**P&T Committee**
**Minutes**

**Date:** March 3, 2005

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

**Time:** 9:35 a.m. to 4:10 p.m.

**Location:** Clive Aquatic Center Meeting Room, Clive, Iowa

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

**Committee Members Absent**: William R. Doucette, Ph.D.

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

**IME Staff Present:** Tim Clifford, M.D.; John Grotton, R.Ph.; Sandy Pranger, R.Ph.; and Julie Bueno, R.Ph.

**IME Staff Absent**: Thomas Kline, D.O., Iowa Medicaid Medical Director; and Andi Dykstra, R.N., CPHQ

Dr. Flaum called the meeting to order. There were six Committee members present at this time, so a quorum was present. (Dr. Ruhe and Dr. Harvey came in shortly after.)

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

II. The minutes from December 2 open session were reviewed. Cheryl Clarke commented under IX on page 2 that the word "Fluoxetine" should be replaced with "Paroxetine" which is the generic for Paxil. Susan Purcell made the motion to approve the minutes with the change. Dr. Frier seconded the motion. All committee members were in favor with none opposing or abstaining.

III. Dr. Clifford gave an update on the PDL. The PA volume was mildly less than anticipated, which is a very good sign, due to the fact that there was time beforehand to become aware of the PDL and to have an override available in the first 30 days at the pharmacy to allow additional time to get prior authorizations submitted.

IV. Dr. Clifford reviewed the report containing the daily prior authorization (PA) statistics since January 15, 2005. The prior authorizations are going back up now

because the 30-day overrides have been used up. These statistics will be looked at on a weekly/monthly basis. The prior authorization unit can use those ongoing statistics to see where some of the resources have to be directed in terms of dealing with the physicians. Cheryl Clarke asked Dr. Clifford if these are PAs that are not related to the PDL. Dr. Clifford said that these statistics are for all PAs. Cheryl Clarke asked about the number of PA requests per day and Sandy Pranger replied that it was 250. Cheryl Clarke then asked about the amount of 30-day overrides, to which Dr. Clifford replied that although he did not include an exact count it was tens of thousands and that the February 15 overrides should be used up. Susan Purcell commented that the PA group has been extremely helpful and have done very well. Dr. Clifford mentioned that the physicians and pharmacists in Iowa are much more cooperative than in Maine and that is why it has gone so smoothly at this point.

V. Dr. Clifford reviewed the report on pre-rebate statistics on Iowa paid non-reversed claims. Dr. Clifford stated that over time practically all of these drugs show upward movement because of price increases, but in this time frame this is not much of a factor. In categories where there is a large amount of script volume, this data is accurate. This report shows where CMS rebates or the supplemental rebates are going to have an important effect on the net cost in those categories. In looking at the Ace Inhibitors and CA Channel Blockers, a deal was taken on those products so the savings there will counteract whatever price increase occurs at the store level because of the rebates. In looking at the Acne Products: Isotretinoin and the Accutane, the real savings in this category is the net savings after disproportionately large rebates have been collected. For this point in time, this is the type of scorecard that will be used to see what is going on. However, this is not final as after the first quarter of 2005 has ended, it will be a wait of about six weeks to get rebate tapes (rebate data) from the Federal government who collects this from the manufacturers and then passes on to the states. This data is used along with what is in the database for accepted supplemental rebate offers and then invoices are given to the State to send to the manufacturers. It is at this point that the books can be closed on the first quarter of 2005. In other words, the books on the first quarter will not be final until the end of May, so the Committee will be able to see the final figures at the June meeting. Dr. Clifford said that the good news with the PDL is that it is expected there will be a savings in money in all categories at this time, with some examples being GI proton pump inhibitors and muscle relaxants.

VI. Dr. Clifford reviewed the non-reversed claims report, which looks at the aggregate savings with the PDL in place. In looking at the chart, it is not always linear in progression but it is generally every three months higher than before. So the increase from month one through month twelve is about a 9% script increase over the course of the year. The average paid per claims numbers are good in the six cycles since the PDL went into effect on January 15.

VII. Dr. Clifford reviewed the report on the top 50 drugs by PA volume, which shows the number of PA requests submitted and approved. At the June meeting these numbers be different because some of these drugs will continue to be affected by prior authorizations because it is a clinical necessity issue whereas other drugs are a one-time issue. The approval percentage is a little misleading because during the first month there were a lot of incompletes so the PA department had to work with the physicians to get all the necessary information.

VIII. There were 13 public speakers: Ketul Patel, PharmD, with VESIcare on the subject of key features on VESIcare and overactive bladders; Dr. Gilbert Honigfeld with Alamo Pharmaceuticals who spoke about the drug Fazaclo; Dr. Louis Gerbino with Broadlawns Hospital who spoke about the drug Fazaclo; John Neiwoehner, PharmD, with Sepracor who spoke about the drug Lunesta (eszopiclone); Andrew Shim with Novartis Pharmaceuticals who spoke about the drug Enablex; Hoa Pham, an employee of Amgen, who spoke about the drug Sensipar; Dr. Craig Shadur, a practicing nephrologist, who spoke about the drug Sensipar; Gregory Burton, Ph.D., with Abbott Laboratories who spoke about the drug Zemplar (paricalcitol injection); Shelley Raebel with Purdue Pharmaceuticals who spoke about the drug Palladone; Steven Woods, PharmD, with Shire US who spoke about the drug Fosrenol; and Glenn Hanson, consumer and with CROP, Inc., who spoke about various issues.

IX. Dr. Flaum made a motion to take a ten-minute break and Dr. Harvey seconded it.

The meeting resumed at 10:13 a.m.

X. Dr. Flaum motioned to go to closed session as authorized by Section 21.5(1)(a) of the Open Meetings Law to review or discuss economic records associated with the PDL which are required or authorized to be kept confidential. Mary Winegardner seconded the motion. A roll call was taken.

Open session reconvened at 11:50 a.m.

XI. Dr. Clifford told the Committee that in the first six weeks (November to December) the supplemental invoices are going to the manufacturers of supplemental rebates will total about $1.4 million. It is expected that for the first quarter of 2005 that the supplemental rebates invoice will be in the range of $3 million to $3.5 million. It will be more than double in six weeks because by that time there will be more people on the preferred products.

XII. Dr. Clifford said that contracts were due at the end of December. A number of contracts have not been received. The practical ramifications from the State's point of view in looking out for its own best interest is that in some of the categories of the PDL, including some of them being reviewed today, is still open to changing PDL categories.

XIII. Dr. Clifford reviewed the newly released drugs, beginning with Amevive. There is a contract with a preferred biological. This category would be considered a closed category due to the conditions specified in the contract. The preferred drugs that are available are effective, have good side effect profiles, and are well tolerated. Due to the supplemental rebate available, especially in the biological Enbrel, there is significant savings accrued by the State. The recommendation would be that it be treated like the other anti-psoriatic biological Raptiva and be considered a non-preferred. The criteria would be that generally if the patient has met the criteria for receiving a biological anti-psoriatic, then the current biological would be Enbrel, as per contract, and if Enbrel fails to bring the psoriasis under control, then they would be specifically eligible for a prior authorization approval for a different biological product. The Committee had no comments on Amevive. Dr. Ruhe made the motion to place Amevive as non-preferred. Dr. Harvey seconded the motion. All were in favor with none opposing or abstaining.

XIV. Dr. Clifford reviewed the newly released drugs Sanctura, Enablex, and Vesicare. There are two preferred products available in the long-acting Antispasmodic category – Detrol LA and Ditropan XL. There is one executed contract on Detrol LA. These drugs are clinically comparable and do not vary significantly in overall side effect profiles. They can differ in individual side effects but if they are good in something, they are bad in something else. For example, in the dry mouth side effect, the established rates are as follows: Detrol LA is 23%, Ditropan XL is 50%, Enablex is 20%, Sanctura is 20%, and Vesicare is 20%. Ditropan XL stands out as being worse than the others in terms of dry mouth. In looking at the side effect of constipation Detrol LA is 6%, Ditropan XL is 13%, Enablex is 15%, Sanctura is 10%, and Vesicare is 7%. Regardless of what side effect is looked at, one drug will be the best and one will be the worst. These medications are all similarly effective. From Dr. Clifford's point of view, the drug category is overpriced in terms of how much it costs per day and considering how much relief is obtained, but the good thing about this category is that the competition that is available will drive down the pricing in the category. Since there is no signed contract on the Ditropan XL right now, Dr. Clifford believes it would be possible to consider adding one of these drugs to the preferred drug list and that the best choice at this point to consider adding would be Vesicare. Vesicare has made a substantial supplement rebate offer. In terms of what would happen with Ditropan XL, trying to renegotiate the terms would be looked at. If contracts are not received on a timely basis, then the State needs to make adjustments as necessary in making sure that there are good choices available. The Committee had no comments on these three drugs. Dr. Harvey made a motion to add Vesicare to the PDL and to keep Sanctura and Enablex as non-preferred. Mary Winegardner seconded the motion. All were in favor with none opposing or abstaining.

XV. Dr. Clifford reviewed the newly released drug Factive. The preferred products Arelox and Levaquin provide the same coverage against organisms that cause chronic bronchitis and pneumonia as the Factive does. Factive is very expensive

and there is a huge price differential between a 7-day course of Factive and that of Avelox or Levaaquin. Dr. Clifford recommended making Factive non-preferred. The Committee had no comments on Factive. Cheryl Clarke made the motion to place Factive on the list as non-preferred. Dr. Ruhe seconded the motion. All were in favor with none opposing or abstaining.

XVI. Dr. Clifford reviewed the newly released drug Fosrenol. In terms of how this is used, it is sub-categorized with phosphate binders so it is being compared with Renagel and PhosLo, which are both preferred. Both Renagel and PhosLo are under contract, and the contracts have been signed and executed. There is always additional room for control over the phospherus levels. There is an issue with having to take multiple medications per day and that is a consideration in taking a look at this medication. When looking at the equivalent doses of what would be needed for Renagel and PhosLo to obtain the same results as Fosrenol, there is a very substantial cost difference – up to a double-digit difference in terms of percentages. An initial supplemental rebate offer has been received, so the State will be willing to consider other offers. Dr. Clifford recommended making this a non-preferred drug. Mary Winegardner questioned Dr. Clifford on his recommendation that the Committee take action now despite future negotiations and Dr. Clifford responded that the Committee take action today and if there was still room to act on an improved offer in the future then the Committee will be able to change its mind at that point. Mary Winegardner made a motion to put Fosrenol on the list as non-preferred. Cheryl Clarke seconded the motion. All were in favor with none opposing or abstaining.

XVII. Dr. Clifford reviewed the newly released drug Lunesta. The comparable product Ambien (preferred) is under contract, however, there is a huge difference in cost between where Ambien is right now and Lunesta is estimated to be without any supplemental rebate offer. Dr. Clifford believes that from a clinical point of view, there will be some advantages with this medication compared to the others, but a lot of the non-preferred drugs are best reserved for people that fail under the preferred choices and because of the huge cost difference, this is where Lunesta is lined up at this point. A discussion ensued about Ambien being preferred but limited to a quantity of 15 per month. Susan Parker told the Committee that this was under review by the DUR. Susan Purcell made a motion to put Lunesta on the PDL as non-preferred. Dr. Ruhe seconded the motion. All were in favor with none opposing or abstaining.

XVIII. Dr. Clifford reviewed the newly released drug Palladone. As part of the cost comparison, there was a substantial difference with allowing people to go from the shorter-acting type of Palladone as to going to the long-acting there is a huge cost premium and also there are a number of preferred long-acting narcotics available from different chemical classes within the category and the equi-analgesic doses are available at a substantial savings to the State compared to Palladone. Dr. Clifford recommended that, from a clinical point of view, this is a very small niche product and should be non-preferred. The Committee held a

discussion. Cheryl Clarke made a motion to put Palladone on the list as non-preferred. Susan Purcell seconded the motion. All were in favor except Mary Winegardner and Dr. Archer, who opposed. The motion passed.

XIX. Dr. Clifford reviewed the newly released drug Sensipar. This drug attracted a lot of comments on the website. The drug is quite expensive but is a good medication. Some people do obtain control with calcium phosphorus using the product with calcitriol and with the phosphate binders. When that occurs, it occurs in a very cost effective manner to the State. It is probable that a good number of these people aren't going to take control and will need to graduate up to Sensipar. The Veterans Administration (VA), who has a lot of people on dialysis, is closely watched to see what they're doing with Sensipar. Sensipar does require prior authorization at the VA and their criteria makes as much sense as others and is similar to others. The VA has set up exlcusion criteria in that it shouldn't be used if serum calcium levels are less than at 8.4. The VA deals with diagnoses saying that Sensipar should be for secondary hyperparathyroidism in a patient with chronic kidney disease on dialysis or parathyroid carcinoma with surgery not an option. Dr. Clifford believes that in terms of parathyroid cancer that people can have an extremely easy accrual on the medication, and that the only rationale way of controlling utilization at this point in trying to minimize the financial impact on the State would be to have Sensipar be non-preferred and that people should have an elevated PTH level and they should have failed maximum tolerated doses of the preferred vitamin D or phosphate binder products. The PA impact can be minimized several months down the road. After July 1 the pharmacy claims processing system will be taken over from the current fiscal agent and at that point programming could be created that would online recognize therapeutic doses of vitamin D, therapeutic doses of the phosphate binders, and if both conditions are met to allow the script to pass through without requiring prior authorization. It would cut down the PA volume and the criteria are very well lineated and fairly consistent across the various PDMs and other types of medical organizations that look at this drug. Dr. Clifford recommended to the Committee to make Sensipar non-preferred to require prior authorization to see that the criteria has been met regarding therapeutic trials of the preferred products, but then over the course of the summer to have programming in place to recognize when the conditions have been met and go ahead and reduce the final authorization burden at that point. Dr. Clifford suggested adopting criteria consistent with the VA criteria and that if the PA unit uses the same criteria as the VA, the majority of people that should be encouraged to obtain better control with go ahead and get Sensipar. This is the only mechanism available to try to ensure that the people that can be controlled without Sensipar are controlled without Sensipar. The Committee questioned Dr. Clifford further and then held a discussion. Mary Winegardner made a motion to add Sensipar to the list as non-preferred. Dr. Hayley seconded the motion. All were in favor except Cheryl Clarke who abstained.

XX. Dr. Clifford reviewed the newly released drug Somavert. There is a substantial price difference in that it is 10 to 20 times more expensive in relationship to other medical therapies and not including the non-medical therapies that are potentially available. In this particular class, Bromocriptine can be a difficult medication to tolerate; where the Dostinex is more probable and is easier to be utilized so many people would be better with the Dostinex than the Bromocriptine. Dr. Clifford recommended to the Committee Somavert would be a non-preferred drug based on failure or not being able to tolerate the preferred products. The Committee had no comments on Somavert. Susan Purcell made a motion to add Somavert to the list as non-preferred. Dr. Ruhe seconded the motion. All were in favor with none opposing or abstaining.

XXI. Dr. Clifford reviewed the newly released drug Tysabri, which is works in an entirely different manner. The company has suspended this product since there are two recorded cases of progressive multifocal leukoencephalopathy (PML) where one of the patients has died. Both cases occurred during concomitant Avonex use. Dr. Clifford recommended to the Committee, even if this product stays on the market and on the PDL, to make Tysabri a non-preferred medication. Dr. Frier made a motion to add Tysabri to the list as non-preferred. Cheryl Clarke seconded the motion. All were in favor with none opposing or abstaining.

XXII. Dr. Clifford reviewed the newly released drug Xifaxan. Quinolone is available, one of them being generic and very inexpensive. This is a second line agent for when there is quinolone failure or in younger age groups potentially quinolone contraindications. It has not been proven to be more effective than the preferred drugs available but it does have a niche group that it could be used for. The cost difference is substantial. Dr. Clifford recommended to the Committee making Xifaxan non-preferred but that specifically it would not necessarily require failure on a preferred drug. If someone in a younger age group couldn't be put on quinolone, it would be legitimate. But there is some dissent among physicians as to switch to other antibiotics that are also suitable for treatment of travelers diarrhea, it depends on the resistance rates in the area, but some physicians would use Bactrim that is an option for the younger age groups. The Committee had no comments on Xifaxan. Dr. Ruhe made a motion to add Xifaxan to the list as preferred. Dr. Archer seconded the motion. All were in favor with none opposing or abstaining.

XXIII. Dr. Clifford reviewed the newly released drug Xigris, which is a unique drug for inpatient treatment of sepsis/septic shock. Dr. Clifford recommended to the Committee to make Xigris preferred. The Committee had no comments on Xigris. Dr. Archer made the motion to add Xigris to the list as preferred. Dr. Ruhe seconded the motion. All were in favor with none opposing or abstaining.

XXIV. Dr. Clifford reviewed the newly released drug Zemplar. Right now physicians can order and administer the drug at their offices, so for the most part people are not getting this at the pharmacy. If this was not the case and assuming that the

Medicaid Program was able to exert some control over Zemplar in relationship to the other drugs, it is different in terms of who might respond as opposed to taking Sensipar. As with Sensipar, a good number of people can be brought under control that would not be able to obtain control with the oral calcitriol products with phosphate binders available. This is second line as Sensipar would be and also, like Sensipar, is very costly as there is no supplemental rebate offer right now on the product. From a clinical point of view, the only concern with the Zemplar is that sometimes especially when the drug is initiated it can have a fairly dramatic effect on calcium, so there really should be an expert supervising the usage because the drug is potentially dangerous in a fairly short period of time. The outpatient utilization is practically none because people have access to this through J codes billing and also because a certain part of the amount referred is probably already migrated over to use Sensipar. Although there is a cost difference between Zemplar and Sensipar, Zemplar should be used after Sensipar but from a practical point of view it would not make much of a difference if the Zemplar were treated similar to the Sensipar. The Committee had no comments on Zemplar. Dr. Frier made a motion to add Zemplar to the list as non-preferred. Susan Purcell seconded the motion. All were in favor with none opposing or abstaining.

XXV. The Committee ended the morning session at 12:45 p.m. and took a lunch break.

Open session reconvened at 2:00 p.m.

XXVI. Dr. Flaum asked Eileen Creager to introduce herself as she had arrived later.

XXVII. Dr. Clifford reviewed the new generic drug Citalopram. At this moment the AWPs of the most commonly utilized labelers providing Citalopram result in a net price of a generic that's still above where the rebate brand is, which shouldn't last long. The next time Myers & Stauffer looks at this drug, it will most likely have a MAC put in place and then it will become preferred. Dr. Flaum commented that Celexa is currently recommended so that if a generic becomes available, one or the other or both can be put on the preferred list. Dr. Clifford responded that Celexa would be temporarily still preferred and Citalopram would be non-preferred, and it would not require a meeting but as soon as the MAC hits the generic then it will allow the access to the generic. The Committee held a discussion. Cheryl Clarke made a motion to defer this discussion until the next P&T Committee meeting and to keep things the way they are. Dr. Flaum seconded the motion. All were in favor with none opposing or abstaining.

XXVIII. Dr. Clifford talked about the atypical anti-psychotics, referring the Committee to the chart on paid non-reversed claims with fill dates in calendar year 2004. During this calendar year, $63.6 million was spent on these six atypicals: Risperdal, Clozapine, Seroquel, Zyprexa, Abilify, and Geodon. Out of the entire drug budget, that is 16.3%, which is large as most Medicaid programs run 10% to 12% of their drug budget for atypicals. Being outside the PDL right now, when

you bring the cost under control in the other categories over the course of the year what is going to happen is the atypicals remain relatively untouched and this 16% is going to look more like 20%. This category is going to become more and more of a dominating effect over the entire drug budget. In these particular drugs that represent the $63 million, Risperdal represents about 25%, Zyprexa represents 25%, Seroquel represents 21%, Abilify represents just under 14%, Clozapine represents just under 9%, and Geodon represents just under 6%. Although there were some minor changes that would be considered the most expensive, it was overall fairly consistent. Risperdal is the least expensive over time whether looking at per claim, per day supply, or per user. The data for Clozapine was normalized. Clozapine has the highest persistence rates in terms of people continually taking medication and taking it for the greatest number of days a year. Clozapine would have an annual cost to Medicaid of $4,300 per user for the year. The next highest would be Abilify at $4,200 per year, then Zyprexa at $4,100 per year, then Geodon at $3,000 per year, then Seroquel at $2,600, and then Risperdal at $2,400 per year. These annual costs are based on how the doctors use it across the population. The percentage differences hold up even if the rebates are probably not applied. At this point, Dr. Clifford explained the chart in more detail to the Committee, and then a discussion ensued about Clozapine being difficult to classify. Dr. Clifford said that as shown on the chart as currently selected by physicians right now Risperdal evidently works for just about 80% of the people. It's a very solid atypical. Seroquel is very popular as a second atypical and it is very popular in a low dose as low dose augmentation is seen a lot, which is why their numbers are so high relative to the other atypicals. Because there is a lot of off-labeled use as a sleeper agent, that is one of the factors in addition to augmentation in low dose that probably skews the Seroquel cost data down lower than it really would be if talking head-to-head with schizophrenic type doses. The Committee held a discussion at this point. Dr. Flaum made a motion that Risperdal, Seroquel, and Abilify become recommended, and Zyprexa and Geodon become non-recommended, however, he invited further discussion from the Committee. The Committee held a discussion. Dr. Flaum amended his motion to make Risperdal, Seroquel and Geodon recommended drugs, and to make Abilify and Zyprexa non-recommended drugs. Cheryl Clarke added to the motion that before the RDL would be converted to the PDL that the Committee takes a look at this again later. Dr. Ruhe seconded the motion. All were in favor with none opposing or abstaining.

XXIX. The Committee discussed other dosage forms of anti-psychotics: atypicals. Dr. Clifford recommended that the annual cost be the same. Dr. Flaum made the motion that Zyprexa Zydis, Risperdal M-tab, and Risperdal Consta be made non-recommended. Cheryl Clarke seconded the motion. All were in favor with none opposing or abstaining.

XXX. The Committee discussed Compazine in the category of anti-psychotics: typicals. Dr. Flaum made a motion to move generic and brand Compazine over to the anti-

histamine and make Compazine non-preferred and its generic preferred. Dr. Ruhe seconded the motion. All were in favor with none opposing or abstaining.

XXXI. Dr. Flaum made a motion to approve the rest of the typicals as recommended except for Moban, which will be non-recommended. Cheryl Clarke seconded the motion. All were in favor with none opposing or abstaining.

XXXII. The Committee reviewed special atypicals. Dr. Flaum made a motion to make Clozapine and Fazaclo recommended and Clozaril non-recommended. Mary Winegardner seconded the motion. All were in favor with none opposing or abstaining.

XXXIII. The Committee talked about Topamax. Dr. Clifford recommended that internally the PA unit allow access to Topamax for seizure patients.

XXXIV. Dr. Clifford explained the chart titled "Pre-rebate Stats – Maine vs. Iowa – Paid Non-reversed Claims with Rx Dates in CY2004."

XXXV. Dr. Flaum motioned to go to closed session as authorized by Section 21.5(1)(a) of the Open Meetings Law to review or discuss economic records associated with the PDL which are required or authorized to be kept confidential. Cheryl Clarke seconded the motion. A roll call was taken.

Open session reconvened at 4:00 p.m.

XXXVI. The Committee talked about temporarily making products preferred before the next meeting. Dr. Clifford suggested that the Committee not take a vote at this time, but to consider putting a draft recommendation on the website saying that the draft recommendation is to make the drug preferred, and the supplemental rebate be taken, and then the Committee can vote on this at the next meeting.

The meeting adjourned at 4:10 p.m. The next scheduled meeting will be June 2, 2005, in Room 116 at the Iowa State Capitol Building.