

**MINUTES OF THE May 13, 2008  
PHARMACY AND THERAPEUTICS (P & T) COMMITTEE MEETING**

**MEMBERS ATTENDING:** John Cook, M.D.; Jennifer Gholsen, M.D.; Jeff Jones, R.Ph.; Robert Lomenick, R.Ph.; Garry McFerrin, R.Ph.; Michael O'Dell, M.D.; Manisha Sethi, M.D.; Robert Smith, M.D.; Pearl Wales, Pharm.D.

Also present: Judith Clark, R.Ph., Pharmacy Director, DOM; Paige Clayton, Pharm.D., DOM; Terry Kirby, R.Ph., DOM; Phyllis Williams, DOM; Steve Liles, Pharm.D., Provider Synergies

**MEMBERS ABSENT:** Larry Calvert, R.Ph.; Deborah King, FNP; Steve Roark

**CALL TO ORDER:** Acting Chairman Dr. Michael O'Dell called the meeting to order at 10:15 am. Dr. O'Dell noted that Mr. Calvert is not in attendance due to a family medical emergency.

**INTRODUCTIONS:** Ms. Clark welcomed committee members and guests in the audience. She thanked Committee members for volunteering their time. She thanked Jennifer Gholsen, Mike O'Dell and Pearl Wales for continuing to serve on the Committee even though their terms expired one year ago. Ms. Clark noted that the P&T Committee is a volunteer group of practicing physicians and pharmacists that is charged with making PDL recommendations to DOM based on safety, efficacy and cost. Ms. Clark noted that the PDL classes being reviewed at this and the last meeting would all be implemented on July 1, 2008.

**EXECUTIVE DIRECTOR'S COMMENTS:** Ms. Clark stated that Phyllis Williams, Deputy Administrator of Health Services, was unable to attend today's meeting.

**ADMINISTRATIVE MATTERS:** Ms. Clark presented an overview of the proceedings of today's meeting. She stated that Provider Synergies would make a clinical presentation and present recommendations for each therapeutic class. DOM Pharmacy staff would present Provider Synergies' and the Committee's recommendations to the Executive Director, who would make the final PDL decisions. She noted that the decisions from this meeting and from last month's meeting would be posted on the website no later than 30 days before implementation. Ms. Clark stated that, pursuant to the Open Meetings Act, the Committee is required to record the minutes of the meeting within thirty days after the meeting is recessed or adjourned.

Ms. Clark introduced members of the DOM Pharmacy staff and thanked them for their hard work and dedication.

Ms. Clark asked guests to sign in and said that those signed up to speak would be given three minutes. If there is more than one speaker per product, the three minutes would be divided among those speakers.

Ms. Clark reminded the Committee and guests that the meeting room must be left clean and that no food or drinks are allowed. She asked that cell phones, pagers and PDAs be silenced or turned off during the meeting. She also requested that guests leave the room only during breaks to minimize noise and distractions. Ms. Clark reviewed the safety exits for the meeting room and for the building. She explained that the meeting room is

limited to a maximum capacity of ninety persons and that at no time would more than ninety be allowed to remain in the room due to state fire regulations.

Ms. Clark noted that voting is now done by hand and/or voice vote, rather than paper ballots. She announced that meetings are no longer being taped for the purpose of recording minutes. She also stated that, effective July 1, 2008, DOM will no longer be accepting one-page dossiers from the manufacturers. Ms. Clark called Committee members' attention to their packets that contain a copy of the state's PDL, a PA form, a description of the limitations on Soma, a colorized version of the External Cost Sheets that had previously been sent by Provider Synergies and their travel vouchers. She instructed members to fill out travel vouchers and return them before leaving the meeting.

**APPROVAL OF APRIL 8, 2008 MEETING MINUTES:** Dr. O'Dell asked if there were additions, changes or deletions to the minutes of the last meeting. None were brought to the attention of the Committee. Dr. O'Dell asked for a motion to approve the minutes of the April 8, 2008 meeting as presented. Dr. Gholsen made a motion to accept and Mr. Lomenick offered a second. The motion carried unanimously.

**THERAPEUTIC CLASS REVIEWS:** Dr. Liles gave a brief overview of Providers Synergies' methods for drug literature evaluation. Dr. Liles moderated the therapeutic class reviews.

#### **ERYTHROPOIESIS STIMULATING PROTEINS**

Dr. Liles reviewed the agents in this class, which consists of recombinant human epoetin alfa and darbepoetin alfa. He noted that the two recombinant human epoetin alfa products, Epogen and Procrit, were identical and that darbepoetin, Aranesp, has been modified to give it a longer half-life. He stated that Epogen and Procrit have more indications than Aranesp but that the agents were similar in all respects, other than their frequency of administration. Dr. Liles presented the following PDL recommendations:

Brand Name	Current PDL Status	PDL Recommendation
ARANESP (INJECTION)	ON	ON
EPOGEN (INJECTION)	OFF	OFF
PROCRIPT (INJECTION)	ON	ON

Brad Clay of Amgen spoke on behalf of Aranesp.

Mr. Jones made a motion to accept Provider Synergies' recommendations as presented. The motion was seconded by Dr. Sethi. Dr. O'Dell asked members to raise their hands if they approved of the motion. The motion passed unanimously, 9-0.

#### **PHOSPHATE BINDERS**

Dr. Liles reviewed the goal of these agents related to the NKF/K-DOQI guidelines for management of hyperphosphatemia in patients with kidney disease. He outlined the differences between the calcium based phosphate binder and the non-calcium containing agents. He stated that the new agent in the class, Renvela, may be better than Renagel at maintaining bicarbonate levels in the recommended range, but that there is not, at this time, solid evidence of that. He stated that, other than the higher risk of hypercalcemia with the calcium-containing phosphate binder, the adverse effects of these agents were similar. He outlined the average pill burden of the drugs in this class

and noted that there were few directly, comparative, double-blind clinical trials. Dr. Liles then presented the following PDL recommendations:

Brand Name	Current PDL Status	PDL Recommendation
FOSRENOL (ORAL)	ON	ON
PHOSLO (ORAL)	ON	ON
RENAGEL (ORAL)	ON	ON
RENVELA (ORAL)	NR	OFF

No speakers addressed the Committee.

Dr. Wales made a motion to accept the recommendations as presented. Dr. Cook seconded the motion. Dr. O'Dell asked members to raise their hands if they approved of the motion. The motion passed unanimously, 9-0.

### **BONE RESORPTION SUPPRESSION AND RELATED AGENTS**

Dr. Liles noted that this is a heterogeneous group of drugs used for the treatment of postmenopausal osteoporosis as well as some other specific indications outlined in the TCR. He reviewed the bisphosphonates and their combinations, noting that, in general these drugs increased BMD by 2-5%. He stated that alendronate is now available generically. Dr. Liles reviewed the calcitonin-salmon products, stating that they are not as effective as the bisphosphonates, increasing BMD by only 1-2%. Dr. Liles presented the additional indication for raloxifene for reduction in risk of invasive breast cancer. He said that teriparatide, a PTH analog, results in the greatest increase in BMD. Dr. Liles reviewed the placebo-controlled and directly comparative clinical trials of the drugs in this class. He also reviewed the black box warnings for teriparatide and raloxifene and the frequency of dosing for the drugs in the class. Dr. Liles presented the following recommendations for this class:

Brand Name	Current PDL Status	PDL Recommendation
ACTONEL (ORAL)	OFF	ON
ACTONEL W/CALCIUM (ORAL)	OFF	OFF
ALENDRONATE SODIUM (ORAL)	NR	ON
BONIVA (ORAL)	ON	ON
DIDRONEL (ORAL)	NR	OFF
EVISTA (ORAL)	ON	ON
FORTEO (SUBCUTANE.)	OFF	OFF
FORTICAL (NASAL)	OFF	OFF
FOSAMAX PLUS D (ORAL)	ON	ON
FOSAMAX SOLUTION (ORAL)	ON	ON
MIACALCIN (NASAL)	ON	ON

In response to a question from the Committee, Dr. Liles noted that this review does not include the intravenous dosage forms.

One speaker, Bill White, representing Roche, spoke on behalf of Boniva.

Dr. Smith made a motion to approve the recommendations. The motion was seconded by Mr. Jones. Dr. O'Dell asked for a hand vote of those in favor and opposed. The motion was approved by a vote of 9-0.

## **GROWTH HORMONE**

Dr. Liles outlined Provider Synergies' view of the growth hormone products, noting that "growth hormone is growth hormone" and that the products differ only in their packaging and delivery devices. He presented the following recommendations:

Brand Name	Current PDL Status	PDL Recommendation
GENOTROPIN (INJECTION)	ON	ON
HUMATROPE (INJECTION)	OFF	OFF
NORDITROPIN (INJECTION)	ON	OFF
NUTROPIN (INJECTION)	ON	ON
NUTROPIN AQ (INJECTION)	ON	ON
OMNITROPE (INJECTION)	OFF	OFF
SAIZEN (INJECTION)	ON	ON
SEROSTIM (INJECTION)	ON	OFF
TEV-TROPIN (INJECTION)	ON	OFF
ZORBTIVE (INJECTION)	OFF	OFF

Rusi Pasipanodye of Teva spoke on behalf of Tev-Tropin. Kaysen Bala of Novo-Nordisk spoke on behalf of Norditropin. Lee Ann Griffin of Pfizer spoke on behalf of Genotropin. Diane Lee Smith of Genentech spoke on behalf of Nutropin and Nutropin Aq. Angela Spencer of EMD Serono spoke on behalf of Saizen.

Dr. Smith noted that some patients go out of state for treatment and that they may come back into the state with a prescription for a non-preferred agent.

Dr. Smith made a motion that all growth hormone products be placed on the PDL. The motion was seconded by Mr. Jones. The motion was approved by a vote of 7-2, with Drs. Gholson and O'Dell dissenting.

## **HYPOGLYCEMICS, MEGLITINIDES**

Dr. Liles noted the similarities and differences among the two drugs in this class. He stated that Starlix has a longer half-life and more significant renal elimination and the Prandin is metabolized by the CYP450 3A4 system. He said that meta-analyses and a recent AHRQ review both indicated that Prandin is more effective at reducing HbA1c, but that Starlix causes less hypoglycemia. Dr. Liles reviewed the role of these drugs as presented in the ADA guidelines. Dr. Liles made the following recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
PRANDIN (ORAL)	OFF	ON
STARLIX (ORAL)	ON	ON

No speakers addressed the Committee.

Dr. Gholson made a motion to accept the recommendations as presented. Dr. Smith's motion was seconded by Dr. O'Dell. Dr. O'Dell asked for those in favor of the motion to signify by hand vote. The motion passed 9-0.

## **HYPOGLYCEMICS, TZDS**

Dr. Liles presented an overview of the TZDs and the TZD combination products. He reviewed the box warning for the class regarding fluid retention and the box warning for Avandia regarding the potential increase in myocardial ischemic events. He noted the

conclusions of several systematic reviews regarding the safety of these drugs. After presenting the ADA guidelines regarding the use of the TZDs, Dr. Liles made the following recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
ACTOPLUS MET (ORAL)	ON	ON
ACTOS (ORAL)	ON	ON
AVANDAMET (ORAL)	ON	ON
AVANDARYL (ORAL)	ON	ON
AVANDIA (ORAL)	ON	ON
DUETACT (ORAL)	ON	ON

No speakers addressed the Committee.

Dr. Wales made a motion to accept the recommendations. Mr. Lomenick seconded the motion, which was approved, 10-0, by hand vote.

### **HYPOGLYCEMICS, INCRETIN MIMETICS/ENHANCERS**

Dr. Liles noted that this class consists of drugs with different mechanisms of actions that follow the same basic concept. He reviewed the data showing the effects of these drugs on HbA1c and body weight. He also noted that Symlin had a box warning regarding its potential to cause severe hypoglycemia. Following the presentation, he made the following recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
BYETTA PENS (SUBCUTANE.)	ON	ON
JANUMET (ORAL)	ON	ON
JANUVIA (ORAL)	ON	ON
SYMLIN (SUBCUTANE.)	OFF	OFF
SYMLIN PENS (SUBCUTANE.)	OFF	OFF

No speakers addressed the Committee.

Dr. Smith made a motion, seconded by Mr. Jones, to accept the recommendations as presented. Dr. O'Dell asked for a hand vote of those in favor; the motion passed 9-0.

### **HYPOGLYCEMICS, INSULINS**

Dr. Liles outlined the groupings of the drugs in this class based on their duration of action. He then presented the following recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
APIDRA (SUBCUTANE.)	ON	OFF
APIDRA PENS (SUBCUTANE.)	ON	OFF
HUMALOG (SUBCUTANE.)	OFF	OFF
HUMALOG MIX (SUBCUTANE.)	OFF	OFF
HUMALOG MIX PENS (SUBCUTANE.)	OFF	OFF
HUMALOG PENS (SUBCUTANE.)	OFF	OFF
HUMULIN (SUBCUTANE.)	OFF	OFF
HUMULIN PENS (SUBCUTANE.)	OFF	OFF
LANTUS (SUBCUTANE.)	ON	ON
LANTUS PENS (SUBCUTANE.)	ON	OFF
LEVEMIR (SUBCUTANE.)	ON	OFF
LEVEMIR PENS (SUBCUTANE.)	ON	OFF

NOVOLIN (SUBCUTANE.)	ON	ON
NOVOLIN PENS (SUBCUTANE.)	ON	ON
NOVOLOG (SUBCUTANE.)	ON	ON
NOVOLOG MIX 70/30 (SUBCUTANE.)	ON	ON
NOVOLOG MIX 70/30 PENS (SUBCUTANE.)	ON	ON
NOVOLOG PENS (SUBCUTANE.)	ON	ON

Dr. Sorally Servera of NovoNordisk spoke on behalf of Novolog, Novolog Mix and Levemir. Kelly Betts of Eli Lilly spoke on behalf of Humalog. Belinda Hardin of Sanofi-Aventis spoke on behalf of Lantus and Apidra. Marshall Bouldin of UMC spoke on behalf of Novo Nordisk's line of insulin pens.

Dr. Smith noted that Mississippi has a high prevalence of diabetes and that there were many patients in the state on insulin. He stated that Humulin is a better known insulin product. Mr. Lomenick stated that pens are not necessarily more expensive than vials.

Dr. Smith made a motion to add all insulin products to the PDL. The motion was seconded by Mr. Jones. Dr. O'Dell asked for a hand vote of those in favor. There were seven votes in favor of the motion with Dr. Wales dissenting and Dr. O'Dell abstaining.

### **PROTON PUMP INHIBITORS**

Dr. Liles noted that the drugs in this class are all similar, although they do vary in their indications as presented on page 2 of the TCR. He stated that these variations in indications are a function more of what the manufacturer filed for than the effectiveness of the drugs. He informed the Committee that Nexium now has an additional pediatric indication for children as young as one year of age. He stated that clinical trials showed no consistently significant differences among the drugs in the class, noting that, in several studies, incomparable doses of the drugs were used. Dr. Liles presented Provider Synergies' PDL recommendations for this class:

Brand Name	Current PDL Status	PDL Recommendation
ACIPHEX (ORAL)	OFF	OFF
NEXIUM (ORAL)	OFF	OFF
NEXIUM SUSPENSION (ORAL)	OFF	OFF
OMEPRAZOLE RX (ORAL)	OFF	ON
OMEPRAZOLE OTC (ORAL)	OFF	OFF
PANTOPRAZOLE (ORAL)	NR	OFF
PREVACID (ORAL)	ON	ON
PREVACID SOLUTAB (ORAL)	ON	ON
PREVACID SUSPENSION (ORAL)	ON	ON
ZEGERID (ORAL)	ON	ON

Deborah Walters of AstraZeneca spoke on behalf of Nexium.

Dr. Gholson made a motion to accept the recommendations; the motion was seconded by Mr. Jones. The motion passed 9-0.

### **ULCERATIVE COLITIS AGENTS**

Dr. Liles noted that aminosalicylates are the foundation of therapy for ulcerative colitis with oral dosage forms allowing for high concentrations of 5-ASA in the lumen with minimal absorption and rectal dosage forms being more specific for active ulcerative

proctitis. He reviewed the indications and pill burdens for the drugs in the class, then presented the following recommendations:

Brand Name	Current PDL Status	PDL Recommendation
ASACOL (ORAL)	ON	ON
BALSALAZIDE (ORAL)	NR	ON
CANASA (RECTAL)	ON	ON
DIPENTUM (ORAL)	ON	ON
LIALDA (ORAL)	ON	ON
MESALAMINE (RECTAL)	ON	ON
PENTASA (ORAL)	ON	ON
SULFASALAZINE (ORAL)	ON	ON

No speakers addressed the Committee.

Mr. Lomenick made a motion to approve the recommendations. The motion was seconded by Dr. Cook. Dr. O'Dell called for those approving of the motion to signify by raising their hands; the motion passed 8-0 with Dr. Smith abstaining.

**ANTIHISTAMINES, MINIMALLY SEDATING**

Dr. Liles noted that the drugs in this class differ in their drying ability, which is generally related to their degree of sedation. He noted that loratadine, desloratadine and fexofenadine are not-sedating and that acrivastine and cetirizine do cause some sedation. He stated that Xyzal, levocetirizine, is the active enantiomer of Zyrtec and that it has not been shown to cause much sedation. He stated that Zyrtec is now available generically OTC and that the branded Zyrtec OTC is not covered by Medicaid. Dr. Liles reviewed the pediatric indications for the drugs in the class with cetirizine, desloratadine and fexofenadine being indicated for children as young as 6 months and loratadine for children as young as 2 years of age. Dr. Liles presented the following recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
ALLEGRA ODT (ORAL)	OFF	OFF
ALLEGRA SYRUP (ORAL)	OFF	ON
ALLEGRA-D 12 HOUR (ORAL)	OFF	OFF
CETIRIZINE / CETIRIZINE-D OTC (ORAL)	ON	ON
CLARINEX / CLARINEX-D (ORAL)	ON	OFF
FEXOFENADINE (ORAL)	ON	OFF
LORATADINE / LORATADINE-D (ORAL)	ON	ON
SEMPREX-D (ORAL)	NR	ON
XYZAL (ORAL)	OFF	OFF
ZYRTEC / ZYRTEC-D (ORAL)	ON	OFF
ZYRTEC SYRUP (ORAL)	ON	OFF

The Committee discussed the availability of generic cetirizine syrup, noting that they did not think that it was available. Dr. Liles noted that there has been utilization in some Provider Synergies' states.

Dr. Todd Adkins of Sanofi-Aventis spoke on behalf of Xyzal. Akshaya Patel of Schering Plough addressed the Committee on behalf of Clarinex.

Mr. Jones made a motion to approve the recommendations with the exception of adding

Clarinet and Xyzal. After being seconded by Dr. Cook, the Committee approved the motion, 8-1, with Dr. O'Dell dissenting.

Dr. O'Dell adjourned the Committee for lunch, after which the meeting reconvened with Dr. Liles continuing the class reviews.

### **INTRANSAL RHINITIS AGENTS**

Dr. Liles noted that this class consists of both steroids and non-steroids. He called the Committee's attention to the fact that there is a new steroidal agent, ciclesonide or Omnaris, in the class. He reviewed the pediatric indications for these drugs. Dr. Liles stated that the older agents in the class, Beconase AQ and flunisolide, generally have a higher incidence of nasal irritation than the new drugs. He reviewed the frequency of dosing of these agents and stated that, in clinical trials, there is no evidence of superiority of one agent over another. He stated that Astelin is an alternative to steroids and that it is as effective as oral antihistamines. He noted that Atrovent is effective for non-allergic rhinorrhea. Dr. Liles then presented the following recommendations:

Brand Name	Current PDL Status	PDL Recommendation
ASTELIN (NASAL)	ON	<b>ON</b>
BECONASE AQ (NASAL)	OFF	<b>OFF</b>
FLONASE (NASAL)	ON	<b>OFF</b>
FLUNISOLIDE (NASAL)	ON	<b>ON</b>
FLUTICASONE (NASAL)	ON	<b>ON</b>
IPRATROPIUM (NASAL)	NR	<b>ON</b>
NASACORT AQ (NASAL)	OFF	<b>OFF</b>
NASAREL (NASAL)	OFF	<b>ON</b>
NASONEX (NASAL)	ON	<b>ON</b>
OMNARIS (NASAL)	NR	<b>OFF</b>
RHINOCORT AQUA (NASAL)	OFF	<b>OFF</b>
VERAMYST (NASAL)	OFF	<b>ON</b>

Cecil Fuselier of Sanofi Aventis spoke on behalf of Nasacort Aq. Kevin Byrne of GSK spoke on behalf of Veramyst.

Mr. Jones made a motion to accept Provider Synergies' recommendations. The motion was seconded by Dr. Wales. Dr. O'Dell called for a show of hands of those approving the motion; the motion passed 9-0.

### **LEUKOTRIENE MODIFIERS**

Dr. Liles noted that this class consists of both leukotriene receptor antagonists and 5-lipoxygenase inhibitors. He stated that Zylflo has been replaced with Zylflo CR. He reviewed the NAEPP and GINA guidelines that indicate that these drugs are useful as controller therapy in patients under 5 years and that, in older patients, long acting beta-2 agonists are preferred as adjuncts to inhaled corticosteroids. He reviewed the role of Singulair in allergic rhinitis, noting that it is most useful for patients with comorbid asthma or who are unresponsive to other treatments. Dr. Liles noted that Singulair is indicated for children as young as 6 months of age and that Accolate is indicated for children as young as 5 years. He stated that these drugs all undergo hepatic metabolism and that the contraindications and warnings that Accolate and Zylflo CR have are related to their potential for hepatotoxicity. He reviewed the drug interactions as presented in the TCR and noted that there are no directly comparative trials of the drugs in this class.

Dr. Liles presented the following recommendations:

Brand Name	Current PDL Status	PDL Recommendation
ACCOLATE (ORAL)	OFF	<b>ON</b>
SINGULAIR (ORAL)	ON	<b>ON</b>
ZYFLO CR (ORAL)	NR	<b>OFF</b>

No speakers addressed the Committee.

Dr. Smith made a motion to approve the recommendations. The motion was seconded by Dr. Cook and passed by the Committee, 9-0.

### **BRONCHODILATORS, BETA AGONIST**

Dr. Liles noted that this class review was separated between two TCRs, one for short acting agents and one for long acting agents. He reiterated that CFC inhalers will be off of the market by the end of the year. He noted that there is no evidence that any one short acting agent is more effective than another, but that less beta-2 specific agents, such as metaproterenol, tend to have more cardiovascular effects, as do oral agents compared to inhaled dosage forms. He noted that albuterol is indicated for children as young as two years of age and that the other short acting agents are indicated for children as young as four, six or 12 years of age. Dr. Liles noted that, in outpatients, there is no evidence that either albuterol or levalbuterol is more effective or safe than the other. He outlined several studies to support this statement. Dr. Liles reviewed the indications for the oral, DPI and inhalation solution dosage forms of the long acting beta-2 agonists. He stated that the LABAs have become valuable adjuncts to steroids in the treatment of asthma, but that they were not for use as monotherapy due to safety issues. He reviewed the box warning on Serevent and Advair, as well as the 2006 FDA-mandated labeling change. Dr. Liles presented the following PDL recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
ALBUTEROL (ORAL)	ON	ON
ALBUTEROL INHALER (INHALATION)	ON	ON
ALBUTEROL NEBULIZER (INHALATION)	ON	ON
ALUPENT INHALER (INHALATION)	OFF	OFF
BROVANA (INHALATION)	OFF	OFF
FORADIL (INHALATION)	OFF	OFF
MAXAIR (INHALATION)	ON	ON
METAPROTERENOL (INHALATION)	ON	OFF
METAPROTERENOL (ORAL)	ON	OFF
PERFOROMIST (INHALATION)	NR	OFF
PROAIR HFA INHALER (INHALATION)	ON	ON
PROVENTIL HFA (INHALATION)	ON	ON
SEREVENT (INHALATION)	OFF	OFF
TERBUTALINE (ORAL)	ON	ON
VENTOLIN HFA (INHALATION)	ON	ON
XOPENEX NEBULIZER (INHALATION)	ON	OFF
XOPENEX HFA (INHALATION)	ON	OFF

Patrick Harvey of Sepracor spoke on behalf of Xopenex and Xopenex HFA.

Dr. Wales made a motion to approve the recommendations. This motion was approved by Dr. Gholson and passed by a vote of 9-0.

## **BRONCHODILATORS, ANTICHOLINERGIC**

Dr. Liles stated that this class of COPD drugs consists of ipratropium in various forms and tiotropium, which has a longer half-life. He noted that guidelines do not give any specific preferential recommendations regarding the use of LABAs or anticholinergic for the management of COPD. He stated that tiotropium has been shown to improve outcomes compared to ipratropium. Dr. Liles presented the following recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
ATROVENT HFA (INHALATION)	OFF	<b>ON</b>
COMBIVENT (INHALATION)	ON	<b>ON</b>
IPRATROPIUM / ALBUTEROL NEBULIZER (INHALATION)	ON	<b>ON</b>
IPRATROPIUM NEBULIZER (INHALATION)	ON	<b>ON</b>
SPIRIVA (INHALATION)	ON	<b>ON</b>

No speakers addressed the Committee.

Mr. Jones made a motion to accept the recommendations; the motion was seconded by Dr. Gholson. Dr. O'Dell asked those in favor to raise their hands; the motion passed by a vote of 9-0.

## **GLUCOCORTICIDS, INHALED**

Dr. Liles stated that the TCR includes an outline of the NAEPP-3 stepwise approach to management of asthma. He said that this class consists of numerous agents available in aerosol or DPI formulation and that one agent, budesonide, was available as a suspension for inhalation. He noted that there were two ICS/LABA combination agents in the class as well, Symbicort and Advair. Dr. Liles states that, when given in equipotent doses, ICS's were equally effective and that they differ primarily in their frequency of administration and potency. He reviewed the pediatric indications for these drugs, as well as noting that budesonide is the only drug in the class that is pregnancy category B. Dr. Liles presented the following recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
ADVAIR / ADVAIR HFA (INHALATION)	ON	ON
AEROBID / AEROBID-M (INHALATION)	OFF	ON
ASMANEX (INHALATION)	ON	ON
AZMACORT (INHALATION)	OFF	ON
FLOVENT / FLOVENT HFA (INHALATION)	ON	ON
PULMICORT FLEXHALER (INHALATION)	ON	OFF
PULMICORT RESPULES (INHALATION)	ON	ON
QVAR (INHALATION)	OFF	ON
SYMBICORT (INHALATION)	OFF	OFF

Benjamin Everett of AstraZeneca spoke on behalf of Symbicort and Pulmicort.

Dr. Cook made a motion to accept the recommendations with the exception of adding Symbicort to the PDL. The motion was seconded by Mr. Jones. Dr. O'Dell asked those in favor to raise their hands; the motion passes 9-0.

## **SEDATIVE HYPNOTICS**

Dr. Liles stated that there are three broad groups of drugs in this class. The

benzodiazepines are effective, but there are concerns with daytime sedation, especially in the elderly. This is less of an issue with the short acting agents, such as triazolam, than with the longer acting agents, such as flurazepam and quazepam. He stated that the newer non-benzodiazepines, zolpidem, zaleplon and Lunesta have a shorter duration of action and that generic zolpidem is effective for the vast majority of patients with insomnia. He noted that Rozerem is non-addicting but generally effective only in patients who have not previously been treated with a sedative hypnotic. Dr. Liles presented the following recommendations to the Committee:

Brand Name	Current PDL Status	PDL Recommendation
AMBIEN CR (ORAL)	ON	OFF
ESTAZOLAM (ORAL)	ON	ON
FLURAZEPAM (ORAL)	ON	ON
LUNESTA (ORAL)	ON	OFF
ROZEREM (ORAL)	ON	ON
SONATA (ORAL)	OFF	OFF
TEMAZEPAM (ORAL)	ON	ON
TRIAZOLAM (ORAL)	ON	ON
ZOLPIDEM (ORAL)	ON	ON

Patrick Harvey of Sepracor spoke on behalf of Lunesta. Cecil Fuselieo of Sanofi Aventis spoke on behalf of Ambien CR.

Dr. Cook noted that many patients need these agents for longer than six months.

Dr. Cook made a motion to accept the recommendations with the exception of adding Ambien CR and Lunesta to the PDL. The motion was seconded by Mr. Jones. Dr. O'Dell asked those in favor to raise their hands; the motion passed by a vote of 9-0.

**OTHER BUSINESS**

Ms. Clark reminded Committee members to complete and submit the travel vouchers in their packets. She stated that, according to the open meetings act, the minutes from this meeting must be recorded within 30 days.

**NEXT MEETING DATE**

Ms. Clark stated that the next P&T Committee meeting would be October 14, 2008.

**ADJOURNMENT**

There being no further business, Dr. O'Dell adjourned the meeting.