Pharmacy and Therapeutics Committee Meeting
September 19, 2019
Draft Minutes

Members Present:
Chethan Bachireddy, M.D.
Ira Bloomfield, M.D.
Tim Jennings, Pharm.D.
Megan Sarashinsky, Pharm.D.
Susan Lee, D.O.
Carol Forster, M.D.
Sarah Melton, Pharm.D.

DMAS Staff:
Donna Proffitt, R.Ph., Pharmacy Manager
Rachel Cain, Pharm.D., Clinical Pharmacist
Usha Koduru, Counsel to the Board, Office of the Attorney General
Danielle Adeeb, CPhT., Pharmacy Contract Administrator
MaryAnn McNeil, R.Ph., CCC Plus Pharmacist

Absent:
Sue Cantrell, M.D.
Ananda Basu, M.D.
Rachel M. Selby-Penczak, M.D.
Gill Abernathy, M.S., R.Ph.
Alexis Aplasca, M.D.

Staff: Magellan Rx Management
Debbie Moody, R.Ph., Pharmacist Account Executive, Virginia
Nancy Eldin Pharm.D., Clinical Manager, Virginia
Doug Brown, R.Ph., MBA, VP, Account Management
Jeni Hodzic, CPhT, Lead Formulary Analyst, Magellan Health Services

A quorum was present

Guests:
43 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 and thanked them for their participation in the PDL program. 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 shared that Dr. Jennifer Lee, Agency Director, has resigned her postion effective October 9, 2019 after successfully leading the Medicaid agency through the largest expansion of health coverage in Virginia in decades. Dr. Lee served an essential leadership role in Virginia's historic expansion of the Medicaid program this year, bringing health care to more than 300,000 hard-working Virginians. In two years under Dr. Lee's leadership, DMAS has significantly expanded coverage and implemented new initiatives that will contribute to higher quality, more equitable and more affordable health care in Virginia. DMAS launched a Medicaid Member Advisory Committee, completed a comprehensive review of forecasting and rate-setting, made investments in program research and evaluation, created a new Office of Value-Based Purchasing and an Office of Quality and Population Health, and tripled its investment in staff training and development.

Dr. Lee is transitioning her responsibilities to Karen Kimsey, Chief Deputy Director, who will serve as the new Agency Director. Ms. Kimsey has served the agency for almost 25 years, in a variety of roles, including Deputy Director of Complex Care and Services, Director of Policy and Research, and Director of the Office of Behavioral Health. Ms. Kimsey has a bachelor's degree in social work from James Madison University, and a master's degree in social work and gerontology from Virginia Commonwealth University.

Dr. Bachireddy introduced and welcomed new Board member Dr. Carol Forster to the Committee. Dr. Forster is a pharmacist and practicing primary care physician, and former physician director of the P&T

and Medication Safety for the Mid-Atlantic Permanente Medical Group. She led the opioid reduction strategy in the Kaiser Permanente Mid-Atlantic region, where high-dose opioid prescribing has decreased by almost 70 percent over the last five years, while resources to manage patients with chronic pain increased.

Dr. Bachireddy discussed Healthy Birthday Virginia. He mentioned that the goal of Health Birthday Virginia is to ensure Medicaid mothers and their infants are able to celebrate the child's first birthday together. Healthy Birthday Virginia will lay the foundation for a healthy future for Medicaid families and the next generation of Virginians.

Dr. Bachireddy noted that as the Agency continues its mission of providing high quality health care for our Medicaid members, the recommendations made by this Committee become critical to the success of the Common Core Formulary and patients' access to drug therapies. The medical community continues to extoll the benefits of the Common Core Formulary especially with new lives covered by Medicaid expansion.

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

Approval of Minutes from March 29, 2019 meeting Dr. Bachireddy 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.

DMAS' Drug Utilization Review (DUR) Board Update: Dr. Rachel Cain provided the DUR update. The DMAS DUR Board has met once since the March 29, 2019 P&T Committee meeting and reviewed the following 1 new drug: Inbrija™. The Board also reviewed 3 physician administered drugs – Intravenous Immune Globulins (IVIG), Mozobil® and Imlygic®. The Board recommended service authorization (SA) criteria on these drugs. Additionally, the Board reviewed the results of several utilization analyses: children with peanut allergies, compounded prescriptions, adult and pediatric narcotic utilization, concurrent use of opioids and benzodiazepines, opioids use with risk factors and no naloxone and antipsychotic duplication. The DUR Board will continue to review these issues. Dr. Cain announced that the next DUR Board meeting is scheduled for September 26, 2019.

PDL Management

PDL Phase II – New Drug Review *(Therapeutic Class)*

Brand Drugs

1. **Tremfya® and Skyrizi® *(Cytokine and CAM Antagonists)* *(Closed Class)*:**

   Speaker
   - Brian Calamari, PharmD, Medical Outcomes Science Liaison, AbbVie (Skyrizi®)

   Dr. Nancy Eldin presented the clinical information for Tremfya® (guselkumab) and Skyrizi® (risankizumab). A member of the Committee motioned that Tremfya® and Skyrizi® be PDL eligible. With the motion seconded, the Committee voted unanimously to consider both drugs as PDL eligible.

2. **Mayzent® and Mavenclad® *(Multiple Sclerosis Agents):***

Speaker

- Sharon Reizner, PharmD, Regional Account Medical Science Liaison, Novartis (Mayzent®)

Dr. Eldin presented the clinical information for Mayzent® (siponimod) and Mavenclad® (cladribine). A member of the Committee motioned that Mayzent® and Mavenclad® be PDL eligible. With the motion seconded, the Committee voted unanimously to consider both drugs as PDL eligible.

3. **Duobrii™ (*Psoriasis, Topical)*:** Dr. Eldin presented the clinical information on Duobrii™ (halobetasol/tazarotene). A member of the Committee motioned that Duobrii™ be PDL eligible. With the motion seconded, the Committee voted unanimously to consider this drug as PDL eligible.

4. **Adhansia XR™, Jornay PM™, and Sunosi™ (*Stimulants and Related Agents) (Closed Class):***

Speaker

- Ryan Gregg, PhD, Medical Science Liaison, Ironshore (Jornay PM™)

Dr. Eldin presented the clinical information for Adhansia XR™ (methylphenidate), Jornay PM™ (methylphenidate) and Sunosi™ (solriamfetol). A member of the Committee motioned that Adhansia XR™, Jornay PM™ and Sunosi™ be PDL eligible. With the motion seconded, the 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:

- benzhydrocodone/acetaminophen (authorized generic for Apadaz®) *(Analgesics, Narcotics Short)*
- aspirin/omeprazole (generic for Yosprala®) *(Platelet Aggregation Inhibitors) (Closed Class)*
- naftifine (generic for Naftin® Gel) *(Antifungals, Topical)*
- febuxostat (generic for Uloric®) *(Antihyperuricemics)*
- solifenacin succinate (generic for Vesicare®) *(Bladder Relaxant Preparations)*

A member of the Committee motioned that the new generics and new dosage forms be PDL eligible. With the motion seconded, the Committee voted unanimously to consider these drugs as PDL eligible.

PDL Phase I – Annual Review

1. ***Hepatitis C Agents (Closed Class):***

Speakers

- Brian Calamari, PharmD, Medical Outcomes Science Liaison, AbbVie (Mavyret™)
- Katherine Klem, PharmD, Associate Director, Medical Sciences, Gilead (authorized generic for Epclusa®)

Dr. Eldin presented the Hepatitis C Agents clinical information. A member of the Committee motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

2. ***Angiotensin Modulators II (Direct Renin Inhibitors & Combination Products):*** Dr. Eldin presented the Angiotensin Modulators II (Direct Renin Inhibitors & Combination Products) clinical information. A member of the Committee motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

3. ***Beta Blockers:*** Dr. Eldin presented the Beta Blockers clinical information. A member of the Committee motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as 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, Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitor and Omega 3 Agents):***

   Speaker
   - Ahmad Nessar, PharmD, Sr. Health Outcomes Specialist, Amgen (Repatha®)

   Dr. Eldin presented the Lipotropics, Other clinical information. A member of the Committee motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

5. ***Lipotropics, Statins:*** Dr. Eldin presented the Lipotropics, Statins clinical information. A member of the Committee motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

6. ***PAH Agents, Oral/Inhaled/Injectable:*** Dr. Eldin presented the PAH Agents, Oral/Inhaled/Injectable clinical information. A member of the Committee motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

7. ***Anticonvulsants:***

   Speaker
   - Bart Brown, PharmD, Medical Science Liaison, Biocodex (Diacomit®)

   Dr. Eldin presented the Anticonvulsants clinical information. A member of the Committee motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

8. ***Antidepressants, SSRI:*** Dr. Eldin presented the Antidepressants, SSRI clinical information. A member of the Committee motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

9. ***Antipsychotics (includes oral and long-acting injectables) (Closed Class – long-acting injectables only):***

   Speakers
   - Michael Nelson, PharmD, Director Health Economics and Outcomes, Sunovion (Latuda®)
   - Anne DePriest, PharmD, Senior Scientific Account Lead, Janssen (Invega Sustenna® and Invega Trinza®)

Dr. Eldin presented the Antipsychotics clinical information. A member of the Committee motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

10. ***Sedative Hypnotics:*** Dr. Eldin presented the Sedative Hypnotics clinical information. A member of the Committee motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

11. ***Immunomodulators, Atopic Dermatitis:*** Dr. Eldin presented the Immunomodulators, Atopic Dermatitis clinical information. A member of the Committee motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

12. ***Glucocorticoids, Oral:*** Dr. Eldin presented the Glucocorticoids, Oral clinical information. A member of the Committee motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

13. ***Hereditary Angioedema (HAE):*** Dr. Eldin presented the Hereditary Angioedema (HAE) clinical information. A member of the Committee motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

14. ***GI Motility, Chronic:*** Dr. Eldin presented the GI Motility, Chronic clinical information. A member of the Committee motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

15. ***Ulcerative Colitis:*** Dr. Eldin presented the Ulcerative Colitis clinical information. A member of the Committee motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

16. ***Ophthalmic Anti-Inflammatory Agents (includes Ophthalmic NSAIDs and Corticosteroids):*** Dr. Eldin presented the Ophthalmic Anti-Inflammatory Agents clinical information. A member of the Committee motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

17. ***Ophthalmics, Glaucoma Agents (includes Alpha-2 Adrenergics, Beta-blockers, Carbonic Anhydrase Inhibitors and Prostaglandin Inhibitors):*** Dr. Eldin presented the Ophthalmics, Glaucoma Agents clinical information. A member of the Committee motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

18. ***Anti-Allergens, Oral:*** Dr. Eldin presented the Anti-Allergens, Oral clinical information. A member of the Committee motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

19. ***Epinephrine, Self-Injected:*** Dr. Eldin presented the Epinephrine, Self-Injected clinical information. A member of the Committee motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

20. ***Glucocorticoids, Inhaled (includes nebulized solutions, metered dose inhalers and combinations) (Closed Class):*** Dr. Eldin presented the Glucocorticoids, Inhaled clinical information. A member of the Committee motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

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

- Antibiotics, Vaginal
- Bile Salts
- Phosphate Binders
- Angiotensin Modulators (ACEs, ARBs, & CCB combination products)
- Antihypertensives, Sympatholytics (Closed Class)
- Calcium Channel Blockers (includes dihydropyridine and non-dihydropyridine agents)
- Alzheimer's Agents
- Antidepressants, Other
- Steroids, Topical
- Growth Hormones (Closed Class)
- Progestins for Cachexia
- Antiemetic/Antivertigo Agents
- H. Pylori Agents
- Histamine-2 Receptor Antagonists (H-2RA)
- Proton Pump Inhibitors
- BPH Agents (includes Alpha Blockers, Androgen Hormone Inhibitors and Phosphodiesterase (PDE) 5 Inhibitors for BPH treatment)
- Bladder Relaxants
- Ophthalmic Allergic Conjunctivitis (includes Ophthalmic Antihistamines & Mast Cell Stabilizers)
- Ophthalmic Antibiotics
- Ophthalmic Antibiotic/Steroid Combinations
- Antibiotics Inhaled (Closed Class)
- Antihistamines Minimally Sedating
- Bronchodilators, Long Acting Beta Adrenergics
- Bronchodilators, Short Acting Beta Adrenergics
- Cough & Cold Agents (Legend)
- COPD (includes Anticholinergics, Bronchodilators and Phosphodiesterase 4 (PDE4) Inhibitors) (Closed Class)
- Intranasal Rhinitis (includes Antihistamines and Corticosteroids)
- Leukotriene Modifiers

Dr. Eldin noted that the above therapeutic classes had no significant changes since the last P&T Committee review. A member of the Committee motioned that these classes continue to be PDL eligible. With the motion seconded, 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.

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.

The motion was seconded and unanimously approved by the Committee.

Following the Confidential Session, the Committee members re-assembled in the 7th floor conference room. Dr. Bachireddy 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. A motion was made to resume the meeting. The motion was seconded and unanimously approved by the Committee.

PDL Generic Watch Changes Effective October 1, 2019

Dr. Jennings made a motion to make the following generic formulations preferred and the brand name equivalents non-preferred effective October 1, 2019. The motion was seconded and approved unanimously by the Committee:

1. ***Glucocorticoids, Inhaled (Closed Class):*** fluticasone/salmeterol is preferred. Advair Diskus® is non-preferred.

2. ***Influenza:*** oseltamivir capsule is preferred. Tamiflu® capsule is non-preferred.

3. ***Neuropathic Pain:*** pregabalin preferred with clinical step edit. Lyrica® is non-preferred.

PDL Changes Effective January 1, 2020

New Drugs Phase II:

All new drugs (brand and generic) presented at the September 19th meeting, will remain non-preferred. These include Tremfya®, Skyrizi®, Mayzent®, Mavenclad®, Duobrii™, Adhansia XR™, Jornay PM™, and Sunosi™.

Phase I 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. ***Growth Hormone (Closed Class):*** Norditropin® Pen is preferred. Nutropin® AQ Pen is non-preferred.

2. ***Antibiotics, Inhaled (Closed Class):*** tobramycin inhalation solution is non-preferred.

3. ***Anticonvulsants:*** clobazam tablet is preferred. Dilantin®, felbamate tablet and felbamate suspension are non-preferred.

4. ***Ulcerative Colitis Agents:*** Canasa®, Lialda® and mesalamine (rectal) are non-preferred.

5. ***Phosphate Binders:*** Renvela® tablet is non-preferred.

6. ***Ophthalmic Antibiotics:*** Vigamox® is non-preferred.

7. ***Ophthalmics, Glaucoma Agents:*** Rhopressa® and Rocklatan® are preferred. Simbrinza® is non-preferred.

8. ***Angiotensin Modulators:*** irbesartan, irbesartan/HCTZ, olmesartan and olmesartan/HCTZ are preferred.

9. ***Antiemetic/Antivertigo Agents:*** doxylamine succinate/vitamin B6 and prochlorperazine (rectal) are non-preferred.

10. ***Antihistamines, Minimally Sedating:*** levocetirizine tablets OTC is non-preferred.

11. ***Ophthalmic Antibiotic-Steroid Combinations:*** sulfacetamide/prednisolone is preferred.

12. ***PAH Agents, Oral/Inhaled/Injectable:*** tadalafil is preferred. Adcirca® is 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:

- Alzheimer's Agents
- Angiotensin Modulator Combinations
- Anti-Allergens, Oral
- Antibiotics, Vaginal
- Antidepressants, Other
- Antidepressants, SSRIs
- Antihypertensives, Sympatholytics (Closed Class)
- Antipsychotics (Closed Class – long-acting injectables only)
- Beta-Blockers
- Bile Salts
- Bladder Relaxant Preparations
- BPH Treatments

- Bronchodilators, Beta Agonist
- Calcium Channel Blockers
- COPD Agents (Closed Class)
- Cough and Cold, Cold
- Cough and Cold, Narcotic
- Epinephrine, Self-Injected
- GI Motility, Chronic
- Glucocorticoids, Oral
- H. Pylori Treatment
- HAE Treatments
- Hepatitis C Agents (Closed Class)
- Histamine II Receptor Blocker
- Immunomodulators, Atopic Dermatitis
- Intranasal Rhinitis Agents
- Leukotriene Modifiers
- Lipotropics, Other
- Lipotropics, Statins
- Ophthalmics for Allergic Conjunctivitis
- Progestins for Cachexia
- Proton Pump Inhibitors
- Sedative Hypnotics
- Steroids, Topical

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:

- Dupixent® (move the drug to the Cytokine and CAM Antagonists Class)
- Entresto™ (remove clinical criteria)
- Hemangeol™
- Hepatitis C (DMAS will update/develop clinical criteria and revisit at the next P&T Meeting)
- Lipotropics – Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitor
- Mavenclad®
- Mayzent®
- Motegrity™
- Short and Long-Acting Opioids (DMAS will update/develop clinical criteria and revisit at the next P&T Meeting)
- Skyrizi®
- Sunosi™
- Tremfya®

The next P&T Committee Meeting is tentatively scheduled for March 19, 2020.

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