

**Meeting of the
Pharmacy and Therapeutics Committee
October 24, 2013
Draft Minutes**

Members Present:

Tim Jennings, Pharm.D., Chair
Krishna Madiraju M.D.
Gill Abernathy, M.S., R.Ph.
Rachel M. Selby-Penczak, M.D.
Henry Ivey, M.D.
Barbara Exum, Pharm.D.
Jason Vourlekis, M.D.

DMAS Staff:

Cynthia Jones, Agency Director
Cheryl Roberts, Agency Deputy Director
Bryan Tomlinson, Director, Division of Health Care Services
Usha Koduru, Counsel to the Board, Office of the Attorney General
Donna Proffitt, R.Ph., Pharmacy Manager
Keith Hayashi, R.Ph., Clinical Pharmacist
Maryanne Paccione, Information Management Consultant
Danielle Adeeb, Information Technology Specialist

Absent:

Mark Oley, R.Ph.
Avtar Dhillon, 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 Director Rebate Contracting Management

A quorum was present

Guests:

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

Welcome and Comments from Tim Jennings, Chairman

Dr. Jennings welcomed and thanked the members for their continued participation in the PDL program.

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

Comments from Tim Jennings, Pharm.D, Chairman

Dr. Jennings welcomed new P&T Committee member Dr. Jason Vourlekis. Dr. Vourlekis is from Inova Health System in northern Virginia. He is a pulmonary/critical care specialist and enrolled in a part-time MBA program with the Carey Business School at Johns Hopkins University.

Dr. Jennings announced that Dr. Hank Ivey has resigned from the P&T Committee effective after the October 25, 2013 meeting. Dr. Jennings recognized and thanked Dr. Ivey for his service on the P&T Committee. Dr. Jennings expressed how Dr. Ivey's role has been very important to the P&T Committee.

Welcome and Comments from Cynthia Jones, DMAS Agency Director

Cindi Jones welcomed the members of the Committee and thanked them for their continued participation in the PDL program. Ms. Jones briefly discussed Medicaid Reform and Expansion. She shared that the Commonwealth of Virginia decided not to create its own Exchange on the Affordable Care Act but has defaulted to the federal exchange. Ms. Jones also shared that the Virginia General Assembly established the Medicaid Innovation and Reform Commission to oversee Medicaid Expansion. The legislation identifies three major phases of "reform" for expansion. These phases include (1) advancing reforms currently in progress (implementation of the Medicare-Medicaid Demonstration pilot, enhanced program integrity and fraud prevention efforts, inclusion of children enrolled in foster care in managed care, implementation of a new eligibility and enrollment information system,

improved coordination for behavioral health services), (2) implementing innovations in service delivery, administration and beneficiary engagement and (3) transitioning members in long-term care and home- and community-based waiver services into cost-effective, managed and coordinated delivery systems.

DMAS' Drug Utilization Review (DUR) Board Update: In the absence of Dr. Dhillon, Donna Proffitt, DMAS Pharmacy Manager, provided an update on the activities of DUR Board. Since the last P&T meeting, the Board has reviewed twenty-seven (27) new drugs and approved both prospective and retrospective clinical edits for these drugs. In addition, the Board approved clinical edits for six (6) new drugs not in drug classes subject to Virginia Medicaid's Preferred Drug List (PDL). Prescribers will need to complete and submit a service authorization for Mekinist™ (trametinib), Revlimid® (lenalidomide), Tafinlar® (dabrafenib), Fulyzaq™ (crofelemer), Ravicti™ (glycerol phenylbutyrate), and Signifor® (pasireotide). Ms. Proffitt also shared that the DUR Board continues to monitor the use of atypical antipsychotics prescribed for children under the age of six. Dr. Neil Sonenklar, a child and adolescent psychiatrist contracted through Magellan Medicaid, reviews all service authorization requests that do not meet the approved criteria for the utilization of atypical antipsychotics in this population and recently informed the DUR Board that the service authorization requirement appears to be ensuring appropriate use of these drugs in this population.

Old Business

- Long Acting Beta Agonist (LABAs) in Children: Dr. Madiraju shared the results of the LABA edit in children since the edit was implemented on July 1, 2013. Eighty-three (83) requests for a service authorization (SA) for sixty-nine (69) distinct recipients were submitted from July 1 through September 25, 2013. Forty-nine (49) of those SA requests received an approval for the first request. Twenty (20) of the SA requests were offered a change in therapy. Eleven (11) of these requests were resubmitted with additional clinical information and the requests were approved. The remaining nine (9) did not provide additional information. Dr. Madiraju stated this edit appears to be minimizing the inappropriate use of LABAs in children.
- Narcotic Utilization: Dr. Jennings reviewed a narcotic utilization report that identified three paid prescription claims for narcotics and/or prescribed by three or more prescribers and/or filled by three or more pharmacies for fee-for service members during the period of March 1, 2013 through August 31, 2013. The report identified 632 distinct members meeting these criteria with an average number of prescriptions per member equal to 7.75 and the average number of prescribers per member equal to 3.59. Dr. Jennings requested to have the number of prescriptions per prescriber "normalized" to prescriptions per 1000 members. Dr. Jennings explained that some prescribers see more Medicaid patients than others and this filter should provide a truer representation of their prescribing habits.

Dr. Jennings also discussed the Prescription Monitoring Program (PMP) and asked the Committee members to consider for those patients that have a service authorization for narcotics, to make it mandatory for the prescriber to fax in the actual PMP form to Magellan Health demonstrating that the prescriber had accessed the PMP site. Dr. Ivey expressed a concern about the time it would take prescribers to complete this step. Dr. Selby-Penczak also expressed her concern for physicians who see patients in their home and how accessing the PMP site and faxing the form would be a challenge. This proposal was tabled and Dr. Jennings requested DMAS to contact the Virginia Board of Pharmacy and ask what other states are doing and bring this information back to the next P&T meeting.

- Update on ADHD Medication Utilization in Foster Children Population: During the period of January 1 to March 31, 60,857 children under 18 years of age were enrolled in Medicaid's fee-for-service (FFS) program. Of those children, 7,882 has a pharmacy claim for a drug used to treat ADHD. The number of foster children enrolled in Medicaid's FFS program during this period was 5,610 foster children of which 998 had a pharmacy claim submitted for an ADHD drug (35 received a drug outside the FDA approved age for the drug). For the children not in foster care (55,247 children), there were 123 members who received ADHD drugs under the FDA approved age for the drug. Dr. Madiraju proposed the implementation of a service authorization for the use of an ADHD drug when it is prescribed outside the FDA approved age for a drug.
- Anticoagulant Therapy and Hospitalizations Due to Bleeding Episodes: Dr. Jennings shared the data from this report that did not identify any correlation between anticoagulant utilization and hospitalizations due to bleeding episodes.

Approval of minutes from April 18, 2013 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

Potential New Therapeutic Class Review (PDL Category)

1. Alzheimer's Agents (*contains Cholinesterase Inhibitors, NMDA Receptor Antagonist*) (CNS)

Speaker

- Jolan Turner-Rosenthal, PharmD, Medical Science Liaison, Forest Research (Namenda[®] XR)

Dr. Ivey noted the drugs in this class include donepezil, galantamine, rivastigmine, and memantine. He also stated these drugs are not approved for children.

Dr. Ivey presented potential new criteria for this drug class:

Length of Authorizations: Length of the prescription (up to 3 months) -- Routine PDL edits

- Donepezil ODT (Aricept[®] ODT): patient is unable to swallow or absorb oral medications.
- Aricept[®] 23mg (donepezil): patient is currently established on therapy with the 10 mg tablet for at least 3 months.

Dr. Ivey motioned that the Alzheimer's Agents Class be PDL eligible with the addition of the above criteria. With the motion seconded, the Committee voted unanimously to consider this class and the criteria as PDL eligible.

2. Antibiotics, Inhaled (*Antibiotic-Anti-Infective*)

Speaker

- Shilpa Patel, PharmD, Regional Scientific Director, Novartis (Tobi[®] Podhaler)
- Michael Schechter, MD, Director of VCU Cystic Fibrosis (CF) Center (Tobi[®] Podhaler)

Dr. Jennings asked Dr. Schechter if non-compliance impacts patient failures and re-hospitalizations. Dr. Schechter referenced one study that showed a relationship between adherence and hospitalizations and overall care. He stated that disease self-management is the most important reason why lower social economic status patients have worse outcomes in the CF world. Ms. Abernathy asked Dr. Schechter if he could cite a study that demonstrates that the use of the Tobi[®] Podhaler decreases hospitalizations. Dr. Schechter stated he could not.

Dr. Exum stated that there are three drugs in this class: aztreonam (Cayston[®]) and tobramycin (Tobi[®] and Tobi[®] Podhaler). Inhaled aztreonam (Cayston[®]) is a beta-lactamase-resistant monobactam antibiotic that only has activity against aerobic gram-negative bacteria, including *P. aeruginosa*. Safety and efficacy of inhaled aztreonam (Cayston[®]) have not been established in pediatric patients less than seven years of age. Safety and efficacy of inhaled tobramycin (TOBI[®], TOBI[®] Podhaler) have not been established in pediatric patients less than six years of age.

Dr. Exum presented potential new criteria:

Length of Authorization: 1 Year plus routine PDL edits and

- Tobi Podhaler[®] (tobramycin inhalation powder)
 - Clinical reason as to why Tobi nebulizer 300mg/5 ml solution cannot be used
 - Minimum age restriction of 6 years of age
 - Quantity limit = 8 capsules per day
 - Patient is not pregnant
- Cayston[®] requires the following criteria be met:
 - Diagnosis of Cystic Fibrosis
 - Previous therapy with tobramycin via nebulizer
 - Demonstration of Tobi[®] compliance
 - Minimum age restriction of 7 years of age
 - Quantity limits = 84 ml per 28 days

Dr. Exum motioned that the Antibiotics, Inhaled Class be PDL eligible with the addition of the above criteria. With the motion seconded, the Committee voted unanimously to consider this class and the criteria as PDL eligible.

3. Antibiotics, Vaginal (*Antibiotic-Anti-Infective*)

Dr. Exum cited that there are three drugs in this class that are indicated for the treatment of bacterial vaginosis: clindamycin vaginal 2% cream (Cleocin[®], Clindesse[™]), clindamycin vaginal ovules (Cleocin[®]), and metronidazole vaginal 0.75% gel (Metrogel Vaginal[®], Vandazole[™]). The safety and efficacy of clindamycin vaginal products and metronidazole vaginal gel in premenarchal females have not been established. Clindamycin and metronidazole are Pregnancy Category B. According to FDA prescribing information, clindamycin 2% may be used in second and third trimester of pregnancy for the treatment of bacterial vaginosis. The CDC does not support the use of intravaginal metronidazole to treat pregnant women.

Dr. Exum proposed the following potential new criteria:

Length of Authorization: Date of Service (3-day window) plus routine PDL and

- For clindamycin cream --- patient is unable to insert the Cleocin Ovules and/or needs to apply a cream.

Dr. Exum motioned that the Antibiotics, Vaginal Class be PDL eligible with the addition of the above criteria. With the motion seconded, the Committee voted unanimously to consider this class and the criteria as PDL eligible.

4. **Antiemetic/Antivertigo Agents(delta-9THC derivatives, 5HT3 Receptor Blockers, NK-1 Receptor Antagonist, Other) (Gastrointestinal)**

Dr. Ivey noted the list of Antiemetic/Antivertigo Drugs:

NK1 receptor antagonist

aprepitant (Emend[®])

5-HT3 antagonists

dolasetron (Anzemet[®])

granisetron (GranisolTM)

granisetron transdermal (Sancuso[®])

ondansetron (Zofran[®], Zuplenz[®])

Cannabinoids

dronabinol (Marinol[®])

nabilone (Cesamet[®])

Others

trimethobenzamide (Tigan[®])

Antihistamines

meclizine (Antivert[®])

Phenothiazines

promethazine (Phenergan[®])

prochlorperazine (Compro[®])

Anticholinergics

scopolamine (Transderm-Scop[®])

Dr. Ivey presented the following potential new criteria:

1. **Cannabinoids (delta-9THC derivatives)**

Length of Authorization: 6 months routine PDL edit plus Clinical edit

***Cesamet[®]**

- Diagnosis of severe, chemotherapy induced nausea and vomiting
- Patient has tried and failed, has a contraindication to, an intolerance, or a medical reason not to try the combination of Emend[®] plus a 5HT3 receptor antagonist plus a corticosteroid

****Dronabinol**

- Diagnosis of severe, chemotherapy induced nausea and vomiting
- Patient has tried and failed, has a contraindication to, an intolerance, or a medical reason not to try the combination of Emend[®] plus a 5HT3 receptor antagonist plus a corticosteroid
- Diagnosis of AIDS-relating wasting
- Patient has tried and failed Megestrol acetate oral suspension OR has a contraindication, intolerance, drug-drug interaction, or medical reason Megestrol acetate cannot be used.

2. **5HT3 Receptor Blockers**

Length of Authorization: 3 months, unless otherwise noted routine PDL edit plus Clinical edit

- Nausea or vomiting related to radiation therapy, moderate to highly emetogenic chemotherapy, or post-operative nausea and vomiting

- Patient has tried and failed therapeutic doses of, or has adverse effects or contraindications to, 2 different conventional antiemetics (e.g., promethazine, prochlorperazine, meclizine, metoclopramide, dexamethasone, etc.)
- Ondansetron solution and Zuplenz[®] requires a clinical reason the patient cannot use Ondansetron ODT or patient is taking less than 4 mg per dose

3. NK-1 Receptor Antagonist

Length Of Authorization: Length of chemotherapy regimen or a maximum of 6 months. Routine PDL edit plus Clinical edit

Emend[®] (aprepitant):

- Emend[®] does NOT require treatment failure with preferred drugs when used for moderately or highly emetogenic chemotherapy. Approval may be granted if either of the bullet points below apply:
 - May be approved for use in patients receiving highly or moderately emetogenic chemotherapy in addition to dexamethasone and a 5-HT₃ antagonist. This includes patients on the following: AC combination (Doxorubicin or Epirubicin w/Cyclophosphamide), Aldesleukin, Amifostine, Arsenic trioxide, Azacitidine, Bendamustine, Busulfan, Carmustine, Carboplatin, Cisplatin, Clofarabine, Cyclophosphamide, Cyterabine, Dacarbazine, Dactinomycin, Danorubicin, Doxorubicin, Epirubicin, Etoposide, Hexamethylmelamine, Idarubicin, Ifosfamide, Imatinib, Interferon alfa, Ironetecan, Mechlorethamine, Melphalan, Methotrexate, Oxaliplatin, Procarbazine, Streptozocin, Temozolomide.
 - May be approved for other uses restricted to patients receiving other chemotherapy who have failed maximum doses of ondansetron combined with dexamethasone.
- Quantity limits: one Emend[®] BiPack (2-80 mg tablets) per chemotherapy treatment or one Emend[®] TriPack (1-125 mg tablet and 2-80 mg tablets) per chemotherapy treatment.

4. Other

Clinical edit for the following:

****Diclegis[®]** (doxylamine/pyridoxine) - Patient must be pregnant

*****Promethazine** – for patients under 2 years old, inform prescriber that promethazine is contraindicated in patients less than 2 years of age due to the risk of fatal respiratory depression.

******Transderm-Scop[®]** may be approved for 3 months if:

- Tried and failed at least one of the following: meclizine, promethazine, dimenhydrinate, diphenhydramine, or metoclopramide; OR
- is unable to swallow or absorb oral medications
- will be in an area/situation for an extended period of time where taking short acting agents would not be feasible

Dr. Ivey motioned that the Antiemetic/Antivertigo Agents Class be PDL eligible with the addition of the above criteria. With the motion seconded, the Committee voted unanimously to consider this class and the criteria as PDL eligible.

5. **Bile Acid Salts**(*Gastrointestinal*)

Dr. Ivey cited the drugs in this class: chenodiol (Chenodal™), ursodiol (URSO 250®), ursodiol (URSO Forte®), and ursodiol USP (Actigall®). Dr. Ivey noted that chenodiol contraindications include biliary tract disease including bile ductal abnormalities such as primary biliary cirrhosis, intrahepatic cholestasis, or sclerosing cholangitis, in patients whose gallbladder is confirmed as non-visualizing after two consecutive single doses of dye, and in patients with calcified radiopaque stones. Patients with gallbladder disease or gallstone complications necessitating surgery due to unremitting acute cholecystitis, cholangitis, biliary obstruction, gallstone pancreatitis, or biliary-GI fistula are not candidates for chenodiol therapy. All ursodiol products in this category are Pregnancy Category B. Chenodiol is Pregnancy Category X.

Dr. Ivey presented the following potential new criteria:

Length of Authorization: 1 year with routine PDL edit

Dr. Ivey motioned that the Bile Acid Salts Agents Class be PDL eligible with the addition of the above criteria. With the motion seconded, the Committee voted unanimously to consider this class and the criteria as PDL eligible.

6. **H. Pylori Treatment** (*Gastrointestinal*)

Speaker

- Devrim Eren, PhD, Medical Science Liaison, Aptalis Pharma (Pylera®)

Dr. Ivey cited the drugs in this class: bismuth subsalicylate, metronidazole, tetracycline (Helidac®), omeprazole, amoxicillin, clarithromycin (Omeclamox-Pak™), lansoprazole, amoxicillin, clarithromycin (Prevpac®), and bismuth subcitrate potassium, metronidazole, tetracycline (Pylera®). Omeclamox-Pak™ and Prevpac® are both Pregnancy Category C, and Helidac® and Pylera® are Pregnancy Category D.

Dr. Ivey presented the following potential new criteria:

Length of Authorization: 14 days with routine PDL edit

Dr. Ivey motioned that the H. Pylori Treatment Class be PDL eligible with the addition of the above criteria. With the motion seconded, the Committee voted unanimously to consider this class and the criteria as PDL eligible.

7. **Hereditary Angioedema (HAE)** (*Blood Modifiers potential new PDL Class*)

Ms. Abernathy cited the drugs in this class: C1-INH (Cinryze®) indicated for prophylaxis of HAE in adolescents and adults; C1-INH (Berinert®) indicated for the treatment of acute HAE facial, laryngeal, or abdominal attacks in adolescents and adults; ecallantide (Kalbitor®) indicated for the treatment of acute HAE attacks in ages ≥ 16 years; and icatibant (Firazyr®) indicated for the treatment of acute HAE attacks in ages ≥ 18 years.

Ms. Abernathy presented the following potential new criteria:

Length of Authorization: DOS

- Must be prescribed and under direct care by a board-certified allergist, immunologist or hematologist
- For Prophylaxis must have
 - HAE attacks occur at least once monthly
 - Disabled at least 5 days per month
 - History of attacks with airway compromise / hospitalization
 - History of prior prophylaxis with Danazol

FDA indicated Diagnosis

Beriner[®]: Acute abdominal, facial or laryngeal HAE attacks

Cinryze[™]: Prevention of HAE attacks.

Kalbitor[®]: Acute HAE attacks in patients 16 years of age and older.

Firazyr[®]: Acute attacks of (HAE) in adults 18 years of age and older

Ms. Abernathy motioned that the Hereditary Angioedema Class be PDL eligible with the addition of the above criteria. With the motion seconded, the Committee voted unanimously to consider this class and the criteria as PDL eligible.

8. Irritable Bowel Syndrome (*Gastrointestinal*)

Speaker

- Kara Sperandeo, PharmD, Medical Science Liaison, Forest Research (Linzess[®])

Dr. Ivey cited that there are three drugs in this class: alosetron (Lotronex[®]), linaclotide (Linzess[®]), and lubiprostone (Amitiza[®]). Alosetron is indicated for the treatment of severe, diarrhea-predominant irritable bowel syndrome (IBS-D) in women who have failed conventional therapy. Linaclotide is indicated for the treatment of chronic idiopathic constipation (CIC) and for the treatment of irritable bowel syndrome with constipation (IBS-C). Lubiprostone is indicated for the treatment of chronic idiopathic constipation (CIC), for the treatment of irritable bowel syndrome with constipation (IBS-C) in females, and for the treatment of opioid-induced constipation in adults with chronic, non-cancer pain. Safety and effectiveness have not been established in pediatric patients for alosetron (Lotronex[®]), linaclotide (Linzess[®]) or lubiprostone (Amitiza[®]). Linaclotide is contraindicated in pediatric patients up to six years of age and should be avoided in patients six years through 17 years of age.

Dr. Ivey presented the following potential new criteria:

Length of Authorization: 6 Months with routine PDL edits plus

- Amitiza[®]
 - Must be 18 or older and
 - Have one of the 3 diagnosis
 1. Idiopathic Constipation

Treatment failure of at least ONE agent from TWO of the following classes:

 - a. Osmotic Laxatives (examples: lactulose, polyethylene glycol (PEG), sorbitol)
 - b. Bulk Forming Laxatives (examples: Metamucil[®] (psyllium), Citrucel[®], Fiber)
 - c. Stimulant Laxatives (examples: bisacodyl, senna)

2. *Diagnoses of Constipation Predominant Irritable Bowel Syndrome (IBS-C)*
Patient is female AND Treatment failure on at least ONE agent from TWO of the following classes:
 - a. Osmotic Laxatives
 - b. Bulk Forming Laxatives
 - c. Stimulant Laxatives
 3. *Diagnosis of Opioid Induced Constipation in chronic NON-cancer pain*
Paid claims history confirms use of opioids for at least 150 out the last 180 days; AND patient has tried both PEG (i.e., Miralax[®]) AND lactulose without adequate results – trials must be confirmed in paid claim history.
- Linzess[®]
 - *Diagnosis of Idiopathic Chronic Constipation or Constipation-Predominant Irritable Bowel Syndrome (IBS)*
 - Patient must be at least 6 years of age; AND
 - Treatment failure on at least ONE agent from TWO of the following classes:
 - Osmotic Laxatives
 - Bulk Forming Laxatives
 - Stimulant Laxatives
 - Lotronex[®]
 - Diagnosis of severe, diarrhea predominant Irritable Bowel Syndrome
 - Patient is female and at least 18 years of age; AND
 - Prescriber is enrolled in the Promethus Prescribing Program for Lotronex[®], AND
 - Patient has had chronic IBS symptoms for at least 6 months; AND
 - Patient has tried and failed bulk producing agents (e.g., Psyllium, fiber), unless two of the following: antispasmodic agents (e.g., dicyclomine, hyoscyamine), antidiarrheal agents/opiates (e.g., loperamide, diphenoxylate/atropine, codeine)

Dr. Ivey motioned that the Irritable Bowel Syndrome Class be PDL eligible with the addition of the above criteria. With the motion seconded, the Committee voted unanimously to consider this class and the criteria as PDL eligible.

9. **Ophthalmic Antibiotic/Steroid Combinations (*Ophthalmic*)**

Dr. Madiraju cited the drugs in this class: dexamethasone/neomycin sulfate/polymyxin B sulfate (Maxitrol[®]), dexamethasone/tobramycin (Tobradex[®]), dexamethasone/tobramycin (Tobradex[®] ST), hydrocortisone/neomycin sulfate/polymyxin B sulfate, hydrocortisone/bacitracin zinc/neomycin sulfate/polymyxin B sulfates, loteprednol/tobramycin (Zylet[™]), prednisolone acetate/gentamicin sulfate (Pred-G[®]), prednisolone acetate/gentamicin sulfate (Pred-G[®] S.O.P), and prednisolone acetate/sulfacetamide sodium (Blephamide[®], Blephamide[®] S.O.P.). Dr. Madiraju noted these combination agents are contraindicated in most viral diseases of the cornea and conjunctiva, in mycobacterial infection of the eye and fungal diseases of ocular structures. Prolonged use of corticosteroids may result in glaucoma, as well as increase the hazard of secondary ocular infections. Dr. Madiraju stated that ophthalmic antibiotic/steroid combinations should not be used as first line agents in children.. Dr. Madiraju requested information with respect to the number of physicians that are prescribing ophthalmic antibiotics versus ophthalmic antibiotic/steroid combinations and the duration of use. He also would like to know how many times these agents have been refilled and the

FDA approved age limits for these drugs. This information will be presented to the Committee at the next P&T meeting.

Dr. Madiraju presented the following potential new criteria: Length of Authorization: Date of Service with routine PDL edits.

Dr. Madiraju motioned that the Ophthalmic Antibiotic/Steroid Combinations Class be PDL eligible with the addition of the above criteria. With the motion seconded, the Committee voted unanimously to consider this class and the criteria as PDL eligible.

PDL Phase II – New Drug Review (Therapeutic Class)

- 1. tretinoin microsphere (*Acne Agents, Topical*):** Gill Abernathy noted this is a “first time” generic for Retin-A[®] Micro. Ms. Abernathy motioned that tretinoin microsphere be PDL eligible. With the motion seconded, the Committee voted unanimously to consider this product as PDL eligible.
- 2. zolmitriptan tablet and zolmitriptan ODT (*Antimigraine Agents*):** Ms. Abernathy noted this is a “first time” generic for Zomig[®] and Zomig[®] ODT. Ms. Abernathy motioned that zolmitriptan tablet and zolmitriptan ODT be PDL eligible. With the motion seconded, the Committee voted unanimously to consider these products as PDL eligible.
- 3. acyclovir ointment (*Antivirals, Topical*):** Dr. Exum noted this is a “first time” generic for Zovirax[®] ointment. Dr. Exum motioned that acyclovir ointment be PDL eligible. With the motion seconded, the Committee voted unanimously to consider the new generic product as PDL eligible.
- 4. alendronate solution (*Bone Resorption Suppression and Related Agents - Bisphosphonates*):** Dr. Ivey noted this is a “first time” generic for Fosamax[®] Solution. Dr. Ivey motioned that alendronate solution be PDL eligible. With the motion seconded, the Committee voted unanimously to consider the new generic product as PDL eligible.
- 5. Suprax[™] Capsule (*Cephalosporins*):** Ms. Abernathy noted the new capsule dosage form for Suprax[™] 400 mg (cefixime). Ms. Abernathy motioned that Suprax[™] 400 mg capsule be PDL eligible. With the motion seconded, the Committee voted unanimously to consider this product as PDL eligible.
- 6. Oseni[™] (*Hypoglycemics – Dipeptidyl Peptidase IV (DPP-IV) Inhibitors*):** Dr. Ivey noted this is a combination product with alogliptin/pioglitazone. Oseni[™] is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both alogliptin and pioglitazone is appropriate. Dr. Ivey motioned that Oseni[™] be PDL eligible. With the motion seconded, the Committee voted unanimously to consider this product as PDL eligible.

Nesina[™] (*Hypoglycemics – Dipeptidyl Peptidase IV (DPP-IV) Inhibitors*): Dr. Ivey noted Nesina[™] (alogliptin) is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Dr. Ivey motioned that Nesina[™] be PDL eligible. With the motion seconded, the Committee voted unanimously to consider this product as PDL eligible.

Kazano[™] (*Hypoglycemics – Dipeptidyl Peptidase IV (DPP-IV) Inhibitors*): Dr. Ivey noted Kazano[™] is a combination of alogliptin and metformin and is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both

alogliptin and metformin is appropriate. Dr. Ivey motioned that Kazano™ be PDL eligible. With the motion seconded, the Committee voted unanimously to consider this product as PDL eligible.

7. Invokana™ (*Hypoglycemics – Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitors*):

Speaker

- James Wigand, MD , Endocrinologist (Invokana™)
- Phillip Wiegand, PharmD, Health Economic & Outcomes Liaison, Janssen (Invokana™)

Dr. Ivey noted that Invokana™ (canaglifozin) is a sodium-glucose cotransporter 2 inhibitor (SGLT2) indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. The safety and effectiveness in pediatric patients have not been established. Dr. Ivey motioned that Invokana™ be PDL eligible. With the motion seconded, the Committee voted unanimously to consider this product as PDL eligible.

8. pioglitazone-glimepiride (*Hypoglycemics – Thiazolidinedione – TZD*): Dr. Ivey noted pioglitazone-glimepiride is the first time generic for Duetact®. Dr. Ivey motioned that pioglitazone-glimepiride be PDL eligible. With the motion seconded, the Committee voted unanimously to consider this product as PDL eligible.

9. Rebif™ Rebidose (*Multiple Sclerosis Agents*)

Tecfidera™ (*Multiple Sclerosis Agents*)

Speaker

- Faith McKeone, PharmD, Sr. Medical Science Liaison, Biogen Idec (Tecfidera®)

Dr. Exum cited Rebif™ Rebidose 22 mcg, 44 mcg, and titration pack autoinjector is a new dosage form. Rebif™ Rebidose is indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS) to slow the accumulation of physical disability and decrease the frequency of clinical exacerbations. Dr. Exum noted that the safety and efficacy have not been established in children for Tecfidera™. Dr. Exum motioned that Rebif™ Rebidose and Tecfidera™ be PDL eligible. With the motion seconded, the Committee voted unanimously to consider these products as PDL eligible.

10. Zubsolv® (*Opiate Dependence Treatments*)

Dr. Exum cited Zubsolv® (buprenorphine/naloxone 1.4/0.36 mg and 5.7/1.4 mg sublingual tablet) is a new product in the class. It is indicated for the maintenance treatment of opioid dependence. The recommended target dose is buprenorphine 11.4 mg/naloxone 2.8 mg once daily. The safety and effectiveness of buprenorphine/naloxone have not been established in children.

buprenorphine-naloxone (*Opiate Dependence Treatments*): Dr. Exum noted buprenorphine-naloxone 8mg-2mg and 2mg-0.5mg sublingual tablet is a new generic for Suboxone® sublingual tablet. The brand Suboxone® sublingual tablets are no longer on the market.

Dr. Exum presented the following potential additions to clinical criteria for Zubsolv®, Suboxone® SL/Film, and buprenorphine SL tablets:

- Quantity Limit for both strengths of Zubsolv® is 68 per 34 days.

- Same Suboxone[®] Clinical Criteria will apply to Zubsolv[®]. The following need to be true:
 - Diagnosis of opiate abuse/dependence.
 - Prescribed by a qualified physician with Substance Abuse and Mental Health Services Administration Waiver
 - Patient is receiving addiction counseling
 - A chemical dependency assessment has been performed AND
 - Criteria for chemical dependency is met
 - Patient is 16 years of age or older (no exceptions allowed); AND
 - Patient is not pregnant (Suboxone[®] SL/Film, buprenorphine/ naloxone, and Zubsolv[®]).
 - Maximum duration is 24 months
 - Maximum dose is 16mg/day
- Duration of SA is 3 months for a total of 24 months.

Add to Criteria:

- The prescriber has an active “X” DEA number; AND
- The prescription is written under the “X” DEA number such that this patient counts toward the patient limits established for individual prescribers by the DATA 2000 waiver; AND
- The prescriber has reviewed the Virginia Controlled Substance Database on the date of the request. Document the number of concomitant narcotic prescriptions and the date and name of the last controlled substance filled. (Out of state prescribers can register to check the database if they are dual licensed in VA. Do NOT approve if the prescriber has not or cannot check the database. Forward the request to a pharmacist.)
- Mandatory for the prescriber to fax the actual top portion of the PMP form with the individuals name and date of inquiry to Magellan Health demonstrating that they did look at the individual’s information on the PMP site.

Dr. Exum motioned that Zubsolv[®] and buprenorphine-naloxone sublingual tablet be PDL eligible with the addition of the above criteria. With the motion seconded, the Committee voted unanimously to consider these products as PDL eligible.

- 11. Zenedi[™] (Stimulants/ADHD Medications):** Dr. Madiraju cited the new product Zenedi[™] tablet, generic name dextroamphetamine sulfate. It is indicated for the treatment of Attention Deficit Disorder with Hyperactivity and for the treatment of narcolepsy. Dr. Madiraju noted the Black Box Warning in which amphetamines have a high potential for abuse. Zenedi[™] is not recommended for pediatric patients under 3 years of age for attention deficit disorder.

dextroamphetamine 5 mg/5 ml solution (Stimulants/ADHD Medications): Dr. Madiraju cited the new generic dextroamphetamine solution, the generic for Procentra[®].

Dr. Madiraju motioned that Zenedi[™] and dextroamphetamine solution be PDL eligible. With the motion seconded, the Committee voted unanimously to consider these products as PDL eligible.

PDL Phase I – Annual Review

1. Antivirals – Hepatitis C

Speaker

- Michelle Mattox, PharmD, Managed Care Liaison, Vertex (Incivek®)

Dr. Jennings cited that this class has a very strong pipeline of drugs to be coming out in the near future. Dr. Exum motioned that the Antivirals-Hepatitis C class continues to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

- 2. Angiotensin Modulators – ACE Inhibitors and Renin Inhibitors:** Ms. Abernathy noted that there were no significant changes in this class since the last review and motioned that the ACE Inhibitors and Renin Inhibitors class continues to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.
- 3. Angiotensin Modulators – Angiotensin II Receptor Blockers:** Ms. Abernathy stated that there is a new generic product in this class, candesartan (Atacand®). Ms. Abernathy also noted that the Food and Drug Administration (FDA) has issued a new safety warning that the angiotensin II receptor blocker (ARB), olmesartan medoxomil, can cause intestinal problems known as sprue-like enteropathy. Ms. Abernathy motioned that Angiotensin II Receptor Blockers class including the new generic, candesartan, be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.
- 4. Angiotensin Modulators – Angiotensin Modulators Combinations:** Ms. Abernathy noted that there were no significant changes in this class since the last review and motioned that the Angiotensin Modulators Combinations class continues to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.
- 5. Beta Blockers:** Ms. Abernathy noted that there were no significant changes in this class since the last review and motioned that the Beta Blockers class continues to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.
- 6. Calcium Channel Blockers:** Ms. Abernathy noted that there were no significant changes in this class since the last review and motioned that the Calcium Channel Blockers class continues to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.
- 7. Lipotropics – HMG CoA Reductase Inhibitors – Statins (includes combinations with niacin, CAI agent, CCBs):** Ms. Abernathy cited the new product in the class, Liptruzet® (ezetimibe and atorvastatin). Ms. Abernathy motioned that HMG CoA Reductase Inhibitors – Statins class including the new product Liptruzet® be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.
- 8. Lipotropics – Other (includes Bile Acid Sequestrants, CAI agent, Fibric Acid Derivatives, Niacin, Omega 3 Fatty Acid, and Apolipoprotein B Synthesis Inhibitors):**

Dr. Madiraju shared that he is seeing children as young as five years are age with elevated triglycerides and LDL. Dr. Madiraju noted that some of the lipotropics are FDA approved for use in

children age ten and older.. Dr. Madiraju requested lipotropic drug utilization in pediatric patients for review at the next P&T Committee meeting.

Ms. Abernathy cited the new product in the class, Vascepa[®] (icosapent ethyl). Vascepa[®] is an Omega 3 Fatty Acid agent used as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Safety and efficacy have not been established in children. Ms. Abernathy also noted that there is a new generic product in this class, fenofibrate capsule (Antara[®]). Another new generic product is fenofibric acid capsule (Trilipix[®]). Ms. Abernathy noted the new product Juxtapid[®](lomitapide). Juxtapid[®] is used as an adjunct to a low-fat diet and other lipid-lowering treatments, including low-density lipoprotein (LDL) apheresis where available, to reduce LDL cholesterol, total cholesterol, apolipoprotein B (apo B), and non-high-density lipoprotein cholesterol (non-HDL-C) in patients with homozygous familial hypercholesterolemia. There is a Black Box Warning for the risk of hepatotoxicity. Prescribers must undergo training and be certified in the Juxtapid[®] REMS program. Only pharmacies certified in the Juxtapid[®] REMS Program will dispense lomitapide. Ms. Abernathy noted the new product Kynamro[®] (mipomersen sodium). Kynamro[®] is used as an adjunct to lipid-lowering medications and diet to reduce low-density lipoprotein cholesterol (LDL-C), apolipoprotein B (apo B), total cholesterol (TC), and non-high-density lipoprotein cholesterol (non-HDL-C) in patients with homozygous familial hypercholesterolemia. There is a Black Box Warning for the risk of hepatotoxicity. Prescribers must undergo training and be certified in the Kynamro[®] REMS program. Only pharmacies certified in the Kynamro[®] REMS Program will dispense mipomersen sodium. Ms. Abernathy motioned that the Lipotropics – Other class including the new products Vascepa[®], Juxtapid[®], and Kynamro[®] as well as the new generics fenofibrate capsule and fenofibric acid capsule, be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

9. Pulmonary Arterial Hypertension Agents (PDE-5 Inhibitors; Endothelin-1 Agents, and Prostacyclin Analogues):

Speaker

- Melanie Jardim, PharmD, Medical Science Liaison, United Therapeutics (Adcirca[®])

Ms. Abernathy noted that the Letairis[®] REMS Program has been modified to include only female patients because of the reproductive concerns. Ms. Abernathy cited that ambrisentan is contraindicated in patients who have idiopathic pulmonary fibrosis, including idiopathic pulmonary fibrosis patients with pulmonary hypertension due to a lack of efficacy and an increase risk of disease progression. Ms. Abernathy motioned that this class continues to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

10. Sedative Hypnotics and Other Hypnotics: Dr. Madiraju shared new data that shows blood levels of zolpidem in some patients may be high enough the morning after use to impair activities that require alertness, including driving. FDA is requiring the manufacturers of Ambien[®], Ambien[®] CR, Edluar[®], and Zolpimist[®] to lower the recommended dose for women, from 10 mg to 5 mg for immediate-release products and from 12.5 mg to 6.25 mg for extended-release products. Dr. Madiraju motioned that this class continues to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

11. Atopic Dermatitis - Topical: Ms. Abernathy noted that there were no significant changes in this class since the last review and motioned that Atopic Dermatitis - Topical class continues to be PDL

eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

12. Growth Hormones:

Speaker

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

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

13. Progestins for Cachexia: Ms. Abernathy noted that there were no significant changes in this class since the last review and motioned that Progestins for Cachexia class continues to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

14. Histamine-2 Receptor Antagonists: Dr. Ivey noted that there were no significant changes in this class since the last review and motioned that Histamine-2 Receptor Antagonists class continues to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

15. Proton Pump Inhibitors: Dr. Ivey noted that there were no significant changes in this class since the last review and motioned that Proton Pump Inhibitors class continues to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

16. Ulcerative Colitis (oral and rectal):

Speaker

- Michale Steidle, PharmD, Medical Science Liaison, Salix Pharmaceuticals (Apriso®)
- Leslie Vollenweider, PharmD, Medical Science Liaison, Shire (Lialda®)

Dr. Ivey cited the new product Delzicol® 400 mg Delayed-Release Capsules (mesalamine). Delzicol® is an aminosalicylate indicated for the treatment of mildly to moderately active ulcerative colitis and for the maintenance of remission of ulcerative colitis. Dr. Ivey noted it is Pregnancy Category B. In addition, the safety and effectiveness of Delzicol® in pediatric patients have not been established. Dr. Ivey motioned that Ulcerative Colitis class, including Delzicol®, continue to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

17. Bladder Relaxants: Dr. Exum noted that there were no significant changes in this class since the last review and motioned that Bladder Relaxants class continues to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

18. BPH Agents (includes Alpha Blockers, Androgen Hormone Inhibitors, and Phosphodiesterase (PDE) 5 Inhibitors for BPH Treatment: Dr. Exum noted that there were no significant changes in this class since the last review and motioned that BPH Agents class continues to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

19. **Phosphate Binders:** Dr. Exum noted that there were no significant changes in this class since the last review and motioned that Phosphate Binders class continues to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.
20. **Ophthalmic Glaucoma Agents (includes Alpha-2 Adrenergic, Beta-Blockers, Carbonic Anhydrase Inhibitors, and Prostaglandin Inhibitors):** Dr. Exum cited a new product in the class, Rescula[®] (unoprostone isopropyl). Rescula[®] is for the lowering of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. Safety and effectiveness have not been established in children. Dr. Exum also noted another new product in the class, Simbrinza[®], (brinzolamide/brimonidine tartrate). Simbrinza[®] is indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. Dr. Exum also stated that there is a new generic product in this class, travoprost (Travatan[®]). Dr. Exum motioned that the Ophthalmic Glaucoma Agents class including new products Rescula[®] and Simbrinza[®] as well as the new generic travoprost, be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.
21. **Ophthalmic Anti-Inflammatory Agents:** Ms. Abernathy cited a new product in the class, Prolensa[®] (bromfenac). In addition, she stated that ophthalmic corticosteroids are being added to this class including: fluorometholone, prednisolone acetate, Durezol[®], dexamethasone, prednisolone sod phosphate, FML[®], Pred Forte[®], Omnipred[®], Maxidex[®], Flarex[®], Pred Mild[®], FML Forte[®], Lotemax[®] Drops/Gel/Ointment, FML S.O.P.[®], and Vexol[®]. Ms. Abernathy motioned that the Ophthalmic Anti-Inflammatory Agents class including the new product Prolensa[®], be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.
22. **Ophthalmic Antibiotics (includes Quinolones & Macrolides):** Dr. Madiraju noted that there were no significant changes in this class since the last review and motioned that the Ophthalmic Antibiotics class continues to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.
23. **Ophthalmics for Allergic Conjunctivitis (includes Ophthalmic Antihistamines & Mast Cell Stabilizers):** Dr. Exum noted that there were no significant changes in this class since the last review and motioned that the Ophthalmics for Allergic Conjunctivitis class continues to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.
24. **Antihistamines – Minimally Sedating:** Dr. Madiraju noted the new generic products in this class: desloratadine ODT (Clarinx RediTabs[®]). Dr. Madiraju motioned that the Antihistamines – Minimally Sedating class including the new product discussed, continues to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.
25. **Long-Acting Beta2 Adrenergic Agents (includes nebulized and combinations):** Dr. Madiraju noted that there were no significant changes in this class since the last review and motioned that the Long-Acting Beta2 Adrenergic Agents class continues to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.
26. **Short-Acting Beta2 Adrenergic Agents (includes nebulized and combinations):** Dr. Madiraju noted that there were no significant changes in this class since the last review and motioned that the Short-Acting Beta2 Adrenergic Agents class continues to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

27. COPD (includes Anticholinergics, Bronchodilators, and Phosphodiesterase 4 Inhibitors):

Speaker

- Laurie Schmitt, PharmD, Medical Science Liaison, Forest Research (Daliresp[®])
- Kara Sperandio, PharmD, Medical Science Liaison, Forest Research (Tudorza[®])

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

28. Cough and Cold (includes 1st Generation Antihistamines, Antihistamines & Expectorant combination, Expectorants, Narcotic Antitussive & Decongestant combinations, Narcotic Antitussive & Expectorant combinations, Non-narcotic Antitussive & Decongestant combinations, Non-narcotic Antitussive, 1st Generation Antihistamine & Decongestant combinations): Dr. Madiraju noted that there were no significant changes in this class since the last review and motioned that Cough and Cold class continues to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

29. Glucocorticosteroids, Inhaled:

Speaker

- Christine Oh, PharmD, Medical Science Liaison, Teva (QNASL[®])

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

30. Intranasal Rhinitis (includes Antihistamines and Corticosteroids): Dr. Madiraju cited the FDA's Nonprescription Drugs Advisory Committee recently voted to switch triamcinolone acetonide (Nasacort[®] AQ) from prescription to over-the-counter (OTC). Dr. Madiraju motioned that the Intranasal Rhinitis class continues to be PDL eligible. With the motion seconded, the Committee voted unanimously to maintain this class as PDL eligible.

31. Leukotriene Formation Inhibitors and Modifiers: Dr. Madiraju noted that there were no significant changes in this class since the last review and motioned that Leukotriene Formation Inhibitors and Modifiers class continues 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 45 reasons listed in that statute. The discussion of manufacturer and wholesaler prices is not one of the 45 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 to 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.

Changes to the Brands Preferred Over Generics: Dr. Jennings noted effective **November 1, 2013**, the following brands will become non-preferred and its generic will become preferred.

- Maxalt MLT[®] is non-preferred and rizatriptan ODT is preferred
- Diovan HCT[®] is non-preferred and valsartan HCTZ is preferred
- Retin-A[®] Micro Pump is non-preferred and tretinoin microspheres is preferred
- Retin-A[®] Micro is non-preferred and tretinoin microspheres is preferred

Dr. Jennings motioned the above generics to be preferred and their brand to be non-preferred effective November 1, 2013. The motion was seconded and unanimously approved by the Committee.

<p><i>PDL Changes Effective January 1, 2014</i></p>

New Drugs Phase II: Dr. Jennings motioned that all products presented remain non-preferred with the exception of Zubsolv[™], which will be preferred. The motion was seconded and unanimously approved by the Committee.

New Therapeutic Classes Added

Dr. Madiraju made the following motions that were seconded and approved unanimously by the Committee (note the motions are for additions to the current PDL):

1. **Alzheimer's Agents:** donepezil tablet, Exelon[®] Transderm, Namenda[®] Solution and Tablet are preferred. Aricept[®], donepezil ODT, Namenda[®] Tablet Dose Pack, Aricept[®] ODT, galantamine tablet/solution, Exelon[®] capsules/solution, rivastigmine capsules, Namenda[®] XR, galantamine ER, Aricept[®] 23 mg, donepezil 23 mg are non-preferred.
2. **Antibiotics, Inhaled:** Tobi[®] and Tobi[®] Podhaler are preferred. Cayston[®] is non-preferred.

3. **Antibiotics, Vaginal:** Metrogel[®], Vandazole[®], and Cleocin[®] Ovules are preferred. Metronidazole, Clindesse[®], clindamycin, and Cleocin[®] Cream are non-preferred.
4. **Antiemetic/Antivertigo Agents:** Promethazine tablet/syrup/rectal, ondansetron tablet/ODT, prochlorperazine, meclizine, and Marinol[®] are preferred. Transderm-Scop[®], trimethobenzamide, Granisol[®] Solution, prochlorperazine rectal, ondansetron solution, Compro[®] Rectal, Zofran[®] Solution/ Tablets/ODT, granisetron, Emend[®], Emend[®] Pack, promethazine 50 mg rectal, Diclegis[®], dronabinol, Sancuso[®] Transdermal, Anzemet[®], and Cesamet[®] are non-preferred.
5. **Bile Salts:** Ursodiol 300 mg capsule is preferred. Actigall[®], ursodiol tablet, Urso[®]/Urso Forte[®] tablet, and Chenodal[®] are non-preferred.
6. **H. Pylori Treatment:** Helidac[®], Pylera[®], and Prevpac[®] are preferred. Omeclamox-Pak[®] and lansoprazole/amoxicillin/clarithromycin are non-preferred.
7. **HAE Treatments:** Kalbitor[®] (Sub-Q), Cinryze[®] (IV), and Berinert[®] (IV) are preferred. Firazyr[®] (Sub-Q) is non-preferred.
8. **Irritable Bowel Syndrome:** Amitiza[®] is preferred. Linzess[®] and Lotronex[®] are non-preferred.
9. **Ophthalmic Antibiotic-Steroid Combinations:** Tobradex[®] Suspension, neomycin/polymyxin/dexamethasone, and Tobradex[®] Ointment are preferred. Blephamide[®], Maxitrol[®] Drops Suspension/Ointment, Blephamide[®] S.O.P., Pred-G[®] Drops Suspension/Ointment, sulfacetamide/ prednisolone, Zylet[®], neomycin/bacitracin/poly/Hc, Tobradex[®] ST, tobramycin/dexamethasone suspension, and neomycin/polymyxin/Hc are 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):

ACE Inhibitors + Calcium Channel Blocker Combinations: Lotrel[®] is non-preferred.

1. **Antihistamines: Intranasal:** Astepro[®] is preferred.
2. **Antivirals: Hepatitis C – Pegylated Interferon:** Pegasys[®] Syringe/Kit/Vial/Proclick are non-preferred.
3. **Bladder Relaxants:** Vesicare[®] is preferred. Flavoxate is non-preferred.
4. **Cough and Cold:** Centergy[®] is non-preferred.
5. **Nasal Steroids:** Nasacort AQ[®] is non-preferred.
6. **Ophthalmic for Allergic Conjunctivitis – Antihistamines:** Optivar[®] is non-preferred.
7. **Ophthalmic Glaucoma Agents – Beta Blockers:** Combigan[®] and betaxolol drops are non-preferred.
8. **Ophthalmic Glaucoma Agents – Carbonic Anhydrase Inhibitors:** Simbrinza[®] is preferred.

9. **Ophthalmics, Anti-Inflammatories (Added Ophthalmic Corticosteroids to this class):** Ophthalmic NSAIDS are no change. Ophthalmic Corticosteroids: fluorometholone, prednisolone acetate, Durezol[®] are preferred. Dexamethasone, prednisolone sod phosphate, FML[®], Pred Forte[®], Omnipred[®], Maxidex[®], Flarex[®], Pred Mild[®], FML Forte[®], Lotemax[®] Drops/Gel/Ointment, FML S.O.P.[®], and Vexol[®] are non-preferred.

10. **PAH Agents, Oral and Inhaled – PDE5 Inhibitor:** Adcirca[®] is non-preferred.

11. **Proton Pump Inhibitors:** lansoprazole suspension – preferred for children under 12 years old. Prevacid[®] Soltab – non-preferred for children under 12 years old (SA required for all ages).

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

- ACE Inhibitors and ACE Inhibitors + Diuretic Combinations
- Alpha-Blockers for BPH
- Androgen Hormone Inhibitors for BPH
- Angiotensin Receptor Blockers + Calcium Channel Blocker Combinations
- Angiotensin Receptor Blockers
- Angiotensin Receptor Blockers + Diuretic Combinations
- Antivirals: Hepatitis C – Protease Inhibitors
- Atopic Dermatitis – Topical
- Beta Adrenergic Agents Long Acting
- Beta Adrenergic Agents Short Acting
- Beta Adrenergic Agents Short Acting Nebulizers
- Beta Blockers
- Beta Blockers + Diuretic Combinations
- Calcium Channel Blockers (Dihydropyridine & Non-Dihydropyridine)
- COPD: Bronchodilators and Phosphodiesterase 4 (PDE4) Inhibitors
- Cough and Cold, Narcotic
- Cough and Cold, Non-Narcotic
- Direct Renin Inhibitors (Includes Combinations)
- Growth Hormones
- H2 Receptor Antagonists
- Inhaled Glucocorticoids (includes Metered Dose Inhalers, Nebulizer Solution and Combination Products)
- Leukotriene Modifiers
- Lipotropics – Bile Acid Sequestrates
- Lipotropics – Cholesterol Absorption Inhibitor (CAI)
- Lipotropics – Fibric Acid Derivatives
- Lipotropics – HMG CoA Reductase Inhibitors (Statins)
- Lipotropics – HMG CoA Reductase Inhibitors and Combinations (High Potency Statins)
- Lipotropics – Microsomal Triglyceride Transfer Protein Inhibitor
- Lipotropics – Niacin Derivatives
- Lipotropics – Niacin Derivatives & HMG CoA Reductase Inhibitors (Statins) Combinations
- Lipotropics – Oligonucleotide Inhibitor
- Lipotropics – Omega 3 Fatty Acid Agents

- Ophthalmic Antibiotics
- Ophthalmic for Allergic Conjunctivitis – Mast Cell Stabilizers
- Ophthalmic for Allergic Conjunctivitis – Other
- Ophthalmic Glaucoma Agents – Alpha 2 Adrenergic Agents
- Ophthalmic Glaucoma Agents – Prostaglandin Analogs
- Ophthalmic NSAIDs
- PAH Agents, Oral and Inhaled – Endothelin-1 Agents
- PAH Agents, Oral and Inhaled – Prostacyclin Analogues
- Phosphate Binders
- Phosphodiesterase (PDE) Type 5 Inhibitor for BPH
- Progestins Used for Cachexia
- Second Generation Antihistamines and Combinations
- Sedative Hypnotics (Benzodiazepines)
- Sedative Hypnotics (Non-Benzodiazepines)
- Ulcerative Colitis – Oral
- Ulcerative Colitis – Rectal

The next P&T Committee Meeting is tentatively scheduled for April 24, 2014.

Dr. Jennings adjourned the meeting.