LOUISIANA DEPARTMENT OF HEALTH AND HOSPITALS
Medicaid Pharmaceutical and Therapeutics Committee Meeting
August 11, 2010
Galvez Building
Oliver Polluck/Pensacola Rooms
602 North Fifth Street
Baton Rouge, LA

MINUTES

MEMBERS PRESENT:
Damion Cummins, PhD
John E. Firestone, Jr., MD
Conchetta Fulton, PharmD
Mary Gauthier-Lewis, Pharm D
Amy Givler, MD
Larry J. Hebert, MD
James E.Hussey, MD
Edward C. Mader, Jr, MD
Marty R.McKay, RPh
Fred Mills,RPh, State Rep.
Melvin Murrill, MD
Julie Wilkinson, PharmD
Rodney Wise, MD
Pamela Wiseman, MD
Neil Wolfson, MD
Lolie C. Yu, MD

MEMBERS ABSENT:
Anita Kablinger, MD
Kenyatta D. Shamlin, MD
Mohammad Suleman, MD
Leonard Weather, Jr, MD

DHH PHARMACY PROGRAM STAFF PRESENT:
M. J. Terrebonne, RPh Director
Rachel Broussard, RPh
Germaine Becks-Moody, PhD, BHSF Program Manager
Timothy Williams, BHSF Program Manager
Carol Rumfola, Administrative Assistant

OTHER DHH STAFF PRESENT:
Kimberly Sullivan, Attorney
Daniel L. Duhon, Attorney

CONTRACTORS PRESENT:
Chris Andrews, PharmD, Provider Synergies
Melissa Dear, PharmD, University of La at Monroe School of Pharmacy
Tara Torres-Blank, Certified Court Reporter

OTHERS PRESENT:
Presenters are listed in the minutes, and sign in sheets of others in attendance are available from DHH, Bureau of Health Services Financing, Pharmacy Benefits Section upon request.

Call to Order:
Dr. Larry Hebert, Chairman, called the meeting to order at 8:56 a.m.

Parliamentary Business:

A. **Introduction of Members and DHH Staff.** Committee members introduced themselves, and Ms. M. J. Terrebonne introduced the DHH staff. Roll call followed.

B. **Approval of Minutes.** Dr. Murrill offered a motion to approve the minutes of the February 10, 2010 meeting as submitted. Dr. Wilkinson seconded the motion which passed.

P&T Committee Overview:

A. **Pharmaceutical and Therapeutics Committee Background.** Ms. M. J. Terrebonne, RPh, the DHH Medicaid Pharmacy Program Director, presented an overview of the Pharmaceutical and

Therapeutics (P&T) Committee and the legislation that authorized the creation of a prior authorization (PA) drug program, a preferred drug list (PDL), supplemental rebates, and the P&T Committee. Her comments follow.

"Act 395 authorizes the Department of Health and Hospitals to establish a drug list utilizing a prior approval process or any other processes or combination of processes that prove to be cost effective in the Medicaid program.

We have entered in contractual arrangements with the University of Louisiana at Monroe (ULM) to perform the PA function and also with Provider Synergies.

The Medicaid P&T Committee was established in August of 2001. It consists of 21 members appointed by the Governor. Their charge is to review clinical and cost data on various therapeutic classes of drugs. We currently meet biannually.

On June 10, 2002, the Department implemented the preferred drug list (PDL) with prior authorization (PA) as well as a Supplemental Drug Rebate Program through a phased in approach.

With ULM, through the PA function, and Provider Synergies to negotiate the State supplemental rebates, the preferred drug list is updated biannually in April and October based on the Committee's recommendations.

Provider Synergies negotiates the State supplemental rebates with the drug manufacturers. They prepare therapeutic class reviews; they provide cost analysis information from the therapeutic classes; and they develop clinically sound and cost-effective recommendations to develop and manage the PDL.

As you can see from this slide, through the years the number of classes has grown. We currently have seventy-four (74) therapeutic classes that are reviewed.

Just to give you a little information on the Pharmacy Program, as you can see, in Fiscal Year 2010, there were 10.9 million pharmacy claims paid for about 861,000 Medicaid patients for an expenditure total of $857 million.

In federal rebates we obtained $280 million, and we received $43.6 million in State supplemental rebates.

So you can see the net growth over the pharmacy program over the last three Years has really been very manageable; that's been a good thing, but still very costly, but still the increase has not been so great."

The presentation is attached. ***(Attachment 1)***

B. **P&T Bylaws.** DHH Staff Attorney, Mr. Daniel Duhon, presented the Committee's Bylaws. He told the Committee that it serves at the pleasure of the Governor, and the members may not entertain individuals lobbying or marketing or partake of any other activities that would call into question their impartiality when they vote on drugs recommended for the preferred drug list.

The chairman and vice chairman are elected by the members of the Committee. The Committee shall meet quarterly or as prescribed by the chairman. Regular meetings are held on the first Wednesday of the month or on the next available Wednesday.

He said the Committee is governed by Robert's Rules of Order and must provide an opportunity for public comment, subject to reasonable rules that are adopted by the Committee. The Committee cannot take up an item that is not on the agenda, unless there's unanimous approval of all the members present at the meeting. Prior to any vote on the motion to take up a new agenda item, there shall be an opportunity for public comment.

The Bylaws can be amended by the majority of the members, and a copy of any new proposed Bylaws must be provided at least two weeks before anyone votes on them.

A quorum of this Committee is established by the presence of the majority, and five have to be physicians and one has to be a pharmacist. If there is no quorum, the meeting must be cancelled and rescheduled at the earliest possible date.

C. **Ethics Review.** Mr. Duhon then addressed the Committee regarding ethics and provided updated information on the Louisiana Code of Governmental Ethics as it relates to the Committee. He said members of the Committee must comply with the Louisiana Code of Governmental Ethics.

Mr. Duhon said actions by the P&T Committee are considered Executive Branch actions, and the state statute specifically prohibits lobbying P&T Committee members.

He told the members they are deemed State employees and that's why they must comply with the Code. Section 115 of the Code prohibits a public servant from soliciting or accepting a thing of economic value from a person who has or seems to have a contractual business or financial relationship with the public servant's agency or who has a substantial economic interest or would be substantially affected by the performance or nonperformance of a public servant's official duties. There have been some rulings about things of economic value.

He said pharmaceutical samples are not considered a thing of economic value as long as they are given to a patient at no cost, and Committee members can accept notepads, pens and similar items from pharmaceutical companies. Also, members can have meals paid for by a pharmaceutical company as long as the meals are consumed in the pharmaceutical company representative's presence. The new $50 limit per event applies. The limit does not apply to a gathering held in conjunction with a meeting relating to a national or regional organization or a meeting of a statewide organization of government officials.

He told the members they are prohibited from receiving honorariums or reimbursement of any kind, including grants from pharmaceutical companies included or seeking to be included on the PDL or have matters before the Committee. Members can attend a conference or seminar sponsored by a pharmaceutical company, but the members must pay their own expenses associated with the trip. Also, if a member is employed by a university, the member cannot solicit grants from the pharmaceutical companies on behalf of the university. Mr. Duhon also informed the members they are not required to file financial disclosure statements under the new ethics rules.

He cautioned the members they should get an advisory opinion from the Louisiana Board of Ethics if they have any questions or concerns about compliance with the Code of Ethics. The

website for the Board of Ethics is www.ethics.state.la.us. The Board's address is P.O. Box 4368, Baton Rouge, LA 70821, and the telephone numbers are 225-219-5600 or 1-800-842-6630.

Mr. Duhon offered to answer any questions the members may have. His email address is Daniel.duhon@la.gov, and his telephone number is 225-342-2520.

D. **Travel Regulations.** Ms. Terrebonne told the Committee members the Travel Regulations Guide was sent to them. prior to the meeting. She requested they contact Dr. Germaine Becks-Moody, her staff member, after the meeting if they had any questions.

Reports:

A. **Prior Authorization (PA) Monthly Report.** Ms. M. J. Terrebonne called the Committee members' attention to the PA Report included in their packets. She said the report shows monthly PA data and indicates trends in PA requests. ***(Attachment 2)***

B. **PDL Reflecting February 10, 2010 P & T Committee Recommendations.** Ms. Terrebonne reported copies of the latest version of the PDL, which included the Pharmaceutical and Therapeutics (P&T) Committee's February 10, 2010 meeting recommendations were in the members' packets. These recommendations became effective April 1, 2010. ***(Attachment 3)***

Old Business:

A. **Plavix/Omeprazole Issue.** Ms. Terrebonne reported that at the February meeting, the Committee recommended to the Department that staff discuss with the DUR Board the issue of concurrent use of Plavix and Omeprazole.

The following is a chronology of the Board's actions.

In October and November of 2009, the DUR committees did send out intervention letters to providers for recipients who were utilizing those drugs concurrently.

In February 2010, the P&T Committee recommended that DHH staff go to the DUR Board and implement clinical edits for the use of those two drugs at the same time.

In March and included in the Committee's stack of papers today, the DHH drug utilization committees began sending out provider updates to the providers and there was an article in regards to that topic. The Committee members were given a handout of that article. ***(Attachment 4)***

In July 2010, DHH, through its Point of Sale pharmacy claims editing, established an educational alert which alerts the pharmacist of the use of Plavix with the proton pump inhibitors.

So DHH staff did take some action and is continuing to monitor this issue.

New Business:

A. **Affordable Care Act.** Mr. Chris Andrews with Provider Synergies presented the next agenda item, the federal Affordable Care Act. In early 2010, the US Congress passed the federal Affordable Care Act that is going to negatively impact states' Supplemental Rebate Programs. Mr. Andrews' presentation is attached per the Committee's request. ***(Attachment 5)***

B. **Explanation of TOP$, Monographs and Cost Sheets.** Dr. Chris Andrews, Provider Synergies, explained that Provider Synergies currently works with seven (7) states in their PDL programs.

He explained Louisiana is a member of the TOP$ Program. It is a multi-state purchasing pool. TOP$ stands for *The Optimal PDL Solution*. Louisiana is a charter member of the pool established in 2005. This year Louisiana is one of seven states participating in the pool. He emphasized, while Provider Synergies tries to make recommendations that are the same across all states, the state does have final authority on its PDL.

He said that federal rebates are paid by manufacturers covered by the Medicaid program. In addition some states require state supplemental rebates, and that is the program with which Provider Synergies works. Provider Synergies negotiates rebates for its contract states. The supplemental rebate contracts are negotiated for one year. He said Provider Synergies does not receive any portion of the rebates.

Dr. Andrews then explained the therapeutic classifications selected for review and the monographs used by the Committee for deliberations. The date on the title page of each class monograph represents the date of the last edit of the monograph. The relative cost symbols shown on the monograph cost sheets are used to explain the relative costs of products in a class as state law requires confidentiality on the rebates.

A copy of Dr. Andrews' presentation is attached per Dr. Givler's request. ***(Attachment 5)***

C. **SMAC/Revised Reimbursement Methodology for Generics.** Ms. Terrebonne informed the Committee that DHH has been addressing the issue of reimbursement methodologies regarding generic drugs. On February 1, 2010, the Department implemented a new reimbursement methodology for approximately 1,010 unique generic descriptions. As a result the Committee members will probably see more generics on the PDL. However, that does not mean there will always be generics on the PDL. The new methodology may have some impact on some of the therapeutic classes that are scheduled for review in future meetings. Ms. Terrebonne said she was sharing this information with the Committee, because the Committee has questioned generics requiring PAs in the past. She said Dr. Chris Andrews, Provider Synergies, and she would be available to answer the members' questions.

D. **Public Testimony.** In accordance with state law and the P&T Committee's Bylaws, the following provided public testimony or answered questions raised by the Committee during the Committee's review of the therapeutic classes.

PRESENTER	REPRESENTING	DRUG/ISSUE
Paul Dammers, MD		Namenda
Mike DeLucia, RPh	Forest	Namenda
Todd Berner	Endo	Lidoderm
Sherwanna Clarke	Abbott	Androgel
Esther Liu, PharmD	Eli Lilly	Cymbalta
Cherie Robertson	Pfizer	Pristiq
Paul Dammers, MD		Lexapro
Mike DeLucia, RPh	Forest	Lexapro
Andrew Cardison, MD	Strateva Pharma	Oravig

Jay Collinsworth, MD		Ovide
Steve Whiten	TARO	Ovide
Kenneth Jackson	Shionogi	Ulesfia
Mark Gordon, MD	Boehringer Ingelheim	Mirapex ER
Tarolyn Carlton	Otsuka	Abilify
Jennifer Jantz	NAMI	
Sylvia Pearson	Extra Mile	
Fran Kaiser, MD	Merck & Co	Saphris
Jamie Street, MD	Astra Zeneca	Seroquel/Seroquel XR
Julie Comptom	Novartis	Fanapt
Cherie Robertson	Pfizer	Geodon
Melanie Cruin	Ortho McNeil Janssen	Invega Sustenna, Risperdal Consta, Invega
Aruen Podesta, MD	Merck & Co	Saphris
Marilyn Ripoll	Astellas	Protopic
Derek Terada, MD	Boehringer Ingelheim	Spiriva
James Osborne	Glaxo Smith Kline	Ventolin HFA, Serevent
Kelly Flint	Nephron Pharmaceuticals	Albuterol
Shane Perrilloux	TEVA Respiratory	Pro Air HFA
Steven Rucgardsib	Lupin	Suprax
Courtney Walker, PharmD	Centocor	Stelara, Simpoi, Remicade
Scott Sabrsulla	Amgen	Enbrel
Sherwanna Clarkes	Abbott	Humira
Tanya Kidd	UCB	Cimzia
James Osborne	Glaxo Smith Kline	Flovent, Advair
Benjamin Everett	Astra Zeneca	Symbicort
Fran Kaiser, MD	Merck & Co	Asmanex
Shane Perrilloux	TEVA Respiratory	QVAR
Marjan Massoudi	Amylin	Byetta
Kristie Raker, MD	Novo Nordisk	Victoza
Fran Kaiser, MD	Merck & Co	Januvia, Janumet
Esther Liu, PharmD	Eli Lilly	Humalog
Lori Long, Pharm D	Sanofi Aventis	Lantuis
Kristie Raker, MD	Novo Nordisk	Levimir, Novolog, Novolog Mix
James Osborne	Glaxo Smith Kline	Veramyst
Fran Kaiser, MD	Merck & Co	Singulair
Cherie Robertson	Pfizer	Celebrex
Lonnie Wen	Pfizer	Sutent
Mitchell Berger, MD	OLOL & Mary Bird Perkins	All Oral Oncolytics
Mary Jo Wickers	LA Oncology Association	All Oral Oncolytics
Deanne Halliman, Phd	Bausch & Lomb	Besivance
		Alrex
		Lotemax
Cherie Robertson	Pfizer	Xalatan
Sherwanna Clarke	Abbott	Creon
Derek Terada, MD	Boehringer Ingelheim	Aggrenox
Esther Liu, PharmD	Eli Lilly	Effient
Kathleen Pinto, MD	Bristol Myers Squibb	Plavix

Esther Liu, PharmD	Eli Lilly	Strattera
Angela LeDay	Shire	Intuniv
John deBack, MD	Self	Intuniv
Melanie Crain	J&J	Concerta
Phillip Kenner	Acorda	Ampyra

(Transcripts of testimonies are available from DHH, Bureau of Health Services Financing, Pharmacy Benefits Section, upon request.)

E. **Therapeutic Classes Reviews.** Forty three (43) therapeutic classes in ***Group Two*** of the ***Ninth Review Cycle*** were reviewed. Monograph summaries were sent to the Committee prior to the meeting. Public comment was received for each therapeutic class prior to Committee discussion and action in accordance with state law and the P&T Committee's Bylaws. Committee proceedings follow:

Class Review Number

9-2;1. Alzheimer's Agents

Dr. Murrill offered the motion to accept Provider Synergies' recommendation. The motion seconded by Dr. Lewis, passed unanimously with a roll call vote.

*Committee Recommendations for the **PDL** are:*
Donepezil (Aricept)
Donepezil (Aricept ODT)
Memantine HCl (Namenda)
Rivastigmine Oral Capsules (Exelon)
Rivastigmine Transdermal (Exelon Transdermal)

*Committee Recommendations for the **NPDL** are:*
Galantamine
Galantamine ER
Rivastigmine Oral Solution (Exelon Solution)

Note: Tacrine (Cognex) is no longer available.

9-2;2. Analgesics-Anesthetics, Topical

The Committee was instructed by Dr. Chris Andrews to disregard Qutenza in its deliberations as it is a physician administered product. Mr. McKay offered the motion to accept Provider Synergies' recommendations which excluded Qutenza. The motion seconded by Dr. Firestone, passed unanimously with a roll call vote.

*Committee Recommendations for the **PDL** are:*
Diclofenac Sodium Gel (Voltaren)
Lidocaine Patch (Lidoderm)

*Committee Recommendations for the **NPDL** are:*
Diclofenac Epolamine Patch (Flector)
Diclofenac Sodium (Pennsaid)

9-2;3. Androgenic Agents

Mr. McKay offered the motion to accept Provider Synergies' recommendation. The motion seconded by Dr. Wilkinson, passed unanimously with a roll call vote.

*Committee Recommendations for the **PDL** are:*
Testosterone Transdermal Patch (Androderm)
Testosterone Gel 1% (Androgel)

*Committee Recommendations for the **NPDL** are:*
Testosterone Gel 1% (Testim)

9-2;4. Antibiotics, Inhaled – *New Category*

Dr. Firestone offered the motion to accept Provider Synergies' recommendation. The motion seconded by Mr. McKay, passed unanimously with a roll call vote.

*Committee Recommendations for the **PDL** are:*
Tobramycin (Tobi)

*Committee Recommendations for the **NPDL** are:*
Azteonam (Cayston)

9-2;5. Antibiotics, Vaginal

Mr. McKay offered the motion to accept Provider Synergies' recommendation. The motion seconded by Dr. Murrill, passed unanimously with a roll call vote.

*Committee Recommendations for the **PDL** are:*
Clindamycin Vaginal Cream
Clindamycin Vaginal Ovules (Cleocin)
Metronidazole Vaginal Gel Cream
Metronidazole Vaginal Gel Cream (Vandazole)

*Committee Recommendations for the **NPDL** are:*
Clindamycin Vaginal Cream (Clindesse)

9-2;6 Antidepressants, Other

Dr. Hussey offered the motion to accept Provider Synergies' recommendation. The motion was seconded by Dr. Mader.

Discussion followed. Dr. Andrews, Provider Synergies, noted there were several extended release (XR) drugs in this category. He pointed out that it seems Effexor XR would be one of those XR products included under the Affordable Care Act line extension provisions. He said it was his guess the result under the new law would be decreased reimbursement to the state because the federal rebate would go to the federal government. This would also apply to the Venlafaxine ER tablets, but to a lesser extent as it is a generic. The best option for the state according to Dr. Andrews is to use the

generic form of that product.

During the discussion, Dr. Andrews noted Cymbalta is normally reviewed in the fibromyalgia class, however, since that class was not reviewed by Louisiana in February, Cymbalta was being reviewed today as part of this class.

Mr. McKay asked Dr. Andrews since Effexor XR has been out for a significant portion of time, did he think the federal government is going to pull the rebates from it. Dr. Andrews replied that it is their expectation that any product existing on the market is going to be subject to line extension provisions of the yet to be enacted federal legislation. Also, the current interpretation is even ER products that have been generic f or several years will have their rebates taken by the federal government.

In response to Mr. McKay's question, Mr. Andrews explained the supplemental rebate program does not currently solicit for rebates on generics.

The Committee then voted and passed Provider Synergies' recommendations unanimously with a roll call vote.

*Committee Recommendations for the **PDL** are:*
Bupropion HCl IR
Bupropion HCl SR
Mirtazapine
Trazodone
Venlafaxine ER Tabs
Venlafaxine ER Tabs (generic only)

*Committee Recommendations for the **NPDL** are:*
Bupropion HBr ER (Aplenzin)
Bupropion HCl XL
Desvenlafaxine (Pristiq)
Duloxetine (Cymbalta)
Nefazodone
Selegiline Patch (Emsam)
Venlafaxine
Venlafaxine ER Cap
Venlafaxine ER (Effexor XR)

9-2;7. Antidepressants, Selective Serotonin Reuptake Inhibitors (SSRIs)
Mr. McKay offered the motion to accept Provider Synergies' recommendation. The motion seconded by Dr. Wilkinson, passed unanimously with a roll call vote.

*Committee Recommendations for the **PDL** are:*
Citalopram
Escitalopram (Lexapro)
Fluoxetine
Fluvoxamine
Paroxetine
Sertraline

*Committee Recommendations for the **NPDL** are:*
Fluvoxamine CR (Luvox CR)
Fluoxetine Weekly
Paroxetine CR
Paroxetine Mesylate (Pexeva)

9-2;8. Antiemetics

Dr. Yu offered the motion to accept Provider Synergies' recommendation. The motion seconded by Mr. McKay, passed unanimously with a roll call vote.

*Committee Recommendations for the **PDL** are:*
Dronabinol (Marinol – Brand Only)
Ondansetron / Ondansetron ODT

*Committee Recommendations for the **NPDL** are:*
Aprepitant (Emend)
Dolasetron (Anzemet)
Dronabinol (generic only)
Granisetron
Granisetron Transdermal (Sancuso)
Nabilone (Cesamet)

9-2;9. Antifungals, Oral

Dr. Lewis offered the motion to accept Provider Synergies' recommendation. The motion seconded by Dr. Wolfson, passed unanimously with a roll call vote.

*Committee Recommendations for the **PDL** are:*
Fluconazole
Griseofulvin Suspension
Griseofulvin (Gris-PEG)
Ketoconazole
Nystatin
Terbinafine (no granules)

*Committee Recommendations for the **NPDL** are:*
Clotrimazole Troches
Flucytosine (Ancobon)
Griseofulvin (Grifulvin V Tablets)
Itraconazole
Micanazole (Oravig)
Posaconazole (Noxafil)
Terbinafine (Terbinex)
Terbinafine Granules (Lamisil Granules)
Voriconazole (Vfend)

9-2;10. Antifungals, Topical

Dr. Fulton offered the motion to accept Provider Synergies' recommendation. The

motion was seconded by Dr. Firestone.

Dr. Murrill offered an amendment to add Oxistat topical to the Provider Synergies' recommendations for the PDL. The motion seconded by Mr. McKay, passed unanimously by voice vote.

The amended motion to accept Oxistat plus Provider Synergies' recommendation passed unanimously with a roll call vote.

*Committee Recommendations for the **PDL** are:*
Clotrimazole Rx
Clotrimazole/Betamethasone
Ketoconazole Cream
Ketoconazole Shampoo (Rx only)
Naftifine (Naftin)
Nystatin
Nystatin/Triamcinolone
Oxiconazole (Oxistat)

*Committee Recommendations for the **NPDL** are:*
Butenafine (Mentax)
Ciclopirox (CNL-8)
Ciclopirox Cream
Ciclopirox Gel
Ciclopirox Shampoo
Ciclopirox Solution
Ciclopirox Suspension
Econazole
Ketoconazole Foam (Extina)
Ketoconazole (Xolegel)
Miconazole/zinc oxide/white petrolatum (Vusion)
Sertaconazole (Ertaczo)
Sulconazole (Exelderm)

9-2-11. Antihyperuricemics

Mr. McKay offered the motion to accept Provider Synergies' recommendation. The motion seconded by Dr. Wilkinson, passed unanimously with a roll call vote.

*Committee Recommendations for the **PDL** are:*
Allopurinol
Colchicine
Probenecid
Probenecid/Colchicine

*Committee Recommendations for the **NPDL** are:*
Colchicine (Colcrys)
Febuxostat (Uloric)

9-2;12. Antiparasitic Agents, Topical

Dr. Lewis offered the motion to accept Provider Synergies' recommendation. The motion seconded by Dr. Murrill, passed unanimously with a roll call vote.

Committee Recommendations for the PDL are:
Benzyl Alcohol (Ulesfia)
Crotamiton (Eurax)
Malathion (Ovide – Brand Only)
Permethrin

Committee Recommendations for the NPDL are:
Lindane
Malathion (generic only)

9-2;13. Antiparkinson's Agents

Mr. McKay offered the motion to accept Provider Synergies' recommendation. The motion was seconded by Dr. Murrill.

Dr. Mader offered a motion to amend the motion to add Requip XL. Dr. Firestone seconded the motion. Discussion followed. The amendment failed with a voice vote of fourteen nays and one yea, Dr. Mader.

The original motion to accept Provider Synergies' recommendation then passed unanimously by roll call vote.

*Committee Recommendations for the **PDL** are:*
Benztropine
Levodopa/Carbidopa
Levodopa/Carbidopa/Entacapone (Stalevo)
Pramipexole (Generic only)
Ropinirole
Selegiline
Trihexyphenidyl

*Committee Recommendations for the **NPDL** are:*
Bromocriptine
Entacapone (Comtan)
Levodopa/Carbidopa ODT
Pramipexole (Mirapex)
Pramipexole ER (Mirapex ER)
Rasagiline (Azilect)
Ropinirole ER (Requip XL)
Selegiline (Zelapar)
Tolcapone (Tasmar)

9-2;14. Antipsychotics

Dr. Hussey offered the motion to accept Provider Synergies' recommendation. The motion was seconded by Dr. Fulton. Discussion followed.

Dr. Givler offered a motion to amend the original motion and add Seroquel XR to the PDL. Dr. Yu seconded the motion. Discussion and roll call vote followed. There were eleven yeas and four nays by Dr. Hussey, Rep. Mills, Mr. McKay and Dr. Wiseman. The original motion was amended to add Seroquel XR.

Dr. Hussey then offered an amendment to add Saphris to the PDL. Dr. Wolfson seconded the motion. Discussion followed. Dr. Wolfson requested an economic impact report on changes made to the PDL in the various categories. Ms. Terrebonne reported that Provider Synergies does prepare an annual report that should have been sent to the Committee. It was disclosed the report had not been finalized in time for the February meeting, but would be sent to the Committee.

Discussion continued. The question was asked regarding the difference in overall cost of Clozapine, including mandated laboratory costs, versus the cost of Saphris. The amendment then passed to add Saphris by a roll call vote of thirteen yeas and two nays by Rep. Mills and Dr. Yu.

A third motion, made by Dr. Murrill, was to add Abilify to the Provider Synergies' recommendations. Dr. Wiseman seconded the motion. Discussion followed. The motion failed with a roll call vote of six yeas and nine nays by Dr. Lewis, Dr. Givler, Dr. Hussey, Mr. Mills, Mr. McKay, Dr. Wilkinson, Dr. Wise, Dr.Wolfson and Dr. Yu.

The original motion, as amended to add Seroquel XR and Saphris, passed in a roll call vote with ten yeas and one nay by Rep. Mills.

ORAL

*Committee Recommendations for the **PDL** are:*

Amitriptyline/Perphenazine
Asenapine (Saphris)
Chlorpromazine
Clozapine
Fluphenazine
Haloperidol
Iloperidone (Fanapt)
Molindone (Moban)
Perphenazine
Pimozide (Orap)
Quetiapine (Seroquel)
Quetiapine ER (Seroquel XR)
Risperidone
Thioridazine
Thiothixene
Trifluoperazine
Ziprasidone (Geodon)

*Committee Recommendations for the **NPDL** are:*

Aripiprazole (Abilify)
Clozapine (Fazaclo)
Olanzapine (Zyprexa)
Olanzapine/Fluoxetine (Symbyax)

Paliperidone ER (Invega)

INJECTIONS
*Committee Recommendations for the **PDL** are:*
Fluphenazine Decanoate
Haloperidol Decanoate
Risperidone (Risperdal Consta)
Ziprasidone (Geodon)

*Committee Recommendations for the **NPDL** are:*
Olanzapine (Zyprexa)
Olanzapine (Zyprexa Relprevv)
Paliperidone (Invega Sustenna)

9-2;15. Antiviral Agents, Topical

Mr. McKay offered the motion to accept Provider Synergies' recommendation. The motion was seconded by Dr. Givler.

Discussion followed. Dr. Wolfson then offered a motion, seconded by Mr. McKay to remove Denavir from the PDL. Discussion followed. Passage of this motion would remove all of the drugs from the PDL. The motion failed with a roll call vote of seven yeas and eight nays by Dr. Firestone, Dr. Hussey, Rep. Mills, Mr. McKay, Dr. Wilkinson, Dr. Wise, Dr. Wiseman, and Dr. Yu.

The Committee then voted on the original motion to accept Provider Synergies recommendations. The motion passed with a roll call vote of twelve yeas, two nays by Dr. Lewis and Dr. Mader, and Dr. Wolfson abstaining.

Dr. Hussey requested Provider Synergies perform a study and prepare a report for the Committee on other states' experiences with prescription volumes between Denavir and Acyclovir when Denavir is a non-preferred drug.

*Committee Recommendations for the **PDL** are:*
Penciclovir Cream (Denavir)

*Committee Recommendations for the **NPDL** are:*
Acyclovir Cream (Zovirax)
Acyclovir Ointment (Zovirax)

9-2;16 Atopic Dermatitis

Dr. Wilkinson offered the motion to accept Provider Synergies' recommendation. The motion seconded by Dr. Givler, passed unanimously with a roll call vote.

*Committee Recommendations for the **PDL** are:*
Pimecrolimus (Elidel)
Tacrolimus (Protopic)

*Committee Recommendations for the **NPDL** are:*
None

9-2;17 Bile Acid Salts

Dr. Givler offered the motion to accept Provider Synergies' recommendation. The motion seconded by Dr. Yu, passed unanimously with a roll call vote.

*Committee Recommendations for the **PDL** are:*
Ursodiol (Generics)
Ursodiol USP (Actigall)

*Committee Recommendations for the **NPDL** are:*
Chenodiol (Chenodal)
Ursodiol (URSO 250)
Ursodiol (URSO Forte)

9-2;18. Bone Resorption Suppression and Related Agents

Dr. Givler offered the motion to accept Provider Synergies' recommendation. The motion seconded by Dr. Firestone, passed unanimously with a roll call vote.

*Committee Recommendations for the **PDL** are:*
Alendronate
Calcitonin-salmon Nasal (Generics)
Calcitonin-salmon Nasal (Miacalcin)

*Committee Recommendations for the **NPDL** are:*
Alendronate Solution (Fosamax Solution)
Alendronate/Vit D (Fosamax plus D)
Calcitonin-salmon Nasal (Fortical)
Etidronate Disodium (Generics)
Etidronate (Didronel)
Ibandronate Sodium (Boniva)
Raloxifene (Evista)
Risendronate (Actonel)
Risendronate/Calcium (Actonel with Calcium)
Teriparatide Subcutaneous (Forteo)

9-2;19. Bronchodilators, Anticholinergic

Dr. Givler offered the motion to accept Provider Synergies' recommendation. The motion seconded by Dr. Murrill, passed unanimously with a roll call vote.

INHALATION

*Committee Recommendations for the **PDL** are:*
Albuterol Sulfate/Ipratropium MDI (Combivent)
Ipratropium Nebulizer
Ipratropium Inhalation Aerosol MDI (Atrovent HFA)
Tiotropium Inhalation Powder (Spiriva)

*Committee Recommendations for the **NPDL** are:*
Albuterol Sulfate/Ipratropium Nebulizer

9-2;20. Bronchodilators, Beta Adrenergic Agents

Dr. Lewis offered the motion to accept Provider Synergies' recommendation. The motion seconded by Dr. Firestone, passed unanimously with a roll call vote.

INHALATION

*Committee Recommendations for the **PDL** are:*
Albuterol Sulfate Nebulizer
Albuterol Sulfate HFA (ProAir HFA)
Albuterol Sulfate HFA MDI (Proventil HFA)
Albuterol Sulfate HFA MDI (Ventolin HFA)
Levalbuterol HCL (Xopenex)
Pirbuterol MDI (Maxair Autohaler)

*Committee Recommendations for the **NPDL** are:*
Albuterol Sulfate Nebulizer Low-Dose
Arformoterol Inhalation Solution (Brovana)
Formoterol DPI (Foradil)
Formoterol Inhalation Solution (Perforomist)
Levalbuterol HCL (Generic)
Levalbuterol HFA (Xopenex HFA)
Salmeterol Xinafoate (Serevent Diskus)

ORAL

*Committee Recommendations for the **PDL** are:*
Albuterol Sulfate
Albuterol Sulfate ER
Terbutaline Sulfate

*Committee Recommendations for the **NPDL** are:*
Metaproterenol Sulfate

9-2;21. Cephalosporins and Related Antibiotics

Dr. Givler offered the motion to accept Provider Synergies' recommendation. The motion seconded by Dr. Wilkinson, passed unanimously with a roll call vote.

*Committee Recommendations for the **PDL** are:*
Amoxicillin/Clavulanate Suspension
Amoxicillin/Clavulanate Tablets
Amoxicillin/Clavulanate Susp (Augmentin 125 & 250)
Cefadroxil
Cefixime (Suprax)
Cefprozil
Cefuroxime
Cephalexin

*Committee Recommendations for the **NPDL** are:*
Amoxicillin/Clavulanate ER
Amoxicillin/Clavulanate ER (Augumentin XR)
Cefaclor
Cefaclor ER 500mg
Cefdinir
Cefditoren Pivoxil
Cefpodoxime
Ceftibuten (Cedax)
Cefuroxime Axetil Susp (Ceftin)

9-2;22. Cytokine and CAM Antagonists

Dr. Wolfson offered the motion to accept Provider Synergies' recommendation. The motion was seconded by Dr. Fulton. Discussion followed. Ms. Terrebonne agreed to verify that Stelara, Simponi, and Remicade are not specialty pharmacy drugs, but are available through the physician program. The motion passed unanimously with a roll call vote.

*Committee Recommendations for the **PDL** are:*
Adalimumab Injection (Humira)
Certolizumab Pegol (Cimzia)
Etanercept Injection (Enbrel)

*Committee Recommendations for the **NPDL** are:*
Abatacept (Orencia)
Alefacept Injection (Amevive)
Anakinra Injection (Kineret)
Golimumab (Simponi)
Infliximab Injection (Remicade)
Tocilizumab (Actemra)

9-2;23. Fluoroquinolones, Oral

Dr. Mader offered the motion to accept Provider Synergies' recommendation. The motion seconded by Dr. Givler, passed unanimously with a roll call vote.

*Committee Recommendations for the **PDL** are:*
Ciprofloxacin Tablets
Moxifloxacin (Avelox)

*Committee Recommendations for the **NPDL** are:*
Ciprofloxacin Suspension (Cipro Suspension)
Ciprofloxacin ER
Ciprofloxacin ER (Proquin XR)
Gemifloxacin (Factive)
Levofloxacin (Levaquin)
Norfloxacin (Noroxin)
Ofloxacin

9-2;24. Glucocorticoids, Inhaled

Dr. Givler offered the motion to accept Provider Synergies' recommendation. The motion was seconded by Dr. Murrill. Discussion followed. The motion passed unanimously with a roll call vote.

*Committee Recommendations for the **PDL** are:*
Beclomethasone MDI (QVAR)
Budesonide/Formoterol MDI (Symbicort)
Budesonide Respules - ***8 years old and under***
Budesonide Respules (Pulmicort Respules) - ***8 years old and under***
Flunisolide MDI (Aerobid)
Flunisolide MDI (Aerobid-M)
Fluticasone MDI (Flovent)
Fluticasone MDI (Flovent HFA Inhaler)
Fluticasone/Salmeterol DPI (Advair Diskus)
Fluticasone/Salmeterol MDI (Advair HFA)
Mometasone DPI (Asmanex)

*Committee Recommendations for the **NPDL** are:*
Budesonide DPI (Pulmicort Flexhaler)
Budesonide Respules - ***9 years old and over***
Budesonide Respules (Pulmicort Respules) - ***9 years old and over***
Ciclesonide MDI (Alvesco)

Note: *Triaminolone MDI (Azamacorte) is no longer available.*

9-2;25. Hypoglycemics, Incretin Mimetics/Enhancers

Dr. Givler offered the motion to accept Provider Synergies' recommendation. The motion was seconded by Dr. Wolfson. Discussion followed. The motion passed with fourteen yeas and one nay by Dr. Wolfson.

*Committee Recommendations for the **PDL** are:*
Exenatide Pens (Byetta Pens)
Pramlintide (Symlin)
Pramlintide Pens (Symlin Pens)
Saxagliptin (Onglyza)
Sitagliptin Oral (Januvia)
Sitagliptin/Metformin Oral (Janumet)

*Committee Recommendations for the **NPDL** are:*
Liraglutide (Victoza)

9-2;26. Hypoglycemics, Insulins

Dr. Givler offered the motion to accept Provider Synergies' recommendation. The motion seconded by Dr. Yu, passed unanimously with a roll call vote.

*Committee Recommendations for the **PDL** are:*
Human Insulin & Pens (Humulin)

Insulin Glargine & Pens (Lantus)
Insulin Lispro & Pens (Humalog)
Insulin Lispro/Protamine Lispro & Pens (Humalog Mix)

*Committee Recommendations for the **NPDL** are:*
Human Insulin & Pens (Novolin)
Insulin Aspart & Pens (Novolog)
Insulin Aspart/Protamine Lispro & Pens(Novolog Mix 70/30)
Insulin Detemir & Pens(Levemir)
Insulin Glulisine & Pens (Apidra)

9-2;27. Intranasal Rhinitis Agents

Dr. Givler offered the motion to accept Provider Synergies' recommendation. The motion seconded by Dr. Murrill, passed unanimously with a roll call vote.

*Committee Recommendations for the **PDL** are:*
Azelastine (Astelin)
Azelastine (Astepro)
Fluticasone
Ipratropium Nasal
Mometasone (Nasonex)
Olopatadine (Patanase)
Triamcinolone (Nasacort AQ)

*Committee Recommendations for the **NPDL** are:*
Beclomethasone (Beconase AQ)
Budesonide Aqua (Rhinocort Aqua)
Ciclesonide (Omnaris)
Flunisolide
Fluticasone Furoate (Veramyst)

***Note:** Flunisolide (Nasarel) brand name product is no longer available. Flunisolide generic is available.*

9-2;28. Leukotriene Modifiers

Dr. Murrill offered the motion to accept Provider Synergies' recommendation. The motion seconded by Dr. Lewis, passed unanimously with a roll call vote.

*Committee Recommendations for the **PDL** are:*
Montelukast (Singulair)
Zafirlukast (Accolate)

*Committee Recommendations for the **NPDL** are:*
Zileuton CR (Zyflo CR)

9-2;29. Macrolides – Ketolides

Dr. Givler offered the motion to accept Provider Synergies' recommendation. The

motion seconded by Dr. Mader, passed unanimously with a roll call vote.

*Committee Recommendations for the **PDL** are:*
Azithromycin
Erythromycin

*Committee Recommendations for the **NPDL** are:*
Azithromycin ER (Zmax)
Clarithromycin
Clarithromycin ER
Telithromycin (Ketek)

9-2;30. Nonsteroidal Anti-Inflammatories (NSAIDS)
Dr. Givler offered the motion to accept Provider Synergies' recommendation. The motion seconded by Dr. Firestone, passed unanimously with a roll call vote.

*Committee Recommendations for the **PDL** are:*
Diclofenac
Esomeprazole/naproxen (Vimovo)
Etodolac
Flurbiprofen
Ibuprofen Rx
Indomethacin Oral and Rectal
Ketoprofen
Ketorolac
Meloxicam
Naproxen Rx
Oxaprozin
Piroxicam
Sulindac

*Committee Recommendations for the **NPDL** are:*
Celecoxib (Celebrex)
Diclofenac/Misoprostol (Arthrotec)
Diclofenac Potassium (Zipsor)
Fenoprofen
Indomethacin Susp (Indocin Suspension)
Meclofenamate Sodium
Mefenamic Acid
Nabumetone
Tolmetin Sodium

9-2;31. Oncology Agents, Oral *(New Category)*
Dr. Wolfson offered the motion to accept Provider Synergies' recommendation. The motion was seconded by Dr. Wilkinson. Discussion followed; it was noted that other TOP$ states had deferred action on this category of drugs..

Rep. Mills offered a substitute motion to table action on this category for a year. Dr. Wilkinson seconded the motion which passed unanimously with a roll call vote. Further

action was tabled for a year.

*Provider Synergies Recommendations for the **PDL** were:*
Capecitabine (Xeloda)
Dasatinib (Sprycel)
Erlotinib (Tarceva)
Gefitinib (Iressa)
Imatinib (Gleevec)
Lapatinib (Tykerb)
Sorafenib (Nexavar)

Provider Synergies *Recommendations for the **NPDL** were:*
Everolimus (Afinitor)
Nilotinib (Tasigna)
Pazopanib (Votrient)
Sunitinib malate (Sutent)

Committee Action: The Committee deferred review and action on this category for one year.

9-2;32. Ophthalmic Antibiotics

Rep. Mills offered the motion to accept Provider Synergies' recommendation. The motion seconded by Dr. Wilkinson, passed unanimously with a roll call vote.

*Committee Recommendations for the **PDL** are:*
Bacitracin/Polymyxin
Erythromycin
Gentamicin
Moxifloxacin (Vigamox)
Neomycin-Polymyxin-Gramacidin
Polymyxin/Trimethoprim
Sulfacetamide
Tobramycin (Generic)
Tobramycin (Tobrex)
Triple Antibiotic

*Committee Recommendations for the **NPDL** are:*
Azithromlycin (Azasite)
Bacitracin
Besifloxacin (Besivance)
Ciprofloxacin Ointment (Ciloxan)
Ciprofloxacin Solution
Gatifloxacin (Zymar)
Levofloxacin (Iquix)
Levofloxacin (Quixin)
Natamycin (Natacyn)
Ofloxacin Solution

9-2;33. Ophthalmics For Allergic Conjunctivitis

Dr. Givler offered the motion to accept Provider Synergies' recommendation. The motion seconded by Rep. Mills, passed unanimously with a roll call vote.

*Committee Recommendations for the **PDL** are:*
Cromolyn Sodium
Loteprednol (Alrex)
Olopatadine HCl (Pataday)
Olopatadine HCl (Patanol)

*Committee Recommendations for the **NPDL** are:*
Azelastine HCl
Bepotastine (Bepreve)
Emedastine Difumarate (Emadine)
Epinastine HCl (Elestat)
Ketorolac Tromethamine
Lodoxamide Tromethamine (Alomide)
Nedocromil Sodium (Alocril)
Pemirolast Potassium (Alamast)

Note: *Ketotifen RX is no longer available.*
Ketorolac (Acular) and Azelastine (Optivar) are now available as generics.

9-2;34. Ophthalmic Anti-Inflammatories

Dr. Givler offered the motion to accept Provider Synergies' recommendation. The motion seconded by Dr. Wolfson, passed unanimously with a roll call vote.

*Committee Recommendations for the **PDL** are:*
Dexamethasone (Maxidex)
Dexamethasone Sodium Phosphate
Diclofenac
Fluorometholone
Fluorometholone (Flarex)
Fluorometholone (FML Forte)
Fluorometholone (FML S.O.P.)
Flurbiprofen
Loteprednol (Lotemax)
Prednisolone Aacetate (Pred Mild)

*Committee Recommendations for the **NPDL** are*
Bromfenac (Xibrom)
Difluprednate (Durezol)
Ketorolac LS
Ketorolac (Acuvail)
Nepafenac (Nevanac))
Rimexolone (Vexol)

Note: *Dexamethasone (Ozurdex), Fluocinolone (Retisert), and Triamcinolone Acetonide (Triesence), products which have invasive administration, are no longer going to be reviewed by the PDL process. These drugs will process*

without prior authorization.

Note: Ketorolac PF (Acular PF) is no longer available.

9-2;35. Ophthalmics, Glaucoma Agents

Dr. Wolfson offered the motion to accept Provider Synergies' recommendation. The motion seconded by Dr. Lewis, passed unanimously with a roll call vote.

*Committee Recommendations for the **PDL** are:*
Betaxolol
Betaxolol (Betoptic S)
Brimonidine
Brimonidine Tartrate (Alphagan P)
Brimonidine/Timolol (Combigan)
Brinzolamide (Azopt)
Carteolol
Dipivefrin (Propine)
Dorzolamide (Trusopt – Brand Only)
Dorzolamide/Timolol (Cosopt – Brand Only)
Latanoprost (Xalatan)
Levobunolol
Metipranolol
Pilocarpine
Timolol Maleate
Timolol (Betimol)
Timolol-LA (Istalol)
Travoprost (Travatan, Travatan Z)

*Committee Recommendations for the **NPDL** are:*
Bimatroprost (Lumigan 2.5ml, 5ml and 7.5ml)
Brimonidine P (Generic only)
Dorzolamide (Generic only)
Dorzolamide/Timolol (Ggeneric only)

9:2;36. Pancreatic Enzymes

Dr. Wolfson offered the motion to accept Provider Synergies' recommendation. The motion seconded by Rep. Mills, passed unanimously with a roll call vote.

*Committee Recommendations for the **PDL** are:*
Creon
Pancreaze
Pancrelipase
Zenpep

*Committee Recommendations for the **NPDL** are:*
None

Note: Due to the FDA approval deadline in April 2010, many pancreatic

enzyme products have left the market. FDA approved products include Creon, Zenpep and Pancrelipase (generic), and Pancreaze.

9-2;37. Platelet Aggregation Inhibitors

Dr. Mader offered the motion to accept Provider Synergies' recommendation. The motion seconded by Dr. Firestone, passed unanimously with a roll call vote.

*Committee Recommendations for the **PDL** are:*
Aspirin/Dipyridamole ER (Aggrenox)
Dipyridamole
Clopidogrel (Plavix)

*Committee Recommendations for the **NPDL** are:*
Prasugrel (Effient)
Ticlopidine

9-2;38. Steroids, Topical High

Dr. Givler offered the motion to accept Provider Synergies' recommendation. The motion seconded by Dr. Lewis, passed unanimously with a roll call vote.

*Committee Recommendations for the **PDL** are:*
Betamethasone Valerate
Fluocinonide
Fluocinonide-E
Fluocinonide Emollient
Triamcinolone Acetonide

*Committee Recommendations for the **NPDL** are:*
Amcinonide
Betamethasone Dipropionate
Desoximetasone
Diflorasone Diacetate
Fluocinonide (Vanos)
Halcinonide (Halog)
Triamcinolone Acetonide Aerosol (Kenalog Aerosol)

9-2;39. Steroids, Topical Low

Dr. Lewis offered the motion to accept Provider Synergies' recommendation. The motion seconded by Dr. Firestone, passed unanimously with a roll call vote.

*Committee Recommendations for the **PDL** are:*
Alclometasone Dipropionate
Desonide
Fluocinolone Acetonide Shampoo (Capex)
Hydrocortisone

*Committee Recommendations for the **NPDL** are:*
Desonide (Verdeso)

Fluocinolone Acetonide (Derma-Smoothe-FS)
Hydrocortisone (Pediaderm HC)

9-2;40. Steroids, Topical Medium

Dr. Givler offered the motion to accept Provider Synergies' recommendation. The motion seconded by Dr. Wolfson, passed unanimously with a roll call vote.

*Committee Recommendations for the **PDL** are:*
Fluocinolone Acetonide
Fluticasone Propionate – G30eneric
Hydrocortisone Butyrate
Hydrocortisone Butyrate Lipocream (Locoid Lipocream)
Hydrocortisone Probutate (Pandel)
Hydrocortisone Valerate
Mometasone Furoate -generic
Prednicarbate

*Committee Recommendations for the **NPDL** are:*
Betamethasone Valerate (Luxiq)
Clocortolone Pivalate (Cloderm)
Flurandrenolide Tape (Cordran Tape)
Fluticasone Propionate Lotion (Cutivate Lotion)
Mometasone Furoate (Momexin)

9-2;41. Steroids, Topical Very High

Dr. Givler offered the motion to accept Provider Synergies' recommendation. The motion seconded by Dr. Wilkinson, passed unanimously with a roll call vote.

*Committee Recommendations for the **PDL** are:*
Clobetasol Emollient
Clobetasol Propionate
Halobetasol Propionate - generic

*Committee Recommendations for the **NPDL** are:*
Clobetasol Propionate (Clobex)
Clobetasol Propionate (Olux-Olux-E Pack)
Clobetasol Propionate (Olux-E)
Halobetasol Propionate (Halonate; Halonate PAC)

9-2;42. Stimulants and Related Agents

Rep. Mills offered the motion to accept Provider Synergies' recommendation. The motion seconded by Dr. Firestone, passed unanimously with a roll call vote.

*Committee Recommendations for the **PDL** are:*
Amphetamine Mixed Salt
Dexmethylphenidate
Dexmethylphenidate (Focalin)

Dextroamphetamine
Dextroamphetamine (Procentra)
Guanfacine ER (Intuniv)
Lisdexamfetamine (Vyvanse)
Methylphenidate
Methylphenidate ER - generic
Methylphenidate ER (Concerta, Metadate CD)
Methylphenidate IR (Methylin Chewable & Solution)
Methylphenidate Transdermal Patches (Daytrana)

*Committee Recommendations for the **NPDL** are:*
Amphetamine Mixed Salt ER (generic)
Amphetamine Mixed Salt ER (Adderall XR)
Armodafinil (Nuvigil)
Atomoxetine (Strattera)
Dexmethylphenidate ER (Focalin XR)
Modafinil (Provigil)
Methamphetamine
Methamphetamine (Desoxyn)
Methylphenidate ER (Ritalin LA)

9-2;43. Tetracyclines - Oral

Dr. Mader offered the motion to accept Provider Synergies' recommendation. The motion seconded by Dr. Yu, passed unanimously with a roll call vote.

*Committee Recommendations for the **PDL** are:*
Doxycycline Hyclate (generic)
Doxycycline Hyclate DR (generic)
Doxycycline Monohydrate
Minocycline Cap
Minocycline Tab
Tetracycline

*Committee Recommendations for the **NPDL** are:*
Demeclocycline
Doxycycline Calcium Suspension (Vibramycin)
Doxycycline Hyclate (Doryx)
Doxycycline DR (Oracea)
Minocycline ER – (generic)
Minocycline ER (Solodyn)

II. NEW DRUGS REVIEW

The new drug reviews or single drug reviews are on products that have come to the market since the last review of the class. The reviews at this meeting were on new products in classes reviewed at the February 10, 2010 meeting. Three (3) new drugs in three (3) therapeutic classes were reviewed and recommendations were made. P&T Committee recommendations follow:

Class Review Number

9-1;1. Analgesics, Narcotics Long Acting

Dr. Lewis offered the motion to accept Provider Synergies' recommendation to place the new drug Hydromorphone Hydrochloride ER **(Exalgo)** on the **NPDL**. The motion was seconded by Dr. Givler and passed unanimously with a roll call vote.

9-1;2. Analgesics, Narcotics Short Acting

Rep. Mills offered the motion to accept Provider Synergies' recommendation to place the new drug Tramadol ODT **(Rybix ODT)** on the **NPDL**. The motion was seconded by Dr. Lewis and passed unanimously with a roll call vote.

9-1;21. Multiple Sclerosis Agents

Rep. Mills offered the motion to accept Provider Synergies' recommendation to place the new drug Dalfampridine **(Ampyra)**on the **NPDL**. The motion was seconded by Dr. Firestone and passed unanimously with a roll call vote.

Other Business:

A. **Ms. M. J. Terrebonne.** Ms. Terrebonne told the new Committee members her staff would send them an email requesting their preferences for receiving future drug monographs via hard copy, CD, or Secure Mail.

Next Steps:

A. **Therapeutic Classes proposed to be reviewed at Next Meeting.** Therapeutic classes proposed for review at the next meeting are:

Analgesics, Narcotic Long
Analgesics, Narcotics Short
Angiotensin Modulators
Angiotensin Modulators /CCB Combinations
Antibiotics, GI
Anticoagulants, Injectable
Antihistamines, Minimally Sedating
Antimigraine Agents, Triptans
Beta-Blockers
Bile Salts
Bladder Relaxant Preparations
BPH Treatments
Calcium Channel Blockers
Colony-Stimulating Factor
Erythropoiesis Stimulating Proteins
Fibromyalgia Agents
Growth Hormones
H Pylori Agents
Hepatitis C Agents
Hypoglycemics, Meglitinides
Hypoglycemics, TZD
Immunosuppressants
Impetigo Agents, Topical
Lipotropics, Other
Lipotropics, Statins
Multiple Sclerosis Agents
Otic Antibiotics
PAH Agents, Oral
Phosphate Binders
Proton Pump Inhibitors
Sedative Hypnotics
Skeletal Muscle Relaxants
Thrombopoiesis Stimulating Proteins
Ulcerative Colitis Agents

Note: Therapeutic Classes scheduled for review are posted on the following websites:
DHH Medicaid - (www.lamedicaid.com)
Provider Synergies -
(http://www.providersynergies.com/services/medicaid/default.asp?content=Louisiana)

Next Meeting Date:
The next Committee meeting is scheduled for Wednesday, April 27, 2011.

Public Comment:
There were no additional public comments\

Adjournment:
The meeting adjourned at 2:20 p.m.

Attachments (5)

Dr. Larry Hebert
Chairman, P & T Committee
April 27, 2011

P & T Committee Overview

Medicaid Pharmacy Director

M. J. Terrebonne, P.D.

August 11, 2010

Attachment 1

Pharmaceutical and Therapeutics Committee Overview

ACT 395 –

Authorizes the Department of Health and Hospitals (DHH) to establish a drug list utilizing a prior approval process or any other process or combination of processes that prove to be cost effective in the Medical Assistance Program

Allows DHH to enter into contractual arrangements to perform the prior approval (PA) function

Pharmaceutical and Therapeutics Committee Overview

The Louisiana Medicaid Pharmaceutical and Therapeutics Committee (P & T):

- Established in **August 2001;**
- Consists of **twenty-one (21)** members, appointed by the Governor;
- Reviews clinical and cost data on various **Therapeutic Classes of drugs**; and
- meets **Bi-Annually**.

Pharmaceutical and Therapeutics Committee Overview

On June 10, 2002, the Department implemented a Preferred Drug List (PDL) with a Prior Authorization (PA) process and a Supplemental Drug Rebate Program through a phased-in approach

- The University of Louisiana at Monroe (ULM) School of Pharmacy administers the PA function;
- DHH contracts with Provider Synergies to negotiate State Supplemental Rebates;
- The Preferred Drug List is updated bi-annually (April & October) based on committee's recommendations

Pharmaceutical and Therapeutics Committee Overview

Provider Synergies, LLC

- Negotiate State Supplemental Rebates with Drug Manufacturers
- Prepare therapeutic class reviews
- Provide cost analysis information for the therapeutic classes
- Develop clinically sound and cost-effective recommendations to develop and manage the PDL

Therapeutic Classes

State Fiscal Year	Number of Classes
2008	57
2009	68
2010	74

Pharmacy Program

YEAR	# of Rxs	# of Recipients	Total Expenditures	Federal Rebates	State Supplemental Rebates	NET
2008	9,969,582	772,696	**$767,707,137**	$202,853,376	$37,833,592	**$527,020,170**
2009	10,180,045	800,831	**$830,089,481**	$256,002,121	$45,635,734	**$528,643,713**
2010	10,879,384	861,179	**$857,337,138**	$280,317,434	$43,684,069	**$533,335,635**

Source: Medical Vendor Report, Data Warehouse, LAPRIMS & MW-M-01
Rebate Total computations do not include interest and all figures were derived from State Fiscal Year parameters (July 1st thru June 30th)

Pharmaceutical and Therapeutics Committee Overview

Daniel Duhon
DHH Attorney

Pharmaceutical and Therapeutics Committee Overview

BYLAWS –

- Committee members shall serve at the pleasure of the Governor unless removed in accordance with the provisions set forth in Article 1 – Section 7.

- Members shall not entertain individuals lobbying or marketing, or partake in any other activity/discussions with pharmaceutical manufacturers or their representatives which would call into question their impartiality when it comes to deciding which drugs may or may not be included on the preferred drug list.

Pharmaceutical and Therapeutics Committee Overview

BYLAWS cont' –

- The Chairman and Vice-Chairman of the Committee shall be elected by the members of the Committee. The Department shall designate staff to assist the Chairman in his duties.

- The Committee shall meet quarterly or as prescribed by the Chairman.

- Regular meetings will be held on the first Wednesday of every month or on the next available Wednesday of the Committee's regular meeting place.

Pharmaceutical and Therapeutics Committee Overview

BYLAWS cont' –

- The rules contained in Robert's Revised Rules of Order shall govern the Committee in cases to which they are applicable, and in which they are not inconsistent with the bylaws of the Committee.

- In accordance with La.R.S 42:5, all Committee meetings subject to La.R.S. 42:7(A) shall provide for an opportunity for public comment at such meeting, subject to reasonable rules, regulations, and restrictions as adopted by the public body.

Pharmaceutical and Therapeutics Committee Overview

BYLAWS cont' –

The committee shall not take up an item not on the agenda unless there is unanimous approval of all the committee members present at the meeting. Prior to any vote on the motion to take up a new agenda item, there shall be an opportunity for public comment.

These bylaws may be amended by a majority of voting members. The Chairman shall provide a copy of proposed amendments to each Committee member at least two weeks prior to voting on the amendments.

Pharmaceutical and Therapeutics Committee Overview

BYLAWS cont' –

A quorum shall be established by the presence of a majority of voting members of whom at least five (5) must be physicians and one (1) must be a pharmacist. If quorum is not obtained for a regular scheduled meeting, the meeting will be rescheduled at the earliest possible date, and all Committee members informed at the discretion of the Chairman.

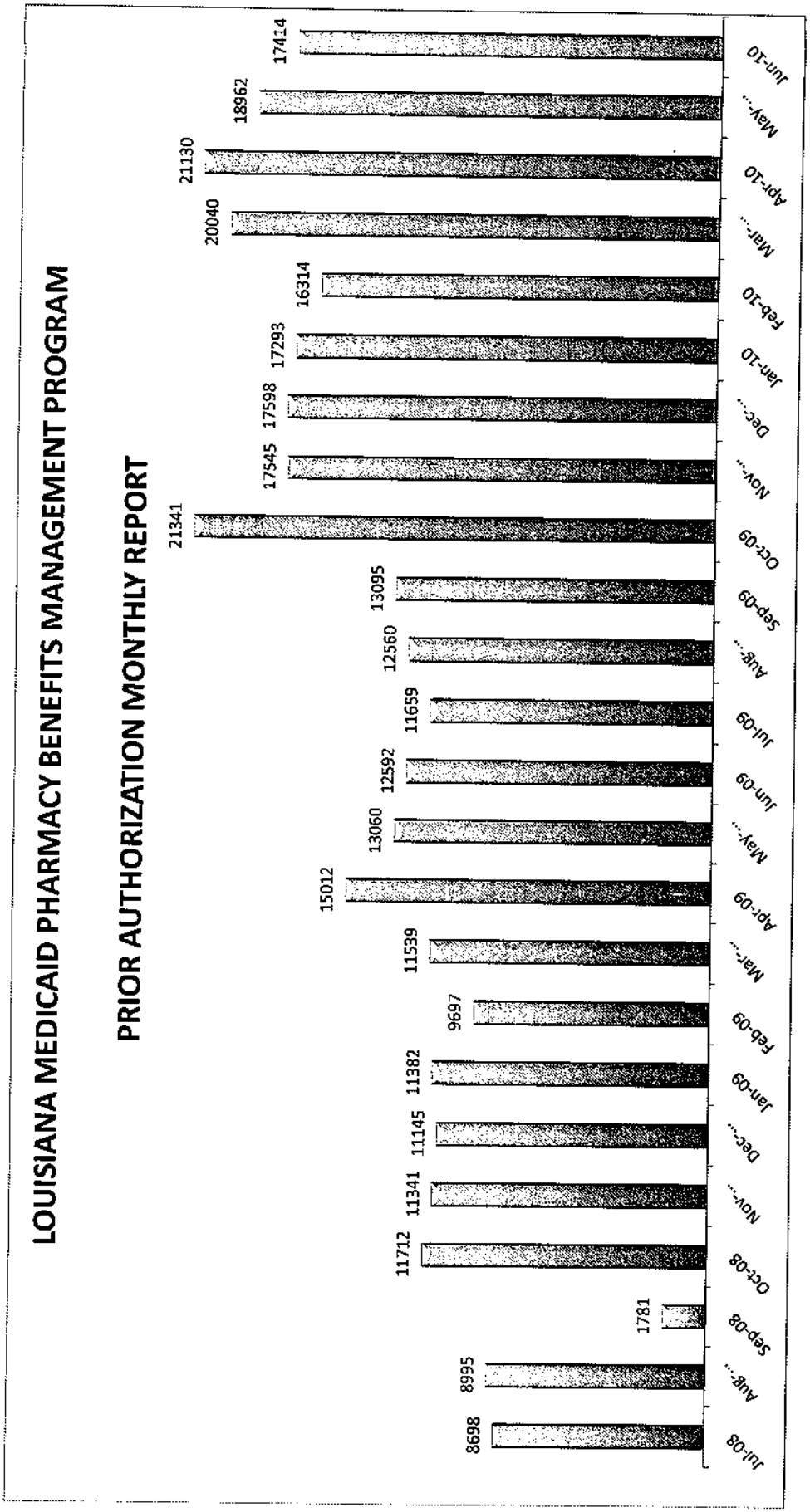
Pharmaceutical and Therapeutics Committee Overview

ETHICS

P&T / DHH Staff

- M. J. Terrebonne – Pharmacy Director
- Carol Rumfola – Administrative Assistant
- Rachel Broussard – Pharmacist
- Daniel Duhon – DHH Attorney
- Germaine Becks-Moody – Program Manager
- Timothy Williams – Program Manager

Attachment 2



Prior Authorization PDL Implementation Schedule

02/26/2010

Item Nbr	Descriptive Therapeutic Class	Drugs on PDL	Drugs which Require PA	Effective Date: April 1, 2010
1	ADD/ADHD			
	Stimulants and Related Agents	Amphetamine Mixed Salt	Amphetamine Mixed Salt ER (generic only)	
		Amphetamine Mixed Salt ER (Adderall XR® - Brand only)	Armodafinil (Nuvigil®)	
		Dexmethylphenidate	Atomoxetine (Strattera®)	
		Dexmethylphenidate (Focalin ®)	Dextroamphetamine (Procentra®)	
		Dexmethylphenidate ER (Focalin XR®)	Modafinil (Provigil®)	
		Dextroamphetamine	Methamphetamine (Desoxyn®)	
		Guanfacine (Intuniv®)	Methylphenidate LA (Ritalin LA®)	
		Lisdexamfetamine (Vyvanse®)		
		Methylphenidate		
		Methylphenidate ER		
		Methylphenidate ER (Concerta®, Metadate CD®)		
		Methylphenidate Transdermal (Daytrana Transdermal®)		
2	ALLERGY			
	Antihistamines - Minimally Sedating	Cetirizine (Generic)	Acrivastin/Pseudoephedrine (Semprex-D®)	
		Cetirizine Chewable (Generic)	Desloratadine (Clarinex®)	
		Cetirizine-D (Generic)	Desloratadine Syrup (Clarinex®)	
		Cetirizine Syrup OTC	Desloratadine/Pseudoephedrine (Clarinex-D®)	
		Cetirizine Syrup Rx	Fexofenadine	
		Loratadine (Generic)	Fexofenadine-D 12-hour (Generic)	
		Loratadine-D (Generic)	Fexofenadine ODT(Allegra ODT®)	
		Loratadine Syrup (Generic)	Fexofenadine/Pseudoephedrine (Allegra-D 12-hour®)	
			Fexofenadine/Pseudoephedrine (Allegra-D 24-hour®)	
			Fexofenadine Syrup (Allegra Syrup®)	
			Levocetirizine (Xyzal®)	
			Levocetirizine Syrup (Xyzal®)	
			Loratadine Chewable OTC - (Claritin®)	

Attachment 3

Prior Authorization PDL Implementation Schedule

02/26/2010

Item Nbr	Descriptive Therapeutic Class	Drugs on PDL	Drugs which Require PA	Effective Date: April 1, 2010
	Rhinitis Agents, Nasal	Azelastine (Astelin®)	Beclomethasone AQ (Beconase AQ®)	
		Azelastine (Astepro®)	Budesonide Aqua (Rhinocort Aqua®)	
		Mometasone (Nasonex®)	Ciclesolide (Omnaris®)	
			Flunisolide (Nasarel®)	
			Flunisolide	
			Fluticasone	
			Fluticasone Furoate (Veramyst®)	
			Ipratropium Nasal	
			Olopatadine HCL (Patanase®)	
			Triamcinolone (Nasacort AQ®)	
3	**ALZHEIMER'S**			
	Alzheimer's Agents	Donepezil (Aricept®)	Galantamine	
	Cholinesterase Inhibitors	Donepezil (Aricept ODT®)	Galantamine ER	
		Memantine HCl (Namenda®)	Rivastigmine Oral Solution (Exelon Solution®)	
		Rivastigmine Oral (Exelon®)	Tacrine (Cognex®)	
		Rivastigmine Transdermal Patch (Exelon Transdermal®)		
4	**ANTIPSYCHOTIC AGENTS**	**ORAL**		
	Antipsychotic Agents	Amitriptyline/Perphenazine	Aripiprazole (Abilify®)	
		Chlorpromazine	Asenapine sublingual (Saphris)	
		Clozapine (Fazaclo®)	Clozapine	
		Fluphenazine	Olanzapine/Fluoxetine (Symbyax®)	
		Haloperidol	Olanzapine (Zyprexa®)	
		Molindone (Moban®)	Paliperidone ER (Invega®)	
		Perphenazine		
		Quetiapine (Seroquel®)		
		Quetiapine ER (Seroquel XR®)		
		Risperidone		
		Thioridazine		
		Thiothixene		
		Trifluoperazine		
		Ziprasidone (Geodon®)		

Prior Authorization PDL Implementation Schedule

02/26/2010

Item Nbr	Descriptive Therapeutic Class	Drugs on PDL	Drugs which Require PA	Effective Date: April 1, 2010
	Antipsychotic Agents , cont.	INJECTIONS		
		Fluphenazine Decanoate	Olanzapine (Zyprexa®)	
		Haloperidol Decanoate	Paliperidone Palmitate (Invega Sustenna®)	
		Ziprasidone (Geodon®)	Risperidone (Risperdal Consta®)	
5	ASTHMA/COPD			
	Bronchodilator, Beta-Adrenergic			
	Agents	INHALATION		
		Albuterol Sulfate Nebulizer	Albuterol Sulfate HFA MDI (Proventil HFA®)	
		Albuterol Sulfate HFA (ProAir HFA®)	Albuterol Sulfate Nebulizer Low-Dose	
		Albuterol Sulfate HFA MDI (Ventolin HFA®)	Arformoterol Inhalation Solution (Brovana Inhalation Solution®)	
		Formoterol DPI (Foradil®)	Formoterol Inhalation Solution (Perforomist Inhalation Solution®)	
		Levalbuterol Nebulizer HCL (Xopenex ®)	Levalbuterol HFA (Xopenex HFA®)	
		Salmeterol Xinafoate (Serevent Diskus®)	Pirbuterol (Maxair Autohaler®)	
		ORAL		
		Albuterol Sulfate	Metaproterenol Sulfate	
		Albuterol Sulfate ER		
		Terbutaline Sulfate		
	Bronchodilator, Anticholinergics	INHALATION		
		Albuterol Sulfate/Ipratropium MDI (Combivent®)	Albuterol Sulfate/Ipratropium Nebulizer	
		Ipratropium Nebulizer		
		Ipratropium Inhalation Aerosol MDI (Atrovent HFA®)		
		Tiotropium Inhalation Powder (Spiriva®)		

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Item Nbr	Descriptive Therapeutic Class	Drugs on PDL	Drugs which Require PA	Effective Date: April 1, 2010
	Corticosteroids, Inhalation	Beclomethasone MDI (QVAR®)	Budesonide DPI (Pulmicort Flexhaler®)	
		Budesonide/Formoterol MDI (Symbicort®)	Budesonide Respules - 9 years old and over	
		Budesonide Respules - 8 years old and under	Budesonide Respules (Pulmicort - Respules®) - 9 years old and over	
		Budesonide Respules (Pulmicort - Respules®) - 8 years old and under	Ciclesonide (Alvesco®)	
		Flunisolide MDI (Aerobid®)	Mometasone DPI (Asmanex®)	
		Flunisolide MDI (Aerobid M®)		
		Fluticasone MDI (Flovent®)		
		Fluticasone MDI (Flovent HFA Inhaler)		
		Triamcinolone MDI (Azmacort®)		
		Fluticasone/Salmeterol DPI (Advair Diskus®)		
		Fluticasone/Salmeterol MDI (Advair HFA®)		
	Leukotriene Modifiers	Montelukast (Singulair®)	Zileuton CR (Zyflo CR®)	
		Zafirlukast (Accolate®)		
6	DEPRESSION			
	Antidepressants, Other	Bupropion HCl IR	Bupropion HBr ER (Aplenzin®)	
		Bupropion HCl SR	Bupropion HCl XL	
		Mirtazapine	Bupropion HCl XL (Wellbutrin XL®)	
		Trazodone	Desvenlafaxine (Pristiq®)	
		Venlafaxine ER	Duloxetine (Cymbalta®)	
			Nefazodone	
			Selegiline Patch (Emsam®)	
			Venlafaxine	
			Venlafaxine ER (Effexor XR brand only)	
	Selective Serotonin	Citalopram	Fluvoxamine CR (Luvox CR®)	
	Reuptake Inhibitors (SSRIs)	Escitalopram (Lexapro®)	Fluoxetine ER (Prozac Weekly®)	
		Fluoxetine	Paroxetine CR	
		Fluvoxamine	Paroxetine Mesylate (Pexeva®)	
		Paroxetine		

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02/26/2010

Item Nbr	Descriptive Therapeutic Class	Drugs on PDL	Drugs which Require PA	Effective Date: April 1, 2010
		Sertraline		
7	DERMATOLOGY			
	Antifungals - Topical	Ciclopirox Shampoo (Loprox®)	Butenafine (Mentax®)	
		Clotrimazole Rx	Ciclopirox (CNL8®)	
		Clotrimazole/Betamethasone	Ciclopirox Cream	
		Ketoconazole Cream	Ciclopirox Gel	
		Ketoconazole Shampoo (Rx only)	Ciclopirox Solution	
		Naftifine (Naftin®)	Ciclopirox Suspension	
		Nystatin	Econazole	
		Nystatin w/ Triamcinolone	Ketoconazole Foam (Extina Foam®)	
		Oxiconazole (Oxistat®)	Ketoconazole (Xolegel®)	
			Miconazole/zinc oxide/white petrolatum (Vusion®)	
			Sertaconazole Nitrate (Ertaczo®)	
	Antiparasitic Agents, Topical	Benzyl Alcohol (Ulesfia®)	Lindane	
		Crotamiton (Eurax®)	Malathion (generic only)	
		Malathion (Ovide® - Brand only)		
		Permethrin		
	Antiviral Agents, Topical	Penciclovir Cream (Denavir®)	Acyclovir Cream (Zovirax®)	
			Acyclovir Ointment (Zovirax®)	
	Atopic Dermatitis	Pimecrolimus (Elidel®)	NONE	
	Immunomodulators	Tacrolimus (Protopic®)		
	Impetigo Agents, Topical	Mupirocin Ointment	Mupirocin Cream (Bactroban®)	
			Retapamulin (Altabax®)	

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Item Nbr	Descriptive Therapeutic Class	Drugs on PDL	Drugs which Require PA	Effective Date: April 1, 2010
	STERIODS, TOPICAL			
	Low Potency	Alclometasone Dipropionate	Desonide (Verdeso®)	
		Desonide	Desonide (Desonate®)	
		Fluocinolone Acetonide (Derma-Smoothe-FS)	Hydrocortisone 2% Lotion (Pediaderm HC®)	
		Fluocinolone Acetonide Shampoo (Capex®)		
		Hydrocortisone		
	Medium Potency	Fluocinolone Acetonide	Clocortolone Pivalate (Cloderm®)	
		Fluticasone Propionate	Flurandrenolide Tape (Cordran Tape®)	
		Fluticasone Propionate Lotion (Cutivate Lotion)	Hydrocortisone Butyrate (Locoid Lipocream®)	
		Betamethasone Valerate (Luxiq®)	Mometasone Furoate 0.1% Cream (Momexin®)	
		Hydrocortisone Butyrate		
		Hydrocortisone Valerate		
		Mometasone Furoate		
		Prednicarbate		
	High Potency	Amcinonide	Desoximetasone	
		Betamethasone Dipropionate	Diflorasone Diacetate	
		Betamethasone Valerate	Fluocinonide (Vanos®)	
		Fluocinonide	Halcinonide (Halog®)	
		Fluocinonide-E		
		Fluocinonide Emollient		
		Triamcinolone Acetonide		
	Very High Potency	Clobetasol Emollient	Clobetasol Propionate (Clobex®)	
		Clobetasol Propionate	Clobetasol Propionate (Olux-Olux-E Pack®)	
		Halobetasol Propionate	Clobetasol Propionate (Olux-E®)	
8	DIABETES			
	Hypoglycemics, Meglitinides	Repaglinide (Prandin®)	Nateglinide	
			Nateglinide (Starlix®)	

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Item Nbr	Descriptive Therapeutic Class	Drugs on PDL	Drugs which Require PA	Effective Date: April 1, 2010
			Repaglinide/Metformin (Prandimet®)	
	Hypoglycemics, Thiazolidinediones (TZDs)	Pioglitazone (Actos®)	None	
		Pioglitazone/Glimeperide (Duetact®)		
		Pioglitazone/Metformin (Actoplus Met®)		
		Rosiglitazone (Avandia®)		
		Rosiglitazone/Glimepiride ((Avandaryl®)		
		Rosiglitazone/Metformin (Avandamet®)		
	Hypoglycemics	Human Insulin & Pens (Humulin®)	Human Insulin & Pens (Novolin®)	
	Insulins & Related Agents	Insulin Glargine & Pens (Lantus®)	Insulin Aspart & Pens (Novolog®)	
		Insulin Lispro & Pens (Humalog®)	Insulin Aspart/Insulin Aspart Protamine & Pens (Novolog Mix 70/30®)	
		Insulin Lispro/Protamine Lispro & Pens (Humalog Mix®)	Insulin Detemir & Pens (Levemir®)	
			Insulin Glulisine & Pens (Apidra®)	
	Hypoglycemics	Exenatide (Byetta, Pens®)	NONE	
	Incretin Mimetics/Enhancers	Pramlintide (Symlin®)		
		Pramlintide Pens (Symlin Pens®)		
		Saxagliptin (Onglyza®)		
		Sitagliptin (Januvia®)		
		Sitagliptin/Metformin (Janumet®)		
9	DIGESTIVE DISORDERS			
	Antiemetic Agents	Dronabinol (Marinol® - Brand only)	Aprepitant (Emend®)	
		Ondansetron / Ondansetron ODT	Dolasetron (Anzemet®)	
			Dronabinol (generic only)	
			Granisetron	
			Granisetron Transdermal (Sancuso®)	
			Nabilone (Cesamet®)	

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02/26/2010

Item Nbr	Descriptive Therapeutic Class	Drugs on PDL	Drugs which Require PA	Effective Date: April 1, 2010
	GERD AND RELATED DISORDERS			
	Proton Pump Inhibitors	Esomeprazole (Nexium®)	Dexlansoprazole (Kapidex®)	
		Omeprazole (Legend only)	Esomeprazole Suspension (Nexium®)	
			Lansoprazole - generic	
			Lansoprazole Capsule (Prevacid®)	
			Lansoprazole Solutabs (Prevacid®)	
			Omeprazole Suspension (Prilosec®)	
			Pantoprazole	
			Pantoprazole Suspension (Protonix®)	
			Rabeprazole (Aciphex®)	
	Pancreatic Enzymes	Dygase	Pancrecarb MS	
		Lapase	Ultrase	
		Pancrelipase		
		Viokase		
		Pancrease MT		
		Creon		
		Pancrelipase (Zenpep®)		
9	DIGESTIVE DISORDERS			
	ULCERATIVE COLITIS			
	Ulcerative Colitis Agents	Balsalazide	Mesalamine ER Oral (Apriso®)	
		Mesalamine Enemas	Sulfite-free Mesalamine Suspension Enema (SF Rowasa®)	
		Mesalamine (Asacol®)	Mesalamine MMX (Lialda®)	
		Mesalamine Suppositories (Canasa®)	Mesalamine Oral (Pentasa®)	
		Sulfasalazine	Olsalazine Oral (Dipentum®)	
10	GROWTH DEFICIENCY			
	Growth Hormones	Somatropin (Genotropin®)	Somatropin (Humatrope®)	
		Somatropin (Norditropin®)	Somatropin (Omnitrope®)	
		Somatropin (Nutropin®)	Somatropin (Saizen®)	
		Somatropin (Nutropin AQ®)	Somatropin (Serostim®)	
			Somatropin (Tev-Tropin®)	

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Item Nbr	Descriptive Therapeutic Class	Drugs on PDL	Drugs which Require PA	Effective Date: April 1, 2010
			Somatropin (Zorbtive®)	
11	Gout Agents			
	Antihyperuricemics	Allopurinol	Febuxostat (Uloric®)	
		Colchicine	Colchicine (Colcrys®)	
		Probenecid		
		Probenecid/Colchicine		
12	HEART DISEASE			
	HYPERLIPIDEMIA			
	Lipotropics, Other	Cholestyramine	Colesevelam (Welchol®)	
		Colestipol	Ezetimibe (Zetia®)	
		Fenofibrate (Antara®)	Fenofibrate (Fenoglide®)	
		Fenofibrate (Tricor®)	Fenofibrate (Generics)	
		Fenofibric Acid (Trilipix®)	Fenofibrate (Lipofen®)	
		Gemfibrozil	Fenofibrate (Triglide®)	
		Niacin ER (Niaspan®)	Fenofibric Acid (Generic®)	
		Niacin IR (Niacor®)	Fenofibric Acid (Fibricor®)	
			Omega-3-acid ethyl esters (Lovaza®)	
	Statins & Statin Combination Agents	Atorvastatin (Lipitor®)	Amlodipine/Atorvastatin (Caduet®)	
		Fluvastatin (Lescol®)	Ezetimibe/Simvastatin (Vytorin®)	
		Fluvastatin XL (Lescol XL®)	Lovastatin ER (Altoprev®)	
		Lovastatin	Niacin ER/Lovastatin (Advicor®)	
		Niacin ER/Simvastatin (Simcor®)		
		Pravastatin		
		Rosuvastatin (Crestor®)		
		Simvastatin		

Prior Authorization PDL Implementation Schedule

02/26/2010

Item Nbr	Descriptive Therapeutic Class	Drugs on PDL	Drugs which Require PA	Effective Date: April 1, 2010
	HYPERTENSION			
	ACE Inhibitors & Direct Renin Inhibitors	Benazepril	Aliskiren (Tekturna®)	
		Benazepril/HCTZ	Aliskiren/HCTZ (Tekturna HCT®)	
		Captopril	Candesartan (Atacand®)	
		Captopril/HCTZ	Candesartan/HCTZ (Atacand HCT®)	
		Enalapril	Eprosartan (Teveten®)	
		Enalapril/HCTZ	Eprosartan/HCTZ (Teveten HCT®)	
		Fosinopril	Irbesartan (Avapro®)	
		Fosinopril/HCTZ	Irbesartan/HCTZ (Avalide®)	
		Lisinopril	Moexipril	
		Lisinopril/HCTZ	Moexipril/HCTZ	
		Losartan (Cozaar®)	Olmesartan (Benicar®)	
		Losartan/HCTZ (Hyzaar®)	Olmesartan/HCTZ (Benicar HCT®)	
		Quinapril	Perindopril (Aceon®)	
		Quinapril/HCTZ	Perindopril (Generic)	
		Ramipril (Altace®)		
		Telmisartan (Micardis®)		
		Telmisartan/HCTZ (Micardis HCT®)		
		Trandolapril		
		Valsartan (Diovan®)		
		Valsartan/HCTZ (Diovan HCT®)		
	Angiotensin Modulators/Calcium Channel Blockers Combination Products	Amlodipine/Benazepril - Generic only	Amlodipine/Telmisartan (Twynsta®)	
		Amlodipine/Benazepril (Lotrel®)		
		Amlodipine/Olmesartan (Azor®)		
		Amlodipine/Valsartan (Exforge®)		
		Amlodipine/Valsartan/HCTZ (Exforge HCT®)		
		Valsartan/Aliskiren (Valturna®)		
		Verapamil SR/Trandolapril (Tarka®)		

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Item Nbr	Descriptive Therapeutic Class	Drugs on PDL	Drugs which Require PA	Effective Date: April 1, 2010
	Beta Adrenergic Receptor	Acebutolol	Betaxolol	
	Blocking Agents	Atenolol	Carvedilol CR (Coreg CR®)	
		Atenolol/Chlorthalidone		
		Bisoprolol		
		Bisoprolol/HCTZ		
		Carvedilol		
		Labetalol		
		Metoprolol		
		Metoprolol /HCTZ		
		Metoprolol Succinate ER		
		Metoprolol Succinate ER (Toprol XL®)		
		Nadolol		
		Nadolol/Bendroflumethiazide		
		Nebivolol (Bystolic®)		
		Penbutolol (Levatol®)		
		Pindolol		
		Propranolol		
		Propranolol ER (Innopran XL®)		
		Propranolol LA		
		Propranolol/HCTZ		
		Sotalol		
		Sotalol AF		
		Timolol Maleate		
	Calcium Channel Blockers	Amlodipine	Diltiazem ER (Cardizem LA®)	
		Diltiazem IR	Isradipine SR (Dynacirc CR®)	
		Diltiazem ER (Generics)	Nicardipine SR (Cardene SR®)	
		Diltiazem SR	Nisoldipine (Sular®)	
		Felodipine ER	Nisoldipine – Generics	
		Isradipine IR	Verapamil ER (Covera HS®)	
		Nicardipine	Verapamil ER PM	
		Nifedipine ER		

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Item Nbr	Descriptive Therapeutic Class	Drugs on PDL	Drugs which Require PA	Effective Date: April 1, 2010
		Nifedipine IR		
	Calcium Channel Blockers cont.	Nimodipine		
		Verapamil		
		Verapamil ER (Generics)		
		Verapamil IR		
		Verapamil SR		
	PLATELET AGGREGATION INHIBITORS			
	Platelet Aggregation Inhibitors	Aspirin/Dipyridamole ER (Aggrenox®)	Prasugrel (Effient®)	
		Clopidogrel (Plavix®)	Ticlopidine	
		Dipyridamole		
	ANTICOAGULANTS, INJECTABLES			
	Anticoagulants,	Dalteparin (Fragmin®)	NONE	
	Injectable	Enoxaparin (Lovenox®)		
		Fondaparinux (Arixtra®)		
	PULMONARY ARTERIAL HYPERTENSION (PAH)	Ambrisentan (Letairis®)	Tadalafil (Adcirca®)	
		Bosentan (Tracleer®)	Treprostinil (Tyvaso®)	
		Iloprost (Ventavis®)		
		Sildenafil (Revatio®)		
13	HEMATOLOGIC AGENTS			
	HEMATOPOIETIC AGENTS			
	Erythropoietins	Darbepoetin (Aranesp®)	Epoetin alfa (Epogen®)	
		Epoetin alfa (Procrit®)		
	Anticoagulants - refer to			
	HEART DISEASE			
14	HEMODIALYSIS			
	Phosphate Binders	Calcium Acetate (PhosLo®)	Calcium Acetate (Generics)	
		Lanthanum (Fosrenol®)	Calcium Acetate (Eliphos®)	

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Item Nbr	Descriptive Therapeutic Class	Drugs on PDL	Drugs which Require PA	Effective Date: April 1, 2010
		Sevelamer HCL (RenaGel®)	Sevelamer Carbonate (Renvela®)	
15	HORMONE THERAPY			
	Androgenic Agents	Testosterone Transdermal Patch (Androderm®)	Testosterone Gel 1% (Testim®)	
		Testosterone Gel 1% (Androgel®)		
16	HYPERLIPIDEMIA - REFER TO HEART DISEASE			
17	IMMUNE DISORDERS - REFER TO MULTIPLE SCLEROSIS			
18	INFECTIOUS DISORDERS			
	ANTIBIOTICS	Amoxicillin/Clavulanate Tablets	Cefdinir	
	Cephalosporin and Related	Amoxicillin/Clavulanate Suspension	Cefpodoxime	
	Antibiotics	Amoxicillin/Clavulanate Susp (Augmentin®)		
		Amoxicillin/Clavulanate ER (Augmentin XR®)		
		Cefaclor		
		Cefaclor ER		
		Cefadroxil		
		Cefditoren Pivoxil (Spectracef®)		
		Cefixime (Suprax®)		
		Cefprozil		
		Ceftibuten (Cedax®)		
		Cefuroxime Axetil		
		Cephalexin		
	Fluoroquinolones	Ciprofloxacin Tablets	Ciprofloxacin Suspension (Cipro Suspension®)	
		Moxifloxacin (Avelox®)	Ciprofloxacin ER	
			Ciprofloxacin ER (Proquin XR®)	
			Gemifloxacin Mesylate (Factive®)	
			Levofloxacin (Levaquin®)	
			Norfloxacin (Noroxin®)	

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02/26/2010

Item Nbr	Descriptive Therapeutic Class	Drugs on PDL	Drugs which Require PA	Effective Date: April 1, 2010
			Ofloxacin	
	Antibiotics, Gastrointestinal	Metronidazole	Metronidazole ER (Flagyl ER®)	
		Neomycin	Rifaximin (Xifaxan®)	
		Nitazoxanide (Alinia®)		
		Tinidazole (Tindamax®)		
		Vancomycin (Vancocin®)		
	Macrolides - Ketolides	Azithromycin	Azithromycin ER (Zmax®)	
		Erythromycin Base	Clarithromycin	
		Erythromycin Estolate	Clarithromycin ER	
		Erythromycin Ethylsuccinate	Telithromycin (Ketek®)	
		Erythromycin Stearate		
	Tetracyclines	Doxycycline	Demeclocycline	
		Minocycline	Doxycycline Monohyrate (Nutridox®)	
		Tetracycline	Doxycycline DR (Oracea®)	
			Minocycline ER (Solodyn®)	
	Vaginal	Clindamycin Vaginal Cream	NONE	
		Clindamycin Vaginal Cream (Clindesse®)		
		Clindamycin Vaginal Ovules (Cleocin®)		
		Metronidazole Vaginal Gel Cream		
		Metronidazole Vaginal Gel (Vandazole®)		
	OPHTHALMIC ANTIBIOTICS - refer to Ophthalmic Disorders			
	OTIC ANTIBIOTICS - refer to OTIC Agents			
	ANTIFUNGALS			
	Antifungals, Oral	Fluconazole	Clotrimazole Troches	

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Item Nbr	Descriptive Therapeutic Class	Drugs on PDL	Drugs which Require PA	Effective Date: April 1, 2010
		Griseofulvin (Gris-Peg®)	Flucytosine (Ancobon®)	
	Antifungals, Oral, Cont.	Griseofulvin Suspension	Griseofulvin Tablets (Grifulvin V®)	
		Ketoconazole	Itraconazole	
		Nystatin	Posaconazole (Noxafil®)	
		Terbinafine (no granules)	Terbinafine Granules (Lamisil Granules®)	
			Terbinafine Hydrochloride/Hydroxpyropyl Chitosan (Terbinex Eco-Formula®)	
			Voriconazole (VFEND®)	
	HEPATITIS AGENTS			
	Hepatitis C Agents	Ribavirin	Consensus Interferon (Infergen®)	
		Peginterferon alfa 2A (Pegasys®)	Peginterferon alfa 2B (Peg-Intron®)	
			Peginterferon alfa 2B (Peg-Intron Redipen®)	
19	MULTIPLE SCLEROSIS	Glatiramer (Copaxone®)	Interferon beta - 1b (Extavia®)	
	Multiple Sclerosis Agents	Interferon beta - 1a (Avonex®)		
	(Immunomodulatory Agents)	Interferon beta - 1a (Rebif®)		
		Interferon beta - 1b (Betaseron®)		
20	OPHTHALMIC DISORDERS			
	Allergic Conjunctivitis	Loteprednol (Alrex®)	Azelastine Hydrochloride (Optivar®)	
		Olopatadine HCl (Pataday®)	Bepotastine Besilate (Bepreve®)	
		Olopatadine HCl (Patanol®)	Cromolyn Sodium	
			Emedastine Difumarate (Emadine®)	
			Epinastine HCl (Elestat®)	
			Ketorolac Tromethamine (Acular®)	
			Ketotifen Fumarate	
			Lodoxamine Tromethamine (Alomide®)	
			Nedocromil Sodium (Alocril®)	
			Pemirolast Potassium (Alamast®)	

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Item Nbr	Descriptive Therapeutic Class	Drugs on PDL	Drugs which Require PA	Effective Date: April 1, 2010
	Glaucoma Agents			
	Intraocular Pressure (IOP)	Betaxolol	Bimatroprost (Lumigan®)	
	Reducers	Betaxolol (Betoptic S®)	Dorzolamide (generic only)	
		Brimonidine Tartrate (Alphagan P®)	Dorzolamide/Timolol (generic only)	
		Brimonidine Tartrate		
		Brimonidine/Timolol (Combigan®)		
		Brinzolamide (Azopt®)		
		Carteolol		
		Dipivefrin (Propine®)		
		Dorzolamide (Trusopt® - Brand only)		
		Dorzolamide/Timolol (Cosopt® - Brand only)		
		Latanoprost (Xalatan®)		
		Levobunolol		
		Metipranolol		
		Pilocarpine		
		Timolol (Betimol®)		
		Timolol Maleate		
		Timolol LA (Istalol®)		
		Travoprost (Travatan, Travantan Z®)		
	Ophthalmics, Antibiotic	Bacitracin/Polymyxin	Azithromycin 1% (AzaSite®)	
		Erythromycin	Besifloxacin (Besivance®)	
		Gentamicin	Ciprofloxacin Ointment (Ciloxan®)	
		Moxifloxacin (Vigamox®)	Ciprofloxacin Solution	
		Neomycin-Polmyxin-Gramacidin	Gatifloxacin (Zymar®)	
		Tobramycin (Tobrex®)	Levofloxacin (Iquix®)	
		Triple Antibiotic	Levofloxacin (Quixin®)	
			Natamycin (Natacyn®)	
			Ofloxacin Solution	
	Ophthalmics, Anti-Inflammatories	Dexamethasone (Maxidex®)	Bromfenac (Xibrom®)	
		Dexamethasone Sodium Phosphate	Difluprednate (Durezol®)	

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		Diclofenac	Fluocinolone (Retisert®)	
	Ophthalmics, Anti-Inflammatories cont.	Fluorometholone	Ketorolac (Acular LS®)	
		Fluorometholone (Flarex®)	Ketorolac PF (Acular PF®)	
		Fluorometholone (FML Forte®)	Ketorolac Tromethamine (Acuvail®)	
		Fluorometholone (FML S.O.P.®)	Nepafenac (Nevanac®)	
		Flurbiprofen	Rimexolone (Vexol®)	
		Loteprednol (Lotemax®)	Tramnolone Acetonide (Triesence®)	
		Prednisolone Acetate (Prep Mild®)		
21	OTIC AGENTS			
	Otic Antibiotics	Ciprofloxacin/Dexamethasone (Ciprodex OTIC®)	Ciprofloxacin (Cetraxal Otic)	
		Neomycin/Colistin/Thonzonium/HC (Coly-Mycin S®)	Ciprofloxacin/Hydrocortisone (Cipro HC OTIC®)	
		Neomycin/Colistin/Thonzonium/HC (Cortisporin TC®)		
		Neomycin/Polymyxin/HC		
		Ofloxacin - Generics		
		Ofloxacin (Floxin®)		
22	OSTEOPOROSIS			
	Bone Resorption Suppression	Alendronate Sodium	Alendronate Solution (Fosamax Solution®)	
	Agents	Calcitonin - Salmon Nasal (generic)	Alendronate/Vit D (Fosamax Plus D®)	
		Calcitonin-Salmon Nasal (Miacalcin®)	Calcitonin-Salmon Nasal (Fortical®)	
		Ibandronate Sodium (Boniva®)	Etidronate Disodium	
		Risedronate (Actonel®)	Raloxifene (Evista®)	
			Risedronatel/Calcium (Actonel with Calcium®)	
			Teriparatide Subcutaneous (Forteo®)	
23	PAIN MANAGEMENT			
	Analgesics/Anesthetic, Topical	Diclofenac Sodium Gel (Voltaren®)	Diclofenac Epolamine Patch (Flector®)	
		Lidocaine Patch (Lidoderm®)		
	Analgesics, Narcotics Short Acting	Acetaminophen w/Codeine	Acetaminophen/Caffeine/Dihydrocodeine Bitartrate (Panlor DC®)	
		Butalbital Compound with Codeine	Fentanyl Citrate Buccal - Generics	

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		Codeine Phosphate	Fentanyl Buccal (Fentora®)	
	Analgesics, Narcotics Short Acting, cont.	Codeine Sulfate	Fentanyl Buccal (Onsolis®)	
		Dihydrocodeine Bitartrate/Acetaminophen/Caffeine (Generics)	Hydrocodone/Acetaminophen (Zamicet®)	
		Hydrocodone/Acetaminophen	Hydrocodone/Ibuprofen (Ibudone®)	
		Hydrocodone/Ibuprofen	Hydromorphone Liquid (Dilaudid®)	
		Hydrocodone/Ibuprofen (Reprexain®)	Opium Tincture	
		Hydromorphone	Oxymorphone (Numorphan®)	
		Meperidine HCL	Oxymorphone IR (Opana®)	
		Morphine Sulfate IR	Propoxyphene Napsylate (Darvon-N®)	
		Oxycodone	Tapentadol (Nucynta®)	
		Oxycodone/Acetaminophen		
		Oxycodone w/Aspirin		
		Oxycodone/Ibuprofen		
		Pentazocine/Acetaminophen		
		Pentazocine/Naloxone		
		Propoxyphene		
		Propoxyphene w/APAP		
		Propoxyphene Napsylate w/APAP		
		Tramadol		
		Tramadol/Acetaminophen		
23	Analgesics, Narcotics Long Acting	Fentanyl Transdermal (Generic only)	Fentanyl Transdermal (Duragesic Matrix)	
		Methadone HCL	Fentanyl Transdermal (Duragesic Transdermal)	
		Morphine Sulfate ER (Kadian®)	Morphine Sulfate ER (Avinza®)	
		Morphine Sulfate ER (Generic)	Morphine Sulfate ER/Naltrexone (Embeda®)	
		Tramadol ER (Generics only)	Oxycodone ER	
			Oxycodone (Oxycontin®)	
			Oxymorphone ER (Opana ER®)	
			Tramadol ER (Ryzolt®)	
			Tramadol ER (Ultram ER®)	
	Nonsteroidal Anti - Inflammatories	Diclofenac	Celecoxib (Celebrex®)	
	(NSAIDs)	Etodolac	Diclofenac/Misoprostol (Arthrotec®)	
		Fenoprofen	Diclofenac Potassium (Zipsor®)	

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		Flurbiprofen	Nabumetone	
	Nonsteroidal Anti - Inflammatories	Ibuprofen Rx		
	(NSAIDs), Cont.	Indomethacin Oral and Rectal		
		Ketoprofen		
		Ketorolac		
		Meclofenamate Sodium		
		Meloxicam		
		Naproxen Rx		
		Oxaprozin		
		Piroxicam		
		Sulindac		
		Tolmetin Sodium		
	Immunomodulators and Related Agents for Arthritis	Adalimumab (Humira®)	Abatacept (Orencia®)	
		Etanercept (Enbrel®)	Alefacept (Amevive®)	
			Anakinra (Kineret®)	
			Certolizumab Pegol (Cimzia®)	
			Golimumab (Simponi®)	
			Infliximab (Remicade®)	
	Antimigraine Agents,	Rizatriptan (Maxalt®, Maxalt MLT®)	Almotriptan (Axert®)	
	Triptans	Sumatriptan (Imitrex® Injection-Brand only)	Eletriptan (Relpax®)	
		Sumatriptan (Imitrex ® Nasal -Brand only)	Frovatriptan (Frova®)	
		Sumatriptan (Imitrex® Oral – Brand only)	Naratriptan (Amerge®)	
		Sumatriptan/Naproxen (Treximet®)	Sumatriptan Injection – Generic only	
			Sumatriptan Nasal – Generic only	
			Sumatriptan Oral – Generic only	
			Zolmitriptan (Zomig, Zomig ZMT®)	
			Zolmitriptan (Zomig® Nasal)	
	Skeletal Muscle Relaxants	Baclofen	Carisoprodol (Soma 250 mg®)	
		Carisoprodol	Cyclobenzaprine (Fexmid®)	

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		Carisoprodol Compound	Cyclobenzaprine ER (Amrix®)	
	Skeletal Muscle Relaxants, Cont.	Chlorzoxazone	Dantrolene Sodium	
		Cyclobenzaprine	Metaxalone (Skelaxin®)	
		Methocarbamol	Orphenadrine	
		Tizanidine – Generics only	Orphenadrine Compound	
			Tizanidine (Zanaflex® - Brand Only)	
24	PARKINSON'S			
	Antiparkinson Agents -	Benztropine	Bromocriptine	
	Anticholinergic and Other	Levodopa/Carbidopa	Entacapone (Comtan®)	
		Levodopa/Carbidopa/Entacapone (Stalevo®)	Levodopa/Carbidopa ODT	
		Ropinirole	Pramipexole (Mirapex®)	
		Selegiline	Rasagiline (Azilect®)	
		Trihexyphenidyl	Ropinorole ER (Requip XL®)	
			Selegiline (Zelapar®)	
			Tolcapone (Tasmar®)	
25	SEDATIVE/HYPNOTICS			
	Sedative/Hypnotics	Chloral Hydrate	Estazolam	
		Temazepam	Eszopiclone (Lunesta®)	
		Triazolam	Flurazepam	
		Zaleplon	Quazepam (Doral®)	
		Zolpidem	Ramelteon (Rozerem®)	
			Zolpidem Sublingual (Edluar®)	
			Zolpidem CR (Ambien CR®)	
26	UROLOGY			
	INCONTINENCE			
	Bladder Relaxant Preparations	Darifenacin (Enablex®)	Oxybutynin ER	
		Fesoterodine Fumarate (Toviaz®)	Oxybutynin Gel (Gelnique Transdermal®)	
		Oxybutynin	Oxybutynin Transdermal (Oxytrol®)	
		Solifenacin (VESIcare®)	Tolterodine (Detrol®)	

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			Tolterodine ER (Detrol LA®)	
	Bladder Relaxant Preparations, Cont.		Trospium (Sanctura®)	
			Trospium (Sanctura XR®)	
	PROSTATE			
	Benign Prostatic Hyperplasia Treatment (BPH)	Alfuzosin (Uroxatral®)	Doxazosin XL (Cardura XL®)	
		Doxazosin	Dutasteride (Avodart®)	
		Finasteride	Silodosin (Rapaflo®)	
		Tamsulosin (Flomax®)		
		Terazosin		

Clinical Considerations for Proton Pump Inhibitor (PPI) Use

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Proton pump inhibitors are among the most frequently prescribed medications in the world, most likely due to their efficacy in reducing gastric acid and positive safety profile.[1] However, decisions to prescribe PPIs must include an assessment of patient-specific factors, such as concomitant medication use and the potential for adverse effects. Because proton pump inhibitors are used in long-term management for certain indications, these assessments become all the more important.

Interaction between Clopidogrel (Plavix®) and Proton Pump Inhibitors (PPIs)

- The prodrug, clopidogrel, is metabolized to a bioactive form by the cytochrome P450 (CYP2C19) isoenzyme. Studies have shown that patients with reduced activity of CYP2C19 due to loss-of-function polymorphism of the enzyme experience a diminished clinical effectiveness of clopidogrel.[2-4]

- In vitro studies have shown that the FDA-approved PPIs exhibit competitive inhibition for CYP2C19 at varying degrees of affinity by agent, which has led to the suspicion of an interaction between PPIs and clopidogrel.[5]

- The findings of several observational studies have supported the suspicion that the use of PPIs possibly alter clopidogrel's pharmacokinetics and potentially increase the risk of adverse cardiac outcomes.[6-10]

- Not all studies have been able to reproduce these findings as noted in an observational study by Simon, et al[11] and a nonrandomized study by Siller-Matual, et al.[12] Additionally, researchers that conducted a posthoc analysis of data from the PRINCIPLE-TIMI 44 and TRITON-TIMI 38 trials were not able to show that the use of PPIs is associated with increased risk of adverse clinical outcomes when used with clopidogrel or the new oral antiplatelet drug in these studies, prasugrel (Effient®).[13,14] However, authors reported, "In our analysis, individual subgroups might have been underpowered to show an association between PPI use and risk of pharmacodynamic or clinical outcomes, if such a relation existed."[15]

- In a January 2009 Early Communication, the FDA recommended a thorough investigation of the potential interaction between clopidogrel and PPIs and asked healthcare providers to reevaluate the need of initiation or continuation of PPI treatment in patients taking clopidogrel.[16]

- In November 2009, the FDA issued a follow-up to its January Early Communication and required labeling revisions regarding the interaction. The follow-up is based on study results from the manufacturer of clopidogrel and advised prescribers AGAINST the concomitant use of clopidogrel with two specific PPIs, omeprazole and esomeprazole. According to the FDA, there is currently not enough information about drug interactions between clopidogrel and the other PPIs to advise against concomitant use.[16-18]

- In addition to omeprazole and esomeprazole, the FDA advised AGAINST the co-administration of clopidogrel with other potent inhibitors of the CYP2C19 isoenzyme. These inhibitors include: cimetidine, fluconazole, ketoconazole, voriconazole, etravirine, felbamate, fluoxetine, fluvoxamine, and ticlopidine.[17]

- Figure 1 provides an excerpt from the FDA Postmarketing Drug Safety Information on the interaction.[18] For the complete update, visit: http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/ucm190787.htm

Figure 1. FDA Information for Healthcare Professionals: Clopidogrel-Omeprazole Interaction

Considerations for Healthcare Professionals

- The concomitant use of omeprazole and clopidogrel should be avoided because of the effect on clopidogrel's active metabolite levels and anti-clotting activity. Patients at risk for heart attacks or strokes, who are given clopidogrel to prevent blood clots, may not get the full protective anti-clotting effect if they also take prescription omeprazole or the OTC form (Prilosec OTC).

- Separating the dose of clopidogrel and omeprazole in time will not reduce this drug interaction.

- Other drugs that should be avoided in combination with clopidogrel because they may have a similar interaction include: esomeprazole (Nexium), cimetidine (which is available by prescription Tagamet and OTC as Tagamet HB), fluconazole (Diflucan), ketoconazole (Nizoral), voriconazole (VFEND), etravirine (Intelence), felbamate (Felbatol), fluoxetine (Prozac, Serafem, Symbyax), fluvoxamine (Luvox), and ticlopidine (Ticlid).

- At this time FDA does not have sufficient information about drug interactions between clopidogrel and PPIs other than omeprazole and esomeprazole to make specific recommendations about their co-administration. Healthcare professionals and patients should consider all treatment options carefully before beginning therapy.

- There is no evidence that other drugs that reduce stomach acid, such as most H2 blockers ranitidine (Zantac), famotidine (Pepcid), nizatidine (Axid), except cimetidine (Tagamet and Tagamet HB - a CYP2C19 inhibitor) or antacids interfere with the anti-clotting activity of clopidogrel. Ranitidine and famotidine are available by prescription and OTC to relieve and prevent heartburn and antacids are available OTC to relieve heartburn.

- Talk with your patients about the OTC medicines they take. Be aware that patients may be taking non prescription forms omeprazole and cimetidine.

Possible Safety Issues Related to the Long-term Use of PPIs

For over a decade, concerns have been raised regarding the appropriateness of long-term antisecretory therapy (AST) for treatment of gastroesophageal reflux disease (GERD) symptoms, predominately with PPIs. According to studies, up to 70% of patients on chronic AST lack an indication verified endoscopically.[19,20] Indications for long-term AST include symptomatic GERD, GI bleeding, erosive esophagitis, NSAID prophylaxis, and pathologic GI hypersecretory conditions (e.g., Zollinger-Ellison, multiple endocrine adenomas, systemic mastocytosis).[21] Potential risks associated with prolonged and potentially imprudent use of PPIs have been investigated and are discussed below.

Nutritional Deficiency

- Vitamin B-12: Vitamin B-12 deficiency has been associated with PPI long-term use, yet no association has been determined between either past or short-term PPI use.[22-24] Recent studies have produced mixed results.[25,26] The overall body of evidence is based on case reports and small nonrandomized retrospective studies, which cannot firmly establish the association of PPI use with B-12 deficiency or the need for routine monitoring of B-12 levels.

- Iron: Several clinical studies have suggested that prolonged gastric acid hyposecretion might result in clinically significant iron malabsorption.[27,28] Poor response to oral iron supplement absorption in 2 iron-deficient individuals improved after cessation of omeprazole in a published report.[29] One study showed that continuous treatment with omeprazole for 6 years did not cause decreased body iron stores or iron deficiency in patients with Zollinger-Ellison syndrome, suggesting that monitoring for iron deficiency is not necessary.[30] There is a need for long-term safety studies regarding iron deficiency in patients using PPIs for more general indications.

- Calcium: Increased risk of osteoporosis with AST has been speculated to be related to a reduction in absorption of calcium. However, the mechanism for increased fracture risk with AST has not been proven. Studies have demonstrated a reduction of calcium absorption with PPI use.[31,32] Multiple studies have investigated the association between long-term PPI therapy and hip fracture, however, results are conflicting.[33-36] Currently, there is not enough evidence to suggest all patients on long-term PPI therapy be screened for osteoporosis.[32] However, there remains an urgent need to understand the effects of PPIs on calcium metabolism. It is recommended that these patients receive increased dietary calcium from food sources or calcium supplements. Supplements in the form of calcium citrate may allow greater bioavailability when acid-suppression therapy is being used and may be absorbed better than calcium carbonate regardless of whether co-administered with food. Calcium carbonate supplements taken with a meal may increase bioavailability.[33, 37]

Infectious Disease

- *Clostridium difficile*: There are data that link PPI use with an increase in C. *difficile* colitis[38-41] and bacterial gastroenteritis,[42] but in each case the magnitude of risk is slight. The most recent evidence suggested only a slight association and concluded that "in settings with low rates of C. *difficile* infection (CDI), the benefit of PPI therapy outweighs the risk of developing CDI."[43]

- Community-Acquired Pneumonia (CAP): Results from observational studies have suggested that PPI use is associated with an increased risk for developing CAP.[44-46]

  - The results of these studies demonstrated a temporal association between PPI use and risk for CAP, with risk being most pronounced among current users who initiated PPI therapy within the past 7 [46] to 30 [44, 45] days. Of note, the study by Sarkar et al found that CAP risk was not associated with long-term PPI use.[45] Interestingly, Laheij et al observed a dose-response relationship among current users of PPIs such that persons using greater than 1 defined daily dose had a 2.3 times greater risk of CAP compared with past users of PPIs.[44] For this study, daily doses were defined as: omeprazole 20mg, esomeprazole 20mg, lansoprazole 30mg, pantoprazole 40mg, and rabeprazaole 20mg.

  - "It should be considered that certain patients (e.g., those with pleuritic chest pain, hypothermia, systolic hypotension, tachypnea, diabetes mellitus, neoplastic disease, neurologic disease, bacteremia, leukopenia, multilobar pulmonary infiltrate) are at increased risk for developing infections and in these individuals community-acquired pneumonia may be associated with increased mortality."[47] Therefore, PPI use in these individuals and in other patient populations for whom pneumonia is often severe should be considered only when necessary and at the lowest effective dose.[44,47]

Malignancy

- The risk of increased gastric and colon malignancy associated with long-term PPI use has been theorized due to results of animal studies, but has not been observed in humans.[48]

- A study conducted by Jalving et al to determine whether PPI use contributed to fundic gland polyp development concluded the following: "Long-term (1-5 years) proton pump inhibitor use is associated with an up to fourfold increase in the risk of fundic gland polyps. Risk of dysplasia is negligible. Aetiologically, these polyps seem to arise because of parietal cell hyperplasia and parietal cell protrusions resulting from acid suppression."[49]

- The FDA's Gastrointestinal Drugs Advisory Committee stated the following in the F-D-C Report ("*The Pink Sheet*"): "In the presence of [*Helicobacter pylori*] infection, data do not demonstrate that long-term antisecretory drug treatment increases the prevalence of atrophic gastritis, the prevalence of intestinal metaplasia, or the risk of developing gastric adenocarcinoma."[50] The committee also agreed that the evidence does not lead to the conclusion that "it is unsafe to treat *H. pylori*-positive patients with long-term antisecretory drugs."[50]

PPI Withdrawal

- Though past studies investigating rebound acid hypersecretion (RAHS) after cessation of PPI treatment have not provided strong supportive evidence for acid rebound,[51-53] data from a more recent, well-designed study suggested that discontinuation of PPI therapy results in acid-related symptoms.[54] This evidence raises a concern that if a patient who does not truly need a PPI reports withdrawal effects after discontinuation, the clinician might conclude that a relapse has occurred and resume PPI therapy unnecessarily.

- Future studies investigating how long RAHS symptoms persist may help guide decisions regarding the resumption of PPI therapy.

- Tapering of therapy over a 3-week period has not demonstrated an advantage over instant discontinuation for preventing RAHS.[55] Because studies have indicated that acid rebound may persist longer than 8 weeks, tapering over a longer period of time may be worthy of consideration.[52,56]

Step-Down, Intermittent and On-Demand Therapy Strategies

- Concerns about cost, inconvenience, and/or potential adverse effects of continuous maintenance treatment using PPIs have led to the evaluation of various long-term strategies, including 'Step-Down,' 'Intermittent,' and 'On-Demand' therapy. These strategies are supported by clinical trials that have demonstrated efficacy, cost-effectiveness, and patient preference. According to a study conducted by Inadomi et al, almost 80% of patients taking a higher PPI dose could be reduced to a standard once daily dosing.[57]

  - 'Step Down' therapy involves using a lower PPI dose or alternate day dosing, a less expensive PPI, or *stepping down* to an alternate therapy such as an H2-receptor antagonist.[57] In GERD, patients taking more than once daily or high-dose PPI treatment, a *step down* to once daily or standard dose therapy should be attempted.[58]

  - 'Intermittent' therapy uses repeated short courses (2-4 weeks) of AST to manage relapses. This method has been shown to be effective in about half of the patients in one study.[58]

  - 'On-Demand' therapy is the administration of medication in response to symptoms followed by discontinuation after symptoms are alleviated. 'On-demand' PPI treatment may be appropriate in endoscopy-negative reflux disease.[58]

- The best candidates for these strategies are patients with GERD symptoms that resolve with PPI treatment and that do not have complicated disease, such as those with esophageal stricture, Barrett's esophagus, extra-esophageal manifestations or diagnosed GERD.[58,59]

Conclusion

Patient safety is an important consideration in all prescribing decisions, including the potential for drug-drug interactions or the possibility of adverse effects associated with long-term treatment. These are important considerations, even for medications, such as PPIs, that are considered safe, very efficacious, and are frequently prescribed.

In light of current information, the FDA has advised against the co-administration of clopidogrel (Plavix®) and omeprazole (Prilosec®) or esomeprazole (Nexium®). Additionally, the FDA indicated that this interaction is not reduced by separation of doses. The FDA further recommended that clopidogrel and other potent CYP2C19 inhibitors should not be used together. Further studies are ongoing.

A variety of potential adverse effects related to long-term PPI use have been evaluated. While there is not sufficient evidence to establish a causal relationship, many of these observational studies have demonstrated an association between long-term PPI use and an increased risk for certain adverse effects. However, considering the number of patients using PPIs, these findings of possible risk for adverse effects warrant consideration in patient care.

PPIs are effective medications with a good safety profile; however, they should be prescribed only when clearly indicated, at the lowest effective dose, and for the shortest duration of treatment. Treatment decisions should be re-evaluated on a frequent basis. "After all, in the absence of benefit, a risk-benefit ratio is always unacceptable."[32]

The Louisiana Drug Information Center (DIC) located at the University of Louisiana at Monroe (ULM) College of Pharmacy (COP) provides assistance with areas such as literature retrieval and evidence-based recommendations. The DIC provides a healthcare provider-focused service for the State of Louisiana that is also available to Medicaid providers through support from the Louisiana Medicaid Pharmacy Benefits Management Program. Healthcare providers can contact us at the following telephone number for drug information requests:

318-342-5501

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