Pharmacy and Therapeutics Committee Meeting
March 23, 2023
Draft Minutes
REVISED April 26,2023

Members Present:	**DMAS Staff:**
John Morgan, M.D.	Cheryl J. Roberts, J.D., Medicaid Director
Tim Jennings, Pharm.D.	MaryAnn McNeil, R.Ph., Pharmacy Manager
Sarah Melton, Pharm.D.	JoeMichael T. Fusco, Pharm.D., MCO Pharmacy Compliance Manager
Gill Abernathy, M.S., R.Ph.	Rachel Cain, Pharm.D., Clinical Pharmacist
Carol Forster, M.D.	Usha Koduru, Counsel to the Board, Office of the Attorney General
Olugbenga Obasanjo, M.D.	Kiara M. Jasper, MHA, CPhT. Pharmacy Systems Administrator
Angela Venuto-Ashton, M.D.	
Michele Thomas, Pharm.D.	
Absent:	**Staff: Magellan Rx Management**
Ananda Basu, M.D.	Jenni Pandak, R.Ph., Senior Director, Clinical Account Management
Alexis Aplasca, M.D.	Nancy Eldin, Pharm.D., Pharmacist Account Executive, Virginia
Megan Sarashinsky, Pharm.D.	Kristen M. Haloski, Pharm.D., AAHIVP, Senior Director, Value Based Pricing
Rachel M. Selby-Penczak, M.D.	
Ira Bloomfield, M.D.	Jeni Hodzic, CPhT, Senior Account Management Specialist, Virginia
A quorum was present	**Guests:** 38 representatives from pharmaceutical companies, providers, advocates, associations, etc.

Welcome and Comments from Cheryl J. Roberts, J.D. Acting 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 informed the committee of the upcoming changes at Virginia Medicaid such as Medicaid Unwinding, Behavioral Health Program called "Right Help Right Now" and "Eclipse".

Welcome and Comments from John Morgan, M.D., Acting Chief Medical Officer and Chairman
Dr. John Morgan welcomed the members of the Committee and thanked them for their participation in the PDL program. Dr. Morgan shared that DMAS is in the process of coming into compliance with Federal Cures Compliance Requirements.

Call to Order and Housekeeping: The meeting was called to order by Dr. Morgan, he 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.

Approval of Minutes from September 22, 2022, meeting
Dr. Morgan 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.

March 9, 2023, DUR Meeting:

The Board reviewed and approved Service Authorization (SA) criteria for 3 new medications (Hyftor, Lytgobi, and Rezlidhia)
The Board also reviewed and approved new class criteria for oral oncology medications. Additionally, the Board reviewed the results of ProDUR and RetroDUR reports, several utilization analyses: concurrent use of opioids and benzodiazepines, concurrent use of opioids and antipsychotics, antipsychotics in children, antidepressant medications in children, and mood stabilizer medications in children.

The next DUR Board meeting is scheduled for June 8, 2023.

The minutes from these meetings can be found at:
https://www.virginiamedicaidpharmacyservices.com/provider/drug-utilization-review/

PDL Management

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

Brand Drugs

1. **Xaciato™ Gel (Antibiotics, Vaginal)*:*** Dr. Eldin presented the clinical information for Xaciato™.

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

2. **Ztalmy®** ***(Anticonvulsants)*** ***(Closed Class):*** Dr. Eldin presented the clinical information for Ztalmy®.

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

3. **Auvelity™** ***(Antidepressants, Other):***

   Speaker
   - Charlotte Wincott, PhD, Associate Director, Medical Affairs, Axsome

   Dr. Eldin presented the clinical information for Auvelity™.

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

4. **Entadfi®** ***(BPH Treatments):*** Dr. Eldin presented the clinical information for Entadfi®.

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

5. **Ryaltris®** ***(Intranasal Rhinitis Agents):*** Dr. Eldin presented the clinical information for Ryaltris®.

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

6. **Verkazia® *(Ophthalmic, Anti-Inflammatory/ Immunomodulator)* *(Closed Class)*:**

Speaker
- Mike Dismuke, PhD, Senior Medical Science Liaison, Santen USA

Dr. Eldin presented the clinical information for Verkazia®.

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:

- *(PAH Agents, Oral And Inhaled)*
  - Tadliq® Suspension (new formulation of tadalafil)
- *(Anticonvulsants)* *(Closed Class)*
  - Zonisade™ Suspension (new formulation of zonisamide)
- *(COPD Agents)* *(Closed Class)*
  - roflumilast (generic for Daliresp®)
- *(Cough And Cold, Narcotic)*
  - hydrocodone-homatropine methylbromide (generic for Tussigon® oral tablets)
- *(Ophthalmic, Glaucoma Agents)*
  - tafluprost (generic for Zioptan® ophthalmic solution)

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. ***Opioid Dependency Treatment Agents (Closed Class) (includes oral buprenorphine):***
Dr. Eldin presented the Opioid Dependency Treatment clinical information.

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

2. ***Opioids: Short Acting (includes combination drugs and lozenges):*** Dr. Eldin presented the Opioids, Short Acting clinical information.

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

3. ***Antifungals, Oral:*** Dr. Eldin presented the Antifungals, Oral clinical information.

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

4. ***Antivirals for Influenza, Oral:*** Dr. Eldin presented the Antivirals for Influenza, Oral clinical information.

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

5. ***Anticoagulants (includes oral agents, low molecular weight heparins & Factor XA Inhibitors) (Closed Class):***

   Speaker
   - Howard Becker, Pharm.D., Regional Account Executive, Bristol Myers Squib (Eliquis®)

   Dr. Eldin presented the Anticoagulants clinical information.

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

6. ***Antihyperkinesis/CNS Stimulants (Closed Class):*** Dr. Eldin presented the Antihyperkinesis/CNS Stimulant Agents clinical information.

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

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

8. ***Multiple Sclerosis Agents (Closed Class):***

   Speaker
   - Emily J. Volger, Pharm.D, MSCR, BCACP Associate Director, Medical Science Liaison Neurosciences (Kesimpta®)

   Dr. Eldin presented the Multiple Sclerosis Agents clinical information.

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

9. ***Psoriasis Agents:*** Dr. Eldin presented the Psoriasis Agents clinical information.

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

10. ***Bone Resorption Suppression and Related Agents (includes bisphosphonates, calcitonin and others):*** Dr. Eldin presented the Bone Resorption Suppression and Related Agents clinical information.

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

11. ***Hypoglycemics: Incretin-Mimetics/Enhancers (includes DPP-IV Inhibitors & Combinations) (Closed Class):*** Dr. Eldin presented the Hypoglycemics: Incretin-Mimetics/Enhancers clinical information.

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

12. ***Hypoglycemics: Insulins:*** Dr. Eldin presented the Hypoglycemics: Insulins clinical information.

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

13. ***Hypoglycemics: Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitor (Closed Class):*** Dr. Eldin presented the Hypoglycemics: SGLT2 **Inhibitor** clinical information.

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

14. ***Cytokine and CAM Antagonists and Related Agents (Closed Class):***

    Speaker
    - Donna Cook, PharmD, Senior Medical Science Liaison | US Medical Capabilities Inflammation Therapeutic Area – Rheumatology/GI (Amjevita™)

    Dr. Eldin presented the Cytokine and CAM Antagonists and Related Agents clinical information.

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

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

    - Acne Agents (includes benzoyl peroxide, clindamycin, retinoids & combinations)
    - Alzheimer's Agents (Cholinesterase Inhibitors & NMDA Receptor Antagonist)
    - Androgenic Agents
    - Antibiotics (topical)
    - Antifungal Agents, Topical
    - Antihyperuricemics
    - Antimigraine Agents
    - Antimigraine Agents Other (Closed Class)
    - Antivirals for Herpes (HSV)
    - Cephalosporins (Second and Third Generations)
    - Erythropoiesis Stimulating Proteins
    - Estrogens (vaginal and oral)
    - Gastrointestinal Antibiotics

- Hypoglycemics: Alpha-Glucosidase Inhibitors
- Hypoglycemics: Meglitinides
- Hypoglycemics: Metformin
- Hypoglycemics: Sulfonylureas
- Hypoglycemics: Thiazolidinediones
- Ketolides & Macrolides (Adult and Pediatric)
- Long-Acting Reversible Contraceptives (LARCS) (includes long-acting IUDs & injectable)
- Neuropathic Pain
- Non-Steroidal Anti-Inflammatory Drugs (NSAID) (includes Cox-2 inhibitors and topical agents)
- Opioids: Long Acting
- Pancreatic Enzymes
- Platelet Aggregation Inhibitors
- Progestational Agent (Closed class)
- Quinolones (Otic)
- Quinolones (Second and Third Generations)
- Rosacea Agents
- Skeletal Muscle Relaxants
- Smoking Cessation Agents

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; Acne Agents (includes benzoyl peroxide, clindamycin, retinoids & combinations), Alzheimer's Agents (Cholinesterase Inhibitors & NMDA Receptor Antagonist), Androgenic Agents, Antibiotics (topical), Antifungal Agents, Topical, Antihyperuricemics, Antimigraine Agents, Antimigraine Agents Other, Antivirals for Herpes (HSV), Cephalosporins (Second and Third Generations), Erythropoiesis Stimulating Proteins, Estrogens (vaginal and oral), Gastrointestinal Antibiotics, Hypoglycemics: Alpha-Glucosidase Inhibitors, Hypoglycemics: Meglitinides, Hypoglycemics: Metformin, Hypoglycemics: Sulfonylureas, Hypoglycemics: Thiazolidinediones, Ketolides & Macrolides (Adult and Pediatric), Long-Acting Reversible Contraceptives (LARCS) (includes long-acting IUDs & injectable), Neuropathic Pain, Non-Steroidal Anti-Inflammatory Drugs (NSAID) (includes Cox-2 inhibitors and topical agents), Opioids: Long Acting, Pancreatic Enzymes, Platelet Aggregation Inhibitors, Progestational Agent, Quinolones (Otic), Quinolones (Second and Third Generations), Rosacea Agents, Skeletal Muscle Relaxants, and Smoking Cessation Agents.

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

PDL Changes Effective July 1, 2023

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. ***Antipsychotics (Closed Class):*** Vraylar and Perseris are preferred. Effective April 1st, 2023; lurasidone is preferred and Latuda is non-preferred.

2. ***Progestational Agents (Closed Class):*** ~~hydroxyprogesterone caproate is preferred. Makena Auto Injector is non-preferred.~~ These drugs are no longer FDA approved and have been removed from the PDL.

3. ***Multiple Sclerosis Agents (Closed Class):*** dalfampridine ER, fingolimod, and Aubagio are preferred.

4. ***Antimigraine Agents Other (Closed Class):*** Aimovig and Ubrelvy are preferred.

5. ***Cytokine & CAM Antagonists (Closed Class):*** Infliximab is preferred. Arcalyst and Inflectra vial are non-preferred.

6. ***Anticonvulsants (Closed Class):*** lamotrigine ODT and Nayzilam are preferred. Lamictal ODT and lacosamide solution unit dose are non-preferred.

7. ***Hypoglycemics SGLT2 Inhibitors (Closed Class):*** Invokamet XR is non-preferred.

8. ***Hypoglycemics, Insulin And Related Agents:*** insulin glargine pen and insulin glargine vial are preferred. Novolog vial continues to be preferred. Insulin lispro protamine mix kwikpen (Authorized Generic) is non-preferred.

9. ***Antidepressants, Other:*** Viibryd is preferred.

10. ***Intranasal Rhinitis Agents:*** Dymista is preferred.

11. ***Acne Agents, Topical:*** adapalene gel OTC is preferred. Differin gel OTC is non-preferred.

12. ***Antibiotics, Vaginal:*** Vandazole is non-preferred.

13. ***Androgenic Agents:*** testosterone gel pump is preferred.

14. ***NSAIDs:*** diclofenac sodium is preferred.

15. ***Erythropoiesis Stimulating Proteins:*** Retacrit (VIFOR) and Reblozyl are non-preferred.

16. ***Antifungals, Topical:*** clotrimazole solution Rx is preferred. Mycozyl AC cream OTC and tolnaftate solution OTC are non-preferred.

17. ***Antihyperuricemics:*** allopurinol 200 mg (Authorized Generic) is non-preferred.

18. ***Hypoglycemics, Incretin Mimetics/Enhancers (Closed Class):*** Kombiglyze XR, Onglyza, Jentadueto XR and Ozempic are preferred.

    ** DMAS has rejected the Ozempic recommendation. Ozempic will remain non-preferred **

19. ***Rosacea Agents, Topical:*** metronidazole gel and metronidazole cream are preferred. Metrogel and Metrocream are non-preferred.

20. ***Stimulants And Related Agents (Closed Class):*** methylphenidate solution is preferred.

21. ***Contraceptives, Other:*** Depo-SubQ Provera 104 is 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 (Cholinesterase Inhibitors & NMDA Receptor Antagonist)
- Analgesics, Narcotics Long & Short
- Antibiotics, GI
- Antibiotics, Topical
- Antibiotics, Vaginal
- Anticoagulants

- Antifungals, Oral
- Antihyperuricemics
- Antimigraine Agents, Triptans
- Antipsoriatics, Topical
- Antivirals for Herpes (HSV) & Influenza
- Bone Resorption Suppression And Related Agents
- BPH Treatments
- Cephalosporins And Related Antibiotics
- COPD Agents
- Cough And Cold, Narcotic
- Estrogens (vaginal)
- Fluoroquinolones, Oral
- Gastrointestinal Antibiotics
- Hypoglycemics: Alpha-Glucosidase Inhibitors
- Hypoglycemics: Meglitinides
- Hypoglycemics: Metformin
- Hypoglycemics: Sulfonylureas
- Hypoglycemics: Thiazolidinediones
- Ketolides & Macrolides
- Neuropathic Pain
- Ophthalmics, Anti-Inflammatory/Immunomodulator (Closed Class)
- Ophthalmic, Glaucoma Agents
- Otic Antibiotics
- PAH Agents, (Oral & Inhaled)
- Pancreatic Enzymes
- Platelet Aggregation Inhibitors
- Psoriasis Agents
- Quinolones (Otic)
- Quinolones (Second and Third Generations)
- Skeletal Muscle Relaxants
- Smoking Cessation

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 Oral Buprenorphine Products SA fax form
- Updates to Short And Long-Acting Opioids SA fax form
- Updates to Stimulants/ADHD Medications SA fax form
- Updates to Lucemyra criteria
- New Verkazia criteria with revisions requested by the board members
- Criteria updates to the following classes: Antipsychotics, Antimigraine Agents - Other, Anticonvulsants, and Hypoglycemics: Incretin Mimetics

P&T Bylaws

The P&T Committee approved the Committee Bylaws.

The next P&T Committee Meeting is tentatively scheduled for September 21, 2023

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

Virginia
Pharmacy and Therapeutics Committee
Bylaws
Approved March 23,2023

ARTICLE I

COMMITTEE STRUCTURE

1.1 Name - This body shall be known as the Virginia Pharmacy and Therapeutics Committee, Hereinafter referred to as the P&T Committee.

1.2. Composition - The P&T Committee shall be composed of eight to 12 members, including the Commissioner of the Department of Behavioral Health and Developmental Services or a designee. Other members shall be selected or approved by the Department of Medical Assistance Services (the Department or DMAS). The membership shall include a ratio of physicians to pharmacists of 2:1 and the Department shall ensure that at least one-half of the physicians and pharmacists are either direct providers or are employed with organizations that serve recipients for all segments of the Medicaid population. Physicians on the Committee shall be licensed in Virginia, one of whom shall be a psychiatrist, one of whom provides care to the pediatric members and one of whom specializes in care for the aging. Pharmacists on the Committee shall be licensed in Virginia, one of whom shall have clinical expertise in mental health drugs, and one of whom has clinical expertise in community-based mental health treatment.

1.3 Appointments and Terms - Vacancies on the P&T Committee shall be filled in the same manner as original appointments. The Department shall appoint individuals for the committee that assures a cross-section of the physician and pharmacy community.

1. P&T Committee members shall serve four-year terms and may be reappointed to additional terms at the discretion of the Director of the Department. The committee replacement will be staggered, to ensure no more than 3 new members at any time.

2. Members of the Committee shall attend all regular and special meetings unless the member provides prior written notice of good cause (including emergency situations) to the Director or Committee Chair.

3. The Director of the Department may terminate the appointment of any P&T Committee member at any time or for violating these bylaws.

ARTICLE II

P&T Committee Meetings

2.1 Regular Meetings - Meet at least bi-annually and may meet at other times at the discretion of the chairperson and members.

2.2 Special Meetings – The P&T Committee may meet at such other times and places as the Director of DMAS or the chairperson determines to be necessary and appropriate. Reasonable effort must be made by or on behalf of the chairperson to notify each P&T Committee member of the meeting.

2.3 Unless otherwise notified, meetings will be held in Richmond, VA.

2.4 Notice - an agenda will be prepared and posted at least three (3) business days prior to the meeting. The clinical data used for drug class review will be prepared and distributed to the P&T Committee members and Department staff at least one week in advance of meetings to allow for sufficient review time. Notice of all regular meetings shall also be announced at least three (3) working days in advance of the meeting by publication in the Virginia Register or the Virginia Regulatory Town Hall.

2.5 Quorum – Seven (7) members of the P&T Committee shall constitute a quorum or a simple majority if there are less than twelve (12) appointed members on Committee. A quorum of the Committee must be physically assembled at the primary or central meeting location identified in the public notice required for the meeting, unless the meeting is held during a declared state of emergency.

2.6 Closed meetings – Prior to meeting in a closed meeting, the P&T Committee must vote affirmatively to do so and must announce the purpose of the meeting. This purpose shall consist of one or more of the reasons for which closed meetings are permitted in accordance with Section § 2.2-3711 of the Code of Virginia.

Discussion in the closed session must be limited to the subject or subjects stated in the motion. No final action may be taken in the closed session. Upon return to open session, any action taken, or motion adopted must be restated, voted upon, and placed in the minutes in order to become effective.

2.7 Conduct of Business — The rules contained in the most recently published edition of Roberts Rules of Order Newly Revised shall govern the P&T Committee in all cases to which they are applicable, to the extent that they are not inconsistent with the laws of Virginia, these Bylaws, or any special rule which the P&T Committee may adopt.

2.8 Administrative Duties - The P&T Committee shall be assisted in carrying out its administrative duties, including the maintenance of minutes and records, by staff provided by the Director of DMAS and the Preferred Drug List (PDL) Vendor.

2.9 Electronic Participation in Meetings Excluding during Declared States of Emergency – An individual member may participate in a meeting of the P&T Committee or a public meeting of any committee established by the P&T Committee through electronic communication from a remote location for the following reasons:

1. A temporary or permanent disability or other medical condition prevents the member's physical attendance;
2. A family member's medical condition that requires the member to provide care for such family member, thereby preventing the member's physical attendance;
3. A member's principal residence is more than 60 miles from the meeting location; or
4. A personal matter prevents the member's physical attendance and identifies with specificity the nature of the personal matter.

Procedure for Approval:

1. Notification: The member requesting to participate through electronic communication from a remote location must notify the P&T Committee or Committee Chair on or before the day of the meeting.

2. Quorum: A quorum of the P&T Committee, or a simple majority of the Committee, must be

physically assembled at the primary or central meeting location identified in the public notice required for the meeting.

3. Technological Arrangements: Arrangements must be made for the voice of the remote participant to be heard by all persons at the primary or central meeting location.

4. Documentation: The specific reason the member is unable to attend the meeting, and the remote location from which the member participates, shall be recorded in the meeting minutes; notwithstanding this disclosure requirement, the specific medical condition(s) or related clinical information affecting the member requesting virtual participation shall not be publicly disclosed but will instead be treated as consistent with Protected Health Information. The nature of the personal matter shall also be included in the minutes. The remote location from which the member participates need not be open to the public and may be identified in the minutes by general description.

5. Limitation: Members may only participate through electronic communication due to personal matters for no more than two meetings of the P&T Committee. If a Committee votes to disapprove the member's electronic participation from a remote location, such disapproval shall be recorded in the minutes.

2.10 Electronic Participation in Meetings During Declared States of Emergency – The P&T Committee may meet by electronic communication means without a quorum of the public body physically assembled at one location when the Governor has declared a state of emergency in accordance with Virginia Code § 44-146.17 or the locality in which the public body is located has declared a local state of emergency pursuant to Virginia Code § 44-146.21, provided that:

A. the catastrophic nature of the declared emergency makes it impracticable or unsafe to assemble a quorum in a single location and

B. the purpose of the meeting is to provide for the continuity of operations of the P&T Committee or the discharge of its lawful purposes, duties, and responsibilities. The P&T Committee shall:

1. Give public notice using the best available method given the nature of the emergency, which notice shall be given contemporaneously with the notice provided to members of the P&T Committee;

2. Arrange for public access to such meeting through electronic communication means, including videoconferencing if already used by the P&T Committee; and

3. Provide the public with the opportunity to comment at P&T Committee meetings when public comment is customarily received.

The nature of the emergency, the fact that the meeting was held by electronic communication means, and the type of electronic communication means by which the meeting was held shall be stated in the minutes.

2.11 Oral Presentations - The P&T Committee in conjunction with the Department will allocate time slots for interested parties to present scientific and clinical information only on the drug classes scheduled for review on the agenda and will be limited to a maximum of two minutes, unless otherwise stated by the P&T Committee Chair or the Department. One presentation per product will be permitted.

a. The time limit does not include follow-up questions by the P&T Committee or answers to those follow-up questions. Stakeholders will be called to present in the order of the agenda or as

determined by the chair.
b. Stakeholders must disclose if they receive any compensation from pharmaceutical manufacturers.
c. Presentations must be limited to verbal comments. No visual aids, other than designated handouts, are permitted. Presentations should follow the summary that was submitted to the Department.
d. All presentations must include information published in a peer reviewed journal (per guidelines below) that is clinical in nature and based on scientific material.
e. The references used to authorize presentations must be within the following timeframes:
1. PDL classes that are for Annual review on the agenda, within the past year
2. New Drugs in PDL Phase I or II Drug Classes on the agenda, within the past year
3. Potential new PDL Phase Drug Classes on the agenda, within the past two years
f. Speakers will be decided by the Chairperson based on relevancy of the information.
g. Speakers must receive a confirmation number to verify the presentation is scheduled.
h. Anyone interested in providing specific clinical information to the Committee at the meeting must submit an outline of discussion points, clinical references (within the stated guidelines above) and a written request to speak with the name/title of the presenter. Please send requested information to pdlinput@dmas.virginia.gov and the second e-mail identified on the agenda by 5 p.m. EST on the published deadline.
i. Written information/comments: All stakeholders (including manufacturers) submitting comments shall include a one-page summation (one side only) of the drug product that will be included in the review packet provided to the P&T Committee members. The summary must be limited to clinical information only.
j. No late requests will be approved.

2.12 Stakeholder Comments – The P&T Committee in conjunction with the Department, will allocate up to two minutes for practicing clinicians who care for Virginia Medicaid members to share clinical recommendations regarding the drug classes scheduled for review. Guidelines for clinical recommendations are included below.

a. Clearly indicate the product and drug class the comments represent.

b. Limit to clinical information only.

c. Exclude any reference to cost.

d. Exclude anecdotal content.

e. Exclude general drug or disease specific economic information.

f. Please send written information/comments to pdlinput@dmas.virginia.gov and the second e-mail identified on the agenda by 5 p.m. EST on the published deadline.

g. No late comments will be included.

ARTICLE III

OFFICERS

3.1. Types of Officer - The Chair and Vice-Chair

3.2 Duties of the Chair - The Chair presides over the meetings of the P&T Committee.

3.3 Duties of the Vice-Chair - The responsibilities of the Vice-Chair are to preside over meetings of the P&T Committee in the Chair's absence.

ARTICLE IV

P&T COMMITTEE AUTHORITY

4.1 Powers and Duties - The P&T Committee shall, among other things:

a. Receive and review clinical and pricing data related to the drug classes. The P&T Committee's medical and pharmacy experts shall make recommendations to DMAS regarding various aspects of the pharmacy program. For the PDL program, the Committee shall select drugs to be deemed preferred that are safe and clinically effective, as supported by available clinical data, and that advance population health and that meet pricing standards.

b. Consider the population health implications of recommendations, as appropriate. Population health includes the absence of disparities or avoidable differences among socioeconomic and demographic groups or geographical areas in health status and health outcomes such as disease, disability, or mortality.

c. Consider cost effectiveness or any pricing standard only after the coverage of a drug is determined to be safe, clinically effective and advance population health wherever possible. The Committee shall recommend to the Department:
   (1) Which therapeutic classes of drugs should be subject to the PDL program and prior authorization requirements;
   (2) Specific drugs within each therapeutic class to be included on the PDL;
   (3) Appropriate exclusions for therapeutic classes in which there is only one drug in the therapeutic class or there is very low utilization, or for which it is not cost effective to include in the PDL program;
   (4) Appropriate exclusions for medications, including atypical anti-psychotics, used for the treatment of serious mental illnesses such as bi-polar disorders, schizophrenia, and depression;
   (5) Appropriate exclusions for medications used for the treatment of brain disorders, cancer and HIV-related conditions;
   (6) Appropriate exceptions when prior authorization would interfere with established complex drug regimens that have proven to be clinically effective; and
   (7) Guidance and recommendations regarding the department's pharmacy programs.

d. Ensure that the P&T Committee will evaluate the drug for clinical effectiveness and safety as the United States Food and Drug Administration approves new drug products. Based on clinical information, population health impact and pricing standards, the P&T Committee will determine if the drug will be included in the PDL.

(1) If the new drug product falls within a drug class previously reviewed by the P&T Committee, until the review of the new legend drug is completed, it will be classified as no preferred, requiring prior authorization in order to be dispensed. The new legend drug will be evaluated for inclusion in the PDL no later than at the next review of the drug class.

(2) If the new drug product does not fall within a drug class previously reviewed by the P&T Committee, the new drug shall be treated in the same manner as the other drugs in its class.

e. To the extent feasible, the P&T Committee shall review all drug classes included in the PDL at least every 12 months and may recommend additions to and deletions from the PDL.

4.2. Administration - P&T Committee administrative activities are supported by a vendor as designated by DMAS. These activities include management, implementation and administration of the Medicaid pharmacy benefits Preferred Drug List (PDL), as directed and authorized, and as may be amended from time to time, by DMAS.

The Department, as the sole Title XIX authority for the Commonwealth, shall retain final administrative authority over all pharmacy services.

4.3 Inducements prohibited - The Department shall not offer or pay directly or indirectly any material inducement, bonus, or other financial incentive to a program contractor based on the denial or administrative delay of medically appropriate prescription drug therapy, or on the decreased use of a particular drug or class of drugs, or a reduction in the proportion of beneficiaries who receive prescription drug therapy under the Medicaid program. Bonuses shall not be based on the percentage of cost savings generated under the benefit management of services.

ARTICLE V

DISCLOSURES AND CONFLICTS

5.1 Annual Disclosure - P&T Committee members must disclose annually at the beginning of any P&T Committee meeting, any conflicts of interest that would make it difficult to fulfill P&T Committee duties in an objective manner.

a. Disclosure to Committee and Recusal

1. If a P&T Committee member has an actual or apparent conflict of interest, the member must announce that during the meeting and prior to voting.

2. If the member has an actual conflict of interest, the member should recuse, despite voluntary disclosure. After announcing recusal, the member shall not participate in the deliberation and vote.

b. Apparent conflict of interest

1. If the Committee member does not self-recuse, then the Committee shall vote whether the member shall be permitted to participate in discussion and vote. The Department will consider the Committee's vote and make a final determination whether the member shall be permitted to participate in the particular PDL class' discussion and vote.

ARTICLE VI

REVISION AND COMPLIANCE

6.1 Review -The Bylaws shall be reviewed at least every three years. Revisions shall be made as necessary, and the Bylaws signed and dated to indicate the time of the last review.

6.2 Amendments – The Bylaws may be amended at any regular meeting of the P&T Committee by a majority vote, provide that the proposed amendment was submitted in writing at the previous regular meeting of the P&T Committee and is also included in the notice of the meeting at which a vote is to be taken.

Approved

John_Morgan 4/18/2023

Chair, Pharmacy & Therapeutics Committee Date