

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

**Pharmacy and Therapeutics (P&T) Committee Meeting**  
**August 4, 2004**  
**MINUTES**

**1. Call To Order**

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

**2. Introductory Remarks**

P&T Committee Chairman, Dr. LaCroix, recognized Jim Bracewell, SC Pharmacy Association Executive Director. On behalf of the Pharmacy Association, Mr. Bracewell welcomed the group. Mr. Bracewell invited anyone interested to participate in the SCPhA Pharmaceutical Industry Advisory Council. The organizational meeting will be held at the Pharmacy Association building on October 6<sup>th</sup> at 12:00 noon.

**3. Committee Members Present:**

Edward M. Behling, M.D.	Thomas Phillips, R.Ph.
Joseph A. Horvath, M.D.	Deborah J. Tapley, R.Ph.
Albert Humphrey, M.D.	George E. Vess, Pharm.D.
Robin K. LaCroix, M.D.	Wayne Weart, Pharm.D.
James M. Lindsey, M.D.	Jamee Lucas, M.D.
Mark A. O'Rourke, M.D.	Jerome E. Kurent, M.D.

**Committee Members Absent:**

Matthew K. Cline, M.D.	Harry H. Wright, M.D.
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**DHHS Staff Present:**

James Assey	Byron Roberts
Marion Burton, M.D.	Caroline Sojourner
Melanie Giese	Linda Van Hoose

**Other Representation:**

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

4. **Welcome**

Dr. LaCroix, Chairperson welcomed all meeting attendees.

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.

5. **Discussion Topics**

**A. Committee Meeting Minutes, Wednesday, June 2, 2004**

Draft minutes were amended to reflect that Coreg® be reserved for those patients with hypertension in the presence of heart failure.

**B. General Issues**

Due to the large number of scheduled presentations, Dr. LaCroix asked that speakers attempt to limit their presentations to two minutes in order to allow sufficient time for all speakers to be heard.

**C. Public Comment**

The following speakers discussed those drugs or issues listed below:

<b><u>Company</u></b>	<b><u>Speaker</u></b>	<b><u>Drug</u></b>
3M Pharmaceuticals	Tom Bulen, O.P.A.	Maxair®
Schering-Plough	Green B. Neal, M.D.	Nasonex®
Schering-Plough	Green B. Neal, M.D.	Claritin®/Clarinex®
Schering-Plough	David Armstrong, M.D.	Foradil®
Dey, L.P.	Adam Kopp	AccuNeb®
Sepracor	Randy Rowen, Pharm.D.	Xopenex®
AstraZeneca	Christy Scott, Pharm.D.	Rhinocort AQ®
KOS Pharmaceuticals	Green B. Neal, M.D.	Azmacort®
AstraZeneca	Christy Scott, Pharm.D.	Pulmicort Turbuhaler®
GlaxoSmithKline	Rodney Schlosser, M.D.	Flonase®
GlaxoSmithKline	Patrick Flume, M.D.	Advair®
GlaxoSmithKline	Al Walker, M.D.	Imitrex®
Merck	Kerry Edwards, M.D.	Singulair®
Merck	Kerry Edwards, M.D.	Maxalt®
Pfizer	David Rogers, M.D.	Relpax®
Pfizer	Dennis Pontani, M.S., Ph.D.	Zyrtec®/Zyrtec-D®
MedPointe	Charles Shissias, M.D.	Zomig®
King Pharmaceuticals	Troy Yarborough	Sonata®

Following the period of public comment, Dr. LaCroix thanked each speaker for his or her individual presentation.

**D. PDL Discussions And Selections For The Following Drug Classes**

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

1. Beta Adrenergic Agents Short-Acting Inhalers
2. Beta Adrenergic Agents Long-Acting
3. Beta Adrenergic Agents Nebulized
4. Beta Adrenergic Corticosteroid Combinations
5. Inhaled Corticosteroids
6. Intranasal Corticosteroids
7. Leukotriene Modifiers
8. Low Sedating Antihistamines & Decongestant Combinations
9. Sedative Hypnotics
10. Serotonin Receptor Agonists

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

No PA Required "Preferred"	PA Required
<b><u>BETA-ADRENERGIC AGENTS</u></b>	
<b>BETA-ADRENERGIC AGENTS SHORT ACTING METERED DOSE INHALERS OR INHALATION DEVICES</b>	
ALBUTEROL (generic for Proventil®, Ventolin®)	ALUPENT MDI ® (Metaproterenol) BRETHAIR MDI® (Terbutaline) MAXAIR MDI® (Pirbuterol) MAXAIR AUTOHALER® (Pirbuterol) PROVENTIL® (generic available without a PA) PROVENTIL HFA ® (Albuterol) VENTOLIN HFA ® (Albuterol) VENTOLIN® (generic available without a PA)
<b>BETA-ADRENERGIC AGENTS LONG-ACTING METERED DOSE INHALERS</b>	
SEREVENT DISKUS® (Salmeterol)	FORADIL® (Formoterol)
The Committee discussed the presence of a black box warning for Serevent®. The major concern surrounds the use of this long-acting agent in an acute or deteriorating illness.	
<b>BETA-ADRENERGIC AGENTS SHORT-ACTING NEBULIZERS</b>	

<b>No PA Required “Preferred”</b>	<b>PA Required</b>
ALBUTEROL (generic for Proventil®, Ventolin®), 0.083% Premixed nebulizers, 0.5% Concentrated Solution METAPROTERENOL (generic for Alupent®)	ACCUNEB® (Albuterol – pediatric dosing of premixed nebulizers) ALUPENT® (generic available without PA) PROVENTIL® (generic available without PA) VENTOLIN® (generic available without PA) XOPENEX® (Levalbuterol nebulization)
There was discussion regarding whether Xopenex® should be preferred.	
<b>INHALED AND NASAL STEROIDS</b>	
<b>INHALED AND NASAL STEROIDS GLUCOCORTICOIDS: INHALED INHALED DEVICES</b>	
AZMACORT® FLOVENT® QVAR®	AEROBID® AEROBID-M® FLOVENT Rotadisk® PULMICORT TURBUHALER® VANCERIL®
As a point of clarification, Committee members were advised that Pulmicort Respules® are not included in this class and are not currently under consideration for PDL. Pulmicort Respules® will continue to be available without prior authorization.	
<b>INHALED AND NASAL STEROIDS GLUCOCORTICOIDS AND LONG-ACTING BETA<sub>2</sub> ADRENERGIC AGENTS</b>	
ADVAIR DISKUS® (Salmeterol/Fluticasone)	
There was discussion of including a clinical edit for Advair 500/50®. The Committee asked that DHHS review utilization to determine the need for such a clinical edit.	
<b>INHALED AND NASAL STEROIDS GLUCOCORTICOIDS: INTRANASAL STEROIDS</b>	
FLONASE® NASAREL® NASONEX® RHINOCORT AQ®	BECONASE BECONASE AQ® FLUNISOLIDE NASACORT® NASACORT AQ® NASALIDE® RHINOCORT® TRI-NASAL®
<b>LEUKOTRIENE RECEPTOR ANTAGONISTS</b>	

No PA Required "Preferred"	PA Required
ACCOLATE® SINGULAIR®	
<p>The Committee recommended a clinical edit for Singulair® to require prior authorization if used to treat allergic rhinitis. An electronic step edit will be implemented to allow Singulair® without prior authorization in the presence of inhaled steroid or inhaled beta agonist therapy.</p>	
<b>ANTI-HISTAMINES: SECOND GENERATION</b>	
<b>ANTI-HISTAMINES: SECOND GENERATION AND DECONGESTANT COMBINATIONS</b>	
LORATADINE OTC – tabs, rapid dissolve tabs, syrup (generic for Claritin®) LORATADINE-D OTC (generic for Claritin D®) Zyrtec® Syrup (for patients less than 2 years of age)	ALAVERT® ALLEGRA® ALLEGRA D® CLARINEX® CLARITIN D® (all strengths) CLARITIN® (all formulations) ZYRTEC® ZYRTEC® SYRUP (PA required for patients 2 years of age and older) ZYRTEC D®
<b>ANTI-MIGRAINE MEDICATIONS: SEROTONIN 5HT<sub>1</sub> RECEPTOR AGONISTS</b>	
AMERGE® AXERT® 6.25, 12.5 MG IMITREX® INJECTION 6 MG IMITREX® NS IMITREX® TABLETS MAXALT-MLT® MAXALT® RELPAX® ZOMIG® ZOMIG® SPRAY ZOMIG ZMT®	FROVA® 2.5 MG
<b>SEDATIVE/HYPNOTICS (NON-BARBITURATE)</b>	

No PA Required “Preferred”	PA Required
TEMAZEPAM (generic for Restoril®) TRIAZOLAM (generic for Halcion®) RESTORIL® 7.5MG	AMBIEN® DORAL® ESTAZOLAM (all brands) FLURAZEPAM (all brands) HALCION® (generic available without PA) RESTORIL® (15 & 30mg) (generic available without PA) SOMNOTE® SONATA®
The Committee recommends that either Ambien® or Sonata® be preferred and the Committee asked that DHHS use its discretion in the selection of one of those agents.	

**6. Old Business**

**A. Chairman’s Comments**

Dr. LaCroix reminded the group that the PA process excludes no drugs from availability to Medicaid patients.

**B. Discussion of Vioxx®**

Dr. Weart brought concerns to the attention of the Committee regarding a study that has revealed cardiovascular complications in some patients receiving Vioxx®. The Committee agreed to re-evaluate the PDL status of Vioxx® (not the entire class) at the October 2004 meeting.

**C. Discussion of Strattera®**

The group was advised that in accordance with the Committee’s recommendation, there will be an electronic step edit for Strattera®.

**D. Proton Pump Inhibitors Update**

The Committee was advised that DHHS has revised the PDL status of Prevacid® to allow children age 12 and younger to receive Prevacid® without PA.

**7. New Business**

**A. Discussion of Pain Management**

The Committee was provided with draft guidelines on pain management and Dr. Kurent presented information regarding the appropriate treatment of pain. Dr. LaCroix asked the Committee to review this information to prepare for discussion at the next meeting.

**B. Selection/Designation of Drug Classes for PDL Formulary**

The following drug classes were presented as classes for potential discussion at the October 6th meeting:

Insulins  
Oral Sulfonylureas Second Generation  
Biguanides and Combinations  
Meglitinides  
Alpha Glucosidase Inhibitors  
Thiazolidinediones  
Statins  
Long Acting Opiates

Although the Committee agreed that all of these classes should be considered for the PDL, there was concern that there will not be sufficient time to review all of these classes in a single meeting. Depending upon requests for public comment, some classes may be deferred until the December meeting.

**8. Resolved Items**

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

1. Beta Adrenergic Agents Short-Acting Inhalers
2. Beta Adrenergic Agents Long-Acting
3. Beta Adrenergic Agents Nebulized
4. Beta Adrenergic Corticosteroid Combinations
5. Inhaled Corticosteroids
6. Intranasal Corticosteroids
7. Leukotriene Modifiers
8. Low Sedating Antihistamines & Decongestant Combinations
9. Sedative Hypnotics
10. Serotonin Receptor Agonists

**9. Unresolved Items**

None.

**10. Closing Comments**

Dr. LaCroix thanked the Pharmacy Association for hosting the P&T Committee meeting.

**11. Adjournment**

The meeting adjourned at 7:15 p.m.