MARYLAND DEPARTMENT OF HEALTH
Medicaid Pharmacy Program

# Preferred Drug List (PDL)
# Pharmacy and Therapeutics (P&T) Committee Meeting
# Minutes from November 1, 2018

Medicaid Pharmacy Program

PDL P&T Meeting

Minutes- November 1, 2018

## Attendees:

P&T Committee

Devang Patel (Chairperson); Esther Alabi (Vice Chairperson); Sharon Baucom; Zakiya Chambers; Damean W.E. Freas; Evelyn White Lloyd; Marie Mackowick; Emily Pherson; Karen Vleck; Jenel Steele Wyatt

Maryland Department of Health (MDH)

Athos Alexandrou (Medicaid Pharmacy Program Director); Dixit Shah (Medicaid Pharmacy Program Deputy Director); Mangesh Y. Joglekar (Chief, Clinical Services, Medicaid Pharmacy Program); Malika Closson (Medicaid Pharmacy Program Physician Program Specialist); Paul Holly (Consultant Pharmacist to Medicaid Pharmacy Program); Lucy Karanja (Medicaid Pharmacy Program Pharmacist); Kim Rogers (Consultant Pharmacist to Medicaid Pharmacy Program)

Conduent State Healthcare LLC

Karriem Farrakhan (Clinical Manager, MD PBM Account)

Provider Synergies LLC

Honesty Peltier (Pharmacist Account Manager)

## Proceedings:

The public meeting of the PDL P&T Committee was called to order by the Chairperson, Dr. Patel, at 9:06 a.m. The meeting began with brief introductions of all the representatives including the P&T Committee members, and MDH staff. The Committee then approved the minutes from the previous P&T Committee meeting held on May 3, 2018.

Dr. Patel then called upon Mr. Joglekar to provide a status update on the Medicaid Pharmacy Program. Mr. Joglekar stated that this meeting marks the ending of the 15th year of Maryland's Preferred Drug List. The Medicaid program has saved well- over $100 million in its expenditures for prescription drugs due to the Preferred Drug List. These savings have allowed Maryland to manage costs without reducing covered services for Medicaid participants and provide safe, clinically appropriate, and cost-effective medications to Medicaid participants.

Mr. Joglekar continued that the State of Maryland is experiencing an opioid addiction and overdose epidemic. As part of the State's comprehensive approach to combating this epidemic, the Department has worked with the nine Medicaid managed care organizations in Maryland to implement minimum standards that were applied by both the fee-for-service program and the

managed care organizations. These standards were implemented on July 1, 2017, and include coverage of non-opioids to be considered first-line treatment for chronic pain, and prior authorizations for all long-acting opioids, fentanyl, and methadone for pain and any opioid prescription that results in a patient exceeding 90 morphine milligram equivalents (MME) per day. Additionally, the standard 30-day quantity limit for all opioids is set at or below 90 MME per day. The standards do not apply to patients with cancer, sickle cell anemia, or patients who are receiving palliative care or who are in hospice. Mr. Joglekar reminded the Committee that naloxone is covered by Maryland Medicaid without a prescription as of June 1, 2017 and is available under the Statewide Standing Order issued by Maryland Department of Health. Mr. Joglekar reported that these initiatives implemented by the Maryland Medicaid Pharmacy Program have been progressing as anticipated and continue to facilitate improvements in appropriate opioid prescribing and curb concerns related to the epidemic.

Mr. Joglekar further reminded everyone that the prior authorization process is quick, simple and significantly less cumbersome than many other prior authorization processes. When compared to other states and the private sector, the Maryland Medicaid Preferred Drug List stands out, in that, Maryland Medicaid provides more options for preferred drugs. During the second quarter of 2018, prescribers achieved a 96.2% compliance rate with the Preferred Drug List.

Mr. Joglekar provided an update to the clinical criteria for HCV therapy that includes pre-treatment evaluations, hepatitis C management and enhanced management plans, and starting December 1, 2018 the coverage will be expanded to read, "Liver fibrosis correspond to metavir score of greater than or equal to 2, unless the patient has a viral condition which is known or documented to result in an accelerated hepatic disease progression and/or hepatic decompensation than what is normally expected from the course of chronic HCV."

Mr. Joglekar updated everyone on Formulary Navigator, an on-line resource provided by Managed Markets Insight and Technology (MMIT). The Formulary Navigator tool went live in February 2018. The Preferred Drug List may be accessed via the MMPP website, the newly designed website, www.mmppi.com, where mmppi stands for Maryland Medicaid Pharmacy Program Information, and lastly, through Formulary Navigator. The mmppi.com website provides active links and quick access to the Fee-for-Service PDL as well as PDLs and/or formularies for nine Maryland Medicaid Managed Care Organizations.

In addition, Mr. Joglekar stated that the pharmacy hotline remains active, answering on average less than 2,400 calls each month from September 2017 to August 2018, of which, approximately 44 calls pertain to the PDL. This call volume is a test to how effectively the PDL is being managed and a reflection on the hard work, dedication, and expertise of the entire team.

Lastly, Mr. Joglekar reminded everyone that the new reimbursement methodology for Fee-for-Service Program which is based upon provider actual acquisition cost and a professional dispensing fee as per CMS Covered Outpatient Final Rule (CMS-2345-FC), was successfully implemented over a year and a half ago. In closing, Mr. Joglekar sincerely thanked all the Committee participants for dedicating their time to participate on the Committee.

Dr. Patel thanked Mr. Joglekar for the updates and 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 or demonstrations.

| Name | Affiliation | Class/Medication of Interest |
|---|---|---|
| Michael Nelson, PharmD | Sunovion | Aptiom, Latuda |
| Jinesh Patel, PharmD, BCPS | Aerie Pharmaceuticals | Rhopressa |
| Christy Skibicki, MD | Indivior | Perseris |
| William Seidel, PhD | Tris Pharma | Dyanavel XR, Quillichew ER, Quillivant XR |
| Ahmad Nessar, PharmD | Amgen | Enbrel |
| Michael Boskello, RPh | Alkermes Pharmaceutical | Aristada, Aristada Initio |
| Anne DePriest, PharmD, BCPS | Janssen Scientific Affairs | Invega Sustenna, Invega Trinza |
| Orlando R. Davis, MD | Consumer | Aristada, Aristada Initio |

Following the presentation by 8 speakers, Dr. Karriem Farrakhan from Conduent State Healthcare LLC, the claims processor, was called upon to present the prior authorization report. He stated that in the third quarter of 2018, there were 5,052 new PDL prior authorizations (PAs), a decrease from the second quarter of 2018 by 27%. The top ten therapeutic classes decreased by 37% from 6,148 during the second quarter of 2018 to 4,441 for the third quarter of 2018. These top ten classes accounted for 88% of the total authorized PA approvals. The top ten classes for which PAs were requested during the third quarter of 2018 in descending order: Antidepressants, Other; Anticonvulsants; Stimulants and Related Agents; Antipsychotics; Sedative Hypnotics; Antidepressants, SSRIs; Opioid Use Disorder Treatments; Analgesics, Opioid; Neuropathic Pain; Inhaled Glucocorticoids. There was a decrease in PDL PAs for nine of the top ten classes. Inhaled Glucocorticoids was the only class with an increase from 45 in the second quarter to 50 in the third quarter of 2018. The number of PAs for the top three PDL classes decreased by 31%. From the top three classes, Trintellix, Viibryd, Onfi, Vimpat, and Mydayis showed the largest decreases in PDL PAs. Opioid Use Disorder Treatments decreases from 329 in the second quarter to 217 in the third quarter of 2018, a 34% decrease. Inhaled Glucocorticoids are new to the top ten list replacing Phosphate Binders and Related Agents.

Dr. Patel stated that the classes of drugs that were scheduled for review will be discussed next. He stated that these were posted on the Maryland Medicaid Pharmacy Program website and are listed on the meeting agenda. There were 25 classes that had no recommended changes from the

existing PDL. Dr. Patel also stated that there were no potential conflicts of interest noted by the P&T Committee members. Dr. Honesty Peltier from Provider Synergies provided clinical updates on the 25 classes of drugs with no new recommendations.

| Class | Voting Result |
|---|---|
| Antidepressants, Other | **Maintain current preferred agents:** generics (bupropion (IR, SR, XL); mirtazapine (tablets, ODT); phenelzine; trazodone; venlafaxine (IR, ER, capsules)); Parnate |
| Antidepressants, SSRIs | **Maintain current preferred agents:** generics (citalopram (tablets, solution); escitalopram tablets; fluoxetine (capsules, solution (excludes 60mg, weekly)); fluvoxamine; paroxetine; sertraline (tablet, concentrated solution)) |
| Antihistamines, Minimally Sedating | **Maintain current preferred agents:** generics (cetirizine (RX, OTC); cetirizine D; fexofenadine OTC (tablets, suspension); levocetirizine tablets; loratadine (RX, OTC); loratadine D)) |
| Antihypertensives, Sympatholytics | **Maintain current preferred agents:** generics (clonidine tablets; 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; carbidopa/levodopa (IR, ER); carbidopa/levodopa/entacapone; pramipexole IR; ropinirole; selegiline tablets; trihexyphenidyl) |
| Bile Salts | **Maintain current preferred agents**: generics (ursodiol (tablets, capsules)) |

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| Colony Stimulating Factors | **Maintain current preferred agents:** Granix; Neupogen |
| Cytokine and CAM Antagonists | **Maintain current preferred agents:** Enbrel; Humira; Cosentyx |
| Epinephrine, Self-Injected | **Maintain current preferred agents**: generics (epinephrine 0.15mg (Epipen Jr.); epinephrine 0.3mg (Epipen)) |
| Erythropoiesis Stimulating Proteins | **Maintain current preferred agents**: Aranesp; Procrit |
| Glucocorticoids, Inhaled | **Maintain current preferred agents**: Advair (Diskus, HFA); Asmanex; Dulera; Flovent HFA; Pulmicort Respules; Symbicort |
| Immunomodulators, Atopic Dermatitis | **Maintain current preferred agents**: generics (tacrolimus); Elidel |
| Intranasal Rhinitis Agents | **Maintain current preferred agents**: generics (azelastine (Astelin); fluticasone; ipratropium) |
| Leukotriene Modifiers | **Maintain current preferred agents**: generics (montelukast (tablets, chewables); zafirlukast) |
| Neuropathic Pain | **Maintain current preferred agents**: generics (capsaicin OTC; duloxetine (Cymbalta); gabapentin (capsules, tablets); lidocaine patch); Lyrica |
| NSAIDs | **Maintain current preferred agents**: generics (diclofenac; diclofenac XL; flurbiprofen; ibuprofen (OTC, RX); indomethacin; ketorolac; meloxicam; nabumetone; naproxen (OTC, RX); sulindac) |
| Ophthalmics, Antibiotic-Steroid Combinations | **Maintain current preferred agents**: generics (neomycin/polymyxin/dexamethasone; sulfacetamide/prednisolone; tobramycin/dexamethasone suspension); Tobradex ointment |

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| Ophthalmics, Antibiotics | **Maintain current preferred agents**: generics (bacitracin/polymyxin B ointment; ciprofloxacin solution; erythromycin; gentamicin; moxifloxacin; neomycin/bacitracin/polymyxin ointment; neomycin/polymyxin/gramicidin; ofloxacin; polymyxin/trimethoprim; sulfacetamide solution; tobramycin) Ciloxan; Moxeza; Tobrex ointment |
| Ophthalmics for Allergic Conjunctivitis | **Maintain current preferred agents**: generics (cromolyn; ketotifen OTC); Alrex; Pazeo |
| Ophthalmics, Anti-Inflammatories | **Maintain current preferred agents**: generics (diclofenac; fluorometholone; flurbiprofen; ketorolac); Durezol; Flarex; FML S.O.P; Ilevro; Lotemax drops; Maxidex; Pred Mild |
| Ophthalmics, Anti-Inflammatory/Immunomodulators | **Maintain current preferred agents**: Restasis (single-use); Restasis (multi-dose) |
| Ophthalmics, Glaucoma Agents | **Maintain current preferred agents**: generics (brimonidine 0.1%; carteolol; dorzolamide; dorzolamide/timolol; latanoprost; levobunolol; pilocarpine; timolol); Alphagan P 0.15%; Azopt; Combigan; Simbrinza; Travatan Z |
| Otic Antibiotics | **Maintain current preferred agents**: generics (neomycin/polymyxin/hydrocortisone; ofloxacin); Ciprodex |
| Sedative Hypnotics | **Maintain current preferred agents**: generics (flurazepam; temazepam (15mg, 30mg); triazolam; zaleplon; zolpidem) |

Dr. Patel asked if there were any objections to keeping all of the drugs in the classes as they currently are. There were no objections. Since there were no objections, Dr. Patel stated that the Committee will recommend that these classes remain unchanged.

Immediately following were reviews of 6 classes with modified recommendations from the existing PDL.

Dr. Patel indicated that there were no potential conflicts of interest noted by the P&T Committee members for the class reviews. The following table reflects the voting results for each of the affected therapeutic categories:

| Class | Voting Result |
|---|---|
| Alzheimer's Agents | **REMOVE**: memantine dose pack; memantine solution<br><br>**Maintain current preferred agents:** generics (donepezil (tablets, ODT); memantine tablets; rivastigmine (capsules, patches)) |
| Anticonvulsants | **ADD:** topiramate sprinkles; Vimpat (tablets, solution)<br><br>**REMOVE:** lamotrigine tablet dose pack; Celontin; Peganone; Trileptal suspension<br><br>**Maintain current preferred agents:** generics (carbamazepine (IR, ER, tablets, chewable); clonazepam tablets; diazepam rectal; divalproex (IR, ER, sprinkle); lamotrigine (tablets, chewable); levetiracetam (tablets, solution); oxcarbazepine (tablets, suspension); phenobarbital (tablets, elixir); phenytoin (IR, ER, capsules, chewables, suspension); primidone; topiramate tablets; valproic acid (capsules, solution); zonisamide); Gabitril; Tegretol suspension |
| Antipsychotics | **ADD:** Aristada; Aristada Initio<br><br>**DO NOT ADD:** Nuplazid capsules; Perseris<br><br>**Maintain current preferred agents:** generics (aripiprazole (tablets, ODT, solution); chlorpromazine; clozapine tablets; fluphenazine; haloperidol; loxapine; olanzapine; perphenazine; perphenazine/amitriptyline; pimozide; quetiapine (IR, XR); risperidone; thioridazine; thiothixene; trifluoperazine; ziprasidone); Abilify Maintena; Geodon IM; Invega |

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|---|---|
| Antipsychotics (continued) | Sustenna; Invega Trinza; Latuda; Risperdal Consta |
| Bronchodilators, Beta Agonist | **REMOVE:** terbutaline<br><br>**Maintain current preferred agents:** generics (albuterol (nebules, syrup)); Proair HFA; Proventil HFA; Serevent |
| COPD Agents | **ADD:** Stiolto Respimat<br><br>**Maintain current preferred agents:** generics (ipratropium nebules; ipratropium/albuterol nebules); Atrovent HFA; Combivent Respimat; Spiriva Handihaler |
| Stimulants and Related Agents | **ADD:** Quillichew ER<br><br>**REMOVE:** methylphenidate ER 72mg tablets<br><br>**Maintain current preferred agents:** generics (amphetamine salt combo; atomoxetine; dextroamphetamine (capsules, tablets); guanfacine ER; methylphenidate tablets; methylphenidate CD capsules; methylphenidate CR tablets; methylphenidate ER capsules; methylphenidate ER tablets (except 72mg)); Adderall XR; Daytrana; Focalin; Focalin XR; Kapvay; Methylin solution; Quillivant XR; Vyvanse (capsules, chewable) |

Following the clinical presentation and recommendation for the Antipsychotic class, Dr. Wyatt questioned whether there was a means to review if changes to the PDL for this class were assessed for impact on the total cost of healthcare due to decreased hospitalizations or decreased repeat admissions, for example. Mr. Alexandrou responded that the Pharmacy Program does not currently have the ability to review this impact as the information is in different units and administrations, but may be something that is reviewed in the future. Dr. Pherson followed with a question specifically directed to the transition of patients currently taking Abilify Maintena to transition to Aristada from a cost-effectiveness perspective. Mr. Alexandrou noted that the Pharmacy Program performed some internal analyses to predict potential transitions to different strengths, but would not discuss the information in an open meeting. Dr. Peltier followed with a

reminder that there is no information in the package insert for either product to describe a transition.

Immediately following were reviews of 7 classes with single drug reviews.

Dr. Patel indicated that there were no potential conflicts of interest noted by the P&T Committee members for the single drug reviews. The following table reflects the voting results for each of the affected therapeutic categories:

| Single Drug Reviews | Voting Result |
|---|---|
| Analgesics, Narcotics Short | **DO NOT ADD:** Roxybond |
| Antiemetic/Antivertigo Agents | **DO NOT ADD:** Akynzeo IV |
| Beta-Blockers | **DO NOT ADD:** Kapspargo |
| Cephalosporins and Related Antibiotics | **DO NOT ADD:** Daxbia |
| Hypoglycemics, Insulins and Related Agents | **DO NOT ADD:** Toujeo Max Solostar Pen |
| Lipotropics, Statins | **DO NOT ADD:** Zypitamag |
| Proton Pump Inhibitors | **DO NOT ADD:** Esomep-EZS |

~ 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. Patel informed the panel that the next meeting is scheduled for May 2, 2019, at 9:00am in Ballroom C in the West Village Commons building on the campus of Towson University. Dr. Patel asked if there was any further business to come before the Committee.

Dr. Freas noted that on review of the relative cost sheets for Neuropathic Pain provided to the Committee members prior to the meeting, he was surprised to see a brand product have a lower cost than a similar generic. Dr. Freas noted that this was the opposite of the traditional assumption that generics are less expensive and may be something that is considered more closely as a cost containment measure. Mr. Alexandrou responded that this type of analysis, to review net costs after federal and supplemental rebates, along with utilization is done with the PDL vendor to determine which product is cheaper. In these cases, a brand may be preferred over its generic, as part of the DAW6 program. As noted earlier in the presentation, this determination is outside the function of the PDL. Dr. Patel pointed out that this type of information is not known to prescribers unless they are members of the P&T Committee, and it would be helpful to disseminate to physicians across the state. Dr. Freas, a member of the board

of physicians, agreed that this would be useful to work together to design a joint letter to communicate to the 45,000 emails. Mr. Alexandrou cautioned that the information related to the net net cost of drugs is confidential and proprietary as a trade secret. Dr. Peltier reminded the Committee that the cost sheets are confidential and use a relative cost, but that recommendations to the Committee reflect consideration of the relative cost. Dr. Peltier cautioned that the pricing on the cost sheets was potentially unique to the Medicaid space and may not translate to other plans. Dr. Freas noted that there are times prescribers think they are saving money to use a generic medication that is more difficult to dose with potentially more side effects that does not make sense even financially. Dr. Chambers shared that in the community pharmacy setting; the POS system directs the pharmacist to dispense brand or generic if one is preferred. As long as a prescriber is not writing Dispense as Written, the pharmacist will switch between preferred brands and preferred equivalent generics with no problems. Dr. Patel summarized that the communication should be that as far as the Medicaid FFS PDL, the cost for similar brand and generic products is part of the consideration to determine when it is appropriate to have a product preferred.

Dr. Wyatt asked a question regarding naloxone prescribing and how many of the prescriptions have been dispensed through the standing order based on Mr. Joglekar's presentation. Mr. Alexandrou responded that Maryland Medicaid Pharmacy Program can provide how many prescriptions have been dispensed specifically to Medicaid participants but there is no way to determine or differentiate the origin of the prescription.

Dr. Chambers asked the final question regarding any updates to the shortage for EpiPen. Mr. Joglekar confirmed that Maryland Medicaid Pharmacy Program receives updates about shortages and acts accordingly. Mr. Alexandrou noted that in instances where the shortage is widespread, the program has the ability to authorize the Point of Sale vendor to allow other manufacturers' products to dispense without a PDL PA if necessary. This is regularly monitored for all drugs through FDA notifications. Mr. Joglekar also noted that the prior authorization process is quick and easy and in shortage situations, if a provider prescribes a different manufacturer, the program will honor the request. Dr. Freas added one final comment to praise Medicaid for its approach to opioid regulations.

Dr. Patel reintroduced the final business to vote on the next meeting scheduled for May 2, 2019, at 9:00 am in Ballroom C in the West Village Commons building on the campus of Towson University. Dr. Patel asked if there was any further business to come before the Committee. None appearing, the meeting was adjourned at 11:00am.