Minutes of the November 17, 2005
Drug Utilization Review (DUR) Board Meeting

Members Attending: Harold Blakely, RPh, Montez Carter, RPh, Randy Calvert, RPh, John Mitchell, M.D., Lee Montgomery, M.D., Lee Anne Ross, PharmD,
Rudy Runnels, M.D., Wallace Strickland

Members Absent: Billy Brown, PharmD, Andrea Phillips, M.D., Troy Griffin

Also Present: Judith Clark, RPh, Terri Kirby, RPh, Don Thompson, Deputy Director MS Division of Medicaid, Carlos Faler, Bureau Director Program Integrity MS Division of Medicaid, - DOM
Dennis Smith, RPh, Samuel Warman, RPh, Lew Anne Snow, R.N., Kathleen Burns, R.N.-HID
Frankie Rutledge, Comprehensive Neuroscience, Inc

Dr. John Mitchell called the meeting to order at 2:07 p.m.

Approval of the minutes for the September 29, 2005 meeting:
Dr. Runnels made a motion to accept the minutes as submitted. Randy Calvert seconded the motion. All voted in favor of approval.

CNS Update:
Ms. Rutledge presented a CNS update regarding the following projected goals:

1. Improve continuity of care
2. Eliminate redundant treatments
3. Coordinate care among providers
4. Decrease risks associated with inappropriate use

Ms. Rutledge continued with the prescriber feedback response rate being between 8% and 10%. The most common response being "this is not my patient". The clinical concerns were pointed out. Those are:

1. patients on high numbers of behavioral health drugs
2. long-term use of benzodiazepines
3. multiple prescribers of anticonvulsants/mood stabilizers
4. switching atypical antipsychotics without sufficient trial

With the implementation of MMA Part D as of Jan 1, 2005, BPM will redesign the 2006 enhancement. The focus will include up to 60 indicators being distributed among adults age 64 and younger and children. Indicators for opiates have also been added.

Updates
Cost management analysis:
Dennis Smith presented the top 25 drugs based on the number of claims dated 8/01/05 thru 8/31/05. The top drug was hydrocodone w/acetaminophen with 19,428 paid claims. This was in response to a request from the DUR Board to do a month by month report on the top 25 drug in paid claims. Ms. Clark included that Hurricane Katrina may have had an impact on the increase

in mental health prescriptions. She continued that there are many outstanding claims due to Hurricane Katrina from other states.

Osteoporosis:
Dennis Smith suggested tabling this intervention until after January 1, 2006 in light of the change to the Medicaid beneficiary pool with Medicare Part D.

Narcotic Utilization:
Mr. Smith presented an overview of narcotic utilization in response to the P & T Committees' request that this data be reviewed by the DUR Board. In the first nine months of 2005, there were over 83,000 claims for hydrocodone-containing products billed to Medicaid. A pharmacy claims search was made to identify all beneficiaries who have received narcotic prescriptions from more than one prescriber within a 30 day time frame. Beneficiaries with any cancer diagnosis were excluded from this search. The analysis yielded the following observations:

1. 4, 075 beneficiaries received more than one narcotic within 30 days from more than one prescriber
2. 1,864 beneficiaries received three or more narcotics from more than one prescriber during the 90 day search period
3. 884 beneficiaries received narcotics from three or more prescribers during the 90 day search.

Due to the national scope of this problem, many state Medicaid programs have responded in various ways .The most common policy is the imposition of monthly quantity limits on these products. Another common action is "lock-in" of high-utilizing beneficiaries to a specific prescriber and pharmacy.

Recommendations:

1. Evaluate and explore a prospective DUR edit in the POS system for any duplicate narcotic prescription from a second prescriber within a 31 day period, excluding beneficiaries with a cancer diagnosis.
2. Intensify the quantity limits.
3. Encourage a lock-in program which would limit high-utilizing beneficiaries to a specific primary care physician and/or pain management specialist and a specific pharmacy

After much discussion, a motion was made by Randy Calvert to limit all narcotics to two (2) units per day. This motion was seconded by Montez Carter. All voted in favor of the motion. Carlos Faler, Director of Program Integrity for the Division of Medicaid, informed the Board that his department has an ongoing process to deal with the above mentioned problems. He asked that his department be given time to implement certain restrictions they have researched for several months.

Synagis
Lew Anne Snow presented an overview of the Synagis prior authorization program. Medicaid beneficiaries must obtain prior authorization to receive Synagis. The current Medicaid criteria are based on the American Academy of Pediatrics guidelines. Dr Mitchell commented to the Board that the Synagis PA process appears to be effective, and he concluded that unless the Board had further directions, HID would continue without changes. No recommendations were made.

Pharmacy Program Update:
Judy Clark introduced Don Thompson, Deputy Director of Health Services. Ms. Clark gave a brief pharmacy program update. She also distributed to the board members a copy of the current Product Quantity Limits which included changes that became effective on November 1, 2005.

New Business

Marinol Utilization:
Dennis Smith presented information regarding Marinol utilization. Dronabinol is indicated for the treatment of nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional treatments. It is also approved to treat appetite loss associated with weight loss in people with AIDS. In July, Megace was re-categorized in terms of its primary therapeutic class. Whereas its therapeutic class was previously steroid antineoplastics, the classification is now appetite stimulants. As a result of this change, megestrol acetate suspension is no longer covered by Medicaid. This has resulted in a search for a substitute agent for the treatment of cachexia. Mr. Smith continued with the study on Marional pointing out dosing and administration with mention of adverse effects and abuse potential. The utilization during the year between 10/01/2004 and 09/30/2005 was 1545 claims for this agent at a cost of over $760,000. Among these claims, there was only one beneficiary with a diagnosis of HIV or AIDS. HID was unable to associate a cancer diagnosis with any of these beneficiaries. There has been no significant increase in the number of claims for this agent since the re-categorization of megestrol acetate suspension.
Conclusion:
Based on the above information, almost all of the patients receiving treatment with Marinol did not have a diagnosis related to the approved indications for this agent.
Recommendation:
Dennis Smith recommended that an intervention letter be sent to all prescribers for their patients who have received Marinol without a diagnosis of HIV, AIDS, or cancer. The letter would include information about the approved indications, appropriate use and abuse potential of this agent. Dr Ross made a motion to accept HID's recommendation. Dr. Montgomery seconded the motion. All voted in favor of this motion.

Oxandrin Utilization:
Data regarding the utilization of Oxandrin was presented by Dennis Smith. Oxandrin is indicated as adjunctive therapy to promote weight gain after weight loss following extensive surgery, chronic infections or severe trauma. It is also indicated to offset the protein catabolism associated with prolonged administration of corticosteroids, as well as for the relief of the bone pain frequently accompanying osteoporosis. The number of claims has not significantly increased since the re-categorization of megestrol acetate suspension.
Conclusion:
There is no evidence to support inappropriate use of this agent.
Recommendation:
HID recommended no intervention at this time, but will continue to monitor Oxandrin utilization.

Lyrica Utilization:
Dennis Smith presented data regarding Lyrica utilization. Pregabalin is indicated for the management of neuropathic pain associated with diabetic peripheral neuropathy and post herpetic neuralgia. It is also indicated as adjunctive therapy for adult patients with partial onset seizures.
Recommendation:
Mr. Smith recommended that HID continue to monitor the utilization of Lyrica over the coming months to evaluate any changes in utilization trends. Dr. Montgomery made a motion to accept the recommendation. Dr. Runnels seconded the motion. All voted in favor of the motion.

Black Box Warnings:
Dennis Smith presented black box warnings issued by the FDA concerning the following:
Avinza:
Audience: pain specialists, other healthcare professionals and consumers
Posted 11/03/2005 Ligand pharmaceuticals and FDA notified healthcare professionals of revisions to BOXED WARNING, WARNINGS, PRECAUTIONS, and CLINICAL PHARMACOLOGY and DOSAGE AND ADMINISTRATION sections of the prescribing information to highlight and strengthen the warning that patients should not consume alcohol while taking Avinza. Additionally, patients must not use prescription or non-prescription medications containing alcohol while on Avinza therapy.

Cylert and generic pemoline products:
Audience: Neuropsychiatric healthcare professionals, Pediatricians, Pharmacists and consumers.
Posted 10/24/2005 FDA has concluded that the overall risk or liver toxicity from Cylert and generic pemoline products outweighs the benefits of this drug.. In May 2005, Abbott chose to stop sales and marketing of Cylert in the U.S. All generic companies have also agreed to stop sales and marketing of this product. Health care professionals who prescribe Cylert or any of its generics, should transition their patients to an alternative therapy. Cylert will remain available through pharmacies and wholesalers until supplies are exhausted. No additional product will be available.

Cymbalta:
Audience: Neuropsychiatric and other healthcare professionals
POSTED 10/17/2005 Eli Lilly and FDA notified healthcare professionals of revision to the PRECAUTIONS/Hepatotoxicity section of the prescribing information for Cymbalta. This medication is indicated for treatment of major depressive disorder and diabetic peripheral neuropathic pain. Post marketing reports of hepatic injury suggest that patients with preexisting liver disease who take duloxetine may have an increased risk for further liver damage. The new labeling extends the precaution against using Cymbalta in patients with substantial alcohol use to include those patients with chronic liver disease. It is recommended that Cymbalta not be administered to patients with any hepatic insufficiency.

Paxil:
Audience: Neuropsychiatric and other healthcare professionals
Posted 09/27/2005 GlaxoSmithKline Kline and FDA notified healthcare professionals of changed to the pregnancy/PRECAUTIONS sections of the prescribing Information for Paxil and

Paxil CR to describe the results of a GSK retrospective epidemiologic study of major congenital malformations for paroxetine as compared to other antidepressants. Healthcare professionals are advised to carefully weigh the potential risks and benefits of using parosetine therapy in women during pregnancy and to discuss these findings as well as treatment alternatives with their patients.

Toprol XL
Topamax
Audience: All healthcare professionals
Posted 09/26/2005 AstraZeneca and FDA notified healthcare professionals with reports of medication dispensing or prescribing errors between Toprol XL indicated for the treatment of hypertension, long-term treatment of angina pectoris and heart failure NYHA Class 11 or 111 and Topamax, a product of Ortho-McNeil Neurologics, Inc, indicated for the treatments of epilepsy and migraine prophylaxis. These reports include instances where Toprol XL was incorrectly administered to patients instead of Topamax, Tegretol or Tegretol XL and vice versa, some of them leading to adverse events.

Election of officers:
With the conclusion of the meeting being near, Ms Clark reminded the Board that they must elect officers. The following were elected:

- Chairman: Dr. John Mitchell, was nominated by Harold Blakely and seconded by Leigh Ann Ross
- Vice-Chairman: Randy Calvert was nominated by Leigh Anne Ross and seconded by Montez Carter.

All voted in favor of these motions.

Ms. Clark reminded the Board that the dates of the DUR Board for 2006 will be sent out in letter form. She also asked board members to submit topics of interest for the upcoming year and forward them to DOM.

There being no further business, Dr. Mitchell adjourned the meeting at 4:00p.m.

Respectfully submitted:
Health Information Designs