

Pharmacy and Therapeutics Committee Meeting
March 17, 2022
Draft Minutes

Members Present:

Chethan Bachireddy, M.D.
Tim Jennings, Pharm.D.
Megan Sarashinsky, Pharm.D.
Ira Bloomfield, M.D.
Angela Venuto-Ashton, M.D.
Sarah Melton, Pharm.D.
Gill Abernathy, M.S., R.Ph.
Alexis Ablasca, M.D.
Rachel M. Selby-Penczak, M.D.

DMAS Staff:

MaryAnn McNeil, R.Ph., Pharmacy Manager
JoeMichael T. Fusco, Pharm.D., MCO Pharmacy Compliance Manager
Rachel Cain, Pharm.D., Clinical Pharmacist
Usha Koduru, Counsel to the Board, Office of the Attorney General
Nettie Emmelhainz, PharmD, Senior Pharmacy Policy and Data Analyst
Kiara M. Jasper, MHA, CPhT. Pharmacy Systems Administrator
Donna Proffitt R.Ph., Pharmacy Consultant

Absent:

Carol Forster, M.D.
Ananda Basu, M.D.

Staff: Magellan Rx Management

Debbie Moody, R.Ph., Director, Clinical Account Services,
Virginia Nancy Eldin, Pharm.D., Pharmacist Account Executive,
Virginia Eileen Zimmer, Pharm.D., MBA, Senior Director,
Government PDL Markets, Magellan Rx Management
Jeni Hodzic, CPhT, Lead Formulary Analyst

A quorum was present

Guests:

27 representatives from pharmaceutical companies, providers, advocates, associations, etc.

Welcome and Comments from Chethan Bachireddy, M.D., Chief Medical Officer and Chairman

Dr. Chethan Bachireddy welcomed the members of the Committee to the first in person P&T Committee meeting back at the DMAS office in the new conference room and thanked them for their participation during these challenging times. Dr. Bachireddy noted that Medicaid members are receiving high quality prescription medications based on sound clinical criteria at substantially reduced costs to the Commonwealth. Dr. Bachireddy stressed that the work of the Medicaid Agency and this Committee continues and is more important than ever as our members are facing economic, physical, and emotional and challenges.

Call to Order: The meeting was called to order by Dr. Bachireddy.

DMAS' Drug Utilization Review (DUR) Board Update: Dr. Rachel Cain provided the DUR update.

December 1, 2021, DUR Meeting:

The Board reviewed 8 new medications. The Board also approved therapeutic class service authorization criteria for Oral Lung Cancer and Other Neoplasms Drugs and Oral Renal Cell Carcinoma and Other Neoplasms Drugs. Additionally, the Board reviewed the results of several utilization analyses: the impact reports for 7 new DUR medications (Fotivda®, Lumakras™, Myfembree®, Truseltiq™, Wegovy™, Exkivity™ and Welireg™), concurrent use of opioids and benzodiazepines, concurrent use of opioids and antipsychotics, antipsychotics in children, and opioid use with and without naloxone. The Board approved quantity limits for the Movement Disorder Drugs and to remove the metformin step edit for all oral hypoglycemics.

March 10, 2022, DUR Meeting:

The Board reviewed 5 new medications. They continued the Service Authorization (SA) process and Utilization Management (UM) for the Preferred Drug List (PDL) class- HIV (quantity limits) and consolidating service authorization (SA) forms for the oral oncology drugs. The next DUR Board meeting is scheduled for June 2, 2022. The minutes from these meetings can be found at:

<https://www.virginiamedicaidpharmacyservices.com/provider/drug-utilization-review/>

Approval of Minutes from September 14th and 27th, 2021 meeting: Dr. Bachireddy asked if there were any corrections, additions or deletions to the draft meeting minutes. With no revisions or corrections, Dr. Jennings motioned that the minutes be approved as written, and a board member seconded the motion. The Committee unanimously approved the minutes as written.

PDL Management

PDL Phase I – New Drug Review (Therapeutic Class)

Brand Drugs

1. **Eprontia™ Solution (Anticonvulsants) Closed Class:** Dr. Eldin presented the clinical information for Eprontia™ Solution.
2. **Bylvay™ and Livmarli™ (Bile Salts):** Dr. Eldin presented the clinical information for Bylvay™ and Livmarli™.
3. **Skytrofa™ (Growth Hormone) Closed Class:** Dr. Eldin presented the clinical information for Skytrofa™.
4. **Apretude® (HIV PrEP) Closed Class:** Dr. Eldin presented the clinical information for Apretude®.
5. **Opzelura™ (Atopic Dermatitis) Closed Class:** Dr. Eldin presented the clinical information for Opzelura™.
6. **Tyrvaya™ Nasal Spray (Ophthalmic, Anti-Inflammatory/Immunomodulators-Type) Closed Class:** Dr. Eldin presented the clinical information for Tyrvaya™ Nasal Spray.
7. **Vuity™ eye drop (Ophthalmic, Glaucoma Agents):** Dr. Eldin presented the clinical information for Vuity™ eye drop.
8. **Leqvio® (Lipotropics, Others):** Dr. Eldin presented the clinical information for Leqvio®.
9. **Tarpeyo™ (Glucocorticoids, Oral):** Dr. Eldin presented the clinical information for Tarpeyo™.

Dr. Jennings motioned that Eprontia™ Solution, Bylvay™, Livmarli™, Skytrofa™, Apretude®, Opzelura™, Tyrvaya™ Nasal Spray, Vuity™ eye drop, Leqvio®, and Tarpeyo™ be PDL eligible, and a board member seconded the motion. Committee voted unanimously to consider these drugs as PDL eligible.

Generic Drugs or New Dosage Forms: Dr. Eldin noted the following new generics and new dosage forms:

- *(Beta Blockers)*
 - nebivolol (new generic for Bystolic®)
- *(Hepatitis C Agents) Closed Class*
 - Mavyret® and Epclusa® (new Pellet packs)
- *(Lipotropics, Statins)*
 - rosuvastatin-ezetimibe (new generic for Roszet®)
- *(HIV) Closed Class*
 - maraviroc (new generic for Selzentry®)
- *(Ophthalmic, Glaucoma Agents)*
 - brimonidine-timolol (new generic for Combigan®)
- *(Ophthalmic, Anti-Inflammatory/Immunomodulators) Closed Class*
 - cyclosporine (new generic for Restasis®)

Dr. Jennings motioned that the new generics and new dosage forms be PDL eligible, and a board member seconded the motion. The Committee voted unanimously to consider these drugs as PDL eligible.

PDL Phase II – Annual Review

1. **Antimigraine Agents:** Dr. Eldin presented the Antimigraine Agents clinical information. Dr. Jennings motioned that the class continue to be PDL eligible, and a board member seconded the motion. The Committee voted unanimously to maintain this class as PDL eligible.
2. **Antimigraine Agents, Others (New Closed Class):**

Speakers

- Scott Kern, RN, BSN Evidence & Outcomes Liaison Value, Lilly (Emgality®)
- Olawemimo “Mimo” Odebiyi, PharmD Field Value Evidence & Outcomes Teva (Ajovy®)

Dr. Eldin presented the Antimigraine Agents, Others clinical information. Dr. Jennings motioned that the class continue to be PDL eligible, and a board member seconded the motion. The Committee voted unanimously to maintain this class as PDL eligible.

3. **NSAIDs (includes Cox-2 inhibitors and topical agents):** Dr. Eldin presented the NSAIDs clinical information. Dr. Jennings motioned that the class continue to be PDL eligible, and a board member seconded the motion. The Committee voted unanimously to maintain this class as PDL eligible.
4. **Opioid Dependency Treatment Agents (Closed Class) (includes oral buprenorphine):** Dr. Eldin presented the Opioid Dependency Treatment clinical information. Dr. Jennings motioned that the class continue to be PDL eligible, and a board member seconded the motion. The Committee voted unanimously to maintain this class as PDL eligible.

Dr. Jennings asked the DUR Board to investigate the FDA warning that dental problems have been reported with medicines containing buprenorphine that are dissolved in the mouth.

5. **Opioids: Short Acting (includes combination drugs and lozenges):** Dr. Eldin presented the Opioids, Short Acting clinical information. Dr. Jennings motioned that the class continue to be PDL eligible, and a board member seconded the motion. The Committee voted unanimously to maintain this class as PDL eligible.

6. **Antifungals, Oral:** Dr. Eldin presented the Antifungals, Oral clinical information. Dr. Jennings motioned that the class continue to be PDL eligible, and a board member seconded the motion. The Committee voted unanimously to maintain this class as PDL eligible.
7. **Antibiotics, GI:** Dr. Eldin presented the Antibiotics, GI clinical information. Dr. Jennings motioned that the class continue to be PDL eligible, and a board member seconded the motion. The Committee voted unanimously to maintain this class as PDL eligible.
8. **Quinolones (Second and Third Generations):** Dr. Eldin presented the Quinolones (Second and Third Generations) information. Dr. Jennings motioned that the class continue to be PDL eligible, and a board member seconded the motion. The Committee voted unanimously to maintain this class as PDL eligible.

9. **Antivirals for Influenza, Oral:**

Speakers

- Ahmad Nessar, PharmD | Medical Affairs Executive Director - Genentech – (Xofluza®)

Dr. Eldin presented the Antivirals for Influenza, Oral clinical information. Dr. Jennings motioned that the class continue to be PDL eligible, and a board member seconded the motion. The Committee voted unanimously to maintain this class as PDL eligible.

10. **Anticoagulants (includes oral agents, low molecular weight heparins and Factor XA Inhibitors) (Closed class):** Dr. Eldin presented the Anticoagulants clinical information. Dr. Jennings motioned that the class continue to be PDL eligible, and a board member seconded the motion. The Committee voted unanimously to maintain this class as PDL eligible.
11. **Platelet Aggregation Inhibitors:** Dr. Eldin presented the Anticoagulants clinical information. Dr. Jennings motioned that the class continue to be PDL eligible, and a board member seconded the motion. The Committee voted unanimously to maintain this class as PDL eligible.

12. **Antihyperkinesia/CNS Stimulants (Closed class):**

Speakers

- Ryan Gregg, PhD Medical Science Liaison - Northeast (Jornay® PM)

Dr. Eldin presented the Antihyperkinesia/CNS Stimulants clinical information. Dr. Jennings motioned that the class continue to be PDL eligible, and a board member seconded the motion. The Committee voted unanimously to maintain this class as PDL eligible.

13. **Multiple Sclerosis Agents (New Closed Class):** Dr. Eldin presented the Multiple Sclerosis Agents clinical information. Dr. Jennings motioned that the class continue to be PDL eligible, and a board member seconded the motion. The Committee voted unanimously to maintain this class as PDL eligible.

14. **Antipsychotics (New Closed Class for the Orals):**

Speakers

- Michael Boskello, R.Ph. BS Pharmacy Sr. Managed Market Medical Science Liaison I (Lybalvi®)

Dr. Eldin presented the Antipsychotics clinical information. Dr. Jennings motioned that the class continue to be PDL eligible, and a board member seconded the motion. The Committee voted unanimously to maintain this class as PDL eligible.

15. **Neuropathic Pain Agents**: Dr. Eldin presented the Neuropathic Pain Agents clinical information. Dr. Jennings motioned that the class continue to be PDL eligible, and a board member seconded the motion. The Committee voted unanimously to maintain this class as PDL eligible.
16. **Smoking Cessation Agents**: Dr. Eldin presented the Smoking Cessation Agents clinical information. Dr. Jennings motioned that class continue to be PDL eligible, and a board member seconded the motion. The Committee voted unanimously to maintain these classes as PDL eligible.
17. **Acne, Topical Agents (includes benzoyl peroxide, clindamycin, retinoids & combinations)**: Dr. Eldin presented the Acne, Topical clinical information. Dr. Jennings motioned that class continue to be PDL eligible, and a board member seconded the motion. The Committee voted unanimously to maintain these classes as PDL eligible.
18. **Bone Resorption Suppression and Related Agents (includes bisphosphonates, calcitonins and others)**: Dr. Eldin presented the Bone Resorption Suppression and Related Agents clinical information. Dr. Jennings motioned that class continue to be PDL eligible, and a board member seconded the motion. The Committee voted unanimously to maintain these classes as PDL eligible.
19. **Hypoglycemics: Incretin Mimetics/Enhancers (includes DPP-IV Inhibitors, GLP-1 Agonists & comb) (Closed class)**:

Speaker

- Scott Kern, RN, BSN Evidence & Outcomes Liaison Value, Lilly (Trulicity®)

Dr. Eldin presented the Hypoglycemics: Incretin Mimetics/Enhancers clinical information. Dr. Jennings motioned that class continue to be PDL eligible, and a board member seconded the motion. The Committee voted unanimously to maintain these classes as PDL eligible.

20. **Hypoglycemics: Insulins**: Dr. Eldin presented the Hypoglycemics: Insulins clinical information. Dr. Jennings motioned that class continue to be PDL eligible, and a board member seconded the motion. The Committee voted unanimously to maintain these classes as PDL eligible.
21. **Hypoglycemics: Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitors (Closed Class)**: Dr. Eldin presented the Hypoglycemics: Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitors clinical information. Dr. Jennings motioned that class continue to be PDL eligible, and a board member seconded the motion. The Committee voted unanimously to maintain these classes as PDL eligible.
22. **Hypoglycemics: Thiazolidinediones**: Dr. Eldin presented the Hypoglycemics: Thiazolidinediones clinical information. Dr. Jennings motioned that class continue to be PDL eligible, and a board member seconded the motion. The Committee voted unanimously to maintain these classes as PDL eligible.
23. **Cytokine and CAM Antagonists and Related Agents (Closed Class)**:

Speakers

- Scott Kern, RN, BSN Evidence & Outcomes Liaison Value, Lilly (Taltz®)
- Tammy Napolitano, PhD, MA Director, Inflammation & Immunology 1 (Xeljanz®/ Xeljanz® XR)

Dr. Eldin presented the Cytokine and CAM Antagonists and Related Agents clinical information. Dr. Jennings motioned that the class continue to be PDL eligible, and a board member seconded the motion. The Committee voted unanimously to maintain this class as PDL eligible.

24. Therapeutic Drug Classes Without Updates (Reviewed by the Department):

- Acne Agents (includes benzoyl peroxide, clindamycin, retinoids & combinations)
- Alzheimer's Agents (Cholinesterase Inhibitors & NMDA Receptor Antagonist)
- Androgenic Agents
- Antibiotics (topical)
- Antifungals (oral)
- Antivirals for Herpes (HSV)
- Antivirals, Topical
- Cephalosporins (Second and Third Generations)
- Erythropoiesis Stimulating Proteins
- Estrogens (vaginal and oral)
- Hypoglycemics: Alpha-Glucosidase Inhibitors
- Hypoglycemics: Meglitinides
- Hypoglycemics: Metformin
- Hypoglycemics: Sulfonylureas
- Hypoglycemics: Thiazolidinediones
- Long-Acting Reversible Contraceptives (LARCS) (includes long-acting IUDs & injectable)
- Methotrexate
- Pancreatic Enzymes
- Platelet Aggregation Inhibitors
- Progestational Agents (**New Closed class**)
- Psoriasis Agents
- Quinolones (Second and Third Generations)
- Rosacea Agents
- Skeletal Muscle Relaxants

Dr. Eldin noted that the above therapeutic classes had no significant changes since the last P&T Committee review.

Dr. Jennings motioned that these classes continue to be PDL eligible, and a board member seconded the motion. The Committee voted unanimously to maintain these classes as PDL eligible.

Comments from the Office of the Attorney General

Ms. Usha Koduru from the Attorney General's office stated that under the Virginia Freedom of Information Act (FOIA), specifically Virginia Code section 2.2-3711, a public body such as the P&T Committee, may go into a closed session for any one of the 51 reasons listed in that statute. The discussion of manufacturer and wholesaler prices is not one of the 51 reasons listed.

She stated the Attorney General strongly supports the principles of open government embodied by the FOIA and believes in the opportunity of the Commonwealth's citizens to witness the operation of government to the fullest extent.

Federal Law 42 U.S.C. 1396r-8(b) (3) (D) requires such pricing information to be kept confidential. On this point, federal law supersedes the Virginia FOIA. Since the P&T Committee must discuss this pricing information as part of its duties, pursuant to federal law a confidential meeting must occur for the consideration of this pricing information, and she cautioned only this confidential pricing information should be discussed.

Following the Confidential Session, the Committee members re-assembled on the public session. Dr. Jennings confirmed that to the best of each of the Committee member's knowledge the only information discussed at the confidential meeting was information regarding prices charged by the manufacturers and wholesalers of the drug classes discussed at this P&T Committee meeting. As authorized by Federal Law at 42 U.S.C. § 1396r-8(b) (3) (D) that requires this information to be kept confidential. Dr. Jennings motioned to reconvene the meeting, and a board member seconded the motion. The Committee voted unanimously to reconvene.

PDL Changes Effective July 15, 2022

Phase II Annual Review

Dr. Jennings made the following motions that were seconded and approved unanimously by the Committee (note the motions are for changes to the current PDL status):

- ***Antivirals, Topical:*** Acyclovir Ointment and Docosanol OTC are preferred. Abreva[®] OTC and Zovirax[®] Cream are non-preferred.
- ***Antihyperkinesia/CNS Stimulants (Closed class):*** Dexmethylphenidate is preferred. Focalin[®] is non-preferred
- ***Antimigraine Agents, Others (New Closed Class):*** Nurtec[®] ODT is preferred. Ubrovelvy[™] is non-preferred. 90 days to transition for all members.
- ***Antipsychotics (Orals New Closed Class, Long-acting Closed Class):*** Quetiapine ER (Authorized Generic) is non-preferred. Quetiapine ER remains preferred.
- ***COPD Agents (Closed class):*** Spiriva[®] Respimat[®] is preferred.
- ***Cytokine & CAM Antagonists (Closed class):*** Inflectra vial is preferred. Renflexis[®] is non-preferred. New starts are required to follow PDL, allow continuation of therapy if stable.
- ***Hypoglycemics, Insulins and Related:*** Insulin Aspart Cartridge, Insulin Aspart Pen, Insulin Aspart Vial, Insulin Aspart/Insulin Aspart Protamine Insulin Pen, Insulin Aspart/Insulin Aspart Protamine Vial, Insulin Lispro Junior Kwikpen, Insulin Lispro Pen, and Insulin Lispro Protamine Mix Kwikpen are preferred. NovoLog[®] Mix Pen and NovoLog[®] Mix Vial are non-preferred. New starts are required to follow PDL, allow continuation of therapy if stable.
- ***Hypoglycemics, Incretin Mimetics/Enhancers (Closed class):*** Glyxambi[®] is preferred. New starts required to follow PDL, allow continuation of therapy.
- ***Multiple Sclerosis Agents (New Closed Class):*** Dimethyl Fumarate DR and Dimethyl Fumarate DR Starter Pack are preferred. Tecfidera[®] and Tecfidera[®] Starter Pack are non-preferred.
- ***Progestational Agents (New Closed class):*** No changes to current PDL status, the class is now Closed.

Dr. Jennings made the following motion to make no changes to the following PDL drug classes, which was seconded and approved unanimously by the Committee:

- Acne Agents, Topical
- Alzheimer's Agents
- Analgesics, Narcotics Long

- Analgesics, Narcotics Short
- Androgenic Agents
- Antibiotics, Gi
- Antibiotics, Topical
- Anticoagulants
- Anticonvulsants
- Antiemetic/Antivertigo Agents
- Antifungals, Oral
- Antifungals, Topical
- Antihistamines, Minimally Sedating
- Antihypertensives, Sympatholytics
- Antihyperuricemics
- Antimigraine Agents, Triptans
- Antipsoriatics, Topical
- Antivirals, Oral
- Beta-Blockers
- Bile Salts
- Bone Resorption Suppression And
- Cephalosporins And Related Antibiotics
- Contraceptives, Other
- Erythropoiesis Stimulating Proteins
- Fluoroquinolones, Oral
- Glucocorticoids, Inhaled
- Glucocorticoids, Oral
- Growth Hormone
- Hepatitis C Agents
- HIV / AIDS
- Hypoglycemics, Alpha-Glucosidase Inhibitors
- Hypoglycemics, Meglitinides
- Hypoglycemics, Metformins
- Hypoglycemics, SGLT2
- Hypoglycemics, Sulfonylureas
- Hypoglycemics, TZD
- Immunomodulators, Atopic Dermatitis
- Lipotropics, Other
- Macrolides/Ketolides
- Methotrexate
- Neuropathic Pain
- NSAIDs
- Ophthalmics, Anti-Inflammatory/Immodulators
- Ophthalmics, Glaucoma Agents
- Opiate Dependence Treatments
- Otic Antibiotics
- Pancreatic Enzymes
- Platelet Aggregation Inhibitors
- Rosacea Agents, Topical
- Skeletal Muscle Relaxants
- Smoking Cessation

Clinical Criteria and Service Authorization (SA) Forms

The Committee members reviewed the proposed new or revised clinical criteria including new and updated service authorization fax forms. Dr. Jennings made the following motion to approve new or revised clinical criteria for the following drugs and drug classes, which was seconded and approved unanimously by the Committee:

- New criteria for Cibinqo™ (abrocitinib, tablet)
- New criteria for Opzelura™ (ruxolitinib, cream 1.5%)

The next P&T Committee Meeting is tentatively scheduled for September 15, 2022.

Dr. Bachireddy made a motion to adjourn the meeting and a board member seconded the motion. After a unanimous vote, the meeting was adjourned.