuticals, subsidiary of Indivior PLC	Suboxone Sublingual Film
Jeffery Olson, PharmD	Gilead Sciences	Harvoni
Contessa Fincher, PhD, MPH	Teva Pharmaceuticals Industry, Ltd	Copaxone, Granix
Anne Cannon, BSN, RN, CDE, MBA Charles DiPaula, PharmD	Novo Nordisk Inc	Victoza, Levemir, Norditropin FlexPro
Nicole K. Becker, PhD Christine Venuti, PharmD	AstraZeneca Pharmaceuticals	Movantik, Farxiga, Xigduo,
Greg Kitchens, PharmD	Artia Solutions	Opsumit
Tanner Odom, PharmD	Biogen Pharmaceuticals	Plegridy
PhillipWiegand, PharmD, MS	Janssen Scientific Affairs	Xarelto, Invokana, Invokamet
Julie Thompson, PhD	Genzyme Corp	Aubagio
Pallav Raval, PharmD, MBA	Novartis Pharmaceuticals	Gilenya, Cosentyx

Following the speakers, Dr. Karriem Farrakhan from Xerox, the claims processor, presented the prior authorization report. He stated that in the first quarter of 2015, there were 959 new prior authorizations (PAs) which was an increase from previous quarters. The influx of PAs was due to 393 PAs for drugs in the opiate dependence treatments class which was carved out of the HealthChoice MCO's drug coverage along with the other substance use disorder drugs on January 1st, 2015. The opiate dependence treatments class was responsible for the most PAs and the rest of the top 10 classes in decreasing order of PAs are: Long Acting Analgesic Narcotics, Anticonvulsants, Neuropathic Pain, Stimulants and Related Agents, Antipsychotics, Hepatitis C Agents, Phosphate Binders and Related Agents, Sedative/Hypnotics, and Beta Blockers. The top ten therapeutic classes comprise about 95% of PA's. Dr. Boronow asked if there were any requests for drugs in the Multiple Sclerosis Agents class. Dr. Farrakhan said that there were no requests.

Dr. Steele Wyatt stated that there were 35 classes that had no recommended changes from the existing PDL. Dr. Steele Wyatt also stated that Dr. Pinto would recuse himself should any conversation arise in the review of the Bladder Relaxant Preparations, Oral Immunosuppressives, Growth Hormones, and Insulins and Related Hypoglycemics classes due to a potential conflict of interest. Following the review, Dr. Pinto asked if there was a strategy in place for the Opiate Dependence Agents class since there was a great deal of PAs in the class. Dr. Lennertz responded that the high number of PAs was a result of the Substance Use Disorder carve out which resulted in a larger population than previously included under the PDL in this class. This resulted in many new patients

requesting the medications for the first time. Dr. Lennertz explained that MMPP was aware of the potential for an increase in PAs and tried to facilitate a smooth transition.

Dr. Wyatt then said that since no motions were made in regards to specific recommendations, the recommendations in the 35 classes were approved (listed below).

Class	Voting Result
Analgesics, Narcotics (Long Acting)	**Maintain current preferred agents:** generics (fentanyl patch, methadone, morphine sulfate SR), Kadian
Androgenic Agents	**Maintain current preferred agents:** testosterone gel
Angiotensin Modulators	**Maintain current preferred agents:** generics (benazepril, benazepril/HCTZ, captopril, captopril/HCTZ, fosinopril, fosinopril/HCTZ, irbesartan, irbesartan/HCTZ , lisinopril, lisinopril/HCTZ, losartan, losartan/HCTZ, quinapril, quinapril/HCTZ, ramipril, telmisartan, telmisartan/HCTZ, valsartan, valsartan/HCTZ)
Antibiotics, GI	**Maintain current preferred agents:** generics (metronidazole tablets, neomycin, vancomycin), Alinia
Antibiotics, Topical	**Maintain current preferred agents**: generics (bacitracin OTC, bacitracin/polymyxin OTC, gentamicin, mupirocin ointment, triple antibiotic OTC)
Antibiotics, Vaginal	**Maintain current preferred agents**: generics (clindamycin, metronidazole vaginal), Cleocin ovule
Anticoagulants	**Maintain current preferred agents**: generics (enoxaparin, warfarin), Fragmin
Antiemetic/Antivertigo Agents	**Maintain current preferred agents**: generics (dimenhydrinate, dimenhydrinate OTC, meclizine, meclizine OTC, metoclopramide, ondansetron, prochlorperazine, promethazine) Emend capsules, TransDerm Scop

Class	Voting Result
Antifungals, Topical	**Maintain current preferred agents**: generics clotrimazole, clotrimazole OTC, clotrimazole/betamethasone, econazole, ketoconazole cream, ketoconazole shampoo, miconazole OTC, nystatin, nystatin/triamcinolone, terbinafine OTC, tolnaftate OTC)
Anti-Migraine Agents	**Maintain current preferred agents**: generics (rizatriptan, sumatriptan), Relpax
Antiparasitics, Topical	**Maintain current preferred agents:** generics (permethrin, permethrin OTC, piperonyl/pyrethrins OTC, piperonyl/pyrethrins/permethrin OTC), Ulesfia
Antivirals, Oral	**Maintain current preferred agents**: generics (acyclovir, rimantadine, valacyclovir)
Antivirals, Topical	**Maintain current preferred agents:** generics (acyclovir ointment), Abreva OTC, Denavir
Benign Prostatic Hyperplasia Treatments	**Maintain current preferred agents:** generics (alfuzosin, doxazosin, finasteride, tamsulosin, terazosin)
Bladder Relaxant Preparations	**Maintain current preferred agents:** generics (oxybutynin, oxybutynin ER), Toviaz
Bone Resorption Suppression and Related Agents	**Maintain current preferred agents:** generics (alendronate tablets, calcitonin nasal), Fortical
Calcium Channel Blockers	**Maintain current preferred agents:** generics (amlodipine, diltiazem, nicardipine, nifedipine ER, verapamil, verapamil ER), Cardizem LA
Cephalosporin and Related Agents	**Maintain current preferred agents:** generics (amoxicillin/clavulanate, cefaclor, cefaclor ER, cefadroxil capsules, cefdinir, cefprozil, cefuroxime, cephalexin), Suprax capsules and suspension
Erythropoietins	**Maintain current preferred agents**: Aranesp, Procrit

Class	Voting Result
Fluoroquinolones, Oral	**Maintain current preferred agents**: generics (ciprofloxacin tablets, levofloxacin tablets)
Gastrointestinal Motility, Chronic	**Maintain current preferred agents:** Amitiza, Linzess
Growth Hormones	**Maintain current preferred agents**: Genotropin, Norditropin, Nutropin, Nutropin AQ
Hypoglycemics, Insulins and Related Agents	**Maintain current preferred agents**: Humalog, Humulin, Lantus, Levemir, Novolin, Novolog
Hypoglycemics, Meglitinides	**Maintain current preferred agents**: generics (nateglinide, repaglinide)
Hypoglycemics, SGLT2 inhibitors	**Maintain current preferred agents:** Invokana (Step Therapy), Invokamet (Step Therapy)
Hypoglycemics, TZDs	**Maintain current preferred agents**: generics (pioglitazone, pioglitazone/glimepiride)
Immunosuppressives, Oral	**Maintain current preferred agents**: generics (azathioprine, cyclosporine, cyclosporine modified, mycophenolate mofetil, sirolimus, tacrolimus), Rapamune solution, Sandimmune solution
Multiple Sclerosis Agents	**Maintain current preferred agents**: Avonex, Betaseron, Copaxone 20mg, Rebif
Opiate Dependence Treatments	**Maintain current preferred agents**: generics (buprenorphine, naloxone, naltrexone), Suboxone film
Pancreatic Enzymes	**Maintain current preferred agents**: generics (pancrelipase), Creon, Zenpep
Phosphate Binders and Related Agents	**Maintain current preferred agents**: generics (calcium acetate), Calphron OTC
Platelet Aggregation Inhibitors	**Maintain current preferred agents**: generics (clopidogrel, dipyridamole, ticlopidine), Aggrenox

Class	Voting Result
Pulmonary Arterial Hypertension, Oral and Inhaled Agents	**Maintain current preferred agents**: generics (sildenafil), Letairis, Tracleer, Ventavis, Revatio suspension
Skeletal Muscle Relaxants	**Maintain current preferred agents**: generics (baclofen, carisoprodol 350mg, chlorzoxazone, cyclobenzaprine, dantrolene, methocarbamol, orphenadrine, tizanidine tablets)
Tetracyclines	**Maintain current preferred agents:** generics (doxycycline hyclate, doxycycline monohydrate tablets, doxycycline monohydrate 50mg and 100mg capsules, minocycline capsules, tetracycline)

Immediately following were reviews of 15 classes with modified recommendations from the existing PDL and reviews of 8 classes with single drug reviews. Dr. Steele Wyatt indicated that Dr. Pinto would recuse himself should any conversation arise in the Beta Blockers and Incretin Mimetic and Enhancer Hypoglycemics classes due to a potential conflict of interest. The following table reflects the voting results for each of the affected therapeutic categories:

Class	Voting Result
Acne Agents, Topical	**ADD:** erythromycin/benzoyl peroxide **REMOVE**: benzoyl peroxide gel, Retin-A **Other preferred agents:** generics (benzoyl peroxide OTC, clindamycin, erythromycin, tretinoin), Azelex, Differin cream, Differin lotion
Analgesics, Narcotics (Short Acting)	**REMOVE:** hydrocodone/apap solution, oxycodone concentrated solution **Other preferred agents:** generics (apap/codeine, butalbital/apap/codeine/caffeine, butalbital/asa/codeine/caffeine, codeine tablets, hydrocodone/apap, hydrocodone/ibuprofen, hydromorphone tablets, morphine sulfate tablets, morphine sulfate solution, oxycodone capsules, oxycodone tablets, oxycodone solution, oxycodone/apap, tramadol, tramadol/apap)

Class	Voting Result
Angiotensin Modulator Combinations	**REMOVE:** Azor, Tribenzor **Other preferred agents:** generics (amlodipine/benazepril, amlodipine/valsartan, amlodipine/valsartan/HCTZ)
Antibiotics, Inhaled	**ADD:** Bethkis, Kitabis Pak **REMOVE:** tobramycin inhalation solution **Other preferred agents:** Tobi Podhaler (Step Therapy)
Antifungals, Oral	**ADD:** clotrimazole troches **Other preferred agents**: generics (fluconazole, griseofulvin suspension, ketoconazole, nystatin suspension and tablets, terbinafine)
Beta Blockers	**ADD:** metoprolol succinate XL **REMOVE:** Toprol XL **Other preferred agents:** generics (atenolol, atenolol/chlorthalidone, bisoprolol/hctz, carvedilol, labetalol, metoprolol tartrate, nadolol, pindolol, propranolol, propranolol/HCTZ, propranolol LA, sotalol, sotalol AF)
Colony Stimulating Factors	**ADD:** Granix **Other preferred agents**: Neupogen
Hepatitis B Agents	**ADD:** Baraclude, Epivir HBV, Hepsera
Hepatitis C Agents	**ADD:** Harvoni, Viekira Pak **Other preferred agents:** generics (ribavirin) Pegasys, Peg-Intron, Sovaldi
Hypoglycemics, Incretin Mimetics and Enhancers	**ADD:** Bydureon **Other preferred agents**: Byetta, Januvia, Janumet, Janumet XR, Jentadueto, Tradjenta, Symlin

Class	Voting Result
Lipotropics, Other	**ADD:** Colestipol **Other preferred agents**: generics (cholestyramine, fenofibric acid, fenofibrate tablets, gemfibrozil, niacin ER), Niacor
Lipotropics, Statins	**REMOVE:** fluvastatin, Lescol XL, Simcor **Other preferred agents:** generics (atorvastatin, lovastatin, pravastatin, simvastatin)
Macrolides/Ketolides	**ADD:** clarithromycin tablets **Other preferred agents**: generics (azithromycin, erythromycin base), E.E.S., EryPed, Ery-Tab, Erythrocin
Proton Pump Inhibitors	**REMOVE:** lansoprazole solution, omeprazole solution **Other Preferred Agents:** generics (lansoprazole, omeprazole, pantoprazole), Prevacid Solutab, Protonix suspension
Ulcerative Colitis Agents	**REMOVE:** Delzicol **Other Preferred Agents:** generics (balsalazide, sulfasalazine, sulfasalazine DR), Apriso, Canasa
Single Drug Reviews	**Voting Result**
Antiparkinson's Agents	**DO NOT ADD:** Rytary
COPD Agents	**DO NOT ADD:** Incruse Ellipta, Spiriva Respimat
Cytokine and CAM Antagonists	**DO NOT ADD:** Cosentyx
Glucocorticoids, Inhaled	**DO NOT ADD:** Arnuity Ellipta, Asmanex HFA
Ophthalmics, Anti-Inflammatories	**DO NOT ADD:** Iluvien
Ophthalmics for Allergic Conjunctivitis	**ADD:** Pazeo

Single Drug Reviews	Voting Result
Sedative/Hypnotics	**DO NOT ADD:** Belsomra
Stimulants and Related Agents	**DO NOT ADD:** Evekeo

~ 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.).

During the review of the Hepatitis C Agents class, Dr. Schor asked why there were PAs for Harvoni but not Viekira Pak. Dr. Lennertz said that both products were non reviewed so nothing was done by MMPP to promote one drug over the other. Dr. Lennertz indicated that prescribers may prefer prescribing Harvoni over Viekira Pak but he didn't want to speculate on their reasoning for the preference. Dr. Schor suggested that Harvoni may have more PAs because it is indicated for multiple genotypes. Dr. Lennertz explained that one of the ingredients in Harvoni can be used for multiple genotypes but Harvoni is not indicated multiple genotypes. Dr. Hilliard added that it is more cost effective to have Harvoni and Viekira Pak preferred and allow prescribers the choice of the two drugs. Dr. Schor indicated that she understood and agreed with the recommendation.

During the single drug review of Spiriva Respimat, Dr. Pinto asked if Spiriva was preferred. Dr. Lennertz stated that Spiriva HandiHaler is currently preferred. Dr. Pinto said that he presumed the non-preferred recommendation was due to the price and Dr. Lennertz confirmed.

During the single drug review of Iluvien, Dr. Pinto asked if it would be necessary to get a PA before the procedure since it is an intravitreal implant. Dr. Hilliard stated that a PA would be necessary if the doctor writes a prescription. Dr. Pinto asked if a PA would be needed if there wasn't a prescription by submitting the claim through the medical benefit. Mr. Alexandrou stated that if the drug is submitted through the medical benefit it would not need a PA.

During the single drug review of Belsomra, Dr. Boronow asked if the review process was the simple PA form or if there were additional clinical criteria on Belsomra. Dr. Hilliard said that additional clinical criteria must be met and read the criteria of a diagnosis of insomnia, no history of narcolepsy, and a prior trial of one of the following: zolpidem, zaleplon, triazolam, temazepam, flurazepam or chloral hydrate. Dr. Boronow asked how the PA could be completed. Dr. Hilliard stated that it could be completed by a telephone call or faxed form.

After the drug reviews, Dr. Wyatt stated that her time as the chairperson had come to an end. She then asked vice chairperson Chambers if she would serve as the chair. Dr. Chambers agreed and there were no objections. Dr. Wyatt then asked for volunteers for

the vice chairperson position. Since no one volunteered, Dr. Wyatt volunteered to be the vice chairperson and there were no objections.

The next meeting is scheduled for November 5th, 2015. With no further business, the public meeting adjourned at 10:58 a.m.