

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

Members Attending: Larry Calvert, R.Ph., Chairman; Jeff Jones, R.Ph.; Michael O'Dell, M.D.; Jennifer Gholson, M.D.; Pearl Wales, Pharm. D.; Gary McFerrin, R.Ph.; Deborah King, F.N.P.; John Cook, M.D.; Robert Smith, M.D.; Manisha Sethi, M.D.

Also Present: Don Thompson, Deputy Director, DOM; Judith Clark, R.Ph., DOM; Terry Kirby, R.Ph., DOM; Gaye Gipson, DOM; Dennis Smith, R.Ph., HID; Sam Warman, R.Ph., HID; Brenda Winslett, HID

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

Introductions: Judith Clark began by welcoming attendees to the meeting. She briefly explained the purpose and focus of the P & T committee. She then recognized new committee members, including two reappointments from last year. New members Gary McFerrin and Dr. Manesha Sethi were recognized, along with reappointed members, pharmacist Jeff Jones and Dr. John Cook. Ms. Clark introduced those attending from the Division of Medicaid; Don Thompson, Deputy Director of Health Services, Terri Kirby and Paige Clayton, pharmacists with Division of Medicaid, and staff members Gaye Gipson, Vicky Donaho and Ella Holmes.

Administrative Business: Ms. Clark reminded all guests to sign in. She then reminded all attendees that no food or drink are to be brought into the building, to turn off or silence all pagers and cell phones, and that leaving the room should be done between clinical reviews to limit distraction to the meeting. She announced the emergency exits for the building and the procedure for exiting the building in an emergency. She asked committee members to complete travel vouchers before leaving the meeting. She also reminded committee members to speak clearly and announce their names when speaking during the meeting to facilitate recording of the minutes on tape. She explained the process for completing paper ballots for the voting process. Ms. Clark announced that the Division of Medicaid is aggressively pursuing supplemental rebates. She announced that the minutes for the meeting would be posted on the web no later than February 9, 2007.

Approval of Minutes: Mr. Calvert asked the committee members for any additions, deletions or changes to the minutes. Mr. Jones made a motion to accept the minutes as presented. Dr. Cook offered a second to the motion. The motion passed on a voice vote with no audible dissenters. Ms. Clark announced that the election of chair and vice chair would take place at the April meeting, so that new members would have gone through a complete meeting before the election process.

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

5-HT₃ ANTAGONISTS

After directing the committee members to page five of their packets, Mr. Smith summarized the category by saying that HID is recommending only one product, Zofran, which is currently the preferred product. He explained the justification for this recommendation that the drug is indicated for all three FDA approved uses of the products in this class including prevention of nausea and vomiting associated with the emetic cancer chemotherapy, prevention of nausea and vomiting associated with radiation treatment and prevention of post-op nausea and vomiting.

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

ANTIDEPRESSANTS

Mr. Smith began the review of the antidepressant category by stating HID's recommendation that the agents presently considered preferred should remain preferred. HID also recommends Lexapro as a preferred product. Mr. Smith explained that there are studies indicating that Lexapro may be more tolerable than other agents, which may result in improved patient adherence, decreased withdrawal rates due to adverse effects and also effectiveness in treating depression and anxiety. HID also recommends Effexor XR. Mr. Smith added that there is one new product in this category, Emsam, and it is not considered first-line therapy and is not recommended for inclusion on the PDL.

The following speakers were heard: Courtney Walker, Cymbalta, Eli-Lilly; Mike Delucia, Lexapro, Forest Pharmaceuticals; Shelly Seiler, Effexor, Wyeth. Discussion followed only to restate the recommendations.

Dr. O'Dell made a motion to accept HID's recommendation, and Mr. Jones offered a second. After further discussion, Dr. Smith made a motion to amend the recommendation to include Cymbalta on the PDL and Dr. Sethi seconded this motion.

ANTIHYPERLIPIDEMICS

Mr. Smith presented the reviews for the antihyperlipidemics. HID recommends for PDL inclusion the following products: Lipitor, generic cholestyramine, Vytorin, Tricor, gemfibrozil, lovastatin, Niaspan and generic niacin, Advicor, pravastatin, simvastatin, Zetia and Omacor. Triglide is the newest fenofibrate on the market. There is no compelling clinical information to suggest that this fenofibrate preparation offers any advantage over other more widely accepted preparations, therefore HID does not recommend Triglide for inclusion on the PDL.

The following speakers were heard: Kimberly Williams, Vytorin, Schering Plough; Pam Sardo, Tricor, Abbott; Dr. Honey East, Lipitor, UMC; Cheryl Edwards, Triglide, Sciele; Candace Barber, Omacor, Reliant; Dr. Daniel Teat, Crestor, AstraZeneca.

Mr. Jones made a motion to accept HID's recommendation, with the amendment of adding Crestor to the PDL. Dr. Smith seconded this motion.

Committee Vote:

9 Votes Cast

Accept HID recommendation with the addition of Crestor®-6 votes: Calvert, Cook, Gholson, Jones, Smith, Sethi, McFerrin, and King;

Accept HID's recommendations- 1 vote: O'Dell

BPH AGENTS

Mr. Smith began the review of the BPH Agents by stating that HID recommends the following products for inclusion on the PDL: Uroxatral, doxazosin, finasteride, Flomax, and terazosin.

The following speakers were heard: Carol Collins, Avodart, GSK; Majid Tabesh, M.D., Uroxatral, Sanofi-Aventis; William Barkard, Flomax, Boehringer-Ingelheim.

Mr. Jones made a motion that the committee accept HID's recommendation. Dr. Sethi seconded the motion.

ESTROGENS AND PROGESTINS

Mr. Smith stated that HID recommends the status quo in this class. Presently, the PDL includes the following products: generic transdermal estradiol; generic oral estradiol; oral conjugated estrogens (Premarin); generic oral estropipate; vaginal conjugated estrogens (Premarin Vaginal); generic oral medroxyprogesterone; generic oral norethindrone; oral conjugated estrogens and medroxyprogesterone combination (Premphase, Prempro). There was no discussion.

Mr. Jones made a motion to accept HID's recommendation. Dr. O'Dell offered a second.

HEMATOPOIETIC AGENTS

Mr. Smith presented HID's recommendations in the Hematopoietic category. HID recommends Epogen and Procrit as the only preferred products in this category.

One speaker was heard: Sue Watson, Procrit, Ortho Biotech.

Dr. Smith made a motion to accept HID's recommendation as presented. Ms. Wales offered a second to the motion.

ORAL ANTIBIOTICS - CEPHALOSPORINS

Mr. Smith presented the category by stating that HID would recommend the status quo in this class with the addition of one product, Ceftin suspension, to the PDL. Those products currently on the PDL are ceflacor, cephadroxil, Omnicef, Suprax suspension, cefpodoxime, cefprozil, cefuroxime, cephalexin, and cephradine.

The committee heard two speakers: Pam Sardo, Omnicef, Abbott; Donna White, Spectracef, Cornerstone.

Mr. Jones made a motion to accept HID's recommendation.

ORAL ANTIBIOTICS - MACROLIDES

Mr. Smith presented recommendations in the macrolide sub-category. HID recommends the following products for inclusion on the PDL: all generic formulations of erythromycin, including erythromycin/sulfisoxazole combination, generic azithromycin, and clarithromycin, including Biaxin XL.

The committee heard one speaker, Pam Sardo, Biaxin XL, Abbott.

Mr. Jones made a motion to accept HID's recommendation, Dr. Gholson seconded the motion.

ORAL ANTIBIOTICS – MISCELLANEOUS ANTIBACTERIAL AGENTS

Mr. Smith announced that HID's recommendation was to continue with the current products on the PDL, thus recommending clindamycin oral capsules and pediatric solution, which is the branded Cleocin Pediatric Solution. Telithromycin, a ketolide antibiotic, was included in this review and was not recommended for preferred PDL status.

There were no speakers for products in this category.

At this point there was a lengthy discussion about prior authorization procedures surrounding the discharge of a patient from the hospital on an oral antibiotic that is non-preferred. Ms. Clark mentioned that the Division of Medicaid is working systematically

on the capability of allowing an ICD9 code to be transmitted by the dispensing pharmacy to expedite the process.

Dr. Sethi made a motion to accept HID's recommendation as presented and Dr. Smith offered a second.

ORAL ANTIBIOTICS - PENICILLINS

Mr. Smith presented the recommendations for the penicillin category. He stated that HID's recommendation was consistent with the current PDL, which includes amoxicillin, amoxicillin with clavulanate, ampicillin, dicloxacillin, and Penicillin V.

Mr. Jones made a motion that the committee accept HID's recommendation. Dr. Cook seconded the motion.

ORAL ANTIBIOTICS - QUINOLONES

Mr. Smith presented the quinolone class of oral antibiotics. He stated that HID recommends preferred status for generic ciprofloxacin, Avelox, nalidixic acid, and generic ofloxacin.

Two speakers were heard. Rolando Velso, Levaquin, Ortho-Mcneil; William Webster, Avelox, Schering Plough.

Dr. Smith made a motion to accept HID's recommendation with the amendment of adding Levaquin. Mr. Jones offered a second to the motion.

ORAL ANTIOTBIOTICS - SULFONAMIDES

Mr. Smith presented the sulfonamide category by stating that HID is recommending co-trimoxazole, sulfisoxazole, sulfasalazine, and sulfadiazine (to include Gantrisin pediatric suspension).

Mr. Jones made a motion to accept HID's recommendation as presented. Dr. Gholson offered a second to the motion.

ORAL ANTIBIOTICS - TETRACYCLINES

Mr. Smith presented the tetracyclines. HID recommends status quo in this category of products. Currently, demeclocycline, doxycycline, minocycline, and tetracycline are included on the PDL.

Ms. Wales made a motion to accept the recommendation. Dr. Gholson offered a second to the motion.

ORAL ANTIFUNGALS

Mr. Smith presented HID's recommendations for the antifungal category of products. HID recommends fluconazole, griseofulvin microsize and ultramicrosize (Grifulvin V, Gris-Peg), generic itraconazole, ketoconazole, nystatin, and Lamisil tablets.

Dr. Sethi made a motion to accept HID's recommendation as presented and Mr. Jones offered a second to the motion.

ORAL ANTIVIRALS

Mr. Smith presented the recommendations for the oral antivirals. HID's recommendation is to continue with the current preferred products including acyclovir, ribavirin (Copegus, Rebetol, generic), Hepsera, ganciclovir, Valtrex and Valcyte.

Two speakers were heard: Richard Prejeen, Famvir, Novartis; Carol Collins, Valtrex, GSK.

Mr. Jones made a motion to accept HID's recommendation as presented. Mr. McFerrin offered a second. Discussion followed regarding single day dosing of Famvir for recurrent genital herpes from a pricing standpoint. Mr. Jones and Mr. McFerrin withdrew their motion and second.

Dr. Smith made a motion recommending postponement of the vote in this class until the April meeting. The motion was seconded by Dr. Cook.

MISCELLANEOUS SKIN AND MUCOUS MEMBRANE AGENTS

Mr. Smith explained that he would present subcategories for this group as they appear on the PDL, as the group is so large. For the antineoplastic and pre-malignant lesion agents, only generic products are recommended for inclusion, which limits it to fluorouracil products. For the antipsoriatic agents, generic anthralin is recommended. For the diabetic ulcer preps, there are no recommended products. For the immunomodulators, Aldara is recommended. In the immunosuppressive agents no products are recommended. For the keratolytics, generic podofilox and urea products are recommended. The mucous

membrane/subcutaneous enzymes category includes collagenase, papain/urea, papain/urea/chlorophyllin, and trypsin/balsam Peru/castor products. Only generic products are recommended. No mucositis/stomatitis agents or systemic acne agents are recommended.

Mr. Jones made a motion to accept HID's recommendation on all subcategories. Dr. Cook seconded the motion.

Committee Vote:

SKELETAL MUSCLE RELAXANTS

Mr. Smith presented the skeletal muscle relaxants by stating that HID recommends chlorzoxazone, cyclobenzaprine, dantrolene, methocarbamol, orphenadrine. Metaxalone is not recommended for inclusion on the PDL. A discussion regarding carisoprodol followed. Ms. Clark suggested that the committee wait a few months and allow DOM to direct academic detailing efforts toward the promotion of appropriate utilization of carisoprodol and bring the class back to the committee at a later date.

Mr. Calvert made a motion to remove carisoprodol from the vote and allow the remainder of the vote to go on as presented. Mr. Jones made a second to that motion.

Committee Vote:

TOPICAL ANTIBACTERIALS

For the antibacterials, Mr. Smith stated HID's recommendation to include bacitracin, bacitracin/polymixin B, gentamycin cream and ointment, mupirocin ointment and triple antibiotic ointment on the PDL. For the vaginal antibacterial products, HID recommends Clindesse vaginal cream.

One speaker was heard: Michael Livingston, Clindesse, Ther-RX.

Dr. Sethi made a motion to accept HID's recommendation and Dr. Cook offered a second.

Committee Vote:

TOPICAL ANTIFUNGALS

Mr. Smith stated HID's recommendations for the topical antifungals. The following products are recommended: ciclopirox cream and solution, clotrimazole one percent cream and solution, clotrimazole/betamethasone cream and lotion, econazole cream, ketoconazole cream and shampoo, miconazole cream, nystatin cream and ointment, nystatin/triamcinolone, tolnaftate, and miconazole nitrate/zinc oxide (Vusion).

Dr. Sethi moved to accept the HID recommendation and amend to also include Naftin. Mr. McFerrin seconded the motion.

Committee Vote:

TOPICAL ANTI-INFLAMMATORIES

Mr. Smith stated HID's recommendation regarding the anti-inflammatory category by explaining that each potency group is represented by at least one generically available product. No studies offer a statistically significant clinical advantage of the brand name agent over the generic alternative. Therefore, no brand topical corticosteroids are recommended for preferred status at this time. Only available generic products, as well as generic combination products, are recommended for preferred status. Specifically, HID recommends the following generic products: alclometasone ointment, amcinonide, betamethasone dipropionate, betamethasone valerate, clobetasol propionate, desonide, desoximetasone, diflorasone diacetate, fluocinolone acetonide, fluocinonide, fluticasone, hydrocortisone, hydrocortisone acetate, hydrocortisone butyrate, hydrocortisone valerate, mometasone furoate and triamcinolone acetonide.

Three speakers were heard by the committee: John Abide, Locoid Lipocream, Ferndale Labs; Melissa Miller, Desonate, Skin Medica; Jimmy Stewart, Cutivate, Pharma Derm.

Dr. O'Dell made a motion to accept HID's recommendation and Mr. McFerrin offered a second.

Committee Vote:

TOPICAL ANTIPRURITICS

Mr. Smith stated that HID does not recommend any of the products listed in the review material for inclusion on the PDL. He explains that making those products available through the prior authorization process will encourage appropriate utilization. Those products include: Prudoxin cream, Zonalon cream and Hylira lotion.

A motion was made to accept HID's recommendation by Ms. Wales and seconded by Dr. Cook.

Committee Vote:

TOPICAL ANTIVIRALS

Mr. Smith stated that HID does not recommend any of the products listed in the review material for inclusion on the PDL. Those products listed in the review material include acyclovir and penciclovir.

Ms. Wales made a motion to accept HID's recommendation as presented. Dr. Cook offered a second to that motion.

Committee Vote:

TOPICAL SCABICIDES AND PEDICULICIDES

For the topical scabicides and pediculicides category of products, Mr. Smith began with crotamiton (Eurax), which is primarily indicated for topical treatment of scabies. Crotamiton is available as a cream or lotion. Although this agent has seen relatively low levels of use in this population, it is an important tool and should be readily available. HID recommends it for inclusion on the PDL.

HID also recommends Ovide for inclusion on the PDL. Ovide, or malathion, holds an advantage over other available agents in terms of efficacy and safety. Although resistance to other treatments is increasing, no resistance has been reported for this product. Malathion offers superior efficacy and quicker eradication times.

Lindane, permethrin, and pyrethrins with piperonyl butoxide are not recommended for inclusion on the PDL.

Lindane has had a black box warning placed by the FDA recommending that its use be limited to patients who have failed treatment with safer medications. Due to its neurotoxic potential, lindane is not recommended for use in infants and children or anyone weighing less than 110 pounds. Access to this agent should be limited to appropriate patients through prior authorization.

Lastly, permethrin and pyrethrins are over the counter products. Resistance to over the counter permethrin and pyrethrins preparations has been demonstrated to be widespread and increasing throughout the United States. The availability of these agents over the counter may contribute to the development of resistance. Repeated applications are common with this product, leading to increased school absenteeism.

In summary, Mr. Smith stated that HID recommends Eurax for scabies and Ovide for head lice.

One speaker was heard: Howard Rutman, M.D., Ovide, Taro. A discussion followed regarding lindane safety and its potential use in children.

Dr. Sethi made a motion to accept HID's recommendation with the addition of Elimite to the PDL. This motion was discussed by the committee, then seconded by Mr. McFerrin.

Committee Vote:

There being no further business brought before the committee, Chairman Calvert thanked the committee for their attendance and their time. The meeting was adjourned by the chair at approximately 3:45pm.