Virginia Medicaid
Pharmacy & Therapeutics Committee Meeting
Agenda
600 East Broad Street – 1st Floor Conference Rooms
Richmond, VA 23219
Thursday, March 23, 2023 – 10 AM

Welcome and Comments	**Cheryl J. Roberts, J.D. Medicaid Director**
Call to Order	**John Morgan, MD, Chief Clinical Innovation Officer, Chair**
Drug Utilization Review (DUR) Board Report	**Rachel Cain, PharmD**
Approval of Minutes from September 15, 2022, Meeting	**P&T Committee Members**
Old Business • **Bylaws**	**P&T Committee Members**
PDL (PREFERRED DRUG LIST) Management	**P&T Committee Members**

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

Brand Drugs

• Xaciato™ Gel	(Antibiotics, Vaginal)
• Ztalmy®	(Anticonvulsants) (Closed Class)
• Auvelity™	(Antidepressants, Other)
• Entadfi®	(BPH Treatments)
• Hemgenix®	(Hemophilia Treatments) (Closed Class)
• Ryaltris®	(Intranasal Rhinitis Agents)

Generics Drugs or New Dosage Forms

• Tadliq® Suspension	(PAH Agents, Oral And Inhaled)
• Zonisade™ Solution	(Anticonvulsants) (Closed Class)
• roflumilast	(COPD Agents) (Closed Class)
• hydrocodone-homatropine MBR	(Cough And Cold, Narcotic)
• tafluprost	(Ophthalmic, Glaucoma Agents)

PDL Phase II – Annual Review: Classes with updates

Analgesics
- Antimigraine Agents
- Antimigraine Agents Other (Closed Class)
- Non-Steroidal Anti-Inflammatory Drugs (NSAID) (includes Cox-2 inhibitors and topical agents)
- Opioid Dependency Treatment Agents (Closed Class) (includes oral buprenorphine)
- Opioids: Short Acting (includes combination drugs and lozenges)
- Opioids: Long Acting

Antibiotics / Anti-Infectives
- Antifungal (oral)
- Antibiotics (topical)
- Cephalosporins (Second and Third Generations)
- Gastrointestinal
- Ketolides & Macrolides (Adult and Pediatric)
- Quinolones (Second and Third Generations)
- Quinolones (Otic)

Antivirals
- Antivirals for Influenza
- Antivirals for Herpes (HSV)

Blood Modifiers
- Antihyperuricemics
- Erythropoiesis Stimulating Proteins

Cardiac
- Anticoagulants *(includes oral agents, low molecular weight heparins & Factor XA Inhibitors)* (Closed Class)
- Platelet Aggregation Inhibitors

Central Nervous System
- Alzheimer's Agents (Cholinesterase Inhibitors & NMDA Receptor Antagonist)
- Antihyperkinesis/CNS Stimulants (Closed class)
- Antipsychotics (Closed class)
- Multiple Sclerosis Agents (Closed class)
- Neuropathic Pain
- Skeletal Muscle Relaxants
- Smoking Cessation Agents

Contraceptives
- Long-Acting Reversible Contraceptives (LARCS) (includes long-acting IUDs & injectable)

Dermatologic Agents (Topical)
- Acne Agents (includes benzoyl peroxide, clindamycin, retinoids & combinations)
- Antifungal Agents, Topical
- Psoriasis Agents
- Rosacea Agents

Endocrine and Metabolic Agents
- Androgenic Agents
- Bone Resorption Suppression and Related Agents (includes bisphosphonates, calcitonin and others)
- Estrogens (vaginal ~~and oral~~)
- Hypoglycemics: Alpha-Glucosidase Inhibitors
- Hypoglycemics: Meglitinides
- Hypoglycemics: Metformin
- Hypoglycemics: Sulfonylureas
- Hypoglycemics: Incretin- mimetics- Exenatide (includes DPPIV & combination) (Closed class)
- Hypoglycemics: Insulins
- Hypoglycemics: Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitor (Closed class)
- Hypoglycemics: Thiazolidinediones
- Pancreatic Enzymes
- Progestational Agent (Closed class)

Immunological Agents
- Self-administered Cytokine & CAM Antagonists with Related Agents including Methotrexate (*all indications: Rheumatoid Arthritis (RA), Juvenile Idiopathic Arthritis (JIA), Ankylosing Spondylitis (AS), Plaque Psoriasis, Psoriatic Arthritis (PsA), Crohn's Disease (CD), Ulcerative Colitis, Cryopyrin-Associated Periodic Syndromes (CAPS)* (Closed class)

Confidential Meeting (Pricing Information Discussion)	**P&T Committee Members & DMAS Staff**
Criteria Discussion of Phase I New Drugs	**P&T Committee Members**
Criteria Discussion of Phase II Drugs	**P&T Committee Members**

**Criteria discussions will be held for classes only if deemed PDL eligible by the P&T Committee during Drug Class Discussions.*

Other Business	**Chair**
Next Meeting – September 21, 2023 (tentative)	**Chair**

Oral Presentations: The P&T Committee in conjunction with the Department will be allocating time slots for interested parties to present scientific and clinical information on ***only*** the drug classes in Phase II scheduled for review at the March meeting and new drugs in PDL Phase I listed on the Agenda. **All presentations must include information published in a peer reviewed journal (per guidelines below) that is clinical in nature and based on scientific material. The references used to authorize presentations must be within the following timeframes:**

- PDL Phase II Annual Reviews – March 2022 to present
- New Drugs in PDL Phase I or II Drug Classes – March 2021to present

No anecdotal accounts are to be given. Each speaker will be allocated no more than 2 minutes to present. Speakers will be decided by the Chairperson based on relevancy of the information. **Speakers must receive a confirmation number to verify the presentation is scheduled.**

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** dfmoody@magellanhealth.com **by 5 p.m. EST on Thursday, February 23, 2021.**

Written information/comments: The P&T Committee will also accept written comments for consideration. Please send statements to pdlinput@dmas.virginia.gov **by 5 p.m. EST Thursday, February 23, 2023.**

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Virginia
Pharmacy and Therapeutics Committee
Bylaws
Presented to P&T Committee Members 9/22/2022

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, 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 chairperson.

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 Location – 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 2.1-344§ 2.2-3711 of the Code of Virginia, the pertinent portion of the Virginia Freedom of Information Act.

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

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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 Chairperson 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.

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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

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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 bipolar 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 non-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.

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   (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.

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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.

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rperson, Pharmacy & Therapeutics Committee

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