

**MEDICAID PHARMACY PRIOR AUTHORIZATION ADVISORY
COMMITTEE
Final Meeting Summary
March 2, 2005**

Opening Remarks/Introductions

The Medicaid Pharmacy Prior Authorization Committee met on March 2, 2005 to review the next 14 categories of drugs to be implemented on the Wisconsin Medicaid preferred drug list (PDL) as well as three changes to existing categories of drugs on the PDL.

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

- The meeting will begin with a review and approval of the December 1, 2004 meeting minutes.
- The meeting will proceed into public comment.

Review/Approval of December 1, 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.

Vote on motion – Voting to approve were:

- | | |
|----------------------------|-----------------------|
| ▪ Tom Frazier – aye | ▪ Peg Smelser – aye |
| ▪ Christine Sorkness – aye | ▪ James Heersma – aye |
| ▪ Bradley Fedderly – aye | ▪ Tom Hirsch – aye |
| ▪ Kevin IZard – aye | |

There were no votes opposed and no abstentions.

Public Testimony

Mark 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. Stacey Olson 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 OF PUBLIC TESTIMONY

Time	Name	Company	Product/Topic	Notes
8:54	Dr. W. Bushman	UWHC	Bladder Relaxants	Provided clinical support for non-generic alternatives to oxybutinin on the PDL
8:58	Dr. Memmen	WI Academy of Ophthalmologists	Glaucoma Agents	Provided clinical support for Xalatan and Cosopt.
9:02	Dr. Clevidencein	Family Practice	Caduet	Provided clinical support for Caduet as efficient product for treating comorbidity of hypertension and dislipidemia.
9:06	Dr. Susan Higgins	Allergy and Asthma Center in Milwaukee	Zyrtec	Provided clinical support for making Zyrtec a preferred product in the class of non-sedating antihistamines.
9:11	Dr. Steven Donatello	Milwaukee Pain Clinic	Narcotic Analgesics	Spoke in support of not restricting physician pain control prescribing options.
9:15	Ryan Honl	Vistakon	Quixin, Betamol, Alamast	Provided clinical support for glaucoma/ocular products, including Quixin, Betamol and Alamast.
9:18	Kelly Olson	Ortho-McNeil	Ditropan XL	Provided clinical support for Ditropan XL to treat overactive bladder.
9:21	Greeta Cherayil	Pfizer	Caduet, Detrol LA, Xalatan, Zyrtec	Provided clinical support for Caduet for CV and cholesterol lowering
9:26	Dr. Bonnie Weigert	Alpharma	Kadian	Provided clinical support for Kadian for pain management.
9:31	Dr. Ganse	Internal Medicine Practice		Provided clinical support for making Zyrtec a preferred product in the class of non-sedating antihistamines.
9:36	Jeanie Choi	Boehringer Ingelheim	Spiriva	Provided clinical support for Spiriva for treatment of COPD.
9:41	Dr. Karen Shimshak	Proctor & Gamble	Asacol	Provided clinical support for Asacol for treatment of ulcerative colitis.
9:48	Jonell Lanta	Shire	PhosLo	Provided clinical support for Fosrenol for treatment of hyperphosphatemia.
9:53	Don Nickels	GlaxoSmithKline	Avodart, Vesicare, Zofran	Provided clinical support for Vesicare for overactive bladder, Zofran for nausea and Avodart for enlarged prostate.
9:59	Andrew Otoo	Nabi Pharm	PhosLo	Provided clinical support for PhosLo for treatment of hyperphosphatemia.
10:03	John DeBoer	Eli Lilly	Humalog Products	Provided clinical support for Humalog for treatment diabetes.
10:08	Dr. Michael Shapiro	Alcon	Travatan, Patanol, Vigamox, Azopt	Provided clinical support for Travatan, Patanol, Vigamox and Azopt.
10:12	Dr. Warren Slaten	Organon & Ligand	Avinza	Provided clinical support for Avinza for pain management.
10:34	Dr. Thomas Castillo	Ophthalmologist	No Particular Product	Spoke on behalf of not restricting access physician treatment options by implementing a PDL.
10:40	Dr. Clyde Cooper	Reliant Pharmaceuticals	Antara	Provided clinical support for Antara for treatment of dislipidemia.
10:43	Greg Navarro	Sepracor	Xopenex	Provided clinical support for Xopenex for treatment of pediatric asthma.
10:48	Tim Birner	Sanofi Aventis	Uroxatrol, Lantus, AllegraD	Provided clinical support for Uroxatrol for treatment of BPH, Lantus for treatment of diabetes and AllegraD for allergies.
10:53	Dr. Douglas Dewire	WI Urological	Bladder Relaxants	Suggests availability of once per day

Time	Name	Company	Product/Topic	Notes
		Society		treatment options. Suggests subcommittee be used to determine which one.
11:01	Anthony DeFilippo	Novo Nordisk	Novalin, Novalogue	Provided clinical support for novalin and novolog for treatment of diabetes
11:07	Dr. Alexander Yezzin	UWHC Nephrologist	Caduet	Provided clinical support for Caduet for patients with kidney disease who have comorbid high blood pressure and high cholesterol.
11:13	Dr. Pardep Sood	Genzyme	Renegel	Provided clinical support for Renegel for treatment of hyperphosphatemia.
11:16	Dr. Gokul Gopalan	Schering Plough	Clarinex, Proventil, Foradil	Provided clinical support for Clarinex for allergies, Proventil and Foradil for treatment of asthma.
11:22	Shelley Raebel	Purdue Pharma	Oxycontin, Palladone	Provided clinical support for Oxycontin and Palladone for the treatment of pain.
11:27	Kathy Gerard	American Diabetes Association	Insulins	Advocated for not restricting access to insulins for Medicaid recipients.

Follow-Up From December Meeting

Mike Mergener reviewed actions that have been taken to resolve issues left outstanding from the December meeting.

- 1) Ofloxacin has been made a non-preferred agent.
- 2) Oral ganciclovir has been made a non-preferred agent.
- 3) Tamiflu remains preferred and will be reviewed in June after flu season.
- 4) Betaxolol and bisoprolol remain preferred agents. Dr. Hirsch asked that we review Innapran XL again, which is currently non-preferred.
- 5) Caduet has been made a non-preferred agent.
- 6) PPI PA criteria have not been changed.
- 7) Bextra and Celebrex remain third-tier covered agents. Dr. Hirsch adds they he isn't clear on what the indication for the COX-2 is at this point. Says, despite FDA vote, concerns remain about safety of Celebrex. Dr. Fedderly moved to bring COX-2's back for review in June. Dr. Hirsch seconded and motion passed unanimously.
- 8) Ketek remains a non-preferred agent.
- 9) High Cost Generics – DHFS will continue to use an aggressive MAC policy to keep the cost of generics down. Dr. Fedderly said the question had more to do with what other states are doing in terms of covering high cost generics. Mark said we would address this specific question for follow-up in June.
- 10) Separating antivirals by their primary indication – Mr. Mergener indicated DHFS is already doing this.
- 11) Compliance/Efficacy of combination products versus two separate components – Analysis concluded that the combination products are less expensive than the separate components.
- 12) Coreg is going off patent March 5, 2007.

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. Motion made by Dr. Izard. Voting in favor were:

- Tom Frazier – aye
- Christine Sorkness – aye
- Bradley Fedderly – aye
- Kevin Izard – 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) Lipotropic, Statins -- Caduet (Blood pressure and cholesterol)

- a) Review – Caduet—manufacturer submitted additional rebate monies.
- b) Recommendation:
 - Add Caduet to PDL as preferred drug.
- c) Discussion – No discussion.
- d) Vote on Recommendation – Motion to accept recommendation was made by Dr. Fedderly, seconded by Dr. Heersma. Voting in favor were:

- Tom Frazier – aye
- Christine Sorkness – aye
- Bradley Fedderly – aye
- Kevin Izard – aye
- Peg Smelser – aye
- James Heersma – aye
- Tom Hirsch – aye

There were no votes opposed and no abstentions.

2) Antifungals, Topical (Skin fungal infections)

- a) Review – Minimal clinical trials in this class comparing products. Typically used for one to four weeks of treatment.
- b) Recommendation:
 - Preferred: nystatin w/triamcinolone, nystatin, clotrimazole/betamethasone, econazole, ketoconazole shampoo, ketoconazole cream, ciclopirox suspension, ciclopirox cream, Naftin, Exelderm, Loprox gel, Loprox shampoo
 - Non-preferred: Oxistat, Mentax, Ertaczo, Penlac
- c) Discussion – Move ciclopirox suspension and cream to non-preferred.
- d) Vote on Recommendation – Motion to accept recommendation as amended in discussion was made by Dr. Hirsch, seconded by Ms. Sorkness. Voting in favor were:
 - Tom Frazier – aye
 - Christine Sorkness – aye
 - Bradley Fedderly – aye
 - Kevin Izard – aye
 - Peg Smelser – aye
 - James Heersma – aye
 - Tom Hirsch – aye

There were no votes opposed and no abstentions.

3) Ophthalmics, Allergic Conjunctivitis (Allergy of the eyes)

- a) Review – All are indicated for treatment of conjunctivitis and cataract surgery. Efficacy is similar across products.
- b) Recommendation:
 - Preferred: cromolyn sodium, Alrex, Acular, Zaditor, Elestat, Patanol
 - Non-preferred: Optivar, Emadine, Alamast, Alocril, Alomide
- c) Discussion : No discussion.
- d) Vote on Recommendation – Motion to accept recommendation was made by Ms. Smelser, seconded by Dr. Izard. Voting in favor were:
 - Tom Frazier – aye
 - Christine Sorkness – aye
 - Bradley Fedderly – aye
 - Kevin Izard – aye
 - Peg Smelser – aye
 - James Heersma – aye
 - Tom Hirsch – aye

There were no votes opposed and no abstentions.

4) Ophthalmics, Antibiotics (Infection of the eyes)

- a) Review – clinical literature was presented.
- b) Recommendation:
 - Preferred: bacitracin, tobramycin, erythromycin, gentamicin, bacitracin/polymyxin, ofloxacin, ciprofloxacin solution, Vigamox, Zymar
 - Non-preferred: Quixin, Ciloxan ointment
- c) Discussion : Sulfa drugs were not included in this category. Dr. Fedderly asked why the sulfa drugs were not reviewed. Response was that the products are mostly available generically.

Dr. Hirsch stated that fourth generation quinolones are superior, so why would we have third generation quinolones Ofloxacin and Cipro on the list, since pricing is the same.

Motion made to adopt recommendation and direct staff to investigate third generation quinolones.

- d) Vote on Recommendation – Motion to accept recommendation as amended in discussion was made by Dr. Hirsch, seconded by Dr. Fedderly. Voting in favor were:

- Tom Frazier – aye
- Christine Sorkness – aye
- Bradley Fedderly – aye
- Kevin Izard – aye
- Peg Smelser – aye
- James Heersma – aye
- Tom Hirsch – aye

There were no votes opposed and no abstentions.

5) Ophthalmics, Glaucoma Agents (Treatment of eye condition that can cause sight loss)

- a) Review – Clinical trials within the class were done across sub-categories. Adverse reactions varied across sub-categories. Guidelines recommend at least on product from each sub-category.

- b) Recommendation:

- Preferred: levobunolol, dipivefrin, pilocarpine, timolol, metipraolol, carteolol, brimonidine, betaxolol, Betimol, Azopt, Travatan 2.5 ml, Betoptic S, Xalatan 2.5 ml, Lumigan 2.5 ml, Trusopt, Alphagan P, Travatan 5 ml, Cosopt, Lumigan 5 ml, Lumigan 7.5 ml
- Non-preferred: Istalol

- c) Discussion: Motion made to move Lumigan 5ml, Lumigan 7.5 and Travatan 5ml to non-preferred.

- d) Vote on Recommendation – Motion to accept recommendation as amended in discussion was made by Dr. Fedderly, seconded by Ms. Sorkness. Voting in favor were:

- Tom Frazier – aye
- Christine Sorkness – aye
- Bradley Fedderly – aye
- Kevin Izard – aye
- Peg Smelser – aye
- James Heersma – aye
- Tom Hirsch – aye

There were no votes opposed and no abstentions.

6) Analgesics, Narcotics (Pain control)

- a) Review – clinical literature was presented. The pharmacology review showed both short and long acting products are indicated for pain management. There is similar efficacy among all agents.

- b) Recommendation:

- Preferred: apap/codeine, tramadol, propoxyphene/apap, asa/codeine, hydrocodone/apap, propoxyphene compound, methadone, oxycodone IR, propoxyphene, oxycodone/apap, morphine sulfate IR, meperidine, codeine, oxycodone/asa, pentazocine/apap, hydromorphone, hydrocodone/ibuprofen, pentazocine/naloxone, butalbital compound w/codeine, morphine sulfate ER, fentanyl, levorphanol, Kadian
 - Non-preferred: Panlor DC/SS, Ultracet, Darvon-N, Synalgos-DC, Oxycontin, Avinza, Palladone, Actiq, Oxycodone ER
- c) Discussion: Ms. Smelser concerned about large number of people who need to be moved from one drug to another.
Dr. Fedderly suggested amending recommendation to move meperidine to non-preferred.
Dr. Izard concerned about efficacy of some generic agents.
- d) Vote on Recommendation – Motion to accept recommendation as amended in discussion was made by Dr. Fedderly, seconded by Ms. Sorkness. Voting in favor were:
- | | |
|----------------------------|-----------------------|
| ▪ Tom Frazier – aye | ▪ Peg Smelser – aye |
| ▪ Christine Sorkness – aye | ▪ James Heersma – aye |
| ▪ Bradley Fedderly – aye | ▪ Tom Hirsch – aye |
| ▪ Kevin Izard – aye | |

There were no votes opposed and no abstentions.

7) Antihistamines, Minimally Sedating (Allergies)

- a) Review – Clinical trials are not consistent in demonstrating whether or not agents are similar with allergic rhinitis. Zyrtec is shown to have higher incidence of drowsiness compared to other agents. There are specific pediatric indications. Otherwise, there is little difference among the four agents.
- b) Recommendation:
- Preferred: loratadine syrup, loratadine, loratadine-D
 - Non-preferred: Clarinex syrup, Clarinex, Zyrtec syrup, Zyrtec-D, Allegra-D, Allegra, Zyrtec, Zyrtec chewable
- c) Discussion: Mr. Mergener noted DERP review supports Provider Synergies recommendation. Risk of arrhythmias with all antihistamine products; highest risk among Zyrtec.
Dr. Sorkness stated most antihistamine studies are short time studies only looking at allergic rhinitis, but not other indications that we use antihistamines for. Add prior authorization criteria allowing Zyrtec for patients with urticaria or atopic dermatitis irrespective of age.
Dr. Hirsch stated that none of these products are labeled for atopic dermatitis.
Ms. Sorkness noted that sedation issues are important for some, but is just a small percent of total population.
- d) Vote on Recommendation – Motion to accept recommendation was made by Dr. Fedderly, seconded by Dr. Hirsch. Voting in favor were:

- Tom Frazier – aye
- Christine Sorkness – aye
- Bradley Fedderly – aye
- Kevin Izard – aye
- Peg Smelser – aye
- James Heersma – aye
- Tom Hirsch – aye

There were no votes opposed and no abstentions.

8) Intranasal Rhinitis -- Astelin (Allergies)

- a) Review – clinical literature was presented.
- b) Recommendation:
 - Add Astelin to PDL as non-preferred.
- c) Discussion: No discussion.
- d) Vote on Recommendation – Motion to accept recommendation was made by Dr. Fedderly, seconded by Dr. Hirsch. Voting in favor were:

- Tom Frazier – not present
- Christine Sorkness – aye
- Bradley Fedderly – aye
- Kevin Izard – aye
- Peg Smelser – aye
- James Heersma – aye
- Tom Hirsch – aye

There were no votes opposed and no abstentions.

9) Lipotropics, Other -- Antara (Cholesterol lowering)

- a) Review – clinical literature was presented.
- b) Recommendation:
 - Add Antara to PDL as non-preferred.
- c) Discussion: No discussion.
- d) Vote on Recommendation – Motion to accept recommendation was made by Dr. Heersma, seconded by Ms. Sorkness. Voting in favor were:

- Tom Frazier – not present
- Christine Sorkness – aye
- Bradley Fedderly – aye
- Kevin Izard – aye
- Peg Smelser – aye
- James Heersma – aye
- Tom Hirsch – aye

There were no votes opposed and no abstentions.

10) Bronchodilators, Beta Agonists (Asthma)

- a) Review – clinical literature was presented.
- b) Recommendation:
 - Preferred: albuterol, albuterol inhaler, albuterol nebulizer, metaproterenol, terbutaline, metaproterenol, Serevent
 - Non-preferred: Maxair, Alupent inhaler, Accuneb, Vospire ER, Foradil, Xopenex

- c) Discussion: Ms. Sorkness noted there is a black box warning compared to Serevent. Trials stopped because asthma-related deaths among African-Americans were numerically greater.
- d) Vote on Recommendation – Motion to accept recommendation was made by Dr. Fedderly, seconded by Dr. Hirsch. Voting in favor were:
 - Tom Frazier – not present
 - Christine Sorkness – aye
 - Bradley Fedderly – aye
 - Kevin Izard – aye
 - Peg Smelser – aye
 - James Heersma – aye
 - Tom Hirsch – aye

There were no votes opposed and no abstentions.

11) Bronchodilators, Anticholinergic (Emphysema)

- a) Review – clinical literature was presented.
- b) Recommendation:
 - Preferred: ipratropium nebulizer, Atrovent inhaler, Combivent, Spiriva
 - Non-preferred: Duoneb
- c) Discussion: No discussion.
- d) Vote on Recommendation – Motion to accept recommendation was made by Dr. Fedderly, seconded by Dr. Heersma. Voting in favor were:
 - Tom Frazier – not present
 - Christine Sorkness – aye
 - Bradley Fedderly – not present
 - Kevin Izard – aye
 - Peg Smelser – aye
 - James Heersma – aye
 - Tom Hirsch – aye

There were no votes opposed and no abstentions.

12) Drugs for BPH (Enlargement of the prostate)

- a) Review – clinical literature was presented.
- b) Recommendation:
 - Preferred: doxazosin, terazosin, Uroxatral, Flomax, Avodart
 - Non-preferred: Proscar
- c) Discussion: No discussion.
- d) Vote on Recommendation – Motion to accept recommendation was made by Ms. Smelser, seconded by Dr. Fedderly. Voting in favor were:
 - Tom Frazier – not present
 - Christine Sorkness – aye
 - Bradley Fedderly – aye
 - Kevin Izard – aye
 - Peg Smelser – aye
 - James Heersma – aye
 - Tom Hirsch – aye

There were no votes opposed and no abstentions.

13) Ulcerative Colitis (Inflammation and sores of the intestine)

- a) Review – clinical literature was presented.
- b) Recommendation:
 - Preferred: sulfasalazine, mesalamine, Dipentum, Pentasa, Asacol, Canasa
 - Non-preferred: Colazal
- c) Discussion: Dr. Hirsch asked if Asacol were exclusive, would there be a better supplemental rebate.
Ms. Taylor stated there would not be a better supplemental rebate.
- d) Vote on Recommendation – Motion to accept recommendation was made by Dr. Izard, seconded by Dr. Fedderly. Voting in favor were:
 - Tom Frazier – not present
 - Christine Sorkness – aye
 - Bradley Fedderly – aye
 - Kevin Izard – aye
 - Peg Smelser – aye
 - James Heersma – aye
 - Tom Hirsch – aye

There were no votes opposed and no abstentions.

14) Bladder Relaxants (Incontinence)

- a) Review – clinical literature was presented.
- b) Recommendation:
 - Preferred: oxybutynin, Detrol, Oxytrol, Sanctura, Enablex, Detrol LA
 - Non-preferred: Ditropan XL, Vesicare
- c) Discussion: Mr. Mergener stated that the DERP recommendations follow PS recommendations. Dosing varies side effects. Long acting less dry mouth than short acting; transdermal product even less dry mouth than long acting, but some skin irritation.
- d) Vote on Recommendation – Motion to accept recommendation was made by Ms. Smelser, seconded by Dr. Hirsch. Voting in favor were:
 - Tom Frazier – not present
 - Christine Sorkness – aye
 - Bradley Fedderly – aye
 - Kevin Izard – aye
 - Peg Smelser – aye
 - James Heersma – aye
 - Tom Hirsch – aye

There were no votes opposed and no abstentions.

15) Phosphate Binders (Removal of phosphate in kidney disease)

- a) Review – clinical literature was presented.
- b) Recommendation:
 - Preferred: Phoslo, Renagel
 - Non-preferred: Magnebind 400 RX, Fosrenol
- c) Discussion: No discussion.
- d) Vote on Recommendation – Motion to accept recommendation was made by Dr. Hirsch, seconded by Ms. Sorkness. Voting in favor were:

- Tom Frazier – not present
- Christine Sorkness – aye
- Bradley Fedderly – aye
- Kevin Izard – aye
- Peg Smelser – aye
- James Heersma – aye
- Tom Hirsch – aye

There were no votes opposed and no abstentions.

16) Antiemetics (Prevention of nausea and vomiting)

- a) Review – clinical literature was presented.
- b) Recommendation:
 - Preferred: Emend, Zofran ODT, Anzemet, Zofran
 - Non-preferred: Kytril
- c) Discussion: Dr. Hirsch noted there may be some over-utilization of these drugs. DUR intervention with quantity limits was mentioned. Dr. Izard stated there is a preference for ODT dosage form.
- d) Vote on Recommendation – Motion to accept recommendation was made by Dr. Hirsch, seconded by Dr. Izard. Voting in favor were:

- Tom Frazier – not present
- Christine Sorkness – aye
- Bradley Fedderly – aye
- Kevin Izard – aye
- Peg Smelser – aye
- James Heersma – aye
- Tom Hirsch – aye

There were no votes opposed and no abstentions.

17) Hypoglycemics, Insulins (Diabetes)

- a) Review – clinical literature was presented.
- b) Recommendation:
 - Preferred: Humulin, Humalog, Lantus, Humalog mix 75/25
 - Non-preferred: Novolin, Novolog, Novolog mix 70/30
- c) Discussion: There was a question raised regarding potential clinical issues with switching from one insulin to another. Dr. Hirsch stated there is no clinical issue with switching. Ms. Taylor noted that other states have used only one product line.
- d) Vote on Recommendation – Motion to accept recommendation was made by Dr. Fedderly, seconded by Dr. Hirsch. Voting in favor were:

- Tom Frazier – not present
- Christine Sorkness – aye
- Bradley Fedderly – aye
- Kevin Izard – aye
- Peg Smelser – aye
- James Heersma – aye
- Tom Hirsch – aye

There were no votes opposed and no abstentions.

Next Meeting

The next meeting is June 8, 2005, Madison, 8:30am – 4:30pm.

Mr. Moody thanked the committee for their service and participation. Mr. Moody adjourned the meeting