MINUTES OF THE October 10, 2006
PHARMACY AND THERAPEUTICS (P & T) COMMITTEE MEETING

Members Attending: Larry Calvert, R.Ph., Chairman; Todd Barrett, R.Ph.; Michael O'Dell, M.D.; Robert Smith, M.D.; Deborah King, F.N.P.; Pearl Wales, PharmD.; Steve Roark; Jennifer Gholson, M.D.; Jeff Jones, R.Ph.; Robert Lomenick, R.Ph.

Also Present: Don Thompson, Deputy Director, DOM; Judith Clark, R.Ph., DOM; Terri Kirby, R.Ph., DOM; Dennis Smith, R.Ph., HID; Sam Warman, R.Ph., HID; Rob DiBenedetto, HID.

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

Introductions: Judith Clark welcomed the P & T Committee members and guests. She expressed her appreciation to the committee members for their service. Ms. Clark then introduced members of the Division of Medicaid: Don Thompson, Deputy Director of Health Services; Gay Gibson, Vicky Donaho, Ella Holmes and Terri Kirby, Pharmacy Bureau. Ms. Clark thanked the DOM Pharmacy staff for their efforts in preparing for the meeting.

There were no Executive Director's comments.

Administrative Business:
Judith Clark announced a change to the agenda in that election of committee officers will be held at the January meeting. Guests were instructed to sign in on the attendance sheets provided. Public comment speakers were instructed to sign in on the speakers sheets provided. Additional copies of the agenda and public comment guidelines are available at the sign-in table. 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. Attendees were reminded that the meeting is audio taped to facilitate the recording of the minutes, and speaker should speak loudly or use the microphone. She also requested that the chairman announce the recommendation motions and the name of the Committee Members making the motions.

Approval of Minutes: The chairman asked for any deletions, corrections, or additions to the minutes. Mr. Roark made a motion to accept the minutes as written. The motion was seconded by Ms. Wales. The minutes were approved by a majority vote.

Pharmacy Update: Mr. Calvert announced that for each category, the reviews would be presented, followed by public comment, discussions and marking of ballots.

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

ANTICONVULSANTS OR ANTIEPILEPSY AGENTS

Dennis Smith directed the committee members' attention to page 32 of the P & T manual. Mr. Smith announced that on September 28, the FDA issued an alert concerning the use of lamotrigine during the first trimester of pregnancy. This alert was based on preliminary data from the Antiepileptic Drug Pregnancy Registry suggesting a possible association between this drug and cleft lip or cleft palate. Agents recommended for non-preferred status include: ethotoin or Peganone, felbamate or Felbatol, methsuximide or Celontin, and pregabalin or Lyrica. All formulations of carbamazepine are recommended for preferred status, including Carbetrol, Equetro, Tegretol XR, as well as generically available formulations of carbamazepine. Valproic acid and divalproex are recommended in all strengths and formulations, including Depakote, Depakote ER, and generic formulations. The generics ethosuximide, gabapentin, primidone and zonisamide are recommended for inclusion. All formulations of phenytoin are recommended, including Dilantin Infatabs. Lamictal, Keppra, Trileptal, Gabitril and Topamax are recommended for inclusion. A discussion followed regarding Lyrica and its utilization. The committee recommended a systematic change to allow for transmittal of the treating diagnosis by the dispensing pharmacy. The intention of this change is to allow for approval of the medication only for specific diagnoses, such as diabetic peripheral neuropathy or postherpetic neuralgia.

The committee discussed the process of public comment. The committee recommended to industry representatives that if their product is recommended for PDL inclusion, please consider taking questions from committee members about their product rather than using the three minutes for comment.

The committee then heard from public speakers. Monica Fay for Keppra; Patrick Weldon, Pfizer, Lyrica; Pam Sardo, Depakote, Abbott; Arika Bell, Lamictal, GSK; Rolando Veloso, Ortho-McNeil Janssen, Topamax.

Mr. Jones made a motion that the committee amend HID's recommendation to include Lyrica on the PDL. Ms. Wales seconded the motion.

Committee Vote:
10 Votes Cast
Accept HID recommendation with the addition of Lyrica®-10 votes

ANTIPSYCHOTIC AGENTS

Mr. Smith announced that the review of the antipsychotic class would focus on the atypicals. He stated that HID's review included many parameters, including approved indications, efficacy in approved and off-label indications and adverse effects, among others. During HID's review of the class, they examined the clinical dossier's submitted by each manufacturer for each product, met with clinical representatives from each of the manufacturers, considered utilization patterns of each agent within the Division of Medicaid pharmacy claims, analyzed any available comparative efficacy data and compared the safety profiles of the agents. He further explained the HID has aggressively sought supplemental rebate proposals from the manufacturers, but have only seen minimal participation.

HID makes the following recommendations. Ziprasidone or Geodon is recommended as the sole preferred atypical antipsychotic. Patients being initiated on atypical antipsychotic therapy will require a trial on the preferred agent. For the atypical antipsychotic agent, we recommend a more liberal stable therapy criterion than what is in place for the other drug classes. HID recognized that patients are often stabilized on these agents during inpatient treatment. Verification of stable therapy during hospitalization will be required to satisfy the stable therapy criterion.

Ms. Clark added that the agency contends that clozapine is neither suitable nor appropriate for placement on the PDL. It will not require prior authorization other than brand name medically necessary.

Dr. Smith made a motion to include all atypicals on the PDL and allow more time to explore ways to lower the cost of these agents. This motion was seconded by Mr. Roark.

The committee then heard from public speakers. Richard Druckenbad for Risperdal, Ortho-Mcneil; Jeff Hill for Zyprexa, Eli Lilly; Julia Wise for Seroquel, Astra-Zeneca; Greg Johnson for Geodon, Pfizer.

A lengthy discussion took place among the members around the issue of limiting these agents. Several questions were posed and answered to clarify the recommendation. Dr. Odell made a motion to amend Dr. Smith's motion to include only Geodon, Risperdal and Zyprexa on the PDL. The motion was seconded by Todd Barrett. The amendment to the motion was passed by unanimous verbal vote.

Committee Vote:
10 Votes Cast
Accept HID recommendation with the addition of Risperdal® and Zyprexa®-
10 votes

DISEASE SPECIFIC IMMUNOSUPPRESSANT AGENTS

This class, commonly referred to as biologics or biologicals, are typically used for rheumatoid arthritis, psoriasis, etc. Mr. Smith pointed out that new information has come out since the printing of the P &T meeting materials. Remicade has received approval for an additional indication for plaque psoriasis. This use is listed in the manual as “off-label”, but has been approved recently.

Abatacept (Orencia) is indicated for rheumatoid arthritis. This agent is administered as an IV infusion under the supervision of the physician. Abatacept is administered monthly and can be used as monotherapy or in combination with disease-modifying antirheumatic drugs. Abatacept has a unique mechanism of action compared to the other biologic RA treatments. Because it is used solely in clinical settings and under professional supervision, this agent is not generally dispensed by pharmacies; and therefore, it is not subject to point-of-sale adjudication. Therefore, HID does not recommend abatacept for preferred status.

Adalimumab (Humira) is one of several TNH-inhibitors included in this review. It is indicated for rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis. This product is now available in a pen device for self-administration by the patient. Humira is generally dosed every two weeks, although, some RA patients who are not on concomitant methotrexate may need weekly dosing. The TNF inhibitors have been shown to be comparable in regards to efficacy. Humira is recommended by preferred PDL inclusion.

Alefacept (Amevive), is approved for the treatment of plaque psoriasis. It is administered as an IV and used in a clinical setting. This agent requires weekly dosing for twelve weeks. An additional twelve week course may be administered if the patient’s T-lymphocyte counts are within normal range. Because it is used solely in clinical settings and under professional supervision, this agent not generally dispensed by pharmacies and subject to point-of-sale adjudication. HID does not, therefore, recommend Amevive for preferred status.

Anakinra (Kineret) is indicated for rheumatoid arthritis. This agent may be self-administered, but requires daily injections, whereas other agents may be administered less frequently. This agent is not recommended for preferred status.

Raptiva is approved for the treatment of plaque psoriasis and is intended for use under the guidance and supervision of a physician. If it is determined to be appropriate, however, patients may self-inject after proper training in the preparation of injection technique and with medical follow-up. This agent is administered as a weekly subcutaneous injection. Raptiva has been demonstrated to offer excellent efficacy in the treatment of plaque psoriasis. This agent is recommended for preferred status.

Etanercept (Enbrel) is indicated for the treatment of rheumatoid arthritis, psoriatic arthritis, plaque psoriasis, ankylosing spondylitis, and juvenile rheumatoid arthritis. This agent may be self-injected and requires weekly dosing for most diagnoses. Treatment for plaque psoriasis calls for twice-weekly dosing for the first three months of therapy. This

agent is the only biologic agent approved for juvenile rheumatoid arthritis and can be administered to children as young as four years old. Enbrel is recommended for preferred status.

Infliximab or Remicade has a broad range of approved indications, including rheumatoid arthritis, psoriatic arthritis, enclosing spondylitis, Crohn's disease, and ulcerative colitis and plaque psoriasis. Although, the recommended dosing frequency varies by indication, this agent is generally given every eight weeks and requires IV infusion in a clinical setting. This agent has proven to be an important tool in the treatment of these disease states and has been studied for use in several other inflammatory diseases. Because it is used solely in clincial settings and under profession, this agent is not generally dispensed in pharmacies. HID does not, therefore, recommend infliximab for preferred status.

Lastly, leflunomide or Arava is approved for one indication, rheumatoid arthritis. This agent is unique among the agents in this review in that it is an oral tablet dosed once a day. There have been no claims for this agent in the point-of-sale pharmacy system. Hepatic enzyme monitoring is required with this agent as often as monthly and this agent is not recommended for preferred status.

Public comment was heard from: Pam Sardo, Abbott, Humira; Sherrill Rudy, Genentech, Raptiva.

Mr. Barrett made a motion to accept HID's recommendations. Mr. Jones offered a second to the motion.

Committee Vote:
10 Votes Cast
Accept HID recommendation-10 votes

INJECTABLE DEEP VEIN THROMBOSIS AGENTS

Mr. Smith presented the recommendations for the Injectable Deep Vein Thrombosis Agents.

For the agent, Fragmin, no evidence was found to separate this agent form other low-molecular-weight heparin (LMWH) agents. Additionally, this agent does not have as many approved uses as other similar agents. HID does not recommend Fragmin for inclusion on the PDL.

No evidence was found to separate Lovenox from other LMWH agents in regard to efficacy. This frequently used agent has many approved uses. HID recommends this agent for inclusion on the PDL.

The agent, Innohep, has the fewest approved uses of the LMWH agents and does not appear to be widely used. No evidence was found to separate this agent from other agents. HID does not recommend Innohep for inclusion on the PDL.

Arixtra is a novel therapeutic option for pulmonary embolism. Indirect comparisons, however indicate that it is no more effective than UFH or LMWH therapy.

Public comment was heard from Mark Haumschild, Sanofi-Aventis, Lovenox.

Mr. Barrett made a motion to accept HID's recommendation. Ms. Wales offered a second to the motion. Dr. O'Dell recommended the addition of Arixtra to the motion and Dr. Gholson seconded the recommendation. Ms. Wales agreed to allow the addition of Arixtra.

Committee Vote:
10 Votes Cast
Accept HID recommendation with the addition of Arixtra®-10 votes

ACNE PREPARATIONS

Mr. Smith called the committee members attention to the summary of HID's recommendations regarding Acne Preparations on pages 151 and 152 of the clinical review.

Mr. Smith listed the agents that HID recommends for preferred status: Generic benzoyl peroxide preparations; Zaclir, a benzoyl peroxide cleansing preparation; generic clindamycin preparations (solutions and gels); Evoclin, which is a clindamycin foam formulation; Duac, which is a clindamycin/benzoyl peroxide gel; generic erythromycin preparations; generic benzoyl peroxide/erythromycin gel; Nuox, a sulfur/benzoyl peroxide gel; and generic tretinoin preparations.

Public comment was heard from the following speakers: Vihba Vig, MD, Steiffel, Duac gel; Matt Johnson, Dermik Labs, Benzaclin; Steve Francesconi, Connetics, Evoclin.

Mr. Jones made a motion that the committee accept HID's recommendations with the addition of Benzaclin. Mr. Lomenick offered a second.

Committee Vote:
10 Votes Cast
Accept HID's recommendation -1 vote: Wales
Accept HID's recommendation with addition of Benzaclin- 9 votes

OTIC ANTIBIOTICS

Mr. Smith called the committee's attention to pages 165 and 166 of the clinical reviews.

Acetic acid is effective against most infections without causing sensitization. This product is recommended for preferred status. Acetic acid combination with hydrocortisone is the second agent and is recommended for preferred status.

Ciprofloxacin with dexamethasone, (Ciprodex), is the third product listed in the review. Studies indicate that this agent is superior to neomycin-polymixin B-hydrocortisone preparation in the treatment of otitis externa. It combines an antibiotic with a steroid, obviously. Although indicated for acute bacterial otitis media, treatment guidelines do not recommend topical agents as first-line treatment, and this agent does not have an indication for chronic suppurative otitis media. This product is recommended for preferred status.

Ciprofloxacin with hydrocortisone (Cipro HC) is another ciprofloxacin combination agent. This product does not appear to have nay advantages over other recommended agents. Unlike other agents, this agent cannot be used in patients with perforated tympanic membrane and has limited indications compared to other recommended agents. This product is not recommended for PDL inclusion.

Hydrocortisone/pramoxine hydrochloride/chloroxylenol is generically available, providing a triple combination of a germicide, an anti-inflammatory, and a topical anesthetic. HID recommends this generic product as a preferred agent.

Neomycin Sulfate/Colistin/Sulfate and Hydrocortisone (Coly-Mycin) is not recommended for preferred status as it offers no apparent advantages as compared to other recommended agents.

Neomycin Sulfate/Colistin Sulfate/ Hydrocortisone/thonzonium bromide (Cortisporin TC) is not recommended by HID as a preferred agent. No advantages are seen with this product compared to other recommended agents.

Neomycin Sulfate/Polymixin B/Hydrocortisone Solution and Suspension are two commonly prescribed products. Although other agents appear to be more effective, there is no disadvantage on keeping these generically available products on the preferred drug list.

Ofloxacin (Floxin Otic) is indicated in studies to be more effective than neomycin/polymixin B/hydrocortisone products. This agent can be used in patients with perforated tympanic membranes and is the only agent indicated for chronic suppurative otitis media. HID recommends this agent for preferred status.

Pramoxine with Chloroxylenol (PramOtic) is not recommended for preferred status as it appears to have no advantage over other recommended products.

Public comment was heard from: John Mark Reed, M.D., Alcon, Ciprodex.

Mr. Barrett made a motion to accept HID's recommendations. Mr. Jones offered a second to the motion.

No discussion followed.

Committee Vote:
10 Votes Cast
Accept HID recommendation-10 votes

GROWTH HORMONES

Mr. Smith asked the P & T committee members to turn their attention to page 190 of the clinical reviews.

Nutropin is a widely used product with approved indications for both children and adults. For children, it may be used with GHD, those with chronic renal insufficiency, and those with short stature associated with Turner syndrome. This product is recommended by HID for preferred status.

Iplex is not recommended for preferred status as claims history indicates limited usage in a POS system.

Increlex is not recommended for preferred status as claims history indicates limited usage in a POS system.

Humatrope is not recommended for preferred status as it does not provide any additional advantages over other products in indications, efficacy or ease of use.

Serostim is the only agent with a unique indication within this review. Because it is indicated for HIV patients with wasting or cachexia to increase lean body mass and body weight and improve physical endurance. This agent is recommended for preferred status.

Norditropin, Norditropin NordiFlex is an effective growth hormone indicated for adults and children. The pre-filled and premixed NordiFlex delivery system offers 120 options to dose and each pen may be used multiple times for up to four weeks. This agent is recommended for preferred status.

Saizen is a somatropin preparation and has multiple indications and many delivery options, including a needle-free device and a device with a hidden needle to ease anxiety. This agent is recommended for preferred status.

Genotropin is the only growth hormone therapy indicated for PWS, as well as SGA, for pediatric patients, because of its unique indications, this product is recommended for preferred status.

Tev-Tropin is the only generically available growth hormone on the market and is recommended for preferred status.

Public comment was heard from the following speakers: George Moll, M.D., UMC Pediatrics, Nutropin and Nutropin AD; Robert Toepfer, NovoNordisk, Norditropin; Angela Spencer, Serono, Saizen.

Mr. Jones made a motion that the committee accept HID's recommendations. Ms. Wales offered a second to the motion.

Committee Vote:
10 Votes Cast
Accept HID recommendation-10 votes

Ms. Clark announced that there would be no pharmacy update at today's meeting. She announced the next P & T Committee meeting date of January 9, 2007.

Ms. Clark thanked Todd Barrett and Jeff Jones for agreeing to serve at this meeting.

Mr. Calvert asked if there was any remaining business to be brought before the Committee. Mr. Calvert thanked Ms. Clark and the Medicaid staff for all their hard work.

There being no further business brought to the attention of the committee, Mr. Calvert adjourned the meeting at 3:20pm.