Drug Utilization Review Board Meeting Minutes
September 21, 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.
Dan Dickman, M.D.
Mary Nemeth-Pyles, M.S.N., R.N., C.S.
Myra Chiang, M.D.
James Bennett, M.D.
Steve Judy, R.Ph.
Pat Regan, PharmD.
Kerry Stitzinger, R.Ph.
Kevin Yingling, M.D., R.Ph.
George Bryant, PA-C
Ernest Miller, D.O.

Members Absent:
Bernie Smith, R.Ph., M.B.A., M.H.A.
David Elliott, PharmD.
Mitch Shaver, M.D.
Matthew Watkins, D.O.
Lester Labus, M.D.

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
Scott Brown, R.Ph., Pharmacy Advocate

Contract Staff:
Steve Small, Rational Drug Therapy Program
Steve Liles, Provider Synergies
Craig Boon, ACS/Heritage Information Systems
KayLynn Wight, Unisys

Interested Parties Present:
AstraZeneca: Tom Farrah
Dey: Sandee Franklin
Hoffman-LaRoche: Archie Shew, Chris Freeman
Johnson & Johnson: Jim Cannon
McNeil: Jeff Evans
MedImmune: Curtis Carney, Colleen Bimle
Merck: Bob Kelley
Novartis: Cathy McGeehan
Novo Nordisk: Clint Houck
Pfizer: Kent Hunter, Jeff Borman
RecKitt BencKiser: Michael Heinzman, Bernie Katsur
Sanofi-Aventis: Walter Gose, Gerry Crowley, Jeff Howerbush
Schering: Rob Marsh
Sepracor: Larry Green, Ryan Payne
TAP: Stacey Poole
United Hospital Center: Mark Povroznik
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 MAY 11, 2005, MINUTES

A motion was made to accept the minutes of the May 11, 2005 DUR Board meeting as written. The motion was seconded and passed unanimously.

III. OLD BUSINESS

No old business was discussed.

IV. NEW BUSINESS

Ms. Reed said that, although it did not appear on the agenda, it was time to elect officers for 2006. Ernest Miller and Steve Judy volunteered to serve on the nominating committee along with Ms. Reed. They will present a slate of officers to be voted on at the November meeting.

A. PA Criteria Review for the Preferred Drug List

Ms. Cunningham stated that PA criteria to be reviewed was for the therapeutic classes acted upon at the August Pharmaceutical and Therapeutics (P & T) Committee Meeting.

Antiemetics – Emend was added to the preferred list with a quantity limit of 12 tablets in 28 days. Zofran is also a preferred agent with quantity limits of 14 tablets in 28 days. Emend can be added to Zofran, but no step therapy is required. Motion was made to accept the criteria as just stated. Motion was seconded, votes were taken and the motion passed.

Antifungals, Oral –No changes were made to the category; but Dr. Chiang suggested that Grifulvin Suspension be available without a PA for patients up to age sixteen (16), instead of six (6) years of age. A motion was made to accept the criteria with this change. The motion was seconded, votes were taken, and the motion was passed.

ACE Inhibitors – No changes were made to the PA criteria. Motion was made to accept the criteria as presented. Motion was seconded, votes were taken and the motion passed. At this point, it was then decided that no motions would need to be made for classes with no changes in drugs or previously adopted criteria.

Alzheimer's Agents – There were no changes to the PA criteria, although Razadyne ER was added to the class.

Antidepressants, SSRIs – A lengthy discussion ensued about Paxil CR and whether additional criteria needed to be added for patients who did not tolerate the preferred formulations of paroxetine. It was the concensus of the Board that the exception criteria applied to each therapeutic class would be adequate in ensuring that Paxil CR would be available to patients who needed paroxetine, but needed the CR formulation to achieve optimal results. A motion was made to accept the criteria as presented, seconded, and passed.

Antifungals, Topical –No significant changes were made in this class and the previously adopted PA criteria was accepted.

Antiparkinson's Agents – No changes were made to the PA criteria.

Antipsychotics, Atypical – No changes were made to the PA criteria.

Antivirals – No changes were made to the PA criteria.

Atopic Dermatitis -- No changes were made to the PA criteria.

Bone Resorption Suppression and Related Agents – A discussion ensued about the availability of Boniva for patients who did not tolerate the preferred bisphosphonates. It was agreed that a trial of one month of one of the preferred agents in this group should be required before a non-preferred agent would be approved. A motion was made, seconded, and passed.

Bronchodialtors, Anticholinergic – Ms. Cunningham said that she received a call from a clinic that primarily treats patients with respiratory problems regarding the need for Duoneb for severely compromised patients. Their concern was that, when the albuterol and ipratropim are mixed, the volume increases and becomes difficult to the patient to inhale. Ms. Cunningham said that she had told them that Duoneb could be approved in such cases. There were also questions about the availability of Duoneb and Accuneb for mentally challenged patients. Steve Liles said that the inability to mix or dilute albuterol was a good reason to approve Duoneb or Accuneb. There was a concensus of the group that Accuneb should be available without a PA for children up to 5 years of age.

Bronchodilators, Beta Agonist - A discussion occurred regarding the change in status of Xopenex from preferred to non-preferred. Ms. Cunningham directed the Board member's attention to a folder of letters received from Medicaid prescribers about Xopenex and the decision of the P&T Committee to designate it as a non-preferred drug. Steve Liles mentioned a double-blind study comparing albuterol and Xopenex that found no difference in the adverse effects of the two. One of the Board members asked for a copy of that study and Mr. Liles replied that he would provide it for the next meeting. Another Board member suggested that the lower strengths of Xopenex should not require a PA for children under 6. Ms. Cunningham replied that Xopenex was not indicated for use in children under 6 years of age. Some discussion followed about the off-label use of drugs. Dr. Yingling said that the pulmonologists and pediatricians with whom he had discussed this did not feel that Xopenex had a clear therapeutic advantage over albuterol. More discussion ensued about the cost of Xopenex and whether or not it provided any clear advantages for use in children. Ms. Cunningham suggested that if there has been a documented trial of albuterol and there was an intolerance to it, then Xopenex could be approved. Ms. Reed asked if the Board would consider no PA for the use of Accuneb in children up to age 5 and discussing Xopenex at the next Board meeting after current studies have been made available to the Board members. Dr. Chiang also suggested a presentation from Dr. Robert Kaslovsky, a pediatric pulmonologist. Ms. Cunningham will provide current utilization data and Provider Synergies will provide information relating to the financial impact of this drug on the program. A motion was made that Accuneb would not require prior approval for children up to age 5 and that Xopenex would be reviewed again in November, but require documentation of an albuterol trial for prior approval until that time. Motion was seconded, votes were taken and motion passed.

Cephalosporins and Related Antibiotics – No changes were made to the PA criteria.

Cytokine and CAM Antagonists – It was stated that new starts were to try the preferred agents, but those established on a drug in this class would continue to receive prior authorization. A motion was made, seconded, votes were taken and the motion passed.

Fluoroquinolones, Oral – The previous criteria that had been established required a trial of the non-preferred agents before a preferred agent would be approved. It was recommended that it be changed to one of the preferred agents, because both of them are

not appropriate for the same diagnoses. Ms. Reed proposed that the criteria require that that **one** of the preferred agents must be tried before a non-preferred agent will be authorized unless there was the possibility of an adverse drug-drug or drug-disease interaction, an intolerance to the preferred agent, or a documented allergy to the preferred agent.

Glucocorticoids, Inhaled – Motion was made to change the criteria for patients unable to use a metered dose inhaler. Ms. Cunningham stated that the Board could look at the utilization data at the next meeting for requests for Pulmicort Respules for patients over eight (8) years of age. It was stated that we should include criteria stating that there is an exception for people unable to use an MDI. Ms. Cunningham said that we would work with RDTP to make that exception understood and that we would review the utilization data in six months.

Hypoglycemics, Insulins and Related Agents – Peggy King pointed out that the insulin pens no longer required a PA. There were no changes to the PA criteria.

Hypoglycemics, Metformins – The criteria was amended to require a trial of the separate preferred agents for 12 weeks before a non-preferred agent will be approved. (A trial of the preferred combination of metformin/glyburide is not required.) A motion was made, seconded, and passed to adopt this criteria.

Intranasal Rhinitis Agents – No changes were made to the PA criteria.

Leukotriene Receptor Antagonists – No changes were made to the PA criteria.

Macrolides/Ketolides – There was no change in the criteria for the Macrolide class. The PA criteria that had been adopted for Ketek after its introduction to the market was discussed. The growing problem of antibacterial resistance and the need for appropriate use of antibiotics entered into this discussion. Members of the Board suggested that requiring a culture, failure or tolerance to another macrolide was no longer appropriate. Dr. Joseph said that Ketek should be a second line drug. Ms. Cunningham suggested that PA criteria for Ketek in the treatment of community acquired pneumonia (CAP) should require a failure or tolerance to a preferred macrolide, doxycycline, or a quinolone or a history of having been on antibiotics the preceding six weeks, because those are the ones that have been selected out for penicillin resistance. The Board reviewed a letter sent to them by Mark Povroznik, Pharm.D., regarding antibiotic resistance and the appropriate utilization of Ketek. Ms. Cunningham stated that critiera for community acquired pneumonia could require a failure of a preferred antibiotic within the last 28 days or a documented lack of bacterial sensitivity to two preferred agents indicated for CAP. Motion was seconded, votes were taken and motion passed. Ms. Cunningham suggested criteria for the treatment of acute bacterial sinusitis and acute exacerbations for chronic bronchitis (AECB) should be a failure of two of the following: amoxicillin or amoxicillin/clavulanate, a preferred cephalosporin, the preferred respiratory fluoriquinolone, or documented lack of bacterial sensitivity to two preferred agents indicated for ABS/AECB. A Board member said that he was concerned about whether or not there would be a real diagnosis of sinusitis and that requests for Ketek should be approved, if there has been a documented use of any antibiotic within the past 28 days. A motion was made to approve Ketek, with no diagnosis required, if there has been documented use of any antibiotic within the past 28 days. The motion was seconded, voted upon, and passed.

NSAIDS – No changes were made to the PA criteria.

Ophthalmics, Allergic Conjunctivitis– No changes were made to the PA criteria.

Ophthalmics, Antibiotics– No changes were made to the PA criteria.

Ophthalmics, Glaucoma Agents – No changes were made to the PA criteria.

Platelet Aggregation Inhibitors – No changes were made to the PA criteria.

Stimulants and Related Agents –Ms. Cunningham stated that Concerta had been designated as non-preferred and that the decision had been made from a financial standpoint. She provided a letter for Board members to read that would be sent to prescribers with patients on Concerta and explained that the therapeutic substitutions could not be made by the implementation date for this phase of October 3. Efficacy and abuse that occurred in this class were discussed. A motion was made to grandfather patients that were already established on this drug and to require a failure on only one of the preferred agents before a non-preferred agent would be approved. It was agreed that 14 days was an adequate time for a trial. The decision of the P&T Committee to make Concerta non-preferred was discussed and Steve Liles said that Provider Synergies had actually recommended that it remain a preferred drug. The financial impact of grandfathering the patients on Concerta was discussed and it was decided that it would have a significant impact. The Board voted to ask the Pharmaceutical and Therapeutics Committee to reconsider its recommendation. In the interim, the recommendation of the Board is to continue the preferred status of Concerta.

See Attachment A

1. **Step Therapy for Atopic Dermatitis -** Because implementing step therapy in this class would violate rebate agreements, step therapy is not an option.

2. Letter Regarding Stimulants on PDL

B. Policy for Coverage of Erectile Dysfunction Drugs

Ms. Reed read the proposed criteria for Erectile Dysfunction Drugs. Ms. Cunningham said that she wanted to reduce coverage from six units a month to one unit, because of budget constraints. Ms. King said that some states were not covering this class at all, but that we were required to do so by the Federal Government. Part of the criteria for coverage is that the RDTP staff checks the sex offender registry before granting a PA.

C. Prior Authorization Criteria for Revatio

Ms. Reed read the proposed criteria for Revatio.

C. Tablet Splitting Initiative

Ms. Cunningham said that this was an initiative that had been explored with PEIA and Worker's Compensation. A calculation to show the savings possibility from splitting Zoloft was included in the information packets. The potential savings was $1.7 million dollars, even with paying pharmacists $0.25 to split each tablet. Ms. King said that PEIA is adopting this policy for Zoloft, Celexa and Toprol XL. It was discussed that tablets that were scored did not always split evenly and they should not be split ahead of time. Dr. Joseph said that the VA splits most tablets. Ms. Cunningham stated that reports from other states with this program were included in the packets and most reported no problems with it. No action was taken on this matter.

D. Prior Authorization for Xanax XR

Ms. Reed read the proposed criteria for Xanax XR.

E. Step Therapy for Selected Preparation (Classes not on PDL)

1. AnaMantle Cream Kits
2. AnaMantle Forte Cream Kits

Ms. Reed informed the group that these two preparations each cost $149.30 for 20 days of therapy. Preparations with the same active ingredients, although not in combination or with applicators, would cost less than $10.00. Ms. Cunningham asked the Board for permission to institute step therapy in scenarios like this, when there are costly agents with similar older generic preparations available. The Board agreed that this was a reasonable thing to do.

V. REPORTS

A. Rational Drug Therapy Program (See Attachment)

Steve Small gave an abbreviated presentation on the denials and approvals for this quarter. There were no comments from the Board regarding the Report.

B. Heritage Information Systems

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

Rob Berringer proposed two population based educational interventions. The first one dealt with appropriate use of gabapentin. He gave a brief summary of criteria to be used in the intervention. The second proposal dealt with the Treatment of Depression. The Board approved the implementation of the intervention promoting the appropriate use of gabapentin.

C. Second Quarter Report - ACS and Unisys (See Attachment)

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

VI. OTHER BUSINESS

No other business was discussed.

VII. OPEN TO THE FLOOR

Sandy Prescott, Dey Pharmaceuticals, spoke about the need to grandfather patients who are currently using Duoneb and who have problems with visual acuity, hand dexterity or are mentally incapacitated. She asked that the Board to consider those patients. She said that there were many patients who benefited from having albuterol and ipratropium premixed.

Larry Green, Sepracor, offered to provide studies showing the benefits of Xopenex. He also mentioned that Provider Synergies recommended that Xopenex remain on the PDL and that Accuneb be removed. He asked about the requirement of a trial of albuterol and whether patients who had already had one would have to repeat it for approval of Xopenex. Ms. King replied that the trial had only to be documented to RDTP. Ms. Cunningham reminded him that this matter would be discussed again in November.

An audience member asked about the status of Concerta. Ms. Cunningham replied that it will

remain preferred until the next P&T Committee meeting where it will be considered again

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, November 16, 2005 from 4:00 p.m. - 6:00 pm.

Respectfully submitted,

Lynda L. Edwards
Secretary