MINUTES OF THE
APRIL 11, 2006
PHARMACY AND THERAPEUTICS (P & T) COMMITTEE MEETING

Members Attending: Larry Calvert, R.Ph.-Chairman; Michael O'Dell, M.D., Vice-Chairman; Robert Smith, M.D.; Myrna Alexander, M.D.; Deborah King, F. N.P.; Pearl Wales, PharmD; John Cook, M.D.; Jennifer Gholson, M.D.

Members Absent: Steve Roark; Jeff Jones, R.Ph.; Todd Barrett, R.Ph.; Robert Lomenick, R.Ph..

Also Present: Don Thompson, Deputy Administrator of Health Services; Judith Clark, R.Ph., Philip Meredith, M.D.,J.D., Medical Director; Terri Kirby, R.Ph.; Susan Brown, R.Ph.; Gay Gibson, R.N., Pharmacy Technician– DOM; Rob DiBenedetto; Sam Warman, R.Ph., Dennis Smith, R.Ph., Lew Anne Snow, R.N.– HID

Chairman Larry Calvert called the meeting to order at 1:01 p.m.

Introductions:
Judith Clark welcomed attendees to the meeting and thanked the committee members for their service and dedication to the P & T committee. Ms. Clark recognized the Deputy Administrator for Health Services, Don Thompson, Dr. Philip Meredith, Medical Director, as well as pharmacy bureau staff members Terri Kirby, pharmacist, Gay Gibson, Pharmacy Program Nurse, and Susan Brown, pharmacist.

Administrative Business:
Judith Clark instructed guests to sign in on the attendance sheets provided; public comment speakers were instructed to sign in on the appropriate sheet provided. All present were asked to assist in keeping the premises clean, and refrain from bringing food or beverages into the meeting area. All present were requested to turn off and/or silence all cell phones and pagers. Guests in the audience were requested to limit all leaving and entering the conference room to the break time, so as not to disrupt the meeting. Instructions were given regarding exit procedures from the building in the case of an emergency.

Committee members were reminded to sign and date their ballots and travel vouchers, and place in the manila envelope which would be collected at the end of the meeting. Ballots would be signed and collected, but not counted until after the meeting. Ms. Clark informed the committee that several speakers would present at today's meeting: Kathy Mosbaugh and Carrie Tort from Gold Standard and Tom Hood from the Mississippi Ethics Commission. Ms. Clark reminded the committee that DOM is aggressively pursuing supplemental rebates and that PDL implementation for the classes discussed today will be July 1, 2006.

Approval of Minutes:
Dr. O'Dell made a motion to accept the minutes as written. The motion was seconded by Dr. Cook. All voted in favor and the minutes were approved.

New Business:
Dr. O'Dell asked Ms. Clark for clarification on the process of reconciling the Committee's recommendations with the PDL. Ms. Clark responded that supplemental rebate information is confidential and all available information is considered by DOM in determining the best decision for the greatest number of beneficiaries.

Ms. Clark introduced Kathy Mosbaugh and Carrie Tort as representatives for Gold Standard Multimedia. Kathy Mosbaugh, Director of Operations for Gold Standard presented a demonstration of eMPOWERx, the PDA program currently being utilized by select Medicaid physician providers throughout the state.

Ms. Clark then introduced Tom Hood, Commissioner and Legal Counsel for the Ethics Commission. Mr. Hood described the primary roles and duties of the Ethics commission and discussed the MS Ethics Law as it relates to the P & T Committee and its membership.

Therapeutic Category Reviews:
Dennis Smith, R.Ph. of Health Information Designs, Inc., (HID), moderated the therapeutic class reviews.

ADHD AGENTS

Public comments in the ADHD agent category were presented by the following:
Susan Butross, M.D.; Celltech- Metadate and Metadate CD; Eileen Wall; McNeil –Concerta; Drew Johnson; Novartis, -Focalin XR

Dennis Smith reported that stimulant medications have been the staple of treatment for many years and perhaps the most significant change that has occurred among the stimulants has been the marketing of controlled release formulations which allow for less frequent dosing and more consistent delivery of the medication throughout the day. While the stimulants continue to be considered the first line treatment for typical ADHD patients, the availability of atomoxetine has offered an alternative to stimulants.

Atomoxetine is the only non-stimulant medication currently approved for the treatment for ADHD. It has been shown in a clinical trial to offer efficacy comparable to methylphenidate. It is generally dosed once daily. It is not a schedule II controlled substance, which offers some level of convenience to the patient and physician. HID recommends Straterra for inclusion on the PDL.

Dexmethylphenidate is the pharmacologically active d-enantiomer of the racemic methylphenidate molecule. It is available in both immediate and extended-release formulations. The extended release allows for once daily dosing and is comparable to methylphenidate in terms of safety and efficacy. Focalin is a well-priced sustained-action stimulant and is recommended for inclusion on the PDL. Immediate release Focalin is not recommended for PDL inclusion at this time. HID recommends Focalin XR for inclusion on the PDL.

Dextroamphetamine is currently available generically as both an immediate-release tablet and a sustained-release capsule. It has been on the market for quite some time and has established efficacy in the treatment of ADHD. It is very inexpensive, relative to other agents. HID recommends dextroamphetamine for inclusion on the PDL.

Methylphenidate is a well-established agent, available in several strengths, as well as in extended-release versions. Generic methylphenidate is limited cost-wise by a Federal Upper Limit (FUL), which makes it very inexpensive. HID recommends methylphenidate for inclusion on the PDL.

Concerta is the most frequently prescribed version of methylphenidate among Mississippi Medicaid beneficiaries. This agent was the first methylphenidate product to introduce a unique delivery system several years ago; which essentially mimics a multiple dose regimen in a single dose. Several strengths are available. It delivers 22 percent immediate release and 78 percent sustained-release methylphenidate. While this agent is effective and well-known to physicians, Concerta is considerably more expensive than other methylphenidate formulations with similar delivery systems. It fails to offer a clinical advantage to justify its higher cost. HID does not recommend brand name Concerta for inclusion on the PDL.

Metadate CD is another methylphenidate formulation with an immediate-release and sustained-release combination in the same dose. Across its three strengths, this agent delivers 30 and 70 percent immediate-release and sustained-release methylphenidate, respectively. It can be sprinkled for pediatric use. HID recommends Metadate CD for inclusion on the PDL.

Metadate ER is available generically and is therefore included with the generic methylphenidate agents.

Ritalin LA is very similar to other combination immediate-release, sustained-release agents. It is a 50/50 combination. While it is established as a safe and effective version of methylphenidate, it does not offer a clinical advantage to justify its higher costs. HID does not recommend Ritalin LA for inclusion on the PDL.

Amphetamine mixture (IR), is a mixture of amphetamine salts and is available as an immediate-release tablet and a sustained-release capsule (Adderall XR). The various versions of this ingredient combination are among the most commonly prescribed agents in the treatment of ADHD in the Mississippi Medicaid population. The efficacy of this agent for long-term use is well-established with a two-year study. This agent is a well-priced cost-effective stimulant therapy for ADHD and is recommended for preferred status. HID recommends the generic versions as well as brand name Adderall XR for inclusion on the PDL.

Methylin is a unique formulation of methylphenidate. The name methylin is associated with a generic line of methylphenidate products, but there are also chewable tablets and an oral solution. It is well priced, compared to other generic versions of methylphenidate. HID recommends the chewable tablet and solution formulations of Methylin for preferred status.

There is no rebated generic version of methamphetamine, therefore HID does not recommend this agent for inclusion on the PDL.

A question was brought to the committee regarding the ability of the committee to make sound recommendations without cost information. Mr. Smith referred the committee members to relative cost information handed out to the members with no actual dollar amounts given.

Dr. Meredith asked whether there were specific cost-savings estimates available to predict the cost savings to Medicaid with the implementation of HID recommendations. Mr. Smith answered that this information was not available. Dr. O'Dell expressed concern about the overall cost involved with changing a patient's drug therapy, assuming increased cost for additional office visits.

A discussion followed regarding stable therapy criteria. Ms. Clark stated that if stable therapy for 90 days is verified by paid pharmacy claims, the PA criteria for a non-preferred product will be met.

Dr. Cook made a motion to accept HID's recommendations (generic amphetamine mixture, Adderall-XR, Strattera, Focalin XR, generic dextroamphetamine, generic methylphenidate, Metadate CD) with the addition of Concerta. Dr. Gholson seconded the motion.

Committee Vote:
8 Votes Cast
Accept HID recommendation-1 vote: Smith
Accept HID recommendation with the addition of Concerta-7 votes: Alexander, Calvert, Cook, Gholson, King, O'Dell, Wales

DIGESTIVE HEALTH AGENTS

There was no public comment in the digestive health agent category.

Mr. Smith began the review of Digestive Health Agents with a short explanation of Inflammatory Bowel Disease and the negative impact that it has on quality of life for affected patients and the increased risk of colon cancer.

Asacol (mesalamine) is an enteric coated tablet which is important in the treatment of ulcerative colitis. This agent produces its benefit locally in the colon with limited systemic absorption and it has been proven safe and effective. HID recommends Asacol as a preferred agent.

Canasa, a mesalamine suppository, exhibits a local effect in the colon. While this formulation represents a relatively small portion of mesalamine utilization, availability of this alternate dosage form offers flexibility for patients who do not tolerate oral mesalamine products, or for patients who benefit from the combination of oral and topical aminosalicylate treatments. HID recommends Canasa for inclusion on the PDL.

Colazal (balsalazide) has seen very limited utilization among Medicaid patients. This aminosalicylate is converted in the colon to mesalamine and an inert molecule. It is considerably more expensive than oral mesalamine formulations and has no significant clinical advantage to justify its higher cost. HID does not recommend Colazal for inclusion on the PDL.

Dipentum (olsalazine) is another aminosalicylate which is converted into mesalamine. It has a local effect in the colon. With twice daily dosing, this agent offers a more convenient administration schedule when compared to other oral aminosalicylates. This agent has the lowest daily cost among the agents included in this review. HID recommends Dipentum for inclusion on the PDL.

Entocort EC (budesonide) is an oral corticosteroid formulation with an indication for mild to moderate active Crohn's disease in the ileum and/or ascending colon. While it appears to have fewer side effects than other oral corticosteroids, it appears to be less effective and considerably more expensive. HID does not recommend Entocort EC for inclusion on the PDL.

Pentasa is an oral controlled-release capsule mesalamine formulation with a safety profile and dosing regimen similar to other oral mesalamine products. HID recommends Pentasa for inclusion on the PDL.

Rowasa, a mesalamine retention enema, offers another alternative dosage form of mesalamine, particularly in patients who need both a topical and oral aminosalicylate. HID recommends Rowasa for inclusion on the PDL.

Ms. Wales made a motion to accept HID's recommendations (generic mesalamine 4 g/60ml enema, Asacol, Pentasa, Canasa, Dipentum) with the addition of Entocort EC. Ms. King seconded the motion.

Committee Vote:
8 votes cast
Accept HID recommendation-2 votes: Calvert, Smith
Accept HID recommendation with the addition of Entocort EC-6 votes: Alexander, Cook, Gholson, King, O'Dell, Wales

Dr. Gholson voiced concern over the antibiotics that were placed on the PDL and the effect that it might have on patient care. Mr. Calvert suggested that Dr. Gholson provide specific information to Ms. Clark as to which subclasses of antibiotics were of particular concern.

Pharmacy Program Update:
Ms. Clark gave a brief update on Medicare Part D as it relates to the Division of Medicaid.

There being no further business, Dr. Calvert adjourned the meeting at 3:15 pm.