

**Pharmacy and Therapeutics Committee**  
**September 14, 2021, Virtual Meeting**  
**Draft Minutes**

**Members Present:**

Chethan Bachireddy, M.D.  
Tim Jennings, Pharm.D.  
Ira Bloomfield, M.D.  
Carol Forster, M.D.  
Sarah Melton, Pharm.D.  
Gill Abernathy, M.S., RPh.  
Michele Thomas, Pharm.D. for  
Alexis Ablasca, M.D.

**DMAS Staff:**

MaryAnn McNeil, RPh., Pharmacy 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  
John Morgan, M.D., Chief Clinical Innovation Officer

**Absent:**

Rachel M. Selby-Penczak, M.D.  
Ananda Basu, M.D.  
Angela Venuto-Ashton, M.D.  
Megan Sarashinsky, PharmD

**A quorum was present**

**Staff: Magellan Rx Management**

Debbie Moody, RPh., Director, Clinical Account Services, Virginia  
Nancy Eldin, Pharm.D., Pharmacist Account Executive, Virginia  
Marcie Morris, RPh., Rebate Pharmacist  
Jeni Hodzic, CPhT, Lead Formulary Analyst

**Guests:** 56 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 during these unprecedented times. Dr. Bachireddy acknowledged their time and expertise in serving on the DMAS Pharmacy & Therapeutics Committee especially during our latest COVID surge. Because of their work, Virginia's Medicaid members have access to high quality drug therapies that are both clinically appropriate and cost-effective.

This meeting will be different from all of our other P&T meetings. Based on 17.a Chapter 1 of 2021 Special Session II- the state PHE ended, and all public meetings must have an in person quorum for any votes to take place. The Committee, based on member access to Suboxone film in SW VA, DMAS added generic buprenorphine/naloxone SL tablets to our PDL

**DMAS' Drug Utilization Review (DUR) Board Update:**

Dr. Rachel Cain provided the DUR update.

**June 10, 2021, DUR Meeting:**

The Board reviewed 12 new medications.

Additionally, the Board reviewed the results of several utilization analyses: the impact reports for the 12 new DUR medications, concurrent use of opioids and benzodiazepines, concurrent use of opioids and antipsychotics, antipsychotic medications in children, respiratory drugs (excluding ICS and SABAs) in members less than 4 years of age, utilization of anticoagulant reversals when using the novel oral anticoagulants and opioid use with and without naloxone.

For the respiratory drugs in members less than four years of age, data was reviewed from the period of October 1, 2020, through March 31, 2021. For the FFS population, there was one member age 1. For the MCO population, there were 53 members under the age of 4.

For the Anticoagulant reversals, reports were created with both FFS and MCO data during the time frame of October 1, 2020 through March 31, 2021 for utilization data on newer anticoagulant reversals when using the Novel Oral Anticoagulants (NOACs).

The newer anticoagulant reversals are Praxbind (HIC3 = M9W) and Andexxa (HIC3 = M9Y)

The NOACs we looked for were Pradaxa, Xarelto, Eliquis, and Savaya.

There were no utilization of any of the newer anticoagulant reversals for both FFS and the MCOs.

Results of the Type 2 diabetes and treatment with oral hypoglycemics will be presented at the spring meeting.

**September 9, 2021, DUR Meeting:**

Due to current regulations since this meeting was virtual, the board was not allowed to vote and was used for informational purposes. Hopefully voting will take place at the December DUR Meeting.

The Board reviewed 8 new medications

They began consolidating service authorization (SA) forms for the oral oncology drugs.

The Synagis criteria is reviewed annually at the September DUR meeting. The season is typically October – March. This year due to the surge in RSV in Virginia, DMAS opened the season on August 15, 2021.

The next DUR Board meeting is scheduled for December 9, 2021.

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. **Kloxxado® Spray (Nasal) (Opiate Dependence Treatments):** Dr. Eldin presented the clinical information for Kloxxado® Spray.

**2. Plegridy® (IM) and Ponvory™ (Oral) (Multiple Sclerosis Agents):**

Speaker

- Belkys (Barbosa) Dean, PharmD, BCGP, Principal Scientific Account Lead, Value & Evidence Scientific Engagement – Field, Janssen Scientific Affairs, LLC (Ponvory™)

Dr. Eldin presented the clinical information for Plegridy® and Ponvory™.

**3. Qelbree® (Oral) (Stimulants and Related Agents):**

Speaker

- Opeoluwa Fagbemi, PharmD. Senior Medical Science Liaison & Regional Manager. Supernus Pharmaceuticals, Inc. (Qelbree®)

Dr. Eldin presented the clinical information for Qelbree®.

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

- (Acne Agents, Topical)
  - tazarotene (generic for Fabior®)
- (Cytokine and Cam Antagonists)
  - Skyrizi™ Pen new dosage form
- (Steroids, Topical Very High)
  - Clobetex® Kit new dosage form

**PDL Phase I – Annual Review**

1. **Antibiotics, Vaginal:** Dr. Eldin presented the Antibiotics, Vaginal clinical information.

2. **HIV (Potential new PDL class and new Closed Class):**

Speakers

- Katherine Klem, PharmD, Principal Medical Scientist- Managed Care, Medical Affairs | Gilead Sciences, Inc (Biktarvy®)
- Katherine Klem, PharmD, Principal Medical Scientist- Managed Care, Medical Affairs | Gilead Sciences, Inc (Descovy®)
- Lisa Wright, DNP, ANP-C, CPHQ, Health System Medical Affairs Director/US Medical Affairs Merck Research Laboratories/Merck & Co (Pifeltro™)

Dr. Eldin presented the HIV clinical information.

3. **Bile Salts:** Dr. Eldin presented the Bile Salts clinical information.

4. **Angiotensin Modulators II (includes Direct Renin Inhibitors & combination products):** Dr. Eldin presented the Angiotensin Modulators II clinical information.

5. **Lipotropics, Statins:** Dr. Eldin presented the Lipotropics, Statins 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 and Omega 3 agents):** Dr. Eldin presented the Lipotropics, Other clinical information.

7. **Pulmonary Arterial Hypertension Agents, Oral/Inhaled/Injectable (includes Endothelin-1 agents, PDE-5 Inhibitors, Prostacyclin analogues, Prostacyclin Vasodilator, Soluble Guanylate Cyclase Stimulators) Central:**

Speaker

- Wes Blankenship, Pharm D., Medical Science Liaison, for United Therapeutics (Tyvaso®)

Dr. Eldin presented the PAH Agents clinical information.

8. **Anticonvulsants (Potential new Closed class):** Dr. Eldin presented the Anticonvulsants clinical information.

9. **Movement Disorder Agents (Potential new PDL class and new Closed class):**

Speakers

- Ryan C. Norman, Pharm.D. MBA, Medical Outcomes Liaison, Field Medical Affairs (Austedo™)
- Mark B Golick, PharmD, Senior Managed Care Liaison Neurocrine Biosciences, Inc., Medical Affairs (Ingrezza®)

Dr. Eldin presented the Movement Disorder Agents clinical information.

10. **Immunomodulators, Atopic Dermatitis (Potential new Closed class):** Dr. Eldin presented the Immunomodulators, Atopic Dermatitis clinical information.

11. **Hereditary Angioedema (HAE):** Dr. Eldin presented the Hereditary Angioedema (HAE) clinical information.

12. **Bladder Relaxants:** Dr. Eldin presented the Bladder Relaxants clinical information.

13. **Allergic Conjunctivitis (includes Ophthalmic Antihistamines & Mast Cell Stabilizers):** Dr. Eldin presented the Allergic Conjunctivitis (includes Ophthalmic Antihistamines & Mast Cell Stabilizers) clinical information.

14. **Ophthalmic Antibiotics:** Dr. Eldin presented the Ophthalmic Antibiotics clinical information.

15. **Ophthalmic Anti-inflammatory/ Immunomodulators (Potential new PDL class and new Closed Class):** Dr. Eldin presented the Ophthalmic Anti-inflammatory/ Immunomodulators clinical information.

16. **Bronchodilators, Long-Acting Beta Adrenergics:** Dr. Eldin presented the Bronchodilators, Long-Acting Beta Adrenergics clinical information.

17. **Glucocorticoids (includes nebulized solutions, metered dose inhalers and combinations) (Closed Class):** Dr. Eldin presented the Glucocorticoids clinical information.

18. **Intranasal Rhinitis (includes Antihistamines and Corticosteroids):** Dr. Eldin presented the Intranasal Rhinitis clinical information.

Next Meeting – Voting Meeting – September 27, 2021

**Next Meeting – March 17, 2022 (tentative)**

**Pharmacy and Therapeutics Committee Meeting  
September 27, 2021, In Person Meeting  
Draft Minutes**

**Members Present:**

Chethan Bachireddy, M.D.  
Tim Jennings, Pharm.D.  
Ira Bloomfield, M.D.  
Carol Forster, M.D.  
Gill Abernathy, M.S., RPh.  
Alexis Ablasca, M.D.  
Megan Sarashinsky, PharmD

**DMAS Staff:**

MaryAnn McNeil, RPh., Pharmacy Manager  
Rachel Cain, Pharm.D., Clinical Pharmacist  
Kiara M. Jasper, MHA, CPhT Pharmacy Systems Administrator Usha  
Koduru, Counsel to the Board, Office of the Attorney General John  
Morgan, M.D., Chief Clinical Innovation Officer

**Absent:**

Rachel M. Selby-Penczak, M.D.  
Ananda Basu, M.D.  
Angela Venuto-Ashton, M.D.  
Sarah Melton, Pharm.D.

**Staff: Magellan Rx Management**

Debbie Moody, RPh., Director, Clinical Account Services, Virginia  
Nancy Eldin, Pharm.D., Pharmacist Account Executive, Virginia  
Jeni Hodzic, CPhT, Lead Formulary Analyst

**A quorum was present**

**Guests:**

2 in person 8 virtually 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 this in person voting meeting.

Dr. Bachireddy and MaryAnn McNeil mentioned that the P&T Board will be responsible for reviewing service authorizations for preferred products. DMAS will work in combination with the DUR Board for service authorization for non-preferred products and utilization management. DMAS has been working with the MCOs in getting their recommendations for utilization management that can be used at the P&T for the preferred drug list. This is an effort to consolidate the process and get more uniformity.

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

**Approval of Minutes from March 18, 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. Dr. Bachireddy seconded the motion. The Committee unanimously approved the minutes as written.

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. Dr. Bachireddy seconded the motion. The Committee voted unanimously to reconvene.

## **PDL Management**

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

#### **Brand Drugs**

1. Kloxxado® Spray (Nasal) (*Opiate Dependence Treatments*)
2. Plegridy® (IM) and Ponvory™ (Oral) (*Multiple Sclerosis Agents*)
3. Qelbree® (Oral) (*Stimulants and Related Agents*)

#### **Generic Drugs or New Dosage Forms:**

1. Tazarotene – generic for Fabior® (Acne Agents, Topical)
2. Skyrizi™ Pen new dosage form (Cytokine and Cam Antagonists)
3. Clobetex® Kit new dosage form (Steroids, Topical Very High)

Dr. Jennings motioned that Kloxxado® Spray, Plegridy®, Ponvory™, Qelbree®, tazarotene, Skyrizi™ Pen and Clobetex® Kit be PDL eligible. Gill Abernathy seconded the motion. The Committee voted unanimously to consider these drugs as PDL eligible.

### **PDL Phase I – Annual Review**

1. Antibiotics, Vaginal
2. HIV (*Potential new PDL class and new Closed Class*)
3. Bile Salts
4. Angiotensin Modulators II
5. Lipotropics, Statins
6. Lipotropics, Other
7. Pulmonary Arterial Hypertension Agents, Oral/Inhaled/Injectable
8. Anticonvulsants (*Potential new Closed class*)
9. Movement Disorder Agents (*Potential new PDL class and new Closed class*)
10. Immunomodulators, Atopic Dermatitis (*Potential new PDL class and new Closed class*)
11. Hereditary Angioedema (HAE)
12. Bladder Relaxants
13. Ophthalmic Allergic Conjunctivitis
14. Ophthalmic Antibiotics
15. Ophthalmic Anti-inflammatory/ Immunomodulators (*Potential new PDL class and new Closed Class*)
16. Bronchodilators, Long-Acting Beta Adrenergics
17. Glucocorticoids (includes nebulized solutions, metered dose inhalers and combinations) (*Closed Class*)
18. Intranasal Rhinitis (includes Antihistamines and Corticosteroids)

Dr. Jennings motioned that Vaginal Antibiotics, HIV, Bile Salts, Angiotensin Modulators II, Lipotropics (Statins), Lipotropics (Other), Pulmonary Arterial Hypertension Agents (Oral/Inhaled/Injectable), Anticonvulsants, Movement Disorder Agents, Immunomodulators for Atopic Dermatitis, Hereditary Angioedema, Bladder Relaxants, Ophthalmic Allergic Conjunctivitis, Ophthalmic Antibiotics, Ophthalmic Anti-inflammatory/ Immunomodulators, Bronchodilators

(Long-Acting Beta Adrenergics), Glucocorticoids (includes nebulized solutions, metered dose inhalers and combinations) and Intranasal Rhinitis classes continue to be PDL eligible. Dr. Bachireddy seconded the motion. The Committee voted unanimously to maintain these classes as PDL eligible.

## **PDL Phase I – Annual Review Therapeutic Classes without Significant Updates (reviewed by the Department)**

### **Antivirals**

- Hepatitis C

### **Blood Modifiers**

- Phosphate Binders

### **Cardiac Medications**

- Angiotensin Modulators (includes ACEs, ARBs, & CCB combination products)
- Antihypertensives, Sympatholytics (Closed Class)
- Beta Blockers (includes combination products)
- Calcium Channel Blockers (includes dihydropyridine and non-dihydropyridine agents)

### **Central Nervous System**

- Alzheimer's Agents
- Antipsychotics (includes oral and long acting injectables) This class will be reviewed in the Spring.
- Antidepressants, SSRI
- Antidepressants, Other
- Sedative Hypnotics

### **Dermatitis**

- Steroids, Topical

### **Endocrine & Metabolic Agents**

- Growth Hormones (*Closed Class*)
- Progestins for Cachexia

### **Gastrointestinal**

- Antiemetic/Antivertigo Agents
- GI Motility, Chronic
- H. pylori Agents
- Histamine-2 Receptor Antagonists (H-2RA)
- Proton Pump Inhibitors
- Ulcerative Colitis

### **Genitourinary**

- BPH Agents (includes Alpha Blockers, Androgen Hormone Inhibitors and Phosphodiesterase (PDE) 5 Inhibitors for BPH treatment)

### **Ophthalmic**

- Antibiotic/Steroid Combinations
- Anti-Inflammatory Agents (includes Ophthalmic NSAIDs & Corticosteroids)
- Glaucoma

## Respiratory

- Anti-Allergens
- Antibiotics, Inhaled (*Closed Class*)
- Antihistamines Minimally Sedating
- Bronchodilators, Short Acting Beta Adrenergics
- COPD (*includes Anticholinergics, Bronchodilators and Phosphodiesterase 4 (PDE4) Inhibitors*) (*Closed Class*)
- Cough & Cold Agents (*Legend*)
- Epinephrine, Self-Injected
- Leukotriene Modifiers

Dr. Jennings motioned that Hepatitis C, Phosphate Binders, Angiotensin Modulators, Antihypertensives-Sympatholytics, Beta Blockers, Calcium Channel Blockers, Alzheimer's Agents, Antipsychotics, Antidepressants (SSRI), Antidepressants (Other), Sedative Hypnotics, Topical Steroids, Growth Hormones, Progestins for Cachexia, Antiemetic/Antivertigo Agents, GI Motility(Chronic), H. pylori Agents, Histamine-2 Receptor Antagonists (H-2RA), Proton Pump Inhibitors, Ulcerative Colitis, BPH Agents, Ophthalmic Antibiotic/Steroid Combinations, Ophthalmic Anti-Inflammatory Agents, Glaucoma, Anti-Allergens, Antibiotics (Inhaled), Antihistamines Minimally Sedating, Bronchodilators (Short Acting Beta Adrenergics), COPD, Cough & Cold Agents (Legend), Epinephrine(Self-Injected), Leukotriene Modifiers classes continue to be PDL eligible. Dr. Bachireddy seconded the motion. The Committee voted unanimously to maintain these classes as PDL eligible.

## ***PDL Changes Effective January 1, 2022***

### ***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. ***HIV / AIDS (Closed Class):*** Abacavir Tab/Sol, Abacavir-Lamivudine, Abacavir-Lamivudine-Zidov Tab, Aptivus Cap/Sol, Atazanavir Sulfate Cap, Atripla Tab, Biktarvy Tab, Cimduo Tab, Combivir Tab, Complera Tab, Crixivan Cap, Delstrigo Tab, Descovy Tab, Didanosine Cap, Dovato Tab, Edurant Tab, Efavir-Emtricitabine, Efavirenz Cap, Efavirenz-Lamiv-Tenof, Emtricitabine Cap, Emtricitabine-Tenofv, Emtriva Cap/Sol, Epivir Tab/Sol, Epzicom Tab, Evotaz Tab, Fosamprenavir Tab, Fuzeon Vial, Genvoya Tab, Intelence Tab, Invirase Tab, Isentress Tab/Powder Pac, Juluca Tab, Kaletra Tab/Sol, Lamivudine Tab/Sol, Lamivudine-Zidovudine Tab, Lexiva Tab/Susp, Lopinavir-Ritonavir, Nevirapine Tab/Susp, Norvir Tab/Sol/Powder Packet, Odefsey Tab, Pifeltro Tab, Prezobix Tab, Prezista Tab/Susp, Retrovir Cap/Syrup, Reyataz Cap/ Powder Pack, Ritonavir Tab, Rukobia ER Tab, Selzentry Tab/Sol, Stavudine Cap, Stribild Tab, Sustiva Tab/Cap, Symfi Tab, Symfi Lo Tab, Symtuza Tab, Temixys Tab, Tenofovir disoproxil fumarate Tab, Tivicay Tab/Tab for Susp, Trimeq Tab, Trizivir Tab, Truvada Tab, Tybost Tab, Videx Cap/Pediatric Sol, Viracept Tab, Viramune Tab/Susp, Viread 150 Mg Tab/Powder, Ziagen Tab/Sol, Zidovudine Tab are preferred. Trogarzo is non-preferred.
2. ***Anticonvulsants (Closed Class):*** Diastat Acudial, Diastat, Trileptal suspension, Tegretol XR, Carbatrol, Lamictal ODT and ODT dose pack, Clobazam suspension are preferred. Diazepam device (rectal), diazepam (rectal), carbamazepine XR, carbamazepine ER, oxcarbazepine suspension are non-preferred.
3. ***Movement Disorders (Closed Class):*** Tetrabenazine, Xenazine, Austedo, Ingrezza tab and initiation pack are preferred.
4. ***Ophthalmic, Anti-Inflammatory/Immunomodulators (Closed Class):*** Restasis and Restasis Multidose and

Xiidra are preferred. Eysuvis and Cequa are non-preferred.

5. **Immunomodulators, Atopic Dermatitis (Closed Class)**: Tacrolimus and Eucrisa are preferred.
6. **COPD Agents (Closed Class)**: Bevespi Aerosphere is non-preferred.
7. **Proton Pump Inhibitors**: Protonix Suspension is preferred. Pantoprazole Suspension is non-preferred.
8. **Steroids, Topical Low**: Hydrocortisone Acetate Cream and ointment OTC, Hydrocortisone Cream OTC and Hydrocortisone-Aloe Cream OTC are preferred. Scalpicin OTC 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:***

- Antibiotics, Inhaled (*Closed Class*)
- Antihypertensives, Sympatholytic (*Closed Class*)
- Growth Hormone (*Closed Class*)
- Glucocorticoids, Inhaled (*Closed Class*)
- Hepatitis C (*Closed Class*)
- Alzheimer's Agents
- Angiotensin Modulator Com
- Angiotensin Modulators
- Anti-Allergens, Oral
- Antibiotics, Vaginal
- Antidepressants, Other
- Antidepressants, SSRIs
- Antiemetic/Antivertigo Agents
- Antihistamines, Minimally Sedating
- Beta-Blockers
- Bile Salts
- Bladder Relaxant Preparation
- BPH Treatments
- Bronchodilators, Beta Agonists
- Calcium Channel Blockers
- Cough And Cold, Narcotic
- Epinephrine, Self-Injected
- GI Motility, Chronic
- Glucocorticoids, Oral
- H. Pylori Treatment
- HAE Treatments
- Intranasal Rhinitis Agents
- Histamine II Receptor Blocker
- Leukotriene Modifiers
- Lipotropics, Other
- Lipotropics, Statins
- Ophthalmic Antibiotics
- Ophthalmic Antibiotic-Steroid
- Ophthalmic For Allergic Conjunctivitis
- Ophthalmic, Anti-Inflammatory

- PAH Agents, Oral and Inhaled
- Phosphate Binders
- Progestins For Cachexia
- Sedative Hypnotics
- Steroids, Topical High
- 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. 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:

- Eliminate the Hepatitis C Preferred SA fax form
- Updates to Anticonvulsants AutoPA and criteria
- Updates to Immunomodulators, Atopic Dermatitis AutoPA and criteria

The next P&T Committee Meeting is tentatively scheduled for March 17, 2022 (tentative).

Dr. Bachireddy made a motion to adjourn the meeting that was seconded by Dr. Jennings. After a unanimous vote, the meeting was adjourned.