Iowa Medicaid Pharmaceutical and Therapeutics Committee
Minutes

Date: March 8, 2007

Chair: Michael A. Flaum, M.D.

Time: 9:37 a.m. to 2:35 p.m.

Location: Department for the Blind, Des Moines, Iowa

Committee Members Present: Bruce Alexander, R.Ph., Pharm.D., BCPP; Matthew Osterhaus, R.Ph.; 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: Bradley J. Archer, M.D

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

II. The November 9th open session minutes were reviewed. Dr. Carol Frier made the motion to approve the minutes. Hayley Harvey seconded the motion. The motion passed with no objections.

III. Legislation (Susan Parker): Susan Parker said that there was not a lot to update on legislation, specifically which would pertain to the P&T Committee. There is one bill that, as of the day before the meeting, was a Study Bill on Antiepileptic Drugs that would prevent generic substitution for brand name products by pharmacists. Matt Osterhaus asked if there was an update on the Antipsychotic drugs from the legislature. Susan Parker responded by saying no update was available.

IV. PDL (Dr. Clifford): Dr. Clifford reviewed attachment 1, regarding generic utilization rates. He explained how the rates could be calculated differently, depending on the data source (MediSpan vs. First Data Bank). Over time, generic utilization has gone up in the Medicaid population and in the commercial populations as well. Then he asked the committee to look at Report 1. There were just fewer than 5000 PA requests in January, and just under 4000 in February. In January, there were 126 for Anticonvulsants, 237 for Antihistamines, 76 for Insulin, and 1000+ for Proton Pump Inhibitors. There is also a new Nicotine Replacement

category, which providers and recipients are just becoming aware of. Another big category was the RSV prophylaxis, however, this is a seasonal drug and will drop off soon. Dr. Clifford said the numbers will grow substantially quarter to quarter. There was also a lot of activity in the Topical Acne category and the sedative hypnotics class has also emerged as a big Prior Authorization (PA) class based on these data. The average monthly approval rate is 67%, and the average determination time is 1/3 of an hour.

V. PA Criteria/Pro-DUR Edits (Susan Parker): Susan Parker read through attachment 2 which outlined revisions to existing prior authorization criteria recommended by the Drug Utilization Commission. A: Prior authorization is required for incretin mimetics (Byetta®). Payment will be approved under the following conditions: 1) Diagnosis of Type 2 diabetes mellitus, 2) Concurrent therapy with metformin, a sulfonylurea, a thiazolidinedione, a combination of metformin and a sufonylurea, or a combination of metformin and thiazolidinedione. B: Prior authorization is not required for the preferred proton pump inhibitors (PPI) for cumulative 60-days of therapy per 12-month period. Prior authorization will be required for all non-preferred proton pump inhibitors as indicated on the Iowa Medicaid Preferred Drug List beginning the first day of therapy. Payment for a non-preferred proton pump inhibitor will be authorized only for cases in which there is documentation of previous trial and therapy failure with the preferred agent. Prior authorization is required for any PPI usage longer than 60 days or more frequently than one 60-day course per 12-month period. The 12-month period is patient specific and begins 12 months before the requested date of prior authorization. Payment for usage beyond these limits will be authorized for cases in which there is a diagnosis of: 1) Specific Hypersecretory conditions (Zollinger-Ellison syndrome, systemic mastocytosis, multiple endocrine adenomas), 2) Barrett's esophagus, 3) Erosive esophagitis, 4) Symptomatic gastroesophageal reflux after documentation of previous trials and therapy failure with at least one histamine H2-receptor antagonist at full therapeutic doses, or 5) Recurrent peptic ulcer disease after documentation of previous trials and therapy failure with at least one histamine H2-receptor antagonist at full therapeutic doses and with documentation of either failure of Helicobacter pylori treatment or a negative Helicobacter pylori test result. Prior authorization is NOT required for Prevacid granules for oral suspension or SoluTabs for children age 12 years old or younger for the first 60 days of therapy. Prior authorization is required for Prevacid granules for oral suspension and SoluTabs for patients over 12 years of age beginning day one of therapy. Authorization for Prevacid granules for oral suspension and SoluTabs will be considered for those patients who cannot tolerate a solid oral dosage form. C: Prior authorization is required for short acting oral fentanyl products. Payment will be considered only if the diagnosis is for breakthrough cancer pain in opioid tolerant patients, as these products carry a Black Box Warning.

VI. New Drug Review Process (Dr. Clifford): Dr. Clifford went over the current policy regarding how new drugs classes are handled by the P&T Committee (attachment 3), which states: "New drug entities in therapeutic classes not yet reviewed by the P&T Committee will remain payable, in effect preferred by default, until the therapeutic class is discussed. Once this review occurs for the class, the non-preferred default policy will apply to subsequent new drug entries." In attempting to eliminate loopholes for new drugs, he suggested the following: "New drug entities for conditions without any available PDL choices in therapeutic classes not yet reviewed by the P&T Committee will remain payable,

in effect preferred by default, until the therapeutic class is discussed. Once this review occurs for the new therapeutic class, the non-preferred default policy will apply to subsequent new drug entries." Dr. Ruhe commented that this will be a big change. Dr. Flaum agreed that it would be a good idea to leave such products non-preferred until the committee can have a discussion. Sue Purcell said this was what they had intended to do all along. Bruce Alexander pointed out that it would only be a three month timeframe, but Susan Parker said that would actually depend on the timeliness of receiving information from the manufacturer and could possibly be longer than three months. Bruce Alexander moved to accept the proposed policy, Sue Purcell and Dr. Priscilla Ruhe both seconded simultaneously, and the motion passed unanimously. (The RDL will not be affected by this policy change.)

VII. The public speakers were:

SPEAKER	SUBJECT
Mark Johnson, M.D. from Sanofi-Aventis	Lantus
Diana Noller, RN, CDE from Sanofi-Aventis	Lantus
Boris Stevenin, M.D. from Novo Nordisk	Levemir
Robert Calder, M.D. from Merck	Januvia
Jane Feldmann, BSN, RN, CDE from Mercy Medical Center	Lantus
Shannon Johnson, RN, CDE from Iowa Health Systems	Levemir & Lantus
Udaya M. Kabadi, M.D., from University of Iowa Hospitals	Levemir & Lantus

At 10:55, motion to go to closed session was made by Dr. Carole Frier and seconded by Dr. Hayley Harvey. The motion passed with unanimous approval. Open session resumed at 11:56 pm. (All committee members present, with the exception of Dr. Archer.)

VIII. Newly Released Drugs (Dr. Kline): Dr. Kline went through the new drugs on attachment 6. Duetact, Femcon Fe, Fentora, Januvia, Moviprep, Tyzeka, Verdeso Foam, and Xolegel 2% Gel are recommended to be non-preferred on the PDL, as there are other more cost-effective alternatives. The recommendation for Invega followed this same reasoning, though it would be non-recommended on the RDL instead of non-preferred on the PDL. Noxafil is recommended to be non-preferred on the PDL, because other less expensive drugs have wielded more favorable outcomes. Qualanin is recommended to be non-preferred because of its potentially extensive off-label use. Ziana Gel is also recommended to non-preferred, as it should be used only when the individual drugs (clindamycin and tretinoin) fail. Lastly, Zolinza is recommended to be non-recommended. It is not recommended by the manufacturer as a first line therapy option, and there are other more cost effective options available. Matt Osterhaus motioned to accept the recommendations for all 13 newly released drugs. Dr. Ruhe seconded, and the motion passed unanimously.

IX. Newly Released Generics (Dr. Clifford): Dr. Clifford went through the newly released generic drugs and new dosage forms on attachment 7. Colestipol is recommended to be non-preferred, leaving the brand name Colestid preferred as it is more cost effective. Abilify Dismelt is recommended to be non-recommended just like regular Abilify. There would also be an additional cost for the new form. Travatan Z was recommended to be preferred, as it is cost neutral compared to Travatan, which is also preferred. Sue Purcell

motioned to accept these recommendations. That was seconded by Mary Winegardner, and passed unanimously.

At 12:14, the committee took a break for lunch. Open session resumed at 1:17.

X. PDL Discussion and Deliberation (Dr. Clifford): Dr. Clifford went through the drugs listed in attachment 5 but recommended delaying discussion on Ditropan XL, Hepsera, Lantus, and Levemir, until later in the meeting. It is recommended to change the PDL status of Adderall 5mg, 7.5mg,10mg, 12.5mg, 15mg, 20mg and 30mg tablets and Amoxil 875mg tablets to non-preferred because the generics are now more cost effective for the State. Amoxicillin 875mg tablets, Amoxillin/Clavulanate ES 600mg Suspension, and Amoxicillin/Clavulanate 400mg Chewable Tablets were recommended to change to preferred status because they would be more cost effective for the State. Additionally, Amphetamine Salts 5mg, 7.5mg, 10mg, 12.5mg, 15mg, 20mg and 30mg tablets were recommended to change to preferred because of their cost-effectiveness. Atrovent 0.06% Nasal Spray, Augmentin 400mg Chewable Tablets, Augmentin ES 600mg Suspension, and Azulfidine 500mg were recommended to change to non-preferred because the generics are now less expensive than the brands. Bupropion ER 100mg Tablets and Bupropion SR 150mg & 200mg Tablets were recommended to change to preferred because they are more cost effective. Cardec Syrup will be removed from the PDL since this product is no longer manufactured. Cefzil 250mg & 500mg tablets were recommended to change to non-preferred because the generic is now more cost effective. Cesamet will be moved to PDL category Antiemetic – Tetrahydrocannabinol (THC) Derrivatives, but no change in PDL status was recommended. Cleocin-T 1% Gel, Dextrostrat 10mg tablet, and Diflucan 100mg, 150mg, 200mg tablet and 40mg/ml liquid were recommended to change to non-preferred because all of their generics are now less expensive. Lotrisone Lotion, Monopril, Paxil 10mg and 20mg, Prozac 20mg/5mL Solution, and Selsun 2.5% shampoo were recommended to become non-preferred, given that their respective generics have become more cost effective than the brand names. Also, Ultravate 0.05% Ointment, Wellbutrin 75mg tablet, Xylocaine 2% viscous solution, and Zithromax 250mg and 500mg tablets will become non-preferred for this same reason. On the other hand, Clindamycin 1% gel, Clotrimazole/Betamethasone lotion, Fosinapril, Halobetasol 0.05% ointment, Ipratropium 0.06% nasal spray, Lithium Carbonate CR 300mg caps, Ofloxacin 0.3% eye drops, Paroxetine 10mg and 20mg, and Permethrin 5% cream were recommended to become preferred for greater cost effectiveness. Coumadin was recommended to change to non-preferred because the generic is now more cost effective for the State; established users would be grandfathered. Dr. Frier suggested that an informational letter be sent out to providers to make them aware of the generic names for Coumadin. This could also be presented to the DUR Committee. Levonorgestrel and ethinyl estradiol tab 0.10mg-20mcg will become preferred because the brand name products have been unavailable for greater than six months. Marinol will be moved to PDL category Antiemetic – Tetrahydrocannabinol (THC) Derrivatives, with no change in PDL status recommended. Quinine sulfate products will be removed from the PDL in response to the FDA's order to remove these products from the market (F06-195 December 11, 2006). Urised will become preferred because the generics are unavailable. Matt Osterhaus made a motion to accept all of the above changes to the PDL adding in a ninety-day allowance from the date of

notification for the brands to remain preferred for pharmacy convenience. Dr. Hayley Harvey seconded, and it passed with unanimous approval.

XI. Ditropan XL: There was some concern from universities about children dealing with the side effects of the preferred drugs in this class, none of which are approved for children. Therefore, it was recommended that Ditropan XL be preferred for children 12 years of age or younger. This will be an edit on the POS system. Dr. Flaum motioned for this change to be accepted. Dr. Ruhe seconded, and it passed with no objections.

XII. Hepsera: It is recommended to change the PDL status of Hepsera to non-preferred because of the addition of new drug in this PDL category, Tyzeka. Hepsera would become a second line therapy, as there are three other Hepatitis B drugs with similar efficacies that are more cost effective. Iowa currently has six Hepsera patients, who would be grandfathered. Mary Winegardner motioned to accept the proposed change to Hepsera status. Dr. Ruhe seconded, and it passed unanimously.

XIII. Lantus and Levemir: There was a lengthy discussion with updated data analysis from Dr. Clifford. First, he reviewed the statistics on the marketshare report, and then went over the prior authorization statistics in Report 1. For the month of January 2007, there were 76 total PA requests for Insulin and Insulin Penfills, and 85% of those were for Lantus. From July 1, 2006 to January 1, 2007, there were a total of 479 Insulin PA Requests, and 75% of them were for Lantus. Fifty percent (50%) of those Lantus PA requests were approved. Then Dr. Clifford reviewed Report 3, which included Iowa's (along with Maine's) Levemir and Lantus utilization data. The data for Lantus went all the way back to 2001. In 2006, the units were split pretty evenly between the two drugs, with essentially the same average dose. The data tells a much different story than the public speakers' anecdotes. The problem of the State losing money for patients going to a higher dose has not occurred according to these utilization data. GHS/SSDC hopes to make this into a two-preferred-drug-class with future negotiations. Mary Winegardner and Matt Osterhaus said that while some patients respond better to Lantus, there are others that do better with Levemir. They agreed that the two-drug class option would be a good move. Bruce Alexander disagreed, saying that it made sense to make one drug preferred if that was most cost effective for the State. He thinks the Committee should wait until the numbers are more optimal. Dr. Frier pointed out that Levemir users have fewer hypoglycemic events. Dr. Clifford thinks that there are enough individual variations to justify a two-drug class, and that the State would be better off in doing so. Dr. Clifford recommended a motion to say that the committee prefers a two-drug class, but Dr. Flaum was not convinced there were significant differences between the two drugs. Mary Winegarder interjected that some recipients' glucose levels going up and down would say otherwise. Dr. Clifford suggests watching how well the preferred drug (Levemir) holds its marketshare, to make sure that the State is not paying a large amount on the non-preferred drug (Lantus). In the end, the committee decided they would have a better bargaining position if they did not make a formal motion. No motion was made.

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 2:35 p.m. The next scheduled meeting will be June 14, 2007.