Iowa Medicaid Pharmaceutical and Therapeutics Committee
Minutes

Date: September 14, 2006

Chair: Michael A. Flaum, M.D.

Time: 9:41 a.m. to 2:50 p.m.

Location: Hoover Building, Level A Training Room 6, 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.; Matthew Osterhaus, R.Ph.; Mary Winegardner, PA-C, MPAS; and Susan Purcell, R.Ph, CGP

Committee Members Absent: Bradley J. Archer, M.D. (afternoon session only)

Iowa DHS Staff Present: Susan Parker, Pharm.D., Pharmacy Consultant; and Brad Horn, Attorney General's Office

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.; 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.

II. The June 8th open session minutes were reviewed. Matt Osterhaus made the motion to approve the minutes. Bruce Alexander seconded the motion. The motion passed with no objections, but with the 3 members (Mary Winegardner, Susan Purcell, and Brad Archer) who had been absent at the June meeting, abstaining.

III. PDL: Sovereign States Drug Consortium (SSDC) is in the middle of receiving and processing the supplemental rebate offers for the upcoming year. They were all received as of Friday September 8th, and now it is just a matter of cleaning up some technical issues with some of the offers. The SSDC will be reviewing them with the Department of Human Services on Monday and Tuesday (September 18th and 19th). There is much more interest among the manufacturers with doing long-term deals, which brings more stability to the Preferred Drug List (PDL). Medicare Part D has helped the Medicaid program in the sense that there are better opportunities for PDL savings. During Closed Session, there will be a preview of the economic side of the annual review. Since the committee is more experienced now, they should be able to go through the PDL much more efficiently this time as there will be many instances in these categories where there are not any status changes. Dr. Clifford called attention to the Market Share Report for Iowa between January 1, 2006 and June 30, 2006 (Report

2). This market share report indicates that the population skews much younger now. Before Medicare Part D, the asthma drugs were roughly 8% of the budget, and now they are about 10% of the budget. So there have been some shifts in some of the categories as a result of losing the Dual Eligibles. Overall, the cardiac category has diminished somewhat, of course, but it's still a major part of the budget. Report 1 summarizes the Prior Authorization statistics. This report shows that the Prior Authorization approval rate remains unchanged at 66% and the determination time is running around 0.33 hours. Dr. Clifford goes back to Report 2 (Market Share Report) stating that this will be a resource to use getting ready for the annual review session. On Page 90 of that report, under Miscellaneous Narcotics, Subutex and Suboxone have an unusual ratio compared to other states. Iowa had around 130 prescriptions of both in a 6-month period, while Maine had just less than 7000 and Vermont had 9000. Not only does this pose the question "are we adequately treating substance abuse," but also "how good and established and accessible are the methodone clinics?" A state with a higher rural population, where recipients do not have easy access to clinics, should be prescribing more Suboxone. However, this is a very noticeable difference. Bruce Alexander said that the number of methodone clinics in Iowa has dropped in the last 20 years. Susan Parker pointed out that the East Coast has a lot higher prescription volume than anywhere else in the country. The market share report also gives a good idea of where the state is spending the drug budget. Before the next meeting, there will be a newer, updated version of this report. It will have exactly the same data, but will also illustrate potential changes in the PDL. Dr. Flaum asked for a 6-month total budget, but Dr. Clifford did not have a report with that total. John Grotton said that the total for August was $36 million and July was somewhere around $29 million. The psych drugs make up an increasing percentage of the drug budget. Bruce Alexander asked how many rebate offers had been submitted. In response, Dr. Clifford said that at the NDC-level, there were offers on just over 1000 NDCs, representing 70+ manufacturers. This number seems to go up some every year, which makes sense. More drugs are being made, by more manufacturers. Right now, there are 500-600 labelers on file. Dr. Hayley Harvey referenced the Market Share Report and asked why there had not been a shift in the market share of Oxycontin versus the generic. Dr. Clifford responded by noting that the Market Share Report only referenced data from January to June, 2006. The change in status of Oxycontin and the generic form, Oxycodone ER, did not occur until late May. Dr. Clifford said that there were some mid-transition issues to be discussed in closed session that would affect the offers. Another transition point occurs on page 76 of the Market Share Report, under Proton-Pump Inhibitors. In this 6 month period, Nexium had a 29% market share after its status on the PDL changed to non-preferred in January. The important thing to point out is that these transitions always result in the loss of supplemental rebates when this occurs. This is one of the reasons why choosing the three year deals, thinking long-term, and reducing the amount of transitions that occur, really works in the state's favor. Iowa is better off not chasing a couple of additional pennies, but instead thinking about stabilizing long-term and going with the most cost-effective drugs. Bruce Alexander said that DUR writes a fair amount on Methodone, and that it works 14.2% of the time.

IV. Prior Auth Criteria/ProDUR edits: Susan went over Attachment 1. Back when the PDL was first established, there were several categories that were referred to the DUR

Commission for review and develop the PA criteria. Multiple recommendations were received over a time period. Those changes were implemented in phases as providers became more comfortable with the PDL and the PA process. Attachment 1 is the last phase of the PA recommendations that will be implemented 30 days from the time notification is sent to providers. Bruce Alexander said that at the DUR meeting in September, they went through all the PA categories to decide which ones they were going to re-review this next year. This process will start at the next meeting. The DUR Commission targeted maybe 8-10 categories to review per Bruce Alexander.

V. The public speakers were:

SPEAKER	SUBJECT
Jeffrey Allyn, M.D. from Broadlawns Medical Center	Vivitrol & Chantix
Williams A. Stutts, D.O. from Mercy Medical Center	Vivitrol
Tim Collins, Pharm D. from Bristol-Myers Squibb	Emsam
Amy Blickensderfer, Pharm D. from Amylin Pharmaceuticals	Byetta & Symlin
Jerry Clewell, Pharm D., MBA, BCPS from Abbott Labs	Humira Pen
Hashem Alshurafa, Pharm D. from Bristol-Myers Squibb	Sprycel
Patrick Vojta, Pharm D. from Boehringer Ingelheim	Spiriva Handihaler
Brenda Fabisch from Alkermes, Inc.	Vivitrol
Kris Baerenwald from Endo Pharmaceuticals	Opana & Opana ER
Anthony DeLeon from Shire Pharmaceuticals	Daytrana

At 11:40, motion to go to closed session was made by Sue Purcell and seconded by Mary Winegardner. The motion passed with unanimous approval.

Open session resumed at 1:12 pm. (All committee members present, with the exception of Dr. Archer)

VI. PDL Discussion and Deliberation: Dr. Clifford went over Attachment 3. Adjustments to the existing PDL were considered. Azithromycin, the generic for Zithromax, can now be made preferred, because it is more cost-effective than the existing brand product. Several studies were included in Report 3 concerning Campral. With the COMBINE study, it was somewhat surprising that Campral was not found to be effective. The authors also pointed out many significant differences in the COMBINE trial compared to the other many studies that have shown Campral to be effective. On page 2013, in the comments section at the bottom of the middle column, the authors discuss some of these important differences. One is that they required only four days of abstinence, achieved primarily on an outpatient basis, whereas most of the positive studies had a longer pre-treatment abstinence period established during inpatient treatment. Also, the prior acamprosate trials used less frequent assessment, non-standardized counseling, and patients recruited from clinical, primarily inpatient settings. This raises some red flags. If physicians are not good about patient selection and ensuring abstinence, and giving the patient the best shot at Campral being effective, then there may be wasting of Campral and sabotaging the whole intervention. The third

change to the PDL is that Drysol will become preferred now because the generic product went OTC. Lithium Carbonate, the 450mg CR tablet, needs to change to preferred status, because the brand-name product was discontinued. Mimyx needs to be removed from the PDL, because the FDA no longer considers it to be drug. In closed session, the updated Spiriva offer was discussed, resulting with the recommendation to accept the Spiriva offer and make it preferred, with the condition that the DUR committee would examine the issue of considering a once-per-day dose limit and a clinical edit to be sure the patient was not having duplicate therapy with Atrovent HFA and/or Combivant. Vivaglobin needs to be non-preferred instead of preferred with conditions as it is currently. Also, the Zithromax Tripak should become non-preferred because now there are multiple strengths of Azithromycin that are preferred. In order not to interfere with the current contract, there will be talk about going completely generic preferred with this product at the annual session. However, the only interim decision needed would be what is written in Attachment 3, and that is to make only the brand Tripak non-preferred. The reason the brand name product was left preferred for the time being was to allow a wider transition period for the stores to be able to get people onto the generic and get in the habit of being able to use that generic and use up their brand inventory supply. Dr. Flaum moved to make Spiriva preferred, with a request that the DUR consider the aforementioned restrictions. Dr. Ruhe seconded, and all were in favor of the motion.

VII. Dr Kline's Review of New Drugs (Attachment 4): Dr. Kline reviewed the list of newly released drugs and communicated the PDL status recommendations to the members of the committee. Apidra was recommended to be added as a non-preferred drugs since there is one preferred rapid-acting insulin analog on the PDL that is more cost effective than Apidra. Citracal Prenatal + DHA was recommended to be added as a non-preferred drug since there are several prenatal vitamin products available on the PDL that provide adequate supplementation of folic acid, and calcium with or without iron that are more cost effective. Daytrana was recommended to be added as a non-preferred drug since other forms of methylphenidate are available on the PDL with preferred status that are more cost effective. Durabac Forte was recommended to be added as a non-preferred drug since there are other products on the PDL, both single ingredient and combination products that effectively treat generalized pain without causing significant drowsiness that have preferred status and are more cost effective. Emsam was recommended to be added as a non-recommended drug since other formulations of MAO Inhibitors are on the RDL as Recommended products that are more cost effective than Emsam. Additionally because MAOIs are considered to be third line treatment options for the treatment of depression. Enjuvia was recommended to be added as a non-preferred drug since other synthetic conjugated estrogen products, both of animal and plant derivation, have preferred status on the PDL that are more cost effective. Opana and Opana ER were recommended to be added as non-preferred drugs since there are other long and short acting narcotics currently available on the PDL that are equally effective as Opana and Opana ER that are more cost effective. Optase was recommended to be added as a non-preferred drug since other products used for wound debridement and promotion of healing wounds are available on the PDL as preferred medications which are more cost effective. Oracea was recommended to be added as a non-preferred drug since there are

topical products on the PDL approved for the treatment of rosacea that are effective in treating all signs of rosacea, in addition to preferred forms of doxycycline, that are more cost effective than Oracea. OsmoPrep was recommended to be added as a non-preferred drug since other colonoscopy preparation products appear on the PDL with preferred status that are more cost effective than OsmoPrep. PreCare Premier was recommended to be added as a non-preferred drug since there are several preferred prenatal vitamin products available on the PDL that provide adequate supplementation of folic acid, and calcium with or without iron and docusate sodium that are more cost effective. Prezista was recommended to be added as a recommended drug due to the positive patient outcomes in early trials; this medication is a cost effective choice for management of HIV. Solodyn was recommended to be added as a non-preferred drug since other minocycline and tetracycline antibiotics appear on the PDL that are equally effective at treating acne vulgaris that are preferred and are more cost effective. Sprycel was recommended to be added as a non-recommended drug since other formulations of tyrosine kinase inhibitors are available on the RDL that are more cost effective than Sprycel. Vivitrol was recommended to be added as a non-preferred drug since other drugs on the PDL used to treat alcohol dependence within this drug class, in addition to Antabuse, has preferred status and are more cost effective. Yaz was recommended to be added as a non-preferred drug since other preferred oral contraceptive products exist on the PDL, with varying doses of ethinly estradiol, that are equally effective at preventing pregnancy, and that are more cost effective. Zelapar was recommended to be added as a non-preferred drug since other forms of selegiline are available as preferred medications on the PDL that are equally efficacious and more cost effective than Zelapar. Following the review of the new drugs, the committee voted to accept the recommendations as listed. First, Matt Osterhaus made a motion to make Apidra Injection, Apidra Opticlick Injection, Citrical Prenatal + DHA, Daytrana, Durabac Forte, and Enjuvia non-preferred on the PDL, and Emsam Patch non-recommended on the RDL. Sue Purcell seconded this motion, and it passed with no oppositions or abstentions. (The status of Apidra Injection, and Apidra Opticlick Injection, will be re-addressed at the November 9th P&T meeting.) Secondly, Sue Purcell made a motion to make Opana, Opana ER, Optase, Oracea, OsmoPrep, and Precare Premier non-preferred, and Mary Winegardner seconded. This motion also passed with unanimous approval. (Optase will be discussed further at the November meeting.) Then Dr. Ruhe made a motion to make Solodyn ER, Yaz, and Zelapar non-preferred on the PDL, Prezista recommended on the RDL, and Sprycel non-recommended on the RDL. Mary Winegardner again seconded, and the motion passed unanimously. Finally, there was a lengthy discussion about Vivitrol Injection, which finally resulted with Bruce Alexander proposing the motion to make it non-preferred on the PDL. Sue Purcell seconded that. Again, this passed with no oppositions or abstentions. However, Dr. Ruhe said that she'd almost voted against it because of the public comments given earlier by Dr. Allyn and Dr. Stutts. She asked that someone contact them to see why they had taken the time to come to the meeting to speak. Sandy Pranger volunteered to get this information.

VIII. Injectable drugs: Dr. Kline would like permission from the P&T Committee to research the ability to close the gap between the Medical Program and the Pharmacy PDL as it relates to injectable and infusible drugs. He thinks this would have a significant impact on the Medical budget. Susan Parker pointed out that the pricing works differently on

the different types of claims, and reiterated that the PDL only applies to outpatient drugs that recipients pick up from pharmacies. Bruce Alexander thinks the Committee should put this on the agenda for a future meeting, as it sounds like it's something that would not be an easy fix. Mary Winegardner seconded this idea.

IX. Request for DUR to restrict Antibuse usage: Bruce Alexander referred to an unfortunate death in Cedar Rapids that was essentially prosecuted as a malpractice suit. The physician did not ensure that a follow-up liver test done within four weeks of therapy initiation, which was established to be the standard of practice for Antibuse. The providers in eastern Iowa are basically not prescribing Antibuse as a result of this lawsuit. Dr. Clifford suggested that the DUR should restrict Antibuse usage to 30 days, after which the recipient must have the provider administer a liver function test to continue usage (pending a PA). Then DUR could define how often test results should be required.

X. Newly Released Generic Drugs: Dr. Clifford reviewed Attachment 5, and then the committee voted on the recommended changes. Finasteride, pravastatin, sertraline, simvastatin, and Vandazole were recommended to be added to the PDL as non-preferred drugs because they are not as cost effective as the current preferred equivalent brand name products. Cyclobenzaprine 5mg was recommended to be added to the PDL as a preferred medication because it is equally cost effective as the current preferred 10mg product. Mary Winegardner made a motion to accept the recommendations and make Finasteride, Prevastatin, Sertraline, Simvastatin, and Vandazole 0.75% gel non-preferred, and Cyclobenaprine 5mg preferred. Bruce Alexander seconded. The motion passed, with only Hayley Harvey abstaining.

XI. New Dosage Forms: Dr. Clifford again referred to the rest of the drugs on Attachment 5. Cardura XL and Ultram ER were recommended to be added to the PDL as non-preferred drugs since other forms of these medications are available as preferred products on the PDL that are more cost effective. Accuzme SE, Humira Pen, and Panafil SE were recommended to be added as preferred drugs because they are equally cost effective to other dosage forms currently listed on the PDL as preferred products. Clarinex D was recommended to be added to the PDL as preferred with conditions as it is equally cost effective as other preferred forms of this drug currently listed on the PDL. Due to the clinical PA criteria in place for 2nd generation antihistamines, it will have conditions attached to it. Then Dr. Ruhe made a motion to make Cardura XL and Ultram ER non-preferred, Accuzyme SE, Humira Pen, and Panafil SE preferred, and Clarinex D preferred with conditions. Sue Purcell seconded that, and the motion passed, with both Hayley Harvey and Mary Winegardner abstaining.

XII. November 9th meeting: There was a short discussion regarding the next meeting, and its projected time frame. The agreed upon consensus was to start at 8:30 and go a little past 4:30 if needed.

A motion was made by Dr. Flaum to adjourn the meeting. Mary Winegardner seconded the motion. All in attendance approved the motion. The meeting adjourned at 2:50 p.m. The next scheduled meeting will be November 9, 2006.