STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

Bob Wise
Governor

Paul L. Nusbaum
Secretary

Drug Utilization Review Board Meeting Minutes

September 15, 2004

The Diamond Building – 350 Capitol Street
Rooms B10 and B11
Charleston, West Virginia

The forty-third meeting of the West Virginia Medicaid Drug Utilization Review Board was called to order with the following in attendance:

Members Present:
Karen Reed, R.Ph., Chairperson
Lester Labus, M.D.
Chris Terpening, PharmD., Ph.D.
John R. Vanin, M.D.
Bernie Smith, R.Ph., M.B.A., M.H.A.
George Bryant, PA-C
Mary Nemeth-Pyles, M.S.N., R.N., C.S.
Matthew Watkins, D.O.
Myra Chiang, M.D.
Ernest Miller, D.O.
Mitch Shaver, M.D.
James Bennett, M.D.
David Elliott, PharmD.
Steve Judy, R.Ph.
Kerry Stitzinger, R.Ph.

Members Absent:
Dan Dickman, M.D.
Kevin Yingling, R.Ph., M.D.
Pat Regan, PharmD.

DHHR/BMS Staff Present:
Peggy King, R. Ph., Pharmacy Director
Sandra Joseph, M.D., Medical Director
Vicki Cunningham, R.Ph., DUR Coordinator
Gail Goodnight, R.Ph. Rebate Coordinator
Lynda Edwards, Secretary

Contract Staff:
Steve Small, Rational Drug Therapy Program
Daphne MacDougall, Heritage/ACS
Sandra Dawson, R.Ph. Heritage/ACS
Tom Robinette, R.Ph.,Unisys

Interested Parties Present:
Abbott: Samuel Thomas
Astra Zeneca: JoAnn Shoup
Aventis: Steve Barney, John Adams, Walter Gose, John Buntow
Berlex: Cathy Gore
Bristol Myers Squibb: John Hymen
Cephalon: Deb Bearer
Fujisawa: Linda Eason
GSK: Mark Canterbury
Janssen: Bert Wickey, Sterling Lewis
Johnson & Johnson: Raymona Kinneberg
Lilly: Ron Hart, Steven Babineaux
Merck: Bob Kelley, Michael Tu
Novartis: Jeff Goins
Pam Labs: Mark Hollands
Pfizer: Gary Mueller, Pamela Smith
Purdue: Michael Heinzmann
Schering: Rob Fuente, Feng Ho, Robert Marsh
TAP: Stacey Poole
WVU: Richard Granese
Wyeth: Tim Atchison
Other: Tim Saxe, MD, Kiran Kresa-Reahl, MD

I. INTRODUCTIONS

Karen Reed, Chairperson, welcomed everyone to the Board meeting. Members of the Board and interested parties introduced themselves.

II. APPROVAL OF THE May 19, 2004, MINUTES

A motion was made to accept the minutes of the May 19, 2004 DUR Board meeting as written. The motion was seconded and passed unanimously.

III. OLD BUSINESS

Myra Chiang asked why criteria concerning prior authorization for Growth Hormone for Non-Growth Hormone Deficient Children was not included in the agenda for this meeting. Vicki Cunningham stated that, at the September meeting, a recommendation was made not to cover it for this indication. Dr. Chiang said she understood that the recommendation was to cover growth hormone for this purpose, if it was requested by a board certified endocrinologist. Ms. Cunningham said that her notes reflected that a motion not to cover it for non-growth hormone deficient children was made and seconded, since it could be considered a cosmetic use. Although there was a motion made and seconded, there was some confusion as to whether there was a consensus about no coverage for this indication. It was decided that the policy for this indication should be discussed again by the Board.

A discussion followed between Dr. Joseph and Dr. Chiang about children who needed growth hormone because of stunted growth due to a medical condition, such as chronic renal failure, in contrast to children who would be treated because of idiopathic short stature. Dr. Joseph reiterated that federal guidelines do not allow Medicaid programs to cover drugs for cosmetic reasons and voiced concerns that treatment for idiopathic short stature could be considered as such. Board members also commented that administering growth hormone to children with idiopathic short stature would probably not affect their height at maturity.

Members of the Board asked for more information about other states and PEIA's policy for covering this agent for idiopathic short stature. Vicki Cunningham apologized for the confusion about whether the guidelines were to be reviewed again and will survey other state Medicaid programs and PEIA concerning their coverage guidelines. Criteria will be reviewed at the November meeting.

A. Provigil (modafanil) – Review of New Indications and Criteria for Approval

Dr. Kiran Kresa-Reahl, Medical Director of the Multiple Sclerosis (MS) Clinic of West Virginia, presented information about multiple sclerosis fatigue and current recommendations for treatments. She stated that she had come to advocate for the coverage of Provigil® for MS fatigue. Dr Kresa-Reahl stated that fatigue was a devastating condition that accompanied MS and that Provigi®l was needed to treat patients who did not respond to amantadine.

A discussion followed about the off-label use of both amantadine and Provigil®. Dr. Joseph stated that the studies that had been done on the use of Provigil® for this indication were very small and not peer-reviewed. She also stated her concern that Provigil® does not have FDA approval for this indication, does have some potential for addiction, is a relatively new drug, and does not modify the progression of the disease. Dr. Kresa-Reahl reminded the Board that the fatigue accompanying MS was devastating and that very few agents were available to treat it with. She asked the Board to consider approving it for MS fatigue refractory to amantadine and said that other states were approving it for this reason. She also stated that it had become a standard of care for this condition.

Board members asked for information regarding coverage by other state Medicaid programs and for the Consortium of Multiple Sclerosis Clinics (CMSC) guidelines to review. It was agreed that draft criteria should be written and reviewed by the Board at the next meeting.

Ms. Cunningham asked the Board if they wanted to proceed with voting on the criteria for FDA approved indications, as proposed and amended at the previous meeting. She stated that the initial reason for reviewing Provigil was because of the new indication for drowsiness related to shift work. The criteria for prior approval for FDA indications was reviewed by the Board and adopted. That criteria will become effective immediately.

See Attachment A

B. Risperdal Consta – Approval Criteria

Ms. Reed read the proposed criteria. Ms. Cunningham stated that the criteria to be voted on reflected the amendments proposed at the May meeting. A motion was made to approve the criteria. Motion was seconded, voted upon and the motion carried. The criteria was adopted and will become effective immediately.

See Attachment B

C. Enbrel – Review of New FDA Indication and Approval Criteria

Ms. Reed read the criteria. A motion was made to accept the criteria. The motion was seconded, voted upon and the motion carried. The criteria was adopted and will become effectively immediately.

See Attachment C

IV. NEW BUSINESS

A. Zelnorm – Review of New Indication and Proposed PA Criteria

Ms. Reed stated that prior authorization of this drug had been proposed because of a new indication for chronic constipation in both men and women. Ms. Reed read the criteria. Ms. Cunningham stated that the criteria came from the manufacturer's package insert and asked the Board for their comments. The suggestion was made to eliminate the requirement for evaluation by a gastroenterologist. A Board member also suggested that the initial prior authorization be given for 3 months and the patient's response be evaluated at that time. If it is still needed, prior authorizations should be given for one year. Peggy King suggested that we ask a gastroenterologist to review our draft criteria. The draft criteria will be reviewed by a gastroenterologist, amended as recommended, and then voted upon at the next meeting. Vicki Cunningham said that she would obtain utilization data for the Zelnorm since the new indication had been given.

See Attachment D

B. Review of PDL Changes from August 10, 2004 P & T Meeting

Ms. Cunningham presented changes that had been made to the Preferred Drug List. She stated that these changes would be implemented on October 1, 2004. Prior authorization criteria for each therapeutic category was reviewed. The following changes were made:

Xalatan-Since Xalatan was made non-preferred, Board members expressed concern that it should be made available to patients who were stabilized on it. A motion was made to

grandfather patients who were using Xalatan as a single agent. Motion was seconded, voted upon and carried.

Prevacid-Since supplies of Prilosec OTC were not sufficient to meet the demand, Prevacid became the preferred agent in the PPI catergory. Single daily dosing will not require a prior authorization, but twice daily dosing will. Dosing two times daily will be approved for Barrett's esophagus and Barrett's Syndrome. Patients must have a trial of the preferred agent before a non-preferred one will be approved.
See Attachment D

Dr. Vanin asked why clonazepam was not included on the list with the approved sedatives and hypnotics. Peggy King replied that it was included in the anticonvulsant category, but was covered without a prior approval for either diagnosis.

Dr. Vanin also asked about the possibility of covering the stimulants for adults with ADD without a prior authorization. Vicki Cunningham will provide utilization statistics about these agents in recipients over 21 years of age.

See Attachment E

C. Presentation - Ketek

Dr. Timothy Saxe made a presentation about a new antibiotic, Ketek. Following his presentation, the draft criteria for prior authorization of Ketek was reviewed. A Board member suggested that only one or the other of the two criteria should have to be met before a prior authorization would be granted. Ms. Cunningham will amend the criteria and it will be voted upon at the next meeting.

See Attachment F

D. Review of Letters Concerning COX-II Inhibitors

Ms. Reed said that there was a letter of concern about the policy for prior authorizing the COX-II inhibitors. She asked the Board if they were interested in hearing a presentation about these concerns and data that could be supplied by the author of the letter. A Board member suggested that the new data be submitted in writing to the Board and then, if it seemed appropriate, an oral presentation could be scheduled. She said that she would request the written information and include it in the next packet of information for the Board.

See Attachment G

V. REPORTS

A. Rational Drug Therapy Program (See Attachment)

Steve Small, Director of the Rational Drug Therapy Program, summarized his written report for the members of the Board.

B. Heritage/ACS Information Systems, Inc.

Sandra Dawson, R.Ph, presented population based educational interventions to the Board. They were allergic rhinitis, asthma, use of COX-II inhibitors, and dose simplification. There was some discussion about the COX-II inhibitor prior authorization policy. After discussion of the policy and reiteration that COX-II inhibitors were approved for those who had GI risk or were over 70 years of age, it was decided that other interventions proposed would be more

effective. The Board chose the Asthma and Dose Simplification educational interventions for this quarter.

(See attachment)

C. ACS Second Quarter Report (See Attachment)

There were no comments from the Board regarding the ACS Quarterly Report.

VI. OTHER BUSINESS

No other business was discussed. Vicki Cunningham announced that Karen Reed, DUR Board Chairperson, was selected as spokesperson for the American Pharmaceutical Association during pharmacy week. She was congratulated by the Board members. Members of the Board also congratulated Dr. Watkins on becoming the father of twin sons.

VII. OPEN TO THE FLOOR

An audience member asked if the PA report on growth hormone therapy was available to the public or on the website. Ms. Cunningham said that she would send a copy of the RDTP report to John Brown, PhRMA representative.

VIII. NEXT MEETING AND ADJOURNMENT

A motion was made and seconded that the meeting be adjourned. All were in favor. The meeting was concluded at 6:45 p.m. The next meeting will be held on Wednesday, November 17, 2004 from 4:00 p.m. - 6:00 p.m.

Respectfully submitted,

Lynda L. Edwards
Secretary