**Iowa Medicaid Pharmaceutical and Therapeutics Committee**
**Minutes**

**Date:** November 9, 2006

**Chair:** Michael A. Flaum, M.D.

**Time:** 8:40 a.m. to 2:30 p.m.

**Location:** Department for the Blind, Des Moines, Iowa

**Committee Members Present:** Bruce Alexander, R.Ph., Pharm.D., BCPP; Bradley J. Archer, M.D.; Michael A. Flaum, M.D.; Carole A. Frier, D.O.; Hayley L. Harvey, DDS, MS; Priscilla Ruhe, M.D.; Mary Winegardner, PA-C, MPAS; and Susan Purcell, R.Ph, CGP

**Committee Members Absent:** Matthew Osterhaus, R.Ph

**Iowa DHS Staff Present:** Susan Parker, Pharm.D., Pharmacy Consultant; Dan Hart, Assistant Attorney General; and Eileen Creager, Bureau Chief (afternoon session only)

**Iowa Medicaid Enterprise (IME) Staff Present:** Thomas Kline, D.O., Iowa Medicaid Medical Director; Tim Clifford, M.D.; John Grotton, R.Ph.; Sandy Pranger, R.Ph.; Chad Bissell, R.Ph., Pharm.D.; and Melissa Biddle, Administrative Coordinator

Chairperson Michael Flaum called the meeting to order.

I. Michael Flaum asked that each committee member, DHS staff, and IME staff introduce themselves to the public. Dr. Archer arrived at 8:49 and Dr. Ruhe at 8:53, so they introduced themselves later.

II. The September 14th open session minutes were reviewed. Sue Purcell made the motion to approve the minutes. Hayley Harvey seconded the motion. The motion passed with no objections.

III. PDL ( Dr. Clifford): The negotiations with the pool went very well this year. With several thousand drugs on the PDL, there will only be forty-something proposed changes. Longer term contracts were accepted for some of the important medicines.

IV. Prior Auth Criteria/ProDUR edits (Susan Parker): An issue has come up with some of the OTC products that Medicaid covers. CMS (Center for Medicare and Medicaid Services) has been going through a process of removing items from the Medicaid drug rebate system that are considered non-drugs. At this time, it impacts some of the iron products. The pharmacy unit is working with Medical services during the transition. Attachment 1 includes some information regarding smoking cessation prior authorization criteria that the DUR (Drug Utilization Review) has finalized. Recently, the DUR Commission discussed whether the new drug, Chantix, should be added to the PDL as part of the smoking cessation program. The Commission decided not to recommend adding the drug as a covered productat this

time, and therefore, not cover payment for the drug until more independent studies had been made available. At the last P&T meeting, the committee recommended that the DUR Commission require a PA and liver testing for Antabuse usage. However, the DUR decided that other drugs requiring routine monitoring did not require testing as part of their prior authorization criteria, so Antabuse should not either. The DUR also decided that a duration restriction on Antiemetics was not necessary at this time. They did recommend that the quantity on Spiriva be limited to one unit per thirty days, and that an edit be placed on the POS that would keep Spiriva from being used in combination with Atrovent and/or Combivent. Lastly, there was a request from the DUR Commission to the P&T that they would like PEG 3350 to have a preferred status for children 12 years and under. Mary Winegardner commented that the finalized smoking cessation criteria do not comply with industry standards and would like the document provided to the P&T Committee (Treating Tobacco Dependence in a Medical Setting: Best Practices Richard D. Hurt, M.D.) be forwarded to the DUR Commission. Susan Parker agreed to forward the document.

V. The public speakers were:

| SPEAKER | SUBJECT |
|---|---|
| Jeffrey Allyn, M.D. from Broadlawns Medical Center | Campral |
| Maureen Kubacki, Pharm.D., MBA from Ortho Biotech | Procrit |
| Geoffrey Wall, Pharm.D. from Iowa Methodist/Drake University | Levaquin |
| Vic Verni from Epilepsy Foundation of North/Central IL, IA, NE | Epilepsy Drugs |
| Alan Koslow, M.D. from Heartland Vascular Medicine & Surgery | Lantus |
| Wendy Waldman, M.D. from Iowa Health Physicians | Topamax |
| Michael Jacoby, M.D. from Ruan Neurology Clinic | Topiramate |
| Cynthia Schmeichel, MS, Ph.D. from Centocor, Inc. | Remicade |
| Michele Evink, MS, R.Ph., CGP from Clark County Hospital | Levaquin |
| Kerri Taylor, R.N. from Indevus Pharmaceuticals | Sanctura |
| Gary Levine, R.Ph., CDM from Hy-Vee | Lilly's Insulin |
| Hoa Pham from Amgen | Enbrel |
| Rick Szymialis, R.Ph. from Eli Lilly and Company | Humalog |
| Sandra Carpenter, R.N., BSN from Genentech | Nutropin |
| Sherrill Rudy, MSN, RN, CRNP from Genentech | Raptiva |
| Tricia Coleman, Ph.D. from Abbott | Zemplar |
| Russ Sobotta, R.Ph., MBA from Sanofi-Aventis | Lantus |
| Nancy Bell, Pharm.D. from Pfizer | Exubera |
| Louis Gerbino, M.D. from Avanir Pharmaceuticals | FazaClo & Antiq |
| George Clavenna, D.O. from Allergan, Inc. | Zymar,Lumigan,Restasis |

At 10:42, motion to go to closed session was made by Mary Winegardner and seconded by Dr. Flaum. The motion passed with unanimous approval.

Open session resumed at 12:56 pm. (All committee members present, with the exception of Matt Osterhaus)

VI. PDL Discussion and Deliberation (Dr. Clifford): Dr Flaum wanted to know if it would be possible for certain providers, such as specialists, to prescribe non-preferred drugs without

having to go through the PA process. Susan Parker said that the system would not be able to do that at this time, but that NPI could give that capability when it goes into effect on May 23rd, 2007. Even though nothing is highlighted in the Alcohol Deterrents category, Dr. Clifford opened up a discussion about Campral, since there had been some public comments about it. The biggest risk, savings-wise, for the State is what occurs with Vivitrol. There is a huge gap in daily cost between Campral and Vivitrol. Dr. Archer asked how other states had handled Campral. Dr. Clifford responded by saying it had recently been given preferred status in Maine. Dr. Ruhe thinks it is supposed to be used with an organized counseling approach. Dr. Frier would like to see some scientific proof that Campral is effective, and Bruce Alexander agreed. Dr. Flaum proposed a motion to make Campral preferred, and Mary Winegardner seconded. Then the committee asked for Bruce Alexander's opinion. He reiterated his earlier feeling about scientific research. They brought the motion to a vote. Dr. Frier and Bruce Alexander opposed it, and Hayley Harvey abstained. All others were in favor, so the motion passed. Then Dr. Clifford reviewed the proposed PDL changes, beginning with page one of the draft PDL. In the Alzheimer's category, the change would be that the preferred drugs would shrink to two, Aricept and Namenda, making Exelon non-preferred. In the Angiotensin Receptor Blockers, there would be a switch with Avapro becoming preferred, and Atacand and Teveten non-preferred. In the Aniasthmatic–Adrenergic Combos category, the Advair HFA would also be treated as preferred. Then in the Antiasthmatic-Beta-Adrenergics, just a minor detail, making all forms of terbutaline sulfate preferred. Finishing off the Antiasthmatics, in the Nasal Steroids, Beconase AQ and Nasarel will become non-preferred and Nasacort AQ preferred. Hayley Harvey moved to accept the proposed changes from page one through the Antiasthmatics. Sue Purcell seconded the motion, and it passed unanimously. In Anticonvulsants, Equetro will become non-preferred, (Dr. Clifford skipped over Antiemetics because the recommendation in this category involves a new drug to be discussed later.). In the Antifungals, Lamisil will become a preferred product. In the Anti-Parkinsonian Drugs, Parcopa will become preferred. Looking at the Antispasmodics-Long-Acting, there is a potentially significant change, making Ditropan XL non-preferred and Sanctura preferred. This represents a significant savings opportunity for the State. The other thing is that there is a substantial improvement in the side effects when comparing Ditropan XL to Sanctura. Then in the ARB's and Diuretics, the Teveten HCT will go non-preferred and the Avalide preferred. In the Cephalosporins, Ceftin and Cedax will both become preferred. Dr. Flaum and Dr. Archer thought that switching people off of Ditropan XL could be a problem due to the high utilization, so Dr. Clifford suggested that physicians be given a 90-day transition period to get their members to a preferred product without requiring a PA. Sue Purcell moved to accept the proposed changes from Anticonvulsants through Cephalosporins. Dr. Frier seconded the motion, and it passed unanimously. With Cholesterols, the category has been broken up into higher and lower potency agents. Due to price, it is recommended that the Lipitor remain as preferred. At this point, it is expected that Simvastatin will become much more cost effective early next year. So initially, what is recommended is that for the beginning of next year, keep the brand Zocor as preferred and line up the generic Simvastatin as preferred, but then give the stores a 30 days notice when it can clearly be seen that it is time to prefer just the generic Simvastatin. In the low-potency cholesterol drugs, the lovastatin will become preferred, and the brand Altoprev will become non-preferred. (Then we skipped the new drug in the Contraceptives, the generic meloxicam in

the Cox-2 Inhibitors, and the new drug Exubera in the Diabetic Insulins.) The next proposed change was in the Ear category, where Floxin Otic Singles will become preferred. In the Fluoroquinolones, it is recommended to accept the deal on Levaquin, making it preferred, and the Avelox and the Cipro XR would become non-preferred. There was a competition to be the exclusive preferred brand in the category. Then, although it's not highlighted, in the GI-Anti-Flatulents/GI Stimulants section, where the generic Miralax products are located, the polyethylene glycol powders and the packets, will be preferred for children 12 years and younger per the DUR Commission request. In the GI-Digestive Enzymes, it is recommend that the Committee add the Viokase product line as preferred after the clinical PA process has been satisfied. In the GI-Inflammatory Bowel Agents, though there is not much utilization, it is recommended to make Canasa non-preferred. Under GI-Miscellaneous, the Urso Forte 500mg Tab will also be non-preferred. In the Proton Pump Inhibitors, Prevacid Solutab should be recommended as preferred only for children 12 years of age and under once clinical PA criteria are met, and non-preferred for all others. It was then discussed how the Levemir deal runs from March to March, and how there is not accurate utilization data for Lantus vs. Levemir yet, considering the late transition of some recipients. Dr. Clifford recommends that the basal insulin discussion take place at the March P&T Meeting, and consider re-bidding out those two products at that time. Dr. Ruhe moved to accept the proposed changes from the Cholesterol through GI-Proton Pump Inhibitor categories, omitting the new medications. Dr. Archer seconded the motion, and it again passed unanimously. The next status change proposed is in the Glucocorticoids category, where it is recommended the new ODT (oral disintegrating tablet) form of Orapred be non-preferred. Then for Growth Hormones, Nutropin will become preferred after all of the clinical PA requirements are satisfied. In the Long-Acting Narcotics, all strengths of the morphine sulfate sustained release tabs will be preferred. Then there is the new category Nicotine Replacement Therapy where the nicotine patches and the gum would all be preferred, and would all be subject to the same PA requirements. In the Opthalmic Beta Blockers, Betimol should be made non-preferred. In the Opthamlmic Prostaglandins, the labelers were looking for two preferred products in this category. The makers of Lumigan and Travatan wanted to be preferred, and the maker of Xalatan did not wish to bid on keeping their preferred status. So Xalatan will become non-preferred, but with a grandfathering requirement for the established users. Moving to the Opthalmic Quinolones, Quixin would become non-preferred. In the Osteoporosis category, Actonel, which had about 1/3 of the market, would become non-preferred, and the once-a-month Boniva would be added as its preferred replacement. The Boniva and Fosamax deals would become three-year deals. Mary Winegardner again voiced her opinion that the approved nicotine replacement therapies will be inadequate, as she believes that some patients will require more patches. Sandy Pranger responded that there would always be the option of an exception to policy, and she also said that generic Zyban will be available January 1, 2007 without a PA. At the moment, all recipients have to go through the Quitline, who then contacts the Prior Authorization department. However, even with a PA, they would still only be eligible for a 3-monh supply. There was a lengthy discussion about Xalatan, and Dr. Clifford suggested selective grandfathering, using a POS look-back, for the recipients who have already tried the other products. Then they could have a 90-day period to phase out the rest. Dr. Frier moved to accept the changes from Glucocorticoids through Osteoporosis, and Dr. Ruhe seconded. The decision was unanimous. It was requested by the Committee to move Nevanac to the

PDL Category, Opthalmic NSAIDs. In the Platelet Aggregation Inhibitors, the generic for Plavix, clopidogrel bisulfate, will be non-preferred. In the Rheumatoid Arthritis category, it is recommended that the PDL add Enbrel Sureclick as preferred. Then in the Sedative/Hypnotics category, right now Lunesta is the only preferred non-benzodiazepine in the category, so it is proposed that the Committee add Ambien CR as preferred for financial reasons. To go along with the smoking cessation program, the bupropion (FDA indicated for smoking cessation) will be preferred. In the Topical-Immunomodulators, there was an opportunity to add Protopic, so it will be co-preferred with Elidel. Dr. Flaum moved to accept the changes from Platelet Aggregation Inhibitors through Topical-Immunomodulators. Sue Purcell seconded the motion, and it passed unanimously.

VII. RDL Discussion and Deliberation (Dr. Clifford): On the Antidepressants, the brand Effexor would be preferred and its generic equivalent, venlafaxine, will be added as non-preferred. In the Long-Acting Methylphenidate Stimulants, it is recommended that the PDL add Daytrana as recommended, Metadate CD as non-recommended, and the Metadate ER as non-preferred. Dr. Flaum moved to accept these recommendations, and Sue Purcell seconded. The motion passed with no objections or abstentions.

VIII. Newly Released Drugs (Dr. Kline): Atripla has been recommended to be added as Recommended on the RDL, because of its unique formulation and potential positive impact it could have on treating HIV. Azilect has been recommended to be non-preferred on the PDL, since it has not shown any superiority over other drugs in its class. Cesamet has been recommended to be non-preferred on the PDL, because there are other, more cost-effective options with fewer side effects. Exubera has been recommended to be preferred with conditions on the PDL. Dr. Clifford added that it should only be given to type II diabetics who are at least 18 years old that have previously failed on two kinds of potent oral medications, and who are not on any kind of nicotine replacement therapy or asthma/COPD inhalers. There will be a POS edit put into place to deny the claim if these criteria are not met. Revlimid has been recommended to be non-recommended on the RDL because of its limited availability and toxicity. Seasonique has been recommended to be non-preferred on the PDL, since the extended cycle that it produces is not appropriate for all women. Dr. Frier motioned to accept these recommendations, and Hayley Harvey seconded. The motion passed with all committee members in attendance voting unanimously. Mary Winegardner abstained as she excused herself from the meeting at 2:18; she was not present for the vote.

VIII. Newly Released Generics (Dr. Clifford): The brand Mobic would remain non-preferred, and its generic version Meloxicam would also be non-preferred. This may be temporary, as the prices have dropped down tremendously. There is a good chance discussion will be opening up on the generic at the March meeting. Sue Purcell motioned to accept the recommendation for Meloxicam, and Dr. Ruhe seconded. All committee members in attendance approved the motion.

IX. New Dosage Forms: Advair HFA, Enbrel Sureclick, and Orapred ODT had already been discussed and voted on during the PDL deliberation, so the committee did not need to vote on their status again.

X. There will be a preliminary discussion about Typical vs. Atypical Psychotics at the March meeting. Dr. Flaum will bring three articles.

A motion was made by Dr. Flaum to adjourn the meeting. Sue Purcell seconded the motion. All in attendance approved the motion. The meeting adjourned at 2:30 p.m. The next scheduled meeting will be March 8, 2007.