

Pharmacy and Therapeutics Committee Meeting
April 19, 2018
Draft Minutes

Members Present:

Kate Neuhausen, M.D., MPH
Krishna Madiraju, M.D.
Tim Jennings, Pharm.D.
Gill Abernathy, M.S., R.Ph.
Rachel M. Selby-Penczak, M.D.
Nathan Charlton, M.D.
Barbara Exum, Pharm.D.
Keith Kittinger, R.Ph.

DMAS Staff:

Jennifer Lee, M.D., Agency Director
Kathy Sardegna, M.D., Pediatric Medical Director
Matthew Keats, M.D., MMM, Behavioral Health Medical Director
Usha Koduru, Counsel to the Board, Office of the Attorney General
Donna Proffitt R.Ph. Pharmacy Manager
Rachel Cain, Pharm.D., Clinical Pharmacist
Keith Hayashi, R.Ph., Pharmacist
Dean Beuglass, R.Ph., Senior Pharmacy Policy and Data Strategist

Absent:

Ira Bloomfield, M.D.
Sue Cantrell, M.D.
Jack Barber, M.D.

Staff: Provider Synergies/Magellan Medicaid Administration

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:

60 representatives from pharmaceutical companies, providers, advocates, associations, etc.

Welcome and Comments from Kate Neuhausen, M.D., Chief Medical Officer and Chairman

Dr. Neuhausen welcomed the members of the Committee and thanked them for their participation in the PDL program. Dr. Neuhausen introduced Dr. Jennifer Lee, DMAS' new Agency Director.

Comments from Jennifer Lee, M.D., Agency Director

Dr. Lee welcomed and thanked the members for their continued participation in the PDL Program. She shared that she started as the DMAS Agency Director in January 2018. Dr. Lee is board-certified in Emergency Medicine and was previously the Deputy Secretary of Health and Human Resources under Dr. Hazel. She also served as the Deputy Under Secretary for Health for Policy and Services for the Department of Veterans Affairs (VA). She served as a White House Fellow in VA's Office of the Secretary.

Dr. Lee mentioned the new Medallion 4.0 Medicaid Managed Care Program will go live in August of this year. Dr. Lee stated that she is hopeful for the opportunity of Medicaid Expansion to provide healthcare to 400,000 of the neediest Virginians.

Call to Order: Kate Neuhausen, M.D., Chairman called the meeting to order.

DMAS' Drug Utilization Review (DUR) Board Update: Dr. Rachel Cain provided the DUR update. Since the last P&T Committee meeting, the DUR Board met twice. The DUR Board reviewed the following new drugs: Idhifa®, Nerlynx®, Calquence®, Gocovri™, Hemlibra®, Juluca™, Prevymis™, Rebinyn®, Verzenio™ and Ximino™. The DUR Board approved Service Authorization (SA) criteria for Idhifa®, Nerlynx®, Calquence®, Gocovri™, Hemlibra®, Juluca™, Prevymis™, Verzenio™ and Ximino™.

Dr. Cain shared that the DUR Board reviewed the utilization for orphan drugs, compounded prescriptions, adult and pediatric opioids, naloxone, Synagis®, Proton Pump Inhibitors, and Gender point-of-sale edits. She stated that the DUR Board approved service authorization criteria for members using long-term PPIs for more than 3 months.

Approval of Minutes from October 19, 2017 meeting Dr. Neuhausen 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 I – New Drug Review (Therapeutic Class)

1. **Odactra™ (Anti-Allergens, Oral):** Dr. Nancy Eldin presented the clinical information on Odacra™ (house dust mite [*Dermatophagoides farinae* and *Dermatophagoides pteronyssinus*] allergen extract). A Committee member motioned that Odacra™ be PDL eligible. With the motion seconded, the Committee voted unanimously to consider this drug as PDL eligible.
2. **Cinvanti™ (Antiemetic/Antivertigo Agents):** Dr. Eldin presented the clinical information on Cinvanti™ (polysorbate-80-free formulation of aprepitant). A Committee member motioned that Cinvanti™ be PDL eligible. With the motion seconded, the Committee voted unanimously to consider this drug as PDL eligible.
3. **Symproic® (GI Motility, Chronic):** Dr. Eldin presented the clinical information on Symproic® (naldemedine). A Committee member motioned that Symproic® be PDL eligible. With the motion seconded, the Committee voted unanimously to consider this drug as PDL eligible.
4. **QVAR® Redihaler™ and Trelegy™ Ellipta® (Glucocorticoids, Inhaled):** Dr. Eldin presented the clinical information on QVAR® Redihaler™ (beclomethasone dipropionate HFA) and Trelegy™ Ellipta® (fluticasone furoate/umeclidinium/vilanterol). Dr. Kathy Sardegna presented additional information on QVAR® Redihaler™. A Committee member motioned that QVAR® Redihaler™ and Trelegy™ Ellipta® be PDL eligible. With the motion seconded, the Committee voted unanimously to consider these drugs as PDL eligible.
5. **Xhance™ (Intranasal Rhinitis Agents):** Dr. Eldin presented the clinical information on Xhance™ (fluticasone propionate). A Committee member motioned that Xhance™ be PDL eligible. With the motion seconded, the Committee voted unanimously to consider this drug as PDL eligible.
6. **Vyzulta™ (Ophthalmics, Glaucoma Agents):** Dr. Eldin presented the clinical information on Vyzulta™ (latanoprostene bunod). A Committee member motioned that Vyzulta™ be PDL eligible. With the motion seconded, the Committee voted unanimously to consider this drug as PDL eligible.
7. **Generic Drugs and New Dosage Forms:** Dr. Eldin noted the following new generics and new dosage forms:
 - carvedilol ER (generic Coreg CR™) (Beta-Blockers)
 - paroxetine (generic Brisdelle®) (Antidepressants, SSRIs)
 - timolol (generic Istalol®) (Ophthalmics, Glaucoma Agents)
 - esomeprazole magnesium (generic Nexium® 24 HR OTC) (Proton Pump Inhibitors)

A Committee member motioned that the new generics and new dosage forms be PDL eligible. With the motion seconded, the Committee voted unanimously to consider these drugs as PDL eligible.

PDL Phase II – Annual Review

1. **Antimigraine Agents:** Dr. Eldin presented the Antimigraine Agents clinical information. A Committee member 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. **Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) (includes COX-2 inhibitors and topical agents):** Dr. Eldin presented the Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) clinical information. A Committee member 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. **Opioid Analgesics & Dependency (includes oral buprenorphine & methadone) (Closed Class):**

Speakers

- Michale Boskello, MD, Sr. Medical Science Liaison, Alkermes (Vivitrol®)

Dr. Eldin presented the Opioid Analgesics & Dependency clinical information. Dr. Matthew Keats presented additional information on Sublocade™. A Committee member 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. **Antifungals, Oral:** Dr. Eldin presented the Antifungals, Oral clinical information. A Committee member 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. **Cephalosporins (Second and Third Generations):** Dr. Eldin presented the Cephalosporins (Second and Third Generations) clinical information. A Committee member 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. **GI Antibiotics:** Dr. Eldin presented the GI Antibiotics clinical information. A Committee member 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. **Quinolones (Second and Third Generations):** Dr. Eldin presented the Quinolones (Second and Third Generations) clinical information. A Committee member 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. **Antivirals for Influenza:** Dr. Eldin presented the Antivirals for Influenza clinical information. A Committee member 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. **Antihyperuricemics:** Dr. Eldin presented the Antihyperuricemics clinical information. A Committee member 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. **Anticoagulants (includes oral agents, low molecular weight heparins & Factor XA Inhibitors)**
(Closed Class):

Speakers

- Elizabeth Stanley, Outcomes Research, Boehringer-Ingelheim (Pradaxa®)
- Chakita Williams, PhD, Health Economics & Outcomes Scientist, BMS (Eliquis®)
- Anne Depriest, PharmD, Medical Science Liaison, Janssen (Xarelto®)

Dr. Eldin presented the Anticoagulants clinical information. A Committee member 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. **Antihyperkinesis/CNS Stimulants (Closed Class):**

Speakers

- George Kehner, Neos Therapeutics (Cotempla XR-ODT™)

Dr. Eldin presented the Antihyperkinesis/CNS Stimulants clinical information. A Committee member 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. **Multiple Sclerosis Agents:**

Speakers

- Tanner Odom, PharmD, Senior Medical Value Liaison, Biogen (Tecfidera®)

Dr. Eldin presented the Multiple Sclerosis Agents clinical information. A Committee member 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. **Neuropathic Pain:**

Speakers

- Mark Vaughan, PharmD, Medical Outcomes Specialist, Pfizer (Lyrica® CR)

Dr. Eldin presented the Neuropathic Pain clinical information. A Committee member 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. **Androgenic Agents:** Dr. Eldin presented the Androgenic Agents clinical information. A Committee member 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. **Hypoglycemics: Incretin Mimetics/Enhancers (includes DPP-IV Inhibitors, GLP-1 Agonists & Combinations (Closed Class):** Dr. Eldin presented the Hypoglycemics, Incretin Mimetics/Enhancers

clinical information. A Committee member 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. **Hypoglycemics: Insulins:** Dr. Eldin presented the Hypoglycemics, Insulins clinical information. A Committee member 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. **Hypoglycemics: Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitors (Closed Class):**

Speakers

- Anne Depriest, PharmD, Medical Science Liaison, Janssen (Invokana®)
- Elizabeth Stanley, Outcomes Research, Boehringer-Ingelheim (Jardiance®)

Dr. Eldin presented the Hypoglycemics, Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitors clinical information. A Committee member 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. **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):**

Speakers

- Peter Synder, PhD, Field Medical Director, Pfizer (Xeljanz®)
- Pallav Raval, PharmD, Medical Science Liaison, Novartis (Cosentyx®)

Dr. Eldin presented the Self-Administered Cytokine & CAM Antagonists clinical information. A Committee member 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. **Therapeutic Classes Without Updates (Reviewed by the Department):**

- Opioids: Long Acting
- Opioids: Short Acting (includes combination drugs and lozenges)
- Antibiotics (topical)
- Ketolides & Macrolides (Adult and Pediatric)
- Quinolones (Otic)
- Antivirals for Herpes (HSV)
- Antihyperuricemics
- Erythropoiesis Stimulating Proteins
- Platelet Aggregation Inhibitors
- Non-Ergot Dopamine Receptor Agonists
- Skeletal Muscle Relaxants
- Smoking Cessation Agents
- Long-Acting Reversible Contraceptives (includes IUDs & injectables)
- Acne Agents, Topical (includes benzoyl peroxide, clindamycin, retinoids & combinations)
- Antifungal Topical Agents
- Antivirals, Topical

- Psoriasis Topical Agents
- Rosacea Topical Agents
- Bone Resorption Suppression and Related Agents (includes bisphosphonates, calcitonins and others)
- Estrogens (vaginal and oral)
- Hypoglycemics: Alpha-Glucosidase Inhibitors
- Hypoglycemics: Meglitinides
- Hypoglycemics: Metformins
- Hypoglycemics: Sulfonylureas
- Hypoglycemics: Thiazolidinediones
- Pancreatic Enzymes

Speaker

- Joel Schmidt, MD, Professor, Pediatric Pulmonology, VCU (Pancreatic Enzyme Replacement Therapy)

- Progestational Agents

Dr. Eldin noted that the above therapeutic classes had no significant changes since the last review. A Committee member motioned that these classes continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain these classes 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 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 she cautioned only this confidential pricing information should be discussed.

Dr. Krishna 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. Neuhausen 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 July 1, 2018

New Drugs Phase I: All new drugs (brand and generic) presented will remain non-preferred.

Phase II 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. **Stimulants and Related Agents (CLOSED CLASS):** Concerta® and atomoxetine (generic Strattera®) are preferred. Quillichew ER® and Strattera® are non-preferred. (Dr. Kate Neuhausen, CMO acting on behalf of the Agency Director reversed the Committee's recommendation to make Quillichew ER non-preferred. It will remain preferred on the PDL).
 2. **Macrolides/Ketolides:** EryPed® 200 suspension is preferred. Erythromycin ethylsuccinate 200 suspension (generic EryPed® 200 suspension) is non-preferred.
 3. **Antifungals, Topical:** clotrimazole cream (RX) is preferred. Clotrimazole-betamethasone cream, nystatin-triamcinolone cream, and nystatin-triamcinolone ointment are non-preferred.
 4. **Platelet Aggregation Inhibitors:** prasugrel (generic Effient®) is preferred. Effient® is non-preferred.
 5. **Analgesics, Narcotic Short:** Nucynta®, butalbital/caffeine/APAP w/codeine, Oxaydo®, and Panlor® are non-preferred.
 6. **Hypoglycemics, SGLT2 (CLOSED CLASS):** Synjardy® and Jardiance® are preferred.
 7. **Hypoglycemics, Incretin Mimetics/Enhancers (CLOSED CLASS):** Glyxambi® is preferred. Bydureon® BCise™ (this was misread as Bydureon® subcutaneous) is non-preferred.
 8. **Antivirals, Oral:** oseltamivir suspension is preferred. Tamiflu® suspension is non-preferred.
 9. **Acne Agents, Topical:** clindamycin/benzoyl peroxide, clindamycin phosphate med swab, and Differin® Gel OTC are preferred. Benzaclin® and Differin® Cream/Gel(Rx)/Gel Pump/Lotion are non-preferred.
 10. **Antiparkinson's Agents:** amantadine capsule is preferred.
 11. **Opiate Dependence Treatments (CLOSED CLASS):** Sublocade™ is non-preferred.
- No other changes noted.***

Clinical Criteria

The Committee members discussed the proposed new clinical criteria presented by Debbie Moody. A Committee member made the following motion to implement new clinical criteria for the following drugs and drug classes, which was seconded and approved unanimously by the Committee:

- Stimulants/ADHD Medications
 - A service authorization is required for stimulants prescribed for any member 18 years of age or older. Service authorization requirements will require the prescriber to check the Virginia Prescription Monitoring Program (PMP) and review a urine drug screen prior to initiating therapy.
 - A service authorization is required for stimulants prescribed for any member 4 years of age or younger. Service authorization requirements will require the prescribing provider be a Psychiatrist, Neurologist, Developmental/Behavioral Pediatrician or a Pediatrician.
- Oral Hypoglycemics
 - The service authorization criteria for Sodium Glucose Co-Transporter 2 Inhibitor (SGLT2) and DPP-IV Inhibitors includes that the member be compliant with and has not achieved adequate glycemic control with a 60 days trial on metformin. (Dr. Kate Neuhausen, CMO acting on behalf of the Agency Director revised the metformin trial to 90 days based on current ADA guidelines)
- Mavyret™
 - Added to the criteria is to screen for Hepatitis B or HIV. If the screening verifies there is co-infection with Hepatitis B or HIV then need to refer to a specialist.
- Hepatitis C Antivirals
 - Added to the criteria is to screen for Hepatitis B or HIV. If the screening verifies there is co-infection with Hepatitis B or HIV then need to refer to a specialist.
- Sublocade™
 - Similar to the buprenorphine service authorization criteria with the addition of:
 - The patient initiated treatment with a transmucosal buprenorphine-containing product followed by dose adjustment for a minimum of seven days.
 - Sublocade™ dosing be in accordance with the U. S. Food and Drug Administration approved labeling: 300mg subcutaneously monthly for the first 2 months, followed by a maintenance dose of 100 mg monthly. Increasing the maintenance dose to 300 mg monthly may be considered for patients in which the benefits outweigh the risks.
 - Because of the risk of serious harm or death that could result from intravenous self-administration, Sublocade™ is only available through a restricted program called the Sublocade REMS Program. Healthcare settings and pharmacies that order and dispense Sublocade™ must be certified in this program and comply with the REMS requirements.

The next P&T Committee Meeting is tentatively scheduled for October 4, 2018.

Dr. Neuhausen adjourned the meeting.