Drug Utilization Review Board Meeting Minutes
November 16, 2005

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
Chris Terpening, PharmD., Ph.D.
John R. Vanin, M.D.
Mary Nemeth-Pyles, M.S.N., R.N., C.S.
Myra Chiang, M.D.
James Bennett, M.D.
Steve Judy, R.Ph.
Kevin Yingling, R.Ph., M.D.
Ernest Miller, D.O.
David Elliott, PharmD.
Mitch Shaver, M.D.
Matthew Watkins, D.O.
Lester Labus, M.D.

Members Absent:
George Bryant, PA-C
Kerry Stitzinger, R.Ph.
Pat Regan, PharmD.
Dan Dickman, M.D.
Bernie Smith, R.Ph., M.B.A., M.H.A.

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

Contract Staff:
Steve Small, Rational Drug Therapy Program
Craig Boon, ACS/Heritage Information Systems

Interested Parties Present:
AstraZeneca: JoAnn Shoup, Mark DiMaio
Dey: Sandee Franklin, Paul Jacobson
Eli Lilly: Mark Baldridge
Forest: Wayne Miller
GSK: S. Mitchell
Merck: Bob Kelley
Organon: Tim Stanley
Pfizer: Kent Hunter, Jeff Borman
Reliant: Lisa Holly, Kim Deering, Geoff Fusco
Sanofi-Aventis: Walter Gose
Schering: Rob Marsh
Sepracor: Larry Green, Ryan Payne, Keith Caldwell, Keith Pearson
TAP: Stacey Poole
WVU Pediatrics: Robert Kaslovsky
Other: Thom Stevens

I. INTRODUCTIONS

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

II. APPROVAL OF THE SEPTEMBER 21, 2005, MINUTES

A motion was made to accept the minutes of the September 21, 2005 DUR Board meeting as written. The motion was seconded and passed unanimously.

III. OLD BUSINESS

A. Report from Nominating Committee and Election of Officers

Karen Reed stated that the Nominating Committee had been unable to meet during the past quarter. A slate of officers will be presented for election at the February meeting.

B. Review of Policy for Coverage of Erectile Dysfunction Agents

Ms. Reed read the guidelines for prior authorization and quantity limits for the Erectile Dysfunction Agents. It was moved and seconded to accept the criteria as presented. Dr. Yingling asked if the DUR Board made recommendations on quantity limits for any other classes of drug. He expressed the feeling that Prior Authorization Criteria was a clinical decision that should be handled by the Board, but that limits such as the one considered were financial decisions and should be decided upon by the Bureau. Ms. Cunningham replied that the quantity limits originally imposed were decisions made by the Board. Another member asked if other therapeutic categories had quantity limits that had been decided by the Board. Ms. Reed replied that the antiemetics and antimigraine classes had quantity limits which also had been voted upon by the Board. There was some discussion regarding defining drugs that were considered life-sustaining medications referred to in criterion #1.

Steve Small said that drugs for diabetes, hypertension, and cardiac conditions were all considered as life-sustaining in making prior authorization decisions. He also said that current standards recommended that physicians look at other therapies before adding drugs to treat the side effects of their current regimen. Ms. Reed asked the Board if they would like to amend the motion to include a clearer definition of life-sustaining agents. Ms. Cunningham said that they could broaden the classes specified in criterion #1 to include beta blockers and antidepressants, as well as others considered life-sustaining by the prescriber. She added criterion #2 had been included as a matter of legality. Ms. Reed said the decision regarding quantity had not been finalized and the Board agreed to leave decisions regarding quantity limits to the Bureau. Ms. Reed read the criteria as amended, a vote was taken, and the amended motion was passed.

See Attachment A

C. Review of Prior Authorization Criteria for Revatio

Ms. Reed read the criteria for Revatio. A member asked the need to wait for the records to be faxed and reviewed if a pressure measurement is available. Another said that, if a patient was catherized, records for review should not be required. Ms. Cunningham said that this criteria was only proposed and could be amended as the Board chose. She also said that this was the PA criteria used by the PEIA program. A Board member asked if it was necessary to require a prior authorization for this drug. Ms. Cunningham stated that it was very expensive and, since it was sildenafil, could be used for ED and should be prior authorized. A motion was made, seconded and votes were taken to pass the criteria as amended.

See Attachment B

D. Review of Prior Authorization Criteria for Xanax XR

Ms. Reed read the criteria for Xanax XR. It was stated that Xanax was not first line therapy for panic disorder. The Board recommended changing criteria #2 to require a trial of an antidepressant for thirty days and adding criterion #3 to require a failed trial of generic alprazolam. Ms. Reed read the amended criteria and a motion was made, seconded and passed for acceptance.

See Attachment C

E. Review of Prior Authorization Criteria for Xopenex
Presentation by Dr. Robert Kaslovsky – Pediatric Pulmonology – Charleston Area Medical Center

Robert Kaslovsky, pediatric pulmonlogist spoke to the Board about Xopenex and the issues to be considered in developing PA criteria. He stated that clinical studies showed that Xopenex had equivalent bronchodilator activity of albuterol at half the dose. He also said for that reason it was more effective for emergency room use, but there was a lack of studies regarding its use in the home setting and in the treatment of children.

A Board member remarked that, considering the cost of the two agents and the lack of evidence regarding use in children and advantages of home use, it seemed appropriate for Xopenex to require prior authorization. Some discussion followed regarding the MDI formulation that is to be released soon.

A discussion followed regarding appropriate criteria for the prior authorization of Xopenex. Dr Kaslovsky shared the list of criteria that he used in determining appropriateness for prescribing this agent. They are: tachycardia, tremor, hyperactive behavior, heart disease or documented failure of albuterol. A Board member asked if the PA could be lifted for prescriptions for children under six years of age. Ms. Cunningham replied that the Pharmaceutical and Therapeutics (P & T) Committee had made the decision to place the drug on the non-preferred list and that the DUR Board was charged with establishing criteria to ensure that it was used appropriately. A discussion ensued regarding whether hyperactive behavior or heart disease should be documented. The Board members felt that this was not necessary.

A Board member inquired about the parameters for the documentation of failure of albuterol It was decided that a trial of albuterol could not be considered a failure unless the patients was also on an asthma control medication. The Board agreed that Xopenex should be authorized for twelve months for patients with a diagnosis of asthma or COPD for failure of albuterol, if the patient is concurrently on a controller medication and only for thirty days if not. RDTP will explain this criterion to the prescriber and when the controller is added the PA will be extended to twelve months. Controller medications discussed were steroids and leukotriene antagonists. The group felt that this was a good way to promote the appropriate treatment of asthma. Ms. King suggested that we ask Heritage to send a letter to all prescribers who have patients with a diagnosis of asthma having prescriptions for short-acting beta agonists, but no concurrent controller medications. This suggestion was approved by the Board.

A motion was made to adopt the following criteria:

> Xopenex will be prior authorized for a diagnosis of asthma or COPD with one of the following conditions: tachycardia, tremor, hyperactive behavior, heart disease or documented failure of albuterol. (Failure of albuterol will not be considered a condition for authorization unless the patient is concurrently on an asthma controller medication (e.g. steroid or leukotriene receptor antagonist.) The motion was seconded, voted upon and passed.

See Attachment D

IV. NEW BUSINESS

A. Prior Authorization Criteria for Omacor®

Ms. Reed read the proposed prior authorization criteria for Omacor. The Board reviewed the information provided and suggested that certain parts of the criteria be consolidated. Ms Reed read the revised criteria: Omacor will be authorized for the treatment of high triglyceride levels (≥ 400 mg/dl) not responsive to or intolerant of other lipid lowering

agents or not a candidate for nicotinic acid or fibrate. Ms. Reed announced that this would be voted upon at the next meeting.

See Attachment E

B. Calendar for 2006

Wednesday, February 15, 2006
Wednesday, May 17, 2006
Wednesday, September 20, 2006
Wednesday, November 15, 2006

V. REPORTS

A. Heritage/ACS Information Systems

Craig Boon reviewed the outcomes report on the Drug Regimen Simplification and Asthma Disease Management interventions from January and February 2005. He also presented a proposal for a new intervention, Short-Acting Opiate Utilization. Ms. Cunningham commented that these agents were often misused and that the number dispensed had increased steadily over the past two years. The Board voted to adopt this intervention.

B. Quarterly Reports/Unisys

A discussion of the ratio of generic to brand name utilization ensued. Ms. King reported that the utilization of generics in the West Virginia program, approximately 50%, is consistent with other Medicaid programs across the country. There was also a discussion regarding the average number of tablets dispensed per month reported by Unisys. The average number of tablets dispensed for some once daily agents was 26 instead of 30, Ms. King said that this may be caused because pharmacists had entered an incorrect days' supply or non-compliance by patients, especially since some of these agents are used in long term care settings.

There was a question regarding the tablet splitting initiative discussed at a prior meeting. Ms. Cunningham said that implementation would require a change in the State Plan Amendment. Ms. King stated that this had been implemented by PEIA, although pharmacists were not being paid for the service and that patient participation was voluntary.

C. Rational Drug Therapy Program

There were no comments from the Board regarding the written report.

Steve Small reported on prior authorization denials and approvals for this quarter. He stated that his reporting capabilities were limited because of difficulty in obtaining data from the Unisys system.

VI. OTHER BUSINESS

No other business was discussed.

VII. OPEN TO THE FLOOR

An inquiry was made regarding the implementation of the Xopenex PA criteria and if patients would have to repeat a trial of albuterol if there was one presently in their history. Ms.

Cunningham said that the criteria would be implemented immediately and that a trial would not have to be repeated if already documented or a PA currently in effect. She also said that a renewal of a prior authorization would require a review to ensure that patients are on asthma controller therapy.

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 6:30 p.m. The next meeting will be held on Wednesday, February 15, 2006 from 4:00 p.m. - 6:00 pm.

Respectfully submitted,

Lynda L. Edwards
Secretary