MINUTES OF THE SEPTEMBER 28, 2004
PHARMACY AND THERAPEUTICS (P & T) COMMITTEE MEETING

Members Attending (10) : Myrna Alexander, M.D., Todd Barrett, R. Ph., Larry Calvert, R. Ph., Gary Davis, 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 (2): Betsy Cummings, C.F.N.P, Craig Dawkins, M.D.

Also Present: Warren A. Jones, M.D. Philip Merideth, M.D., J.D., Sharon Barnett-Myers, Deputy Director of Health Services, Judith Clark, R. Ph., Terri Kirby, R. Ph., Phyllis Williams, Staff Officer II, 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: Rod Reedy, ACS Account Manager, Nicole Stofer, Governor's Office

Old Business- None

New Business

The meeting was called to order by Larry Calvert at which time Dr. Warren A. Jones was recognized. Dr. Jones commended committee members for their dedication and attendance, especially during pre-hurricane hours. He reiterated charges which were stated at the first meeting, that the committee members use their own professional knowledge and experience to evaluate the science, safety, and efficacy components provided in HID reviews and engage in open and frank dialogue about what ought to be recommended for the mandatory preferred drug list. Dr. Jones emphasized that federal law mandates that every product that participates in the federal drug rebate program must be made available to Medicaid and Medicare beneficiaries. He stated that safety, efficacy and science should drive their recommendations. The PA (prior approval) process Medicaid is developing and implementing will make sure that these pharmaceuticals are available and that MS Medicaid will be in compliance with federal law. He stated that Medicaid wants to try to make the prior approval process as little of an annoyance as possible for clinicians who feel they have unique situations when medications needed are not on the PDL. He invited committee members to feel free to call him or his staff if they have any concerns. Dr. Jones commented that there may be some concerns about the 90 day PDL implementation/transitional period. He believes that 90 days is a reasonable period of time. He stated that Medicaid never wants to put beneficiaries in a position of hardship and that they are valued as well as the health care providers who serve them. Dr. Jones discussed the recent projected shortfall of the Medicaid budget. He emphasized that the P&T committee's role is critical in reducing Medicaid expenditures. He welcomed questions and then excused himself from the proceedings.

Dr. Calvert recognized Dr. Alexander for service as chairman of the P&T committee for the last two years. Judy Clark recognized one of the new members, Dr. Raymond Wynn

and made general announcements. Judy Clark apologized for cancellation of September DUR meeting due to the chairperson and co-chairperson being unable to attend. She stated that the 9/14/04 minutes will not be provided or discussed at this meeting due to the complexity of the last meeting. Jeff Jones inquired as to the status of their recommendations from 9/14/04 meeting. He stated he thought it was unfair to the committee members not to have a summary of their recommendations as well as Medicaid's decision in their hands. Judy Clark deferred this question to Sharon Myers. Sharon Myers stated that she and Dr. Jones have been traveling a great deal and that the Department of Medicaid had not yet reviewed the information. In addition, time required to tally votes proved to be lengthy due to format of the ballot. Jeff Jones asked if eliminating the paper ballots would speed the process. Sharon Myers answered no. Todd Barrett asked for a copy of the minutes from the September 14th meeting. Judith Clark stated they were not finalized. Todd Barrett motioned to get rid of the paper ballots. Dr. O'Dell seconded the motion. Dr. Alexander commented that she liked the format of the revised ballot. Judy Clark explained the reasons vote tabulation was so time-consuming; bad handwriting, areas of the ballot not being marked appropriately and the need to call some members to clarify their votes. She also stated that paper ballots were being used to accommodate some members who had previously expressed that they wished to vote anonymously. She stated that according to the MS Open Meetings Act the minutes do have to reflect how each member has voted. She also assured members that the ballots are secure and locked in her office and that many other states use paper ballots as well. Voice vote on the motion failed. Mr. Calvert made it clear that the committee would eventually have the minutes and have an opportunity to add, correct and approve them at a future meeting.
Jeff Jones asked who would handle the PA process in the future, specifically whether they will be processed by pharmacists and/or nurses. Ms. Clark stated that PA s will continue to be processed by HID and that specifics are still being developed.

Therapeutic Category Review

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

ANTIDIABETIC AGENTS

Biguanides: HID recommended only generic Metformin IR and ER. Jeff Jones motioned to accept the recommendation. David Hudson seconded the motion. Larry Calvert noted that nutrition and exercise programs are an important component of diabetes prevention and management. He stressed the vital role health care professionals play in education and prevention.

Ballot Results:
Accept HID recommendation to include only generic Metformin IR and ER (No Brands) on the PDL - All voted in favor

Insulins: HID recommended ALL VIAL insulin products be included on the PDL. This includes all Humulin, Novolin, Lantus, Humalog, Novolog and all the mixtures. Dr. Jennifer Gholson asked if the insulin pumps were factored in the review. Ms. Clark explained that insulin pumps would not be billed point of sale in the pharmacy but would be billed through medical services. Jeff Jones motioned to accept the recommendation. Todd Barrett seconded the motion.

Ballot Results:
Accept HID recommendation to include ALL VIAL insulin products on the PDL
All voted in favor

Meglitinides: HID recommended repaglinide (Prandin) as the preferred agent. Mr. Calvert asked what percentages of patients are using Starlix. Jeff Jones commented that Prandin causes a higher incidence of hypoglycemia and therefore questioned why it was recommended over Starlix. Ms. DeRuiter stated potential drug interactions seen with Starlix in that it's an inhibitor of 2C9 as well as the package insert warning not to replace the sulfonylurea agents with Starlix. Mr. Jones and Mr. Hudson commented that they dispense more Starlix than Prandin. Jeff Jones motioned to accept the recommendation and also include Starlix. Dr. O'Dell seconded the motion. Dr. Wynn was concerned about the cost of these two drugs. Mr. Calvert explained that Dr. Warren Jones had directed the board not to consider cost in their deliberations.

Ballot Results:
Accept HID recommendation to include only Prandin on the PDL - No Votes
Amend to include both Prandin and Starlix on the PDL – Barrett, Calvert, Davis, Gholson, Hudson, Jones, O'Dell, Wales, Wynn
Abstain – Alexander

Sulfonylureas: HID recommended that only the generic forms of Glyburide, Glyburide Micronized, Glipizide, Glipizide ER, Tolbutamide, Chlorpropamide, Tolazamide, and Acetohexamide be considered preferred. No brand name products would be included. Dr. Alexander motioned to accept the recommendation. Jeff Jones seconded the motion.

Ballot Results:
Accept HID recommendation to include only generic
Acetohexamide, Chlorpropamide, Glipizide (& ER), Glyburide, Tolbutamide and Tolazamide and NO Brands. - Alexander, Barrett, Calvert, Davis, Gholson, Jones, O'Dell, Wales, Wynn
Accept all generics recommended except Acetohexamide, Tolbutamide & Tolazamide – Hudson

Thiazolidinediones: HID recommended Rosiglitazone (Avandia) over Pioglitazone (Actos) due to less drug interactions. Dr. O'Dell stated that Avandia must often be dosed twice daily and thus presents compliance issues, whereas Actos is a true once daily drug. Dr. Gholson stated that she has had great success with both agents and considering the

high incidence of diabetes in the Medicaid population she stressed both agents should be preferred. Jeff Jones motioned to accept the recommendation and amend to also include Actos. Jennifer Gholson seconded the motion.

Ballot Results:
Accept HID recommendation to include brand Avandia only - No votes
Amend to include Avandia and Actos on PDL - All voted in favor

Combination products: HID recommended the generic formulation of Glyburide/Metformin and Avandamet as preferred agents. Jeff Jones motioned to accept the recommendation. Dr. Wynn seconded the motion. Mr. Calvert questioned why Metaglip was not chosen. Ms. DeRuiter stated that there is no conclusive evidence that any one combination product is superior to another. Dr. Gholson stated if there is no conclusive evidence that one agent is better than another then why not recommend all three agents rather than just two. Dr. Wynn inquired why HID picked the two out three drugs they chose. Ms. DeRuiter stated that she did not actually do the drug review she was presenting. Sam Warman stated that Metaglip was not recommended because the two drugs it is composed of, Metformin and Glipizide, both are available generically and are bioequivalent. Larry Calvert commented that two prescriptions would be required. Dr. Wynn moved to amend the motion to add Metaglip to the PDL. Dr. O'Dell seconded.

Ballot Results:
Accept HID recommendation to include brand Avandamet and generic Glyburide/Metformin- Alexander, Barrett, Davis, Hudson, Wales, Wynn
Amend to include brand Avandamet and Metaglip as well as generic Glyburide/Metformin - Calvert, Gholson, Jones, O'Dell

Alpha-Glucosidase Inhibitors: HID recommended Precose for preferred status because it had shown a reduction in both cardiovascular events and hypertension in the 'STOP' study. Mr. Barrett motioned to accept HID recommendation. Pearl Wales seconded the motion.

Ballot Results:
Accept HID recommendation to include Brand Precose only - All voted in favor

ANXIOLYTIC/SEDATIVE HYPNOTICS

Anxiolytics: HID recommended the generic agents Alprazolam, Chlordiazepoxide, Diazepam, Lorazepam, Oxazepam, Buspirone, and Hydroxyzine (both salt forms) as the only preferred anxiolytic agents. No single source brand agent is preferred. Meprobamate is not recommended due to warnings regarding use in the elderly cited in the Beers criteria. Mr. Jones motioned to amend HID's recommendation by also including generic Clonazepam and Clorazepate. Dr. O'Dell seconded the motion.

Ballot Results:
Accept HID recommendation to include only generic formulations of Alprazolam, Chlordiazepoxide, Diazepam, Lorazepam, Oxazepam, Buspirone and Hydroxyzine-Davis
Amend recommendation to also include generic Clonazepam and Clorazepate – Alexander, Barrett, Calvert, Gholson, Hudson, Jones, O'Dell, Wales, Wynn

Sedative hypnotics: HID recommended that no name brand agents in the sedative-hypnotic class be included as a preferred agent at this time. In addition, with the exception of Phenobarbital, access to barbiturates should be limited to a prior authorization. Specifically, the recommended agents are Temazepam, Flurazepam, Estazolam, Triazolam and Chloral Hydrate and Phenobarbital. Jeff Jones questioned the rationale not to include Ambien. Dr. O'Dell commented literature shows that Ambien has less 'hangover', less rebound and a better duration of sleep. Mr. Jones made a motion to amend recommendation to include Ambien. Todd Barrett seconded.
Discussion followed concerning products strengths. Ms. Clark explained that the committee wouldn't vote on dosages, but rather, drug entities. She then elaborated that this class is associated with abuse, misuse and diversion and many states therefore enforce quantity limits. Currently MS limits this class to one unit per day and many other states limit to fifteen units per month. Mr. Jones commented that the sedative/hypnotics are not covered by the Medicare discount cards. Dr. O'Dell stated that all of these agents are appropriate for short term use only.
Mr. Calvert questioned the rationale of including Chloral Hydrate as a preferred agent. Ms DeRuiter stated that it is still used for children. Questions arose concerning whether children would be required to adhere to the PDL. Ms Clark explained that if an agent is medically necessary for a child, it is imperative that Medicaid make every effort to meet that child's needs. Sharon Myers explained the overall guidelines for children and adults are different. Pearl Wales inquired about quantity limits on Chloral Hydrate. Ms. Clark distributed DOM's sedative/hypnotic maximum quantity list to the committee.
Mr. Calvert asked if a drug could be 'revisited' once reviewed or if the 'door is shut' on it until it comes up for review again. Sharon Myers stated that DOM will incorporate new developments and/or items to 'revisit' in the format of future meetings, probably beginning with the January 2005 P& T meeting.
Dr. Wynn motioned to add Sonata (friendly amendment). Dr. O'Dell seconded the motion. Dr. O'Dell made a motion to limit Chloral Hydrate to the pediatric population, and then later withdrew the motion. Mr. Calvert clarified the vote. Members were instructed to vote on amendments to accept recommendation and add Ambien and Sonata and disapprove Chloral Hydrate if they desire that it be a non preferred agent. Dr. Alexander moved to reconsider Chloral Hydrate. Jeff Jones seconded the motion. Dr. Meredith stated that Chloral Hydrate is occasionally used as a sedative and prior to outpatient procedures in children. Chloral Hydrate abuse potential was discussed. Dr. Alexander then stated she thought Chloral Hydrate should require a PA. Mr. Jones and Mr. Calvert expressed their wish that PAs have a 'life' of one year.

Ballot Results:

Accept HID recommendation to include only generic Estazolam, Flurazepam, Chloral Hydrate, Phenobarbital, Temazepam and Triazolam – Davis

Approve Amendments to also include Ambien and Sonata and disapprove Chloral Hydrate - Barrett, Calvert, Gholson, Jones, O'Dell

Approve Amendment to include Ambien and disapprove Chloral Hydrate – Alexander, Wales, Wynn

Approve Amendment to include Ambien and include Chloral Hydrate for short-term use in pediatric patients only - Hudson

INTRANASAL CORTICOSTEROIDS

Ms. DeRuiter stated that trials are inconclusive regarding the efficacy of one agent over another and adverse effects are similar among all of these agents. Flonase and Nasonex are both indicated for pediatric use. Flonase is indicated for children 4 years and older and Nasonex is indicated in children 2 years and older and both have 'qd' dosing.
HID recommends Flonase, Nasonex and the generic Flunisolide nasal spray as preferred agents in this class. Jeff Jones motioned to accept HID recommendation. David Hudson seconded the motion.
Discussion followed. Dr. O'Dell stated that Budesonide (Rhinocort AQ) is now category B and not C as indicated in the review packet. Discussion followed that pregnancy could considered as rationale for PA approval.

Ballot Results:
Accept HID recommendation to include generic Flunisolide and brand Flonase and Nasonex - All voted in favor

SKELETAL MUSCLE RELAXANTS

Ms. DeRuiter stated that the brand name agents offer no significant advantages over the generic agents. Dantrolene is the only direct-acting agent but does have a Black Box Warning due its potential to cause hepatotoxcity. Studies show Skelaxin to be no more effective than placebo.
HID recommended no brand-name agents for the PDL. Recommended agents include generic Baclofen, Carisoprodol, Chlorzoxazone, Cyclobenzaprine, Methocarbamol, Orphenadrine, and Tizanidine.
Dr. O'Dell stated that he did not think all generic skeletal muscle relaxants should be included on the PDL.

He explained that studies have shown Carisoprodol to be ineffective in addition being a drug with high abuse potential. Further, a Chlorzoxazone review in the Medical Letter concluded it to be ineffective and therefore should not be used. Both Methocarbamol and Orphenadrine have not been studied and therefore should not be included on the PDL. Dr. O'Dell made a motion to include only Baclofen, Cyclobenzaprine and Tizanidine on the PDL. Jeff Jones seconded the motion.
Mr. Barrett asked if the study cited in the HID packet which showed Skelaxin to be no more effective than placebo had used the 400mg or the 800 mg. strength. He stated that the 400 mg. is no longer manufactured and the 800 mg is. Ms. DeRuiter stated that she will research and report back to the committee. Dr. Gholson made a motion to add an amendment to table Skelaxin and discuss it at the next meeting. Mr. Barrett seconded the motion.

Ballot Results:
Accept HID recommendation to include NO Brands and include generic Baclofen, Carisoprodol, Chlorzoxazone, Cyclobenzaprine, Methocarbamol, Orphenadrine and Tizanidine - No Votes

Amend to include only generic Baclofen, Cyclobenzaprine and Tizanidine as preferred and table Skelaxin for future meeting – All voted in favor

Other Business

Todd Barrett motioned to have the next ballot revised to be able to vote yes or no on motions and amendments en block. Dr. Alexander seconded the motion. All committee members voted in favor by voice vote. None opposed.

Judy Clark announced the next P&T committee meeting will be held October 12, 2004 @ 10:00 AM.

There being no further business, the meeting was adjourned at 3:30 PM.