MINUTES OF THE OCTOBER 14, 2004
PHARMACY AND THERAPEUTICS (P & T) COMMITTEE MEETING

Members Attending: Todd Barrett, R. Ph., Larry Calvert, R. Ph., Betsy Cummings, C.F.N.P., Gary Davis, M.D., Craig Dawkins, M.D., Jennifer Gholson, M.D., David Hudson, R. Ph., Jeff Jones, R. Ph., Micheal O'Dell, M.D., Pearl Wales, Pharm. D. , Raymond Wynn, M.D.

Members Absent: Myrna Alexander, M.D.

Also Present: Philip Merideth, M.D., J.D., Judith Clark, R. Ph., Terri Kirby, R. Ph., Gay Gipson, R.N., Laureta Cameron- DOM, Rob DiBenedetto, Sam Warman, R. Ph, Lew Anne Snow, R.N., Pam DeRuiter, R. Ph.-HID

Guests Present: Nicole Stofer-Governor's Office, Rob Reedy-ACS

Administrative Business
Approve minutes of the September 14, 2004 P&T Committee meeting. Jeff Jones moved that the minutes which had been mailed to the committee be accepted as read. Dr. O'Dell seconded. All voted in favor of approval by a show of hands.

New Business
The meeting was called to order by Larry Calvert at 10 AM. Judy Clark made announcements and gave tentative dates for future P&T committee meetings. The tentative dates are January 18, 2005, March 8, 2005, May 10, 2005, July 12, 2005, September 13, 2005 and November 8, 2005 (all dates fall on Tuesdays). These dates are subject to change. The new paper ballots were introduced and explained. Voting would be en bloc, FOR a motion, AGAINST a motion or Abstention.

Dr. Calvert gave committee members an opportunity to make comments and ask questions. Jeff Jones voiced his concern about the committee not receiving the ballot vote results from the last two meetings. Dr. Dawkins asked why and by whom the decision was made to replace the University of MS School of Pharmacy by HID to perform the clinical reviews. Judith Clark replied that this decision was given to her and she did not know who made it. Dr. Dawkins also asked if UMC Pharmacy School had any input in the reviews. Ms. Clark stated that they did not. Jeff Jones asked about the action taken on their recommendations. Judith Clark replied that Dr. Jones was out of town and Sharon Myers was under the weather and may attend the meeting later in the day to answer their questions. Ms. Clark stated that she would relay their concerns to Ms. Myers.

THERAPEUTIC CATEGORY REVIEWS

Pam DeRuiter, R.Ph., with Health Information Designs (HID) moderated the therapeutic class reviews.

Skelaxin Review (Tabled at Sept. 28th meeting)

Ms. DeRuiter addressed the question raised previously as to which Skelaxin strength was used in the study which concluded it to be no more effective than placebo. She stated that no recent studies are available. All studies found dated back to 1975 and 1976 at which time the 400 mg. was the only strength available. Most authorities attribute the beneficial effects of Skelaxin to its sedative properties. There was no discussion or motion after this information was presented therefore consideration for preferred status dies.

ALZHEIMERS AGENTS

HID recommended Aricept as the preferred cholinesterase inhibitor because it may be given once daily and may be better tolerated. Namenda was also recommended in that its mechanism of action is different and is the only agent in this class approved for moderate to severe Alzheimers disease. Dr. O'Dell motioned to accept the recommendation and also include Exelon and Reminyl on the PDL. Jeff Jones seconded the motion. Dr. Gholson commented that she was concerned about issues with switching AD therapy in that patients may decline when therapy is interrupted and this can be devastating. Ms. Clark explained that patients on stable therapy may be 'grandfathered' in and DOM is currently developing the definition of 'stable' therapy. Mr. Calvert expressed interest in a 'paperless' PA process. Dr. O'Dell presented statistics on the increased cost burden the PA process places upon physicians. Dr. Dawkins remarked that the PA process is done to limit the use of name brand drugs. He then asked for differences between Aricept, Exelon and Reminyl. Ms. Deruiter stated that Rivastigmine (Exelon) is dosed BID and has a higher incidence of adverse effects than Aricept. Galantamine (Reminyl) has warnings of severe hepatic and renal impairment and titration must be done even more cautiously in patients with moderate hepatic or renal impairment and it also has multi-day dosing.

Mr. Calvert recommended having a meeting with the Legislative Medicaid Committee to discuss the PA process. Ms. Clark replied that she will take this recommendation to her supervisor.

Dr. Davis recommended adding Rivastigmine (Exelon) because it has less drug interactions and it would be beneficial to have at least one agent available in the liquid formulation.

Mr. Barrett made a motion to amend the initial motion by accepting HID' recommendation and adding only Rivastigmine (Exelon) as preferred. Dr. Gholson seconded the motion. Voice vote on Mr. Barrett's amendment. All in favor.

Ballot Results

HID recommendation for PDL inclusion: Donepezil (Aricept) and Memantine (Namenda). Motion to amend recommendation by also including Rivastigmine(Exelon). ALL voted FOR the motion.

PLATELET AGGREGATION INHIBITORS

HID recommended Aspirin, Clopidogrel (Plavix), Dipyrdamole and Ticlopidine. Mr. Jones motioned to accept the recommendation and exclude Ticlopidine. Betsy Cummings seconded the motion. Mr. Barrett questioned why Pletal was not included in the recommendation. Ms. DeRuiter stated that it will be included with the intermittent claudication agent review on Nov.5th, 2005.

Ballot Results
Motion to accept HID's recommendation and amend by excluding Ticlopidine from PDL-
FOR motion: Barrett, Calvert, Cummings, Davis, Dawkins, Hudson, Jones, O'Dell, Wales, Wynn
AGAINST motion: Gholson

OSTEOPOROSIS AGENTS

HID recommended Alendronate (Fosamax), Calcitonin (Miacalcin) and Raloxifene (Evista). Discussion ensued regarding the Actonel data and studies contained in HID's clinical review. Jeff Jones cited the study referenced page 23 of the packet which found patients taking Actonel had a 59% lower risk of nonvertebral fracture than patients receiving Fosamax. Dr. O'Dell cited the Mayo Clinic and Houston VA studies and added that Actonel seems to have a safer GI side effect profile. Jeff Jones motioned to accept the recommendation and amend by adding Risedronate (Actonel). Jennifer Gholson seconded the motion.

Ballot Results
Motion to accept recommendation and amend to also include Risedronate (Actonel).

ALL voted FOR the motion

ANTIHISTAMINES

HID recommended all OTC antihistamines covered by Medicaid, Generic Legend Antihistiamines and Astelin Nasal Spray .David Hudson stated that previously there was an exclusion for children age 21 and under for Zyrtec and other non-sedating antihistamines. Ms.Clark stated that she sees this criteria remaining the same but as yet the PA process has not been finalized for each class. Dr. Gholson discussed her use of Carbinoxamine in the pediatric population. Discussion ensued and it was determined that Carbinoxamine is available generically. Jeff Jones motioned to accept HID's recommendation and to amend by including all dosage forms of Zyrtec. Pearl Wales seconded the motion.

Ballot Results
Motion to accept HID's recommendation and amend to also include all dosage forms of Cetirizine (Zyrtec)-
ALL voted FOR the motion.

H2 ANTAGONISTS

HID recommended all generic H-2 antagonists as preferred agents ; Cimetidine, Famotidine, Nizatidine, and Rantidine. All agents in this class are similar in effectiveness with the exception of Cimetidine which has greater potential for more drug interactions. There are no studies which show the brand name products as being more effective than generics. Jeff Jones motioned to accept HID's recommendation. Todd Barrett seconded the motion. Motion was then amended by Dr. Gholson to also include Zantac Syrup (unavailable generically) for age 21 and under. David Hudson seconded.

Ballot Results
Motion to accept recommendation and amend to also include Zantac (Brand) Syrup for Age 21 and under.
ALL voted FOR the motion.

PROTON PUMP INHIBITORS

HID recommended Prilosec OTC. Ms DeRuiter stated that the overall effectiveness of the PPIs in treating GERD, duodenal ulcers and erosive esophagitis appears to be similar. Jeff Jones discussed the current unavailability of Prilosec OTC and asked what will happen in the future when a preferred drug is unavailable. John Dorsey, representative from Proctor and Gamble commented on the the status of the Prilosec OTC shortage. Betsy Cummings asked how much money has been spent for upper endoscopy procedures since the PPIs have required prior approval. Jeff Jones commented that the money saved by requiring prior authorization for the PPIs may be offset by the money spent for endoscopies. Ms. Cummings motioned to table this class for discussion until the next meeting in January 2005 at which time DOM
shall provide a report including total money spent on upper endoscopy procedures. Jeff Jones seconded the motion.

Ballot Results

Motion to **TABLE** discussion for a later meeting.
Motion carried by a show of hands.

NSAIDS and COX2 Inhibitors

Ms. DeRuiter stated there is no conclusive evidence which demonstrates a significant difference in the efficacy between the COX-2 inhibitors and other NSAIDS, however, there are differences in the adverse drug reactions between these two classes. Evidence does suggest decreased adverse GI events of the COX-2 inhibitors when compared to NSAIDS. There are limitations to the studies and they do not offer convincing data that these agents offer significant advantages over the NSAIDS. In a recent article in the U.S. Pharmacist regarding the reduction of risk of upper GI toxicities in patients requiring chronic NSAID therapy a strategy was suggested for different risk groups. For those in

low risk category (less than 65, no aspirin, no prior ulcer or GI complications) use a non-selective NSAID alone. For those in moderate risk group (one or 2 risk factors, ie; age over 65, high dose NSAID/low dose aspirin) use a partially selective NSAID plus PPI or misoprostol or selective COX 2 inhibitor. The suggested management for high risk patients (greater than or = to 3 risk factors or concomitant aspirin, corticosteroids or warfarin) is a selective COX-2 inhibitor plus PPI or misoprostol. Management of those at very high risk (prior ulcer or ulcer related complications) should consider selective COX-2 inhibitor plus PPI or misoprostol or consider avoiding non-selective NSAIDS and selective COX-2 inhibitors. These are only suggestions and do not represent a complete agreement.
HID recommends all generic NSAIDS as preferred as this class of agents is used quite frequently. A PA would be required for
Selective COX-2 inhibitors; Celebrex and Bextra (Vioxx withdrawn from the market 9-30-2004) and Mobic (non-selective agent)and single source brands which currently include Arthrotec, Ponstel and Prevacid NapraPAC..
Dr. O'Dell stated that he dislikes the NSAIDs due to the risk of renal failure and GI bleeds. Dr. Dawkins said he believes that in many of his patients he sees in his urology practice renal problems are dose related and associated with patient self medication of OTC NSAIDs in excess of recommended dosages. Dr. Davis added that both NSAIDSs and COX-2s have the potential to cause acute renal failure.
Other discussion followed concerning imposing quantity limits on the NSAIDs as a whole, especially Toradol tablets. Dr. Davis also stated that some NSAIDs are worse than others as far as their adverse effects. Ms. Clark stated that currently quantities are limited to a 34 day supply and a window to allow 150% over the maximum daily dose. She said that it may be prudent for DOM to strictly limit the NSAID class to 100% of their maximum recommended daily dose.

Dr. O'Dell motioned to accept HID's recommendation of generic NSAIDS but table discussion on the COX-2s due to recent developments associated with Vioxx withdrawal from the market. He explained that he was not sure that an informed decision could be made at this time. Jeff Jones seconded the motion.

Ballot Results
Motion to accept HID recommendation on NSAIDs but TABLE discussion on COX-2s due to recent developments associated with Vioxx withdrawal from market.

All voted FOR the motion

Other business

Larry Calvert stated that he personally wishes to go back to the old P&T meeting format whereby a subcommittee meets initially, makes recommendations and then brings them back to the full committee later that same day. Ms. Clark replied that she will relay this request to her supervisors.

Judy Clark announced that ACS (DOM's fiscal agent) is adding the PLADs (Poverty Level, Aged, Disabled) back to the system in increments to comply with the federal court order. She thanked all providers, prescribers and industry for working with DOM to assist the PLAD population. Ms. Clark announced that the Executive Director's signature will no longer appear on the P&T minutes, however, his recommendations will be posted on the DOM website. She then invited all committee members to lunch.

There being no further business, the meeting was adjourned at 12:45 PM.