



Preferred Drug List (PDL) Pharmacy and Therapeutics (P&T) Committee Meeting Minutes from November 2, 2023

Attendees:

P&T Committee

Yen Dang (Chairperson/Pharmacist); Damean Freas (Vice Chairperson/Physician); Kim Bright (Psychiatrist); Zakiya Chambers (Pharmacist); Laverdis Davis (Physician); Latoya Edwards (Physician); Agnes Ann Feemster (Pharmacist); Timothy Romanoski (Physician); Evelyn White Lloyd (Consumer); Marie Mackowick (Psychiatric Pharmacist); Adetoro Oriafio (Pharmacist); Karen Vleck (Consumer).

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); Lucy Karanja (Medicaid Pharmacy Clinical Pharmacist); Nisha Purohit (Advance Practice Pharmacist); Iuliana Frank (Psychiatrist, Physician Program Specialist).

Conduent State Healthcare LLC

Jenai Paul (Clinical Manager, Maryland PBM Operations)

Provider Synergies LLC

Kara Delaney (Interim Pharmacist Account Manager)

Andrew Wherley (Incoming Pharmacist Account Manager)

Proceedings:

The public meeting of the PDL P&T Committee was called to order by the Chairperson, Dr. Dang, at 9:05 a.m. The meeting began with a welcome by Dr. Dang. There were brief introductions from 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 4, 2023.

Dr. Dang then called upon Mr. Joglekar to provide a status update on the Medicaid Pharmacy Program.

Mr. Joglekar began his remarks with a thank you to everyone, especially the P&T committee members. Mr. Joglekar reiterated the purpose and importance of the P&T Committee meetings, which are held twice a year, to go over the clinical updates on medications in the therapeutic classes under review and their relative cost information which aids the P&T Committee to make appropriate clinical and budget-conscious decisions to create wide accessibility of cost-effective therapies and continue to make those available via the PDL to the Marylanders.

He stated that this 8th virtual meeting marks the end of the 20th year of Maryland's PDL. Over these years, the Office of Pharmacy Services (OPS) has saved over \$270 million in its expenditures for prescription medications due to the PDL. These savings have enabled Maryland to manage costs without reducing covered services for Medicaid participants and to provide clinically appropriate and cost-effective medications to the Maryland Medicaid participants.

Mr. Joglekar congratulated new team member and Pharmacist Account Manager for the PDL with Provider Synergies/Magellan Rx Management/Prime Therapeutics Dr. Andrew Wherley who will be replacing Dr. Kara Delaney. Going forward he will be managing all the contractual responsibilities under this contract for the program. Including but not limited to managing the pharmacy and therapeutics committee meetings. He congratulated Dr. Wherley and welcomed him to the fee for service pharmacy team.

Mr. Joglekar 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 PDL stands out in that Maryland Medicaid provides more options for preferred drugs on the PDL. During the first quarter of this year, prescribers achieved a 96.7% compliance rate with the PDL as compared to the average of 95.2% for other states with similar PDL arrangements.

In addition, Mr. Joglekar stated that the pharmacy hotline remains active; answering on average of 9,009 calls from April to September of this year, out of which an average of 77-78 calls a month pertained to the PDL during the same timeframe. Additional updates may be

found on the Medicaid Pharmacy website at:

mmcp.health.maryland.gov/mmcp/pap/Pages/paphome.aspx

Mr. Joglekar spoke of changes being implemented by the program. Effective January 3rd, 2024, pharmacy claims for Fee-for-Service Medicaid participants for non-behavioral health medications, prescribed by a prescriber who is not enrolled as a Medicaid provider with Maryland Medicaid, will deny with the following message “Unenrolled prescriber, Medicaid Rx will continue to deny unless the prescriber enrolls with Medicaid via EPREP”. Behavioral health medications that are prescribed by unenrolled prescribers will continue to pay until sometime in late spring or summer with the following message “Missing invalid prescriber identification number, unenrolled prescriber, future Medicaid Rx will deny unless prescriber enrolls with Medicaid via EPREP.” The program highly encourages you to visit health.maryland.gov/mmcp/provider/pages/enrollment.aspx to log in and enroll. Please stay tuned for additional information and outreach currently being done by the department.

Mr. Joglekar then stated he would also like to inform everyone about another important mandate.

Mr. Joglekar provided background on the: American Rescue Plan (ARP) Act of 2021 includes a provision that eliminates the statutory cap on rebates that drug manufacturers pay to Medicaid. Beginning in January 2024 Medicaid rebates will no longer be capped at 100 percent of the quarterly Average Manufacturing Price (AMP). URA is the Unit Rebate Amount. The Best Price is the lowest price from the manufacturer to any entity in the U.S. CPI-U, which is the Consumer Price Index-Urban, also known as the inflation penalty.

Mr. Joglekar stated this presentation will not specify any specific products due to the confidentiality of the rebates and pricing and thus such pricing information is guided and protected under the federal law of CFR 42 1396r-8.

Mr. Joglekar continued: Prior to January 1st, 2024, manufacturers' statutory rebates to Medicaid could not exceed the AMP, which is called the AMP cap. This means that manufacturers are not required to pay any additional rebates for these drugs even if the price of the drugs increases over time.

The American Rescue Plan includes a provision that eliminates the statutory AMP cap on rebates that drug manufacturers pay to Medicaid. This is referred to as the AMP Cap Removal Project by CMS, Center for Medicare and Medicaid Services. The AMP cap will be removed starting January 1st, 2024, meaning that manufacturers can owe Medicaid rebates.

Mr. Joglekar continued by stating manufacturers have several options that they can choose to address the potential exposure of statutory rebates exceeding the AMP. Manufacturers may implement strategies and adjustments. Manufacturers have various choices including but not limited to the following:

keep status quo and do nothing, reduce the list price to reduce inflationary rebates, either choose to discontinue the product, or choose not to participate in the drug rebate program.

Mr. Joglekar stated that some of these changes may result in the need to make off-cycle changes to the PDL.

Mr. Joglekar then presented some scenarios showing how these changes could affect the final price paid by Medicaid for a medication.

Mr. Joglekar ended the AMP cap presentation stating again that there may be some off-cycle changes needed to the Maryland Medicaid Fee-for-Service Preferred Drug List.

Mr. Joglekar reminded everyone that the OPS provides live continuing medical education to all interested prescribers and continuing education to all interested pharmacists every year at no cost. The Department successfully provided a two-hour live program on October 21st, 2023, on “Disparities in pain management in the Sickle Cell population”. He stated it was a highly informative and educational program and encouraged everyone to visit mmppi.com for additional details about this seminar as well as some of the most important past seminars that have been conducted. He noted that the Department is planning to provide one four-hour live program sometime next year (2024) in the late spring. Please stay tuned for additional information about the topic, day, date, early registration, website link, and other details.

In closing, Mr. Joglekar thanked all the Committee participants for dedicating their time to participate on the Committee and asked that if they have any questions to bring them to his attention.

Dr. Dang 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
Brittany Woller, PharmD, BCPP, BCMAS	Indivior	Opvee / Perseris
Wallene Bullard, PharmD	Novartis	Cosentyx
Suzan Tsang, PharmD	LEO Pharma	Adbry
Timothy Birner, PharmD MBA	Alkermes	Lybalvi

Paul Miner, PharmD	Ascendis Pharma	Skytrofa
Kristen Heard, PhD	Neurelis, Inc.	Valtoco
Janetta Bekman, PharmD, MBA	Abbvie	Rinvoq / Skyrizi / Vraylar
John Charpentier	Ipsen	Bylavy
Allyson Fonte, PharmD	Nestle Health Sciences	Vowst
Mimo Odebiyi, PharmD	Teva Pharmaceuticals	Uzedy
John Landis	Braeburn	Brixadi
Shantell Gooden, PharmD	Janssen Scientific Affairs	Invega Hafyera
Arden Arslanyan, PharmD	Otsuka	Abilify Asimtufii
Donna Cook, PharmD	Amgen	Amjevita / Otezla
Willis Lonzer, PhD	Amgen	Ravicti

Dr. Dang announced the arrival of committee member Dr. Karen Vleck who was asked to state herself as present.

Dr. Vleck stated “present.”

Dr. Paul from Conduent State Healthcare, LLC the gave an update about claims processing and prior authorizations of PDL drugs. Dr. Paul stated that for the third quarter of 2023, there were 4,402 PDL PAs. Dr. Paul then listed the top 10 therapeutic classes for the third quarter of 2023 as follows: Stimulants and Related Agents with 1,013; Anticonvulsants with 716; Antidepressants, Other with 645; Antipsychotics with 510; Opioid Use Disorder Treatments with 234; Sedative Hypnotics with 211; Antidepressants 142; Neuropathic Pain with 125; Antidepressants, SSRIs with 121; Analgesics, Narcotics Long-Acting with 74 for a total of 3,791 PDL PAs for the top 10 therapeutic classes which accounts for 86 percent of the total PDL PAs for the third quarter of 2022.

Chairman, Dr. Dang, then announced that the classes of drugs that were scheduled for review would be discussed next. She stated that these were posted on the Medicaid Pharmacy Program’s website and were listed on the meeting agenda. There were 15 classes that had no recommended changes from the existing PDL. Dr. Dang also stated that there were no potential conflicts of interest noted by the P&T Committee members. Dr. Kara Delaney, from Provider Synergies, provided clinical updates on the 15 classes of drugs with no new recommendations on PDL status.

Class	Voting Result
Alzheimer's Agents	Maintain current preferred agents: generics (donepezil tablets (except 23mg); donepezil ODT; memantine tablets; rivastigmine capsules, patches)
Anticonvulsants	Maintain current preferred agents: generics (carbamazepine (chewable, suspension, tablets); clobazam (suspension and tablets); clonazepam tablets; diazepam rectal; divalproex (IR, ER); lacosamide (solution, tablet); lamotrigine tablets; levetiracetam (tablets, solution); oxcarbazepine tablets; phenobarbital (tablets, elixir); phenytoin (IR, ER, capsules, chewable, suspension); primidone; tiagabine; topiramate (sprinkles, tablets); valproic acid (capsules, solution); zonisamide); Depakote Sprinkle; Nayzilam; Trileptal suspension; Valtoco
Antihistamines, Minimally Sedating	Maintain current preferred agents: generics (cetirizine tablets, solution; RX, OTC; cetirizine-D; desloratadine; fexofenadine tablets, OTC; levocetirizine tablets, OTC; loratadine tablets, solution, ODT; RX, OTC; loratadine-D)
Antihypertensives, Sympatholytics	Maintain current preferred agents: generics (clonidine patches; clonidine tablets; guanfacine; methyldopa); New agent Clonidine ER (Nexiclon) Non-preferred
Bile Salts	Maintain current preferred agents: generics (ursodiol capsules, tablets)
Bronchodilators, Beta Agonists	Maintain current preferred agents: generics (albuterol HFA; albuterol nebulas; albuterol syrup); Serevent

Epinephrine, Self-Injected	Maintain current preferred agents: generics (epinephrine 0.15mg (EpiPen Jr.); epinephrine 0.3mg (EpiPen))
Immunomodulators; Atopic Dermatitis	Maintain current preferred agents: generics (pimecrolimus; tacrolimus); Eucrisa
Intranasal Rhinitis Agents	Maintain current preferred agents: generics (azelastine nasal; fluticasone nasal; ipratropium)
Neuropathic Pain	Maintain current preferred agents: generics (capsaicin OTC; duloxetine (Cymbalta); gabapentin capsules, tablets; lidocaine patches; pregabalin capsules) New Drugs DermacinRx Lidocan Patch and Xyliderm nonpreferred
Ophthalmics, Antibiotics	Maintain current preferred agents: generics (bacitracin/polymyxin B ointment; ciprofloxacin solution; erythromycin; gentamicin; moxifloxacin; neomycin/bacitracin/polymyxin ointment; ofloxacin; polymyxin/trimethoprim; sulfacetamide solution; tobramycin); Ciloxan ointment; Tobrex ointment
Ophthalmics, Antibiotic/Steroid Combinations	Maintain current preferred agents: generics (neomycin/polymyxin/dexamethasone; sulfacetamide/prednisolone; tobramycin/dexamethasone drops); Tobradex ointment
Ophthalmics, Glaucoma Agents	Maintain current preferred agents: generics (brimonidine 0.2%; brimonidine P 0.15%, brimonidine/timolol; carteolol; dorzolamide; dorzolamide/timolol; latanoprost; levobunolol; pilocarpine; timolol (Timoptic, Timoptic XE); travoprost); Rhopressa; Rocklatan; New drugs Durysta and Iyuzeh nonpreferred
Otic Antibiotics	Maintain current preferred agents: generic (ciprofloxacin/dexamethasone;

	neomycin/polymyxin/hydrocortisone; ofloxacin)
Sedative Hypnotics	Maintain current preferred agents: generics (eszopiclone; ramelteon; temazepam (15mg, 30mg); triazolam; zaleplon; zolpidem tablet IR, ER (Ambien)) New drug Zolpidem capsules nonpreferred

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

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

Dr. Dang 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
Antidepressants, Other	ADD: Vilazodone Maintain current preferred agents: generics (bupropion (IR, SR, XL); desvenlafaxine ER tablets (Pristiq); miratazapine (ODT, tablets); trazodone, venlafaxine (IR, ER capsules))
Antidepressants, SSRIs	ADD: Escitalopram solution Maintain current preferred agents: generics (citalopram (solution, tablets); escitalopram tablets; fluoxetine (capsules, solution, tablets (excludes 60mg and weekly)); fluvoxamine; paroxetine; sertraline (concentrated solution, tablets))
Antihyperuricemics	ADD: Febuxostat (Uloric) Maintain current preferred agents: generics (allopurinol; colchicine tablets; probenecid;

	probenecid/colchicine) New generic Allopurinol 200 mg non-preferred
Antiparkinson's Agents	<p>ADD: Entacapone</p> <p>Maintain current preferred agents: generics (amantadine, benztropine, carbidopa/levodopa IR, ER; carbidopa/levodopa/entacapone; pramipexole IR; ropinirole; selegiline, trihexyphenidyl)</p>
Antipsychotics	<p>ADD: Abilify Asimtufii; Invega Hafyera; Paliperidone; Perseris</p> <p>Maintain current preferred agents: generics (aripiprazole; chlorpromazine; clozapine; fluphenazine; haloperidol; loxapine, lurasidone olanzapine; perphenazine; perphenazine/amitriptyline; pimozide; quetiapine IR/ER; risperidone; thioridazine; thiothixene; trifluoperazine; ziprasidone); Abilify Maintena; Aristada; Aristada Initio; Invega Sustenna; Invega Trinza; Risperdal Consta; Vraylar New Drugs Rykindo, Uzedy non-preferred</p>
Colony Stimulating Factors	<p>ADD: Fylnetra</p> <p>Remove: Granix Vial</p> <p>Maintain preferred agent: Neupogen New drug Udenyca Autoinjector non-preferred</p>
COPD Agents	<p>ADD: Roflumilast (Daliresp)</p> <p>Maintain current preferred agents: generics (ipratropium nebules; ipratropium/albuterol nebules); Anoro Ellipta; Atrovent HFA; Combivent Respimat; Spiriva Handihaler; Spiriva Respimat; Stiolto Respimat</p>
Cytokine & CAM Antagonists	<p>ADD: infliximab (Remicade)</p> <p>Maintain current preferred agents: Enbrel; Humira; Otezla New Drugs adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, Hadlima, Idacio, Yflyma, Yusimry non-preferred</p>

Erythropoiesis Stimulating Proteins	<p>Remove: Reacrit Vifor</p> <p>Maintain other current preferred agents: Aranesp; Epogen; Retacrit New Drug Jesduvroq non-preferred</p>
Glucocorticoids; Inhaled	<p>ADD: Arunity Ellipta & Trelegy Ellipta</p> <p>Maintain current preferred agents: generics (budesonide inhalation suspension (Pulmicort respules)); Advair HFA; Asmanex; Dulera; Flovent HFA; Symbicort New drug Airsupra HFA non-preferred</p>
Leukotriene Modifiers	<p>ADD: montelukast granules (Singulair granules)</p> <p>Maintain current preferred agents: generics (montelukast chewable, tablets; zafirlukast)</p>
NSAIDs	<p>Remove: diclofenac potassium tablets</p> <p>Maintain remaining current preferred agents: generics (celecoxib; diclofenac sodium; diclofenac gel; ibuprofen (OTC, RX); indomethacin; meloxicam; nabumetone; naproxen; naproxen sodium OTC; sulindac) new drugs indomethacin rectal, Lofena non-preferred</p>
Ophthalmics, Allergic Conjunctivitis	<p>ADD: olopatadine (Pataday)</p> <p>Maintain current preferred agents: generics (azelastine; cromolyn; ketotifen OTC; olopatadine (Patanol)); Alrex</p>
Ophthalmics; Anti-Inflammatories	<p>ADD: Nevanac</p> <p>REMOVE: Ilevro</p> <p>Maintain current preferred agents: generics (diclofenac; difluprednate; fluorometholone, ketorolac; prednisolone acetate); Pred Mild</p>
Ophthalmics; Anti-Inflammatory/Immunomodulators	<p>ADD: Eysuvis</p> <p>REMOVE: Restatis Multi-Dose</p>

	Maintain other preferred agents: generic (cyclosporine (Restasis single-use)); Xiidra
Stimulants and Related Agents	ADD: Qelbree Maintain current preferred agents: generics (amphetamine salt combo; atomoxetine; clonidine ER; dexamethylphenidate tablets, dexmethylphenidate XR; dextroamphetamine tablets; dextroamphetamine ER capsules; guanfacine ER; lisdexamfetamine chewable; methylphenidate (solution, tablets); methylphenidate CD capsules; methylphenidate ER capsules (Ritalin LA); methylphenidate ER tablets; modafinil); Adderall XR; Concerta; Daytrana; Focalin XR; Quillivant XR; Vyvanse capsules)
Urea Cycle Disorders	Add Class for Review ADD: Carglumic Acid; Sodium Phenylbutyrate Powder and tablet; Pheburane

Immediately following were reviews of 9 classes with single drug reviews.

Dr. Dang 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
Acne Agents, Topical	DO NOT ADD: ZMA Clear Cleanser
Antibiotics, GI	DO NOT ADD: Vowst
Antimigraine Agents, Other	DO NOT ADD: Zavzpret
Growth Hormone	DO NOT ADD: Ngenla, Sogroya
Hypoglycemics, Insulin and Related Agents	DO NOT ADD: Fiasp pumpcart, Rezvoglar Kwikpen
Hypoglycemics, SGLT-2	DO NOT ADD: Inpefa

Lipotropics, Statins	DO NOT ADD: Atorvaliq
Opioid Use Disorder treatments	ADD: Brixadi Monthly and Weekly, Narcan OTC, Naloxone OTC; Opvee
PAH Agents, Oral and Inhaled	DO NOT ADD: Liqrev

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 brand 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. Dang then announced there is an item of new business to be provided by Mangesh Joglekar

Mr. Joglekar then stated that the program also operates the Drug Use Review (DUR) Board and Medicaid Managed Care Advisory Committee, and requested from the P&T members to contact their peers and their network to inform them that the Maryland Medicaid DUR Board is looking for physicians and anyone interested should contact Mr. Joglekar.

Before adjourning Mr. Joglekar thanked everyone for their attendance and expertise and time.

Dr. Dang then informed everyone that the next P&T meeting is scheduled for May 2, 2024, at 9:00 am, EST at the Best Western Plus Hotel and Conference Center. Dr. Dang asked if there was any further business to come before the Committee. None appeared, and the meeting was adjourned at 12:20 pm.