MINUTES OF THE November 5, 2008
PHARMACY AND THERAPEUTICS (P & T) COMMITTEE MEETING

MEMBERS ATTENDING: Joyce Brewer, PhD, CNM, C.P.N.P.; Larry Calvert, R. Ph.; John Cook, M.D.; Ryan Harper, Pharm. D.; Garry McFerrin, R. Ph.; Deborah Minor, Pharm. D.; Michael O'Dell, M.D.; Manisha Sethi, 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., DOM; Steve Liles, Pharm. D., Provider Synergies; Alyssa Hoover, Pharm. D., Provider Synergies.

MEMBERS ABSENT: Jeff Jones, R. Ph.; William Sorey, M.D.

CALL TO ORDER: Chairman Dr. Michael O'Dell called the meeting to order at 10:15 am.

INTRODUCTIONS: Ms. Clark welcomed committee members and guests in the audience. She thanked Committee members for volunteering their time, introduced and thanked the members of DOM for their continuing efforts and dedication in improving the State's Medicaid program, and gave recognition to the HID vendors for their contributing work in the program. Ms. Clark noted that the P&T Committee is a advisory group of practicing physicians and pharmacists who volunteer their time and expertise. The Committee is charged with making PDL recommendations based on safety, efficacy and cost. Ms. Clark noted that the PDL classes being reviewed at the October and November meetings would be implemented on January 1, 2009.

EXECUTIVE DIRECTOR'S COMMENTS: Ms. Clark stated that Phyllis Williams, the Deputy Administrator of DOM, was not able to attend today's meeting.

ADMINISTRATIVE MATTERS: Ms. Clark presented an overview of the proceedings of today's meeting. She stated that Provider Synergies would make a clinical presentation and present recommendations for each therapeutic class. She stated that her staff would present those recommendations to the Executive Director, who would make the final PDL decisions. She indicated that the PDL is revised and updated biannually, and the decisions are implemented as of January 1st and July 1st of each year. 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. Ms. Clark stated that, pursuant to the Open Meetings Act, the Committee is required to record the minutes of the meeting within thirty days after the meeting is recessed or adjourned.

Ms. Clark reminded the Committee and guests that the meeting room must be left clean and that no food or drinks are allowed. She asked that cell phones, pagers and PDAs be silenced or turned off during the meeting. She also requested that guests leave the room only during breaks to minimize noise and distractions. Ms. Clark reviewed the safety exits for the meeting room and for the building. 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 noted that voting is done by hand and/or voice vote. Ms. Clark called Committee members' attention to their packets that contain a copy of the state's PDL, a

PA form, a colorized version of the External Cost Sheets that had previously been sent by Provider Synergies and their travel vouchers. She instructed members to fill out travel vouchers and return them before leaving the meeting. She indicated that there would be a break in the meeting for lunch and one afternoon break.

Ms. Clark indicated that the classes Antivirals, Topical and Impetigo Agents, Topical would not be reviewed today.

APPROVAL OF OCTOBER 14, 2008 MEETING MINUTES: Dr. O'Dell asked if there were additions, changes or deletions to the minutes of the last meeting. Corrections and future procedures for correcting the meeting minutes were discussed. O'Dell asked for a motion to approve the minutes of the October 14, 2008 meeting with the corrections. Dr. Brewer made a motion to accept and the motion was seconded. The motion carried unanimously.

THERAPEUTIC CLASS REVIEWS: Dr. Liles gave a brief overview of Providers Synergies' methods for drug literature evaluation. Dr. Liles moderated the therapeutic class reviews.

ANTIPARASITICS, TOPICAL

Dr. Liles presented an overview of the topical antiparasitics, including the indications for the various drugs in the class. He noted the boxed warning on lindane regarding neurologic toxicities and stated that is a significant concern for this drug. He reviewed applicable clinical trials and a systematic review comparing permethrin, crotamiton and lindane. Dr. Liles discussed the current treatment guidelines for head lice, crab lice and scabies, the presented the following PDL recommendations:

Brand Name	Current PDL Status	PDL Recommendation
EURAX (TOPICAL)	PDL	PDL
LINDANE (TOPICAL)	NPD	NPD
OVIDE (TOPICAL)	PDL	PDL
PERMETHRIN (TOPICAL)	PDL	PDL

Ms. Clark requested that the speakers whose drugs are recommended for preferred status on the PDL yield their time to the committee. No objection was made by the speakers or the committee in regards to this request.

Norman Bell on behalf of Taro yielded his time to speak about Ovide since it was on the PDL.

Dr. Harper made a motion to accept Provider Synergies' recommendations as presented. The motion was seconded by Mr. McFerrin. Dr. O'Dell asked members to raise their hands if they approved of the motion. The motion passed unanimously, 9-0.

ANTIFUNGALS, TOPICAL

Dr. Liles noted that the indications for these drugs are listed in the TCR, acknowledging that ciclopirox nail lacquer and Vusion have unique indications within the class. He stated that the clinical trials show no significant differences among the agents and that a meta-analysis shows only that the allylamines are more effective than the azoles for

treatment of fungal infections of the skin and nails of the feet. Dr. Liles presented the following PDL recommendations:

Brand Name	Current PDL Status	PDL Recommendation
CICLOPIROX CR/SUSP/GEL (TOPICAL)	PDL	NPD
CICLOPIROX SOLUTION (TOPICAL)	PDL	NPD
CLOTRIMAZOLE (TOPICAL)	PDL	PDL
CLOTRIMAZOLE OTC (TOPICAL)	PDL	PDL
CLOTRIMAZOLE-BETAMETHASONE (TOPICAL)	PDL	PDL
CNL 8 (TOPICAL)	NR	NPD
ECONAZOLE (TOPICAL)	PDL	PDL
ERTACZO (TOPICAL)	NPD	NPD
EXTINA (TOPICAL)	NR	NPD
KETOCONAZOLE (TOPICAL)	PDL	PDL
KETOCONAZOLE SHAMPOO (TOPICAL)	PDL	PDL
LOPROX SHAMPOO (TOPICAL)	NPD	NPD
MENTAX (TOPICAL)	NPD	NPD
MICONAZOLE OTC (TOPICAL)	PDL	PDL
NAFTIN (TOPICAL)	PDL	PDL
NYSTATIN (TOPICAL)	PDL	PDL
NYSTATIN-TRIAMCINOLONE (TOPICAL)	PDL	PDL
OXISTAT (TOPICAL)	NPD	NPD
TERBINAFINE OTC (TOPICAL)	NR	PDL
TOLNAFTATE OTC (TOPICAL)	PDL	PDL
VUSION (TOPICAL)	PDL	NPD
XOLEGEL (TOPICAL)	NPD	NPD
XOLEGEL COREPAK (TOPICAL)	NPD	NPD
XOLEGEL DUO (TOPICAL)	NPD	NPD

Ron Lubritz, M.D. from Merz yielded his time to speak about Naftin.

Dr. Cook made a motion to accept the recommendations as presented. Dr. Wales seconded the motion. Dr. O'Dell asked members to raise their hands if they approved of the motion. The motion passed unanimously, 9-0.

ACNE AGENTS, TOPICAL

Dr. Liles stated that there are numerous single component and combination products in this class. He noted that the goal of treatment is to minimize scarring and he presented an overview of the various types of drugs in this class. Dr. Liles then presented the following recommendations:

Brand Name	Current PDL Status	PDL Recommendation
AKNE-MYCIN (TOPICAL)	NPD	NPD
ATRALIN (TOPICAL)	NR	NPD
AZELEX (TOPICAL)	NPD	PDL

BENZACLIN (TOPICAL)	PDL	PDL
BENZAMYCIN (TOPICAL)	NPD	NPD
BENZOYL PEROXIDE (TOPICAL)	PDL	PDL
BENZOYL PEROXIDE OTC (TOPICAL)	PDL	PDL
BREVOXYL (TOPICAL)	NPD	NPD
BREZE (TOPICAL)	NPD	NPD
CLINAC BPO (TOPICAL)	NPD	PDL
CLINDAGEL (TOPICAL)	NPD	NPD
CLINDAMYCIN PHOSPHATE (TOPICAL)	PDL	PDL
CLINDAREACH (TOPICAL)	NPD	NPD
DIFFERIN (TOPICAL)	NPD	NPD
DUAC (TOPICAL)	PDL	NPD
ERYTHROMYCIN (TOPICAL)	PDL	PDL
ERYTHROMYCIN-BENZOYL PEROXIDE (TOPICAL)	NPD	PDL
EVOCLIN (TOPICAL)	PDL	NPD
INOVA (TOPICAL)	NPD	NPD
LAVOCLEN (TOPICAL)	NPD	NPD
NEOBENZ MICRO (TOPICAL)	NPD	NPD
NUOX (TOPICAL)	PDL	PDL
RETIN-A MICRO (TOPICAL)	NPD	PDL
SULFACETAMIDE (TOPICAL)	PDL	PDL
TAZORAC (TOPICAL)	PDL	PDL
TRETINOIN (TOPICAL)	PDL	NPD
TRIAZ (TOPICAL)	NPD	NPD
ZACARE (TOPICAL)	NR	NPD
ZACLIR (TOPICAL)	PDL	PDL
ZIANA (TOPICAL)	NPD	NPD

Ms. Clark reminded Committee members that acne agents are approved for Medicaid reimbursement for beneficiaries 21 years of age or younger only.

One speaker, Ron Lubritz, M.D., representing Merz yielded his time to speak about Benzaclin.

A question was brought forward by Dr. Minor concerning the reason for including Azelex on the PDL. Ms. Clark clarified the question by indicating its place in therapy is recognized appropriately, utilization is appropriate, and the financial cost is low as a result.

Dr. Minor questioned whether Tazorac should be on the PDL due to its toxicity and teratogenic potential. Discussion concerning Tazorac and its toxicity was discussed. Dr. Cook asked Dr. Lubritz's professional opinion as a dermatologist about Tazorac's use in the treatment of acne. Per Dr. Lubritz, it has limited use and is useful after other treatment options have been exhausted. In particular, the irritative response to the drug has to be balanced with the clearing response, and it is best used in combination with

other products.

Dr. Minor made a motion to approve the recommendations with the removal of Tazorac from the PDL. The motion was seconded by Dr. Harper. Dr. O'Dell asked for a hand vote of those in favor and opposed. The motion was approved by a vote of 9-0.

STEROIDS, TOPICAL - LOW

Dr. Liles stated that everyone is familiar with the uses of the topical steroids. He stated that there is no evidence to suggest superiority of one agent over another of equivalent potency. He then presented the following recommendations:

Brand Name	Current PDL Status	PDL Recommendation
ALCLOMETASONE DIPROPIONATE (TOPICAL)	PDL	PDL
DESONATE (TOPICAL)	NPD	NPD
DESONIDE (TOPICAL)	PDL	PDL
DESOWEN (TOPICAL)	NPD	NPD
HYDROCORTISONE (TOPICAL)	PDL	PDL
VERDESO (TOPICAL)	NPD	NPD

Dr. L. Millikan of Skinmedica spoke on behalf of placing Desonate on the PDL due to its FDA approved indication for the treatment of mild to moderate atopic dermatitis in patients as young as three months of age. Specifically, it is the only agent studied and approved for atopic dermatitis in patients younger than 6 years of age. Dr. Sethi asked if the generic product desonide is interchangeable in this patient population, but per Dr. Millikan, the generic product had not been studied in this patient population, and the other ingredients in the generic product differ from the branded product.

Dr. Sethi made a motion to add Desonate to the PDL with an age limit of use to six years of age. The motion was seconded by Dr. Cook. The motion was approved by a vote of 10-0.

STEROIDS, TOPICAL - MEDIUM

Dr. Liles made the following recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
CLODERM (TOPICAL)	NPD	NPD
CORDRAN (TOPICAL)	NPD	PDL
CORDRAN TAPE (TOPICAL)	NPD	NPD
FLUTICASONE PROPIONATE (TOPICAL)	PDL	PDL
HYDROCORTISONE BUTYRATE (TOPICAL)	PDL	PDL
HYDROCORTISONE VALERATE (TOPICAL)	PDL	PDL
LOCOID LIPOCREAM (TOPICAL)	NPD	PDL
LUXIQ (TOPICAL)	NPD	PDL

MOMETASONE FUROATE (TOPICAL)	PDL	PDL
PREDNICARBATE (TOPICAL)	PDL	PDL

No speakers addressed the Committee.

Dr. Minor made a motion to accept the recommendations as presented. The motion was seconded by Dr. Harper. Dr. O'Dell asked for those in favor of the motion to signify by hand vote. The motion passed 10-0.

STEROIDS, TOPICAL - HIGH
Dr. Liles made the following recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
AMCINONIDE (TOPICAL)	PDL	NPD
BETAMETHASONE DIPROPIONATE (TOPICAL)	PDL	PDL
BETAMETHASONE VALERATE (TOPICAL)	PDL	PDL
CAPEX SHAMPOO (TOPICAL)	NPD	PDL
DERMA-SMOOTHE/FS (TOPICAL)	NPD	NPD
DESOXIMETASONE (TOPICAL)	PDL	NPD
DIFLORASONE DIACETATE (TOPICAL)	PDL	NPD
FLUOCINOLONE ACETONIDE (TOPICAL)	PDL	PDL
FLUOCINONIDE (TOPICAL)	PDL	PDL
FLUOCINONIDE EMOLLIENT (TOPICAL)	PDL	PDL
FLUOCINONIDE-E (TOPICAL)	PDL	PDL
HALOG (TOPICAL)	NPD	NPD
TRIAMCINOLONE ACETONIDE (TOPICAL)	PDL	PDL
VANOS (TOPICAL)	NPD	NPD

No speakers addressed the Committee.

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

STEROIDS, TOPICAL - VERY HIGH
Dr. Liles made the following recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
CLOBETASOL EMOLLIENT (TOPICAL)	PDL	PDL
CLOBETASOL PROPIONATE (TOPICAL)	PDL	PDL
CLOBEX (TOPICAL)	NPD	NPD
HALOBETASOL PROPIONATE (TOPICAL)	PDL	PDL
OLUX-E (TOPICAL)	NPD	NPD

OLUX-OLUX-E PACK (TOPICAL)	NPD	NPD
ULTRAVATE (TOPICAL)	NPD	PDL

No speakers addressed the Committee.

Dr. Minor made a motion to accept the PDL as present. The motion was seconded by Dr. Cook. Dr. O'Dell asked for a hand vote of those in favor; the motion passed 10-0.

ATOPIC DERMATITIS

Dr. Liles noted that these drugs are second line therapy for non-continuous therapy of atopic dermatitis in patients two years of age and older with Elidel being indicated for mild to moderate AD and Protopic for moderate to severe AD. He discussed the black box warning common to these drugs. Dr. Liles presented the results of a comparative clinical trial, noting that this was a study of patients with moderate to severe disease. He stated that a meta-analysis found no significant difference between the two agents. Dr. Liles then presented the following recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
ELIDEL (TOPICAL)	PDL	PDL
PROTOPIC (TOPICAL)	NPD	PDL

Ben Sosna from Astellas yielded his time to speak about Protopic.

Dr. Tingle made a motion to approve the PDL as recommended. The motion was seconded by Dr. Brewer. Dr. O'Dell asked for a hand vote of those in favor. Motion passed 10-0.

ANDROGENIC AGENTS

Dr. Liles noted that there is no chemical difference between these agents, but that they are supplied in different ways - Androgel in packets or a pump, Testim in tubes and Androderm in patches. He noted that about one-third of patients have application site reactions with the patches. Dr. Liles presented the PDL recommendations for this class:

Brand Name	Current PDL Status	PDL Recommendation
ANDRODERM (TRANSDERM.)	NR	PDL
ANDROGEL (TRANSDERM.)	NR	PDL
TESTIM (TRANSDERM.)	NR	NPD

No speaker addressed the Committee.

Dr. Tingle made a motion to accept the recommendations; the motion was seconded by Mr. McFerrin. The motion passed 10-0.

CYTOKINE AND CAM ANTAGONISTS

Dr. Liles reviewed the indications, pharmacology and routes of administration of the

drugs in this class. He outlined the various safety concerns with these drugs, including serious infection and lymphoma, noting that the FDA is investigating an association between TNF blockers and lymphoma in children and young adults. He stated that there are no directly comparative clinical trials of these drugs. He presented a meta-analysis that showed that the TNF blockers are superior to anakinra in the treatment of RA with patients receiving Remicade being more likely to withdraw from studies due to adverse events and to have infections and patients receiving Enbrel being the least likely to drop out due to adverse events: He then presented the following recommendations:

Brand Name	Current PDL Status	PDL Recommendation
AMEVIVE (INJECTION)	NPD	NPD
CIMZIA (INJECTION)	NR	PDL
ENBREL (INJECTION)	PDL	PDL
HUMIRA (INJECTION)	PDL	PDL
KINERET (INJECTION)	NPD	PDL
ORENCIA (INJECTION)	NPD	NPD
RAPTIVA (INJECTION)	PDL	PDL
REMICADE (INJECTION)	NPD	NPD

Sunni Jenkins from UCB yielded the time to the Committee concerning Cimzia, and Pam Sardo from Abbott yielded the time to the Committee on behalf of Humira.

Dr. Wales made a motion to approve the recommendations. The motion was seconded by Dr. Harper. Dr. O'Dell called for those approving of the motion to signify by raising their hands; the motion passed 10-0.

ANTIEMETICS

Dr. Liles noted that the Committee is only reviewing oral forms of the 5HT3 antagonists, as well and Emend and the cannabinoids. He noted that the ASCO guidelines state that the 5HT3 antagonists are interchangeable. These guidelines also recommend Emend as a first line agent, with a 5HT3 antagonist and dexamethasone, for patients receiving highly emetogenic chemotherapy. He stated that they also recommend Cesamet for breakthrough CINV. Dr. Liles presented the following recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
ANZEMET (ORAL)	NPD	NPD
CESAMET (ORAL)	NPD	NPD
DRONABINOL (ORAL)	NPD	NPD
EMEND (ORAL)	NPD	NPD
GRANISETRON (ORAL)	NPD	NPD
ONDANSETRON / ODT (ORAL)	PDL	PDL

Robert Albert from Merck spoke on behalf of Emend to the Committee

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

ALZHEIMER'S AGENTS

Dr. Liles noted that this class includes the acteylcholinesterase inhibitors and the NMDA receptor antagonist. He stated that all of the acetylcholinesterase inhibitors have an indication for mild to moderate AD, but that Aricept also has the indication for severe AD and Exelon has the indication for dementia of Parkinson's Disease. He said that Namenda is indicated only for moderate to severe AD. Dr. Liles stated that, because of hepatotoxicity, Cognex is rarely used and should not be Preferred. He reviewed the adverse event and drug interaction profiles of these drugs, as well as a few comparative clinical trials and a meta-analysis. Dr. Liles then presented the following recommendations:

Brand Name	Current PDL Status	PDL Recommendation
ARICEPT / ARICEPT ODT (ORAL)	PDL	PDL
COGNEX (ORAL)	NPD	NPD
EXELON (ORAL)	PDL	PDL
EXELON (TRANSDERM.)	PDL	PDL
GALANTAMINE (ORAL)	NPD	NPD
NAMENDA (ORAL)	PDL	PDL
RAZADYNE ER (ORAL)	NPD	NPD

Lee Ann Griffin from Pfizer yielded time to speak about Aricept, Kristen Crouch from Forest yielded time to speak about Namenda, and Dr. Andrea Bloodworth from Novartis yielded time to speak about Exelon Patch.

Dr. Cook made a motion to accept Provider Synergies' recommendations. The motion was seconded by Dr. Wales. Dr. O'Dell called for a show of hands of those approving the motion; the motion passed 10-0.

STIMULANTS AND RELATED AGENTS

Dr. Liles noted that the indications and age ranges for the stimulants and related agents are described in the TCR. He noted that the pharmacokinetics of the stimulants accounts for most of their variability of effect. He reviewed the drug interactions, adverse effects and warnings of these drugs, including Strattera's boxed warning of suicidal ideation in children and adolescents and the stimulant's boxed warning of potential abuse. He stated that the clinical trials do not show evidence of clinical superiority of one stimulant over another, but that extended release dosage forms may be superior to immediate release products. He noted that, in trials comparing the non-stimulant, Strattera, to the stimulants, the only benefit of the former was a lesser effect on sleep than methylphenidate IR. Dr. Liles presented the following recommendations:

Brand Name	Current PDL Status	PDL Recommendation
ADDERALL XR (ORAL)	PDL	PDL
AMPHETAMINE SALT COMBO (ORAL)	PDL	PDL
CONCERTA (ORAL)	PDL	PDL
DAYTRANA (TRANSDERMAL)	PDL	NPD
DESOXYN (ORAL)	NPD	NPD
DEXMETHYLPHENIDATE (ORAL)	PDL	PDL
DEXTROAMPHETAMINE (ORAL)	PDL	PDL
FOCALIN XR (ORAL)	PDL	PDL
LIQUADD (ORAL)	NR	NPD
METADATE CD (ORAL)	PDL	PDL
METHYLPHENIDATE (ORAL)	PDL	PDL
METHYLPHENIDATE ER (ORAL)	PDL	PDL
PROVIGIL (ORAL)	NR	NPD
RITALIN LA (ORAL)	NPD	NPD
STRATTERA (ORAL)	PDL	NPD
VYVANSE (ORAL)	NPD	PDL

Dr. Richard Rhoden from Shire yielded his time to speak about Vyvanse, Dr. Dominic Mantella from Ortho McNeil yielded his time to speak about Concerta, Dr. Andrea Bloodworth from Novartis yielded her time to speak about Focalin XR. Dr. Kirsten Mar from Eli Lilly spoke on behalf of Strattera.

Discussion occurred among the Committee about utilization, age limits, and quantity limits set for this drug class. Ms. Clark indicated that the state reviews the utilization very carefully, and that utilization is appropriate as determined by these reviews. Dr. O'Dell added additional comment about the importance of skilled practitioners in diagnosing and utilizing this class of drugs appropriately.

Dr. Minor made a motion to approve the recommendations with the addition of Strattera to the PDL. The motion was seconded by Dr. Sethi. Committee vote was 9 in favor of the motion and 1 vote, Mr. Calvert, not in agreement with the motion.

ANTIDEPRESSANTS, OTHERS

Dr. Liles noted that this is a heterogeneous group of drugs, consisting of antidepressants with different pharmacologic profiles, including NDRIs, MAO-Is, serotonin modulators, norepinephrine-serotonin modulators and SNRIs. He reviewed the warnings regarding bupropion (seizure disorder), nefazodone (liver failure) and duloxetine (patients with liver disease). He also noted that all antidepressants, including the SSRIs, have a black box warning regarding suicidality in children, adolescents and young adults. He stated that clinical trials do not show evidence of superiority of one agent over another and that there is a need for a selection of antidepressants with varying pharmacologic properties. Dr. Liles briefly reviewed the Mayo Clinic recommendations on the management of neuropathic pain then presented the following PDL recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation

BUPROPION IR (ORAL)	PDL	PDL
BUPROPION SR (ORAL)	PDL	PDL
BUPROPION XL (ORAL)	NPD	NPD
CYMBALTA (ORAL)	NPD	NPD
EFFEXOR XR (ORAL)	PDL	PDL
EMSAM (TRANSDERMAL)	NPD	NPD
MIRTAZAPINE (ORAL)	PDL	PDL
NARDIL (ORAL)	NPD	NPD
NEFAZODONE (ORAL)	NPD	NPD
PARNATE (ORAL)	NPD	NPD
PRISTIQ (ORAL)	NR	PDL
TRAZODONE (ORAL)	PDL	PDL
VENLAFAXINE (ORAL)	PDL	NPD
WELLBUTRIN XL (ORAL)	PDL	PDL

Chris Gulladge from Wyeth yielded time to Committee to speak about Pristiq and Effexor XR. Dr. Kirsten Mar from Eli Lilly spoke on behalf of Cymbalta.

Discussion concerning Cymbalta was held among the Committee. Dr. Tingle indicated a preference toward the utilization of Cymbalta due to intolerance of patients to other agents in this drug class. The utilization of Cymbalta for patients with diabetic neuropathy and fibromyalgia was discussed.

Dr. Tingle made a motion to add Cymbalta to the PDL recommendations. This motion was seconded by Mr. McFerrin and failed by a vote of 2-8; Tingle and McFerrin in favor of the addition and other Committee members not in favor of the motion. After discussion, Dr. Sethi made a motion to add the diagnosis of fibromyalgia to the electronic prior authorization criteria for Cymbalta. Dr. Tingle seconded the motion, and the motion passed by a vote of 10-0.

ANTIDEPRESSANTS, SSRIs

Dr. Liles noted that this group of antidepressants is a more homogenous group than the previous class. He briefly reviewed the indications, drug interactions and adverse effects of these drugs. He reminded the Committee that the SSRIs have the same black box warning as the antidepressants in the previous class. Dr. Liles presented an overview of the directly comparative clinical trials of the SSRIs for the various indications, and then presented the following recommendations to the Committee:

Brand Name	**Current PDL Status**	**PDL Recommendation**
CITALOPRAM (ORAL)	PDL	PDL
FLUOXETINE (ORAL)	PDL	PDL
FLUVOXAMINE (ORAL)	NR	PDL
LEXAPRO (ORAL)	NPD	NPD
LUVOX CR (ORAL)	NR	NPD
PAROXETINE (ORAL)	PDL	PDL

PAROXETINE CR (ORAL)	PDL	NPD
PAXIL CR (ORAL)	NPD	NPD
PEXEVA (ORAL)	NPD	NPD
PROZAC WEEKLY (ORAL)	NPD	NPD
SERTRALINE (ORAL)	PDL	PDL

Michael Trabold from Jazz Pharmaceuticals spoke about Luvox CR, and Brendon Ross from Forest spoke about Lexapro.

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

Ms. Clark addressed the Committee concerning pharmacy claims. She indicated that adjudication of claims occurs very quickly, and that the DOM works very closely with fiscal agents and the PA contractor to process these claims efficiently. Ms. Clark also discussed changes in pharmacy programs, specifically the family planning waiver and how eligible members can obtain oral contraceptive drugs. She also indicated that Depo-Provera is no longer covered at the point of sale, and is only covered when administered at a physician's office.

The meeting was adjourned for lunch and reconvened at 1:15 p.m.

ANTIPSYCHOTICS, ATYPICAL

Dr. Liles reviewed the indications for the drugs in this class as presented in the TCR. He noted that Seroquel XR has new indications for bipolar disorder that are not included in the TCR. He stated that the drugs in this class differ somewhat in their effects on various receptor subtypes, which may explain some interpatient variability in response. He noted that Seroquel and Seroquel XR have the same boxed warning as the antidepressants and that clozapine, although very effective, has a boxed warning regarding a risk of agranulocytosis. He also reviewed the boxed warning common to all of the drugs in the class regarding use in elderly patients with dementia-related psychosis. Dr. Liles provided a brief overview of the drug interaction profiles of the atypical antipsychotics, as well as a review of the differences in their side effect profiles. Finally, he presented an overview of clinical trials, including the CATIE trial. Dr. Liles presented the following recommendations to the Committee:

Brand Name	**Current PDL Status**	**PDL Recommendation**
ABILIFY (ORAL)	PDL	PDL
CLOZAPINE (ORAL)	NR	PDL
FAZACLO (ORAL)	NR	PDL
GEODON (ORAL)	PDL	PDL
INVEGA (ORAL)	NPD	NPD
RISPERDAL (ORAL)	PDL	PDL
RISPERIDONE (ORAL)	PDL	NPD
SEROQUEL (ORAL)	NPD	PDL
SEROQUEL XR (ORAL)	NPD	NPD

SYMBYAX (ORAL)	NPD	NPD
ZYPREXA (ORAL)	NPD	NPD

Bill Davis of Astra Zeneca yielded time to speak about Seroquel and Seroquel XR, Lee Ann Griffin of Pfizer yielded time to speak about Geodon, John Prosser of Ortho McNeil yielded time to speak about Invega, George Kitchens of Azur yielded time to speak about Fazaclo, and Stephen Cooke of BMS yielded time to the Committee to speak about Abilify. Dr. John Norton from Eli Lilly spoke on behalf of Zyprexa.

Mr. Calvert made a motion to accept the recommendations as presented. The motion was seconded by Dr. Harper. Dr. O'Dell asked those in favor to raise their hands; the motion passes 10-0.

NEW DRUGS FOR REVIEW

ANTICONVULSANTS

The committee agreed that Stavzor would not be reviewed at this time.

Dr. Liles noted that Keppra XR is an extended-release form of Keppra, which will shortly be available as a generic. He presented the following recommendation:

Brand Name	**Current PDL Status**	**PDL Recommendation**
KEPPRA XR (ORAL)	NR	NPD

Arleen Cerbone from UCB, Inc spoke on behalf of Keppra XR.

Dr. Brewer noted that Keppra XR should remain on the PDL due to the importance of maintaining stability and preventing seizures from re-occurring in this patient population.

Dr. Brewer made a motion to add Keppra XR to the PDL. The motion was seconded by Dr. Harper. Dr. O'Dell asked those in favor to raise their hands. The motion passed by a majority vote of 8-2; Dr. Wales and Dr. Minor were not in agreement with the motion.

ANTIPARKINSON'S AGENTS

Dr. Liles stated that Requip XL is an extended-release form of Requip, which is now available generically. He then made the following PDL recommendation:

Brand Name	**Current PDL Status**	**PDL Recommendation**
REQUIP XL (ORAL)	NR	NPD

Christine Vaupel from GSK spoke on behalf of Requip XL.

Dr. Minor made a motion to accept the PDL as presented. The motion was seconded by Dr. Brewer. Dr. O'Dell asked those in favor to raise their hands; the motion passed by a vote of 10-0.

INTRANASAL RHINITIS AGENTS

Dr. Liles stated that Omnaris is a new nasal steroid and Patanase is a new nasal antihistamine. He made the following PDL recommendations for these new drugs:

Brand Name	Current PDL Status	PDL Recommendation
OMNARIS (NASAL)	NR	NPD
PATANASE (NASAL)	NR	PDL

No speakers addressed the Committee.

Dr. Brewer made a motion to accept the PDL as presented. The motion was seconded by Dr. Cook. Dr. O'Dell asked those in favor to raise their hands; the motion passed by a vote of 10-0.

OTHER BUSINESS

Ms. Clark reminded Committee members to complete and submit the travel vouchers in their packets, and to leave the cost sheets with Provider Synergies. She stated that according to the open meetings act, the minutes from this meeting must be recorded within 30 days.

NEXT MEETING DATE

Ms. Clark stated that the next P&T Committee meeting would be tentatively held the first Tuesday of April and May 2009.

ADJOURNMENT

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