South Carolina
Department of Health and Human Services
Post Office Box 8206
Columbia, South Carolina 29202-8206

Pharmacy and Therapeutics (P&T) Committee Meeting
May 4, 2005
MINUTES

1. Call To Order

A meeting of the P&T Committee convened at 4:00 p.m. on Wednesday, May 4, 2005.

2. Welcome

Dr. LaCroix opened the meeting by stating that the P&T Committee meetings are held in compliance with the Freedom of Information Act's (FOIA) mandate that the public is notified when the public's business is being done, and that furthermore, the public has been notified that this facility is accessible to individuals with disabilities, and special accommodations could have been provided if requested in advance.
Dr. LaCroix expressed appreciation to the South Carolina Pharmacy Association for providing their building as a meeting location for the Committee.

3. Committee Members Present:

J. Kevin Baugh, M.D.
Edward M. Behling, M.D.
Gregory V. Browning, M.D.
Joseph A. Horvath, M.D.
Kelly Jones, Pharm.D.
Jerome E. Kurent, M.D.
Robin K. LaCroix, M.D.
James M. Lindsey, M.D.
Mark A. O'Rourke, M.D.
Thomas Phillips, R.Ph.
Deborah J. Tapley, R.Ph.
George E. Vess, Pharm.D.
Harry H. Wright, M.D.

DHHS Staff Present:

James M. Assey, R.Ph.
Susan Bowling
Marion Burton, M.D.
Byron Roberts, J.D.
Deirdra Singleton, J.D.
Caroline Sojourner, R.Ph.
Linda Van Hoose

Other Representation:

First Health Services Corporation – Mary Roberts, R.Ph.

Pharmaceutical Industry Representatives

S. C. Psychiatric Association – Deborah Leverette, M.D.

S. C. Society for Allergy, Asthma, & Immunology – Michael Bykowski, M.D.

4. Discussion Topics

A. Committee Meeting Minutes, Wednesday, February 2, 2005.
Minutes from the previous P&T Committee meeting were approved.

B. General Issues

Dr. LaCroix explained that effective with this meeting, re-reviews of PDL therapeutic classes were beginning. She stated that in order for a PDL therapeutic class to be considered for opening for re-review, one or more of the following may have occurred since the initial review: 1) a new drug in the therapeutic class, 2) a new indication for an existing drug in the therapeutic class, 3) a new FDA-approved study or three peer-reviewed studies for a drug in the therapeutic class.

Dr. LaCroix advised the speakers that presentations are limited to three (3) minutes in duration. Dr. LaCroix reminded attendees that information regarding a speaker's name, title, credentials, or curriculum vitae should be submitted to DHHS no later than seven (7) days prior to the meeting date.

C. Public Comment

The following speakers discussed the drugs listed below:

	Company	Speaker	Drug
1)	Astra Zeneca	Tim Briscoe, Pharm.D. Senior Cardiovascular Medical Information Scientist Astra Zeneca	Atacand®
2)	Boehringer Ingelheim	Linda Konigsberg, Pharm.D. Senior Medical Scientist – Cardiovascular, Boehringer Ingelheim Pharmaceuticals	Micardis®, Mobic®
3)	Bristol-Myers Squibb	Keith Latham, Pharm.D. Senior Medical Science Liaison Bristol-Myers Squibb	Avapro®, Avalide®
4)	Merck	Russell Gene Clayton, D.O. Merck Regional Medical Director	Hyzaar®, Cozaar®
5)	Novartis	Raymond E. Lancaster, Pharm.D. Novartis Associate Director of Regional Scientific Operations, Specialty-Internal Medicine, Cardiovascular, Infectious Disease and Pharmacokinetics	Diovan®
6)	Sankyo Pharma	Steven Ross, M.D. Internal Medicine Associates of Florence, Florence, SC	Benicar®, Benicar HCT®
7)	S.C. Society for Allergy, Asthma, and Immunology	Michael J. Bykowski, M.D., Ph.D. President, SC Society for Allergy, Asthma, and Immunology	PDL and low-sedating antihistamines
8)	Pfizer	Barry Cabiness M.D. Palmetto Pediatric and Adolescent Clinic, Columbia SC	Zyrtec®

	Company	Speaker	Drug
9)	Schering Plough Corp.	John F. Howard, Pharm.D. Medical Science Specialist Schering Plough Corp	Clarinex D®
10)	Schering Plough Corp.	John Ansley, M.D. Ear, Nose, Throat Specialty Orangeburg, SC	Clarinex®
11)	Astra Zeneca	Matthew A. Witt, Pharm.D. Senior Medical Information Specialist, Astra Zeneca Pharmaceuticals	Rhinocort AQ®
12)	GlaxoSmithKline	Frederick M. Schaeffer, M.D. National Allergy, Asthma and Urticaria Centers of Charleston SC	Flonase®
13)	Schering Plough Corp	John Ansley, M.D. Ear, Nose, Throat Specialty Orangeburg, SC	Nasonex®
14)	Merck	Russell Gene Clayton, D.O. Merck Regional Medical Director	Fosamax®
15)	Proctor and Gamble	John Roney, Pharm.D, Health Systems Consultant Proctor and Gamble Pharm.	Actonel®
16)	Roche	Ryan B. Leslie, Pharm.D. Primary Care Medical Liaison Roche Laboratories	Boniva®
17)	King Pharmaceuticals	Thomas Seastrunk – *No curriculum vitae submitted*	Sonata®
18)	Sanofi-Aventis	Richard Bogan, M.D. SleepMed of SC, Columbia SC	Ambien®
19)	Sepracor	Judith E. Tolhurst, M.D. Lexington County Community Mental Health, Lexington SC	Lunesta®

Following the period of public comment, Dr. LaCroix thanked each speaker for his or her individual presentation. Dr. LaCroix also reminded Committee members of the requirement to disclose any potential conflicts of interest at this time, prior to discussion of PDL selections.

D. <u>PDL Discussions And Selections For The Following Drug Classes</u>

Mary Roberts, R.Ph., First Health Corporation led the discussion for the following drug classes:

Analgesics – NSAID's

Angiotensin Receptor Blockers and Diuretic Combinations

Biphosphonates used for Osteoporosis

Nasal Steroids

Low-Sedating Antihistamines and Decongestant Combinations

Sedative Hypnotics

The P&T Committee voted to submit the following recommendations to DHHS:

No PA Required "Preferred"	PA Required
NSAID's	
DICLOFENAC POTASSIUM DICLOFENAC SODIUM DIFLUNISAL ETODOLAC FENOPROFEN FLURBIPROFEN IBUPROFEN INDOMETHACIN INDOMETHACIN SR KETOPROFEN KETOPROFEN ER KETOROLAC MECLOFENAMATE SODIUM NABUMETONE NAPROXEN NAPROXEN SODIUM OXAPROZIN PIROXICAM SULINDAC TOLMETIN SODIUM	ANAPROX® ANAPROX DS® ANSAID® ARTHROTEC® CATAFLAM® CLINORIL® DAYPRO® DOLOBID® FELDENE® INDOCIN® INDOCIN SR® LODINE® LODINE XL® MECLOMEN® MOBIC® MOTRIN® NALFON® NAPRELAN® NAPROSYN® ORUDIS® ORUVAIL® PONSTEL® RELAFEN® TOLECTIN® TOLECTIN DS® TORADOL® VOLTAREN® VOLTAREN XR®
ANGIOTENSIN II RECEPTOR BLOCKERS	
COZAAR® DIOVAN® MICARDIS® TEVETEN®	ATACAND® AVAPRO® BENICAR®

No PA Required "Preferred"	PA Required
ANGIOTENSIN II RECEPTOR BLOCKER DIURETIC COMBINATIONS	
DIOVAN HCT® HYZAAR® MICARDIS HCT® TEVETEN HCT®	ATACAND HCT® AVALIDE® BENICAR HCT®
ANTIHISTAMINES: SECOND GENERATION AND DECONGESTANT COMBINATIONS	
LORATADINE OTC – TABS, RAPID DISSOLVE, SYRUP LORATADINE-D OTC ALLEGRA® ALLEGRA D® ZYRTEC® ZYRTEC D®	ALAVERT® CLARINEX ® CLARITIN D® CLARITIN®
BIPHOSPHONATES USED FOR OSTEOPOROSIS	
FOSAMAX®	ACTONEL® BONIVA® FOSAMAX PLUS D®
GLUCOCORTICOIDS: INTRANASAL STEROIDS	
FLONASE® NASACORT AQ® NASONEX®	BECONASE AQ® FLUNISOLIDE NASACORT ® NASAREL® RHINOCORT AQ ® TRI-NASAL®
SEDATIVE/HYPNOTICS (NON-BARBITURATE)	

No PA Required "Preferred"	PA Required
AMBIEN® RESTORIL® 7.5mg TEMAZEPAM	DORAL® ESTAZOLAM (all brands and formulations) FLURAZEPAM (all brands and formulations) LUNESTA® ***(STEP EDIT TO ALLOW WITHOUT PA IF PREFERRED AGENT IN HISTORY)*** RESTORIL® (15 and 30mg) SOMNOTE® SONATA® TRIAZOLAM (all brands and formulations)

5 Old Business

Dr. LaCroix reminded Committee members that the recommendations of the P&T Committee will be submitted to DHHS for approval with final decisions being communicated to providers in a Medicaid bulletin.

Dr. LaCroix asked that all materials that are intended for review by P&T members (e.g., drug information submitted by pharmaceutical companies), be sent electronically to Mr. Assey. He will ensure that the information is posted on the website where Committee members can access it. Dr. Kurent discussed his concern that he views it as a conflict of interest for industry representatives to meet with him to discuss items that are scheduled for P&T discussion. He also indicated displeasure with the volume of drug information that is being mailed/shipped to P&T Committee members by industry representatives. Vice Chair Deborah Tapley suggested that Committee members inform DHHS when they feel like too many materials or visits from industry representatives are inundating them.

Dr. Behling pointed out that the three-minute presentations should not include complaints about the general prior authorization process (e.g., time-consuming, laborious process, etc.). He also mentioned that only factual clinical points, not anecdotal information, should be included in the presentations. Dr. Baugh advised against the establishment of rigid rules for presenters, stating that Committee members can determine the validity of the information being presented.

Dr. Lindsey inquired about the timeline for communicating the Committee's decisions to providers and when those decisions are implemented. In response to his question, it was explained that PDL decisions are effective when the Medicaid bulletin communicating that information is published.

6. New Business

A. Strattera® Discussion:

Discussion was held regarding the conflict that exists in American Academy of Child and Adolescent Psychiatry (AACAP) guidelines recommending Strattera® as first-line therapy versus guidelines from other entities.

B. Adderall XR® Discussion:

The Committee discussed the withdrawal of Adderall XR® from the Canadian market and the fact that the FDA has advised prescribers of the Canadian action, but that no similar action has occurred in the United States. This discussion served as a point of advisement for Committee members; Adderall XR® will remain with its current PDL status pending any action by the FDA. At this time the FDA has advised prescribers of the Canadian action, but no action has been initiated in the United States. Dr. LaCroix asked if DHHS had published the information regarding Adderall XR® and the Canadian market. The Committee was informed that this was not communicated in a Medicaid bulletin due to the time lag between the media's announcement of publication of a hard copy bulletin.

C. Second Generation Antihistamines Discussion:

Dr. Michael Bykowski (SC Society for Allergy, Asthma, and Immunology) spoke to the Committee about evaluating the placement of the therapeutic class, "Antihistamines," on the PDL. He stated that allergists do not consider all antihistamines to be the same or interchangeable and that tissue penetration is different for each of the antihistamines. When asked which agent he preferred, Dr. Bykowski indicated that he did not want to advocate for any particular agent, however, he considered Allegra® to be his first choice. Dr. Bykowski said that the prior authorization (PA) process is burdensome and costly. He also requested consideration of exempting allergists from the antihistamine PA process if the Committee determined that this category would remain on the PDL.

D. Voluntary PDL for Mental Health Drugs:

James Assey advised the committee that DHHS is pursuing the possibility of a voluntary PDL for mental health drugs. At this time, there is a proviso in effect that prevents these agents from being included in the current PDL. DHHS is working with mental health providers to prepare a listing of mental health drugs that would designate products as preferred for first line therapy if clinically appropriate.

Dr. Deborah Leverette, M.D. spoke to the Committee on behalf of the South Carolina Psychiatric Association. Dr. Leverette stated that she did not want any restrictions on mental health drugs and expressed concern over the possibility of a voluntary PDL for these products. However, Dr. Leverette stated that practitioners would benefit from a listing that indicates the comparative costs of the mental health agents by listing dollar signs with more dollar signs signifying higher costs. Such information would assist providers in making more cost-effective choices when appropriate.

E. PDL Savings

Dr. LaCroix announced to the Committee that their efforts thus far on the PDL have translated into total dollar costs savings of $15.6 million.

7. Resolved Items

Recommendations regarding PDL status for drugs in the following drug classes were approved for submission to DHHS:

Analgesics – NSAID's
Angiotensin Receptor Blockers and Diuretic Combinations
Biphosphonates used for Osteoporosis
Nasal Steroids
Low Sedating Antihistamines and Decongestant Combinations
Sedative Hypnotics

The P&T Committee re-validated previous P&T Committee recommendations regarding PDL status for drugs in the following drug classes:

ACE Inhibitors and Diuretic Combinations
ADHD Therapy
Beta-Adrenergic Agents
Inhaled Steroids
Leukotriene Receptor Agonists
Cephalosporins
Anti-Migraine Serotonin Receptor Agonists
Calcium Channel Blockers
ACE Inhibitor/CCB Combinations
Beta Blockers
H_2 Receptor Antagonists
Proton Pump Inhibitors

8. Unresolved Items

None.

9. Closing Comments

Dr. LaCroix thanked the Pharmacy Association for hosting the P&T Committee meeting and announced that the next P&T Committee meeting will be held at the South Carolina Pharmacy Association office on Wednesday, September 7, 2005.

10. Adjournment

The meeting adjourned at 7:40 p.m.