P&T Committee
Minutes

Date: June 2, 2005

Chair: Michael Flaum, M.D.

Time: 9:30 a.m. to 12:41 p.m.

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

Committee Members Present: Bradley J. Archer, M.D.; Cheryl Clarke, R.Ph., CDM; Michael A. Flaum, M.D.; Carole A. Frier, D.O.; Susan Purcell, R.Ph, CGP; Priscilla Ruhe, M.D.; and Mary Winegardner, PA-C, MPAS

Committee Members Absent: William R. Doucette, Ph.D.; Hayley L. Harvey, DDS, MS

Iowa DHS Staff Present: Susan Parker, Pharm.D., DHS Pharmacy Consultant

Iowa DHS Staff Absent: Daniel W. Hart, Attorney General's Office

IME Staff Present: Thomas Kline, D.O., Iowa Medicaid Medical Director; Tim Clifford, M.D.; John Grotton, R.Ph.; Sandy Pranger, R.Ph.; and Julie Bueno, R.Ph.

Dr. Flaum called the meeting to order.

I. Dr. Flaum asked that committee members introduce themselves. Although Dr. Doucette and Dr. Harvey were not in attendance, a quorum was present. Daniel Hart was also noted as being absent.

II. Dr. Flaum reminded everyone of housekeeping rules (clean up after the meeting and cell phones off or on silent mode).

III. Dr. Flaum asked DHS and IME staff to introduce themselves.

IV. The minutes from the March 3 open session were reviewed. Cheryl Clarke made the motion to approve the minutes. Dr. Frier seconded the motion. All committee members approved with none opposing or abstaining.

V. The minutes from the April 29 teleconference were reviewed. Cheryl Clarke made a motion to approve the teleconference minutes. Susan Purcell seconded the motion. All committee members approved with none opposing or abstaining.

VI. Dr. Clifford went through the four sections of the new drug review process, which includes Therapeutic Classes of Drugs Already Reviewed by the P&T Committee, Therapeutic Classes of Drugs not Reviewed by the P&T Committee, Exceptions

to the Non-Preferred Default Policy for New PDL Drugs, and Existing PDL Drugs.

VII. There were three public comment speakers. The first speaker was Jacqueline Travis, Pharm.D. with Roche Laboratories, who spoke about Boniva and osteoporosis. The second speaker was Henry L. Masters, III, M.D. with Boehringer Inglehiem Pharmaceuticals, who spoke about Viramune and HIV/Aids. The third speaker was Ken Thompson, Pharm.D. with Bristol-Myers Squibb Company, who spoke about Erbitux (Cetuximab).

VIII. Dr. Kline reviewed the 21 newly released drugs, which are Aldurazyme as a preferred drug, Alimta as a recommended drug, Apokyn as a preferred drug, Avastin as a recommended drug, Bexxar as a recommended drug, Boniva as a non-preferred drug, Camptosar as a recommended drug, Combunox as a non-preferred drug, Epzicom as a recommended drug, Erbitux as a recommended drug, Fabrazyme as a preferred drug, Gliadel as a recommended drug, Lantus OptiClik Insulin Pen System as a preferred drug, Neutrexin as a recommended drug, Tarceva as a recommended drug, Teslac as a recommended drug, TrelstarDepot/Trelstar LA as a recommended drug, Tev-Tropin as a preferred drug, Truvada as a recommended drug, Velcade as a recommended drug, and Vidaza as a recommended drug.

IX. Before Dr. Clifford began his review of the statistical reports, he told the Committee that the format of the reports would change for the next meeting as Federal and supplemental rebates will be incorporated into these reports, and that today the Committee was looking at the first level rebate, which shows only part of what the PDL does. Dr. Clifford reviewed the reports titled Iowa Paid Non-Reversed Claims With Prescription Fill Dates from January 1, 2004 through May 20, 2005; Iowa Average Pre-Rebate Paid Amount Per Claim; and Pre-Rebate Stats on Iowa Paid Non-Reversed Claims. The next Committee meeting will show the statistical reports with RDL categories broken out and part of the PDL, as well as a trend line on those so that the DUR and the State can use that information for more clinical PAs. Dr. Flaum asked what the Committee should read into the trend line report for 2004. Dr. Clifford said that one should look at what other interventions the State is applying in terms of reimbursement rate changes of a pharmacy, if the State is doing an unusually large amount of generic MACs in one time period compared to what they have historically done, and also what is occurring with eligibility in the State. Dr. Frier asked for a clarification on whether the first quarter of 2005 % Change numbers on the pre-rebate report was compared to prior quarter or to the first quarter of 2004. Dr. Clifford responded that it was the prior quarter.

X. Dr. Clifford began the review of the PA reports. He mentioned that at the next meeting there will be reports that have the RDL categories broken down separately and also the PDL categories will be broken down separately where there were not any other clinical choices, along with a trend line of those

categories. Dr Clifford reviewed the PA Aging Report for July 1, 2004, through May 14, 2005, which is a weekly report. Dr. Clifford calculated that the average is 105,000 PAs for the calendar year, which is less than what was originally projected. Mary Winegardner asked if the time determined included the time of incompletes to group. Dr. Clifford responded that, until the prior authorizations have been processed, all of the prior authorizations including incomplete prior authorizations are built into these determination claims. Dr. Clifford then reviewed the report of PA Statistics Report by PDL Category for Quarter 1 of 2005. Cheryl Clarke commented that this report does not have Admin Closed data, to which Dr. Clifford responded that some things are not drug related. The Committee then held a brief discussion about the numbers shown in the Admin Closed column in the first report. It was pointed out that some of those numbers are not true PAs (i.e., DUR override requests have to close out). The next report reviewed by Dr. Clifford was the PA Statistics Report by PDL Category with YTD Totals for April 2005.

XI. Dr. Flaum made a motion to enter a closed session and Mary Winegardner seconded the motion. A roll call vote was taken and all were in favor.

The meeting resumed at 11:23 a.m. During the closed session, Dr. Archer was called away from the P&T Committee meeting. A quorum was still present.

XII. The Committee discussed the newly released drugs, particularly Boniva. Cheryl Clarke made a motion to accept the new drugs review recommendations. Susan Purcell seconded the motion. All committee members were in favor with none opposing or abstaining.

XIII. Dr. Clifford reviewed the RDL category report titled DUR Referrals for June Meeting as of 05/31/2005, Attachment 2. Dr. Clifford highlighted some of his recommendations that included the drug name Advate as being non-recommended in the Antihemophilic Agents category where all others in this category are being recommended, and in the Antineoplastics categories Arimidex, Roferon and Actimmune are also all recommended, and in the Antiretrovirals category Fuzeon is recommended. Dr. Frier made a motion to accept the RDL categories as is. Cheryl Clarke added to the Dr. Frier's motion a reminder in the last meeting when the Committee talked about recommended and non-recommended that it was suggested that if there ever was a time that the recommended would be converted to a preferred list that it should be brought back before the Committee. Susan Purcell seconded the motion. All were in favor with none opposing or abstaining.

XIV. Dr. Clifford reviewed the report entitled DUR Referrals for June Meeting as of 05/31/2005, Attachment 3. Highlighted recommendations included the following: Cerezyme as recommended, Denser as non-recommended, Carnitor as recommended, Xyrem as recommended, Dostinex as recommended, Acthar as recommended, Orfadin as recommended, and Hectorol Caps as recommended. Dr. Flaum inquired about the status on Diagnostic Biologicals. Dr. Clifford said

that the drug Apisol was the most cost effective form and Tubersol was more expensive, and that both were equivalent products. Dr. Ruhe made a motion to accept this list and Susan Purcell seconded the motion. All were in favor with none opposing or abstaining.

XV. The Committee discussed various issues. One area of discussion was how to handle the duragesic issue on the prior authorization side. Dr. Frier brought up a concern relating to a number of public comment letters that ask why the prior authorization process is so time consuming, and gave an example of how it is time consuming for providers to find out what drugs are preferred after having a prior authorization denied. Dr. Frier asked if a list of preferred drugs could be included in the denial notice as alternatives to the drug denied. John Grotton said that would be difficult to do from a programming standpoint, but that it would be looked into.

XVI. Dr. Flaum asked Susan Parker if there was anything that the P&T Committee has to do as a result of recent legislation. Susan Parker replied that there were a couple of new pieces of legislation pertaining to the P&T Committee. One change is in reference to co-payment effective July 1st, 2005, which says that potentially all drugs are $1 co-pay except for non-preferred brand drugs, and that non-preferred brand products that would cost the state between $25 to $50 would have a $2 co-pay, and then the non-preferred brand that would cost greater than $50 to the state would be $3. Another change that pertains to the P&T Committee is reflected in the Appropriation Bill (House File 825). The following excerpt was read by Susan Parker to the Committee which is from the original bill, not yet signed by the Governor:

> "The medical assistance pharmaceutical and therapeutics committee established pursuant to section 249A.20A shall develop options for increasing the savings relative to psychotropic drugs, while maintaining patient care quality. This subsection shall not be construed to amend, modify, or repeal the exception provided pursuant to section 249A.20A relating to drugs prescribed for mental illness. The committee shall submit a report of any options the committee recommends to the general assembly by January 1, 2006. Any options developed or recommended shall not be implemented without an affirmative action enacted by the general assembly."

Susan also read six excerpts of amendments for House File 825:

> "… the pharmaceutical and therapeutics committee shall respond to all inquiries regarding the process at least 72 hours prior to a meeting of the committee to consider inclusion of the product."

> "The rules shall require that this committee provide a pharmaceutical manufacturer of a product with 20 days' prior written notice of consideration of the manufacturer's product for inclusion on the preferred drug list to allow adequate time for preparation of appropriate materials to be submitted to the committee for review."
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> "The rules shall also require that adequate time be provided for each interested individual to address the committee regarding a product to be considered for inclusion on the preferred drug list…"
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> "A final decision regarding inclusion of a product on the preferred drug list shall not be made in executive session…"
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> "The department shall expand coverage under the medical assistance program to cover smoking cessation drugs."
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> "The department shall expand coverage under the medical assistance program to cover weight reduction treatments and drugs."

After a short discussion, it was determined by the Committee that a sub-committee needs to be formed that would draft a report to present to the Committee at their December meeting. Dr. Flaum and Susan Purcell volunteered to be a part of this sub-committee. Susan Parker said that she would discuss with the Attorney General's Office the chance of broadening the number of people to obtain opinions. Dr. Flaum made a motion to form a sub-committee to generate a report that looks at alternative cost-saving mental health drugs to submit to the Assembly by end of this calendar year. Dr. Ruhe seconded the motion. All were in favor with none opposing or abstaining. Dr. Clifford commented that Maine is forming an ad hoc committee comprised of three P&T members and six to seven psychiatrists and others, and that he would be willing to provide anything that would be of help to this Committee in developing a sub-committee. Cheryl Clarke said that the DUR Commission is also doing additional things like this.

XVII. Dr. Flaum notified the Committee that this meeting would be the last for Cheryl Clarke and Dr. Doucette.

XVIII. Cheryl Clarke made a motion for the meeting to be adjourned and Dr. Flaum seconded it. All were in favor with none opposing or abstaining.

The meeting adjourned at 12:41 p.m. The next scheduled meeting will be Thursday, September 1, 2005, in Capitol Building Senate Room 116 in Des Moines, Iowa.