

Pharmacy and Therapeutics Committee Meeting
April 14, 2003 (Rescheduled from March 4, 2003)
Kellogg Hotel and Conference Center

Draft Minutes

Committee Members in Attendance:

David Johnson, M.D., Chairman
Giovannino Perri, M.D.
Robert Coffey, PharmD
Debera Eggleston, M.D.
Robert Ernst, M.D.
Jonathan Henry, M.D.
Edward Keating, RPh.
Max Robins, D.O.

Not in Attendance: Sandra Campbell, PharmD.

State Representatives in Attendance:

Doris R. Gellert, Director, Pharmacy, Medical and Beneficiary Services Bureau
David Viele, Deputy Director, Budget and Finance Administration
George Baker, M.D., Office of Medical Affairs

First Health Services Corporation Representatives in Attendance:

Annette Paul, Medicaid Clinical Manager
Bruce Edgren, Sr. Director Clinical Program Development

Audience:

Approximately 60 persons in attendance—comprised primarily of physicians, clinicians, pharmacists, and drug manufacturer representatives.

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- I. The meeting was called to order at 6:15 P.M. by Dr. David Johnson.
 - II. Dr. Johnson moderated the public comments. These included:
 - Bristol-Myers Squibb on Metaglip by Jennifer Meredith, Ph.D.
 - Novartis Pharmaceuticals on Zelnorm by Rosemary R. Berardi, Pharm.D., FCCP, FASHP.
 - Merck/Schering Plough on Zetia by Dr. David R. Neff and Dr. John D. Call with West Michigan Heart.
 - Senior's Wellness Group, P.C. on "Clinical benefits of Lexapro as related to Paxil" by Dr. Douglas J. Arends.
 - Pfizer, Inc. on Inclusion of Geodon, Zyrtec and Zolofl on Michigan's PDL—presenter passed on the comment opportunity and moved to next topic.

- Pfizer, Inc. on Vfend by Rick Dettloff, PharmD, BCPS.
- Bristol-Myers Squibb on Abilify by Dr. Carmen McIntyre.
- Abbott Laboratories on Humira by Arlene Price, Pharm.D.
- Andrx labs on Altocor by Dr. Robert Niecestro.
- Forest Laboratories on Lexapro by Dr. A. L. Hughett.
- Primary Care Physicians of Gratiot Health Systems on “cost effectiveness of treating patients” by Dr. Dan Dean.
- Presentation on Restasis by Dr. David Krebs, Ophthalmologist.

Requests to Comment with no speaker present:

- Hoffmann-LaRoche on Pegasys/Copegus for treatment of Hepatitis C.
- Novartis Ophthalmics on Zaditor and Voltaren.

III. Edward Keating, RPh. moved that the December 17, 2002 meeting minutes be accepted as written. Dr. Debera Eggleston seconded the motion and minutes were approved.

Dr. Johnson informed the committee of membership changes with the resignation of Dr. Larry Lawhorn and James Kenyon, RPh.

IV. Pharmacy Program updates were provided by David Viele, Bruce Edgren and Doris Gellert.

Pharma Lawsuit(s) –Dave Viele:

Judge Bates has ruled for CMS in the Washington D.C. lawsuit thereby affirming that CMS and states can move forward with Preferred Drug Lists through expanded prior authorization. That is, Michigan does not have a formulary which is precluded by federal regulations. It is not known at this point if Pharma will appeal this decision to the Supreme Court. In September, CMS issued a letter to State Medicaid directors which requires that a Medicaid state plan amendment be submitted for state funded programs to be included in supplemental rebate agreements.

Michigan state plan amendments for the EPIC and MOMS programs have been approved and state plan requests to include the SMP and state CSHCS programs have been denied. This denial is being appealed.

Waivers –Dave Viele

On April 11th, the department filed a Medicaid Waiver which would incorporate the SMP program as a Medicaid benefit. The department expects approval of the waiver from CMS. Additionally, the Pharmacy Plus Waiver which was submitted in February would change the state EPIC senior pharmacy program to a single benefit (pharmacy) Medicaid program. Medicaid budget neutrality is required as a condition of this waiver approval. Presently about 14,000 low income seniors are enrolled in the EPIC Program. Approval of the waiver would add up to an additional 27,000 participants. CMS is reviewing the waiver with a decision expected by July 1st.

Multi State Purchasing Pool –Dave Viele

The Multi State Purchasing Agreement now has 4 participating states: Michigan, Vermont, South Carolina and Wisconsin with nine other states expressing intent to participate and additional states considering participation.

Multi State Purchasing Pool Process, 4x 4 Matrix – Bruce Edgren

This bid structure provides for a 3 year agreement with annual bid enhancement opportunity. The bid model has two dimensions—1) number of persons with eligibility and 2) exclusivity of drug within a category and consists of 16 bid cells. It is intended to:

1. Create a competitive environment;
2. Accumulate eligibility (number of beneficiaries in state(s) programs)
3. Provide for exclusivity; and
4. Provide each state with the ability to make its own individual choices.

This is a way for states to combine market and pricing yet follow their own roadmap for developing a PDL. FHSC is now reviewing and compiling the manufacturers bids. The supplemental contract year is scheduled to be retroactive to April 1, 2003.

Workgroup meetings/timeframes - Doris Gellert

Similar to last year, the department will schedule several workgroup meetings (which will not be open to the public) with P & T Committee members for clinical review of the drugs and classes to be included in the next PDL. Others expected may be asked to participate in these work groups. Decisions will be made at a special P&T Committee meeting. **Note:** P&T Committee meeting is scheduled for May 13, 2003.

- V. DUR Board update by Doris Gellert. The DUR Board met on February 20, 2003 with the next DUR Board meeting scheduled for May 7, 2003. Staff recommendations resulting from discussions with board members, advocacy groups, input from drug manufacturers, as well as pharmacy and physician input have been forwarded to DCH Leadership. These would expand the DUR Board membership, role and activities within the general framework of utilization review and education.
- VI. Annette Paul and Dr. Johnson presented the new products for review.
***Committee action/decisions on new product coverage is attached to minutes.**

Note: It was the department's intent to request the committee to consider reclassifying all of the current atypical antipsychotic products as preferred. After identification of this omission, Ed Keating amended his motion to include Zyprexa Zydis as a preferred product since Zyprexa is currently preferred and Zyprexa Zydis is simply a different dosage form. This amended motion has been seconded by Jonathan Henry. The outcome of this amended motion results in the inclusion of Abilify, Geodon and Zyprexa Zydis as additional preferred products.

- VII. Issues for Committee Consideration by Doris Gellert.

Zelnorm – Current utilization date was reviewed and the committee voted to continue prior authorization with the initial PA duration extended to 12 weeks. If clinically necessary any continued use would be approved for up to 12 months.

Neulasta – The committee voted to correct the monograph from the September 17, 2002 meeting which erroneously reported a PA requirement for this class and to remove the prior authorization requirement.

Concept of StepTherapies – conversation/discussion regarding:

- non PDL classes
- clinical differences, facilitate assessment with pharmacists, physicians and clinicians.
- best practices
- intensive work with PDL classes

***MDCH to pull together information for the P&T Committee to revisit at a future meeting.**

Prior to adjournment department staff requested that a 5 business day notice for commenters be required. Additional discussion ensued regarding written material on comment presentations.

Next meeting is May 13, 2003

6:00 P.M. – 9:00 P.M.

Location: Kellogg Hotel and Conference Center

Meeting adjourned at approximately 9:45 P.M.

Respectfully submitted by: Lynda M. Cords.

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New Product Coverage Decisions:

Medication	PDL Class	PDL Preferred Drug	Clinical PA Required	Panel Member Comments
Altacor	yes	No—pa required as non preferred	no	Unanimous vote to require prior authorization as non preferred.
Vfend	yes	yes	no	Unanimous vote—utilization to be reviewed after 6 mos.
Lexapro	yes	Deferred temporarily for new PDL; PA required as non-preferred	no	Voted to defer pending PDL review. Note-will be available with PA as non preferred.
Elitek	no	Not applicable	no	Consensus to add to MPPL.
Pegasys	Fyi—no	Fyi—not applicable	Fyi—no	(expedited review outside of mtg.).
Avandamet	yes	No-pa required as non preferred	no	Voted and agreed no clinical evidence to add as preferred.
Metaglip	yes	No-Pa required as non preferred with final decision deferred	no	Voted to defer judgment/action until review with colleagues in the field of pediatrics.
Zetia	yes	yes	no	Unanimous vote in favor of adding to PDL. review in six months.
Copegus (email review)	Fyi—no	Fyi—not applicable	Fyi—no	(expedited review outside of mtg.)
Alinia (email review)	Fyi—no	Fyi—not applicable	Fyi—Age Edit per FDA Approval	(expedited review outside of mtg.).
Abilify, Geodon and Zyprexa Zydis	yes	yes	no	Amended motion and vote in favor of adding to PDL as preferred.
Advodart	no	Not applicable	Edit for gender and age	Unanimous vote to add to PDL.
Restasis	no	Note applicable	Clinical PA required	Voted to make available for 60 days. Review usage pattern after 6 months.

