

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

Pharmacy and Therapeutics (P&T) Committee Meeting
MINUTES

1. Call To Order

A meeting of the P & T Committee convened at 4:00 p.m. on Wednesday, April 7, 2004.

2. Committee Members Present:

Joseph A. Horvath, M.D.	Mark A. O'Rourke, M.D.
Albert Humphrey, M.D.	Deborah J. Tapley, R.Ph.
Robin K. LaCroix, M.D.	Wayne Weart, Pharm.D.
James M. Lindsey, M.D.	Harry H. Wright, M.D.

Committee Members Absent:

Matthew K. Cline, M.D.
Thomas Phillips, R.Ph.
George E. Vess, Pharm.D.

DHHS Staff Present:

Marion Burton	Deirdra Singleton
Melanie Giese	Caroline Sojourner
Byron Roberts	Linda Van Hoose

Other Representation:

First Health Services Corporation – Mary Roberts, R.Ph., Sandra Kapur, R.Ph.
Pharmaceutical Industry Representatives

3. Welcome

Dr. LaCroix, Chairperson and Dr. O. Marion Burton, DHHS Medical Director welcomed the Committee Members and others. It was announced that Mr. James Assey, Division Director of Pharmacy Services & DME was absent due to a conference in Washington D.C.

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.

4. **Introductions**

P & T Committee Members made individual introductions.

5. **Discussion Topics**

A. Committee Meeting Minutes, Wednesday, March 3, 2004

Approved by the Committee without any changes.

B. Drug Presentations For Potential PDL

The discussion began with Dr. LaCroix explaining to Committee Members and others present that Dr. Burton would be the official timekeeper. Dr. Burton explained that no pricing information would be considered and that the time limit set for each presentation would be in accordance with the set of guidelines established for public comments by the Committee at the March 3rd meeting. The following set of guidelines was voted upon and passed by the Committee. They are as follows:

1. An overall limit of one (1) hour for comments with that hour being pre-determined by the Committee.
2. Oral drug presentations are limited to three (3) minutes with two (2) minutes for discussions if warranted (questions from Committee members.)
3. Oral drug presentations are limited per pharmaceutical manufacturer to one (1) presenter per therapeutic class.
4. Oral drug presentations are limited to a maximum of ten (10) presenters per meeting. Presenters will be scheduled to present on a first-come, first-served basis.
5. Presenters are permitted to make available written information in handout form to be distributed to Committee Members prior to the beginning of a presentation. This summary type information sheet will facilitate a clearer understanding of their drug product for later discussion and review by the Committee. Company representation and drugs presented are listed below:

<u>Company</u>	<u>Speaker</u>	<u>Drug</u>
Abbott Laboratories	Martin Jobe	Omnicef®
Bristol-Myers Squibb	Mark Morton	Avapro®/Avalide®
Novartis Pharmaceuticals	Ray Lancaster	Diovan®/Diovan HCT®
Wyeth Pharmaceuticals	Jim Phipps	Altace®
Boehringer Ingelheim	Lona Konigsberg	Micardis®/Micardis HCT®
Merck	Carey Edwards	Cozaar®
Merck	Carey Edwards	Fosamax®
Biovail	Green Neal	Teveten®/Teveten HCT®
Schwarz Pharma	Mark Walsh	Uniretic®

Dr. LaCroix thanked each speaker for his or her individual presentation.

B. Discussions and Selections of PDL for the following Drug Classes

Mary Roberts, R.Ph., First Health Corporation led the discussion.

Discussion was held for the following drug classes:

1. Cephalosporins
2. Angotensin II Receptor Blocking Agents and Combinations
3. Histamine 2 Receptor Antagonists
4. Proton Pump Inhibitors
5. Oral Biphosphonates
6. Angiotensin Converting Enzyme Inhibitors and Combinations

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

No PA Required "Preferred"	PA Required
<u>CEPHALOSPORINS – SECOND GENERATION</u>	
CEFTIN® SUSPENSION CEFUROXIME TABLETS (compares to Ceftin®) CEFZIL® TABLETS AND SUSPENSION	CEFACLOR (generic Ceclor® - all brands and formulations) CEFTIN® TABLETS (generic available without PA) LORABID® (all brands and formulations)
<u>CEPHALOSPORINS – THIRD GENERATION</u>	
OMNICEF® CAPSULES AND SUSPENSION SPECTRACEF®	VANTIN ® TABLETS AND SUSPENSION CEDAX ® CAPSULES AND SUSPENSION
<p>⊙ Suprax® has been withdrawn from the market. Generic cefixime received FDA approval 2/12/04, but it is not yet marketed. Information will be presented for P&T review when this agent becomes available.</p>	
GASTROINTESTINALS: H2RAS	
FAMOTIDINE (Generic for Pepcid®) RANITIDINE (Generic for Zantac®) ZANTAC SYRUP®	AXID® CIMETIDINE (generic Tagamet® - all brands and formulations) NIZATIDINE (Generic for Axid®) PEPCID® TABLETS AND SUSPENSION ZANTAC® TABS AND EFFERVESCENT
*GASTROINTESTINALS: PROTON PUMP INHIBITORS	
NEXIUM® PRILOSEC OTC® PROTONIX®	ACIPHEX® OMEPRAZOLE (generic of Prilosec®) PREVACID® PRILOSEC®
<p>P&T Committee members discussed the implications if the clinical edit were to be removed from the PPI's. No firm decisions were made. *Dr. Weart abstained from voting on this therapeutic class.</p>	

No PA Required "Preferred"	PA Required
**ANGIOTENSIN II RECEPTOR ANTAGONISTS	
AVAPRO® BENICAR® DIOVAN®	ATACAND® COZAAR® MICARDIS® TEVETEN®
**ANGIOTENSIN II RECEPTOR ANTAGONISTS AND DIURETIC COMBINATIONS	
AVALIDE® BENICAR HCT® DIOVAN HCT®	ATACAND HCT® HYZAAR® MICARDIS HCT® TEVETEN HCTZ®
**Dr. Humphrey abstained from voting on this therapeutic class.	
***ACE INHIBITORS	
ACEON® CAPTOPRIL (compares to Capoten®) ENALAPRIL (compares to Vasotec®) LISINOPRIL (compares to Zestril®, Prinivil®)	ACCUPRIL® ALTACE® BENAZEPRIL (generic Lotensin®) CAPOTEN® (generic available without PA) FOSINOPRIL (generic for Monopril®) LOTENSIN® MAVIK® MOEXIPRIL (generic for Univasc®) MONOPRIL® PRINIVIL® (generic available without PA) UNIVASC® VASOTEC® (generic available without PA) ZESTRIL® (generic available without PA)
***ACE INHIBITORS PLUS THIAZIDE DIURETIC COMBINATIONS	
ENALAPRIL/ HCTZ (compares to Vasercetic®) LISINOPRIL/HCTZ (compares to Zestoretic®, Prinzide®)	ACCURETIC® BENAZEPRIL/HCTZ (generic Lotensin HCT®) CAPTOPRIL/HCTZ (generic Capozide® - all brands) LOTENSIN HCT® MONOPRIL HCT® PRINZIDE® (generic available without PA) UNIRETIC® VASERETIC® (generic available without PA) ZESTORETIC® (generic available without PA)
***Dr. Weart abstained from voting on this therapeutic class.	
BIPHOSPHONATES USED FOR OSTEOPOROSIS	
ACTONEL® FOSAMAX®	

7. Old Business

Resignations from Dr. Christie Benet Hopkins and Dr. Gerard C. Jebaily were accepted. Director Kerr will appoint replacements for these positions.

8. New Business

A. Public Comment on Potential PDL Selections

There was no public comment.

B. Selection/Designation of Drug Classes for PDL Formulary

The Committee agreed to discuss the following classes at the June 2nd meeting:

ACE Inhibitor/Calcium Channel Blocker Combinations
Analgesic – Non-Steroidal Antiinflammatory Agents
Antihyperkinesis
Beta Blockers
Calcium Channel Blockers
COX-II Inhibitors

C. General Discussion

Brief discussion was held on Xolair and the possible prior authorization of growth hormone products. Further discussion may take place at the June meeting on these topics in addition to a general discussion on pain management.

9. Resolved Items

A. Minutes from the March 3, 2004 Meeting approved.

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

1. Antibiotics: Cephalosporins
2. Gastrointestinals: H2RAs
3. Gastrointestinals: Proton Pump Inhibitors
4. Angiotensin II Receptor Antagonists (ARB's), ACE Inhibitors, and Diuretic Combinations
5. ACE Inhibitors and ACEI Diuretic Combination Products
6. Biphosphonates Used for Osteoporosis

10. Unresolved Items

Notifications regarding the location of the June 2, 2004 meeting will be e-mailed to Committee members in addition to being posted on the website.

11. Public Comments

No Comments

12. Closing Comments

No Comments

13. Adjournment

The meeting adjourned at 6:30 p.m.