Pharmacy and Therapeutics Committee Meeting

June 27, 2024

Draft Minutes

Members Present:	**DMAS Staff:**
Lisa Price Stevens, M.D.	JoeMichael T. Fusco, Pharm.D., MCO Pharmacy Compliance Manager
Tim Jennings, Pharm.D.	Rachel Cain, Pharm.D., Clinical Pharmacist
Ira Bloomfield, M.D.	Usha Koduru, Counsel to the Board, Office of the Attorney General
Megan Sarashinsky, Pharm.D.	Kiara M. Jasper, MHA, CPhT. Pharmacy Systems Administrator
Olugbenga Obasanjo, M.D.	Rhonda Newsome, General Administration Manager
Alexis Aplasca, M.D.	Talisha Sheppard, RN, Medical Support Specialist
Frederick Moeller, M.D.	Nicole Brickhouse, RN, Medical Support Specialist
Rachel M. Selby-Penczak, M.D.	
Lura Thompson, Pharm.D.	
Absent:	**Staff: Magellan Rx Management**
Sarah Melton, Pharm.D.	Debbie Moody, Pharm.BS, R.Ph., Director Clinical Account Services
Angela Venuto-Ashton, M.D.	Nancy Eldin, Pharm.D., Pharmacist Account Executive
	David D'Amico, Pharm.D., Pharmacist Account Executive
	Nina Bandali, Pharm.D., Senior Director, Value Based Pricing
	Jeni Hodzic, CPhT, Senior Account Management Specialist
A quorum was present	**Guests:**
	32 representatives from pharmaceutical companies, providers, advocates, associations, etc.

Welcome and Comments from Lisa Price Stevens, M.D., Chief Medical Officer and Chairman: Dr. Dr. Lisa Price Stevens welcomed the members of the Committee and thanked them for their participation in this P&T Meeting. Dr. Price-Stevens asked the participants to provide introductions.

Call to Order: The meeting was called to order by Dr. Price-Stevens.

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

June 13, 2024 DUR Meeting:

The Board reviewed 10 new gene therapies for the Physician Adminstered Drugs (PADs) – Casgevy™ (exagamglogene autotemcel), Lyfgenia™ (lovotibeglogene autotemcel), Skysona® (elivaldogene autotemcel), Zynteglo™ (betibeglogene autotemcel), Elevidys (delandistrogene moxeparvovec), Hemgenix® (etranacogene dezaparvovec), Luxturna® (voretigene neparvovec-rzyl), Roctavian™ (valoctocogene roxaparvovec), Vyjuvek® (beremagene geperpavec), and Zolgensma® (onasemnogene abeparvovec-xioi). Information regarding the drugs and the one general drug Service Authorization (SA) form were reviewed. At the March meeting the Board requested an audit on Utilization of oral oncology – Lung cancer and other neoplasms. There are 20 oncology agents on this particular SA form. Reports were created with both FFS and MCO data during the time frame of October 1, 2023 – March 31, 2024 for this utilization data. Further reporting was performed to do a deeper dive on the 36 members to include specific drug and diagnosis details. Upon review of reports, the board felt the therapies were appropriate.

Additionally, the Board reviewed the results of several utilization analyses: concurrent use of opioids and benzodiazepines; concurrent use of opioids and antipsychotics; overlaps in opioids, benzodiazepines

and antipsychotics; naloxone and buprenorphine utilization for members on opioids. Due to time, the ProDUR reports, RetroDUR reports and utilization analysis reports were tabled until the next DUR meeting scheduled September 12, 2024.

The next DUR Board meeting is scheduled for September 12, 2024.
The minutes from previous DUR meetings can be found at:
https://www.virginiamedicaidpharmacyservices.com/provider/drug-utilization-review/

Approval of Minutes from March 21, 2024 meeting:
Dr. Price-Stevens asked if there were any corrections, additions, or deletions to the draft meeting minutes. With no revisions or corrections, the Committee members approved the minutes as written.

Housekeeping: Dr. Price-Stevens mentioned that GLP1 medications will not be discussed at this meeting, but rather at an Ad Hoc Meeting scheduled for July 23, 2024. She informed the committee that Prime will be presenting an overview of the drugs.

PDL Management

PDL Off Cycle – New Drug Review *(Therapeutic Class)*

New Biosimilars: Dr. D'Amico presented the clinical information for the following new biosimilars.

- *(Cytokine and CAM Antagonists) (Closed Class)*
    - Tyenne (tocilizumab-aazg)
    - Simlandi (adalimumab-ryvk)
        - Speaker
        - Olawemimo Odebiyi, PharmD Value, Evidence and Outcomes, Teva Pharmaceuticals

A motion was made and seconded and the committee voted unanimously to consider these drugs as PDL eligible.

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

- *(Ophthalmics, Anti-Inflammatory)*
    - bromfenac sodium 0.075%
- *(Hemophilia Treatment)) (Closed Class)*
    - Hemlibra (emicizumab-kxwh)

A motion was made and seconded and the committee voted unanimously to consider the new generics and new dosage forms as PDL eligible.

Potential New PDL Closed Class: Dr. D'Amico presented the new classes and clinical information:

- ***Colony Stimulating Factors (Potential New Closed Class)***

A motion was made and seconded and the committee voted unanimously for this class to become a new closed class.

- ***Hepatitis B (Potential New Closed Class)***

A motion was made and seconded and the committee voted unanimously for this class to become a new closed class.

- ***Duchenne Muscular Dystrophy (Potential New Closed Class)***

A motion was made and seconded and the committee voted unanimously for this class to become a new closed class.

PDL Quarter II – Annual Review: Classes with Updates

1. ***Hepatitis C Agents (Closed Class):*** Dr. D'Amico presented the Hepatitis C Agents clinical information.

   A motion was made and seconded and the committee voted unanimously for this class to continue to be PDL eligible.

2. ***HIV/AIDS Agents (Closed Class):*** Dr. D'Amico presented the HIV/AIDS Agents clinical information.

   Dr. Jennings requested follow-up for this class, and Dr. Price-Stevens agreed that this would be a good project for the DUR Board.

   A motion was made and seconded and the committee voted unanimously for this class to continue to be PDL eligible.

3. ***Angiotensin Modulatos II:*** Dr. D'Amico presented the Angiotensin Modulators II clinical information.

   A motion was made and seconded and the committee voted unanimously for this class to continue to be PDL eligible.

4. ***Lipotropics, Other (includes Bile Acid Sequestrants, Cholesterol Absorption Inhibitor Agents, Fibric Acid Derivatives, Microsomal Triglyceride Transfer Protein Inhibitors, Niacin Derivatives, Oligonucleotide Inhibitors and Omega 3 Agents):***

   Speaker
   - Kristen Duffey, PharmD, BCPS, Value Evidence Lead, Novartis (Leqvio®)
   - Kerry Francis, PharmD, Senior Medical Science Liason, Amgen (Repatha®)

   Dr. D'Amico presented the Lipotropics, Other clinical information. A motion was made and seconded and the committee voted unanimously for this class to continue to be PDL eligible.

5. ***PAH Agents, Oral/Inhaled/Injectable:***

   Speaker
   - Jacob Jameson, PharmD, Principal Scientific Account Lead, Value & Evidence Scientific Engagement, Johnson & Johnson Innovative (Repatha®)

   Dr. D'Amico presented the PAH Agents, Oral/Inhaled/Injectable clinical information.

6. ***Glucocorticoids, Oral:*** Dr. D'Amico presented the Glucocorticoids, Oral clinical information.

   A motion was made and seconded and the committee voted unanimously for this class to continue to be PDL eligible.

7. ***Growth Hormones (Closed Class):*** Dr. D'Amico presented the Growth Hormones clinical information.

   A motion was made and seconded and the committee voted unanimously for this class to continue to be PDL eligible.

8. ***H. Pylori Agents:*** Dr. D'Amico presented the H. Pylori Agents clinical information.

   A motion was made and seconded and the committee voted unanimously for this class to continue to be PDL eligible.

9. ***Ulcerative Colitis:*** Dr. D'Amico presented the Ulcerative Colitis clinical information.

   A motion was made and seconded and the committee voted unanimously for this class to continue to be PDL eligible.

10. ***Bronchodilators, Beta Agonist:*** Dr. D'Amico presented the Bronchodilators, Beta Agonist clinical information.

    A motion was made and seconded and the committee voted unanimously for this class to continue to be PDL eligible.

11. ***Epinephrine, Self-Injected:*** Dr. D'Amico presented the Epinephrine, Self- Injected clinical information.

    A motion was made and seconded and the committee voted unanimously for this class to continue to be PDL eligible.

12. ***Glucocorticoids (includes nebulized solutions, metered dose inhalers and combinations) (Closed Class):*** Dr. D'Amico presented the Glucocorticoids clinical information.

    A motion was made and seconded and the committee voted unanimously for this class to continue to be PDL eligible.

13. ***Intranasal Rhinitis:*** Dr. D'Amico presented the Intranasal Rhinitis clinical information.

    A motion was made and seconded and the committee voted unanimously for this class to continue to be PDL eligible.

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

- Angiotensin Modulator Combinations
- Beta Blockers (includes combination products)
- Calcium Channel Blockers (includes dihydropyridine and non-dihydropyridine agents)
- Lipotropics, Statins
- Glucagon Agents (Closed Class)
- HAE Treatments
- Antiemetic/Antivertigo Agents
- GI Motility, Chronic
- Proton Pump Inhibitors
- Anti-Allergens, Oral
- Antibiotics, Inhaled (Closed Class)
- Antihistamines, Minimally Sedating
- COPD Agents (Closed Class)
- Leukotriene Modifiers

D'Amico noted that the above therapeutic classes had no significant changes since the last P&T Committee review. A motion was made and seconded and the committee voted unanimously for the above-mentioned classes to continue to be PDL eligible.

- Antihypertensives, Sympatholytics
- Progestins for Cachexia
- Histamine II Receptor Antagonists
- Cough & Cold Agents (Legend)

D'Amico noted that the above therapeutic classes had no significant changes since the last P&T Committee review. A motion was made and seconded and the committee voted unanimously for the above-mentioned classes to no longer be managed under the PDL. Dr. Price Stevens requested that for the next P&T meeting, an overall review of utilization is provided for these classes.

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 fully witness the operation of government.

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.

Dr. Tim Jennings made a motion for the P&T Committee to resume the meeting in another room to discuss this confidential information regarding prices charged by the manufacturers and wholesalers of the drug classes discussed at this P&T Committee meeting. This confidential meeting is authorized by Federal Law at 42 U.S.C. § 1396r-8(b) (3) (D) that requires this information be kept confidential. We are also going into closed session to request legal advice on the proposed Bylaws pursuant to Virginia code 2.2-3711 8B.

The motion was seconded and unanimously approved by the Committee.

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 well as legal advice pertaining to the bylaws. As authorized by Federal Law at 42 U.S.C. § 1396r-8(b) (3) (D) that requires this information to be kept confidential.

A motion was made to resume the meeting and for the members to approve the confidential session statement. The motion was seconded and unanimously approved by the Committee.

PDL Changes Effective October 1, 2024

PDL Quarter 2 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)****:*

1. ***Colony Stimulating Factors (Closed Class):*** Neupogen Syringe, Neupogen Vial and Fulphila are preferred. Fylnetra, Granix Syringe, Granix Vial, Leukine, Neulasta Kit, Neulasta Syringe, Nivestym Syringe, Nivestym Vial, Nyvepria, Releuko Syringe, Releuko Vial, Rolvedon Syringe, Stimufend Syringe, Udenyca, Udenyca Autoinjector, Udenyca Onbody, Zarxio and Ziextenzo Syringe are non-preferred.

2. ***Glucagon Agents (Closed Class):*** Zegalogue Autoinjector and Zegalogue Syringe are preferred. Glucagon, Glucagon Emergency Kit (Amphastar), Glucagon Emergency Kit (Fresenius), Gvoke Pen, Gvoke Syringe and Gvoke Vial are non-preferred.

3. ***Growth Hormone (Closed Class):*** Nutropin AQ Pen is preferred.

4. ***Duchenne Muscular Dystrophy (Closed Class):*** Emflaza tablet and suspension are preferred. deflazacort tablet, Agamree Suspension, Exondys-51, Amondys-45, Vyondys-53 and Viltepso are non-preferred.

5. ***GI Motility, Chronic:*** lubiprostone (AG) is preferred. Amitiza is non- preferred.

6. ***Hepatitis B Agents (Closed Class):*** entecavir tablet and lamivudine HBV tablet are preferred. adefovir dipivoxil, Baraclude Solution, Baraclude Tablet, Epivir Hbv Solution, lamivudine HBV Tablet (AG) and Vemlidy are non-preferred.

7. ***Stimulants And Related Agents (Closed Class):*** amphetamine Salt Combo ER is preferred. dextroamphetamine Capsule ER, Adderall XR and Vyvanse Chewable Tablet are non-preferred. A 6-month conversion period for current members.

8. ***Anticonvulsants (Closed Class):*** carbamazepine XR (AG) is preferred. Valtoco is non-preferred.

9. ***Hypoglycemics, SGLT2 (Closed Class):*** synjardy XR is preferred. Invokana and Invokamet are non-preferred.

10. ***Glucocorticoids, Inhaled (Closed Class):*** Alvesco, Asmanex HFA and Qvar Redihaler are preferred. fluticasone HFA (AG) and fluticasone (FLOVENT DISKUS) (AG) are non-preferred.

11. ***Cytokine and CAM Antagonists (Closed Class):*** Simlandi and Tyenne are non-preferred.

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:

- Angiotensin Modulator Combinations
- Angiotensin Modulators
- Anti-Allergens, Oral
- Antibiotics, Inhaled (Closed Class)
- Antiemetic/Antivertigo Agents
- Antihistamines, Minimally Sedating
- Antihypertensives, Sympatholytics
- Beta-Blockers
- Bronchodilators, Beta Agonist (Closed Class)
- Calcium Channel Blockers
- COPD Agents (Closed Class)
- Cough And Cold
- Epinephrine, Self-Injected
- Glucocorticoids, Oral
- H. Pylori Treatment
- HAE Treatments
- Hepatitis C Agents (Closed Class)
- Histamine II Receptor Blocker
- Hypoglycemics, Incretin Mimetics/Enhancers (Closed Class)
- Intranasal Rhinitis Agents
- Leukotriene Modifiers
- Lipotropics, Other
- Lipotropics, Statins
- PAH Agents, Injectable
- PAH Agents, Oral And Inhaled
- Pancreatic Enzymes
- Phosphate Binders
- Progestins For Cachexia
- Proton Pump Inhibitors
- Ulcerative Colitis Agents
- Weight Management Agents (Closed Class)

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. A Committee member 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 and SA form for Colony Stimulating Factors
- New criteria for Emflaza and delflazacort
- New criteria for Agamree
- New criteria and SA form for Antisense Oligonucleotides for Duchenne Muscular Dystrophy
- New criteria for Vemlidy
- New criteria for Valtoco
- New criteria for Vyvanse chewable

Closing Comments:

A P&T Ad-hoc meeting is scheduled for July 23, 2024. The next P&T Committee Meeting is tentatively scheduled for October 8, 2024 A motion to adjourn the meeting was made and seconded. After a unanimous vote, Dr. Price-Stevens adjourned the meeting.