Maryland Pharmacy Program
PDL P&T Meeting

Minutes from November 3, 2016

UMBC Research and Technology Park

MARYLAND
Department of Health and Mental Hygiene

Maryland Pharmacy Program
PDL P&T Meeting

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Attendees:

P&T Committee

Zakiya Chambers (Chairperson); Jenel Steele Wyatt (Vice Chairperson); Esther Alabi; Sharon Baucom; Kim Leah Bright; Damean Freas; Amol Joshi; Evelyn White Lloyd; Marie Mackowick; Emily Pherson; Karen Vleck

Department of Health and Mental Hygiene (DHMH)

Athos Alexandrou (Maryland Pharmacy Program Director); Dixit Shah (Maryland Pharmacy Program Deputy Director); Paul Holly (Consultant Pharmacist to Maryland Pharmacy Program); Dennis Klein (Maryland Pharmacy Program Pharmacist); Seema Kazmi (Maryland Pharmacy Program Pharmacist)

Xerox

Karriem Farrakhan PharmD; John LaFranchise, Sr., RPh

Provider Synergies/Magellan Health/Medicaid Administration (MH/MMA)

Anju Harpalani, PharmD MBA; Nina Bandali, PharmD

Proceedings:

The public meeting of the PDL P&T Committee was called to order by the Vice Chairperson, Dr. Jenel Steele Wyatt, at 9:00 a.m. The meeting began with brief introductions of all the representatives including the P&T Committee members, DHMH, Xerox, and Provider Synergies/Magellan Health/Medicaid Administration. The Committee approved the minutes from the previous P&T Committee meeting held on May 5, 2016.

Dr. Wyatt then asked Mr. Alexandrou to provide a status update on the Medicaid Pharmacy Program. Mr. Alexandrou, the Director of the Maryland Medicaid Pharmacy Program stated that this meeting marks the thirteenth year of Maryland's Preferred Drug List (PDL) and has saved tens of millions of dollars in expenditures for prescription drugs due to the Preferred Drug List. These savings have allowed the State to manage costs without reducing covered services for Medicaid recipients. Mr. Alexandrou further reminded the Committee that the Program's goal is to provide the safest, clinically sound and most cost effective medications to Maryland Medicaid members.

Mr. Alexandrou recalled mentioning at the last meeting that the State of Maryland is experiencing an opioid addiction and overdose epidemic. As part of the State's comprehensive approach to combatting this epidemic, the Department has been working with the eight Medicaid Managed Care Organizations in Maryland to implement minimum standards that will be applied by both the fee-for-service Program and the Managed Care Organizations to ensure the State addresses this epidemic.
These standards will be implemented no later than July 1st, 2017. These standards will include coverage of non-opioids to be considered first-line treatment for chronic pain and prior authorizations for all long-acting opioids, fentanyl, methadone for pain, and any opioid prescription that results in a patient exceeding 90 morphine milligram equivalents (MME) each day. In addition, a standard 30-day quantity limit for all opioids will be set at or below 90 MME.

Mr. Alexandrou further explained that over the last two years, the Department has been working towards changing the pharmacy reimbursement methodology to utilize National Average Drug Acquisition Cost (NADAC). The NADAC was developed by CMS and was designed to create a national benchmark that reflects the prices paid by retail community pharmacies to acquire prescription and some over-the-counter outpatient medications. In January of this year, the Centers for Medicaid and Medicare Services published the final rule which implements provisions of the Affordable Care Act pertaining to Medicaid reimbursement for Covered Outpatient Drugs. States must ensure that their reimbursement methodologies, as they relate to ingredient costs and professional dispensing fees, are in-line within the final rule. He further stated that their team has selected a vendor to help the State navigate through the multiple provisions of the rule and be ready to implement the requirements of the federal ruling by April 2017. The Department has also been in discussions with their point-of-sale claims processor, Xerox, in order to identify the changes that must be made to the system in order to comply with the federal requirements.

Mr. Alexandrou emphasized that the prior authorization process is quick, simple, and significantly less cumbersome than many other prior authorization processes. The Preferred Drug List stands out due to more options for preferred drugs being provided

and that for the last quarter; prescribers achieved a 92.7% compliance rate with the Preferred Drug List. Mr. Alexandrou reminded everyone that the Preferred Drug List remains accessible on the Maryland Pharmacy Program's website and through Epocrates. In reference to Epocrates, Mr. Alexandrou informed that the State was notified in August of this year that the contract with them will not be renewed and that by sometime in early 2017, Epocrates will stop publishing the Maryland Medicaid Preferred Drug List. The Department is currently in discussions with other on-line formulary vendors, in order to determine the next best alternative and more information will be provided at the next P&T meeting.

The pharmacy hotline remains active, answering over 2,000 calls each month. Approximately 4.6% of these of these calls pertain to the Preferred Drug List. Mr. Alexandrou concluded by thanking all of the Committee members for dedicating their time to participate on the committee.

Dr. Wyatt acknowledged that it was time for the public presentation period to begin. As customary, pre-selected speakers have 5 minutes and there is no question and answer period. (During the public presentations, Dr. Chambers resumed as moderator for the remainder of the meeting).

Name	Affiliation	Class/Drug of Interest
Marjory Levey	UCB, Inc.	Vimpat, Briviact
Robert Lehman, MD	Rhodes Pharmaceuticals	Aptensio XR
Sherry Andes, BSPharm, PharmD	ACADIA Pharmaceuticals Inc.	Nuplazid
Gina McKnight-Smith, PharmD	AbbVie	Humira, Duopa, Viekira XR, Zinbryta
Patricia Rohman, PharmD, MBA	Otsuka	Rexulti, Abilify Maintena
Heidi Belden, PharmD	Tris Pharma, Inc	Dyanavel XR

Ahmad Nessar, PharmD, RPh	Amgen	Enbrel, Repatha
Pamela Smith, Pharm D	Bristol-Myers Squibb	Eliquis
Adan Sosa, PharmD	Sunovion Pharmaceuticals	Latuda
Donna Dalton, RN, BS	Pfizer	QuilliChew ER
Jeremy W. Sharp, PharmD	Neos Therapeutics	Adzenys XR-ODT
Marsha Walkup, PharmD	Shire US	Xiidra
Anne Z. DePriest, PharmD	Janssen Scientific Affairs	Xarelto, Invega Trinza, Invega Sustenna

Dr. Chambers, Chairperson of the P&T committee, thanked the presenters for all their input.

Next, Mr. John LaFrachise from Xerox, the Pharmacy claims processor, was called upon to present the prior authorization (PA) report.

Mr. Lafranchise stated that 12,000 new PDL PA approvals were authorized during the 3rd quarter of 2016. The top ten therapeutic classes accounted for 11,372 or 95% of all PAs. The class of drugs with the most PA approvals was the opiate dependence treatment class. Nine of the drugs within that class accounted for 8,878 PAs. The reason for the high number of PAs in this class is because at the May 2016 P&T Meeting, the P&T Committee recommended to switch from Suboxone film as the preferred agent to Zubsolv effective July 1 2016. The Department had anticipated that during the first few months there would be an influx of PA requests for the film. Currently PA requests have normalized.

Mr. Lafranchise reported that the second class in the top ten classes was that of Anticonvulsants, for which there were 603 PAs. To contrast that with the nine drugs in the opiate class, there were 59 different drugs in that class. Rounding out the top ten, for Neuropathic Pain, there were 387; Antidepressants, Other were 328; Antipsychotics, 259; Stimulants and Related Agents, 258; Narcotic Analgesics 238; Sedative Hypnotics, 223; Anticoagulants, 118; and for Antidepressants, SSRIs, there were 80. Mr. Lafranchise concluded his presentation by thanking the audience.

Dr. Chambers stated that there were 20 classes that had no recommended changes from the existing PDL. Dr. Anju Harpalani, Clinical Account Manager from Provider Synergies/Magellan Health/Medicaid Administration provided an update on the classes since the last review. Since no motions were made with regards to the specific recommendations, the 20 classes were approved without any changes (listed below).

Class	**Voting Result**
Alzheimer's Agents	**Maintain current preferred agents:** generics (donepezil (all strengths except 23mg), donepezil ODT, memantine, rivastigmine)
Anticonvulsants	**Maintain current preferred agents:** generics (carbamazepine (IR, ER), clonazepam, divalproex (IR, ER), lamotrigine, levetiracetam (tablets, solution), oxcarbazepine (tablets, suspension) phenobarbital (tablets, syrup), phenytoin (capsules, suspension, ER), primidone, topiramate, valproic acid, zonisamide, Celontin, Diastat, Gabitril, Peganone, Tegretol Suspension, Trileptal Suspension
Antihistamines, Minimally Sedating	**Maintain current preferred agents:** generics (cetirizine, cetirizine D, fexofenadine OTC, levocetirizine tablets, loratadine, loratadine D)
Antihypertensives, Sympatholytics	**Maintain current preferred agents**: generics (clonidine oral, guanfacine, methyldopa, methyldopa-HCTZ), Catapres TTS (Brand only)
Antihyperuricemics	**Maintain current preferred agents**: generics (allopurinol, probenecid, probenecid-colchicine)
Antiparkinson's Agents	**Maintain current preferred agents**: generics (amantadine, benztropine, levodopa-carbidopa (IR and ER), levodopa-carbidopa-entacapone, pramipexole, ropinirole, selegiline tablets, trihexyphenidyl)
Bile Salts	**Maintain current preferred agents**: generic (ursodiol capsules, ursodiol tablets)

Colony Stimulating Factors	**Maintain current preferred agents:** Granix, Neupogen
COPD Agents	**Maintain current preferred agents:** generics (ipratropium neb, ipratropium-albuterol neb), Atrovent HFA, Combivent Respimat, Spiriva
Cytokine and CAM Antagonists	**Maintain current preferred agents:** Enbrel, Humira
Erythropoiesis Stimulating Proteins	**Maintain current preferred agents:** Aranesp, Procrit
Immunomodulators, Atopic Dermatitis	**Maintain current preferred agent:** Elidel
Leukotriene Modifiers	**Maintain current preferred agents:** generics **(**montelukast (tablets, chewables), zafirlukast)
NSAIDs	**Maintain current preferred agents**: generics (diclofenac (all forms), diflunisal, etodolac, fenoprofen, flurbiprofen, ibuprofen (all forms), indomethacin (IR and ER), ketoprofen, ketorolac, meclofenamate, meloxicam, nabumetone, naproxen (all forms), oxaprozin, piroxicam, sulindac), Voltaren gel
Ophthalmic Antibiotic-Steroid Combinations	**Maintain current preferred agents:** generics (neomycin-polymyxin-dexamethasone, sulfacetamide-prednisolone, tobramycin-dexamethasone drops), Tobradex ointment
Ophthalmics, Antibiotics	**Maintain current preferred agents:** generics (bacitracin-polymyxin, ciprofloxacin solution, erythromycin, gentamicin, neomycin-polymyxin-gramicidin, neomycin-polymyxin-bacitracin, ofloxacin, polymyxin-trimethoprim, sulfacetamide solution, tobramycin), Ciloxan ointment, Moxeza, Tobrex ointment, Vigamox
Ophthalmics for Allergic Conjunctivitis	**Maintain current preferred agents:** generics (cromolyn, ketotifen OTC), Alrex, Pataday, Pazeo

Ophthalmics, Glaucoma	**Maintain current preferred agents**: generics (brimonidine 0.1%, carteolol, dorzolamide, dorzolamide-timolol, , latanoprost, levobunolol, metipranolol, pilocarpine, timolol), Alphagan P 0.15%, Azopt, Betimol, Combigan, Simbrinza, Travatan Z
Otic Antibiotics	**Maintain current preferred agents:** generics (neomycin-polymyxin-HC, ofloxacin), Ciprodex
Sedative Hypnotics	**Maintain current preferred agents**: generics (flurazepam, temazepam (15mg and 30mg), triazolam, zaleplon, zolpidem)

Immediately following was the review of 11 therapeutic classes with modified recommendations from the existing PDL. Dr. Chambers called upon Dr. Anju Harpalani, Clinical Account Manager from Provider Synergies/Magellan Health/Medicaid Administration to lead the class reviews.

Dr. Harpalani started the review with the Anticoagulant class and reminded the committee members that this class was being reviewed off-cycle at the request made by the P&T Committee at the May 5th meeting. Specifically, the Committee had asked the State to consider adding one of the non-vitamin K anticoagulants (NOACs) as preferred on the PDL. As part of the Committee's request, all of the oral anticoagulants including warfarin and the non-VKA oral anticoagulants referred commonly as NOACS or DOACs for Direct-acting Oral Anticoagulants were reviewed. Dr. Harpalani then stated the names of four drugs in their chronological order of FDA approval—dabigatran (Pradaxa; rivaroxaban (Xarelto); apixaban (Eliquis) and edoxaban (Savaysa)

Dr. Harpalani further explained that for these agents, various factors were taken into consideration, such as pharmacokinetics including onset and duration of action, dosing, most are either once or twice daily, and how these are primarily metabolized and excreted as were the FDA-approved indications, safety and monitoring as well as reversal agents available for these new oral anticoagulants. In the landmark clinical studies leading to the approval of these four NOACs, all of the agents were compared against warfarin so there were no head-to-head comparative studies of the NOACs. All agents were found to be at least non-inferior to warfarin. As far as safety, fewer incidents of more severe bleeds, such as ICH or intracranial hemorrhage were reported for the NOACs.

Dr. Harpalani presented the Committee with four different models. The Committee reviewed each model and had discussion on them. Dr. Pherson referred to the CHEST Guidelines recommendation to prefer one of the direct-acting agents over Vitamin K antagonists as far as the treatment of both atrial fibrillation (A-fib) and venous thromboembolism (VTE). Dr. Pherson then indicated her support for a model that included a non-VKA anticoagulant on the PDL.

Dr. Chambers called upon Dr. Pherson to proceed with making a motion as to her preference for one of the NOACs. Dr. Pherson made a motion for the model that had Xarelto as preferred. This motion carried.

Dr. Harpalani then presented Provider Synergies/Magellan Health/Medicaid Administration's recommendation for the remaining therapeutic classes.

The following table reflects the voting results for each of the affected therapeutic categories:

Class	**Voting Result**
Anticoagulants	**ADD:** Xarelto **Other preferred agents**: generics (enoxaparin, warfarin), Fragmin
Antidepressants, Other	**REMOVE:** Marplan, Pristiq **Other preferred agents:** generics (bupropion (IR, SR, XL), mirtazapine (tablets, ODT), phenelzine, trazodone, venlafaxine (IR tablets, ER capsules)), Parnate
Antidepressants, SSRIs	**REMOVE:** Fluoxetine tablets **Other preferred agents**: generics (citalopram, escitalopram tablets, fluoxetine capsules (all strengths except 60mg), fluvoxamine, paroxetine, sertraline)

Antipsychotics	**DO NOT ADD:** Nuplazid **REMOVE:** Aristada **Other preferred agents:** generics (aripiprazole (Tier 1, age 17 and younger), aripiprazole (Tier 2, age 18 or older), chlorpromazine, clozapine, fluphenazine, haloperidol, loxapine, olanzapine (tier 2), perphenazine, perphenazine-amitriptyline, quetiapine, risperidone, thioridazine, thiothixene, trifluoperazine, ziprasidone), Abilify Maintena, Geodon IM, Invega Sustenna, Invega Trinza, Latuda (Tier 2), Orap, Risperdal Consta
Bronchodilators, Beta Agonists	**ADD:** Albuterol nebules 0.63 mg/3 ml and 1.25 mg/3ml **Other preferred agents:** generics (albuterol (tablets, syrup, 0.083% and 5mg/ml nebules, terbutaline), Foradil, ProAir HFA, Proventil HFA
Glucocorticoids, Inhaled	**ADD:** Pulmicort Respules 1 mg/2 ml **REMOVE:** Aerospan **Other preferred agents:** Advair (Diskus, HFA), Asmanex, Dulera, Pulmicort Respules 0.25mg and 0.5mg, Qvar, Symbicort
Intranasal Rhinitis Agents	**REMOVE:** Nasonex **Other preferred agents:** generics (azelastine, fluticasone, ipratropium)
Neuropathic Pain	**ADD:** Gabapentin tablets **Other preferred agents:** generics (capsaicin OTC, duloxetine, gabapentin capsules, lidocaine patch), Lyrica capsules,
Ophthalmics, Anti-Inflammatories	**ADD:** Ilevro **Other preferred agents:** generics (dexamethasone, diclofenac, fluorometholone, flurbiprofen, ketorolac,

	ketorolac LS, prednisolone), Durezol, Flarex, FML SOP, Lotemax drops, Maxidex, Pred Mild
Ophthalmics, Anti-inflammatory/ Immunomodulator (New Class reviewed for the first time.)	**ADD:** Restasis **DO NOT ADD:** Xiidra
Stimulants and Related Agents	**ADD:** Kapvay **Other preferred agents:** generics (amphetamine salt combo, dextroamphetamine tablets, guanfacine ER, methylphenidate tablets (IR, ER, CR)), Adderall XR, Daytrana, Dexedrine Spansules, Focalin, Focalin XR, Metadate CD, Methylin oral solution, Quillivant XR, Ritalin LA, Vyvanse, Strattera (Tier 2)

Dr. Chambers further stated that next on the agenda there were 13 classes of drugs where only one or more new drugs in the category were being reviewed. The following members have notified the committee that they will recuse themselves from participation in the following class reviews due to a potential conflict of interest—Dr. Baucom and Dr. Joshi, both for Hepatitis C Agents.

Single Drug Reviews	**Voting Result**
Acne Agents. Topical	**DO NOT ADD:** Aczone Gel w/Pump
Analgesics, Narcotic long Acting	**DO NOT ADD:** Xtampza ER
Angiotensin Modulator Combinations	**DO NOT ADD:** Byvalson
Angiotensin Modulators	**DO NOT ADD:** Qbrelis
Antiemetic/Antivertigo Agents	**DO NOT ADD:** Emend Powder Packet

Antifungals, Topical	**DO NOT ADD:** Loprox Kit
Antimigraine Agents, Triptan	**DO NOT ADD:** Onzetra Xsail, Zembrace Symtouch, Migranow Kit
GI Motility, Chronic	**DO NOT ADD:** Relistor
Hepatitis C Agents	**ADD:** Epclusa, Viekira XR
Hypoglycemics, Incretins	**DO NOT ADD:** Jentadueto XR
Lipotropics, Other	**DO NOT ADD:** Repatha Pushtronex
Multiple Sclerosis Agents	**DO NOT ADD:** Zinbryta
Tetracyclines	**DO NOT ADD:** Doryx MPC

~ 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.).

Dr. Chambers announced that the next P&T meeting was scheduled for May 4th, 2017 and with no further business, the public meeting was adjourned at 11:17 a.m.