MINUTES OF THE March 9th, 2010
PHARMACY AND THERAPEUTICS (P & T) COMMITTEE MEETING

MEMBERS ATTENDING: Hosan Azomani, MD; Joyce Brewer PhD; Sharon Dickey, MD; Ryan Harper, PharmD; Lonnie Hicks; Deborah Minor, PharmD; Michael O'Dell, MD; William Sorey, MD; Carol Tingle, MD; Lee Voluters MD; Pearl Wales, PharmD

Also present: Judith Clark, RPh, Pharmacy Director, DOM; Paige Clayton, PharmD, DOM; Terry Kirby, RPh, DOM; J. David Wuest RPh Provider Synergies; Steve Wuest, PharmD, Provider Synergies

MEMBERS ABSENT: Larry Calvert, RPh;

CALL TO ORDER: Dr. Minor called the meeting to order.

INTRODUCTIONS: Ms. Clark thanked the Committee members for their work and introduced the DOM pharmacy staff and attendees from DOM's other pharmacy vendors, HID and ACS. ACS listened to the meeting via telephone to assist in the coordination of their work.

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 July 1, 2010. Minutes from the March 9, 2009 meeting would be posted no later than April 9, 2009.

DRUG CLASS ANNOUNCEMENTS: Ms. Clark stated DOM along with PDL vendor, First Health/Provider Synergies continually monitor and/or review drug therapeutic classes either on or being considered for the PDL. A class may be considered for PDL removal if there is low utilization; classes are all or mostly generic; or there is no significant financial or clinical benefit from reviewing. Be advised that DOM may opt to review a 'retired drug class' at a later date if the afore mentioned dynamics change. At today's meeting all classes scheduled for review are being reviewed.

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

THERAPEUTIC CLASS REVIEWS: Mr. Wuest stated that he would be presenting new information not previously covered in the Committee's reviews.

BETA BLOCKERS
Mr. Wuest noted that this class has no new agents in it since the last time the Committee reviewed it. He provided an overview of the class.

Mr. Wuest presented the PDL recommendations for the Beta Blockers class:

Brand Name (Route)	Current PDL Status	PDL Recommendations
ACEBUTOLOL (ORAL)	PDL	PDL
ATENOLOL / CHLORTHALIDONE (ORAL)	PDL	PDL
BETAXOLOL (ORAL)	PDL	PDL
BISOPROLOL / HCTZ (ORAL)	PDL	PDL
BYSTOLIC (ORAL)	PDL	PDL
CARVEDILOL (ORAL)	PDL	PDL
COREG CR (ORAL)	NPD	NPD
INNOPRAN XL (ORAL)	PDL	PDL
LABETALOL (ORAL)	PDL	PDL
LEVATOL (ORAL)	NPD	NPD
METOPROLOL / HCTZ (ORAL)	PDL	PDL
METOPROLOL XL (ORAL)	PDL	PDL
NADOLOL / BENDROFLUMETHIAZIDE (ORAL)	PDL	PDL
PINDOLOL (ORAL)	PDL	PDL
PROPRANOLOL / HCTZ (ORAL)	PDL	PDL
SOTALOL (ORAL)	PDL	PDL
TIMOLOL (ORAL)	PDL	PDL
TOPROL XL (ORAL)	NPD	NPD

Public testimony on this class was provided on Bystolic by William Crowder MD on behalf of Jackson Heart Clinic.

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

CALCIUM CHANNEL BLOCKERS

Mr. Wuest noted that this class has no new agents in it since the last time the Committee reviewed it. He provided an overview of the class.

Mr. Wuest presented the PDL recommendations for the Calcium Channel Blockers class:

Brand Name (Route)	Current PDL Status	PDL Recommendations
AMLODIPINE (ORAL)	PDL	PDL
CARDENE SR (ORAL)	NPD	NPD
CARDIZEM CD 360 MG (ORAL)	NPD	NPD
CARDIZEM LA (ORAL)	NPD	NPD
COVERA-HS (ORAL)	PDL	PDL
DILTIAZEM (ORAL)	PDL	PDL
DYNACIRC CR (ORAL)	PDL	PDL
FELODIPINE ER (ORAL)	PDL	PDL
ISRADIPINE (ORAL)	NPD	NPD
NICARDIPINE (ORAL)	PDL	PDL
NIFEDIPINE ER (ORAL)	PDL	PDL
NIFEDIPINE IR (ORAL)	PDL	PDL
NISOLDIPINE (ORAL)	NPD	NPD
SULAR (ORAL)	NPD	NPD
VERAPAMIL (ORAL)	PDL	PDL
VERAPAMIL ER PM (ORAL)	NPD	NPD

No public testimony on this class was provided.

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

ANGIOTENSIN MODULATORS

Mr. Wuest presented a brief overview of the American College of Cardiology Foundation and the American Heart Association guidelines, which recommend ACE inhibitors as the standard of care for heart failure.

Mr. Wuest presented the following PDL recommendations:

Brand Name (Route)	Current PDL Status	PDL Recommendations
ACEON (ORAL)	PDL	PDL
ATACAND / ATACAND HCT (ORAL)	NPD	NPD
AVAPRO / AVALIDE (ORAL)	PDL	PDL
BENICAR / BENICAR HCT (ORAL)	PDL	PDL
COZAAR / HYZAAR (ORAL)	PDL	PDL
DIOVAN / HCT (ORAL)	PDL	PDL
FOSINOPRIL / HCTZ (ORAL)	PDL	PDL
MICARDIS / MICARDIS HCT (ORAL)	PDL	PDL
MOEXIPRIL / HCTZ (ORAL)	PDL	PDL
PERINDOPRIL (ORAL)	NPD	NPD
RAMIPRIL (ORAL)	PDL	PDL
TEKTURNA / TEKTURNA HCT (ORAL)	NPD	NPD
TEVETEN / TEVETEN HCT (ORAL)	NPD	NPD
TRANDOLAPRIL (ORAL)	PDL	PDL

Public testimony on this class was provided on Micardis and Tekturna by Jon Thornton MD on behalf of Boehringer.

Donna Erwin from Bristol-Myers, Hollye Garner PhD from Daiichi Sankyo, and Julia Compton PharmD from Novartis yielded their time back to the Committee.

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

ANGIOTENSIN MODULATOR COMBINATIONS

Mr. Wuest noted that this class has been expanded from the previous review, which now has Valturna listed in it. He then provided an overview of the class. In general, he stated, there are no significant differences among the agents.

Mr. Wuest presented the PDL recommendations for the Angiotensin Modulator Combinations:

Brand Name (Route)	Current PDL Status	PDL Recommendations
AMLODIPINE / BENAZEPRIL (ORAL)	PDL	NPD
AZOR (ORAL)	PDL	PDL
EXFORGE / EXFORGE HCT (ORAL)	PDL	PDL
LOTREL (ORAL)	NPD	NPD
TARKA (ORAL)	PDL	PDL
TWYNSTA (ORAL)	NPD	NPD

VALTURNA (ORAL)	NPD	PDL

Public testimony on this class was provided on Twynsta by Jon Thornton MD on behalf of Boehringer.

Hollye Garner PhD and Julia Compton PharmD from Novartis yielded their time back to the Committee.

Dr. Voluters made a motion to accept Provider Synergies' recommendations as presented with the exception of preferring Lotrel and non-preferring Valturna. The motion was seconded by Dr. O' Dell. The motion passed unanimously.

LIPOTROPICS, OTHER

Mr. Wuest presented that the preponderance of the outcome date supports that statins are the first line of agents for LDL-C reduction. The agents in this class should be uses as a secondary treatment or when a patient is unable to take statin.

He then presented the PDL recommendations to the Committee:

Brand Name (Route)	Current PDL Status	PDL Recommendations
ANTARA (ORAL)	NPD	NPD
CHOLESTYRAMINE (ORAL)	PDL	PDL
COLESTIPOL (ORAL)	PDL	PDL
FENOFIBRATE (ORAL)	PDL	PDL
FENOFIBRIC ACID (ORAL)	NPD	NPD
FENOGLIDE (ORAL)	NPD	NPD
FIBRICOR (ORAL)	NPD	NPD
GEMFIBROZIL (ORAL)	PDL	PDL
LIPOFEN (ORAL)	NPD	NPD
LOVAZA (ORAL)	PDL	NPD
NIACOR (ORAL)	PDL	PDL
NIASPAN (ORAL)	PDL	PDL
TRICOR (ORAL)	PDL	PDL
TRIGLIDE (ORAL)	NPD	NPD
TRILIPIX (ORAL)	PDL	PDL
WELCHOL (ORAL)	NPD	NPD
ZETIA (ORAL)	NPD	NPD

Public testimony on this class was provided on Welchol by Rosie Walker-McNair MD on behalf of Magnolia, on Fenoglide by Kenneth Jackson on behalf of Shionogi, and on Zetia by Claudia Amidon PharmD on behalf of Merck.

Pam Sardo, PharmD, from Abbott yielded her time back to the Committee.

Dr. Tingle made a motion to approve the recommendations as presented by Provider

Synergies with the exception of preferring Lovaza. The motion was seconded by Dr. Brewer and passed unanimously with the exception of a Nay by Dr. O' Dell.

LIPOTROPICS, STATINS
Mr. Wuest presented that Statins are the standard of care in lowering cholesterol levels. He noted that, Statin combination lack outcome data.

Mr. Wuest presented the PDL recommendations for this class:

Brand Name (Route)	Current PDL Status	PDL Recommendations
ADVICOR (ORAL)	NPD	NPD
ALTOPREV (ORAL)	NPD	NPD
CADUET (ORAL)	PDL	NPD
CRESTOR (ORAL)	NPD	NPD
LESCOL / LESCOL XL (ORAL)	PDL	PDL
LIPITOR (ORAL)	PDL	PDL
LOVASTATIN (ORAL)	PDL	PDL
PRAVASTATIN (ORAL)	PDL	PDL
SIMCOR (ORAL)	PDL	PDL
SIMVASTATIN (ORAL)	PDL	PDL
VYTORIN (ORAL)	NPD	NPD

Public testimony on this class was provided on Lovasa by Shannon Howorth PharmD on behalf of GlaxoSmithKline, on Crestor by Daniel Teat PharmD on behalf of AstraZeneca, on Vytorin by Claudia Amidon PharmD on behalf of Merck, and on Caduet by Leigh Ann Griffin PharmD on behalf of Pfizer.

Pam Sardo, PharmD from Abbott and Leigh Ann Griffin PharmD from Pfizer yielded their time back to the Committee.

Dr. Voluters made the motion to approve the recommendations as presented by Provider Synergies with the exception of Caduet as preferred and Simcor as non-preferred. The motion was seconded by Dr. Tingle and approved unanimously by the Committee.

PLATELET AGGREGATION INHIBITORS
Mr. Wuest noted that this class has no new agents in it since the last time the Committee reviewed it in November 2009. He provided an overview of the class.

Mr. Wuest presented the PDL recommendations:

Brand Name (Route)	Current PDL Status	PDL Recommendations
AGGRENOX (ORAL)	PDL	PDL
DIPYRIDAMOLE (ORAL)	PDL	PDL
EFFIENT (ORAL)	NPD	NPD

PLAVIX (ORAL)	PDL	PDL
TICLOPIDINE (ORAL)	NPD	NPD

Public testimony on this class was provided on Effient by Kirsten Mar PharmD on behalf of Eli Lilly.

Donna Erwin from Bristol-MyersSquibb yielded her time back to the Committee.

Dr. O' Dell made a motion to accept the recommendations as presented. This motion was seconded by Dr. Azomani. The motion passed unanimously.

ANTICOGULANTS, INJECTABLE

Mr. Wuest stated that there was no new pertinent drug information for this class since the last time the Committee reviewed the class.

Mr. Wuest presented the PDL recommendations to the Committee:

Brand Name (Route)	Current PDL Status	PDL Recommendations
ARIXTRA (SUBCUTANE.)	PDL	PDL
FRAGMIN (SUBCUTANE.)	PDL	PDL
LOVENOX (SUBCUTANE.)	PDL	PDL

No public testimony on this class was provided.

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

MULTIPLE SCLEROSIS AGENTS

Mr. Wuest presented guidelines from the American Academy of Neurology and the MS Council fro Clinical Practice state that interferon-beta is appropriate for treatment of MS. He stated that route of administration is not clinical important with regard to effectiveness, but it does have an impact on the side-effect profile.

Mr. Wuest made the following recommendations to the Committee:

Brand Name (Route)	Current PDL Status	PDL Recommendations
AVONEX (INTRAMUSC.)	PDL	PDL
BETASERON (SUBCUTANE.)	PDL	PDL
COPAXONE (SUBCUTANE.)	PDL	PDL
EXTAVIA (SUBCUTANE.)	PDL	NPD
REBIF (SUBCUTANE.)	PDL	PDL

Public testimony on this class was provided on Avonex by Eillen O'Connor PharmD on behalf of BioGen Idec and on Extavia by Julia Compton PharmD on behalf of Novartis.

Dr. Harper made a motion to accept the recommendations as presented with the

exception of preferring Avonex. The motion was seconded by Mr. Hicks and passed unanimously.

SEDATIVE / HYPNOTICS
Mr. Wuest stated that there is no significant new clinical information to present for this class.

He presented the following PDL recommendations:

Brand Name (Route)	Current PDL Status	PDL Recommendations
AMBIEN CR (ORAL)	NPD	NPD
DORAL (ORAL)	NPD	NPD
EDLUAR (SUBLINGUAL)	NPD	NPD
ESTAZOLAM (ORAL)	PDL	PDL
FLURAZEPAM (ORAL)	PDL	PDL
LUNESTA (ORAL)	PDL	NPD
ROZEREM (ORAL)	PDL	NPD
TEMAZEPAM (ORAL)	PDL	PDL
TEMAZEPAM 22.5 MG (ORAL)	PDL	NPD
TEMAZEPAM 7.5 MG (ORAL)	PDL	NPD
TRIAZOLAM (ORAL)	PDL	PDL
ZALEPLON (ORAL)	PDL	PDL
ZOLPIDEM (ORAL)	PDL	PDL

Public testimony on this class was provided on Lunesta by Chelsea Grow MD on behalf of Sepracor.

Dr. O' Dell made a motion to accept the recommendations as presented with the exception of preferring Lunesta. The motion was seconded by Dr. Wales and passed unanimously by the Committee.

ANTICONVULSANTS
Mr. Wuest stated that there were no new agents in this class since the last time the Committee review the class. There were also no new clinical updates.

Mr. Wuest made the following recommendations to the Committee:

Brand Name (Route)	Current PDL Status	PDL Recommendations
BANZEL (ORAL)	NPD	NPD
CARBAMAZEPINE (ORAL)	PDL	PDL
CARBAMAZEPINE XR (ORAL)	PDL	PDL
CARBATROL (ORAL)	PDL	PDL
CELONTIN (ORAL)	NPD	NPD
DEPAKOTE ER (ORAL)	PDL	PDL
DEPAKOTE SPRINKLE (ORAL)	PDL	PDL
DILANTIN INFATAB (ORAL)	PDL	PDL
DIVALPROEX (ORAL)	PDL	PDL
DIVALPROEX ER (ORAL)	PDL	PDL
DIVALPROEX SPRINKLE (ORAL)	PDL	PDL
EQUETRO (ORAL)	PDL	PDL
ETHOSUXIMIDE (ORAL)	PDL	PDL
FELBATOL (ORAL)	NPD	NPD
GABAPENTIN (ORAL)	PDL	PDL
GABITRIL (ORAL)	PDL	PDL
KEPPRA SOLUTION (ORAL)	NPD	NPD
KEPPRA XR (ORAL)	NPD	NPD
LAMICTAL ODT (ORAL)	PDL	PDL
LAMICTAL XR (ORAL)	PDL	PDL
LAMOTRIGINE (ORAL)	PDL	PDL
LEVETIRACETAM SOLUTION (ORAL)	PDL	PDL
LEVETIRACETAM TABLETS (ORAL)	PDL	PDL
OXCARBAZEPINE SUSPENSION (ORAL)	PDL	PDL
OXCARBAZEPINE TABLETS (ORAL)	PDL	PDL
PEGANONE (ORAL)	NPD	NPD
PHENYTEK (ORAL)	PDL	PDL
PHENYTOIN (ORAL)	PDL	PDL
SABRIL (ORAL)	NPD	NPD
STAVZOR (ORAL)	NPD	NPD
TOPAMAX SPRINKLE (ORAL)	NPD	NPD
TOPIRAMATE SPRINKLE (ORAL)	PDL	PDL
TOPIRAMATE TABLETS (ORAL)	PDL	PDL
TRILEPTAL SUSPENSION (ORAL)	PDL	PDL
VALPROIC ACID (ORAL)	PDL	PDL
VIMPAT (ORAL)	NPD	NPD
ZONISAMIDE (ORAL)	PDL	PDL

Public testimony on this class was provided on Keppra XR and Vimpat by Nate Bailey RPh on behalf of UCB Inc.

Shannon Howorth PharmD from GlaxoSmithKline yielded her time back to the Committee.

The Committee discussed the many agents in this class and stated that they have a concern that many practitioners may not understand the proper use of these agents. They requested that the Staff evaluate the possibility of an educational outreach program. Dr. Clark stated that she felt it was a good idea and the Staff would look into it.

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

ANTIPARKINSON'S AGENTS

Mr. Wuest stated that bromocriptine has been added to this class. Otherwise, there was no significant new clinical information to report in this class.

He then presented the following recommendations to the Committee:

Brand Name (Route)	Current PDL Status	PDL Recommendations
AZILECT (ORAL)	NPD	NPD
BENZTROPINE (ORAL)	PDL	PDL
BROMOCRIPTINE (ORAL)	NR	PDL
CARBIDOPA / LEVODOPA (ORAL)	PDL	PDL
CARBIDOPA / LEVODOPA ODT (ORAL)	PDL	PDL
COMTAN (ORAL)	NPD	NPD
MIRAPEX (ORAL)	NPD	NPD
PRAMIPEXOLE (ORAL)	NPD	NPD
REQUIP XL (ORAL)	NPD	NPD
ROPINIROLE (ORAL)	PDL	PDL
SELEGILINE (ORAL)	PDL	PDL
STALEVO (ORAL)	PDL	PDL
TASMAR (ORAL)	NPD	NPD
TRIHEXYPHENIDYL (ORAL)	PDL	PDL
ZELAPAR (ORAL)	NPD	NPD

There was no public testimony.

Dr. Tingle made a motion to approve the PDL as recommended. The motion was seconded by Dr. O' Dell and was passed unanimously.

PAH AGENTS

Mr. Wuest presented clinical data on two new inhaled agents in this class. He stated that these agent were not first line treatment for newly diagnosed patients.

He then presented the following recommendations to the Committee:

Brand Name (Route)	Current PDL Status	PDL Recommendations
ADCIRCA (ORAL)	NPD	NPD
LETAIRIS (ORAL)	PDL	PDL
REVATIO (ORAL)	PDL	PDL
TRACLEER (ORAL)	PDL	PDL
TYVASO (INHALATION)	NR	NPD
VENTAVIS (INHALATION)	NR	NPD

Public testimony on this class was provided on Ventavis by Allison Widitz PA on behalf of Actelion.

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

BLADDER RELAXANTS

Mr. Wuest presented an update from the Agency for Healthcare Research and Quality (AHRQ). The AHRQ released an evidence-based review on the treatment of overactive bladder (OAB), urge urinary incontinence and related symptoms in women. The AHRQ stated that all pharmacologic treatments are effective at improving one or more of the symptoms of Over Activity Bladder when compared to placebo. No single drug was definitively superior to others by a preponderance of evidence including a comparison of newer selective agents to the older antimuscarinic agents.

He then presented the following recommendations to the Committee:

Brand Name (Route)	Current PDL Status	PDL Recommendations
DETROL (ORAL)	NPD	NPD
DETROL LA (ORAL)	PDL	PDL
ENABLEX (ORAL)	PDL	PDL
GELNIQUE (TRANSDERM.)	NPD	PDL
OXYBUTYNIN (ORAL)	PDL	PDL
OXYBUTYNIN ER (ORAL)	NPD	NPD
OXYTROL (TRANSDERM.)	PDL	NPD
SANCTURA (ORAL)	PDL	NPD
SANCTURA XR (ORAL)	PDL	NPD
TOVIAZ (ORAL)	NPD	PDL
VESICARE (ORAL)	NPD	NPD

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

Dr. Voluters made a motion to accept the recommendations as presented. Dr. O' Dell seconded the motion, which then passed unanimously.

BPH AGENTS
Mr. Wuest stated that there is no significant new clinical information to present for this class, but he did provide an overview of the class.

Mr. Wuest presented the PDL recommendations to the Committee:

Brand Name (Route)	Current PDL Status	PDL Recommendations
AVODART (ORAL)	PDL	PDL
CARDURA XL (ORAL)	NPD	NPD
DOXAZOSIN (ORAL)	PDL	PDL
FINASTERIDE (ORAL)	PDL	PDL
FLOMAX (ORAL)	PDL	PDL
RAPAFLO (ORAL)	NPD	NPD
TERAZOSIN (ORAL)	PDL	PDL
UROXATRAL (ORAL)	PDL	PDL

Shannon Howorth PharmD from GlaxoSmithKline yielded her time back to the Committee.

Dr. Harper made a motion to approve the recommendations. The motion was seconded by Dr. Wales. The motion was approved unanimously.

PHOSPHATE BINDERS
Mr. Wuest states that there were no new agents in this class. At the last review of this class it was expected that Renagel would be exiting the market. He added this has not happened to date and it is now expected to available through 2010.

He then presented the following PDL recommendations:

Brand Name (Route)	Current PDL Status	PDL Recommendations
CALCIUM ACETATE (ORAL)	PDL	PDL
ELIPHOS (ORAL)	PDL	PDL
FOSRENOL (ORAL)	PDL	NPD
PHOSLO (ORAL)	PDL	PDL
RENAGEL (ORAL)	PDL	PDL
RENVELA (ORAL)	NPD	PDL

Public testimony on this class was provided on Fosrenol by Andy Kim PharmD on behalf of Shire and on Renvela by Marcelo Ruvinsky MD on behalf of Central Nephrology.

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

ERTHROPOIESIS STIMULATING PROTEINS
Mr. Wuest provided an overview of the class. He also pointed out the 1 to 200 conversion applied to the mcg of Aranesp and units of Procrit and Epogen. He reviewed new updated Box Warning for these drugs

Mr. Wuest presented the following recommendations:

Brand Name (Route)	Current PDL Status	PDL Recommendations
ARANESP (INJECTION)	PDL	PDL
EPOGEN (INJECTION)	NPD	NPD
PROCRIT (INJECTION)	PDL	PDL

Janice Lopez PharmD from Johnson and Johnson yielded her time back to the Committee.

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

OTHER BUSINESS
There was no other business.

NEXT MEETING DATE
Ms. Clark stated that next year's P&T Committee meeting schedule would be April 13th 2010.

ADJOURNMENT
There being no further business, Dr. Miner adjourned the meeting.