MINUTES OF THE OCTOBER 9, 2007
PHARMACY AND THERAPEUTICS (P & T) COMMITTEE MEETING

Members Attending: Larry Calvert, R.Ph.; Jeff Jones, R.Ph.; Michael O'Dell, M.D.; Jennifer Gholson, M.D.; Pearl Wales, Pharm.D.; Garry McFerrin, R.Ph,; Robert Smith, M.D.; Manisha Sethi, M.D.; Robert Lomenick, R.Ph.

Also present: Judith Clark, R.Ph., Pharmacy Director, DOM; Terry Kirby, R.Ph., DOM; Paige Clayton, Pharm.D., DOM; Dennis Smith, R.Ph., HID; Rob DiBenedetto, HID; Chris Benton, Pharm.D., HID; Ashleigh Holeman, Pharm.D, HID

Members Absent: John Cook, M.D., Deborah King, FNP, Steve Roark

Chairman Larry Calvert called the meeting to order at 1:00pm.

Introductions: Ms. Clark welcomed committee members and guests in the audience. She thanked committee members for volunteering their time. She thanked Larry Calvert, Jennifer Gholson, Mike O'Dell and Pearl Wales for agreeing to attend one more meeting. Ms. Clark briefly explained the purpose of the P & T Committee. Ms. Clark introduced new Medicaid staff member, Rosie Moak and DOM staff members, Paige Clayton, Terry Kirby, Vicky Donaho and Ella Holmes.

Administrative Business: Ms. Clark asked guests to sign in. She 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 called committee members' attention to the packet at their seats. She instructed members to fill out travel vouchers and return them before leaving the meeting. She reviewed the ballot format and mentioned that the ballots include retail prices obtained from www.drugstore.com and whether or not acceptance of HID's recommendation will result in a change in PDL status. She instructed committee members to sign and place ballots in the envelope provided for collection at the end of the meeting. She announced that ballots would be tallied after the meeting and that ballots would be destroyed. She stated that the meeting was being taped to facilitate the recording of the minutes and that the tape would be erased or destroyed after completion of the minutes.

Approval of Minutes: Chairman Larry Calvert asked if there were additions, changes or deletions to the minutes of the last meeting. None were brought to the attention of the committee. Mr. Calvert asked for a motion to approve the minutes of the April 10, 2007 meeting as presented. Mr. Jones made a motion to accept and Ms. Wales offered a second

to the motion. Mr. Calvert asked for a vote. A voice vote was unanimous. Meeting minutes were approved as presented.

Administrative Business: 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. She further stated that there is no requirement that the executive director act on the committee's recommendations within thirty days. She stated that the minutes of the meeting would be placed on the web no later than November 10, 2007.

DUR Board Update: Ms. Clark asked Dr. Clayton to provide a DUR Board update. Dr. Clayton stated that several noteworthy issues have been addressed since the last P & T meeting. Regarding HIV, the Board approved implementation of strict criteria on May 1 that reflect the most current HIV guidelines set by NIH. These criteria are intended to encourage appropriate HIV care according to current treatment guidelines. No negative trends have been detected thus far. Regarding utilization of ADHD stimulants, the DUR Board has discussed concerns about possible abuse of ADHD drugs by patients over the age of twenty-one. The Board also reviewed utilization of Singulair for both asthma and allergic rhinitis and will discuss this further at the November meeting. Lastly, Dr. Clayton mentioned that the Board had considered antibiotic use in children under the age of one as it relates to an increased risk of asthma.

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

ACNE PREPARATIONS

Mr. Smith began the clinical review portion of the meeting by stating that the Acne Preparations were introduced to the PDL on January 1 of this year. This is a re-review of the class. Mr. Smith stated that there is a wide offering of topical agents available for the treatment of acne. He further stated that Mississippi DOM makes preferred agents for the treatment of acne available to beneficiaries under the age of twenty-one. HID recommends for continued preferred status: benzoyl peroxide/erythromycin (generics only), generic formulations of benzoyl peroxide, benzoyl peroxide cleansing lotions, benzoyl peroxide/clindamycin preparations including brand name Duac and Benzaclin, benzoyl peroxide/sulfur available as brand name Nuox, clindamycin (foam) sold as brand name Evoclin, generic clindamycin (gel, lotion and solution), generic erythromycin (gel, pledgets, and solution), sodium sulfacetamide/sulfur available as brand name Suphera, tazarotene available as brand name Tazorac, and tretinoin which is available generically (except for Retin-A Micro). The following agents are currently non-preferred and HID does not recommend a change in their status at this time: adapalene (Differin), azelaic Acid (Azelex), benzoyl peroxide/sulfur (Sulfoxyl), brand name clindamycin gel (Clindagel), and erythromycin ointment (Akne-Mycin). The following agents are currently preferred, but are recommended for change to non-preferred status: benzoyl peroxide/erythromycin (Benzamycin pak) and sodium sulfacetamide (Klaron).

One speaker, Adriana Guana of Dermik/Sanofi Aventis for Benzaclin, stood to receive questions from the committee. There was a short discussion regarding age requirements for the acne preparations.

Mr. Calvert asked if there were any questions or discussions from the committee.

Mr. Jones made a motion to accept HID's recommendation. Mr. Lomenick offered a second to the motion. Mr. Calvert asked the committee members to mark their ballots.

Committee Vote:
9 votes cast
Accept HID's recommendations: 9 votes

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GROWTH HORMONES

Mr. Smith stated that HID recommends no changes be made to the PDL in this class. Current preferred products include: Genotropin, Norditropin, Nutropin, Nutropin AQ, Saizen, Serostim, and Tev-Tropin. Current non-preferred products include: Increlex, Iplex, Humatrope, and Omnitrope.

Two industry speakers addressed the committee: George Moll of UMC-Pediatric Endocrinologist for hrGH and Kaysen Bala of Novo Nordisk for Norditropin.

A discussion followed regarding the differences in Nutropin Vial and Nutropin AQ.

Dr. Wales made a motion to accept HID's recommendation as presented. Dr. Gholson offered a second to the motion. Mr. Calvert asked committee members to mark their ballots.

Committee Vote:
9 votes cast
Accept HID's recommendations: 9 votes

OTIC ANTIBIOTICS

Mr. Smith stated that in order to better define the otic antibiotic class, anesthetic otic preparations such as those containing pramoxine, etc., and germicidal/bactericidal/ fungicidal otic preparations such as those containing acetic acid, chloroxylenol, etc., have been excluded from the review. He further stated that otitis externa and otitis media with effusion are best treated with local antibiotic drops and that it is generally accepted that systemic analgesics are a better choice than local anesthetics for treating pain associated with otitis externa. Mr. Smith stated his recommendation that this PDL class be limited to the otic antibiotic and antibiotic/corticosteroid combination agents and that the other otic preparations just described be excluded.

HID recommends for continued preferred status: ciprofloxacin/dexamethasone (Ciprodex), generic neomycin sulfate/polymixin B/hydrocortisone solution and suspension, and ofloxacin (Floxin Otic). The following agents are currently non-preferred and HID recommends no change in their PDL status at this time: ciprofloxacin/ hydrocortisone (Cipro HC), neomycin sulfate/colistin sulfate/hydrocortisone (Coly-Mycin S), neomycin sulfate/colistin sulfate; hydrocortisone/thonzonium bromide (Cortisporin TC), and neomycin/polymyxin B/buffers/hydrocortisone (Pediotic).

A general discussion followed regarding preferred and non-preferred agents and their presence on the Preferred Drug List. HID's recommendation to exclude certain otic anti-infectives from this class was clarified.

No speakers were heard for this class.

Mr. Jones made a motion to accept HID's recommendations as presented. Mr. Lomenick offered a second to the motion. Mr. Calvert instructed committee members to mark their ballots.

Committee Vote:
9 votes cast
Accept HID's recommendations: 9 votes

OPHTHALMIC ANTIBIOTICS

Mr. Smith stated that the Ophthalmic Antibiotics were a new class to the PDL. HID recommends for preferred status: azithromycin ophthalmic solution (~~Azasite~~AzaSite), generic bacitracin ointment, generic ciprofloxacin ophthalmic solution (not to include Ciloxan ophthalmic ointment), erythromycin ophthalmic ointment, gatifloxacin ophthalmic solution (Zymar), generic gentamicin ophthalmic preparations, generic neomycin/ polymyxin B/bacitracin ophthalmic preparations, generic neomycin/polymyxin B/ gramicidin ophthalmic solution, generic ofloxacin ophthalmic solution, generic sulfacetamide ophthalmic preparations, generic tobramycin ophthalmic solution (not to include Tobrex ophthalmic ointment, and trimethoprim/polymyxin B ophthalmic solution(Polytrim). HID recommends the following products for non-preferred status: Chloramphenicol ophthalmic preparations, Levofloxacin ophthalmic solution (Quixin), and Moxifloxacin ophthalmic solution (Vigamox).

One speaker, John Lyon of Inspire, addressed the committee regarding ~~Azasite~~AzaSite.

Dr. O'Dell made a motion to accept HID's recommendation with the amendment of recommending ~~Azasite~~AzaSite for non-preferred status. The motion was seconded by Mr. McFerrin. Mr. Calvert asked the committee to mark their ballots.

Committee Vote:
9 votes cast
Accept HID's recommendations: 1 vote- Smith

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Accept HID's recommendations with the exception of moving AzaSite to non-preferred status: 8 votes-Calvert, O'Dell, Gholson, McFerrin, Sethi, Jones, Lomenick, and Wales.

OCULAR ALLERGY AGENTS

Mr. Smith stated that this was another new PDL class and began the review by listing the agents recommended by HID for inclusion on the PDL as preferred agents: azelastine (Optivar), generic cromolyn sodium ophthalmic preparations, epinastine (Elestat), generic prescription-only ketotifen ophthalmic solution, nedocromil (Alocril), olopatadine (Patanol), olopatadine (Pataday), and pemirolast (Alamast). The following agents are recommended for non-preferred status: emedastine (Emadine), lodoxamide (Alomide), and loteprednol (Alrex). Lotemax is another formulation of loteprednol, but is marketed at a higher concentration with a different set of approved indications. Due to the wide range of indications for this product and its common post-surgical use, HID recommends that this agent be excluded from PDL placement.

Dr. Smith made a motion to accept HID's recommendation with the amendment of removing Alamast and Elestat from the recommendation. Dr. O'Dell offered a second. Mr. Calvert asked committee members to mark their ballots.

Committee Vote:
9 votes cast
Accept HID's recommendations with the exceptions of removing Elestat and Alamast from preferred to non-preferred and adding Lotemax to preferred status: 9 votes

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ANTICONVULSANTS

Mr. Smith announced that HID recommends no changes to the PDL for this class of drugs. Currently, preferred agents in this class include: carbamazepine (generic immediate-release, Tegretol XR, Carbatrol, Equetro), divalproex (Depakote, Depakote ER), ethosuximide, gabapentin, lamotrigine (generic chewable tablet, Lamictal), levetiracetam (Keppra), oxcarbazepine (Trileptal), phenytoin (Dilantin), pregabalin (Lyrica), primidone, tiagabine (Gabitril), topiramate (Topamax), valproic acid, and zonisamide. Current non-preferred agents include: ethotoin (Peganone), felbamate (Felbatol), methsuximide (Celontin).

Three speakers addressed the committee: Ming Walker on behalf of GlaxoSmithKline for Lamictal; Nathaniel Lawson on behalf of Abbott for Depakote; Lee Ann Griffin on behalf of Pfizer for Lyrica.

Mr. Jones made a motion to accept HID's recommendation as presented. The motion was seconded by Dr. Smith. Mr. Calvert asked committee members to mark their ballots.

Committee Vote:
9 votes cast
Accept HID's recommendations: 9 votes

ANTIPSYCHOTICS

Mr. Smith began the review of this class with aripiprazole (Abilify), which is currently non-preferred. HID recommends a change in the status of this agent from non-preferred to preferred. Risperidone (Risperdal) and ziprasidone (Geodon) are currently preferred and HID recommends continued preferred status for these agents. Paliperidone (Invega) is currently non-preferred and HID recommends a change in its status to preferred. Olanzapine/fluoxetine (Symbyax), olanzapine (Zyprexa), quetiapine (Seroquel and Seroquel XR) and pimozide (Orap) are currently non-preferred. HID recommends no change in the status of these agents at this time.

A discussion followed regarding the number of claims for non-preferred atypical antipsychotic agents and the criteria to approve those drugs. Mr. Smith reminded the committee that the ~~criteria for approval of a non-preferred agent in this class is~~criteria for approval of a non-preferred agent in this class are more lenient than for other PDL classes.

Several speakers addressed the committee: Stephen Cooke of BMS for Abilify; Courtney Walker of Lilly for Zyprexa; Bill Davis of AstraZeneca for Seroquel; John Prosser of Janssen for Invega and Lee Ann Griffin of Pfizer for Geodon.

Dr. Smith made a motion to accept HID's recommendation with the following amendments: recommend Seroquel and Zyprexa for preferred PDL status and recommend Invega for non-preferred PDL status. Hearing no second, Mr. Calvert relinquished the chair to Dr. O'Dell. Mr. Calvert seconded the motion. Committee members were instructed to mark their ballots.

Committee Vote:
9 votes cast
Accept HID's recommendations: 4 votes-O'Dell, Jones, Gholsen, Wales
Accept HID's recommendations with the exception of changing Zyprexa and Seroquel to preferred status and Invega to non-preferred status: Sethi, Calvert, Smith, McFerrin
Accept HID's recommendation with the exception of changing Invega to non-preferred status: 1 vote-Lomenick

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DVT AGENTS

Mr. Smith stated that HID recommends no changes in status for the agents in this class. Currently, enoxaparin (Lovenox) and fondaparinux (Arixtra) are preferred agents in this class. The current non-preferred agents are dalteparin (Fragmin) and tinzaparin (Innohep).

Mr. Calvert asked for a motion regarding HID's recommendations. Dr. Smith made a motion to accept HID's recommendation as presented. Mr. Calvert asked the members to mark their ballots.

Committee Vote:
9 votes cast
Accept HID's recommendations: 9 votes

DISEASE SPECIFIC IMMUNOSUPPRESANT AGENTS

Mr. Smith stated that HID recommends no changes to the PDL for this category of agents. Currently the following products are preferred: adalimumab (Humira), efalizumab (Raptiva) and etanercept (Enbrel). Current non-preferred products include abatacept (Orencia), alefacept (Amevive), anakinra (Kineret), infliximab (Remicade), and leflunomide (Arava).

Three industry speakers were heard: Brad Clay of Amgen for Enbrel; Eric Pakarinen of Genentech for Raptiva and Tommy Bush of Abbott for Humira.

Mr. Jones made a motion to accept HID's recommendation as presented. Dr. Gholson offered a second to the motion. Mr. Calvert asked the members to mark their ballots.

Committee Vote:

8 votes cast
Accept HID's recommendations: 8 votes
No vote: Calvert

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Mr. Calvert asked the committee if there was any business to be brought before the committee. Ms. Clark mentioned that the tamper resistant prescription pad requirement implementation had been postponed until April 1, 2008. One feature goes into effect April 1, 2008 and the three go into effect on October 1, 2008. DOM encourages all practitioners to use the next six months to prepare for implementation.

There being no further business brought to the attention of the committee; Mr. Calvert thanked the committee and adjourned the meeting.