Maryland Pharmacy Program
PDL P&T Meeting

Minutes from November 5, 2015

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, John Boronow; Helen Lann; Evelyn White Lloyd; Marie Mackowick; Ryan Scott Miller; Brian Pinto; Anna Schor; Karen Vleck

DHMH Staff

Athos Alexandrou (Maryland Pharmacy Program Director); Dixit Shah (Maryland Pharmacy Program Deputy Director); Lisa Burgess (Maryland Pharmacy Program Child Psychiatrist); Paul Holly (Consultant Pharmacist to Maryland Pharmacy Program); Dennis Klein (Maryland Pharmacy Program Pharmacist)

Xerox Healthcare

John LaFranchise, Sr.

Provider Synergies/Magellan Medicaid Administration (PS/MMA)

Mary Roberts, Nina Bandali, PharmD

Proceedings:

The public meeting of the PDL P&T Committee was called to order by the Chairperson, Dr. Zakiya Chambers, at 9:00 a.m. The meeting began with brief introductions of all the representatives including the P&T Committee members, DHMH, Xerox, and PS/MMA. The Committee approved the minutes from the previous P&T Committee meeting held on May 7, 2015.

Dr. Chambers then asked Mr. Alexandrou to provide a status update on the Medicaid Pharmacy Program. Mr. Alexandrou stated that Renee Hilliard is no longer with the Medicaid Pharmacy Program. She has accepted a position with CMS effective June 1st. In addition, Matt Lennertz, the Maryland Account Manager from Magellan, has resigned effective October 9th. He accepted a management position with another company. Mr. Alexandrou expressed his thanks for their service. Magellan is actively recruiting for a replacement for Matt. Until a replacement is hired, Ms. Mary Roberts and Dr. Nina Bandali will be fulfilling Magellan's contractual requirements for Maryland.

Mr. Alexandrou further stated that this meeting marks the end of the twelfth year of Maryland's Preferred Drug List (PDL) and has saved over a hundred million dollars in expenditures 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.

Mr. Alexandrou stated that injectable naloxone was carved out of the HealthChoice managed care benefit and was being covered under Medicaid fee-for-service since October 1st of last year. The remaining substance use disorder medications have also been carved out on January 1st, 2015, in the same manner that the antiretroviral agents and mental health drugs are currently carved out. He announced that the transition has gone smoothly with no issues to date.

Regarding treatments for Hepatitis C, Mr. Alexandrou recalled that the Committee recommended that both Harvoni and Viekira Pak be made preferred on the PDL. To ensure the safe and appropriate use of these medications, the Department has established clinical criteria which can be utilized by HealthChoice and by fee-for-service. In June of this year, two new drugs came to market. Daklinza which was approved for genotype 3, and Technivie which was approved for genotype 4. Mr. Alexandrou announced that both of these drugs will be reviewed today as single drug reviews.

Mr. Alexandrou further explained that 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. The fiscal impact analysis revealed that utilizing actual requisition costs with an enhanced dispensing fee would be overall cost-neutral to the State. Hence, in March a pharmacy stakeholders' meeting was conducted to share the new reimbursement methodology and the results of the cost feasibility analysis. The comment period ended on April 20th of this year. Feedback from stakeholders has been reviewed. Mr. Alexandrou stated that discussion is being conducted on how to best implement the new reimbursement methodology in order to incorporate most of the comments received. Stay tuned for additional information at the next P&T meeting in May.

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. Last quarter, prescribers achieved a 94.9% 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. The pharmacy hotline remains active, answering over 2300 calls each month. Approximately 4% percent of these of these calls pertain to the Preferred Drug List. He concluded by thanking all of the Committee members for dedicating their time to participate on the committee.

Dr. Chambers 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.

Name	Affiliation	Class/Drug of Interest
Olivia Lee, PharmD	Abbvie Inc.	Technivie, Humira
Ivonne Fuller Cameron	Hepatitis Foundation International	Daklinza, Technivie
Ronnie DePue, PharmD, CGP, FASCP	Sunovion Pharmaceuticals, Inc.	Latuda, Aptiom
Mark Veerman, PharmD	Janssen Scientific Affairs, LLC	Invega Sustenna, Invega Trinza
Mohamed Omar, PhD, RPh	Bristol-Myers Squibb	Daklinza
Patricia A. Rohman, PharmD, MBA	Otsuka	Rexulti
Pallav Raval, PharmD, MBA8	Novartis	Cosentyx, Entresto

Dr. Chambers thanked the presenters for all their input. A presentation from Xerox, the claims processor, was delivered by Mr. John Lafranchise. Mr. Lafranchise stated that 782 new PDL PA approvals (3rd quarter of 2015) were authorized. The top ten therapeutic classes accounted for 93% of all PAs. Within the P&T report, drugs are grouped first by therapeutic class and by individual drug and strength within each class for each PA given. The top ten PDL classes were, in order: Opiate Dependence Treatments, Narcotic Analgesics, Anticonvulsants, Stimulants, Antipsychotics, Sedative Hypnotics, Neuropathic Pain, Antidepressants, Other, Anticoagulants, and Quinolones. Since the carve-out of behavioral or substance use disorder drugs began on January 1, 2015, opiate dependence treatments have been the number one PA for those three quarters. For the last five quarters, there were five therapeutic classes that have been in the top ten in every quarter: Narcotic Analgesics, Anticonvulsants, Stimulants, Antipsychotics, Sedative Hypnotics. Mr. Lafranchise stated that the current PDL was updated on July 1st. No questions were asked of him.

Dr. Chambers stated that there were 20 classes that had no recommended changes from the existing PDL. Dr. Chambers also stated that 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. Miller for the classes of Antidepressants, SSRIs; Antihistamines, Minimally Sedating; Antiparkinson's Agents; COPD Agents; Cytokine and CAM Antagonists; Leukotriene Modifiers; Neuropathic Pain; NSAIDS, Sedative Hypnotics, Stimulants and Related Agents and Dr. Pinto for Immunomodulators and Atopic Dermatitis.

Mary Roberts, Senior Director of Account Services from Magellan Health Services provided a quick update on the classes since the last review. Since no motions were made

in 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 capsules), Exelon transdermal, Namenda solution
Antidepressants, SSRIs	**Maintain current preferred agents**: generics (citalopram, escitalopram tablets, fluoxetine (all strengths except 60mg), fluvoxamine, paroxetine, sertraline)
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)
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)
Neuropathic Pain	**Maintain current preferred agents:** generics (capsaicin OTC, duloxetine, gabapentin capsules), Lidoderm (Brand only), Lyrica capsules,
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
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, Anti-Inflammatories	**Maintain current preferred agents:** generics (dexamethasone, diclofenac, fluorometholone, flurbiprofen, ketorolac, ketorolac LS, prednisolone), Durezol, Flarex , FML SOP, Lotemax drops, Maxidex, Pred Mild
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)
Stimulants and Related Agents	**Maintain current 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)

Immediately following were reviews of 9 classes with modified recommendations from the existing PDL. Dr. Chambers notified the Committee that Dr. Miller would recuse himself from participation in the following class reviews due to potential conflict of interest: Anticonvulsants; Antidepressants, Other; Antipsychotics; Bronchodilators, Beta Agonist; Glucocorticoids, Inhaled; Intranasal Rhinitis Agents; and Ophthalmics, Glaucoma Agents. The following table reflects the voting results for each of the affected therapeutic categories:

Class	**Voting Result**
Anticonvulsants	**ADD:** oxcarbazepine suspension **Other preferred agents:** generics (carbamazepine (IR, ER), clonazepam, divalproex (IR, ER), lamotrigine, levetiracetam (tablets, solution), oxcarbazepine tablets, phenobarbital (tablets, syrup), phenytoin (capsules, suspension, ER), primidone, topiramate, valproic acid, zonisamide, Celontin, Depakote sprinkles, Diastat, Gabitril, Peganone, Tegretol Suspension, Trileptal Suspension
Antidepressants, Other	**ADD:** Pristiq **Other preferred agents:** generics (bupropion (IR, SR, XL), mirtazapine (tablets, ODT), phenelzine, trazodone, venlafaxine (IR tablets, ER capsules)), Marplan, Parnate
Antipsychotics	**ADD:** Invega Trinza **DO NOT ADD:** Rexulti **Other preferred agents:** generics (amitriptyline-perphenazine, chlorpromazine, clozapine, fluphenazine, haloperidol, loxapine, olanzapine (tier 2), perphenazine, quetiapine, risperidone, thioridazine, thiothixene, trifluoperazine, ziprasidone), Abilify (Tier 2, age 18 or older), Abilify Maintena, Geodon IM, Invega Sustenna, Latuda (Tier 2), Orap, Risperdal Consta

Bile Salts	**ADD:** ursodiol tablets **DO NOT ADD:** Cholbam **Other preferred agent:** generic (ursodiol capsules)
Bronchodilators, Beta Agonists	**ADD:** Serevent **DO NOT ADD:** Proair Respiclick **Other preferred agents:** generics (albuterol (tablets, syrup, full dose neb), terbutaline), Foradil, ProAir HFA, Proventil HFA
Glucocorticoids, Inhaled	**ADD:** Aerospan **REMOVE:** Flovent (Diskus, HFA), Pulmicort Flexhaler **Other preferred agents:** Advair (Diskus, HFA), Asmanex, Dulera, Pulmicort 0.25mg and 0.5mg Respules, Qvar, Symbicort
Intranasal Rhinitis Agents	**REMOVE:** azelastine (Astepro generic), olopatadine **Other preferred agents:** generics (azelastine (Astelin generic), fluticasone, ipratropium), Nasonex,
Ophthalmic Antibiotic-Steroid Combinations	**REMOVE:** blephamide S.O.P., Pred-G (drops, ointment) **Other preferred agents:** generics (neomycin-polymyxin-dexamethasone, sulfacetamide-prednisolone, tobramycin-dexamethasone drops), Tobradex ointment
Ophthalmics, Glaucoma	**ADD:** Combigan **REMOVE:** betaxolol, Betoptic S, Istalol **Other preferred agents**: generics (brimonidine 0.1%, carteolol, dorzolamide, dorzolamide-timolol, , latanoprost, levobunolol, metipranolol, pilocarpine, timolol), Alphagan P 0.15%, Azopt, Betimol, Simbrinza, Travatan Z

Next on our agenda there are 10 classes of drugs where we are only considering one or more new drugs in the category. 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. Miller, for Hepatitis C Agents, and Dr. Pinto, for Antifungals, Oral.

Single Drug Reviews	**Voting Result**
Acne Agents. Topical	**DO NOT ADD:** Epiduo Forte Gel w/Pump
Androgenic Agents	**DO NOT ADD:** Natesto
Angiotensin Modulators	**DO NOT ADD:** Entresto
Antifungals, Oral	**DO NOT ADD:** Cresemba
Antimigraine Agents, Triptan	**DO NOT ADD:** Zecuity
Growth Hormone	**DO NOT ADD:** Zomacton
Hepatitis C Agents	**ADD:** Daklinza, Technivie
Hypoglycemics, SGLT2	**DO NOT ADD:** Synjardy
Lipotropics, Other	**DO NOT ADD:** Praluent, Repatha
Phosphate Binders	**DO NOT ADD:** Fosrenol Powder Pack

~ 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 classes with modified recommendations, Dr. Steele Wyatt questioned the 8 prior authorization requests for Abilify. She asked if criteria were not met for those requests that were not approved. Mr. Lafranchise confirmed that it was due to criteria not being met. Dr. Steele Wyatt also questioned if these were unique patient requests. Mr. Lafranchise confirmed that they were. Dr. Baucom asked if they go through an appeal process after the initial rejection. Mr. Lafranchise stated that appeals would go to Dr. Burgess.

Dr. Pinto verified that the State was moving away from Flovent HFA. Ms. Roberts confirmed this. Dr. Pinto informed everyone that more than 90% of ICS therapy for Hopkins Health System is for Flovent. He forewarned that there may initially be a spike from the PA standpoint upon transition. He stated that the pulmonary faculty would be willing to work with the State on this. Dr. Steele Wyatt questioned the availability of Nasonex. Ms. Roberts stated there have not been any reports of such.

During the single drug review of Daklinza and Technivie, Dr. Schor asked if there was an option for physicians to state on the prior authorization form that the medication is being selected for a patient with more than cirrhosis. Mr. Shah responded that each case is reviewed individually, and the State works with the providers for appropriate treatment for the patient.

At the conclusion of the single drug reviews, Dr. Steele Wyatt asked if prior authorizations for chronic medications are for one year. Mr. Lafranchise stated that it is usually a year. Mr. Alexandrou further clarified that PDL PAs are for a year. Dr. Boronow asked if prior authorization approvals are per provider. Mr. Alexandrou stated it is at the patient level. Dr. Pinto questioned if there is open access for the new lipotropics or if requests would have to go through the normal PA process. Mr. Alexandrou responded that Xerox is handling the prior authorization requests and have been instructed on what interim criteria to use until the final criteria are in place. Dr. Boronow asked for confirmation that not all products would have clinical criteria. Mr. Alexandrou confirmed in the affirmative. Dr. Boronow also asked if there could be clinical criteria for something on a preferred list or not preferred. Mr. Alexandrou also confirmed this. Dr. Boronow further inquired whether documentation on clinical criteria was readily available in the public domain. Mr. Alexandrou stated that documentation on clinical criteria is available by accessing the DHMH website under medical programs, Medicaid, under the pharmacy program specifically, where there is a searchable database.

Dr. Steele Wyatt asked the review schedule for new drugs, e.g. Addyi. Mr. Alexandrou stated that if the release of the new drug is during the regular cycle in time for Magellan to provide a bid solicitation and information is available for review then, depending on the cycle of the 2 meetings, in May or November, the State will review as a single drug review or as a part of the entire class. So it depends on timing of when the drug is released to the market. Ms. Roberts added that sufficient time, at least 30 days, would be needed to solicit the bid and get information back to the State. Mr. Alexandrou ended by stating that the drug specifically mentioned by Dr. Steele Wyatt is an ED drug. Medicaid does not cover drugs for erectile dysfunction.

The next meeting is scheduled for May 5th, 2016. With no further business, the public meeting adjourned at 10:52 a.m.