STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

Bob Wise
Governor

Paul L. Nusbaum
Secretary

Drug Utilization Review Board Meeting Minutes

February 16, 2005
The Diamond Building – 350 Capitol Street
Rooms B10 and B11
Charleston, West Virginia

The West Virginia Medicaid Drug Utilization Review Board meeting 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.
Myra Chiang, M.D.
Ernest Miller, D.O.
James Bennett, M.D.
Pat Regan, PharmD.
David Elliott, PharmD.
Kerry Stitzinger, R.Ph.
Mary Nemeth-Pyles, M.S.N., R.N., C.S.
George Bryant, PA-C

Members Absent:
Matthew Watkins, D.O.
Mitch Shaver, M.D.
Steve Judy, R.Ph.
Dan Dickman, M.D.
Kevin Yingling, R.Ph., M.D.

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

Contract Staff:
Steve Small, Rational Drug Therapy Program
Craig Boon, Heritage/ACS
Tom Robinette, R.Ph.,Unisys
KayLynn Wight, Unisys
Peter Griego, Unisys

Interested Parties Present:
Bristol-Myers Squibb: Steve Long
Elan: Mitch Cohen
Janssen: Jim Meyer
Lilly: Ron Hart
Merck: Bob Kelley, Hollie Mason
Organon: Tim Stanley, Chris Ashworth, Mike Roth
Pfizer: Pamela Smith, Darren Ray, Kent Hunter
Purdue: Michael Heinzmann
Sanofi:Aventis: Raymona Kinneberg, George Aiello, Mike Bowen, Tim Dempsey
Schering-Plough: Bob Marsh, Rob Fonte
Sepracor: Sue Shrout, Melissa Kay
Shire: Jonell Lanta
TAP: Stacey Poole

I. INTRODUCTIONS

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

II. APPROVAL OF THE NOVEMBER 17, 2004, MINUTES

A motion was made to accept the minutes of the November 17, 2004 DUR Board meeting as written. The motion was seconded and passed unanimously.

III. OLD BUSINESS

A. Review of Mandatory Generic Substitution Policy

The first item of old business was the review of the mandatory generic substitution policy. Steve Small, Director of RDTP, requested guidance from the Board in enforcing the policy. He reported that brand name medications were being approved upon completion of a MedWatch form, regardless of the complaint about the generic medication. He inquired as to whether the intent of the policy was to approve brand names for only therapeutic failure and significant adverse effects, or for any side effect reported. Peggy King asked who submitted most of the forms and he replied that 40% of them came from physicians. Mr. Small also stated that there had been a total of 143 submitted in the last quarter. A Board member asked if completed forms were submitted to the FDA and Mr. Small reported that they were not. The Board members recommended that the forms should be submitted, although the FDA does not encourage this, so that drugs with adverse effects and therapeutic failures could be tracked. Since completion of the form requires information from both the prescriber and pharmacist, the patient (or their representative) will be responsible for seeing that the form is completed by both parties. Members of the Board decided that the brand name medication requested should not be approved until the form is completed and it has been sent to RDTP. Patients will not be required to try another generic before the brand name can be approved. RDTP will forward these forms to the FDA and notify the Office of Pharmacy Services when they are sent. This will help the Bureau to track generic medications that are ineffective or cause adverse effects. Members of the Board requested a report on this process after it has been in effect for six months.

NEW BUSINESS

B. Prior Authorization Criteria for Tysabri (natalizmab)

Karen Reed read the proposed criteria for the initial review of Tysabri and said that it would be voted on at the next meeting. Vicki Cunningham stated that although it currently requires prior authorization, Steve Small requested that the Board review the criteria being used by RDTP. Ms. Reed asked for comments regarding the criteria. A member asked if a representative from the Multiple Sclerosis Society had reviewed the criteria. Ms. Cunningham said that she has not had any comment from them. It was decided that it would be appropriate to ask Dr. Karen Kresa-Reahl to review the criteria.

See Attachment

B. Prior Authorization Criteria for Marinol

Ms. Cunningham stated that Marinol had been non-preferred when the anti-emetics were a part of the Preferred Drug List. Since this therapeutic class is no longer included in the PDL, no prior authorization is required for it. Because of the potential for inappropriate use, Ms. Cunningham asked the Board to consider requiring prior authorization for Marinol. Ms. Reed read the proposed criteria. A member asked if it should only be restricted to AIDS patients for promoting weight gain. Dr. Joseph stated that these were the FDA approved indications. A Board member inquired about the utilization of this agent. Ms. Cunningham responded that she would provide utilization data for Marinol at the next meeting. Mr. Small said that he receives numerous requests from oncologists and nursing homes for its use and most of the requests were not for FDA approved indications. Ms. Reed asked the price difference between Marinol and Zofran. Ms. Cunningham said that since Zofran is preferred, the price of the two is probably very similar. Ms. Cunningham said that one concern about it use was that it was not an appropriate agent for the elderly because of its sedating properties and potential for causing falls. A Board member suggested adding criteria for approval for patients with cancer if they failed to maintain or gain weight with megestrol. The prior authorization criteria will be amended to reflect this.

See Attachment

C. Ambien Limits

Ms. Reed read the proposed criteria. Ms. Cunningham stated that there have been numerous requests for more than one tablet per day. She asked that the Board approve a quantity limit of 1 tablet per day. She said that it did not seem appropriate to restrict the duration of therapy with Ambien, although it is not indicated for long-term use. Members of the Board agreed, especially since similar agents will soon be available which have indications for chronic use

D. Policy for Heparin Use in Pregnancy

Ms. Reed asked Steve Small to speak about the need to address policies for the use of heparin in pregnancy. He said that the RDTP has been using the guidelines adopted by The American College of Chest Physicians. Because there is not FDA approval for heparin in pregnancy, he felt that it was appropriate for the Board to review the guidelines being used by RDTP. Mr. Small commented that having these guidelines in place would reduce the number of inappropriate denials for this situation. He also stated that this drug was not approved for long-term use and any appeals for such were sent to the Medical Director. Members of the Board said that, since this applied to obstetricians and practitioners delivering babies, it would be wise to ask an obstetrician to review the guidelines. Ms. Cunningham said that she would give it to a maternal-fetal physician at CAMC for review. Members of the Board expressed their confidence in the guidelines adopted by the American College of Chest Physicians and voted to adopt the criteria. Ms. Cunningham will report on any comments made on these by a maternal-fetal specialist.

E. COX-II Inhibitors

Ms. Cunningham said that recent information about COX-II agents had been included in the information packets. Although the Board planned to review prior authorization criteria

at the February meeting, the review has been postponed until FDA hearings are concluded and recommendations are made.

F. Release of Liability Form for Off-label use of Medications

Because of appeals that are made to Dr. Joseph for the off-label use of medications, Ms. Cunningham stated that an informed consent document might be appropriate for use in these situations. She said that she had asked for guidance from the Bureau's counsel and a form is being considered. Many appeals are made to Dr. Joseph for the off-label use of medications and there is no literature to substantiate that this use is widely accepted. Dr. Joseph said the intent of the form would be to make sure that the patient is aware that Medicaid is approving the request based on the physician's affirmation that it is medically necessary for them, even though it is not an FDA approved or widely accepted off-label indication. It would not be meant to infer that we agree or disagree with the prescriber's treatment. Appeals that are difficult are for the use of the atypical antipsychotic agents in children. She said she hoped that this would assure that physicians would discuss the risks and benefits of these medications with the parents of these children. A discussion followed about the need for monitoring the inappropriate prescribing of the mental health drugs, especially the antypical antipsychotics and the lack of evidence about their safety in children.

Some members of the Board expressed the opinion that implementing the use of a disclosure form would be interfering with the physician-patient relationship. Other members said that forms like this are often used by commercial insurance plans, but do not protect anyone from future lawsuits. It was the consensus of the Board that an informed consent document should not be adopted at this time.

See Attachment

IV. REPORTS

A. Heritage/ACS Information Systems, Inc. (See attachment)

Craig Boon, Heritage/ACS Information Systems, presented two suggestions for population-based interventions:

(1) Psychiatric Coordination of Care: Use of Atypical Antipsychotic Drugs
(2) Multiple Drug Therapy Regimen Review.

Ms. Reed asked for comments about the Psychiatric Coordination of Care proposed intervention. A Board member said it would be interesting to see the diagnoses submitted for non-indicated uses and which agents are used off-label most frequently. Ms. Reed stated that she would like to see patients from age 0 -100 included in the intervention. Members of the Board agreed that this was appropriate to do. Mr. Boon said that he could provide a report of off-label diagnoses that were submitted and that the intervention could include all ages. He also suggested that a more focused intervention be provided for those who prescribed these agents at a high frequency. The Board adopted this intervention.

Mr. Boon also presented an intervention aimed at decreasing polypharmacy for recipients. This program helps identify patients who are doctor shopping and pharmacy hopping. The goal of this intervention is to alert physicians about all of their patients' prescription therapies. Alerting them of the possibility of drug-drug interactions, overutilization, and

excessive duration of therapy is also a part of this intervention. He said that all of the assessments are based on the date of service to the patient.

Ms. Cunningham said that she receives many calls from pharmacists and physicians about patients who are doctor shopping. She said that the only thing we can do right now is lock them in to one pharmacy and work with the Medicaid Fraud Unit to prosecute them. She also said that the physicians can call the Board of Pharmacy to get a report on all prescriptions for controlled substances obtained by their patients. However, the polypharmacy intervention would include all prescription drugs for patients who were taking multiple prescriptions. The Board agreed that this intervention should also be implemented.

B. 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.

C. ACS Second Quarter Report (See Attachment)

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

V. OTHER BUSINESS

No other business was discussed.

VI. OPEN TO THE FLOOR

VII. NEXT MEETING AND ADJOURNMENT

A motion was made and seconded that the meeting be adjourned. All were in favor. The meeting was concluded at 6:15 p.m. The next meeting will be held on Wednesday, May 11, 2005 from 4:00 p.m. - 6:00 p.m.

Respectfully submitted,

Lynda L. Edwards
Secretary

(MTG#47)