Pharmacy and Therapeutics Committee Meeting
October 20, 2016
Draft Minutes

Members Present:	**DMAS Staff:**
Tim Jennings, Pharm.D., Chair	Cynthia Jones, Agency Director
Krishna Madiraju M.D.,	Cheryl Roberts, Agency Deputy Director
Gill Abernathy, M.S., R.Ph.	Kate Neuhausen, M.D., MPH, Chief Medical Officer
Jack Barber, M.D.	Usha Koduru, Counsel to the Board, Office of the Attorney General
Rachel M. Selby-Penczak, M.D.	Kim Piner, Counsel to the Board, Office of the Attorney General
Mariann Johnson, M.D.	Donna Proffitt R.Ph. Pharmacy Manager
Nathan Charlton, M.D.	Rachel Cain, Pharm.D., Clinical Pharmacist
Sue Cantrell, M.D.	Keith Hayashi, R.Ph., Pharmacist
Barbara Exum, Pharm.D	
Jason Vourlekis, M.D.	
Keith Kittinger, R.Ph	
Absent:	**Staff: Provider Synergies/Magellan Medicaid Administration**
Avtar Dhillon, M.D	Debbie Moody, R.Ph., Clinical Account Manager, Virginia
	Nancy Eldin Pharm.D., Clinical Manager, Virginia
	Doug Brown, R.Ph., MBA, VP, Drug Rebate Manager Medicaid
A quorum was present	**Guests:**
	46 representatives from pharmaceutical companies, providers, advocates, associations, etc.

Welcome and Comments from Cynthia Jones, Agency Director

Cynthia Jones welcomed the members of the Committee and thanked them for their participation in the PDL program. Ms. Jones stated that it has been thirteen (13) years since the inception of the Virginia Medicaid Pharmaceutical and Therapeutics Committee. Over the past thirteen (13) years, this Committee has done extremely important work that has helped to transform our pharmacy program. Medicaid members are receiving high quality prescription medications based on sound clinical criteria at substantially reduced costs to the Commonwealth.

Ms. Jones introduced the new DMAS Chief Medical Officer, Dr. Kate Neuhausen. Dr. Neuhausen is a family physician and was previously the Associate Director of the VCU Office of Health Innovation. She has worked with DMAS for over a year providing clinical leadership in designing and implementing the Medicaid Addiction and Recovery Treatment Services (ARTS) waiver. She was a Robert Wood Johnson Foundation Clinical Scholar and has a Masters in Public Health. As a fellow at the Center for Medicare and Medicaid Services, she worked on Medicaid innovation and delivery system reform including integrated behavioral health and primary care and interventions to address the needs of high-cost "super-utilizer" patients. She attended medical school at Emory and college at UVA. Ms. Jones stated that Dr. Neuhausen is a member of her Executive Management Team and has responsibility for all clinical policy for medical and pharmacy across our Fee for Service Programs and Managed Care programs. Ms. Jones also mentioned that with Bryan Tomlinson's retirement, she has moved all pharmacy policy and operations under Dr. Neuhausen's leadership. This includes both the P&T Committee and DUR Board.

Ms. Jones acknowledged that within the next 18 months, DMAS will have a new Medallion program, called Medallion 4.0. Medallion 4.0 will focus on children, pregnant women, and adults. DMAS will also have fully implemented the new (Commonwealth Coordinated Care) CCC Plus program, which is the new managed care delivery model for seniors and individuals with disabilities. Two of the key components of

both the CCC Plus Program and the Medallion 4.0 program are a "common core" formulary and standardization of drug policies across the FFS and managed care plans. These changes provide DMAS the unique opportunity to make significant changes in the pharmacy program, which will impact the P & T Committee, its composition, and its role.
Beginning with the April 2017 meeting, Dr. Neuhausen will be the new Chair for the P&T Committee. The key reason for this is that chairing the P&T Committee is typically the role of the Medicaid CMO in other states. In addition, due to the development of the Common Core Formulary and the need to avoid any perceived conflict of interest, DMAS needs to have a DMAS employee who is not affiliated with any health plan as the Chair. With the Common Core Formulary, DMAS recognizes the need for input from the health plans to ensure its success. Ms. Jones stated she will be asking the Virginia Association of Health Plans for recommendations of two members to join the P&T Committee. One for Medallion and one for CCC Plus. Ms. Jones mentioned that she will be sending out a letter at the end of the year to all the committee members to gage their interest in continuing. She hopes that most members will want to continue the important role on this reconfigured committee. DMAS may have to replace a couple of members to make sure that DMAS keeps the composition according to the rules in the statue and still meet the revised Committee purpose which will be to set the PDL formulary for all members regardless of FFS or Managed Care. This gives the P&T Committee a stronger mission.
Ms. Jones recognized the outstanding service of Tim Jennings. He has been a member of the Committee since 2007 and was appointed Chair in 2013. Under his leadership, DMAS added numerous drug classes to the PDL including drugs used for the treatment of mental health disorders, cystic fibrosis and multiple sclerosis. In addition, the Committee has thoughtfully and responsibly dealt with the fiscal challenges associated with new costly pharmacotherapies such as the drugs used for the treatment of hepatitis C.

Comments from Kate Neuhausen, M.D., Chief Medical Officer
Dr. Neuhausen mentioned her excitement of the Common Core Formulary, which a number of other states have moved towards. This will give an opportunity for providers to have a streamline formulary and for the members to have a greater continuity of care and care transitions. She stated that the P&T Committee will be influencing the pharmacy policy for all 1.1 million Medicaid members. She thanked the committee members for their time and clinical expertise to this committee.

Call to Order Tim Jennings, Pharm.D., Chairman called the meeting to order.

Comments from Tim Jennings, Pharm.D., Chairman
Dr. Jennings welcomed and thanked the members for their continued participation in the PDL program. Dr. Jennings introduced and welcomed new Committee member Keith Kittinger, pharmacist, from Richmond Apothecary Group in Central Virginia.
He noted a two-minute time limit for speakers.

DMAS' Drug Utilization Review (DUR) Board Update: Dr. Rachel Cain noted that since the last P&T Committee meeting, the DUR Board met twice. In the May DUR Board meeting, the board reviewed ten new drugs and they approved new service authorization criteria for five of the drugs. They also reviewed several utilization analyses. They reviewed utilization analyses on compounded prescriptions, morphine equivalency, dosing of narcotics, Synagis utilization, concurrent use of opioids for members that are being treated for opioid addiction, and dose optimization. The DUR Board also met in August. They reviewed three new drugs and they approved new service authorization for one of the drugs. They reviewed utilization analyses for compounded prescriptions, pediatric narcotic utilization, and dose optimization. In reference to compounded prescriptions, their main focus was on the topical compounded prescriptions. In reviewing, it was discovered that there was a large utilization for compounded topical prescriptions containing ketamine. The DUR Board requested that topical compounded prescriptions

containing ketamine deny. As of October 1, 2016, those prescriptions started to deny at Point-of-Sale for DMAS. The DUR Board also proposed that the prescribers be sent letters to question the safety and effectiveness of all topical compounded prescriptions. The DUR Board will continue to review the compounded prescriptions. The next DUR Board meeting is November 10, 2016.

Approval of Minutes from April 28, 2016 meeting Dr. Jennings 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.

PDL Management

PDL Phase II – Long Acting Opioids Review*:* Dr. Cantrell presented the Long Acting Opioids clinical information and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

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

1. **Clindamycin/tretinoin (*Acne Agents):*** Dr. Madiraju noted the new generic clindamycin/tretinoin, the generic for Veltin®. Dr. Madiraju motioned that clindamycin/tretinoin be PDL eligible. With the motion seconded, the Committee voted unanimously to consider this product as PDL eligible.

2. **Oxiconazole (*Antifungals, Topical):*** Dr. Madiraju noted the new generic oxiconazole, the generic for Oxistat®. Dr. Madiraju motioned that oxiconazole be PDL eligible. With the motion seconded, the Committee voted unanimously to consider this product as PDL eligible.

3. **Epclusa® and Viekira XR™ *(Antivirals Hepatitis C):***

   Speaker
   - Michael Fuchs, M.D., PH.D., Associate Chief of Hepatology, Board Certified in Internal Medicine and Gastroenterology, Virginia Commonwealth University Medical Center and Hunter McGuire VA Center

   Dr. Exum presented the clinical information on Epclusa® (sofosbuvir; velpatasvir) and Viekira XR™ (dasabuvir; ombitasvir; paritaprevir; ritonavir). Dr. Exum motioned that Epclusa® and Viekira XR™ be PDL eligible. With the motion seconded, the Committee voted unanimously to consider these products as PDL eligible.

4. **Onzetra™ Xsail™, Zembrace™ SymTouch™, frovatriptan, and Migranow® Kit (*Antimigraine Agents):*** Dr. Exum presented the clinical information on Onzetra™ Xsail™ (sumatriptan), Zembrace™ SymTouch™ (sumatriptan), frovatriptan – generic for Frova®, and Migranow® Kit (sumatriptan, camphor, menthol). Dr. Exum motioned that Onzetra™ Xsail™, Zembrace™ SymTouch™, frovatriptan, and Migranow® Kit be PDL eligible. With the motion seconded, the Committee voted unanimously to consider these products as PDL eligible.

5. **Taltz® (*Cytokine & CAM Antagonists):*** Dr. Exum presented the clinical information on Taltz® (ixekizumab). Dr. Exum motioned that Taltz® be PDL eligible. With the motion seconded, the Committee voted unanimously to consider this product as PDL eligible.

6. **miglitol *(Diabetes Hypoglycemics Alpha-Glucosidase Inhibitors):*** Dr. Johnson noted the new generic miglitol, the generic for Glyset®. Dr. Johnson motioned that miglitol be PDL eligible. With the motion seconded, the Committee voted unanimously to consider this product as PDL eligible.

7. **Jentadueto XR®, alogliptin, alogliptin/metformin, and alogliptin/pioglitazone *(Diabetes Hypoglycemics Incretin Mimetics/Enhancers):*** Dr. Johnson presented the clinical information on Jentadueto XR® (linagliptin; metformin), alogliptin – generic for Nesina®, alogliptin/metformin – generic for Kazano®, and alogliptin/pioglitazone- generic for Oseni®. Dr. Johnson motioned that Jentadueto XR®, alogliptin, alogliptin/metformin, and alogliptin/pioglitazone be PDL eligible. With the motion seconded, the Committee voted unanimously to consider these products as PDL eligible.

8. **Zinbryta™ (*Multiple Sclerosis):***

   Speaker
   - Gina McKnight-Smith, PharmD, Medical Outcomes Science Liaison, AbbVie (Zinbryta™)

   Dr. Exum presented the clinical information on Zinbryta™ (daclizumab). Dr. Exum motioned that Zinbryta™ be PDL eligible. With the motion seconded, the Committee voted unanimously to consider this product as PDL eligible.

9. **diclofenac 1% gel, Xrylix® Kit, and Vopac® MDS (*Nonsteroidal Anti-Inflammatory Drugs):*** Dr. Madiraju presented the clinical information on diclofenac 1% gel – generic for Voltaren®, Xrylix® Kit (diclofenac topical solution kit), and Vopac® MDS (diclofenac topical solution kit). Dr. Madiraju motioned that diclofenac 1% gel, Xrylix® Kit, and Vopac® MDS be PDL eligible. With the motion seconded, the Committee voted unanimously to consider these products as PDL eligible.

10. **Otovel® (*Otic Antibiotics):*** Dr. Exum presented the clinical information on Otovel® (ciprofloxacin; fluocinolone). Dr. Exum motioned that Otovel® be PDL eligible. With the motion seconded, the Committee voted unanimously to consider this product as PDL eligible.

11. **Adzenys XR ODT™ and armodafinil (*Stimulants and Related Agents):***

    Speaker
    - George Bright, M.D., Medical Director, Adolescent & Family Health Center (Adzenys XR-ODT™)

    Dr. Madiraju presented the clinical information on Adzenys XR ODT™ (amphetamine) and armodafinil – generic for Nuvigil®. Dr. Madiraju motioned that Adzenys XR ODT™ and armodafinil be PDL eligible. With the motion seconded, the Committee voted unanimously to consider these products as PDL eligible.

PDL Phase I – Annual Review

1. ***Antibiotics, Vaginal:*** Dr. Selby-Penczak noted that there were no significant changes in this class since the last review and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

2. ***Bile Salts:*** Dr. Selby-Penczak presented the Bile Salts clinical information and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

3. ***Phosphate Binders:*** Dr. Selby-Penczak noted that there were no significant changes in this class since the last review and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

4. ***Angiotensin Modulators (ACEs, ARBs, & combination products):*** Ms. Abernathy noted that there were no significant changes in this class since the last review and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

5. ***Angiotensin Modulators II (Direct Renin Inhibitors & combination products):*** Ms. Abernathy presented the Angiotensin Modulators II (Direct Renin Inhibitors & Combination Products) clinical information and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

6. ***Antihypertensives, Sympatholytics:*** Ms. Abernathy noted that there were no significant changes in this class since the last review and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

7. ***Beta Blockers (includes combination products):*** Ms. Abernathy presented the Beta Blockers clinical information and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

8. ***Calcium Channel Blockers (includes dihydropyridine and non-dihydropyridine agents):*** Ms. Abernathy noted that there were no significant changes in this class since the last review and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

9. ***Lipotropics, Others (includes Bile Acid Sequestrants, Cholesterol Absorption Inhibitor agents, Fibric Acid derivatives, Microsomal Triglyceride Transfer Protein Inhibitors, Niacin derivatives, Oligonucleotide Inhibitors and Omega 3 agents):***

   Speaker
   - Ahmad Nessar, PharmD, Sr. Health Outcomes Specialist, Amgen (Repatha®)

   Ms. Abernathy presented the Lipotropics, Others clinical information and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

10. ***Lipotropics, Statins:*** Ms. Abernathy presented the Lipotropics, Statins clinical information and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

11. Pulmonary Hypertension Agents (Endothelin-1 agents, PDE-5 Inhibitors; Prostacyclin analogues, Prostacyclin Vasodilators, Soluble Guanylate Cyclase Stimulators):

Speaker

- Melanie Shadoan, PhD, Medical Science Liaison, United Therapeutics (Orenitram ER®)

Ms. Abernathy presented the Pulmonary Hypertension Agents clinical information and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

12. Alzheimer's Agents: Dr. Barber noted that there were no significant changes in this class since the last review and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

13. Anticonvulsants:

Speakers

- Michael Nelson, PharmD, Director, Health Economics & Outcomes Research, Sunovion Pharmaceuticals, Inc. (Aptiom®)
- Jason Moyer, PhD., Medical Science Liaison, Neurology; UCB (Briviact®)

Dr. Barber presented the Anticonvulsants clinical information and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

14. Antidepressants: Dr. Barber presented the Antidepressants clinical information and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

15. Antidepressants, SSRI: Dr. Barber presented the Antidepressants, SSRI clinical information and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

16. Antipsychotics:

Speaker

- Michael Nelson, PharmD, Director, Health Economics & Outcomes Research, Sunovion Pharmaceuticals, Inc. (Latuda®)

Dr. Barber presented the Antipsychotics clinical information and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

17. Sedative Hypnotics (includes other Hypnotics): Dr. Barber presented the Sedative Hypnotics clinical information and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

18. ***Immunological Atopic Dermatitis:*** Dr. Madiraju noted that there were no significant changes in this class since the last review and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

19. ***Steroids, Topical:*** Dr. Madiraju presented the Steroids, Topical clinical information and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

20. ***Glucocorticoids, Oral:*** Dr. Madiraju noted that there were no significant changes in this class since the last review and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

21. ***Growth Hormones:***

    Speaker
    - Erik Hecht, PharmD., Medical Liaison, Novo-Nordisk (Norditropin®)

    Dr. Madiraju presented the Growth Hormones clinical information and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

22. ***Hereditary Angioedema (HAE):*** Dr. Madiraju noted that there were no significant changes in this class since the last review and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

23. ***Progestins for Cachexia:*** Dr. Selby-Penczak noted that there were no significant changes in this class since the last review and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

24. ***Antiemetic/Antivertigo Agents:*** Dr. Selby-Penczak presented the Antiemetic/Antivertigo Agents clinical information and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

25. ***Gastrointestinal (GI) Motility, Chronic:***

    Speaker
    - Paul Miller, PharmD, Regional Clinical Account Director, Astra Zeneca (Movantik®)

    Dr. Selby-Penczak presented the Gastrointestinal (GI) Motility, Chronic clinical information and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

26. ***H. Pylori Treatment:*** Mr. Kittinger noted that there were no significant changes in this class since the last review and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

27. ***Histamine-2 Receptor Antagonists (H-2RA):*** Mr. Kittinger noted that there were no significant changes in this class since the last review and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

28. ***Proton Pump Inhibitors:*** Mr. Kittinger presented the Proton Pump Inhibitors clinical information and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

29. ***Ulcerative Colitis (oral and rectal):*** Mr. Kittinger presented the Ulcerative Colitis clinical information and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

30. ***BPH Agents (includes Alpha Blockers, Androgen Hormone Inhibitors and Phosphodiesterase (PDE) 5 Inhibitors for BPH treatment):*** Mr. Kittinger presented the BPH Agents clinical information and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

31. ***Bladder Relaxants*:** Dr. Johnson presented the Bladder Relaxants clinical information and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

32. ***Ophthalmics - Allergic Conjunctivitis (includes Ophthalmic Antihistamines & Mast Cell Stabilizers):*** Dr. Johnson noted that there were no significant changes in this class since the last review and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

33. ***Ophthalmics -Antibiotics:*** Dr. Johnson noted that there were no significant changes in this class since the last review and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

34. ***Ophthalmics - Antibiotic/Steroid Combinations:*** Dr. Johnson noted that there were no significant changes in this class since the last review and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

35. ***Ophthalmics - Anti-Inflammatory Agents (includes Ophthalmic NSAIDS & Corticosteroids):*** Dr. Johnson noted that there were no significant changes in this class since the last review and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

36. ***Glaucoma Agents (includes Alpha-2 Adrenergics, Beta-blockers, Carbonic Anhydrase Inhibitors, Prostaglandin Inhibitors:*** Dr. Johnson noted that there were no significant changes in this class since the last review and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

37. ***Anti-Allergens, Oral:*** Dr. Charlton noted that there were no significant changes in this class since the last review and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

38. Antibiotics, Inhaled:

Speaker

- Dana Albon, MD, MS, Asst Professor of Medicine, Adult Program Cystic Fibrosis Medical Director, UVA

Dr. Vourlekis presented the Antibiotics, Inhaled clinical information and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

39. Antihistamines Minimally Sedating: Dr. Vourlekis noted that there were no significant changes in this class since the last review and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

40. Bronchodilators, Long Acting Beta Adrenergics: Dr. Vourlekis presented the Bronchodilators, Long Acting Beta Adrenergics clinical information and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

41. Bronchodilators, Short Acting Beta Adrenergics: Dr. Vourlekis presented the Bronchodilators, Short Acting Beta Adrenergics clinical information and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

42. COPD (includes Anticholingerics, Bronchodilators and Phosphodiesterase 4 (PDE4) Inhibitors): Dr. Vourlekis presented the COPD clinical information and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

43. Cough & Cold Agents (Legend): Dr. Charlton noted that there were no significant changes in this class since the last review and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

44. Epinephrine, Self-Injected:

Speaker

- Marc Bernarducci, PharmD, Director, Medical Science Liaison, Mylan (Epi-Pen®)

Dr. Charlton noted that there were no significant changes in this class since the last review and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

45. Glucocorticoids (includes nebulized solutions, metered dose inhalers and combinations): Dr. Charlton presented the Glucocorticoids, Inhaled clinical information and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

46. Intranasal Rhinitis (includes Antihistamines and Corticosteroids): Dr. Charlton presented the Intranasal Rhinitis clinical information and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

47. Leukotriene Modifiers: Dr. Charlton presented the Leukotriene Modifiers clinical information and motioned that the class continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

Comments from the Office of the Attorney General

Ms. Usha Koduru from the Attorney General's office stated that under the Virginia Freedom of Information Act (FOIA), specifically Virginia Code section 2.2-3711, a public body such as the P&T Committee, may go into a closed session for any one of the 47 reasons listed in that statute. The discussion of manufacturer and wholesaler prices is not one of the 47 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 she cautioned only this confidential pricing information should be discussed.

Dr. Madiraju 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.

The motion was seconded and unanimously approved by the Committee.

Following the Confidential Session, the Committee members re-assembled in the 7th floor conference room. 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. A motion was made to resume the meeting. The motion was seconded and unanimously approved by the Committee.

PDL Changes Effective January 1, 2017

Phase II New Drug/Class Review

Dr. Madiraju 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. Analgesics, Narcotics Long: Butrans® is preferred. Kadian® is non-preferred.

2. Hepatitis C Agents*:* Epclusa® (for Genotype 2 and 3 ONLY), Harvoni®, and Viekira XR™ are preferred. Daklinza™ is non-preferred.

3. Progestational Agents: Progesterone capsule is preferred. Prometrium® is non-preferred.

Phase I Annual Review

Dr. Madiraju 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****:* Aripiprazole tablet is preferred. Abilify® Tablet and Fanapt® Tablet are non-preferred.

2. ***Intranasal Rhinitis Agents****:* Nasonex® is non-preferred.

3. ***Anticonvulsants****:* Divalproex sprinkle and topiramate sprinkle are preferred. Depakote® Sprinkle and Topamax® Sprinkle are non-preferred.

4. ***Bronchodilators, Short Acting Beta Adrenergics****:* Xopenex® Nebulizer Solution Concentrate and Xopenex® Nebulizer Solution are non-preferred.

5. ***Steroids, Topical Medium****:* Hydrocortisone valerate cream, hydrocortisone valerate ointment, and flurandrenolide cream are non-preferred.

6. ***Beta-Blockers****:* Nadolol is non-preferred.

7. ***Steroids, Topical High:*** Betamethasone valerate cream, betamethasone valerate lotion, and betamethasone valerate ointment are preferred. Fluocinonide cream, fluocinonide emollient, fluocinonide gel, and fluocinonide ointment are non-preferred.

8. ***PAH Agents, Oral and Inhaled:*** Adcirca® is preferred. Tyvaso® Inhalation is non-preferred.

9. ***Lipotropics, Other:*** Fenofibrate (generic Tricor®) is preferred. Fenofibrate (generic Fenoglide®), Tricor®, and Repatha® Pushtronex are non-preferred.

10. ***Ophthalmics, Glaucoma Agents:*** Apraclonidine 0.5% drops is non-preferred.

11. ***Lipotropics, Statins:*** Rosuvastatin is preferred.

12. ***Angiotensin Modulators:*** Enalapril/HCTZ is preferred. Captopril is non-preferred.

13. ***Alzheimer's Agents:*** Donepezil ODT is preferred.

14. ***Angiotensin Modulator Combinations:*** Amlodipine/valsartan is preferred. Byvalson™ is non-preferred.

15. ***GI Motility, Chronic:*** Linzess® is preferred. Relistor® is non-preferred.

16. ***Ophthalmics, Anti-Inflammatories***: Nevanac® is non-preferrred.

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

- Anti-Allergens, Oral
- Antibiotics, Inhaled
- Antibiotics, Vaginal

- Antidepressants, Other
- Antidepressants, SSRIs
- Antiemetic/Antivertigo Agents
- Antihistamines, Minimally Sedating
- Antihypertensives, Sympatholytics
- Bile Salts
- Bladder Relaxant Preparations
- BPH Treatments
- Bronchodilators, Long Acting Beta Adrenergics
- Calcium Channel Blockers
- COPD Agents
- Cough And Cold, Cold
- Cough And Cold, Narcotic
- Cough And Cold, Non-Narcotic
- Epinephrine, Self-Injected
- Glucocorticoids, Inhaled
- Glucocorticoids, Oral
- Growth Hormone
- H. Pylori Treatment
- HAE Treatments
- Histamine-2 Receptor Blocker
- Immunomodulators, Atopic Dermatitis
- Leukotriene Modifiers
- Ophthalmic Antibiotics
- Ophthalmic Antibiotic-Steroid Combinations
- Ophthalmics For Allergic Conjunctivitis
- Phosphate Binders
- Progestins For Cachexia
- Proton Pump Inhibitors
- Sedative Hypnotics
- Steroids, Topical Low
- Steroids, Topical Very High
- Ulcerative Colitis Agents

Clinical Criteria

Dr. Madiraju, Dr. Jennings, Dr. Neuhausen, Dr. Barber, Ms. Abernathy, Dr. Charlton, Dr. Johnson, Dr. Selby-Penczak, Dr. Exum, Dr. Cantrell, Dr. Vourlekis, and Mr. Kittinger discussed the proposed new or revised clinical criteria. Dr. Madiraju made the following motion to implement new or revised clinical

criteria for the following drugs and drug classes, which was seconded and approved unanimously by the Committee:

- Short Acting Narcotics
- Long Acting Narcotics
- Buprenorphine Containing Drugs
- Methadone
- Atypical Antipsychotics (Nuplazid™)
- Topical Steroids, High (Sernivo™)
- Multiple Sclerosis Agents (Zinbryta™)
- Stimulants and Related Agents (Adzenys XR ODT™)
- Cytokine and CAM Antagonists (Taltz®)
- Topical NSAIDs (Vopac MDS and Xrylix™ Kit)
- Lipotropics, Other (Repatha®)
- Hepatitis C (Epclusa®, Viekira XR™, Harvoni®, and Olysio®)
    - Hepatitis C Criteria Update for all Hepatitis C Agents
        - Note that the P&T Committee approved a change in the Disease Severity criterion for drugs used in the treatment of hepatitis C. These drugs will no longer require a documentation of a Metavir Score.
        - Member must be evaluated for substance and alcohol abuse and referred to addiction treatment but not denied hepatitis C therapy solely for substance/alcohol abuse.
        - Physician should attest that the patient has an agreement for adherence and that the patient does not have a recent history of non-adherence, such as missed multiple appointments or not taking medications for chronic illnesses.

The next P&T Committee Meeting is tentatively scheduled for April 21, 2017.

Dr. Jennings adjourned the meeting.