MEDICAID PHARMACY PRIOR AUTHORIZATION ADVISORY COMMITTEE
Final Meeting Summary
December 1, 2004

Opening Remarks/Introductions

The Medicaid Pharmacy Prior Authorization (PA) Advisory Committee met on December 1, 2004 to review the next eleven (11) categories of drugs to be implemented on the Wisconsin Medicaid preferred drug list (PDL), as well as changes to two (2) existing categories of drugs on the PDL.

Mark Moody, Administrator of the Division of Health Care Financing (DHCF) opened the meeting by reviewing the committee purpose and schedule for the day. Items covered included:

- The meeting will begin with a review and approval of the September 14, 2004 meeting minutes.
- The meeting will proceed into public comment, followed by a short break at 11:00 a.m. to accommodate the DHFS fire drill.
- Mr. Moody indicated that he would need to leave the meeting at approximately 11:00 a.m., as he was required to testify before the joint audit committee.
- Following the break at 11:00 a.m. the meeting would enter into closed session for one hour. The audience was requested to wait in the building cafeteria to minimize disruption on the seventh floor.
- The meeting will resume into open session at 12:00 p.m. for review and discussion of the applicable therapeutic categories.

Review/Approval of September 14, 2004 Meeting Minutes

Mr. Moody announced that revised meeting minutes were distributed to the committee members, confirmed that the members had the opportunity to review, and requested modifications or motion to approve.

Christine Sorkness made a motion to approve the minutes and Dr. Fedderly seconded the motion. The motion passed 7 to 0. Voting in favor were:

- Tom Frazier – aye
- Christine Sorkness – aye
- Steve Maike – aye
- Bradley Fedderly - aye
- Peg Smelser – aye
- James Heersma – aye
- Tom Hirsch – aye

There were no votes opposed and no abstentions.

Public Testimony

Mr. Moody opened the public testimony portion of the meeting. Mr. Moody reviewed the testimony guidelines for the meeting as follows:

1. Speakers will be required to state name, address and organization represented.
2. Speakers will be limited to a period of five (5) minutes.
3. Only one (1) speaker per company or organization will be permitted.
4. Prior Authorization Committee members will not ask questions or respond to speakers at the meeting.
5. Speakers must submit written material to the DHCF, either in hard copy at the meeting or electronically via email following the meeting. Christine Weidner provided her email address.
6. Speakers will not be permitted to use audio/visual equipment during their presentation.

The table below lists each speaker who testified and the topic of their testimony.

SUMMARY TABLE OF PUBLIC TESTIMONY

Time	Name	Company	Product/Topic	Notes
8:43	Craig Roberts	Community Health & Epidmiology Center - UW	Sexually Transmitted Diseases/Herpes	Provided clinical support for Valtrex for treatment of genital herpes
8:47	Dr. J. Scot McMurray	Professor UW/Alcon Labs	Ear Disease in Children	Provided clinical support for Ciprodex over Floxin for ear disease
8:50	Kathleen Lake	Roche Labs	CMV Retinitis	Provided clinical support for Valcyte over ganciclovir for CMV Disease
8:55	Pheophilus Glover	TAP Pharmaceuticals	Prevacid Oral/Solutab/Naprapac	Provided clinical support for Prevacid (multiple dosag forms) in PPIs, benefits to multiple populations
9:00	Dr. Anthony Starseinic	Aventis	Ketek	Provided clinical support for Ketek for treatment of respiratory infections
9:05	Dr. Clyde Cooper	Reliant	Dynacirc CR	Provided clinical support for Dynacirc over Norvasc fo high blood pressure
9:11	Neil Klutman	Ortho	Levaquin	Provided clinical support for Levaquin for respiratory infections
9:15	Julie Hempel	Schwarz Pharmaceuticals	Verelan PM	Provided clinical support for Verelan PM for treatment of high blood pressure
9:21	Ndidi Yaucher	Astra Zeneca	Nexium	Provided clinical support for Nexium for ulcers and reflux
9:26	Dr. Pinakin Attawala	Schering Plough	Vytorin	Provided clinical support for Vytorin for cholesterol lowering over Zocor and Lipitor to lower LDLs
9:31	Bill Collins	Bayer/Schering Plough	Cipro, Cipro XR, Avelox	Provided clinical support for Avelox for strep Cipro XR for acute urinary tract infection
9:37	Dr. Greeta Cherayil	Pfizer/Faculty UW	Norvasc, Caduet, Zithromax	Provided clinical support for Norvasc for high blood pressure/cardiovascular disease, Caduet (Norvasc/Lipitor) for CV and cholesterol lowering, Zithromax for infection
9:43	Dr. Rajeev Jain	Endrocrinolgist-Milwaukee	High Blood Pressure/Cholesterol Lowering	Provided clinical support for Caduet for treatment of high blood pressure and cholesterol lowering
9:47	Andrew Shim	Novartis	Lotrel, Elidel, Lamisil, Famvir	Provided clinical support for Lotrel for high blood pressure, Elidel for eczema, Famvir for herpes, Lamisil for nail fungus
9:52	Dr. Murray	Associate Professor UW	Coreg	Provided clinical support for Coreg for high blood pressure/heart failure
9:57	Dean Goldberg	Glaxo Smith Klein	Coreg, Valtrex, Augmentin XR	Provided clinical support for Coreg for high blood pressure/heart failure, Valtrex for herpes, Augmentin XR for
10:02	Martin Job	Abbott	Tarka, Omnicef, Biaxin	Provided clinical support for Tarka for high blood pressure/diabetes, Omnicef for , Biaxin for respiratory infections
10:07	Dr. Jonathon Spahr	Pulminory Physician UW	Zithromax	Provided clinical support for Zithromax for pneumonia and cystic fibrosis

Discussion of Manufacturer-Specific Supplemental Rebate Amounts (Closed Session)

Mr. Moody indicated that the next agenda item, a discussion of manufacturer-specific supplemental rebate amounts, was intended for consideration in closed session pursuant to s.19.85(1)(e), Wis. Stats. He further indicated that, under federal and state law, the rebate amounts must remain confidential due to the competitive nature of the rebate agreements and federal drug price confidentiality requirements.

Mr. Moody called for a motion to adjourn into closed session. Dr. Heersma moved and Ms. Smelser seconded to recess the public meeting and convene in closed session. The motion passed 7 to 0. Voting in favor were:

- Tom Frazier – aye
- Christine Sorkness – aye
- Steve Maike – aye
- Bradley Fedderly - aye
- Peg Smelser – aye
- James Heersma – aye
- Tom Hirsch – aye

There were no votes opposed and no abstentions.

Therapeutic Class Reviews, Committee Discussion, and Response to Proposal (Open Session)

Mr. Moody announced that Valerie Taylor from Provider Synergies would present the therapeutic class reviews and recommendations, and that Mike Mergener from APS would present summary conclusions from the Oregon project.

Ms. Taylor presented class reviews as follows:

1) **Atopic Dermatitis (Eczema)**
   a) Review – clinical literature was presented.
   b) Recommendation: Protopic and Elidel as preferred.
   c) Discussion – No discussion.
   d) Vote on Recommendation – Voting in favor were:

      - Tom Frazier – aye
      - Steve Maike – aye
      - Bradley Fedderly - aye
      - Peg Smelser – aye
      - James Heersma – aye
      - Tom Hirsch – aye

      There were no votes opposed and no abstentions.

2) **Otics, Antibiotics (Topical Antibiotics for Ear Infection)**
   a) Review – clinical literature was presented.
   b) Recommendation:
      – Neomycin/polymyxin/HC, Coly-Mycin, Ciprodex, Floxin as preferred.
      – Cipro HC and Cortisporin-TC as non-preferred.

c) Discussion:
Dr. Hirsch asked if Ciprodex and Floxin were being used to treat acute otitis.
Dr. Fedderly confirmed that both drugs could be used to treat acute otitis, but it would be difficult to monitor. Dr. Hirsch voiced his concern regarding the use of these two drugs for this reason.
Dr. Fedderly noted that the generic in this class is expensive relative to the lower cost brand drugs and asked if we could shift it to non-preferred. Ms. Taylor indicated that it would be difficult to move market share from the generic. Dr. Fedderly acknowledged that it might be difficult, however the committee should consider.

d) Vote on Recommendation – Voting in favor were:

- Tom Frazier – aye
- Steve Maike – aye
- Bradley Fedderly - aye
- Peg Smelser – aye
- James Heersma – aye
- Tom Hirsch – aye

There were no votes opposed and no abstentions.

3) Cephalosporins and Related Antibiotics (Antibiotics for Infection)

a) Review – clinical literature was presented.

b) Recommendation:
- Amox tr-potassium clavulanate 600, amoxicillin/clavulanate, cefaclor, cefadroxil, cefpodoxime, cefuroxime, cephalexin, Augmentin XR, Omnicef, Spectracef as preferred.
- Cedax, Cefzil, Lorabid, Panixine, Raniclor, Suprax as non-preferred.

c) Discussion:
Dr. Hirsch asked if Spectracef should be recommended as non-preferred. Ms. Taylor noted the low utilization on Spectracef and indicated that market share would most likely move to a higher cost generic or brand drug.
On behalf of Ms. Sorkness, Dr. Fedderly asked if cefpodoxime should also be recommended as non-preferred instead of preferred given that the generic was higher cost than some of the brand drugs recommended as preferred. Mr. Moody acknowledged the concern with high cost generics on the PDL, and also noted that there is a concerted effort to maintain a consistent message on the use of generics over brand drugs.
Ms. Boroniec also acknowledged and indicated that the department staff would review the high cost generics to determine if additional policies could be implemented.
Mr. Moody asked Ms. Taylor if Augmentin presented any unique attributes within the class. Ms. Taylor confirmed that Augmentin did provide some unique benefits over other drugs in the class.

d) Vote on Recommendation – Voting in favor were:

- Tom Frazier – aye
- Steve Maike – aye
- Bradley Fedderly - aye
- Peg Smelser – aye
- James Heersma – aye
- Tom Hirsch – aye

There were no votes opposed and no abstentions.

4) Macrolides/Ketolides (Antibiotics for Infection)

a) Review – clinical literature was presented.
b) Recommendation:
   – Erythromycin, Zithromax as preferred.
   – Biaxin, Biaxin XL, Ketek as non-preferred.
c) Discussion:
   Dr. Hirsch asked if there was a specific niche for Ketek. Ms. Taylor confirmed niche for Ketek.
   Dr. Fedderly noted the low utilization of Ketek and the public testimony to support Ketek, and requested that the department review more current utilization and report back to the committee.
d) Vote on Recommendation – Voting in favor were:

- Tom Frazier – aye
- Steve Maike – aye
- Bradley Fedderly - aye
- Peg Smelser – aye
- James Heersma – aye
- Tom Hirsch – aye

There were no votes opposed and no abstentions.

5) Fluoroquinolones (Antibiotics for Infection)

a) Review – clinical literature was presented.
b) Recommendation:
   – Ciprofloxacin, ofloxacin, Avelox, Cipro XR, Levaquin, Noroxin, Tequin as preferred.
   – Factive, Maxaquin as non-preferred.
c) Discussion:
   Dr. Hirsch questioned why ofloxacin was recommended as preferred given the high cost and low utilization. Dr. Hirsch further commented that we should not be automatically including generics on the PDL as it sends the wrong message to the generic manufacturers. Dr. Fedderly asked that the department review what other states are doing with high cost generics. Mr. Moody confirmed that the department would review the high cost generics.
d) Motion - Dr. Hirsch made a motion to accept the recommendations with the exception that ofloxacin should be recommended as non-preferred. Mr. Frazier seconded the motion.
e) Vote on Motion – Voting in favor were:

- Tom Frazier – aye
- Steve Maike – aye
- Bradley Fedderly - aye
- Peg Smelser – aye
- James Heersma – aye
- Tom Hirsch – aye

There were no votes opposed and no abstentions.

6) Antivirals (Flu/Herpes)

a) Review – clinical literature was presented.
b) Recommendation:
   – Acyclovir, amantadine, ganciclovir, rimantadine, Tamiflu, Valcyte, Valtrex as preferred.

- Relenza, Famvir as non-preferred.

c) Discussion:
Dr. Fedderly noted that the Antiviral class included drugs for multiple and unique indications and we should consider separating by their primary indication of which there are three. Mr. Mergener noted that the PDL would include two separate groups and that we would review to determine if a third group was necessary.
Dr. Hirsch recommended to the committee that ganciclovir be non-preferred instead of preferred, and that the committee should also review Tamiflu at the next meeting to determine if it should maintain its preferred status. Mr. Moody noted that Tamiflu was included as preferred given the existing shortage of Flu vaccine.

d) Motion – Dr. Hirsch made a motion to accept the recommendations with the exception that ganciclovir should be recommended as non-preferred, and that the committee re-review Tamiflu at the March 2005 committee meeting. Dr. Fedderly seconded the motion.

e) Vote on Motion – Voting in favor were:

- Tom Frazier – aye
- Steve Maike – aye
- Bradley Fedderly - aye
- Peg Smelser – aye
- James Heersma – aye
- Tom Hirsch – aye

There were no votes opposed and no abstentions.

7) Antifungals, Oral (Nail Fungus and Other Fungal Infections)

a) Review – clinical literature was presented.

b) Recommendation:
- Clotrimazole, fluconazole, griseofulvin, ketoconazole, nystatin Grifulvin V Suspension, Lamisil as preferred.
- Ancobon, Mycostatin, Sporanox, Vfend as non-preferred.

c) Discussion:
Dr. Hirsch asked if there was any way we could limit the use of Vfend and verify if it is being used as intended. Ms. Taylor confirmed the appropriate use of Vfend. Dr. Fedderly requested that the meeting minutes reflect the committee discussion and that all follow-up be presented to the committee at the subsequent meeting.

d) Vote on Recommendation – Voting in favor were:

- Tom Frazier – aye
- Steve Maike – aye
- Bradley Fedderly - aye
- Peg Smelser – aye
- James Heersma – aye
- Tom Hirsch – aye

There were no votes opposed and no abstentions.

8) ACE Inhibitor/CCB Combinations (High Blood Pressure)

a) Review – clinical literature was presented.

b) Recommendation: Lexxel, Lotrel, Tarka as preferred.

c) Discussion:
Dr. Hirsch noted the public testimony presented in Open Session regarding higher compliance with combination drugs over their single drug counterparts. Dr. Hirsch asked if Ms. Taylor had reviewed comparisons that supported this testimony. Ms. Taylor

responded that this was not included in their review and that she would bring information related to this topic back to the March 2005 meeting. Dr. Fedderly added that the committee should be reviewing the issues of compliance and efficacy in these comparisons in future discussions. Dr. Heersma further elaborated that based on his experience there may be advantages to prescribing the single products over the combination products as patients are locked in to the dosage forms in the combination products. Dr. Heersma added that some patients are sensitive to the higher doses contained in some of the combinations products.

d) Vote on Recommendation – Voting in favor were:

- Tom Frazier – aye
- Steve Maike – aye
- Bradley Fedderly - aye
- Peg Smelser – aye
- James Heersma – aye
- Tom Hirsch – aye

There were no votes opposed and no abstentions.

9) Beta Blockers (High Blood Pressure and Heart Failure)

a) Review – clinical literature was presented. Mr. Mergener noted the Oregon project's review concurred with Ms. Taylor's review of the Beta Blockers class, specifically mentioning the conclusions with Coreg.

b) Recommendation:
   - Acebutolol, atenolol, betaxolol, bisoprolol, labetalol, metoprolol, nadolol, pindolol, propranolol, sotalol, timolol, Coreg, Toprol as preferred.
   - Cartrol, Inderal LA, Innopran XL, Levatol as non-preferred.

c) Discussion:
Dr. Hirsch asked Ms. Taylor when Coreg is going generic. Ms. Taylor replied that she did not know and would research and report back to the committee.
Dr. Hirsch asked Ms. Taylor if there were any clinical reasons why betaxolol and bisoprolol should be included as preferred products given their relative cost as generics in the class. Ms. Talyor indicated that there were not any unique clinical advantages provided by the two generics.

d) Motion – Dr. Hirsch made a motion to accept the recommendations with the exception that betaxolol and bisoprolol should be recommended as non-preferred, and that the patients currently using one of the recommended non-preferred drugs be grandfathered. Dr. Fedderly seconded the motion.

e) Vote on Motion – Voting in favor were:

- Tom Frazier – aye
- Steve Maike – aye
- Bradley Fedderly - aye
- Peg Smelser – aye
- James Heersma – aye
- Tom Hirsch – aye

There were no votes opposed and no abstentions.

10) Calcium Channel Blockers (High Blood Pressure)

a) Review – clinical literature was presented. Mr. Mergener noted concurrence between the Oregon project's and Provider Synergies' conclusions in this class. Mr. Mergener also added that the clinical trials within this class did not include head-to-head comparison between products.

b) Recommendation:
   - Diltiazem, diltiazem ER, diltiazem SR, felodipine ER, nicardipine, nifedipine ER, verapamil, verapamil SR, Cardizem LA, Dynacirc, Dynacirc CR, Sular, Norvasc as preferred.
   - Cardene SR, Covera-HS, Nimotop, Verelan PM as non-preferred.

c) Discussion:
Dr. Hirsch asked if by grandfathering in the class we could move some of the products from preferred to non-preferred. Ms. Taylor replied that there was one drug in the class, otherwise savings would significantly be impacted.
Mr. Moody questioned the uniqueness of some of the drugs in the class relative to the cost variances. Ms. Taylor replied that some of the generics did have unique indications, but reiterated that there was a single drug in the class that had the greatest impact on savings.
Dr. Hirsch asked Ms. Taylor if Dynacirc utilization reflected the effectiveness of the drug versus the success of the advertising. Mr. Taylor replied it was due more to the success of advertising.
Ms. Taylor concluded that in order to affect utilization and savings in this class, the state would have to drive market share from the highest utilized drug in the class and did not believe it was likely.

d) Vote on Recommendation – Voting in favor were:

- Tom Frazier – aye
- Steve Maike – aye
- Bradley Fedderly - aye
- Peg Smelser – aye
- James Heersma – aye
- Tom Hirsch – aye

There were no votes opposed and no abstentions.

11) Lipotropics, Statins (Cholesterol Lowering)

a) Review – Ms. Taylor noted that the committee was only reviewing the status of two drugs within this class as the class had been reviewed at the September 2004 meeting. The two drugs being reviewed were Vytorin and Caduet.

b) Recommendation: Vytorin and Caduet as preferred.

c) Discussion:
Dr. Hirsch noted that the pricing for Vytorin and Caudet were not comparable, and suggested that the manufacturer of Caduet be requested to provide a better offer.
Dr. Fedderly requested that the department attain who was saving (retail pharmacies or the program) if combination products were being dispensed versus the single products.
Mr. Moody replied that the department will research and report back to the committee.

d) Motion – Dr. Hirsch made a motion to accept the recommendations with the exception that Caduet remain non-preferred until further negotiations could be completed with the manufacturer. Mr. Frazier seconded the motion.

e) Vote on Motion – Voting in favor were:

- Tom Frazier – aye
- Steve Maike – aye
- Bradley Fedderly - aye
- Peg Smelser – aye
- James Heersma – aye
- Tom Hirsch – aye

There were no votes opposed and no abstentions.

Mr. Moody excused himself from the meeting at 12:37 p.m. and indicated that Ms. Boroniec, Deputy Administrator, would facilitate the remainder of the meeting.

12) Proton Pump Inhibitors (Ulcers and Reflux)

a) Review – clinical literature was presented. Ms. Taylor noted that the recommendations for this class were based on a step therapy approach, and the offers presented to the manufacturers were also noted as such. Mr. Mergener added that the clinical trials documented in the Oregon project's summary did not include equivalent dosage comparisons. Mr. Mergener also added that new information had been released regarding Prilosec OTC in that it could be dissolved in liquid and administered via various routes not documented previously.

b) Recommendation:
   - Prilosec OTC as preferred.
   - Protonix as preferred 2nd tier drug.
   - Aciphex, Nexium, omeprazole, Prevacid, Zegerid as non-preferred 3rd tier drugs.

c) Discussion:
On behalf of Ms. Sorkness, Dr. Fedderly indicated that there was not a preferred drug in this class indicated for children with reflux. Dr. Fedderly noted that he believed there was sufficient utilization of the recommended non-preferred PPIs and asked if Ms. Taylor could confirm. Ms. Taylor replied that she did believe Dr. Fedderly's assumption was true, but did not know the exact utilization. Dr. Fedderly requested that the department research the exact indications, age restrictions, and contraindications for Prilosec OTC and Protonix before finalizing the recommendations, and added that the department should not restrict access to the non-preferred drugs if the research concluded a high utilization or contraindication in the non-preferred products and preferred products respectively. Ms. Boroniec and Russell Pederson confirmed that the department would complete the research and act accordingly to provide the appropriate access for children. Mr. Pederson noted that the prior authorization (PA) requirements could be modified to accommodate the additional criteria if necessary. Dr. Fedderly added that the committee and department need to be fair, scientifically rationale, and fiscally sound with all recommendations. Mr. Frazier cited the testimony regarding Prevacid and its various routes of administration, and noted that the committee and department also need to be sensitive to older patients in addition to being sensitive to children. Mr. Frazier requested that the research be reported back to the committee.

d) Motion – Ms. Boroniec made a motion that the department complete the noted research in the discussion prior to finalizing and accepting the recommendations. Dr. Fedderly seconded the motion.

e) Vote on Motion – Voting in favor were:

- Tom Frazier – aye
- Steve Maike – aye
- Bradley Fedderly - aye
- Peg Smelser – aye
- James Heersma – aye
- Tom Hirsch – aye

There were no votes opposed and no abstentions.

13) NSAIDs (Pain)

a) Review – Ms. Taylor noted that the committee was only reviewing the status of Prevacid Naprapac within this class as the class had been reviewed at the September 2004 meeting.
b) Recommendation: Prevacid Naprapac as non-preferred.
c) Discussion:
Dr. Hirsch requested that the committee re-review Celebrex, Bextra, and Mobic and the existing PA criteria at a future meeting.
Dr. Fedderly asked if the department knew what NSAID the patients using Vioxx were shifted to after it was removed from the market. Mr. Pederson replied that they were most likely shifted to Celebrex but did not have the exact shift statistics.
d) Motion – Dr. Hirsch made a motion to accept the recommendations with the request that the committee re-review Celebrex, Bextra, and Mobic and the existing PA criteria at a future meeting. Dr. Fedderly seconded the motion.
e) Vote on Motion – Voting in favor were:

- Tom Frazier – aye
- Steve Maike – aye
- Bradley Fedderly - aye
- Peg Smelser – aye
- James Heersma – aye
- Tom Hirsch – aye

There were no votes opposed and no abstentions.

Other Discussion

Dr. Fedderly requested clarification on the PA process as he was receiving inquiries from several colleagues. Mr. Pederson confirmed that there were three (3) forms of PA; (a) general PA, (b) brand medically necessary (BMN) PA, and (c) PDL/PA. Dr. Fedderly voiced a concern regarding the use of the federal MedWatch form as documentation for BMN PA. Dr. Fedderly indicated that the MedWatch form's intended use is to document adverse affects, and not when the drug is not tolerated or not as effective as another drug. Dr. Fedderly requested that the department consider developing a separate form to document these situations. Mr. Pederson noted that the committee endorsed the use of the MedWatch form at a previous meeting, but also recognized that the criteria on the form may not match the PA requirements for BMN.
Mr. Pederson noted that the department will research creating a separate form.

Ms. Boroniec informed that committee that the department is monitoring other states activities related to BMN and PDL, and will provide the committee an update on the evaluation of the BMN and PDL at the next meeting.

Next Meeting – Ms. Boroniec recommended March 2, 2005, for the next meeting and requested that committee member's reply to Rita Hallett if they have any conflicts with the date.

Ms. Boroniec adjourned the meeting at 1:06 p.m.