

**Pharmacy and Therapeutics Committee Meeting**  
**September 22, 2022**  
**Draft Minutes**

**Members Present:**

Chethan Bachireddy, M.D.  
Tim Jennings, Pharm.D.  
Megan Sarashinsky, Pharm.D.  
Ira Bloomfield, M.D.  
Sarah Melton, Pharm.D.  
Gill Abernathy, M.S., R.Ph.  
Rachel M. Selby-Penczak, M.D.  
Carol Forster, M.D.  
Olugbenga Obasanjo, M.D.

**DMAS Staff:**

Cheryl J. Roberts, J.D. Acting Medicaid Director  
MaryAnn McNeil, R.Ph., Pharmacy Manager  
John Morgan, MD, Chief Clinical Innovation Officer  
JoeMichael T. Fusco, PharmD., 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

**Absent:**

Ananda Basu, M.D.  
Angela Venuto-Ashton, M.D.  
Alexis Ablasca, 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

**A quorum was present**

**Guests:**

40 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. During these unprecedented times, 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. Dr. Bachireddy introduced our new P&T member, Olugbenga Obasanjo, M.D. representing the Virginia Department of Health and thanked him for joining the Committee. Dr. Bachireddy introduced Cheryl Roberts the then Acting Medicaid Director.

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

Ms. 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.

**Call to Order and housekeeping:** The meeting was called to order by Dr. Bachireddy, he informed the committee that 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.

**Approval of Minutes from March 17, 2022, 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.

**June 2, 2022, DUR Meeting:**

The Board reviewed 1 new medication.

The Board also approved service authorization criteria for ReZurock. Additionally, the Board reviewed the results of several utilization analyses: concurrent use of opioids and benzodiazepines, concurrent use of opioids and antipsychotics, and antipsychotics in children.

**September 8, 2022, DUR Meeting:**

The Board reviewed 3 new medications (Camzyos, Vioice, Vonjo)

They approved Service Authorization (SA) for Vioice and Vonjo. Additionally, the Board reviewed the results of several utilization analyses; 2 new topics were Antidepressant medications in children, and Mood Stabilizer medications in children. The board will continue to review these twice a year. Also, the board reviewed and approved the Synagis criteria for this season which runs from October 1, 2022 through March 31, 2023.

The next DUR Board meeting is scheduled for December 15, 2022.

The minutes from these meetings can be found at:

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

**PDL Management**

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

**Brand Drugs**

1. **Twynéo® (Acne Agents, Topical):** Dr. Nancy Eldin presented the clinical information for Twynéo®.
2. **Zimhi™ (Opiate Dependence Treatments) (Closed Class):**

Speaker

- Jake Nichols, Pharm.D., MBA Medical Affairs Consultant US WorldMeds (Zimhi™)

Dr. Eldin presented the clinical information for Zimhi™.

3. **Epsolay® (Rosacea Agents, Topical):** Dr. Eldin presented the clinical information for Epsolay®.
4. **Fleqsuvy™ and Lyvispah™ (Skeletal Muscle Relaxants):** Dr. Eldin presented the clinical information for Fleqsuvy™ and Lyvispah™.

Dr. Jennings motioned that Twyneo<sup>®</sup>, Zimhi<sup>™</sup>, Epsolay<sup>®</sup>, Fleqsuvy<sup>™</sup> and Lyvispah<sup>™</sup> 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:

- *(Analgesics, Narcotics Short)*
  - tramadol solution (generic for Qdolo<sup>®</sup>)
- *(Insulin And Related Agents)*
  - insulin glargine Solostar (generic Lantus<sup>®</sup> Solostar) and insulin glargine (generic for Lantus<sup>®</sup>)
- *(NSAIDS)*
  - diclofenac 2% topical solution (generic for Pennsaid<sup>®</sup>) and diclofenac potassium capsule (generic for Zipsor<sup>™</sup>)
- *(Opiate Dependence Treatments)*
  - naloxone HCL 4 mg nasal spray (generic for Narcan<sup>®</sup>)

Dr. Jennings 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.

### **Potential New PDL Closed Classes**

#### **1. *Glucagon Agents (Potential NEW PDL Closed Class):***

Speaker

- Tapan Patel, PharmD., Senior Director, East Regional Medical Affairs Team, Xeris Pharmaceuticals, Inc (Gvoke<sup>®</sup>)

Dr. Eldin presented the Glucagon Agents clinical information. Dr. Jennings motioned that the class be PDL eligible. With the motion seconded, the Committee voted unanimously to consider the class as PDL eligible.

#### **2. *Hemophilia Treatment (Potential NEW PDL Closed Class):***

Speakers

- Becky Bowers-Lanier, VHF Executive Director
- Ahmad Nessar, PharmD., Medical Affairs Executive Director - DC/MD/VA Ecosystem, U.S. Medical Affairs, Genentech (Hemlibra<sup>®</sup>)
- Erin Zekas Camire, PhD Medical Science Liaison, HEMA Biologics (Sevenfact<sup>®</sup>)

Dr. Eldin presented the Hemophilia Treatment clinical information. The Committee had many questions and a lengthy discussion concerning Hemophilia. Dr. Bachireddy asked to wait until after the closed section to make this class PDL eligible.

#### **3. *Sickle Cell Anemia Treatments (Potential NEW PDL Closed Class):***

Speaker

- Santreis Booze, PharmD., BCGP, Senior Managed Care Liaison (Oxbryta<sup>®</sup>)

Dr. Eldin presented the Sickle Cell Anemia Treatments clinical information. Dr. Jennings motioned that the class become PDL eligible, and a board members seconded the motion. The Committee voted unanimously to consider this class as PDL eligible.

4. **Weight Management Agents (Potential NEW PDL Closed Class):**

Speaker

- Lydia Wang, Pharm D., Novo Nordisk (Wegovy®)

Dr. Eldin presented the Weight Management Agents clinical information. Dr. Jennings motioned that the class be PDL eligible. With the motion seconded, the Committee voted unanimously to consider the class as PDL eligible.

**PDL Phase I – Annual Review**

1. **Antibiotics, Vaginal:** Dr. Eldin presented the Antibiotics, Vaginal clinical information.
2. **Hepatitis C Agents (Closed Class):** Dr. Eldin presented the Hepatitis C Agents clinical information. Dr. Jennings motioned that the class's Antibiotics, Vaginal, Hepatitis C Agents continue to be PDL eligible, and a board member seconded the motion. The Committee voted unanimously to maintain this class as PDL eligible.
3. **HIV/AIDS Agents (Closed Class):** Dr. Eldin presented the HIV/AIDS Agents clinical information.
4. **Angiotensin Modulators II:** Dr. Eldin presented the Angiotensin Modulators II clinical information.
5. **Calcium Channel Blockers:** Dr. Eldin presented the Calcium Channel Blockers clinical information.
6. **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

- Amy Bivens, PharmD, Amgen US Medical Value and Access Senior Health Outcomes and Pharmacoeconomics Specialist (Repatha®)

Dr. Eldin presented the Lipotropics, Other clinical information.

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

Speaker

- Kyle Davis, Pharm. D., BCPS Medical Science Liaison for United Therapeutics (Tyvaso® DPI)

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

8. **Alzheimer's Agents:** Dr. Eldin presented the Alzheimer's Agents clinical information.

9. **Anticonvulsants (Closed Class)**: Dr. Eldin presented the Anticonvulsants clinical information.
10. **Antidepressants, SSRI**: Dr. Eldin presented the Antidepressants, SSRI clinical information.
11. **Antipsychotics (Closed Class)**: Dr. Eldin presented the Antipsychotics clinical information.
12. **Sedative Hypnotics**: Dr. Eldin presented the Sedative Hypnotics clinical information. member seconded the motion. The Committee voted unanimously to maintain this class as PDL eligible.

13. **Immunomodulators, Atopic Dermatitis (Closed Class)**:

Speaker

- Kristin Kollecas, Pharm.D., Associate Director, Medical Value & Outcomes - East (Dupixent®)

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

14. **Ophthalmic for Allergic Conjunctivitis**: Dr. Eldin presented the Ophthalmic for Allergic Conjunctivitis clinical information.
15. **Ophthalmic Antibiotics**: Dr. Eldin presented the Ophthalmic Antibiotics clinical information.
16. **Ophthalmic Antibiotic/Steroid Combinations**: Dr. Eldin presented the Ophthalmic Antibiotic/Steroid Combinations clinical information.
17. **Ophthalmic Anti-Inflammatory Agents**: Dr. Eldin presented the Ophthalmic Anti-Inflammatory Agents clinical information.
18. **Cough & Cold (Legend)**: Dr. Eldin presented the Cough & Cold (Legend) clinical information.
19. **Glucocorticoids, Inhaled (includes nebulized solutions, metered dose inhalers and combinations) (Closed Class)**: Dr. Eldin presented the Glucocorticoids, Inhaled clinical information.
20. **Intranasal Rhinitis (includes Antihistamines and Corticosteroids)**: Dr. Eldin presented the Intranasal Rhinitis clinical information.

Dr. Jennings motioned that the class's HIV/AIDS, Angiotensin Modulators II Agents, Calcium Channel Blockers, Lipotropics, Other, PAH Agents, Oral/Inhaled/Injectable Alzheimer's Agents, Anticonvulsants, Antidepressants, SSRI, Antipsychotics, Sedative Hypnotics, Immunomodulators, Atopic Dermatitis, Ophthalmic for Allergic Conjunctivitis, Ophthalmic Antibiotics, Ophthalmic Antibiotic/Steroid Combinations, Ophthalmic Anti-Inflammatory Agents, Cough & Cold (Legend), Glucocorticoids, Inhaled (includes nebulized solutions, metered dose inhalers and combinations), Intranasal Rhinitis (includes Antihistamines and Corticosteroids) continue to be PDL eligible, and a board member seconded the motion. The Committee voted unanimously to maintain these classes as PDL eligible.

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

- Bile Salts
- Phosphate Binders
- Angiotensin Modulator Combinations
- Antihypertensives, Sympatholytics (*Closed Class*)
- Beta Blockers (includes combination products)
- Lipotropics, Statins
- Antidepressants, Other
- Movement Disorders (*Closed Class*)
- Steroids, Topical
- Glucocorticoids, Oral
- Growth Hormones (*Closed Class*)
- HAE Treatments
- Progestins for Cachexia
- Antiemetic/Antivertigo Agents
- GI Motility, Chronic
- H. Pylori Agents
- Histamine II Receptor Antagonists
- Proton Pump Inhibitors
- Ulcerative Colitis
- Bladder Relaxants
- BPH Agents
- Ophthalmic, Anti-Inflammatory/Immunomodulator (*Closed Class*)
- Ophthalmic, Glaucoma
- Anti-Allergens, Oral
- Antibiotics, Inhaled (*Closed Class*)
- Antihistamines, Minimally Sedating
- Bronchodilators, Beta Agonist
  - Bronchodilators, Long-Acting Beta Adrenergics
  - Bronchodilators, Short Acting Beta Adrenergics
- COPD Agents (*Closed Class*)
- Epinephrine, Self-Injected
- Leukotriene Modifiers

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

Dr. Jennings motioned that the classes' Bile Salts, Phosphate Binders, Angiotensin Modulator Combinations, Antihypertensives, Sympatholytics, Beta Blockers (includes combination products), Lipotropics, Statins, Antidepressants, Other, Movement Disorders, Steroids, Topical, Glucocorticoids, Oral. Growth Hormones, HAE Treatments, Progestins for Cachexia, Antiemetic/Antivertigo Agents, GI Motility, Chronic, H. Pylori Agents, Histamine II Receptor Antagonists, Proton Pump Inhibitors, Ulcerative Colitis, Bladder Relaxants, BPH Agents, Ophthalmic, Anti-Inflammatory/Immunomodulator, Ophthalmic, Glaucoma, Anti-Allergens, Oral, Antibiotics, Inhaled, Antihistamines, Minimally Sedating, Bronchodilators, Beta Agonist Bronchodilators, Long-Acting Beta Adrenergics, Bronchodilators, Short Acting Beta Adrenergics, COPD Agents (*Closed Class*), Epinephrine, Self-Injected, Leukotriene Modifiers

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

Tim Jennings made a motion that at the next meeting the committee takes a vote on the bylaws. The motion was seconded and unanimously approved by the Committee.

***PDL Changes Effective January 1, 2023***

***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. ***Immunomodulators, Atopic Dermatitis (Closed Class):*** Dupixent Pen and Syringe are preferred.

2. **Anticonvulsants (Closed Class)**: lacosamide solution and tablet are preferred. Vimpat solution and tablet are non-preferred.
3. **Sickle Cell Anemia Treatments (Closed Class)**: Droxia, Endari, and Oxbryta are preferred. Adakveo and Siklos are non-preferred.
4. **Glucagon Agents (Closed Class)**: Baqsimi, Glucagon, Glucagon emergency kit (Fresenius), Gvoke pen, syringe, vial and Proglycem suspension are preferred. Diazoxide suspension, Glucagon emergency kit (Lilly) and Zegalogue Autoinjector and syringe are non-preferred.
5. **Weight Management Agents (Closed Class)**: Contrave, Qsymia, Saxenda, Xenical and Wegovy are preferred. Imcivree is non-preferred.

Dr. Jennings motioned that the class be PDL eligible. With the motion seconded, the Committee voted unanimously to consider the class as PDL eligible.

6. **Hemophilia Treatment (Closed Class)**: Advate, Adynovate, Afstyla, Alphanate, Alphanine SD, Alprolix, Benefix Kit, Coagadex, Corifact Kit, Eloctate, Esperoct, Feiba NF, Hemlibra, Hemofil-M, Humate-P Kit, Idelvion, Ixinity, Jivi, Koate-DVI Kit, Koate-DVI Vial, Kogenate FS, Kovaltry, Novoeight, Novoseven RT, Nuwiq, Obizur, Profilnine, Rebinyn, Recombinate, Rixubis, Sevenfact, Tretten, Vonvendi, Wilate, Xyntha Kit and Xyntha Solofuse Syr Kit are preferred.

Dr. Jennings noted that all Hemophilia treatments are included and preferred.

7. **Epinephrine, Self-Injected**: EpiPen and EpiPen JR are preferred. Epinephrine 0.15 mg (EpiPen JR) is non-preferred.
8. **Antihypertensives, Sympatholytics (Closed Class)**: clonidine (transdermal) is preferred. Dr. Jennings motioned that the class be removed from the Closed Classes. With the motion seconded, the Committee voted unanimously to remove the Cass from the Closed Classes.
9. **Bronchodilators, Beta Agonist Agents**: arformoterol (Authorized Generic) is preferred.
10. **Antibiotics, Inhaled (Closed Class)**: tobramycin (Tobi) (inhalation neb) is preferred.

<b><i>PDL Generic Watch Changes Effective January 1, 2023</i></b>
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***Dr. Jennings made a motion to make the following generic formulations preferred and the brand name equivalents non-preferred effective January 1, 2023. The motion was seconded and approved unanimously by the Committee:***

1. **Alzheimer's Agents**: rivastigmine (transdermal) is preferred. Exelon (transdermal) is non-preferred.
2. **Stimulants/ADHD Medications (Closed Class)**: dexamethylphenidate XR is preferred. Focalin XR 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:***

- Acne Agents, Topical
- Angiotensin Modulator Combinations
- Angiotensin Modulators
- Anti-Allergens, Oral
- Antibiotics, Vaginal
- Antidepressants, Other
- Antidepressants, SSRIs
- Antiemetic/Antivertigo Agents
- Antihistamines, Minimally Sedating
- Antipsychotics, (Closed Class)
- Beta-Blockers
- Bile Salts
- Bladder Relaxant Preparations
- BPH Treatments
- Calcium Channel Blockers
- COPD Agents (Closed Class)
- Cough And Cold, Narcotic
- GI Motility, Chronic
- Glucocorticoids, Inhaled (Closed Class)
- Glucocorticoids, Oral
- Growth Hormone (Closed Class)
- H. Pylori Treatment
- HAE Treatments
- Hepatitis C Agents (Closed Class)
- Histamine II Receptor Antagonists
- HIV/AIDS Agents (Closed Class)
- Intranasal Rhinitis Agents
- Leukotriene Modifiers
- Lipotropics, Other
- Lipotropics, Statins
- Movement Disorders (Closed Class)
- Ophthalmic Antibiotics
- Ophthalmic Antibiotic/Steroid Combinations
- Ophthalmics For Allergic Conjunctivitis
- Ophthalmic, Anti-Inflammatory/Immunomodulator (Closed Class)
- Ophthalmic Anti-Inflammatory Agents
- PAH Agents, Oral And Inhaled
- Phosphate Binders
- Progestins For Cachexia
- Proton Pump Inhibitors
- Sedative Hypnotics
- Steroids, Topical High
- Steroids, Topical Low
- Steroids, Topical Medium
- Steroids, Topical Very High

- 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:

- Updates to Sickle Cell Anemia Treatments SA fax form
- Updates to Anti-Obesity SA fax form and rename the fax form as Weight Management Agents SA fax form
- Updates to Immunomodulators, Atopic Dermatitis AutoPA criteria
- Updates to Dupixent criteria and create new AutoPA
- Updates to Eucrisa criteria
- Eliminate Oxbryta SA fax form

The next P&T Committee Meeting is tentatively scheduled for March 16, 2023

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

DRAFT