Members Present: Chethan Bachireddy, M.D. Ira Bloomfield, M.D. Tim Jennings, Pharm.D. Megan Sarashinsky, Pharm.D. Carol Forster, M.D. Sarah Melton, Pharm.D. Sue Cantrell, M.D. Ananda Basu, M.D. Rachel M. Selby-Penczak, M.D. Alexis Aplasca, M.D. Angela Venuto-Ashton, M.D.	DMAS Staff: Karen Kimsey, Agency Director Donna Proffitt, R.Ph., Pharmacy Manager Rachel Cain, Pharm.D., Clinical Pharmacist Usha Koduru, Counsel to the Board, Office of the Attorney General Danielle Adeeb, CPhT., Pharmacy Contract Administrator MaryAnn McNeil, R.Ph., CCC Plus Pharmacist
Absent: Gill Abernathy, M.S., R.Ph.	Staff: Magellan Rx Management Debbie Moody, R.Ph., Pharmacist Account Executive, Virginia Nancy Eldin Pharm.D., Clinical Manager, Virginia Doug Brown, R.Ph., MBA, VP, Account Management Jenni Pandak, R.Ph., Sr. Director, Account Management
A quorum was present	Guests: 38 representatives from pharmaceutical companies, providers, advocates, associations, etc.

Welcome and Comments from Karen Kimsey, Agency Director

Karen Kimsey welcomed the Committee members to the electronic P&T Committee meeting and thanked them for their participation during these unprecedented times. DMAS is hosting an electronic public meeting held pursuant to VA Code § 2.2-3708.2(A)(3) which states "any public body 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 § 44-146.17, provided that (i) the catastrophic nature of the declared emergency makes it impracticable or unsafe to assemble a quorum in a single location and (ii) the purpose of the meeting is to address the emergency."

The Committee's business is limited to providing advice to the Agency that will enable the administration of supplemental drug rebates effective July 1, 2020. As the Commonwealth is facing unprecedented budget deficits as a result of COVID 19, it is critical for the Agency to execute supplemental rebate agreements that will lower the cost of drugs for our Medicaid members.

Ms. Kimsey addressed Medicaid's response to COVID-19 and shared highlights from DMAS' 1135 Waiver. The 1135 Waiver consists of expanded telehealth coverage, elimination of all service and drug co-pays, 90 day supply of all medications (except Schedule 2), extension of all drug service authorizations, and implementing processes to ensure members do not inadvertently lose coverage due to lapses in paperwork or a change in circumstances.

Ms. Kimsey noted that as the Agency continues its mission of providing high quality of health care for its Medicaid members, the recommendations made by this Committee become critical to the success of the

Common Core Formulary and patient's access to drug therapies. Medicaid members are continuing to receive high quality prescription medications based on sound clinical criteria at substantially reduced costs to the Commonwealth.

Welcome and Comments from Chethan Bachireddy, M.D., Chief Medical Officer and Chairman

Dr. Chethan Bachireddy welcomed the Committee members and thanked them for their participation and continued support for the PDL program.

Dr. Bachireddy introduced and welcomed new Board member Dr. Angela Venuto-Ashton. Dr. Venuto-Ashton is a hospitalist at Roanoke Memorial Hospital. She is trained in Internal Medicine and provides medical care on a behavioral health unit. She is a Board-Certified Internal Medicine and Integrative Medicine Physician. Currently, Dr. Venuto-Ashton is Acting Interim Medical Director, Inpatient Pain Management Service at Roanoke Memorial's Carilion Clinic.

Dr. Bachireddy shared that Dr. Susan Lee resigned from the Committee after she accepted a position with Renown Health in Reno, NV.

Dr. Bachireddy took a roll call of the Committee members since this is an electronic meeting. The following members were present: Chethan Bachireddy, Ira Bloomfield, Tim Jennings, Megan Sarashinsky, Carol Forster, Sarah Melton, Sue Cantrell, Rachel M. Selby-Penczak, Alexis Aplasca and Angela Venuto-Ashton. Dr. Ananda Basu joined the meeting after the PDL Phase I new drug review. Gill Abernathy was absent.

Call to Order: Chethan Bachireddy, M.D., Chairman called the meeting to order.

<u>Approval of Minutes from September 19, 2019 meeting</u> Dr. Bachireddy asked if there were any corrections, additions or deletions to the draft meeting minutes. With no revisions or corrections, Dr. Bloomfield motioned the minutes be approved as written. Dr. Selby-Penczak seconded. The Committee unanimously approved the minutes as written. (Reference Attachment 1 for the Committee Vote Talley)

PDL Management

PDL Phase I – New Drug Review (Therapeutic Class)

Brand Drugs

- 1. Nayzilam[™] (*Anticonvulsants*): Dr. Nancy Eldin presented the clinical information for Nayzilam[™] (midazolam).
- 2. Katerzia[™] (*Calcium Channel Blockers*): Dr. Eldin presented the clinical information for Katerzia[™] (amlodipine).
- **3. Duaklir[®] Pressair[®]** (*COPD Agents*): Dr. Eldin presented the clinical information on Duaklir[®] Pressair[®] (aclidinium bromide and formoterol fumarate).

<u>New Dosage Forms or New Strengths</u>: Dr. Eldin noted the following new dosage forms and new strengths:

• ProAir[®] DigihalerTM (albuterol sulfate) (*Bronchodilators, Beta Agonist*)

• Dulera[®] 50 mcg/5 mcg (mometasone furoate and formoterol fumarate dihydrate) (*Glucocorticoids, Inhaled*)

Tim Jennings motioned that NayzilamTM, KaterziaTM, Duaklir[®] Pressair[®], ProAir[®] DigihalerTM, and Dulera[®] 50mcg/5mcg be PDL eligible. Dr. Selby-Penczak seconded the motion. The Committee voted unanimously to consider these drugs as PDL eligible. (Reference Attachment 1 for the Committee Vote Talley)

PDL Phase II – Annual Review

- 1. Antimigraine Agents: Dr. Eldin presented the Antimigraine Agents clinical information.
- 2. <u>Antimigraine Agents, Others Calcitonin Gene-Related Peptide (CGRP) and Others:</u> Dr. Eldin presented the Antimigraine Agents, Others Calcitonin Gene-Related Peptide (CGRP) and Others clinical information.
- 3. <u>Opioid Dependency (Closed Class)</u>: Dr. Eldin presented the Opioid Dependency clinical information.
- 4. <u>Opioids: Long Acting:</u> Dr. Eldin presented the Opioids Long Acting clinical information.

Tim Jennings motioned that the Antimigraine Agents; Antimigraine Agents, Others - Calcitonin Gene-Related Peptide (CGRP) and Others; Opioid Dependency; and Opioids – Long Acting classes continue to be PDL eligible. Dr. Aplasca seconded the motion. The Committee voted unanimously to maintain these classes as PDL eligible. (Reference Attachment 1 for the Committee Vote Talley)

- 5. <u>Antifungals, Oral</u>: Dr. Eldin presented the Antifungals, Oral clinical information.
- 6. <u>Quinolones (Second and Third Generations)</u>: Dr. Eldin presented the Quinolones (Second and Third Generations) clinical information.
- 7. <u>Antivirals for Influenza, Oral</u>: Dr. Eldin presented the Antivirals for Influenza, Oral clinical information. The committee members discussed removing amantadine products from this PDL class.

Tim Jennings motioned that the Antifungals, Oral; Quinolones (Second and Third Generations); and Antivirals for Influenza, Oral classes continue to be PDL eligible. Dr. Venuto-Ashton seconded the motion. The Committee voted unanimously to maintain these classes as PDL eligible. (Reference Attachment 1 for the Committee Vote Talley)

Tim Jennings motioned to remove amantadine products from the Antivirals for Influenza, Oral class. With the motion seconded by Dr. Venuto-Ashton, the Committee voted unanimously to remove amantadine products from the Antivirals for Influenza, Oral class. (Reference Attachment 1 for the Committee Vote Talley)

- 8. <u>Antihyperuricemics</u>: Dr. Eldin presented the Antihyperuricemics clinical information.
- 9. <u>Erythropoiesis Stimulating Proteins</u>: Dr. Eldin presented the Erythropoiesis Stimulating Proteins clinical information.

10. <u>Anticoagulants (Closed Class)</u>: Dr. Eldin presented the Anticoagulants clinical information.

Tim Jennings motioned that the Antihyperuricemics, Erythropoiesis Stimulating Proteins, and Anticoagulants classes continue to be PDL eligible. With the motion seconded by Dr. Selby-Penczak, the Committee voted unanimously to maintain these classes as PDL eligible. (Reference Attachment 1 for the Committee Vote Talley)

- 11. <u>Antihyperkinesis/CNS Stimulants (Closed Class)</u>: Dr. Eldin presented the Antihyperkinesis/CNS Stimulants clinical information.
- 12. <u>Multiple Sclerosis Agents:</u> Dr. Eldin presented the Multiple Sclerosis Agents clinical information.
- 13. *Neuropathic Pain:* Dr. Eldin presented the Neuropathic Pain clinical information.
- 14. <u>Non-Ergot Dopamine Receptor Agonists</u>: Dr. Eldin presented the Non-Ergot Dopamine Receptor Agonists clinical information.
- 15. <u>Skeletal Muscle Relaxants</u>: Dr. Eldin presented the Skeletal Muscle Relaxants clinical information.
- 16. <u>Smoking Cessation Agents</u>: Dr. Eldin presented the Smoking Cessation Agents clinical information.

Tim Jennings motioned that the Antihyperkinesis/CNS Stimulants, Multiple Sclerosis Agents, Neuropathic Pain, Non-Ergot Dopamine Receptor Agonists, Skeletal Muscle Relaxants, and Smoking Cessation Agents classes continue to be PDL eligible. With the motion seconded by Megan Sarashinsky, the Committee voted unanimously to maintain these classes as PDL eligible. (Reference Attachment 1 for the Committee Vote Talley)

- 17. <u>Acne Agents Topical (includes benzoyl peroxide, clindamycin, erythromycin, minocycline, retinoids</u> <u>& combinations</u>): Dr. Eldin presented the Acne Agents Topical clinical information.
- 18. Psoriasis Agents, Topical: Dr. Eldin presented the Psoriasis Agents, Topical clinical information.
- 19. Rosacea Agents: Dr. Eldin presented the Rosacea Agents clinical information.

Tim Jennings motioned that the Acne Agents Topical; Psoriasis Agents, Topical; and Rosacea Agents classes continue to be PDL eligible. With the motion seconded by Dr. Venuto-Ashton, the Committee voted unanimously to maintain these classes as PDL eligible. (Reference Attachment 1 for the Committee Vote Talley)

- 20. <u>Androgenic Agents</u>: Dr. Eldin presented the Androgenic Agents clinical information.
- 21. <u>Bone Resorption Suppression and Related Agents (includes bisphosphonates, calcitonins and others)</u>: Dr. Eldin presented the Bone Resorption Suppression and Related Agents clinical information.
- 22. <u>Hypoglycemics: Incretin Mimetics/Enhancers (includes DPP-IV Inhibitors, GLP-1 Agonists & comb) (Closed Class)</u>: Dr. Eldin presented the Hypoglycemics Incretin Mimetics/Enhancers clinical information.
- 23. <u>Hypoglycemics: Insulins</u>: Dr. Eldin presented the Hypoglycemics Insulins clinical information.

- 24. <u>Hypoglycemics: Metformin's</u>: Dr. Eldin presented the Hypoglycemics Metformin's clinical information.
- **25.** <u>Hypoglycemics: Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitor (Closed Class)</u>: Dr. Eldin presented the Hypoglycemics Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitor clinical information.

Tim Jennings motioned that the Androgenic Agents, Bone Resorption Suppression and Related Agents, Hypoglycemics - Incretin Mimetics/Enhancers, Hypoglycemics – Insulins, Hypoglycemics -Metformin's, and Hypoglycemics - Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitor classes continue to be PDL eligible. With the motion seconded by Dr. Selby-Penczak, the Committee voted unanimously to maintain these classes as PDL eligible. (Reference Attachment 1 for the Committee Vote Talley)

26. <u>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)</u>: Dr. Eldin presented the Self-administered Cytokine & CAM Antagonists with Related Agents including Methotrexate clinical information.

Dr. Jennings motioned that the Self-administered Cytokine & CAM Antagonists with Related Agents including Methotrexate class continue to be PDL eligible. With the motion seconded by Megan Sarashinsky, the Committee voted unanimously to maintain the class as PDL eligible. (Reference Attachment 1 for the Committee Vote Talley)

27. <u>Therapeutic Drug Classes Without Updates (Reviewed by the Department):</u>

- Antibiotics (topical)
- Antifungal Agents, Topical
- Antivirals for Herpes (HSV)
- Antivirals, Topical
- Cephalosporins (Second and Third Generations)
- Estrogens (vaginal and oral)
- Gastrointestinal, Antibiotics
- Hypoglycemics: Alpha-Glucosidase Inhibitors
- Hypoglycemics: Meglitinides
- Hypoglycemics: Sulfonylureas
- Hypoglycemics: Thiazolidinediones
- Ketolides & Macrolides (Adult and Pediatric)
- Long-Acting Reversible Contraceptives (includes IUDs & injectables)
- Non-Steroidal Anti-Inflammatory Drugs (NSAID) (includes Cox-2 inhibitors and topical agents)
- Opioids: Short Acting (includes combination drugs and lozenges)
- Pancreatic Enzymes
- Platelet Aggregation Inhibitors
- Progestational Agent
- Quinolones (Otic)

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

Dr. Jennings motioned that these classes continue to be PDL eligible. With the motion seconded by Dr. Venuto-Ashton, the Committee voted unanimously to maintain these classes as PDL eligible. (Reference Attachment 1 for the Committee Vote Talley)

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 witness the operation of government to the fullest extent.

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. Sarah Melton made a motion for the P&T Committee to resume the meeting in a separate private teleconference 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. The motion was seconded by Dr. Selby-Penczak and unanimously approved by the Committee. (Reference Attachment 1 for the Committee Vote Talley)

Following the teleconferenced Confidential Session, the Committee members re-assembled on the public teleconference session. Dr. Bachireddy took a roll call of the Committee members after the public meeting reconvened. The following members were present: Chethan Bachireddy, Ira Bloomfield, Tim Jennings, Megan Sarashinsky, Carol Forster, Sarah Melton, Sue Cantrell, Rachel M. Selby-Penczak, Alexis Aplasca and Angela Venuto-Ashton and Dr. Ananda Basu. Dr. Bachireddy then 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.

PDL Changes Effective July 1, 2020

New Drugs Phase I:

New Phase I drugs, NayzilamTM, KaterziaTM, Duaklir[®] Pressair[®] and ProAir[®] DigihalerTM remain nonpreferred. The new strength of Dulera[®] (50 mcg/5mcg) will continue to be preferred.

Dr. Melton made the following motions that were seconded by Dr. Jennings and approved unanimously by the Committee (note the motions are for changes to the current PDL status):

<u>Phase II Annual Review</u>

- 1. <u>Androgenic Agents:</u> testosterone gel packet (including the authorized generic) is non-preferred.
- 2. <u>Antimigraine Agents:</u> Relpax[®] is non-preferred.
- 3. Bone Resorption Suppression and Related Agents: ibandronate tablets is preferred.
- 4. <u>Hypoglycemics: Insulins:</u> Humalog[®] Cartridge, Humalog[®] Junior Kwikpen, Humalog[®] Mix Pen, Humalog[®] Pen, Humulin[®] 70/30 Pen (OTC), Humulin[®] Pen (OTC) and insulin lispro vial are preferred.
- 5. <u>Hypoglycemics: SGLT2 (Closed Class)</u>: Invokamet[®], Invokamet[®] XR, and Xigduo[®] XR are preferred.
- 6. <u>Antihyperkinesis/CNS Stimulants (Closed Class)</u>: Dyanavel[®] XR, Quillichew ER[®] and Quillivant XR[®] are non-preferred.

PDL Generic Watch Changes

Urinary Antispasmodics (Bladder Relaxant): solifenacin is preferred. VESIcare[®] is non-preferred.

Dr. Melton made the following motion to make no changes to the following PDL drug classes, which was seconded by Dr. Jennings and approved unanimously by the Committee:

- Acne Agents, Topical
- Alzheimer's Agents
- Analgesics, Opioids, Long-acting
- Analgesics, Opioids, Short-acting
- Antibiotics, GI
- Antibiotics, Topical
- Anticoagulants (Closed Class)
- Antifungals, Oral
- Antifungals, Topical
- Antihyperuricemics
- Antimigraine Agents, Other (includes CGRP)
- Antipsoriatics, Topical
- Antivirals for Herpes (Oral)
- Antivirals for Influenza (Oral)
- Antivirals, Topical
- Cephalosporins and Related Antibiotics
- Contraceptives, (Long-acting Reversible, IUDs and Injectables)
- Cytokine and CAM Antagonists (Closed Class)
- Erythropoiesis Stimulating Proteins
- Estrogens (vaginal and oral)
- Hypoglycemics, Alpha-Glucosidase Inhibitors
- Hypoglycemics, Incretin Mimetics/Enhancers (Closed Class)

- Hypoglycemics, Meglitinides
- Hypoglycemics, Metformins
- Hypoglycemics, Sulfonylureas
- Hypoglycemics, TZD
- Macrolides/Ketolides
- Multiple Sclerosis Agents
- Neuropathic Pain
- Non-ergot Dopamine Receptor Agonists
- NSAIDs
- Opiate Dependence Treatments (Closed Class)
- Pancreatic Enzymes
- Platelet Aggregation Inhibitors
- Progestational Agents
- Quinolones (2nd & 3rd gen), oral
- Quinolones (Otic)
- Rosacea Agents
- Skeletal Muscle Relaxants
- Smoking Cessation

(Reference Attachment 1 for the Committee Vote Talley for changes to the PDL status)

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 by Dr. Forster and approved unanimously by the Committee:

- Antiemetic/Antivertigo Agents
- Antimigraine Agents, Others
- Methadone
- Narcolepsy Medications
- Short and Long Acting Opioids
- Nayzilam[®]
- AmzeeqTM
- Aklief[®]
- Rybelsus[®]
- EmflazaTM
- Vumerity[™]
- RinvoqTM
- Wakix[®]

(Reference Attachment 1 for the Committee Vote Talley)

The Committee reviewed the proposed Cytokine and CAM Antagonists quantity limits. Dr. Jennings motioned to accept the proposed quantity limits as presented. Dr. Selby-Penczak seconded the motion. The Committee voted unanimously to adopt these quantity limits. (Reference Attachment 1 for the Committee Vote Talley)

Hepatitis C Service Authorization Form

Dr. Bachireddy discussed considerations for removing the service authorization requirements on Mavyret[™] and sofosbuvir/velpatasvir (generic Epclusa[®]). The Committee members discussed his proposal and no decision was made by the Committee. The current service authorization for Mavyret[™] and sofosbuvir/velpatasvir (generic Epclusa[®]) will remain in place at this time.

The next P&T Committee Meeting is tentatively scheduled for September 17, 2020.

Dr. Bachireddy made a motion to adjourn the meeting that was seconded by Dr. Venuto-Ashton. After a unanimous vote, Dr. Bachireddy adjourned the meeting. (Reference Attachment 1 for the Committee Vote Talley)

Self administered Cytokine & CAM Antagonists with Related Agents including Methotrexate - Continue PDL Eligibility	Androgenic Agents, Bone Resorption Suppression and related Agents, Incretin Mimetics/Enhancers, Insulines, Metformins, SGLT2 Inhibitors - Continue PDL Eligibility	Acne Agents, Psoriasis Agents, Rosacea Agents - Contine PDL Eligibility	Antihyperkinesis/CNS Stimulants, Multiple Sclerosis Agents, Neuropathic Pain, Non- ergot Dopamine Receptor Agonits, Skeletal Muscle Relaxants, Smoking Cessation Agents - Continue PDL Eligibility	Antihyperuricemics, Erythropoiesis Stimulating Proteins, Anticoagulants - Contine PDL Eligibility	Antifungals (oral), Quinolones (2nd & 3rd gen), Antivirals - Continue PDL Eligibility but remove amantadine from Antiviral class	Antimigraine, Calcitonin Gene Related Peptide, Opioid Dependency, Long-acting Opioids - Contine PDL Eligibility	PDL Phase I New Drugs, Generics or Dosage Forms (Nayzilam, Katerzia, Duaklir, Proair Digihaler, Dulera) Be PDL eligible	P&T Committee Meeting Minutes from Sept 2019	DMAS ADTIL RO, TOTO POPT ALLEY.
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PDL Recommendatons: The following drugs change from preferred to NON-PREFERRED: Testosterone Gel Packet (including authorized generic), Relpax, Dyanavel XR, Quillichew ER, Quillivant XR, VESIcare. The following drugs change from non-preferred to PREFERRED: Ibandronate (oral), Humalog cartridge, Humalog Junior Kwipen, Humalog Mix pen, Humalog pen, Humulin 70/30 pen OTC, Humulin pen OTC, Insulin Lispro vial, Invokamet, Invokamet XR, Xigduo, Solifenacin	Confidential Pricing Meeting Motion	Non-steroidal Anti-inflammatory Drugs, Short-acting Opioids, Antibiotics (topical) Caphalosporins (2nd & 3rd gen), Gl Antibiotics, Ketolides and Macrolines, Quinolones (otic), Antivirals for Herpes, Platelet Aggreation Inhibitors, Long-acting Reversible Contraceptives, Antifungals (topical), Antivirals (topical), Estrogens (vaginal & oral), Alpha-glucosidase Inhibitors, Meglitinides, Sulfonylureas, Thiazolidinedions, Pancreatic Enzymes, Pregestational Agents - Continue PDL Eligibility	Phase II - Reviewed by Dept	DMAS ROTI PO DOTO POT ALER.
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KEY

M = member made motion

S = member seconded motion

A = member approved

D = member voted against

X = member did not vote

Gill Abernathy - absent