

**Pharmacy and Therapeutics Committee Meeting
September 21, 2023**

Members Present:

Lisa Price-Stevens, M.D.
Tim Jennings, Pharm.D.
Sarah Melton, Pharm.D.
Gill Abernathy, M.S., R.Ph.
Carol Forster, M.D.
Olugbenga Obasanjo, M.D.
Michele Thomas, Pharm.D.
representing Alexis Ablasca,
M.D.
Rachel M. Selby-Penczak, M.D.

Absent:

Ananda Basu, M.D.
Megan Sarashinsky, Pharm.D.
Ira Bloomfield, M.D.
Angela Venuto-Ashton, M.D.

A quorum was present

DMAS Staff:

Cheryl J. Roberts, J.D., Medicaid Director
MaryAnn McNeil, R.Ph., Pharmacy Manager
JoeMichael T. Fusco, Pharm.D., MCO Pharmacy Compliance Manager
John Morgan, M.D. Chief Clinical Innovation Officer
Rachel Cain, Pharm.D., Clinical Pharmacist
Morgan Greer, JD, Virginia Assistant AG
Jeff Lunardi, Chief Deputy Director
Kiara M. Jasper, MHA, CPhT. Pharmacy Systems Administrator

Staff: Magellan Rx Management

Debbie Moody, Pharm.BS, R.Ph., Director Clinical Account Services
Nancy Eldin, Pharm.D., Pharmacist Account Executive
Kristen M. Haloski, Pharm.D., AAHIVP, Senior Director, Value Based Pricing
David D'Amico, Pharm.D., Pharmacist Account Executive
Jeni Hodzic, CPhT, Senior Account Management Specialist

Guests:

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

Welcome and Comments from Cheryl J. Roberts, J.D. Medicaid Director

Ms. Cheryl Roberts expressed her thanks to the committee for all the work they do for the Commonwealth, she noted that the Common Core Formulary is very important as it touches not just Medicaid FFS members but encompasses all Medicaid members including MCOs. Ms. Roberts discussed updates in outreach for renewal of members to reach younger generations via email and other methods. Ms. Roberts informed the committee of the upcoming changes at Virginia Medicaid such as Medicaid Unwinding, Behavioral Health Program called "Right Help Right Now". Ms. Roberts discussed variance in SUD by region of the state. Ms. Roberts reminded committee of their importance and effect of their decisions to not only the FFS group but MCOs as well.

Welcome and Comments from Lisa Price-Stevens, M.D., Chief Medical Officer and Chairman:

Dr. Lisa Price Stevens welcomed the members of the Committee and thanked them for their participation in the PDL program. Dr. Price-Stevens introduced herself to the committee and provided her background.

Call to Order and Housekeeping: The meeting was called to order by Dr. Price-Stevens, she informed the committee that Dr. Nancy Eldin, Clinical Manager with Magellan will be presenting an overview of the drugs. Committee members are encouraged to ask questions or request additional information at the end of each drug class presentation.

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

June 8, 2023, DUR Meeting:

The Board reviewed 5 new medications - Jaypirca™, Joenja®, Krazati™, Orserdu™ and Tezspire® Pen. The Board also approved therapeutic class service authorization criteria for Oral Oncology – Breast Cancer and Other Neoplasm Drugs and approved updates to the therapeutic class service authorization criteria for Oral Oncology – Other Cancer Drugs and Oral Oncology – Lung Cancer and Other Neoplasm Drugs. Additionally, the Board reviewed the results of several utilization analyses: the impact reports for 5 new DUR medications (Jaypirca™, Joenja®, Krazati™, Orserdu™ and Tezspire® Pen); the utilization for oral oncology – breast cancer and other neoplasm drugs; compounding of Hyftor™; concurrent use of opioids and benzodiazepines; concurrent use of opioids and antipsychotics; overlaps in opioids, benzodiazepines and antipsychotics; anticholinergic load; ProDUR reports, RetroDUR reports and utilization analysis reports.

September 14, 2023 DUR Meeting:

The Board reviewed information and Service Authorization (SA) criteria for 5 new medications - Cuvrior™ (trientine tetrahydrochloride), Daybue™ (trofinetide), Furoscix® (furosemide injection), Skyclarys™ (omaveloxolone), and Veozah™ (fezolinetant).

Annually, the Board reviews the Synagis criteria at the September meeting prior to the Respiratory Syncytial Virus (RSV) season beginning October 1, 2023 through March 31, 2024.

Additionally, the Board reviewed the results of ProDUR and RetroDUR reports, several utilization analyses: antipsychotic medications in children, antidepressant medications in children, mood stabilizer medications in children, and Overlaps in Antipsychotics, Antidepressants and Mood Stabilizers in Children

The next DUR Board meeting is scheduled for December 14, 2023.

The minutes from these meetings can be found at:

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

Approval of Minutes from March 23, 2023 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.

PDL Management

PDL Phase I – New Drug Review (Therapeutic Class)

Brand Drugs

1. **Vowst™ (Antibiotics, GI):** Dr. Eldin presented the clinical information for Vowst™.

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

2. **Inpefa™ (Hypoglycemics, SGLT2) (Closed Class):** Dr. Eldin presented the clinical information for Inpefa™

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

3. **Brixadi™ (Opiate Dependence Treatments) (Closed Class):**

Speaker

- John Landis, PharmD, Braeburn Medical Affairs

Dr. Eldin presented the clinical information for Brixadi™.

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

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

- *(Cytokine and CAM Antagonists) (Closed Class)*
 - Humira Biosimilars:
 - Adalimumab-Adaz
 - Adalimumab-Fkjp Pen
 - Cyltezo®
 - Hadlima™
 - Hulio®
 - Hyrimoz®
 - Idacio®
 - Yuflyma®
 - Yusimry™
- *(Antibiotics, GI)*
 - vancomycin 25 mg/mL oral solution (generic for Firvanq Kit)

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

PDL Phase II – Annual Review: Classes with Updates

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

Dr. Jennings requested follow-up on patient compliance 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.

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

Dr. Jennings requested follow-up on patient compliance 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. **Bile Acid Salts:** Dr. Eldin presented the Bile Acid Salts clinical information.

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

4. **Hemophilia Treatment (Closed Class):** Dr. Eldin presented the Hemophilia treatment clinical information.

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

5. **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

- Kerry Francis, PharmD, MSL, Amgen (Repatha®)

Dr. Eldin 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.

6. **Lipotropics, Statins:** Dr. Eldin presented the Lipotropics, Statins clinical information.

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

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

Speaker

- Patrick Reed, Pharm.D., BCCCP, MSL, United Therapeutics Corporation (Tyvaso®)

Dr. Eldin presented the PAH Agents, Oral/Inhaled/Injectable clinical information.

8. **Antidepressants, Other:**

Speaker

- Charlotte Wincott, PhD Associate Director, Medical Affairs (Auvelity™)

Dr. Eldin presented the Antidepressants, Other clinical information.

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

9. **Antidepressants, SSRI:** Dr. Eldin presented the Antidepressants, SSRI clinical information.

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

10. **Antipsychotics (Closed Class):**

Speaker

- Mandeep Sohal, Pharm Value, Evidence, and Outcomes Teva Pharmaceuticals (Uzedy™)
- Jessica Saleeby, PharmD, AAHIVE Principal Scientific Account Lead, Value & Evidence Scientific (Invega Hafyera®)
- Timothy Birner, PharmD, R.Ph., MBA Senior Director—Medical Affairs Managed

Markets (Lybalvi™)

- Krista Schladweiler, PhD Medical Science Liaison/Managed Market Liaison (Abilify Asimtufii®)

Dr. Eldin presented the Antipsychotics Agents clinical information.

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

11. Movement Disorders (Closed Class):

Speaker

- Mandeep Sohal, Pharm Value, Evidence, and Outcomes Teva Pharmaceuticals (Austedo® XR)

Dr. Eldin presented the Movement Disorders clinical information.

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

12. Sedative Hypnotics: Dr. Eldin presented the Sedative Hypnotics clinical information.

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

13. Immunomodulators, Atopic Dermatitis (Closed Class):

Speaker

- Hiten Patadia, PharmD, RPh Associate Director, Health Outcomes Liaison (IAI) (Opzelura®)

Dr. Eldin presented the Immunomodulators, Atopic Dermatitis clinical information.

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

14. Hereditary Angioedema (HAE) Agents: Dr. Eldin presented the Hereditary Angioedema (HAE) Agents clinical information.

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

15. Weight Loss Agents (Closed Class):

This discussion was postponed for a special P&T session on October 18, 2023.

16. GI Motility, Chronic: Dr. Eldin presented the GI Motility, Chronic clinical information.

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

17. Proton Pump Inhibitors: Dr. Eldin presented the Proton Pump Inhibitors clinical information.

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

18. **Ophthalmic, Anti-Inflammatory/Immunomodulator (Closed Class)**: Dr. Eldin presented the Ophthalmic, Anti-Inflammatory/Immunomodulator (Closed Class) clinical information.

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

19. **Ophthalmics, Glaucoma**: Dr. Eldin presented the Ophthalmics, Glaucoma clinical information.

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

20. **Anti-Allergens, Oral**: Dr. Eldin presented the Anti-Allergens, Oral clinical information.

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

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

- Antibiotics, Vaginal
- Phosphate Binders
- Sickle Cell Anemia Treatments (*Closed Class*)
- Angiotensin Modulator Combinations
- Angiotensin Modulators II (includes Direct Renin Inhibitors & combination products)
- Antihypertensives, Sympatholytics
- Beta Blockers (includes combination products)
- Calcium Channel Blockers (includes dihydropyridine and non-dihydropyridine agents)
- Anticonvulsants (*Closed Class*)
- Steroids, Topical
- Glucocorticoids, Oral
- Glucagon Agents (*Closed Class*)
- Progestins for Cachexia
- Antiemetic/Antivertigo Agents
- H. Pylori Agents
- Histamine-2 Receptor Antagonists (H-2RA)
- Ulcerative Colitis
- Bladder Relaxants
- BPH Agents
- Allergic Conjunctivitis (includes Ophthalmic Antihistamines & Mast Cell Stabilizers)
- Antibiotics
- Antibiotic/Steroid Combinations
- Anti-Inflammatory Agents (includes Ophthalmic NSAIDS & Corticosteroids)
- Antibiotics, Inhaled (*Closed Class*)
- Antihistamines Minimally Sedating
- Bronchodilators, Beta Agonist
 - i. *Bronchodilators, Long-Acting Beta Adrenergics*

ii. *Bronchodilators, Short-Acting Beta Adrenergics*

- COPD Agents (*Closed Class*)
- Cough & Cold Agents (Legend)
- Epinephrine, Self-Injected
- Glucocorticoids (includes nebulized solutions, MDIs and combinations) (*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 motion was made and seconded and the committee voted unanimously for the following classes to continue to be PDL eligible; Antibiotics, Vaginal, Phosphate Binders, Sickle Cell Anemia treatments, Angiotensin Modulator Combinations, Angiotensin Modulators II (includes Direct Renin Inhibitors & combination products), Antihypertensives Sympatholytics, Beta Blockers (includes combination products), Calcium Channel Blockers (includes dihydropyridine and non-dihydropyridine agents), Anticonvulsants, Steroids, Topical, Glucocorticoids, Oral, Glucagon Agents, Progestins for Cachexia, Antiemetic/Antivertigo Agents, H. Pylori Agents, Histamine-2 Receptor Antagonists (H-2RA), Ulcerative Colitis, Bladder Relaxants, BPH Agents, Allergic Conjunctivitis (includes Ophthalmic Antihistamines & Mast Cell Stabilizers), Antibiotics, Antibiotic/Steroid Combinations, Anti-Inflammatory Agents (includes Ophthalmic NSAIDS & Corticosteroids), Antibiotics, Inhaled, Antihistamines Minimally Sedating, Bronchodilators, Beta Agonist *Bronchodilators, Long-Acting Beta Adrenergics, Bronchodilators, Short-Acting Beta Adrenergics*, COPD Agents, Cough & Cold Agents (Legend), Epinephrine, Self-Injected, Glucocorticoids (includes nebulized solutions, MDIs and combinations), Intranasal Rhinitis (includes Antihistamines and Corticosteroids), and Leukotriene Modifiers.

Comments from the Office of the Attorney General

Mr. Morgan Greer 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.

He 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. Morgan 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. The motion was seconded and unanimously approved by the Committee. Motion to vote on the Bylaws at the next meeting. The motion was seconded and unanimously approved by the Committee.

Dr. Price-Stevens made a motion for the members to approve the confidential session statement. The motion was seconded and unanimously approved by the Committee.

<i>PDL Changes Effective January 1, 2024</i>

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):

- 1. HIV/AIDS (Closed Class):*** Combivir (oral), Epzicom (oral), Trizivir, (oral) efavirenz/lamivudine/tenofovir disoproxil fumarate (Symfi Lo) (oral), efavirenz/lamivudine/tenofovir disoproxil fumarate (Symfi) (oral), Atripla (oral), Sustiva capsule (oral), efavirenz capsule (oral), Retrovir syrup (oral), stadine capsule (oral), Epivir (oral), Ziagen (oral), Viread (oral), Norvir (oral), Lexiva suspension (oral), Viracept (oral), Reyataz capsule (oral), Aptivus capsule (oral), darunavir (oral), Kaletra solution and tablet (oral) are non-preferred.
- 2. Growth Hormone (Closed Class):*** Nutropin AQ Pen (injection) is preferred.
- 3. Immunomodulators, Atopic Dermatitis (Closed Class):*** Adbry (subcutaneous) is preferred.
- 4. COPD Agents (Closed Class):*** roflumilast (oral) is preferred.
- 5. Glucagon Agents (Closed Class):*** Glucagon Emergency Kit (Amphastar) is preferred.
- 6. Antiemetic/Antivertigo Agents:*** Diclegis (oral) is preferred.
- 7. Anticonvulsants (Closed Class):*** Tiagabine (oral) is preferred.
- 8. Antipsychotics (Closed Class):*** Uzedy (subcutaneous) and Abilify Asimtufii (intramuscular) are preferred.
- 9. Glucocorticoids, Inhaled (Closed Class):*** Arnuity Ellipta (inhalation), fluticasone HFA (AG) (inhalation) and Trelegy Ellipta (inhalation) are preferred.
- 10. HAE Treatments:*** Icatibant (subcutaneous) and Sajazir (subcutaneous) is preferred.
- 11. Ophthalmic, Antibiotic-Steroid Combinations:*** tobramycin/dexamethasone suspension (ophthalmic) is preferred.
- 12. Liptropics, Other:*** Vascepa (oral) is preferred.
- 13. Gi Motility, Chronic:*** lubiprostone (oral) is preferred.
- 14. Bronchodilators, Beta Agonist:*** Proair Respiclick (Inhalation) is preferred.

PDL Generic Watch Changes Effective January 1, 2024

Dr. Jennings made a motion to make the following generic formulations preferred and the brand name equivalents non-preferred effective January 1, 2024. The motion was seconded and approved unanimously by the Committee:

1. Antidepressants, Other: vilazodone (oral) is preferred. Viibryd (oral) 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:

- Angiotensin Modulator Combinations
- Angiotensin Modulator
- Anti-Allergens, Oral
- Antibiotics, Inhaled (Closed Class)
- Antibiotics, Vaginal
- Antidepressants, SSRIs
- Antihistamines, Minimally Sedating
- Antihypertensives, Sympatholytic
- Beta-Blockers
- Bile Salts
- Bladder Relaxant Preparations
- BPH Treatments
- Calcium Channel Blockers
- Cough and Cold Agents
- Epinephrine, Self-Injected
- Glucocorticoids, Oral
- H. Pylori Treatment
- Hemophilia Treatment (Closed Class)
- Hepatitis C Agents (Closed Class)
- Histamine II Receptor Antagonists
- Intranasal Rhinitis Agents
- Leukotriene Modifiers
- Lipotropics, Statins
- Movement Disorders (Closed Class)
- Ophthalmic Antibiotics
- Ophthalmics for Allergic Conjunctivitis
- Ophthalmics, Anti-Inflammatories
- Ophthalmics, Anti-Inflammatories/Immunomodulators (Closed Class)
- Ophthalmics, Glaucoma Agents
- PAH Agents, Oral and Inhaled
- Progestins for Cachexia
- Proton Pump Inhibitors
- Sedative Hypnotics
- Sickle Cell Anemia Treatment (Closed Class)
- Steroids, Topical
- Ulcerative Colitis Agents

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 Vowst Criteria
- Updates to the Growth Hormone SA form
- Updates to the Lipotropics, Other SA form

Dr. Price-Stevens motioned for a special session to be on October 18, 2023, to discuss Weight Loss Agents and the associated SA forms. The Committee agreed to this date.

The next P&T Committee Meeting is tentatively scheduled for March 21, 2024.

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