**Iowa Medicaid Pharmaceutical and Therapeutics Committee**
**Minutes**

**Date:** September 9, 2010

**Chairperson:** Matt Osterhaus, R.Ph.

**Time:** 9:30 a.m. to 1:31 p.m.

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

**Committee Members Present:** Bruce Alexander, R.Ph., Pharm.D., BCPP; Matthew Osterhaus, R.Ph.; Hayley L. Harvey, DDS, MS; Charles Wadle, D.O.; Mark Graber, M.D.; Carole Frier, D.O.; and Mary Larew, M.D. (arrived at 9:50).

**Iowa DHS Staff Present:** Susan Parker, Pharm.D., Pharmacy Consultant; and Brad Horn, Assistant District Attorney (left at 12:24).

**Iowa Medicaid Enterprise (IME) Staff Present:** Tim Clifford, M.D.; John Grotton, R.Ph.; Sandy Pranger, R.Ph.; Erin Halverson, R.Ph.; Jason Kessler, M.D. (left at 12:24); Thomas Kline, D.O. (left at 12:24); and Melissa Biddle.

Chairperson Matt Osterhaus called the meeting to order.

I. Matt Osterhaus asked that each committee, DHS staff, and IME staff member introduce themselves to the public. New committee member Mark Graber introduced himself and offered some background information. The new Medical Director, Jason Kessler did this as well. The April 8, 2010 open session minutes were reviewed. Hayley Harvey made the motion to approve the minutes. Bruce Alexander seconded the motion. The motion passed with no objections.

II. Committee Elections: Sue Purcell (via email sent before the meeting) nominated Matt Osterhaus as chairperson. Carole Frier officially nominated him, however, on Sue's behalf. Hayley Harvey seconded this, and the decision was unanimous amongst those present. Bruce Alexander then nominated Chuck Wadle as Vice-Chairperson, and Carole Frier seconded. This vote was also unanimous.

III. Conflict of Interest and Confidentiality Forms: The forms were collected and they are available from Susan Parker at sparker2@dhs.state.ia.us. Any changes to these forms prior to next September's renewal will need to be announced as well.

IV. PDL (Dr. Clifford): The supplemental rebate negotiations are almost complete. The Sovereign States Drug Consortium (SSDC) convened over the summer and finalized most of the deals. This year was much more complicated because of Health Care Reform. Most of the changes in the PDL that are being recommended have been driven by Health Care Reform. There are a couple of key drugs, most notably in the mental health categories, where negotiations have not been completed.

V. Drug Rebate Issues and Healthcare Reform: Dr. Clifford presented a PowerPoint presentation outlining how Health Care Reform would impact PDL status decisions, rebates, and costs to the pharmacy program. This was posted on the www.iowamedicaidpdl.com website. One major point was that states could potentially lose all the CMS rebates on anything identified as line extension drugs (such as long-acting or rapid-absorbing formulations), so they will most likely be non-preferred from now on. CMS is still just talking about draft methodologies on how to calculate rebates. Many items of the bill are open to interpretation, so there could be a big difference between the states' definitions and those of CMS.

VI. PA Criteria/Pro-DUR Edits (Susan Parker): Informational Letter 903 outlined changes to the PDL and ProDUR quantity limits effective May 24, 2010, along with new PA criteria for Cymbalta, Lyrica, and Savella. Informational Letter 909 informed providers that beginning in August 2010, provider payments, informational letters, and Medicaid provider general letters would only be transmitted in an electronic format. Several fax blasts that had gone out to providers with revisions to the PDL were provided to the Committee as well.

VII. Legislation: Notice for the rules that came about from the changes that the legislature put in place last session in regards to the Mental Health Drugs has been provided, and a public hearing was held with comments being accepted up until August 18, 2010. These questions and their respective responses are available on the DHS website under the Rules link. The final review by the Administrative Rules Committee will be November 9, 2010, and the effective date for implementation will be January 1, 2011.

VIII. IME Updates (Dr. Kline): As a result of the contract re-procurement process effective July 1st, 2010, there are some new programs starting at the IME, such as Program Integrity, which is performing a complete analysis of money spent by Medicaid to identify cost-saving strategies. Health Care Reform has brought on the development of new programs in which Medicaid has been involved, such as the IowaCare Expansion program. Beginning October 1, 2010, there will now be more FQAC locations to provide primary care to Iowa Care members in Waterloo and Sioux City. There is a plan that two more sites will be available January 1, 2011, with more being added every 2-4 months. As a result of this change, primary care for members living in the counties surrounding Waterloo and Sioux City that had previously been provided at the University of Iowa will be done at the new sites, and thus alleviate the work load at the University. Also, Dr. Kessler has been working on a project to provide a medical home for children, which would include members of both the Medicaid and hawk-i programs. In 2014, all IowaCare members will be transitioned into Medicaid, along with an additional 80,000-100,000 other Iowans who would qualify for Medicaid when Health Care Reform goes into effect, making Medicaid the largest payer in the state of Iowa. There was no Clinical Advisory Committee meeting over the summer, but one is scheduled for October. The IME Disease Management and Lock-In programs are now run by the Member Services vendor, instead of Medical Services as in the previous contract. Iowa Medicaid Program Integrity was also awarded to a new vendor, Ingenix. The POS and Core processor contracts had longer contract periods, but will be up for renewal in the next year.

IX. The public speakers were:

| SPEAKER | SUBJECT |
|---|---|
| Truce Ordana from Eyerly-Ball Mental Health Services | Invega Sustenna |
| Elizabeth Bacon from Blank Children's CF Clinic | Pancreatic enzyme replacement |
| Kim Lonergan from AstraZeneca | Vimovo |
| Jack Putman from Merck | Saphris |
| Renea Bradley from Novo Nordisk | Victoza |
| Vivian Tucker from GlaxoSmithKline | Jalyn |

At 11:08, motion to go to closed session was made by Chuck Wadle and seconded by Bruce Alexander. The motion passed with unanimous approval. Open session resumed at 12:27.

X. Brand-Name Anticonvulsants for Epilepsy: The committee had a discussion of the possible impact of preferring branded anticonvulsants for a confirmed epilepsy diagnosis. The state had met with representatives from the Epilepsy Foundation the day before. Everyone agreed that it was important to protect access to the brand-name anti-convulsants, specifically for members with a seizure diagnosis, and that the State had been pursuing a sensible policy and should continue to do so. Even though Health Care Reform would penalize some line-extension anti-convulsants, the State will still protect access to them for seizure members. Although they may become non-preferred for other diagnoses, members with a seizure diagnosis would be grandfathered as per the usual policy that has been in place. As new members are identified, they would be allowed to start a brand drug and remain on it. Generic shortages are too common to try to make arrangements for multi-year deals on them as was suggested as a possibility at the April meeting.

XI. PDL Discussion and Deliberation (Dr. Clifford): Per the CMS release dated April 29, 2010, all unapproved digestive enzymes were removed from the PDL. It was recommended to change the status of Ditropan XL to non-preferred and Oxybutynin ER to preferred for children less than 13 years of age, as Ditropan XL is considered a line extension in the Healthcare Reform Bill. It was recommended to change the status of Fanapt to preferred on the PDL; the signed contract requirement is complete (vote held in April meeting). It was recommended to change the status of Invega Sustenna to preferred on the PDL; the signed contract requirement is complete. It was recommended to change the status of Marinol to non-preferred on the PDL, based on the recommendation from the DUR Commission. It was recommended to add OTC Nicotine 2mg and 4mg lozenge to preferred with conditions on the PDL effective October 1, 2010, due to Healthcare Reform Bill 3590. It was recommended to change the status of Prevacid SoluTabs to non-preferred with conditions, as it is considered a line extension in the Healthcare Reform Bill. It was recommended to change the status of Saphris to preferred on the PDL with a POS duplicate therapy edit; the signed contract requirement is complete (vote held in April meeting). It was recommended to change the status of Tegretol XR to non-preferred with conditions and grandfather existing users with seizure diagnosis, as it is considered a line extension in the Healthcare Reform Bill. Finally, it was recommended to change the status of Valturna to preferred on the PDL; the signed contract requirement is complete (vote held in April meeting). Carole Frier motioned to accept these recommendations, and Bruce Alexander seconded. The decision was unanimous.

XII. Manufacturer Discontinuations and Withdrawals: The following drugs will be removed from the PDL since they have been discontinued by the manufacturer: Biohist LA, Bromfed, Bromfed-PD, Brovex CT, Cafergot Suppository, Capitrol, Cardene, Cipro XR, Coldec D, Cytovene 250mg and 500 mg Capsules, Deconamine, Deconamine SR, Duratuss DM, Formalyde-10, Garamycin, Histex CT, Histex IE, Histex PD, Histex PD 12, Lactinol-E, Palgic D, Pediox, Procanbid, Qdall, Rondec-TR, Talwin NX, Tanafed DP, Vantin 200mg, Vesanoid, Winstrol, and Xylocaine Viscous Solution. Carole Frier motioned to accept these recommendations, and Bruce Alexander seconded. The decision was unanimous.

XIII. Changes due to State MAC or FUL additions or deletions: It was recommended to change the status of Biaxin XL and Biaxin XL Pac to non-preferred on the PDL to maximize cost savings to the program. The status of Bupropion SR 100mg will be changed to preferred and Wellbutrin SR (all strengths) to non-preferred on the PDL to maximize cost savings to the program. Bupropion SR 150mg and 200mg are already preferred on the PDL. It was recommended to change the status of clarithromycin 125mg/5ml suspension to preferred and Biaxin 125mg/5ml suspension to non-preferred on the PDL to maximize cost savings to the program. The status of clarithromycin 250mg/5ml suspension will change to preferred on the PDL to maximize cost savings to the program. Biaxin 250mg/5ml suspension will remain preferred due to a large CMS rebate. It was recommended to change the status of clarithromycin 250mg tablets to preferred on the PDL to maximize cost savings to the program. Biaxin 250mg tablets are already non-preferred on the PDL. The status of Deferoxamine will change to preferred and Desferal to non-preferred on the PDL to maximize cost savings to the program. It was recommended to change the status of Ketorolac 0.4% Ophthalmic Solution to preferred and Acular LS to non-preferred on the PDL to maximize cost savings to the program. The status of Ketorolac 0.5% Ophthalmic Solution will change to preferred and Acular to non-preferred on the PDL to maximize cost savings to the program. It was recommended to change the status of Temazepam 7.5mg to non-preferred with conditions on the PDL to maximize cost savings to the program. Restoril 7.5mg is already preferred on the PDL. The status of Voltaren Ophthalmic Solution will change to non-preferred on the PDL to maximize cost savings to the program. The generic, Diclofenac Ophthalmic Solution, is recommended to be added to the PDL as preferred. Carole Frier motioned to accept these recommendations, and Bruce Alexander seconded. The decision was unanimous.

XIV. Newly Released Drugs: Ampyra was recommended to be non-preferred with referral to DUR for creation of PA criteria. Cayston and Lysteda were also recommended to be non-preferred. Oravig and Victoza were both recommended to be non-preferred with conditions. Votrient and Zortress were recommended to be recommended. Bruce Alexander motioned to accept these recommendations, and Mary Larew seconded. The decision was unanimous.

XV. Newly Released Generic Drugs: The following medications were recommended to be non-preferred with conditions: Adapalene Cream, Adapalene Gel, Alprazolam ODT, Amoxicillin/ Clavulanate K ER Tablets, Azelastine Spray, Buprenorphine Sublingual Tablets, Buprenorphine Injection, Fluoxetine 90mg, Losartan, Losartan/ HCT, Metaxalone, and Methamphetamine. These drugs were recommended to be non-preferred: Aztreonam, Cefditoren, Cefepime, Dronabinol, Famotidine Suspension, Imiquimod, Nisoldipine, Tobramycin/Dexamethasone Ophthalmic Suspension, and Trandolapril/Verapamil. Diclofenac 0.1% Ophthalmic Solution and Tamsulosin were both recommended to be preferred, whereas naratriptan will be preferred

with conditions. Hayley Harvey motioned to accept these recommendations, and Bruce Alexander seconded. The decision was unanimous.

XVI. New Dosage Forms: The following medications were recommended to be non-preferred: Actoplus Met XR, Exalgo, Nisoldipine ER, Nitromist, Sular CR, and Tirosint. These drugs will be non-preferred with conditions: Apidra Solostar, Differin Lotion, Mirapex ER, Moxatag, Pennsaid, and Rybix ODT. Nutropin AQ NuSpin will be preferred with conditions. Bruce Alexander motioned to accept these recommendations, and Chuck Wadle seconded. The decision was unanimous.

XVII. New Drug Names/Combinations: Dexilant and Vimovo were recommended to be non-preferred with conditions, and Jalyn was recommended to be non-preferred. Bruce Alexander motioned to accept these recommendations, and Chuck Wadle seconded. The decision was unanimous.

XVIII. New Strengths: Aplenzin, Magnacet, and Pancreaze were all recommended to be non-preferred with conditions. Gammaplex 5%, Zyclara 3.75%, and Zymaxid 0.5% were recommended to be non-preferred. Prolastin-C and Zenpep were recommended to be preferred with conditions, and Wilate was recommended to be recommended. Bruce Alexander motioned to accept these recommendations, and Chuck Wadle seconded. The decision was unanimous.

XIX. Vitamin Supplements: Hayley Harvey motioned that the DUR Commission review the PA criteria for Vitamin D for members less than 21 years of age, especially newborns. In addition, she would like to see a preferred multivitamin without fluoride. Mary Larew seconded, and the committee was unanimously in favor.

XX. New Public Comment Data Requirement: Mark Graber motioned that a rule be put in place requiring speakers who were presenting data in their public comments to provide the articles to the committee members beforehand. Bruce Alexander seconded. There were no objections.

A motion was made by Chuck Wadle to adjourn the meeting. Matt Osterhaus seconded the motion. All in attendance approved. The meeting adjourned at 1:31 p.m. The next scheduled meeting will be November 18, 2010.