

**MINUTES OF THE October 13, 2009
PHARMACY AND THERAPEUTICS (P & T) COMMITTEE MEETING**

MEMBERS ATTENDING: Hosan Azomani, MD; Sharon Dickey, Pharm D; Ryan Harper, PharmD; Lonnie Hicks, R.Ph.; Deborah Minor, PharmD; Carol Tingle, MD; Pearl Wales, PharmD

Also present: Judith Clark, RPh, Pharmacy Director, DOM; Paige Clayton, PharmD, DOM; Terry Kirby, RPh, DOM; Phyllis Williams, Deputy Administrator, DOM; Steve Liles, PharmD, Provider Synergies

MEMBERS ABSENT: Joyce Brewer, PhD, CFNP; Larry Calvert, RPh; Michael O'Dell, MD; William Sorey, MD; Lee Voulters, MD

CALL TO ORDER: Dr. Minor, as acting Chair, called the meeting to order.

INTRODUCTIONS: Ms. Clark introduced the new Committee members and asked all at the table to give a brief introduction. She thanked the Committee members for their work and introduced the DOM pharmacy staff and attendees from DOM's other pharmacy vendors, HID and ACS.

ELECTION OF CHAIR AND CO-CHAIR: Due to Committee absences, Ms. Clark announced that the election of a new Chair and Co-Chair would occur at the next P&T Committee meeting.

EXECUTIVE DIRECTOR'S COMMENTS: Ms. Williams thanked the Committee members for their work on behalf of the state. She outlined the work that DOM is doing with CMS on HB 71 and announced that the state's budget was approved on June 30.

ADMINISTRATIVE MATTERS: Ms. Clark outlined procedural and safety guidelines for the meeting. She noted that the P&T Committee is an advisory Committee and that DOM would make all final PDL decisions. She stated that the PDL decisions for classes reviewed at this meeting would be effective on January 1, 2010 and that minutes from this meeting would be posted no later than November 13, 2009.

DRUG CLASS ANNOUNCEMENTS: Ms. Clark stated that the PDL decisions from the last meeting on May 12 went into effect on July 1, 2009.

APPROVAL OF MAY 12, 2009 MEETING MINUTES: Dr. Minor asked for changes or a motion to approve the minutes from the May 12, 2009 P&T Committee meeting. Dr. Harper moved to approve the minutes. Dr. Tingle seconded the motion and the minutes were approved unanimously.

THERAPEUTIC CLASS REVIEWS: Dr. Liles stated that he would be presenting new information not previously covered in the Committee's reviews. Per Dr. Minor's request, Dr. Liles presented an overview of the External Cost Sheets that had been provided to the Committee members.

OPHTHALMIC ANTI-INFLAMMATORIES

Dr. Liles noted that this class has been expanded from the previous review, which had included only NSAIDs. With the review and going forward, this class will also include

steroidal agents. He noted that the TCR had been expanded to include clinical information on the steroids. In general, he stated, there are no significant differences among the topical agents.

Dr. Liles presented the PDL recommendations for the Ophthalmic Anti-Inflammatories class:

Brand Name	Current PDL Status	PDL Recommendation
ACULAR LS (OPHTHALMIC)	PDL	NPD
ACULAR PF (OPHTHALMIC)	PDL	PDL
DEXAMETHASONE (OPHTHALMIC)	NR	PDL
DICLOFENAC (OPHTHALMIC)	NPD	PDL
DUREZOL (OPHTHALMIC)	NR	NPD
FLAREX (OPHTHALMIC)	NR	PDL
FLUOROMETHOLONE (OPHTHALMIC)	NR	PDL
FLURBIPROFEN (OPHTHALMIC)	PDL	PDL
FML FORTE (OPHTHALMIC)	NR	PDL
FML S.O.P. (OPHTHALMIC)	NR	PDL
LOTEMAX (OPHTHALMIC)	NR	PDL
MAXIDEX (OPHTHALMIC)	NR	PDL
NEVANAC (OPHTHALMIC)	PDL	PDL
PRED MILD (OPHTHALMIC)	NR	PDL
VEXOL (OPHTHALMIC)	NR	PDL
XIBROM (OPHTHALMIC)	NPD	NPD

There was no public testimony on this class.

Dr. Tingle made a motion to accept Provider Synergies' recommendations as presented. The motion was seconded by Dr. Wales. The motion passed unanimously.

OPHTHALMICS FOR ALLERGIC CONJUNCTIVITIS

Dr. Liles presented a brief overview of the 2008 AAO guidelines, which recommend a stepwise approach to treatment of allergic conjunctivitis.

Dr. Liles presented the following PDL recommendations:

Brand Name	Current PDL Status	PDL Recommendation
ACULAR (OPHTHALMIC)	NPD	NPD
ALAMAST (OPHTHALMIC)	NPD	NPD
ALOCRIAL (OPHTHALMIC)	NPD	NPD
ALOMIDE (OPHTHALMIC)	NPD	NPD
ALREX (OPHTHALMIC)	PDL	PDL
CROMOLYN SODIUM (OPHTHALMIC)	PDL	PDL
ELESTAT (OPHTHALMIC)	PDL	PDL

EMADINE (OPHTHALMIC)	NPD	PDL
KETOTIFEN OTC (OPHTHALMIC)	NPD	PDL
OPTIVAR (OPHTHALMIC)	PDL	PDL
PATADAY (OPHTHALMIC)	PDL	PDL
PATANOL (OPHTHALMIC)	PDL	PDL

There was no public testimony.

Dr. Minor asked Dr. Liles if ketotifen was available only in OTC form; Dr. Liles stated that it is now available only as an OTC. Ms. Clark reviewed DOM's policy on coverage of OTC drugs.

Dr. Azomani made a motion to accept the recommendations as presented. Dr. Harper seconded the motion, which passed unanimously.

OPHTHALMIC, GLAUCOMA AGENTS

Dr. Liles presented a new study comparing brimonidine 0.1 and 0.15%. He also noted that Cosopt and Trusopt are now available generically.

He then presented the PDL recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
ALPHAGAN P (OPHTHALMIC)	NPD	NPD
ALPHAGAN P (OPHTHALMIC)	NPD	NPD
AZOPT (OPHTHALMIC)	PDL	PDL
BETAXOLOL (OPHTHALMIC)	PDL	PDL
BETIMOL (OPHTHALMIC)	PDL	PDL
BETOPTIC S (OPHTHALMIC)	NPD	NPD
BRIMONIDINE (OPHTHALMIC)	PDL	PDL
CARTEOLOL (OPHTHALMIC)	PDL	PDL
COMBIGAN (OPHTHALMIC)	PDL	PDL
COSOPT (OPHTHALMIC)	PDL	PDL
DIPIVEFRIN (OPHTHALMIC)	PDL	PDL
DORZOLAMIDE (OPHTHALMIC)	PDL	PDL
DORZOLAMIDE / TIMOLOL (OPHTHALMIC)	PDL	PDL
ISTALOL (OPHTHALMIC)	PDL	PDL
LEVOBUNOLOL (OPHTHALMIC)	PDL	PDL
LUMIGAN 2.5ML (OPHTHALMIC)	PDL	NPD
LUMIGAN 5ML (OPHTHALMIC)	NPD	NPD
LUMIGAN 7.5ML (OPHTHALMIC)	NPD	NPD
METIPRANOLOL (OPHTHALMIC)	PDL	PDL
PILOCARPINE (OPHTHALMIC)	PDL	PDL
TIMOLOL (OPHTHALMIC)	PDL	PDL

TRAVATAN / TRAVATAN Z 2.5 ML (OPHTHALMIC)	PDL	PDL
TRAVATAN / TRAVATAN Z 5 ML (OPHTHALMIC)	PDL	PDL
TRUSOPT (OPHTHALMIC)	PDL	PDL
XALATAN 2.5 ML (OPHTHALMIC)	PDL	PDL

Lee Ann Griffin, PharmD, from Pfizer yielded her time back to the Committee.

Dr. Wales made a motion to approve the recommendations as presented by Provider Synergies. The motion was seconded by Dr. Tingle and passed unanimously.

OPHTHALMIC ANTIBIOTICS

Dr. Liles noted that, like the Ophthalmic Anti-Inflammatories, this class has been expanded. Whereas before it had included only quinolones, it now includes all antibiotics. He noted that the TCR had been expanded to include clinical information for the new additions to the class. Dr. Liles presented information from the most recent release of TRUST data, as well as an overview of the new quinolone, Besivance. He concluded by reviewing data from a study comparing an older combination antibiotic with Vigamox.

Dr. Liles presented the PDL recommendations for this class:

Brand Name	Current PDL Status	PDL Recommendation
AZASITE (OPHTHALMIC)	PDL	PDL
BACITRACIN (OPHTHALMIC)	NR	PDL
BACITRACIN/POLYMYXIN (OPHTHALMIC)	NR	PDL
BESIVANCE (OPHTHALMIC)	NPD	NPD
CILOXAN OINTMENT (OPHTHALMIC)	NPD	NPD
CIPROFLOXACIN SOLUTION (OPHTHALMIC)	NPD	NPD
ERYTHROMYCIN (OPHTHALMIC)	PDL	PDL
GENTAMICIN (OPHTHALMIC)	NR	PDL
IQUIX (OPHTHALMIC)	PDL	PDL
NATACYN (OPHTHALMIC)	NR	NPD
NEOMYCIN-POLYMYXIN-GRAMICIDIN (OPHTHALMIC)	NR	PDL
OFLOXACIN (OPHTHALMIC)	NPD	NPD
POLYMYXIN/TRIMETHOPRIM (OPHTHALMIC)	NR	PDL
QUIXIN (OPHTHALMIC)	NPD	NPD
SULFACETAMIDE (OPHTHALMIC)	NR	PDL
TOBRAMYCIN (OPHTHALMIC)	NR	PDL
TOBREX OINTMENT (OPHTHALMIC)	NR	PDL
TRIPLE ANTIBIOTIC (OPHTHALMIC)	NR	PDL
VIGAMOX (OPHTHALMIC)	PDL	PDL
ZYMAR (OPHTHALMIC)	NPD	NPD

There was no public testimony.

Dr. Minor asked Dr. Liles about the rationale for the inclusion of Iquix on the PDL. Dr. Liles noted that it had a different indication from most of the other agents in this class and that utilization of the drug was minimal.

Dr. Harper made the motion to approve the recommendations as presented by Provider Synergies. The motion was seconded by Dr. Azomani and approved unanimously by the Committee.

OTIC ANTIBIOTICS

Dr. Liles stated that, like the previous class, this one had been expanded to include all otic antibiotics. He presented a brief overview of the new quinolone in the class, Cetraxal, and provided information on new clinical trials comparing quinolones with older agents.

Dr. Liles presented the PDL recommendations:

Brand Name	Current PDL Status	PDL Recommendation
CETRAXAL (OTIC)	NPD	PDL
CIPRO HC (OTIC)	NPD	NPD
CIPRODEX (OTIC)	PDL	PDL
COLY-MYCIN S (OTIC)	NR	PDL
CORTISPORIN-TC (OTIC)	NR	PDL
NEOMYCIN/POLYMYXIN/HC (OTIC)	NR	PDL
OFLOXACIN (OTIC)	PDL	NPD

There was no public testimony.

Dr. Wales made a motion to accept the recommendations as presented. This motion was seconded by Dr. Tingle. The motion passed unanimously.

FLUOROQUINOLONES, ORAL

Dr. Liles reviewed the changes in labeling for agents in this class that have occurred in the past year. He also presented a study comparing levofloxacin and ciprofloxacin in the treatment of UTIs and pyelonephritis. Finally, he discussed a meta-analysis comparing fluoroquinolones with macrolides and beta lactams in the treatment of pneumonia in adults.

Dr. Liles presented the PDL recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
AVELOX (ORAL)	PDL	PDL
CIPRO SUSPENSION (ORAL)	NPD	NPD
CIPROFLOXACIN ER (ORAL)	NPD	NPD
CIPROFLOXACIN TABLETS (ORAL)	PDL	PDL
FACTIVE (ORAL)	NPD	NPD
LEVAQUIN (ORAL)	NPD	NPD

NOROXIN (ORAL)	NPD	NPD
OFLOXACIN (ORAL)	NPD	NPD
PROQUIN XR (ORAL)	PDL	NPD

Helen Ha, PharmD, from Schering yielded her time back to the Committee.

Dr. Harper made a motion to accept the recommendations as presented. The motion was seconded by Dr. Wales and passed unanimously.

CEPHALOSPORINS AND RELATED ANTIBIOTICS

Dr. Liles presented new WHO guidelines for the treatment of non-severe pneumonia in children that recommend amoxicillin as first line treatment with SMZ-TMP as an alternative in some settings.

Dr. Liles made the following recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
AMOXICILLIN/CLAV SUSPENSION (ORAL)	PDL	PDL
AMOXICILLIN/CLAV TABLET (ORAL)	PDL	PDL
AUGMENTIN 125 SUSPENSION (ORAL)	PDL	PDL
AUGMENTIN 250 CHEWABLE (ORAL)	PDL	PDL
AUGMENTIN 250 SUSPENSION (ORAL)	PDL	PDL
AUGMENTIN XR (ORAL)	PDL	PDL
CEDAX (ORAL)	NPD	NPD
CEFACTOR (ORAL)	PDL	PDL
CEFADROXIL (ORAL)	PDL	PDL
CEFDINIR (ORAL)	PDL	NPD
CEFPODOXIME (ORAL)	NPD	NPD
CEFPROZIL (ORAL)	PDL	PDL
CEFUROXIME (ORAL)	PDL	PDL
CEPHALEXIN (ORAL)	PDL	PDL
SPECTRACEF (ORAL)	NPD	NPD
SUPRAX (ORAL)	PDL	PDL

No speakers addressed the Committee.

Dr. Harper asked Dr. Liles about the rationale for the recommendation to remove cefdinir from the PDL. Dr. Liles responded that this is a very costly generic with significant utilization and that movement to less costly alternatives represented an opportunity for significant savings for the state. Dr. Azomani expressed concern that removal of this drug from the PDL would be problematic for the primary care providers in the state due to the high utilization in children.

Dr. Harper made a motion to accept the recommendations with the exception of keeping

cefdinir preferred only for patients under 18 years of age. Dr. Wales seconded the motion. The motion passed unanimously.

MACROLIDES-KETOLIDES

Dr. Liles stated that there is no significant new clinical information to present for this class.

He presented the following PDL recommendations:

Brand Name	Current PDL Status	PDL Recommendation
AZITHROMYCIN (ORAL)	PDL	PDL
CLARITHROMYCIN (ORAL)	PDL	PDL
CLARITHROMYCIN ER (ORAL)	NPD	NPD
ERYTHROMYCIN (ORAL)	PDL	PDL
KETEK (ORAL)	NPD	NPD
ZMAX (ORAL)	NPD	NPD

There was no public testimony.

Dr. Dickey made a motion to accept the recommendations as presented. The motion was seconded by Dr. Harper and passed unanimously by the Committee.

TETRACYCLINES

Dr. Liles presented a summary of the TCR for this class, being reviewed for the PDL for the first time. He noted that there are no quality comparative trials of these drugs.

Dr. Liles made the following recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
ADOXA CK (ORAL)	NA	NPD
ADOXA TT (ORAL)	NA	NPD
DEMECLOCYCLINE (ORAL)	NA	NPD
DOXYCYCLINE (ORAL)	NA	PDL
MINOCYCLINE (ORAL)	NA	PDL
MINOCYCLINE ER (ORAL)	NA	NPD
NUTRIDOX (ORAL)	NA	NPD
ORACEA (ORAL)	NA	NPD
SOLODYN (ORAL)	NA	NPD
TETRACYCLINE (ORAL)	NA	PDL

There was no public testimony.

Dr. Azomani made a motion to accept the PDL as presented. The motion was seconded by Mr. Hicks. The motion passed unanimously.

ANTIBIOTICS, GI

Dr. Liles stated that there was no significant new clinical information to report in this class.

He then presented the following recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
ALINIA (ORAL)	PDL	PDL
FLAGYL ER (ORAL)	NPD	NPD
METRONIDAZOLE (ORAL)	PDL	PDL
NEOMYCIN (ORAL)	PDL	PDL
TINDAMAX (ORAL)	PDL	PDL
VANCOCIN HCL (ORAL)	NPD	NPD
XIFAXAN (ORAL)	NPD	NPD

There was no public testimony.

Dr. Wales made a motion to approve the PDL as recommended. The motion was seconded by Dr. Dickey and was passed unanimously.

ANTIBIOTICS, VAGINAL

Dr. Liles stated that there was no significant new clinical information to report in this class.

He then presented the following recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
CLEOCIN OVULES (VAGINAL)	PDL	PDL
CLINDAMYCIN (VAGINAL)	PDL	PDL
CLINDESSE (VAGINAL)	NPD	NPD
METRONIDAZOLE (VAGINAL)	PDL	PDL
VANDAZOLE (VAGINAL)	NPD	PDL

There was no public testimony.

Dr. Tingle made a motion to accept the recommendations as presented. Dr. Harper seconded the motion, which then passed unanimously.

ANTIFUNGALS, ORAL

Dr. Liles presented a brief overview of the recently published IDSA guidelines for the treatment of candidiasis.

Dr. Liles presented the PDL recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
ANCOBON (ORAL)	NPD	NPD
CLOTRIMAZOLE (MUCOUS MEM)	PDL	PDL
FLUCONAZOLE (ORAL)	PDL	PDL
GRIFULVIN V TABLETS (ORAL)	NPD	NPD
GRISEOFULVIN SUSPENSION (ORAL)	PDL	PDL
GRIS-PEG (ORAL)	PDL	PDL
ITRACONAZOLE (ORAL)	NPD	NPD
KETOCONAZOLE (ORAL)	PDL	PDL
LAMISIL GRANULES (ORAL)	NPD	NPD
NOXAFIL (ORAL)	NPD	NPD
NYSTATIN (ORAL)	PDL	PDL
TERBINAFINE (ORAL)	PDL	PDL
VFEND (ORAL)	NPD	NPD

There was no public testimony.

Dr. Tingle made a motion to approve the recommendations. The motion was seconded by Dr. Dickey. The motion was approved unanimously.

ANTIVIRALS FOR HSV

Dr. Liles presented a new clinical trial that compared a one day course of famciclovir with a two day course of valacyclovir in patients with recurrent genital herpes.

He then presented the following PDL recommendations:

Brand Name	Current PDL Status	PDL Recommendation
ACYCLOVIR (ORAL)	PDL	PDL
FAMCICLOVIR (ORAL)	NR	NPD
FAMVIR (ORAL)	NPD	NPD
VALTREX (ORAL)	PDL	PDL

HEPATITIS C AGENTS

Dr. Liles reviewed the 2009 AASLD treatment guidelines for Hepatitis C that recommend either of the pegylated interferons plus weight based ribavirin as the treatments of choice in previously untreated patients. The guidelines also cover treatment in children and African Americans. He stated the PEG-Intron now has an indication for use in children as young as three years of age. Dr. Liles presented a comparative study of the two pegylated interferons in coinfecting patients that showed no significant difference in outcomes between the two treatments. He also presented the HALT-C study of non-responders with advanced fibrosis.

Dr. Liles presented the following recommendations:

Brand Name	Current PDL Status	PDL Recommendation
INFERGEN (SUBCUTANE.)	NPD	NPD
PEGASYS (SUBCUTANE.)	PDL	PDL
PEG-INTRON (SUBCUTANE.)	NPD	NPD
PEG-INTRON REDIPEN (SUBCUTANE.)	NPD	NPD

Dereck Terry of Roche/Genentech presented information from a recently published study of Pegasys.

Syed Mahmud, MD, from Schering presented the EPIC study that was published in May.

Dr. Azomani made a motion to accept the recommendations presented with the stipulation that PA criteria for PEG-Intron should include patients age under 18 years and treatment failure. The motion was seconded by Dr. Dickey and approved by unanimous vote.

PANCREATIC ENZYMES

Dr. Liles noted that agents in this class that do not apply for and receive FDA approval by April 10, 2010 will be removed from the market. He stated that Creon is the first of these drugs to have received this approval.

Dr. Liles presented the following recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
CREON (ORAL)	PDL	PDL
PANCREASE MT (ORAL)	PDL	PDL
PANCRECARB MS (ORAL)	NPD	NPD
PANCRELIPASE (ORAL)	PDL	PDL
ULTRASE (ORAL)	PDL	PDL
VIOKASE (ORAL)	PDL	PDL

There was no public comment on this class.

Mr. Hicks made a motion to accept the recommendations as presented. The motion was seconded by Dr. Dickey. The motion was passed by unanimous vote.

ANDROGENIC AGENTS

Dr. Liles stated that there was no new significant data to present for this class.

Dr. Liles presented the PDL recommendations:

Brand Name	Current PDL Status	PDL Recommendation
ANDRODERM (TRANSERM.)	PDL	PDL
ANDROGEL (TRANSERM.)	PDL	PDL

TESTIM (TRANSDERM.)	NPD	NPD
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There was no public comment on this class.

Dr. Wales made a motion to accept Provider Synergies' recommendations. The motion was seconded by Dr. Tingle. The motion passed unanimously.

Dr. Minor adjourned the Committee for lunch, after which Dr. Liles resumed the clinical presentations.

FIBROMYALGIA AGENTS

Dr. Liles discussed the composition of this class as being all drugs with an indication for fibromyalgia. He acknowledged that some of the drugs in this class have additional indications and stated that clinical data related to these indications is evaluated and presented. Dr. Liles presented an overview of the new drug, Savella, and outlined placebo-controlled trials of this drug as well as Cymbalta.

Dr. Liles presented the following recommendations:

Brand Name	Current PDL Status	PDL Recommendation
CYMBALTA (ORAL)	NPD	NPD
LYRICA (ORAL)	PDL	PDL
SAVELLA (ORAL)	NA	PDL

Michael DeLucia, RPh, of Forest spoke on behalf of Savella.

Kirsten Mar, PharmD, of Lilly presented information on Cymbalta.

Lee Ann Griffin, PharmD, of Pfizer yielded her time back to the Committee.

The Committee discussed FDA classification of these drugs, noting that Lyrica is Schedule IV.

Dr. Azomani made a motion to approve the recommendations as presented by Dr. Liles. The motion was seconded by Dr. Wales and passed unanimously by the Committee.

Ms. Clark explained that DOM would implement these recommendations by adding the requirement of a trial of preferred agent(s) to Cymbalta's electronic-PA for patients with fibromyalgia. Cymbalta's electronic PA for patients with diabetic neuropathy, GAD and depression will not be effected.

ANTIDEPRESSANTS, OTHER

Dr. Liles noted the release of Aplenzin, bupropion HBr extended-release tablets, and a new branded form of venlafaxine ER. He briefly reviewed the ACP's 2008 guidelines for the use of antidepressants as well as new guidelines from the International Consensus Group on Depression and Anxiety and the World Federation of Biological Psychiatry. Finally, he presented a new placebo-controlled study of Cymbalta in patients with GAD.

Dr. Liles presented the PDL Recommendations:

Brand Name	Current PDL Status	PDL Recommendation
APLENZIN (ORAL)	NPD	NPD
BUPROPION (ORAL)	PDL	PDL
BUPROPION SR (ORAL)	PDL	PDL
BUPROPION XL (ORAL)	PDL	PDL
EFFEXOR XR (ORAL)	PDL	PDL
EMSAM (TRANSDERMAL)	NPD	NPD
MIRTAZAPINE (ORAL)	PDL	PDL
NARDIL (ORAL)	NPD	NPD
NEFAZODONE (ORAL)	PDL	PDL
PARNATE (ORAL)	NPD	NPD
PRISTIQ (ORAL)	PDL	PDL
TRANLYCYPROMINE SULFATE (ORAL)	NR	NPD
TRAZODONE (ORAL)	PDL	PDL
VENLAFAXINE (ORAL)	NPD	NPD
VENLAFAXINE ER (ORAL)	NPD	NPD
WELLBUTRIN XL (ORAL)	PDL	PDL

Clinton Wright of UCB presented information on his company's extended-release venlafaxine product.

Dr. Tingle made a motion to accept the recommendations as presented. This motion was seconded by Dr. Harper. The motion passed unanimously.

ANTIDEPRESSANTS, SSRIS

Dr. Liles noted that Lexapro is now indicated for the treatment of MDD in adolescents 12-17 years old. He also highlighted the Treatment for Adolescents with Depression Study.

Dr. Liles presented the PDL recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
CITALOPRAM (ORAL)	PDL	PDL
FLUOXETINE (ORAL)	PDL	PDL
FLUVOXAMINE (ORAL)	PDL	PDL
LEXAPRO (ORAL)	NPD	NPD
LUVOX CR (ORAL)	NPD	PDL
PAROXETINE (ORAL)	PDL	PDL
PAROXETINE CR (ORAL)	NPD	NPD
PEXEVA (ORAL)	NPD	NPD
PROZAC WEEKLY (ORAL)	NPD	NPD
SERTRALINE (ORAL)	PDL	PDL

Michael DeLucia, RPh, of Forest presented a January 2009 meta-analysis of Lexapro studies and a pediatric study published in July.

Dr. Tingle noted that, with Lexapro now having an indication for adolescents, it would be beneficial to have it available as an alternative to fluoxetine in this patient population.

Dr. Tingle made a motion to accept the recommendations as presented with the exception of allowing Lexapro without a PA for adolescents. After being seconded by Dr. Harper, the Committee approved the motion unanimously.

ANTIPSYCHOTICS

Dr. Liles stated that this class has now been expanded to include conventional and injectable antipsychotics and that clinical data for these drugs has been added to the TCR. He noted the new indications for olanzapine with fluoxetine and Seroquel XR. He presented a retrospective cohort study of Tennessee Medicaid recipients showing that both conventional and atypical antipsychotics increased the risk of SCD compared to non-users of these drugs.

Dr. Liles presented the following recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
ABILIFY (ORAL)	PDL	PDL
AMITRIPTYLINE / PERPHENAZINE (ORAL)	NR	PDL
CHLORPROMAZINE (ORAL)	NR	PDL
CLOZAPINE (ORAL)	NR	PDL
FAZACLO (ORAL)	NR	NPD
FLUPHENAZINE (ORAL)	NR	PDL
FLUPHENAZINE DECANOATE (INJECTION)	NR	NPD
GEODON (INTRAMUSC)	NR	NPD
GEODON (ORAL)	PDL	PDL
HALOPERIDOL (ORAL)	NR	PDL
HALOPERIDOL DECANOATE (INTRAMUSC)	NR	NPD
INVEGA (ORAL)	NPD	NPD
MOBAN (ORAL)	NR	PDL
PERPHENAZINE (ORAL)	NR	PDL
RISPERDAL CONSTA (INTRAMUSC.)	NR	NPD
RISPERIDONE (ORAL)	PDL	PDL
SEROQUEL (ORAL)	PDL	PDL
SEROQUEL XR (ORAL)	NPD	PDL
SYMBYAX (ORAL)	NPD	NPD
THIORIDAZINE (ORAL)	NR	PDL
THIOTHIXENE (ORAL)	NR	PDL
TRIFLUOPERAZINE (ORAL)	NR	PDL
ZYPREXA (INTRAMUSC)	NR	NPD

ZYPREXA (ORAL)	NPD	NPD
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Steven Cook of BMS, Bill Davis of AstraZeneca and Lee Ann Griffin, PharmD, from Pfizer yielded their time to the Committee.

Kirsten Mar, PharmD, of Lilly spoke on behalf of Zyprexa.

Brian Macomson, PharmD, of OMJPI spoke on behalf of Invega.

After discussion, the Committee elected to remove clozapine and Fazaclo from the PDL process due to their unique monitoring requirements.

Dr. Azomani made a motion to accept the recommendations as presented. The motion was seconded by Dr. Dickey. The motion passed unanimously.

STIMULANTS AND RELATED AGENTS

Dr. Liles pointed out that armodafinil, Nuvigil, the r-enantiomer of modafinil, is a new entrant to this class. He also stated that Vyvanse is now indicated for the treatment of ADHD in adults.

He presented the following recommendations:

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

Dr. Jennifer Robinson from Shire waived her time back to the Committee.

Kirsten Mar, PharmD, from Lilly presented clinical information on Strattera.

Brian Macomson, PharmD, of OMJPI spoke on Concerta, noting that it is formulated with a different technology from other drugs in the class.

Dr. Harper made a motion to accept the recommendations as presented by Dr. Liles. This motion, seconded by Mr. Hicks, was passed unanimously.

ALZHEIMER’S AGENTS

Dr. Liles stated that there was no new significant clinical information to present on this class of drugs.

He then presented the following recommendations to the Committee:

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

Mike DeLuscia, R.Ph, from Forest presented information on Namenda.

Lee Ann Griffin, PharmD, of Pfizer waived her time back to the Committee.

Julia Compton, PharmD, from Novartis spoke on behalf of Exelon.

Mr. Hicks made a motion to accept the recommendations as presented by Dr. Liles. The motion was seconded by Dr. Tingle. The motion passed unanimously.

OTHER BUSINESS

There was no other business.

NEXT MEETING DATE

Ms. Clark announced the next meeting would occur on November 10, 2009 and stated that next year’s P&T Committee meeting schedule, including therapeutic class reviews, would be announced shortly.

ADJOURNMENT

There being no further business, Dr. Minor adjourned the meeting.