MINUTES OF THE May 12, 2009
PHARMACY AND THERAPEUTICS (P & T) COMMITTEE MEETING

MEMBERS ATTENDING: Joyce Brewer, Ph.D., CNM, C.P.N.P.; John Cook, M.D.; Ryan Harper, Pharm.D.; Jeff Jones, R.Ph.; Garry McFerrin, R.Ph.; Deborah Minor, Pharm.D.; Michael O'Dell, M.D.; William Sorey, M.D.; Carolyn M. Tingle, M.D.; Pearl Wales, Pharm.D.,

Also present: Judith Clark, R.Ph., Pharmacy Director, DOM; Paige Clayton, Pharm.D., DOM; Terry Kirby, R.Ph.; Steve Liles, Pharm.D., Provider Synergies; Alyssa Hoover, Pharm.D., Provider Synergies.

MEMBERS ABSENT: Larry Calvert, R.Ph.; Manisha Sethi, M.D.

CALL TO ORDER: Chairman Dr. O'Dell called the meeting to order at 11:06 am.

INTRODUCTIONS: Ms. Clark gave introductions and briefly discussed turning off cell phones and pagers; the committee would convene for 30 to 45 minutes for lunch; and per the Fire Marshal's regulations, the maximum capacity of the room is 90 people and should not be exceeded.

Ms. Clark then welcomed committee members and guests in the audience. She thanked Committee members for their dedication in volunteering their time. She then introduced and thanked the members of DOM for their dedication, compassion, and willingness to help and improve the State's Medicaid program. She recognized the HID vendors and ACS members for their contributing work to the program. She also thanked the members from ACS and the fiscal agents for their contributions to helping the department and program.

EXECUTIVE DIRECTOR'S COMMENTS: Ms. Williams, the Deputy Administrator of DOM, was not present at the time to present comments.

ADMINISTRATIVE MATTERS: Ms. Clark reminded the speakers to sign in if they were planning to speak on behalf of a drug. She then mentioned that a copy of the agenda and public guidelines were available at the back table in the room. Ms. Clark reminded the Committee and audience to keep the room clean, and that no food or drink was permitted in the room. She requested the audience to silence or turn off all cell phones, pagers, and PDAs during the meeting. She also requested that guests leave the room only during breaks to minimize noise and distractions, and if necessary to leave during the meeting, to exit quietly. She indicated that any disruption during the meeting will result in removal from the premise. Ms. Clark again reviewed the safety exits for the meeting room and for the building in more detail. She explained that the meeting room is limited to a maximum capacity of ninety persons and that at no time would more than ninety be allowed to remain in the room due to state fire regulations.

Ms. Clark reminded the Committee members to fill out their travel vouchers. She discussed the process of solicitation for supplemental rebates, and that the next PDL will be implemented July 1, 2009. She indicated that copies of the minutes will be posted no later than June 12, 2009 and that the current copy of the minutes has been posted yesterday. Ms. Clark noted that voting is done by hand and/or voice vote, and that the minutes would reflect each member's vote.

Ms. Clark reviewed how the state decides on which classes and drugs to review. She indicated that drugs or classes with low utilization, all or mostly generic, or had no significant financial or clinical benefit were not reviewed. She then presented an overview of the committee meeting's procedure. She explained that the committee members comprised of various doctors, pharmacists, and nurses. She indicated that the committee members and DOM's PDL decisions were based on sound information comprising of the safety, efficacy, and overall cost value of a drug. She indicated that public comment has a three minute limit per drug.

Ms. Clark informed the committee and audience that the votes made by the committee today will be reviewed by the executive director, who will make the final decisions. She noted that the decisions from this meeting and from last month's meeting would be posted on the website no later than 30 days before implementation.

APPROVAL OF APRIL 14, 2009 MEETING MINUTES: Dr. O'Dell asked if there were additions, changes, or deletions to the minutes of the last meeting, and asked for a motion to approve the minutes of the April 14, 2009 meeting. Mr. Jones made a motion to accept and it was seconded by Mr. McFerrin. The motion passed unanimously 10-0.

THERAPEUTIC CLASS REVIEWS: Ms. Clark introduced Dr. Liles from Provider Synergies as presenting the PDL recommendations. Dr. Liles then introduced Dr. Hoover from Provider Synergies as presenting the clinical discussion for each of the drug classes. He indicated that only the newest information; specifically, information not mentioned in the most recent Therapeutic Class Reviews (TCRs) would be covered during the clinical presentation.

BONE RESORPTION SUPPRESSION AND RELATED AGENTS
Dr. Hoover indicated that there was no new significant data to report.

Dr. Liles presented the PDL recommendations for the Bone Suppression and Related Agents with the PDL changes occurring with Actonel with Calcium, Boniva, and Fortical.

Brand Name	Current PDL Status	PDL Recommendation
ACTONEL (ORAL)	PDL	PDL
ACTONEL W/CALCIUM (ORAL)	NPD	PDL
ALENDRONATE TABLETS (ORAL)	PDL	PDL
BONIVA (ORAL)	PDL	NPD
CALCITONIN SALMON (NASAL)	PDL	PDL
EVISTA (ORAL)	PDL	PDL
FORTEO (SUBCUTANE.)	NPD	NPD
FORTICAL (NASAL)	NPD	PDL
FOSAMAX PLUS D (ORAL)	PDL	PDL
FOSAMAX SOLUTION (ORAL)	PDL	PDL
MIACALCIN (NASAL)	PDL	PDL

Bill White on behalf of Roche spoke about Boniva.

Dr. Minor asked why generic calcitonin, which was more expensive than brand Miacalcin was listed as preferred. Ms. Clark answered that the legislature has not changed the current policy of limiting beneficiaries to two brand name drugs instead of two non-preferred drugs, and so the more expensive generic product is now preferred.

Dr. Minor made a motion to accept Provider Synergies' recommendations as presented. The motion was seconded by Mr. Jones. The motion passed unanimously, 10-0.

GROWTH HORMONE

Dr. Hoover indicated that there wasn't any new data to present on the Growth Hormone Class.

Dr. Liles presented the following PDL recommendations with no changes:

Brand Name	Current PDL Status	PDL Recommendation
GENOTROPIN (INJECTION)	PDL	PDL
HUMATROPE (INJECTION)	NPD	NPD
NORDITROPIN (INJECTION)	NPD	NPD
NUTROPIN (INJECTION)	PDL	PDL
NUTROPIN AQ (INJECTION)	PDL	PDL
OMNITROPE (INJECTION)	NPD	NPD
SAIZEN (INJECTION)	PDL	PDL
SEROSTIM (INJECTION)	NPD	NPD
TEV-TROPIN (INJECTION)	NPD	NPD
ZORBTIVE (INJECTION)	NPD	NPD

Julie Hubbard on behalf of EMD Serano yielded her time to speak about Saizen.

Cheryl Pryor on behalf of Novo Nordisk spoke about Norditropin and its use in the pediatric population. She also spoke about the Nordicare program available for patients.

George Moll on behalf of Genetech spoke about Nutropin, and then spoke about Genotropin on behalf of Pfizer. He spoke about the convenience of using both of these agents for patients. He also indicated that patients using Genotropin have fewer reactions to the agent due to the lack of bacteriostatic agent in the product.

Rudi Pesipanodyna on behalf of Teva spoke about Tev-tropin and its indications and easy to use delivery system.

Dr. Minor asked why Tev-tropin was not preferred. Dr. Liles indicated that due to some positioning offers the drug was non-preferred in order to maximize rebates and to minimize disruption, which would occur if a different agent was non-preferred to maintain the positioning offer. He also indicated that the drug has low utilization in other states as well. Ms. Clark indicated that children under 21 have unlimited drug edits on the brands and generics in this class.

Dr. Minor made a motion to accept the recommendations as presented. Dr. Sorey seconded the motion. The motion passed unanimously, 10-0.

HYPOGLYCEMICS, MEGLITINIDES

Dr. Hoover presented information about a new product in this class, Prandimet. She reported that it's a combination of repaglinide and metformin, and discussed its indications, dosing, and administration. She then reported that the 2009 American Diabetes Association's (ADA) consensus algorithm for the medical management of hyperglycemia in diabetes mellitus type 2 (DM II) doesn't list meglitinides in its three-step treatment algorithm.

Dr. Liles presented the PDL recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
PRANDIMET (ORAL)	NR	NPD
PRANDIN (ORAL)	PDL	PDL
STARLIX (ORAL)	PDL	PDL

No speakers addressed the Committee.

Dr. Wales made a motion to approve the recommendations as presented by Provider Synergies. The motion was seconded by Dr. Brewer. The motion was approved by a vote of 10-0.

HYPOGLYCEMICS, TZD

Dr. Hoover discussed the updated 2009 guidelines from the ADA consensus algorithm for the medical management of hyperglycemia in DM II. She noted that the ADA recommended the addition of pioglitazone (Actos) as a tier two intervention in select patients who have not responded to step one interventions and hypoglycemia poses a risk that should be avoided. The ADA guidelines did not recommend the use of rosiglitazone (Avandia) in the treatment algorithm.

Dr. Liles presented the PDL recommendations and indicated there were no changes:

Brand Name	Current PDL Status	PDL Recommendation
ACTOPLUS MET (ORAL)	PDL	PDL
ACTOS (ORAL)	PDL	PDL
AVANDAMET (ORAL)	PDL	PDL
AVANDARYL (ORAL)	PDL	PDL
AVANDIA (ORAL)	PDL	PDL
DUETACT (ORAL)	PDL	PDL

Steve Simmons on behalf of GSK yielded his time to speak about Avandia to the Committee.

Mr. Jones made the motion to approve the recommendations as presented by Provider Synergies, and Dr. Cook seconded the motion. The motion was unanimously passed by a vote of 10-0.

HYPOGLYCEMICS, INCRETIN MIMETICS
Dr. Hoover indicated that there was no new pertinent information available since the TCRs had been updated.

Dr. Liles presented the PDL recommendations and indicated there were no changes:

Brand Name	Current PDL Status	PDL Recommendation
BYETTA PENS (SUBCUTANE.)	PDL	PDL
JANUMET (ORAL)	PDL	PDL
JANUVIA (ORAL)	PDL	PDL
SYMLIN (SUBCUTANE.)	NPD	NPD
SYMLIN PENS (SUBCUTANE.)	NPD	NPD

Cindy Weakley on behalf of Amylin yielded her time to speak about Byetta.

Jack Putman, M.D. on behalf of Merck yielded his time to speak about Januvia and Junumet.

Mr. McFerrin made a motion to accept the recommendations as presented. The motion was seconded by Dr. Cook. The motion passed 10-0.

HYPOGLYCEMICS, INSULIN AND RELATED AGENTS
Prior to discussing insulin and related agents, Dr. O'Dell voluntarily stepped out of the room due to conflict of interest for this drug class. Dr. John Cook served as Chair momentarily for the discussion and voting of this class.

Dr. Hoover indicated that there was no new pertinent information available since the TCRs had been updated.

Dr. Liles presented the PDL recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
APIDRA (SUBCUTANE.)	NPD	NPD
APIDRA PENS (SUBCUTANE.)	NPD	NPD
HUMALOG (SUBCUTANE.)	NPD	NPD
HUMALOG MIX (SUBCUTANE.)	NPD	NPD
HUMALOG MIX PENS (SUBCUTANE.)	NPD	NPD
HUMALOG PENS (SUBCUTANE.)	NPD	NPD
HUMULIN (SUBCUTANE.)	NPD	NPD
HUMULIN PENS (SUBCUTANE.)	NPD	NPD

LANTUS (SUBCUTANE.)	PDL	PDL
LANTUS PENS (SUBCUTANE.)	PDL	PDL
LEVEMIR (SUBCUTANE.)	NPD	PDL
LEVEMIR PENS (SUBCUTANE.)	NPD	NPD
NOVOLIN (SUBCUTANE.)	PDL	PDL
NOVOLIN PENS (SUBCUTANE.)	PDL	PDL
NOVOLOG (SUBCUTANE.)	PDL	PDL
NOVOLOG MIX 70/30 (SUBCUTANE.)	PDL	PDL
NOVOLOG MIX 70/30 PENS (SUBCUTANE.)	PDL	PDL
NOVOLOG PENS (SUBCUTANE.)	PDL	PDL

At this time, Dr O'Dell voluntarily stepped out due to a conflict in interest for this class. He asked Dr. Cook to step in as Chair momentarily to preside over the discussion and voting of this class.

Corey Gambill on behalf of Novo Nordisk spoke about the Novo Nordisk products.

Dr. Minor made a motion to accept the recommendations with the addition of Levemir pens. Mr. Jones seconded the motion. The motion passed 9-0.

Dr. O'Dell returned as Committee Chairperson and presided over the meeting again.

PROTON PUMP INHIBITORS

Dr. Hoover discussed the new product Kapidex and its indication. She also mentioned the two multicenter, double-blinded, 8 week, phase 3 studies, which demonstrated that dexlansoprazole (Kapidex) was non-inferior to lansoprazole for healing of mild to moderate disease. She then noted that the safety and efficacy of dexlansoprazole (Kapidex) has not been established in pediatrics, and currently there isn't any comparative data to support the use of dexlansoprazole (Kapidex) over another PPI. Dr. Hoover also discussed the recent May 2009 retrospective Medco outcomes study that investigated the association in risk of increased major adverse cardiovascular events in patients taking the combination of clopidogrel and PPI's.

Dr. Liles made the following recommendations to the Committee with Zegerid being changed to non-preferred:

Brand Name	**Current PDL Status**	**PDL Recommendation**
ACIPHEX (ORAL)	NPD	NPD
KAPIDEX (ORAL)	NR	PDL
NEXIUM (ORAL)	NPD	NPD
NEXIUM SUSPENSION (ORAL)	NPD	NPD
OMEPRAZOLE (ORAL)	PDL	PDL

PANTOPRAZOLE (ORAL)	NPD	NPD
PREVACID (ORAL)	PDL	PDL
PREVACID SOLUTAB (ORAL)	PDL	PDL
PREVACID SUSPENSION (ORAL)	PDL	PDL
PRILOSEC SUSPENSION (ORAL)	NR	NPD
PROTONIX SUSPENSION (ORAL)	NPD	NPD
ZEGERID (ORAL)	PDL	NPD

No speakers addressed the Committee.

Mr. Jones made a motion to accept the recommendations as presented. Dr. Harper seconded the motion. The motion passed 10-0.

H. PYLORI AGENTS

Dr. Hoover indicated that this is a new class of drugs the state is reviewing. She then discussed the 2007 American College of Gastroenterology guidelines, which recommended 10 to 14 days of triple drug regimen containing a PPI, clarithromycin, and either amoxicillin or metronidazole. She also mentioned that the resistance to clarithromycin has led to a significant decrease in eradication rates by 70 to 85 percent.

Dr. Hoover then presented the differences among the ingredients in the three products: Helidac, Prevpac, and Pylera. She discussed each drug's indications and how each drug is dosed in contrast to the other agents in the class. She discussed the clinical findings of a trial comparing quadruple therapy of Pylera with omeprazole to triple therapy with clarithromycin, amoxicillin, and omeprazole. She presented the results of the study as being no significant differences in outcomes.

Dr. Liles made the following recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
HELIDAC (ORAL)	NR	PDL
PREVPAC (ORAL)	NR	PDL
PYLERA (ORAL)	NR	NPD

Stephen George on behalf of Axcan spoke about Pylera.

Dr. Wales made a motion to accept the PDL as presented. The motion was seconded by Dr. Sorey. The motion passed 10-0.

ULCERATIVE COLITIS AGENTS

Dr. Hoover presented the new products of Apriso and SFRowasa to the committee. She discussed Apriso's indication, unique delivery system, drug interactions, and its dosing regimen. She indicated that SFRowasa was the sulfite free formulation of Rowasa.

Dr. Liles then presented the following recommendations to the Committee with Apriso and SFRowasa recommended as non-preferred:

Brand Name	Current PDL Status	PDL Recommendation
APRISO (ORAL)	NR	NPD
ASACOL (ORAL)	PDL	PDL
BALSALAZIDE (ORAL)	PDL	PDL
CANASA (RECTAL)	PDL	PDL
DIPENTUM (ORAL)	PDL	PDL
LIALDA (ORAL)	PDL	PDL
MESALAMINE (RECTAL)	PDL	PDL
PENTASA (ORAL)	PDL	PDL
SFROWASA (RECTAL)	NR	NPD
SULFASALAZINE (ORAL)	PDL	PDL

Mat Kumer on behalf of Shire yielded his time to speak about Lialda, and Stephen George on behalf of Axcan yielded his time to speak about Canasa.

Dr. Brewer made a motion to approve the PDL as recommended. The motion was seconded by Dr. Cook. Motion passed 10-0.

BLADDER RELAXANT PREPARATIONS

Dr. Hoover stated that the state had requested that this drug class be revisited due to a misunderstanding among some of the Committee membership and DOM staff members regarding the motions and/or voting. She discussed the new products Toviaz and Sanctura XR. She mentioned the indications for Toviaz and the drug having the same active metabolite as Detrol and Detrol LA. She then discussed the difference between Sanctura and Sanctura XR.

Dr. Liles presented the PDL recommendations for this class and indicated that oxybutynin ER, Toviaz, Detrol, and Vesicare were all recommended as non-preferred:

Brand Name	Current PDL Status	PDL Recommendation
DETROL (ORAL)	NPD	NPD
DETROL LA (ORAL)	PDL	PDL
ENABLEX (ORAL)	PDL	PDL
OXYBUTYNIN (ORAL)	PDL	PDL
OXYBUTYNIN ER (ORAL)	PDL	NPD
OXYTROL (TRANSDERM.)	PDL	PDL
SANCTURA (ORAL)	PDL	PDL

SANCTURA XR (ORAL)	PDL	PDL
TOVIAZ (ORAL)	NR	NPD
VESICARE (ORAL)	PDL	NPD

Recommendation: Ms Clark reiterated that DOM strives to have a procedure which is transparent and fair to all parties. She continued by stating that at the end of the previous meeting, it came to DOM's attention that there was confusion regarding the motion and voting in this therapeutic category. At that time, DOM instructed our PDL contractor, Provider Synergies, to restart the entire process. New bid solicitations were released on April 14, 2009, or the date of the April meeting and industry was notified that this class would be re-visited at the May 2009 meeting. Ms Clark thanked Provider Synergies for their prompt response to DOM's request to revisit this drug class.

Ben Sosna on behalf of Astellas spoke about Vesicare.

Cindy Noble on behalf of Allergan yielded her time to speak about Sanctura.

Lee Ann Griffin on behalf of Pfizer spoke about Toviaz, but yielded her time to speak about Detrol LA.

Julia Compton on behalf of Novartis yielded her time to speak about Enablex.

Dr. Wales made a motion to accept the recommendations with the addition of Toviaz, and the motion was seconded by Mr. Jones. The motion passed 10-0.

ANTIHISTAMINES, MINIMALLY SEDATING

Dr. Hoover indicated that there was no new pertinent information available since the TCRs had been updated.

Dr. Liles presented the PDL recommendations to the Committee and indicated that fexofenadine had been removed from the PDL due to cost:

Brand Name	**Current PDL Status**	**PDL Recommendation**
ALLEGRA ODT (ORAL)	NPD	NPD
ALLEGRA SYRUP (ORAL)	NPD	NPD
ALLEGRA-D (ORAL)	NPD	NPD
CETIRIZINE / CETIRIZINE-D (ORAL)	PDL	PDL
CETIRIZINE SYRUP (ORAL)	PDL	PDL
CETIRIZINE SYRUP RX (ORAL)	PDL	PDL
CLARINEX / CLARINEX-D (ORAL)	NPD	NPD
CLARINEX SYRUP (ORAL)	NPD	NPD
CLARITIN CHEW OTC (ORAL)	NPD	NPD
FEXOFENADINE (ORAL)	PDL	NPD
LORATADINE / LORATADINE-D (ORAL)	PDL	PDL

LORATADINE SYRUP (ORAL)	PDL	PDL
SEMPREX-D (ORAL)	PDL	PDL
XYZAL (ORAL)	PDL	PDL
XYZAL SYRUP (ORAL)	PDL	PDL
ZYRTEC / ZYRTEC-D (ORAL)	NPD	NPD
ZYRTEC SYRUP (ORAL)	NPD	NPD

James Tislow on behalf of Schering Plough spoke about Clarinex.

Dr. Sorey asked the speaker for Clarinex if there was any evidence that Clarinex is more efficacious than loratadine. The speaker for Clarinex indicated that there was not.

Todd Adkins on behalf of UCB spoke about Xyzal and the inconvenience the beneficiaries experience when they have to fill the OTC product and can't acquire credit from Medicaid.

Dr. Cook asked if this happens, and Ms. Clark indicated that Medicaid does pay for Xyzal.

Dr. Sorey spoke about the lack of differences between various agents other than cost, with the exception of old versus new agents.

Dr. Minor made a motion to approve the recommendations. The motion was seconded by Dr. Sorey. The motion was approved unanimously, 10-0.

ANTIHISTAMINES/DECONGESTANTS

Dr. Hoover indicated that this is a new class the state is reviewing. She then went over the ACCP 2006 evidence based clinical practice guidelines that recommended using the combination of first generation antihistamines and decongestants to treat acute cough associated with the common cold. She discussed the recent various warnings concerning the use of OTC cough and cold products used in patients less than two years of age that were issued by the CDC, FDA Pediatric Advisory Committee, the FDA Public Health Advisory. She then discussed the outcomes of a 2005 Cochrane review concerning some benefit in the use of first dose nasal decongestants and antihistamine combinations.

Dr. Liles presented the following recommendations:

Brand Name	**Current PDL Status**	**PDL Recommendation**
ALA-HIST (ORAL)	NR	NPD
ALA-HIST D (ORAL)	NR	PDL
ALAHIST LQ (ORAL)	NR	PDL
ALDEX AN (ORAL)	NR	NPD
ALLERX 10 (ORAL)	NR	NPD
ALLERX 30 (ORAL)	NR	NPD
ANTIHISTAMINE / DECONGESTANT BWG (ORAL)	NR	NPD

ANTIHISTAMINE / DECONGESTANT GENERIC (ORAL)	NR	PDL
ANTIHISTAMINE BWG (ORAL)	NR	PDL
ANTIHISTAMINE GENERIC (ORAL)	NR	PDL
BEN-TANN (ORAL)	NR	PDL
BROMHIST (ORAL)	NR	PDL
COLDAMINE (ORAL)	NR	PDL
CPM 12 (ORAL)	NR	PDL
C-TAN D (ORAL)	NR	PDL
DALLERGY (ORAL)	NR	PDL
DECONGESTANT GENERIC (ORAL)	NR	PDL
DECONSAL CT (ORAL)	NR	NPD
DICEL (ORAL)	NR	PDL
DIPHENMAX (ORAL)	NR	NPD
D-TANN (ORAL)	NR	PDL
DUOTAN PD (ORAL)	NR	PDL
DURATUSS DA (ORAL)	NR	NPD
EXPECTORANT GENERIC (ORAL)	NR	PDL
HISTEX SR (ORAL)	NR	NPD
J-TAN (ORAL)	NR	NPD
J-TAN D (ORAL)	NR	NPD
LODRANE 24 (ORAL)	NR	PDL
LODRANE 24D (ORAL)	NR	PDL
LODRANE D (ORAL)	NR	PDL
NALDEX (ORAL)	NR	PDL
PEDIATEX TD (ORAL)	NR	NPD
POLY TAN (ORAL)	NR	PDL
POLY TAN D (ORAL)	NR	NPD
PSE BPM (ORAL)	NR	PDL
P-TEX (ORAL)	NR	PDL
PYRLEX (ORAL)	NR	PDL
PYRLEX PD (ORAL)	NR	PDL
RYNATAN PEDIATRIC (ORAL)	NR	NPD
SUDAL-12 (ORAL)	NR	NPD
TANACOF XR (ORAL)	NR	PDL
TUSNEL PEDIATRIC (ORAL)	NR	PDL
VAZOBID (ORAL)	NR	NPD
VAZOTAB (ORAL)	NR	NPD
VIRAVAN-P (ORAL)	NR	NPD
VISRX (ORAL)	NR	NPD

No speakers addressed the Committee.

Ms. Clark commented about age limits being placed for this class.

Dr. Sorey commented that the lack of data proving efficacy and costliness of many of the agents in this class in unwarranted.

Mr. Jones made a motion to approve the recommendations as presented with the removal of the following products: Alahist D, Bromhist, Alahist LQ, Ben-Tann, Lodrane 24, Pyrlex PD, Dicel, D-Tann, Lodrane 24D, Poly Tan, Pyrlex, Duotan PD. The motion was seconded by Dr. Wales, and passed unanimously, 10-0.

INTRANASAL RHINITIS AGENTS

Dr. Hoover mentioned that even though Astepro was introduced in November 2008 to the market, this is the first time the state is reviewing the drug. She mentioned the indications for this drug and the improvement in tolerance this formulation of azelastine has over the other formulation.

Dr. Liles presented the following recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
ASTELIN (NASAL)	PDL	PDL
ASTEPRO (NASAL)	NPD	PDL
BECONASE AQ (NASAL)	NPD	NPD
FLONASE (NASAL)	NPD	PDL
FLUNISOLIDE (NASAL)	PDL	PDL
FLUTICASONE (NASAL)	PDL	PDL
IPRATROPIUM (NASAL)	PDL	PDL
NASACORT AQ (NASAL)	NPD	NPD
NASAREL (NASAL)	PDL	PDL
NASONEX (NASAL)	PDL	PDL
OMNARIS (NASAL)	NPD	NPD
PATANASE (NASAL)	PDL	PDL
RHINOCORT AQUA (NASAL)	NPD	NPD
VERAMYST (NASAL)	PDL	PDL

Winn Walcott on behalf of Meda yielded time to speak about Astelin and Astepro.

James Tislow on behalf of Schering Plough yielded his time to speak about Nasonex.

Todd Adkins on behalf of GSK yielded time to speak about Veramyst.

Dr. Harper made a motion to accept the recommendations as presented, and was seconded by Mr. Jones. The motion passed unanimously 10-0.

LEUKOTRIENE MODIFIERS
Dr. Hoover indicated that there was no new pertinent information for this class of drugs since the TCR was last updated.

Dr. Liles presented the PDL recommendations with no changes as follows:

Brand Name	Current PDL Status	PDL Recommendation
ACCOLATE (ORAL)	PDL	PDL
SINGULAIR (ORAL)	PDL	PDL
ZYFLO CR (ORAL)	NPD	NPD

Jack Putman, M.D. on behalf of Merck yielded his time to speak about Singulair.

Dr. Minor made a motion to accept Provider Synergies' recommendations. The motion was seconded by Dr. Cook. The motion passed 10-0.

PAH AGENTS
Dr. Hoover introduced this class as a new class the state is reviewing. She mentioned the WHO functional class groupings and the 2007 ACCO guidelines that recommended the use of calcium channel blocker therapy only for patients with acute vasoreactivity. She discussed the indications, warnings, dosing, and pregnancy categories of the three different oral endothelin receptor antagonists: Letairis, Tracleer, and Revatio. She also noted a double-blinded, randomized, 16 week trial of 26 patients with WHO Functional class 3 PAH comparing the efficacy of Revatio to Tracleer. She reported that there wasn't any difference in the outcomes between the two treatment arms in the study.

Dr. Liles presented the following recommendations:

Brand Name	Current PDL Status	PDL Recommendation
LETAIRIS (ORAL)	NR	PDL
REVATIO (ORAL)	NR	PDL
TRACLEER (ORAL)	NR	NPD

Dr. Minor mentioned that the drugs in this class are all indicated for different functional class groupings and is very individualized for treatment.

Dr. Liles noted that three cost sheet models were provided to the Committee to show cost differences.

Allison Widlitz and John Spurzen, M.D. on behalf of Actelion spoke about Tracleer.

Aaron Huwe on behalf of Gilead yielded his time to speak about Letairis.

Mr. Jones made a motion to approve the recommendations with the addition of Tracleer to the PDL. The motion was seconded by Dr. Sorey and passed unanimously by the Committee, 10-0.

BRONCHODILATORS, BETA AGONIST
Dr. Hoover indicated that Albuterol CFC MDIs are no longer available as of December 31, 2008 and that the albuterol HFAs available are Proventil, Proair, and Ventolin.

Dr. Liles presented the PDL Recommendations:

Brand Name	Current PDL Status	PDL Recommendation
ALBUTEROL (ORAL)	PDL	PDL
ALBUTEROL NEBULIZER (INHALATION)	PDL	PDL
ALBUTEROL NEBULIZER LOW-DOSE (INHALATION)	PDL	PDL
BROVANA (INHALATION)	NPD	NPD
FORADIL (INHALATION)	NPD	NPD
MAXAIR (INHALATION)	PDL	NPD
METAPROTERENOL (ORAL)	PDL	PDL
PERFOROMIST (INHALATION)	NPD	NPD
PROAIR HFA INHALER (INHALATION)	PDL	PDL
PROVENTIL HFA (INHALATION)	PDL	NPD
SEREVENT (INHALATION)	NPD	NPD
TERBUTALINE (ORAL)	PDL	PDL
VENTOLIN HFA (INHALATION)	PDL	PDL
XOPENEX (INHALATION)	NPD	NPD
XOPENEX HFA (INHALATION)	NPD	NPD

Mr. Jones commented that he had less complaints from patients on Proventil versus patients on ProAir.

James Tislow on behalf of Schering Plough spoke about Proventil HFA and Foradil.

Ming Walker on behalf of GSK yielded time to speak about Ventolin.

Dr. Minor made a motion to add Proventil HFA and Foradil to the PDL, and remove Proair from the PDL. This motion was seconded by Mr. Jones. The motion passed 10-0.

BRONCHODILATORS, ANTICHOLINERGIC
Dr. Hoover indicated that there was no new pertinent information available since the TCRs had been updated.

Dr. Liles presented the PDL recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
ATROVENT HFA (INHALATION)	PDL	PDL
COMBIVENT (INHALATION)	PDL	PDL

IPRATROPIUM / ALBUTEROL (INHALATION)	PDL	NPD
IPRATROPIUM NEBULIZER (INHALATION)	PDL	PDL
SPIRIVA (INHALATION)	PDL	PDL

Mr. Jones commented that keeping Combivent preferred and generic non-preferred could take up another place due to the brand limit policy implemented by the state.

Ms. Clark indicated that there isn't a state MAC program in place, so the state pays much more for the generic than the branded product.
No speakers addressed the Committee.

Dr. Harper made a motion to approve the recommendations as presented. After being seconded by Dr. Wales, the Committee approved the motion, 10-0.

The Committee convened for lunch and re-convened 30 minutes later.

GLUCOCORTICOIDS, INHALED
Dr. Hoover indicated that Azmacort and Aerobid/Aerobid M are the only two inhalers with CFC MDI formulation available until December 31, 2009. After this date, the products are being discontinued or reformulated.

Dr. Liles presented the following recommendations to the Committee:

Brand Name	**Current PDL Status**	**PDL Recommendation**
ADVAIR / ADVAIR HFA (INHALATION)	PDL	PDL
AEROBID / AEROBID-M (INHALATION)	PDL	PDL
ALVESCO (INHALATION)	NPD	NPD
ASMANEX (INHALATION)	PDL	PDL
AZMACORT (INHALATION)	PDL	PDL
FLOVENT / FLOVENT HFA (INHALATION)	PDL	PDL
PULMICORT FLEXHALER (INHALATION)	NPD	NPD
PULMICORT RESPULES (INHALATION)	PDL	PDL
QVAR (INHALATION)	PDL	PDL
SYMBICORT (INHALATION)	PDL	PDL

Benjamin Everett on behalf of Astra Zeneca spoke about Pulmicort Respules and Flexhaler, but yielded his time to speak about Symbicort.

Todd Adkins on behalf of GSK yielded his time to speak about Flovent and Advair.

James Tislow on behalf of Schering Plough yielded his time to speak about Asmanex.

Dr. Harper made a motion to accept the recommendations as presented. The motion was seconded by Mr. Jones. The motion passed 10-0.

NEW DRUGS FOR REVIEW

STIMULANTS AND RELATED AGENTS
Dr. Hoover discussed the indications for Procentra, and indicated that the drug is a liquid formulation of dextroamphetamine sulfate. .

Dr. Liles presented the following recommendation:

Brand Name	Current PDL Status	PDL Recommendation
PROCENTRA (ORAL)	NR	NPD

Dr. Tingle commented that this is the only agent used in patients three years and older in ADHD and recommended an edit for use in patients age three to six.

Dr. Sorey recommended an edit due to the danger of overdose a liquid has for young patients, and recommends that a PA is also available for these patients.

No speakers addressed the Committee.

Dr. Tingle made a motion to accept the recommendation for Procentra as presented and to leave the decision of its use to the specialists. The motion was seconded by Mr. Jones. The motion passed by a vote of 10-0.

ANTICONVULSANTS
Dr. Hoover discussed the indications of Vimpat and a study that compared the different dosages of this drug to placebo in patients with simple or complex partial onset seizures.

Dr. Liles presented the following PDL recommendation:

Brand Name	Current PDL Status	PDL Recommendation
VIMPAT (ORAL)	NR	NPD

Arleen Cerbone on behalf of UCB spoke about a 30 to 40 percent intolerance or failure for patients taking other drugs indicated for the same use as Vimpat. She also indicated that the company is in the process of compiling safety in the pediatric population for the future.

Dr. Wales asked if this is a scheduled drug. The speaker indicated that the FDA is looking to arrange it as Schedule V.

Dr. Wales made a motion to accept the PDL as presented. The motion was seconded by Mr. McFerrin. The motion passed by a vote of 10-0.

ACNE AGENTS, TOPICAL
Dr. Hoover introduced Aczone and Epiduo. She then discussed the indications, clinical trials, precautions, drug interactions, and common side effects. She noted that the 2007

AAD guidelines recommend topical retinoids, topical antibiotics, benzoyl peroxide, and combination of these products for the standard treatment for acne vulgaris.

Dr. Liles presented the following PDL recommendations:

Brand Name	Current PDL Status	PDL Recommendation
ACZONE (TOPICAL)	NR	NPD
EPIDUO (TOPICAL)	NR	NPD

No speakers addressed the Committee.

Dr. Minor made a motion to accept the PDL as presented for Aczone. Dr. Cook seconded the motion. The motion passed unanimously by a vote of 10-0.

Dr. Minor made a motion to accept the PDL as presented for Epiduo. The motion was seconded by Dr. Cook. The motion passed by a vote of 10-0.

OTHER BUSINESS
Ms. Clark announced that Dr. Sethi, Dr. Cook, Mr. McFerrin, and Mr. Jones are retiring from the Committee with the May 2009 meeting being their last meeting.

Dr. O'Dell thanked the Committee members.

Ms. Clark again thanked the Committee members and complimented them for their active participation during the meeting.

NEXT MEETING DATE
Ms. Clark stated that the next P&T Committee meeting is scheduled for October, 13 2009.

ADJOURNMENT
There being no further business, Dr. O'Dell adjourned the meeting.