MEDICAID PHARMACY PRIOR AUTHORIZATION ADVISORY COMMITTEE
Final Meeting Summary
September 15, 2004

Opening Remarks/Introductions

The Medicaid Pharmacy Prior Authorization (PA) Advisory Committee met on September 15, 2004 to review the first ten (10) categories of drugs to be implemented on the Wisconsin Medicaid preferred drug list (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 purpose of the meeting is to introduce the PA committee members to the process the DHCF will utilize to implement the PDL, receive and review testimony of the manufacturers and other interested parties, present clinical and cost information and the Department's PDL recommendations, and engage the PA committee members in a discussion of the recommendations, with the goal of making recommendations to the Secretary.

- Valerie Taylor, Pharm.D., Provider Synergies (Clinical Director), will provide the PA committee with an overview of the PDL process.

- The testimony guidelines for the meeting are as follows:
  1. Speakers are required to state their name and the organization represented.
  2. Speakers are limited to a period of five (5) minutes.
  3. Only one (1) speaker per company or organization is permitted.

- The current pharmacy spending for Wisconsin Medicaid is over $600 million annually for fee-for-service recipients. The cost of brand name drugs increased over 21% from 2002 to 2004. Wisconsin Medicaid program costs are projected to be $230 million GPR above available funding.

- The Wisconsin Medicaid PDL is not a formulary. Non-preferred products in each reviewed class can still be covered if medically justified through PA. The PA committee will be reviewing the first ten (10) classes out of an expected forty-five (45) classes. These ten (10) classes will be implemented through a phase-in starting on October 1, 2004.

Explanation of the PDL Process

Valerie Taylor provided an overview of the PDL development process. Provider Synergies has assisted with implementation of PDLs and supplemental rebate programs for both commercial and state clients, including seven (7) Medicaid programs.

- The PDL is driven principally by clinical consideration. Financial consideration is secondary.

- A supplemental rebate is not required in order for a drug to be recommended as a preferred product(s).

- Bid requests for supplemental rebates are sent to all manufacturers with drugs in a specific class.

- Provider Synergies' staff review both clinical and cost information, with an emphasis placed on the clinical information. A clinical review is completed for each drug that includes analyzing efficacy, safety, side effects, adverse reactions, indications, and net costs. Drugs that offer superior therapeutic outcomes or are superior for certain conditions can be included even if they are not the lowest cost.

- PDL savings are not limited to the first year as the process is revisited annually for each class.

- In the seven (7) states that Provider Synergies has provided Medicaid PDL and supplemental rebate programs, the states have achieved over 90% compliance with PDL preferred drugs.

Mike Boushon, DHCF Pharmacy Consultant, provided an overview of the PA process required to prescribe and dispense a non-preferred drug on the PDL. Items covered included:

- Mr. Boushon distributed the PA/PDL form and instructions to the PA committee. The physician is required to complete and retain a copy of the PA/PDL form. The physician may fax a copy of the form to the pharmacy, or provide it to the recipient with their prescription. The pharmacy is required to use the existing electronic prior authorization system (STAT PA) or submit the PA request on paper, and retain a copy in their records.

- Mr. Boushon emphasized that this process allows the physician and pharmacist to work together. More information regarding the form, instructions, and process are available via the Medicaid updates distributed to both physicians and pharmacists on September 15, 2004.

- The PDL will be available on the Medicaid web site on September 22, 2004, and also via ePocrates (www.epocrates.com) on October 13, 2004.

The PA committee members asked the following questions:

1. Does the process preclude interaction between the pharmacist and the patient? Mr. Boushon responded that is does not, and should encourage discussion.

2. What are retention requirements of the PA/PDL form? Mr. Boushon responded that both the physician and pharmacist are required to retain a copy of the PA/PDL form.

3. Is the form available? Mr. Boushon responded that the form was included in the Medicaid Update sent to all physicians and pharmacists, and is also posted on the Medicaid web site.

Public Testimony

Mr. Moody opened the public testimony portion of the meeting. He reminded speakers to provide the DHCF a written copy of their testimony, preferably via email. The table below lists each speaker who testified and the topic of their testimony.

SUMMARY TABLE OF PUBLIC TESTIMONY

Speaker	Organization	Product/Topic	Summary of Comments
Holly Quasney	GlaxoSmithKline	Avandia, Advair, Immitrex, Flonase	Provided clinical information and support for products.
Nathan Kanous	Astra Zeneca	Crestor	Provided clinical information and support for product.
Dr. Robert Calder	Merck	Zocor, Vioxx	Provided clinical information and support for products.
Dr. Barry Blackwell	Process	Mental Health & PA	Dr. Blackwell voiced concerns regarding restricting access to drugs, and argued that the FDA standards for approval of generic drugs is not vigorous.
F. Glover	TAP	Prevacid/Naprapac	Provided clinical information and support for product.
Dr. Pinakin Attawala	Schering Plough	Zetia, Nasonex	Provided clinical information and support for products.
Rick Molbye	Takeda Pharmaceuticals	Actos	Provided clinical information and support for product.
Elizabeth Schuler	Bristol-Meyers Squibb	Pravachol	Provided clinical information and support for product.
Jay Gandon	Sanofi	Avapro	Provided clinical information and support for product.
Fran Peterson	KOS Pharmaceuticals	Niaspan, Advicor	Provided clinical information and support for products.
Jodie Jensen	Johnson & Johnson	Axert	Provided clinical information and support for product.

Speaker	Organization	Product/Topic	Summary of Comments
Tom Majerus	Abbott	Tricor	Provided clinical information and support for product.
Diane Zwart	Eli Lily	Evista, Forteo	Provided clinical information and support for products.
Grita Chi	Pfizer	Lipitor, Celebrex, Bextra, Relpax	Provided clinical information and support for products.
Tom Engels	PSW	PDL	Mr. Engels offered his support of the PDL, but voiced reservations regarding the level of work increase that pharmacies will experience.
Lynette Horwath	Arthritis Foundation of Wisconsin	PDL	Ms. Horwath provided testimony on the number of residents in Wisconsin with arthritis and voiced concerns regarding the PDL restricting access to needed medications.
Scott Skiermanski	Reliant Pharmaceuticals	Lescol, XL	Provided clinical information and support for products.
Cynthia Giambrone	Novartis	Diovan, Miacalcin	Provided clinical information and support for products.
Lisa Goetz	Proctor & Gamble	Actonel	Provided clinical information and support for product.
Dr. Kate Chavanu	Sanyo Pharmaceuticals	Benicar, HCT	Provided clinical information and support for products.
Dr. Marzena Krawiec	UW Pediatric	PDL	Dr. Krawiec provided testimony about asthma drugs that benefit pediatric pulmonary patients.
Catherine Gerar	Executive Director, American Diabetes Assn.	Diabetes	Ms. Gerar testified that the PDL must be implemented carefully, considering the patients that will be forced to switch therapy and that experts should be included in the process.

Speaker	Organization	Product/Topic	Summary of Comments
Randy Radtke	Wisconsin Lung Assn and Asthma Coalition	Asthma	Mr. Radtke voiced concerns regarding the use of PA and barriers to access in managing disease.
Wendall Harris	NAACP/Black Health Coalition of Wisconsin	Asthma, Diabetes, Hypotension	Mr. Harris voiced concerns regarding the use of PA and barriers to access in managing disease.
Dr. Alan Rifken	UW Student Health	Migraines, Immitrex	Dr. Rifken testified as a migraine sufferer and in support of Immitrex, and the importance of not restricting access to necessary medications.
Dr. W. Nolten	UW Endocrinologist	Diabetes	Dr. Nolten testified based on his experience treating diabetes patients for 30 years, and voiced concerns regarding access to necessary medications.
Dr. Alvin Wells	Rheumatologist	PDL	Dr. Wells voiced concerns regarding restricting access to necessary medications and ability to treat/manage disease.
Dr. Prince	WI Neurologic Association	PDL	Dr. Prince voiced concerns regarding access/restrictions to triptans, specifically mentioning Immitrex.

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 Mr. Maike seconded to recess the public meeting and convene in closed session.

Mr. Moody said that state law required recording how each committee member voted on a motion to move into closed session, so the motion necessitated a role call vote.

The motion passed 6 to 0. Voting in favor were:

- Tom Frazier – aye
- Christine Sorkness – aye
- Steve Maike – aye
- Larry Flemming – aye
- James Heersma – aye
- Tom Hirsch – aye

There were no votes opposed and no abstentions.

Before the closed session began, the committee voted 6-0 to adjourn the closed session and reconvene in public session to take public testimony from Dr. Alvin Wells.

Following Dr. Well's public testimony, Mr. Frazier motioned to recess the public meeting and to convene in closed session passed 7 to 0 on a roll a call vote. Voting in favor were:

- Tom Frazier – aye
- Christine Sorkness – aye
- Steve Maike – aye
- Peg Smelser – aye
- Larry Flemming – 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)

Ms. Taylor presented class reviews as follows:

1) Leukotriene Modifiers (Asthma)
   a) Review – clinical literature was presented.
   b) Recommendation – Accolate and Singulair as preferred.
   c) Discussion – Dr. Hirsch asked that the DHCF consider adding diagnosis restriction for claims. Recommendation referred to DHCF.
   d) Motion to Approve – Dr. Hirsch; Ms. Sorkness second.
   e) Vote on Motion – Passed unanimously.

2) Corticosteroids, Nasal (Allergies)
   a) Review – clinical literature was presented.
   b) Recommendation – flunisolide, Flonase, Nasarel, and Nasonex as preferred, Beconase AQ, Nasacort AQ, and Rhincort Aqua as non-preferred.
   c) Discussion – no discussion.
   d) Motion to Approve – Dr. Fleming; Dr. Hirsch second.
   e) Vote on Motion – Passed unanimously.

3) Glucocorticoids, Inhaled (Asthma)
   a) Review – clinical literature was presented.
   b) Recommendation – Advair Diskus, Aerobid, Aerobid-M, Azmacort, Flovent, Qvar, and Pulmicort Respules as preferred, Pulimicort Turbuhaler as non-preferred.

c) Discussion – Dr. Hirsch asked if combination therapy involving a long-acting beta-agonist should be pushed and not favor the separate use of inhaled corticosteroids. Mr. Boushon said the issue could be taken up by the Medicaid DUR Board.
d) Motion to Approve – Ms. Sorkness; Mr. Maike second.
e) Vote on Motion – Passed unanimously.

4) Hypoglycemics/TZDs (Diabetes, Oral Meds)
a) Review – clinical literature was presented.
b) Recommendation – Actos and Avandia as preferred.
c) Discussion – no discussion.
d) Motion to Approve – Dr. Heersma; Mr. Frazier second
e) Vote on Motion – Passed unanimously.

5) Bone Resportion Suppression and Related Agents (Osteoporosis)
a) Review – clinical literature was presented.
b) Recommendation – Actonel, Fosamax, and Miacalcin as preferred, Didronel and Evista as non-preferred.
c) Discussion – Dr. Hirsch asked if the system could prospectively identify criteria to avoid PA. Mr. Boushon responded that it has been discussed previously but no current activity to implement.
d) Motion to Approve – Dr. Heersma; Ms. Sorkness second.
e) Vote on Motion – Passed unanimously.

6) Lipotropics, Statins (Cholesterol Lowering)
a) Review – clinical literature was presented.
b) Recommendation – lovastatin, Altoprev, Crestor, Lescol, Lescol XL, Lipitor, Zocor as preferred, Caduet, Pravachol, Pravigard PAC, and Vytorin as non-preferred.
c) Discussion – Ms. Smelser questioned why the state was straying from current approach. Dr. Hirsch commented that the market is moving to higher potent statins, and Ms. Sorkness concurred with Dr. Hirsch's statement. Dr. Flemming also commented that we should delay any step approach until more brand drugs in this class become available in generic form.
d) Motion to Approve – Dr. Fleming; Mr. Frazier second.
e) Vote on Motion – Passed unanimously.

7) Lipotropics, Other
a) Review – clinical literature was presented.
b) Recommendation – cholestyramine, gembfibrozil, niacin, Advicor, Colestid, Lofibra, Niaspan, and Zetia as preferred, Tricor and Welchol as non-preferred.
c) Discussion – Ms. Taylor indicated that Vytorin was not reviewed in time for this meeting as it had entered the market after the process had begun. Vytorin will be considered non-preferred until it is reviewed at the December 2004 meeting.
d) Motion to Approve – Ms. Sorkness; Dr. Hirsch second.
e) Vote on Motion – Passed unanimously.

8) Angiotensin Receptor Blockers (High Blood Pressure)
   a) Review – clinical literature was presented.
   b) Recommendation – Cozaar, Hyzaar, Diovan, Diovan HCT, Micardis, and Micardis HCT as preferred, Atacand, Atacand HCT, Avapro, Avalide, Benicar, Benicar HCT, Teveten, Teveten HCT as non-preferred.
   c) Discussion – Committee engaged in a discussion about first line therapy, adding that this class may also be a good candidate for prospective PA.
   d) Motion to Approve – Dr. Hirsch; Dr. Fleming second.
   e) Vote on Motion – Passed unanimously.

9) Antimigraine/Triptans – (Migraine Headaches)
   a) Review – clinical literature was presented.
   b) Recommendation – Amerge, Axert, and Immitrex as preferred, Frova, Maxalt, Maxalt MLT, Relpax, Zomig (Nasal, ZMT) as non-preferred
   c) Discussion – Committee discussed the issue of patient needing to shift therapy and if grandfathering was a consideration, however committee acknowledged that PA was still available if necessary to continue existing medication. Committee also recommended that the DUR Board research "rebound headaches" in a future meeting.
   d) Motion to Approve – Dr. Fleming, Ms. Sorkness second.
   e) Vote on Motion – Passed unanimously.

10) Nonsteroidal Anti-inflammatory Agents (Pain)
   a) Review – clinical literature was presented
   b) Recommendation – diclofenac potassium, dicolfenac sodium (XL), etodolac (XL), fenoprofen, flurbiprofen, ibuprofen, indomethacin (SR), ketoprofen, ketorolac, meclofenamate, nabumetone, naproxen, naproxen sodium (DS), oxaprozin, piroxicam, sulindac, and tolmetin (DS) as preferred, Bextra, Celebrex, Mobic, Ponstel, and Vioxx as Tier 1 non-preferred, Athrotec as Tier 2 non-preferred.
   c) Discussion – Ms. Taylor clarified that Tier 1 requires use of at least one (1) preferred generic NSAID, and Tier 2 requires the use of both a preferred generic NSAID and a non-preferred Tier 1 NSAID or COX-II. The committee engaged in a discussion involving two (2) amendments to the original recommendation. The committee suggested that the recommendation be modified to include the use of at least three (3) generics prior to the use of a Tier 1 product, and also to modify the preferred list to move five (5) drugs to non-preferred status. The second amendment was not adopted, as it would require renegotiating with the manufacturers. The first amendment was discussed further.
   d) Motion to Approve– The committee passed the first amendment to modify the recommendation to require the use of at least three (3) generics prior to the use of a Tier 1 product by a vote of 6 to 1.[1] Motion to approve amended recommendation: Dr. Fleming, Dr. Hirsch second.
   e) Decision – Passed unanimously.

Next Meeting – To be determined.

[1] Following the meeting Provider Synergies researched modifying the criteria to ascertain conflict with any submitted terms offers. Modifying the criteria would void an offer made by a manufacturer; consequently, the existing 1-step criterion will remain in place.