P&T Committee
Minutes

Date: October 27, 2004

Chair: Michael Flaum, MD

Time: 9:35 a.m. to 6:00 p.m.

Location: Iowa State Capitol, Room 116, Des Moines, Iowa

Committee Members Present: Cheryl Clarke, R.Ph., CDM; William R. Doucette, Ph.D; Hayley L. Harvey, DDS, MS; Bradley J. Archer, MD; Michael A. Flaum, MD; Susan Purcell, R.Ph, CGP; and Priscilla Ruhe, MD

Iowa DHS Staff Present: Eugene Gessow, DHS Medicaid Director; Eileen Creager, DHS Bureau Chief; Susan Parker, Pharm.D., DHS Pharmacy Consultant; and Daniel W. Hart, Attorney General's Office

IME Staff Present: Thomas Kline, DO, Iowa Medicaid Medical Director; Tim Clifford, MD; John Grotton, R.Ph.; Andi Dykstra, RN, CPHQ; Sandy Pranger, R.Ph.; and Julie Bueno, R.Ph.

Dr. Flaum called the meeting to order.

I. Dr. Flaum asked that each committee member, DHS, and IME staff introduce themselves to the public.

II. Dr. Flaum announced that Dr. Carole A. Frier is the newest P&T committee member, and she will join the committee at the December 2nd meeting.

III. Dr. Flaum also announced to the public to pick up all trash in the room and surrounding areas.

IV. Dr. Flaum said that there is a minor change in the by-laws, literally two words need to be changed: that the chairperson and the vice-chairperson shall serve a period of one year instead of two years. Susan Purcell made the motion to accept the new by-laws with changes. Dr. Ruhe seconded it. The committee voted unanimously in favor of the changes.

V. The committee needs to elect two officers, a chairperson and vice-chairperson. Dr. Flaum asked if anyone had any discussion. Cheryl Clarke asked Mr. Hart if the bylaws would allow Dr. Flaum to serve another term since he had not served a complete term as president. Daniel Hart replied, yes, he may remain as chairperson. Dr. Flaum called for nominations. Susan Purcell nominated Dr. Flaum for chairperson. Dr. Harvey seconded the motion. All committee members voted in favor and none opposed. Dr. Harvey nominated Cheryl Clarke as vice-chairperson of

the committee. Susan Purcell seconded the nomination. All committee members voted in favor and none opposed.

VI. The committee members voted in favor with none opposing and Mary Winegardner abstaining, the September 28 and 29 meeting minutes with the correction that Cheryl Clarke's last name has an "e" on the end.

VII. Dr. Flaum asked Dr. Clifford on how best to handle the voting process for the PDL. Dr. Clifford's response was to ask that he be allowed to address each category before discussion.

VIII. Dr. Doucette motioned to go to closed session. Cheryl Clarke seconded. A roll call vote was taken and all were in favor.

Open session reconvened at 11:30 a.m.

I. Dr. Clifford stated that over 70% of the patients were currently using preferred Ace Inhibitors. Dr. Flaum asked if the committee was going to lump the PDL categories. Dr. Clifford's clarification was affirmative of lumping similar categories together. Cheryl Clarke made the motion and Dr. Flaum seconded the motion to approve the PDL recommendations regarding Ace Thiazide Combo's, Ace Inhibitors, Ace Inhibitors and CA Channel Blockers. All committee members were in favor and none opposed.

II. Susan Purcell voiced concerns about the availability of the generic (Disulfiram), if it is preferred and Antabuse if non-preferred. Susan Parker said if the generic was not available, the PA unit would put in a temporary prior authorization for the Antabuse which is the normal process when there are supply issues. Mary Winegardner made the motion and Dr. Archer seconded the motion to approve the PDL recommendations regarding Acne Products: Isotretinoin, Alcohol Deterrents, ALS Drugs, Alzheimer – Cholinomimetics including grandfathering Reminyl. All committee members were in favor and none opposed.

III. Dr. Clifford stated that with the Androgens/Anabolics category, the issue was between the Danazol and Danocrine as the generic (Danazol) 50mg and 100mg are preferred products and the brand (Danocrine) 200mg is preferred. Cheryl Clarke voiced a concern about pharmacies using two of the generic 100mg rather than ordering the brand 200mg, which will be preferred. She said the pharmacies won't stock the brand product. Dr. Clifford said the dose consolidation edits would catch this. Dr. Archer made the motion and Susan Purcell seconded the motion to approve the PDL recommendations regarding Aminoglycosides, Analgesics-Miscellaneous, Androgens/Anabolics with the exception that Danazol 50mg and 100mg and Danocrine 200mg are the preferred products. All committee members were in favor and none opposed.

IV. Cheryl Clarke asked if there would be a preferred enema product or would only the cream be preferred. Dr. Clifford responded that the Cortenema would be preferred. Dr. Doucette made the motion and Dr. Ruhe seconded the motion to approve the PDL recommendations regarding ARB's, ARB/Diuretic Combinations, and Anorectal – Miscellaneous with the amendment of making Cortenema as preferred, and Anthelmintics and Anti-Infective Combos's – Miscellaneous. All committee members were in favor and none opposed.

V. Dr. Clifford stated that in the antiarrhythimics category, the big savings was from using brand over generics. Susan Purcell asked if there had been any discussion about why there was not a short acting disopyramide as a preferred agent, only the long-acting is preferred. Dr.Clifford stated that the short-acting had very low utilization. Dr. Clifford said that Tikosyn is an issue and Maine made it non-preferred but allowed cardiologists to be exempt from the PA process. Dr. Archer felt that they should be exempt since they are already controlling the prescribing and following the prescribing guidelines. Dr. Clifford said the committee also had the option to make the Tikosyn preferred. Susan Purcell wanted clarification that Spiriva was still a non-preferred agent. Dr. Clifford said that the supplemental rebate offer for the Spiriva was not significant so it was still non-preferred. Dr. Clifford suggested that they make Spiriva non-preferred for at least the first 6 months to allow it to prove itself in the Medicaid population. He also suggested placing prior authorization criteria for it's use as follows: FEV1 > 40%, and hospitalization for COPD within the past 12 months. John Grotton explained that the P & T Committee was recommending prior authorizations be placed on certain drugs or therapeutic categories. This recommendation would then go over to the DUR Commission to build the prior authorization criteria. Susan Parker stated that the prior authorization recommendations and quantity limits recommended by the P & T Committee would be sent to the DUR Commission for review. Dr. Flaum made the motion and Susan Purcell seconded the motion to approve the PDL recommendations regarding Antiarrhythmics including Tikosyn are preferred as well as Antiasthmatic – Adrenergic Combo's with a recommendation to the DUR Commission to place Spiriva on PA with the clinical criteria being a FEV1 less than 40% and the member would need to have hospitalization for COPD within the past 12 months, Alpha Proteinase Inhibitors to include Prolastin with a PA recommended to verify diagnosis, and Anti-Cholinergics. All committee members were in favor and none opposed.

VI. Dr. Clifford stated that there was an extremely large rebate for the drug Singulair. He is aware that the DUR Commission is looking into Singulair utilization but feels it is better to take the easy money from the supplemental rebate this year and revisit making a PA for the Leukotriene Receptor Antagonists until next year. Dr. Archer made the motion and Dr. Ruhe seconded the motion to approve the PDL recommendations regarding accepting the following categories for the PDL: Antiasthmatic – Anti-Inflammatory Agents to include a recommendation to the DUR Commission to place a PA on Xolair with the criteria being failure on therapeutic doses of inhaled steroids, Beta-Adrenergics with the addition of terbutaline sulfate as preferred, Hydro-Lytic Enzymes with a PA recommendation for Pulmozyme to verify

an indicated diagnosis of cycstic fibrosis, Nasal Miscellaneous, Nasal Steroids, Steroid Inhalants-for Pulmicort, there will be no PA required for children less than 8 years old for the suspension and the Turbihaler will be payable for children less than 14 years old, Xanthines, and Leukotriene Receptor Antagonists with the removal of the prior authorization recommendation for the entire therapeutic class. All committee members were in favor and none opposed.

VII. Dr. Ruhe made the motion and Dr. Archer seconded the motion to approve the PDL recommendations regarding Antibiotics – Miscellaneous with the change to make metronidazole IR preferred and metronidazole ER non-preferred, and Anticoagulants with a recommendation to be sent to the DUR Commission requesting the Anti-Thrombotic Injectables to require a PA after 7 consecutive days of use. All committee members were in favor and none opposed.

VIII. Dr. Archer voiced concerns about neurologists not being exempt from the PA process when prescribing anticonvulsants. He was concerned about the increased time spent on the prior authorizations. It will cause too much paperwork for the neurologists. Dr. Clifford said that if they would grandfather for seizure disorder patients, it would greatly impact and lessen the amount of prior authorizations required by the neurologists. Dr. Doucette asked if neurologists could be grandfathered. Susan Parker stated it would be very difficult. John Grotton stated that from a programming standpoint it won't work at this time to block the neurologists from the prior authorization process; the next best option is to grandfather for seizure disorder. Dr. Clifford said that it is better to grandfather a class of drugs with a specific diagnosis than to grandfather a specialty. He also stated that in Iowa the utilization for the drug Topamax is 10% seizure disorder, 90% was for non-seizure disorders. Dr. Ruhe made the motion and Cheryl Clarke seconded the motion to approve the PDL recommendations regarding Anticonvulsants with grandfathering for seizure disorders recommended. All committee members were in favor except Dr. Archer who opposed.

IX. Dr. Harvey made the motion and Dr. Doucette seconded the motion to approve the PDL recommendations regarding Antiemetic- 5-HT3 Receptor Antagonists/Substance P N with a recommendation for quantity limits, Antiemetic – Anticholinergic/ Dopaminergic, Antifungals-Assorted. All committee members were in favor and none opposed.

X. Mary Winegardner voiced her concerns about Lariam being preferred and Aralen non-preferred due to the side effect profile on the Lariam. Susan Purcell asked if the elderly population was taken into account in the antihistamine category. Dr. Clifford responded yes. Susan Purcell asked if you would still have to request a prior authorization for Loratadine. Dr. Clifford stated that Loratadine is OTC payable and will require a prior authorization. Susan Purcell asked if a PA for Allegra is in place, can Loratadine be dispensed since the generic trials were already done. Dr. Clifford stated yes, the Loratadine is an in-between category still requiring prior authorization. Dr. Flaum stated that the member is grandfathered to Loratadine. Dr. Archer

commented that he was concerned that Loratadine would cause more paperwork for the physician. Cheryl Clarke made the motion and Mary Winegardner seconded the motion to approve the PDL recommendations regarding Antimycobacterials/Antituberculosis, Antihistamines with the exception to make Allegra preferred and there is a process in place where if a person already has a prior authorization in the antihistamine category they didn't have to get a new PA for Loratadine, and Antimalarial Agents. All committee members were in favor and none opposed.

XI. Mary Winegardner made the motion and Dr. Doucette seconded the motion to approve the PDL recommendations regarding Anti-Parkinson Drugs, Anti-Psoriatics, Antispasmodics, Antispasmodics-Long Acting, Anti-thyroid Therapies, ARB's and Diuretics, Arthritis – Miscellaneous, Artificial Saliva/Stimulants, Beta Blockers – Alpha/Beta, Beta Blockers – Cardio Selective, Beta Blockers – Non-Selective, Beta Blockers and Diuretic Combo's. All committee members were in favor and none opposed.

XII. Dr. Archer asked what happens to a patient on Flomax currently? Flomax currently has no restrictions on it. Dr. Tim Clifford replied once the PDL is in place, Flomax will be non-preferred and the prescriber can submit a prior authorization if the preferred agent is not appropriate. John Grotton stated they have a 30-day override to transition to the preferred agent. Dr. Clifford stated that 50-60% of the patients under 65 years of age successfully use alpha blockers when switched off Flomax. Dr. Archer stated that the utilization report showed a high volume of Flomax prescriptions. Dr. Clifford stated that Flomax has a clinical niche. Dr. Archer said you don't want the elderly population to fall over due to postural hypotension. Susan Purcell was also concerned about the elderly falling over. Dr. Doucette made the motion and Mary Winegardner seconded the motion to approve the PDL recommendations regarding Beta-Lactams/Clavulanate Combo's, BPH , Calcium Channel Blockers – Amlodipines, Calcium Channel Blockers – Diltiazems, Calcium Channel Blockers – Felodipines, Calcium Channel Blockers – Isradipines, Calcium Channel Blockers – Nifedipines, Calcium Channel Blockers – Nisoldipine, and Calcium Channel Blockers – Verapamils. All committee members were in favor and none opposed.

XIII. Dr. Archer and Dr. Doucette had concerns about statin use and transplant patients, making sure that there was an appropriate choice for these patients. Dr. Clifford stated although Pravachol is non-preferred, the PA unit would okay the preferred requirements when a transplant doctor requests Pravachol due to medical contraindications. Dr. Flaum made the motion and Mary Winegardner seconded the motion to approve the PDL recommendations regarding Cardiac Glycosides, Cephalosporins, Chelating Agents, Cholesterol-Bile Sequestrants, Cholesterol-Fibric Acid Derivatives/Other, and Cholesterol-HMG COA + Absorb Inhibitors, and Cholinergics. All committee members were in favor and none opposed.

XIV. Cheryl Clarke made the motion and Dr. Archer seconded the motion to approve the PDL recommendations regarding Contraceptives – Bi-Phasic Combinations, Contraceptives – Emergency Contraceptive, Contraceptives – Injectable, Contraceptive – Progestin Only, Contraceptives – Tri-Phasic Combinations, Contraceptives – Monophasic Combinations, and Contraceptives – Patches/Vaginal Products including the PA recommended Ortho Evra for age 21 and older. All committee members were in favor and none opposed.

XV. Dr. Clifford stated the Cyto-Megalovirus agent Ganciclovir would be added as a preferred drug. Also in that class the other agents Cytovene Capsules, Cytovene Solution, and Valcyte would be preferred due to no significant cost differences among products within the class. Dr. Clifford stated that the dental products are a low dollar category and all will be preferred. Mary Winegardner requested a 3-month grandfathering of insulin products to transfer patients to the preferred agents. Dr. Clifford pointed out that the hard start of the PDL is in January and there also is the 30-day transition supply provision so there is a window of time available to change the insulin patients over to the preferred agents. Dr. Harvey made the motion and Dr. Archer seconded the motion to approve the PDL recommendations regarding Cox 2 Inhibitors, Cyto-Megalovirus Agents, Dental Products to include Prevident 5000 Plus, Ethedent, and SF 5000 Plus as preferred, Diabetic – Thiazolidinediones, Diabetic – Insulin, Diabetic – Penfills, Diabetic – Alphaglucosidase, Diabetic – Meglitinides, Diabetic – Oral Sulfonylureas, Diabetic – Sulfonylurea/ Biguanide, Diabetic – Thiazo/Biguanide Como, and Diabetic – Oral Biguanides. All committee members were in favor and none opposed.

XVI. Susan Purcell asked why Aldactone was preferred since it has low use. Dr. Clifford responded the manufacturer gave a good rebate and the state can receive substantial savings by having Aldactone preferred. Dr. Archer said most pharmacies don't carry brand name Aldactone. Susan Purcell made the motion and Dr. Ruhe seconded the motion to approve the PDL recommendations regarding Diuretics with the recommendation to the DUR Commission to place a PA on Inspra with the criteria being Aldactone failure or gynecomastia resulting from Aldactone use; Ear, Erythropoeitins, Estrogen Combo's, Estrogens – Patches, and Estrogens – Tabs. All committee members were in favor and none opposed.

XVII. There was some discussion regarding the recommendations the P&T Committee was making and the recommendations the DUR Commission makes. Dr. Clifford responded when you do a PDL, the P&T Committee looks at different issues than the DUR Commission and it is good for them (the P&T Committee) to bring these issues up and then have the DUR Commission look at them. Cheryl Clarke stated she had concerns about brand name Cipro being preferred and the member would have to pay a higher co-pay. Dr. Clifford responded you look at the issue from most expensive to least expensive. Cheryl Clarke was concerned about making Cipro preferred. She felt it was going to be a huge financial burden on the pharmacies since they only stock the generic because that is what all other insurance companies pay for. She felt that the brand is so much more than the generic and feared the pharmacies won't

stock it. Dr. Clifford responded that if Ciprofloxacin is allowed to become preferred, then the state will lose roughly $167,000 of projected savings. A solution would be to adjust the MAC pricing on the Ciprofloxacin to make the price more in line with the net price of Cipro after the supplemental rebate. Dr. Archer wants to make Levaquin preferred. He stated that Levaquin has a broader spectrum and does not have the resistance issues that other fluoroquinolones have. Dr. Flaum stated there are two issues. The first issue is to make all Levaquin preferred. The second issue is whether or not to make Ciprofloxacin preferred. Cheryl Clarke made the motion and Dr. Archer seconded the motion to approve the PDL recommendations regarding Fluoroquinolones with the exception that all Levaquin products are preferred. All committee members were in favor except Dr. Ruhe who abstained.

XVIII. Dr. Clifford recommended making Miralax a preferred agent but only for one 14-day course of treatment after which a PA would be required. This would move the chronic users over to less expensive products. Dr. Clifford also pointed out that by having the brand OTC Imodium products preferred over the generics, the State can save an additional $80,000. Cheryl Clarke made the motion and Dr. Ruhe seconded the motion to approve the PDL recommendations regarding GI – Anti-Flatulents/GI Stimulants with the exception that Miralax would have a PA recommendation of one 14-day course therapy and then a PA would be required after that, and that the drug Zelnorm would have a PA recommendation with the PA criteria being other documented treatment failures for IBS or a diagnosis of chronic constipation, GI – Antidiarrheal/Antacid-Miscellaneous, GI – Antiperistaltic Agents, GI – Digestive Enzymes (the entire category would be PA recommended with the PA criteria to verify the diagnosis of malabsorption due to pancreatic insufficiency). GI – H2 Antagonists, GI – Inflammatory Bowel Agents, GI – Irritable Bowel Syndrome Agents, GI – Prostaglandins, GI – Miscellaneous with the recommendation to the DUR Commission that Senna, Senokot, and Sennacon not be covered for patients greater than 21 years old. All committee members were in favor and none opposed.

XIX. Dr. Flaum made the motion and Dr. Archer seconded the motion to approve the PDL recommendations regarding GI – Proton Pump Inhibitors to include Prevpac to have a quantity limit (14 day therapy) in place to prevent billing errors and with the recommendation to the DUR Commission that Prevacid Suspension and packets be preferred for children less than 12 years old and institutionalized patients with documented swallowing disorders; and GI – Ulcer Anti-Infective. All committee members were in favor and none opposed.

XX. Dr. Archer made the motion and Dr. Ruhe and Mary Winegardner seconded the motion to approve the PDL recommendations regarding Glucocorticoids/ Mineralocorticoids, Gout, Granulocyte CSF, Growth Hormone with the recommendation for the drug Zorbitive to have PA criteria verifying the diagnosis of short bowel syndrome (SBS), Hemostatic, Hepatitis B only with the exception that Ribavirin be moved to the Hepatitis C category, Hepatitis C Agents, Herpes Agents, Impotence Agents, Influenza Agents to include the recommendation of Tamiflu, Flumadine, and Rimantadine to have a quantity limit of ten units, K Removing

Resins, and Lincosamides/Oxazolidinones/Leprostatics to include Zyvox with the PA criteria to verify the prescriber is either an infectious disease specialist or has consulted one. All committee members were in favor and none opposed.

XXI. Dr. Clifford stated that all Biaxin and Zithromax products are preferred. He also discussed adding the Ketolytics to the Macrolide/Erythromycin class to include the drug Ketek. Ketek is best used when there is substantial macrolide resistance and the patient is too young to use the fluoroquinolones. Ketek could be a preferred agent with a limit to allow access up to a certain age or it could be completely non-preferred with an age exception put in place. Clinical issues do exist (with Ketek use) with respect to the QT interval prolongation. Many physicians are leary of widening Ketek usage to the primary care setting. The clinical niche is for children up to a certain age. Susan Purcell made the motion and Dr. Ruhe seconded the motion to approve the PDL recommendations regarding Macrolides/Erythromycins to include the recommendation of Ketek to require a PA for greater than 16 years old with the PA criteria being for use when a patient has Macrolide resistance or they are not a candidate for a Fluroquinoline. Migraine – Carboxylic Acid Derivatives, Migraine – Ergotamine Derivatives, Migraine – Miscellaneous, Migraine – Selective Serotonin Agonists (5HT) Injectables and Tabs, and Minerals. All committee members, except Dr. Harvey who was absent, were in favor and none opposed.

XXII. Dr. Clifford said that both the Stadol and the Butorphanol would be non-preferred to discourage their usage. He also stated that Ultracet was non-preferred because it was much more cost effective to use the separate products. For the muscle relaxants, Dr. Clifford stated that the Skelaxin 400 is much less that the 800mg. This is a good source of savings. Another source of savings it to make Zanaflex and Tizanidine non-preferred to force usage of less expensive products. All of the Orphenadrine products are now preferred due to the new SMAC rates put in place. Cheryl Clarke made the motion and Dr. Doucette seconded the motion to approve the PDL recommendations regarding Mouth Anti-Infectives, Mouth Antiseptics, Multiple Sclerosis Agents including grandfathering Copaxone (Dr. Flaum made the motion for Copaxone to be used as first-line therapy for patients with increased risk for major depression and also to grandfather existing patients); Muscle Relaxant–Combinations, Muscle Relaxants, Narcotic Antagonists, Narcotics–Miscellaneous to include the PA recommendation of Actiq according to the black box warning and the exceptions are made for all cancer, hospice and institutionalized patients; also changing the drug Vicoprofen to non-preferred. Exceptions will also be made for the drug Duragesic for the diagnosis of cancer, hospice and institutionalized patients; Narcotics – Selected; and Narcotics – Long Acting. All committee members, except Dr. Harvey who was absent, were in favor and none opposed.

XXIII. Dr. Ruhe made the motion and Cheryl Clarke seconded the motion to approve the PDL recommendations regarding Neurologics – Miscellaneous, Nitrates (all dosage forms), and NSAIDS with the change of Mobic to preferred. All committee members, except Dr. Harvey who was absent, were in favor and none opposed.

Dr. Flaum motioned the meeting be adjourned and Dr. Ruhe seconded it.

The meeting ended at 6:00 p.m. The P&T Committee will reconvene on October 28th.