STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

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Drug Utilization Review Board Meeting Minutes
February 19, 2003

The thirty-ninth 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
Steve Judy, R.Ph.
Bernie Smith, R.Ph., M.B.A., M.H.A.
Lester Labus, M.D.
Kerry Stitzinger, R.Ph.
David Elliott, PharmD.
Chris Terpening, PharmD., Ph.D.
Mary Nemeth-Pyles, M.S.N., R.N., C.S.
Kevin Yingling, R.Ph., M.D.
Pat Regan, PharmD.
Matthew Watkins, D.O.
John R. Vanin, M.D
Dan Dickman, M.D.

Members Absent:
George Bryant, PA-C
Myra Chiang, M.D.
Mitch Shaver, M.D.
Ernest Miller, D.O.
James Bennett, M.D.

DHHR/BMS Staff Present:
Nancy Atkins, Commissioner
Randy Myers, Deputy Commissioner
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

Contract Staff:
Steve Liles, PharmD, Provider Synergies
Steve Small, Rational Drug Therapy Program

Other State Government Agency Staff Present:
Felice Joseph, PEIA

Interested Parties Present:
Abbott Laboratories, Inc.: Laura N. Stinson
Amgen: Joe Crouch
Astra Zeneca: Mark DiMaio
Aventis: Walter Gose, Jeff Hartness, Edwards C. Hilts
Bayer: Cathi McGeehan
Bill J. Crouch & Assoc., Inc.: Raymona Kinneberg
Bristol-Myers Squibb: Stephanie Wilson, Rich Damous, Michael Vandeveer, Karen Long, John Hymen
CAMC: Beth Wise
Cephalon: Dan Knisely
Elan: Bret Anderson
Eli Lilly: Wayne Covert, Gary Chernenko, Ron Haro
General Anesthesia Services, Inc.: Jaime White, J. K. Lilly, M.D.
Government Relations Specialist: Thom Stevens
GSK: Gary Browning, Jim Snyder
Janssen Pharmaceuticals: Bert Wickey
Johnson & Johnson: Jim Cannon
Merck: Robert Kelley
Novo Nordisk: Clint Houck, Kipper Linville
Pfizer: Sean Gatewood, Shawnee Lewis, Doug Woods, Jeff Pack
Pharmacia: Gary Grote, Steven Babineaux, Marty Mekkelsen, Kevin Wemett
PhRMA: Bryan Brown
Physician: F. Joseph Whelan, MD
Purdue: Brian Rosen
Schering-Plough: Rob Marsh, Feng Ho, Mark Smith
TAP Pharmaceuticals: Stacey Poole
UCB: Andreas Anderhou, Terry Miller
Wallace: Douglas Waddell
Wyeth: Philip Reale

I. INTRODUCTIONS

Karen Reed, Chairperson, welcomed everyone to the Board meeting and introductions were made.

II. APPROVAL OF THE DECEMBER 4, 2002, MINUTES

A motion was made that the minutes of the December 4, 2002, DUR Board meeting be accepted as written. The motion was seconded and passed unanimously.

I. OLD BUSINESS

A. Quantity Limits on 5-HT3 Class

Karen Reed, Chairperson, read the proposed criteria for the quantity limits on the 5-HT3 therapeutic class. Vicki Cunningham stated that Kytril liquid had become available since the last

meeting and the criteria contained limits for this agent also. A motion was made to accept the quantity limitations as presented. The motion was seconded, votes were taken, and the motion carried.

See Attachment A.

IV. NEW BUSINESS

A. Prior Authorization Criterial for Preferred Drug List (PDL) Phase II

Vicki Cunningham explained that one of the roles of the DUR Board is to recommend criteria for drugs requiring prior authorization, including non-preferred drugs. She also stated that the discussion was for the Board and the Bureau only and that the meeting would not be interactive.

1. Narcotic Analgesics - The first therapeutic class to be discussed was the narcotic analgesics. Since all of the generics were included on the preferred drug list, the Board was asked if the use of tramadol should still require prior authorization (PA). A discussion followed concerning the indications for tramadol and the combination product, Ultracet. A motion was made to remove the PA designation from tramadol. The motion was seconded, votes were taken and the motion carried. Vicki Cunningham asked the Board for recommendations relating to (1) the number of drugs that would need to be tried before non-preferred narcotic analgesic agents would be authorized; and (2) what length of time constituted a trial. She also stated that in the case of OxyContin, RDTP will contact physicians who are currently treating patients with this agent and work with them to determine appropriate substitutes. There will be authorization of a 30-day supply on medications until this can be accomplished. A motion was made that the length of a trial should consist of at least 72 hours. The motion was seconded, and a discussion ensued. Votes were taken and the motion carried. A motion was then made to require a trial of three preferred agents before a non-preferred agent would be authorized. The motion was seconded, votes were taken, and the motion carried.

2. NSAIDS - Vicki Cunningham asked if step therapy should be removed from this class since most of the available NSAID drugs are now available generically. After a discussion, a motion was made to remove step therapy from this class. The motion was seconded, votes were taken, and the motion carried. Ms. Cunningham explained that the PA requirements for the COX-II agents would still apply. A motion was made that a two-week trial of each of the COX-II preferred agents would be required before a non-preferred agent would be approved, unless one of the exceptions on the PA form was noted. The motion was seconded, votes were taken and the motion carried

3. Hypoglycemics, Insulins - There was a discussion concerning Novolog, which is a preferred insulin, but is only available in a Flex Pen. Ms. Cunningham explained that the PA requirement would not apply to the Flex Pen until the vial becomes available in March. Peggy King noted that there had been requests for the Lilly products for use in pediatric patients. Lilly supplies a specific diluent for their product for use in pediatric patients requiring low doses. The Board agreed that the Lilly products should be authorized for use

by these patients. The Board also recommended that a non-preferred insulin for all other patients should be approved only in the event of a true allergic reaction to the insulin made by Novo Nordisk.

4. Hypoglycemics, Thiazolidinediones - Because all the agents in this class are preferred, no action was required.

5. Macrolides - Since most of these drugs are preferred, no criteria were required other than those listed on the PA form. The Board agreed.

6. Bone Resorption Suppression Agents - Since all agents in this class are preferred, no action was required.

7. Angiotensin II Receptor Blockers - A motion was made to require a trial of five agents on the preferred list before authorization for a non-preferred agent would be given. The motion was seconded, voted upon and the motion carried. A motion was made that an adequate trial of each agent must be for at least two weeks. The motion was seconded, votes were taken and the motion carried.

8. Antifungals, Topical - The Board recommended that three preferred agents should be tried before a non-preferred drug would be authorized. A motion was made to reflect this. The motion was seconded, voted upon, and the motion carried. A motion was made to require a trial length of at least two weeks for each of the preferred agents. This motion was seconded, voted upon, and the motion carried.

9. Antifungals, Oral - Vicki Cunningham recommended that for this class no other exception criteria than those required on the PA form would be needed. A motion was made to accept this recommendation. The motion was seconded, votes were taken and the motion carried.

10. ACE Inhibitor/Calcium Channel Blocker Combinations - A motion was made that 30-day trials of both preferred agents would be necessary before authorization of a non-preferred drug would be given, unless one of the exceptions on the PA form is present. The motion was seconded, votes were taken and the motion carried.

11. Hypoglycemics, Post-prandial - No action was required since all agents in this class are preferred.

12. Estrogen Agents, Oral and Transdermal - A motion was made that no criteria other than those on the PA form would be required to approve the non-preferred drug. Trials should consist of 90-day periods for each of the preferred agents. The motion was seconded, votes were taken, and the motion carried.

13. Hypoglycemics, Sulfonylureas - Dr. Yingling moved that all requests for Tolinase, Dymelor, Diabinese, Orinase and their generic equivalents require prior authorization and be reviewed by the Medical Director, due to safety issues with these agents. The motion was seconded, votes were taken and the motion carried. A second motion was made to

require a trial of the maximum dose of glyburide, glipizide and glimepiride for two months before an non-preferred agent would be authorized. The motion was seconded, votes were taken and the motion carried.

14. Estrogen Agents, Combination - A motion was made that a trial of 90 days of each of the preferred agents would be required before a non-preferred agent would be approved. In cases of requests for Prempro, patients would be required to take the individual agents, Premarin and medroxyprogesterone. Requests for Estratest or Estratest HS would be considered on a case-by-case basis in instances of breast tenderness, decreased libido, or refractory vasomotor symptoms. The motion was seconded, votes were taken and the motion carried.

15. Hypoglycemics, Biguanides - No action was required because all the available agents are preferred.

See Attachment B

B. Prior Authorization Criterial for PDL Phase III

1. Skeletal Muscle Relaxants - Dr. Yingling expressed his concerned about the utilization of these drugs in patients over the age of 65. Vicki Cunningham stated that the Bureau would supply utilization data on this class of drugs at the next meeting. A motion was made to require prior authorization of all muscle relaxants for patients over 65 years of age. The motion was seconded, votes were taken and the motion carried. A second motion was made to require a 14-day trial of each preferred agent before prior authorization of a non-preferred agent would be given. They also recommended that patients with chronic spasticity should be excluded from the trial requirements. This motion was seconded, votes were taken and the motion carried. Dr. Yingling requested that Steve Small give information on the number of requests for these drugs for patients over 65 years of age at the next meeting.

2. Quinolones - It was recommended that both preferred agents be tried before a non-preferred agent can be used. A discussion followed that if neither of the preferred agents was effective, then a different class of antibacterial drugs should be used. No action was taken for this class.

3. Miotics (Selected Intraocular Pressure Reducers) - No action was taken for this class because all available agents are preferred.

4. Prostaglandin Inhibitors, Opthalmic - A motion was made that authorization for the non-preferred agent in this class would only be given in cases of a documented allergic reaction to all of the preferred drugs. This motion was seconded, votes were taken and the motion carried.

5. Benign Prostatic Hyperplasia (BPH)/Micturition Agents - Vicki Cunningham stated that the non-preferred drug, Avodart, would be reviewed at the next P& T meeting. The Board

agreed that the use of the standard prior authorization criteria would be used until the next P & T meeting.

6. Atopic Dermatitis Immune Modulators - A motion was made that a 30-day trial of the preferred drug would be required before the non-preferred drug can be authorized for use. The motion was seconded, votes were taken and the motion carried.

7. Aminosalicylates/Ulcerative Colitis Agents - The Board agreed that the standard prior authorization criteria could be applied to this class of drugs.

8. Sedatives/Hypnotics - A motion was made that prior authorization should be necessary for patients over the age of 65 years for temazepam, due to safety issues. The motion also stated that each of the preferred agents should be tried before the non-preferred drugs would be approved. This motion was seconded and a discussion ensued regarding the length of time that these drugs are taken. Because the Board had concerns about overutilization of these agents, they requested utilization data for patients taking them greater than 60 to 90 days. Vicki Cunningham agreed to provide this data at the next DUR Board meeting. Votes were taken on this motion, and the motion carried.

9. Antiemetic/Antivertigo Agents - Vicki Cunningham recommended that the preferred agents (for corresponding diagnoses and routes of administration) be tried before non-preferred agents would be prior authorized, unless one of the exceptions on the PA form is present. For chemotherapy or radiation-induced nausea, a trial and failure of Zofran is adequate for approval of the other 5HT-3 agents. A motion was made to accept the recommendation as presented. The motion was seconded, votes were taken, and the motion carried.

10. ACE Inhibitors - A motion was made that four preferred agents should be tried for 30 days each before a non-preferred agent would be authorized. The motion was seconded, votes were taken and the motion carried.

11. Cephalosporin and Related Antibiotics - The Board agreed that the standard prior authorization criteria could be used for this drug class.

12. Platelet Aggregation Inhibitors - No action was taken for this class because all available agents are preferred.

13. Intermittent Claudication Medications - No action was taken for this class because all available agents are preferred.

See Attachment C

Note: The SSRIs and Antidepressants were moved to the Phase IV discussions.

C. Prior Authorization Criterial for PDL Phase IV

1. Opthalmics, Allergic Conjunctivitis - Vicki Cunningham recommended that all of the

preferred agents be tried before non-preferred agents would be prior authorized, unless one of the exceptions on the PA form was present. The Board agreed with this recommendation, and because the list of preferred agents was so broad, did not make a motion concerning the length of a trial period.

2. Antivirals, General - Vicki Cunningham recommended that all of the appropriate preferred agents be tried before non-preferred agents could be prior authorized, unless one of the exceptions on the PA form was present. The Board members agreed to accept this recommendation.

3. Nasal Preparations, Other - A motion was made stating that a non-preferred nasal spray would be approved if a patient failed on a non-sedating antihistamine and a steroid nasal spray and was still complaining of rhinorrhea. The motion was seconded, votes were taken, and the motion carried.

4. Erythropoiesis Stimulating Proteins - The Board suggested that prior approval for Aranesp be given in cases where administration of the drug was an issue. Approval will be given on a case-by-case basis.

5. Phosphate Binders - Vicki Cunningham stated RenaGel was non-preferred, but that the P & T Committee had asked Provider Synergies to work with the manufacturer to see if they could make this drug more cost effective. Results of this request will be presented at the April meeting. She suggested that a trial of one of the preferred agents be required before a non-preferred agent could be approved, unless one of the exceptions on the PA form was present. She also stated that Magnebind may not be appropriate for everyone. A motion was made to accept these recommendations. The motion was seconded, votes were taken and the motion carried.

6. Hypoglycemics, Alpha-Glucosidase Inhibitors - The Board agreed that the standard prior authorization could be applied to this drug class.

7. Immunomodulatory Agents for Multiple Sclerosis. - After a lengthy discussion about these agents, a motion was made stating that one of the preferred agents must be tried before a non-preferred agent would be approved. This would apply only to drug naive patients. The trial period is to be left to the discretion of the treating physician. Also included in the motion was the recommendation to grandfather patients on current therapy for one additional year. The motion was seconded, votes were taken and the motion carried.

8. Anticoagulants, Injectables - The Board recommended that the preferred agents be tried before approval would be given for the non-preferred drugs, unless one of the exceptions noted on the PA form was present.

9. Zetia - Dr. Joseph asked the Board to consider whether this drug was going to be used as monotherapy or add-on therapy. If this drug is to be used for add-on therapy, there should be some limitations. The discussion continued that monotherapy with Zetia would only be appropriate in patients who could not take statins or other available agents, due to limited information relating to the safety of this new drug. A motion was made to recommend

Zetia and WelChol to be used as add-on therapy only, after an insufficient response to the maximum tolerable dose of a statin for 12 weeks of therapy and failure of a binding agent. Vicki Cunningham suggested that Rational Drug report on the number of requests for Zetia in May 2003. The motion was seconded, votes were taken, and the motion carried.

10. SSRIs - A discussion ensued about Celexa becoming available generically in 2004. Vicki Cunningham read the Bureau's recommendations which were that a preferred agent must be tried and failed before a non-preferred agent would be prior authorized. After some discussion, a motion was made that patients would have to have a documented allergy to all the preferred drugs before a non-preferred agent would be approved. The motion was seconded, votes were taken and the motion carried.

11. Antidepressants, Other - It was stated that Remeron is now available in generic form. A motion was made that a trial of an SSRI and a preferred agent from this category for a period of six weeks each, with ineffective results, would be required before Effexor, Effexor XR and Serzone would be approved. The motion was seconded, votes were taken and the motion carried.

12. Stimulants - It was stated that Provigil was only FDA approved for narcolepsy. A motion was made that a failure of two preferred agents, one in each class (methylphenidate and amphetamine) for two weeks each is required before a non-preferred agent would be approved. The motion was seconded, votes were taken and the motion carried. A second motion was made to approve Ritalin LA only if there was an allergy to the excipients of the other long-acting methylphenidate preparations. The motion was seconded, votes were taken and the motion carried.

13. Antipsychotics, Atypical - Vicki Cunningham stated that the Bureau had determined that these drugs should be grandfathered and that the PDL would apply only to drug naive patients. It was stated that these drugs have differing adverse effects - Seroquel has the potential to cause cataract formation; Geodon can cause QTC changes; and Zyprexa can cause weight gain and increased glucose levels in certain patients. There was a discussion that the dosage should be increased to an appropriate level before switching to a different drug and that failures of treatment could be caused by an inadequate dose. A motion was made to require a trial of one preferred atypical antipsychotic agent for a trial of two weeks before a non-preferred one would be authorized. The motion was seconded, votes were taken and the motion carried.

14. Alzheimer's Agents - Vicki Cunningham stated that these agents would also be grandfathered. The motion made was that Cognex would only be approved if there was a documented allergic reaction to all of the preferred drugs in this class. The motion was seconded, votes were taken and the motion carried.

See Attachment D

V. REPORTS

A. Heritage Information Systems

Because of the length of the Board meeting, Heritage Information Systems distributed a written report but did not review the report with the Board.

See Attachment E

B. Rational Drug Therapy Program

Also, due to the length of the Board meeting, RDTP did not present an oral report. A written report was distributed.

See Attachment F

C. ACS Fourth Quarter Report

There were no comments regarding the ACS quarterly report.

See Attachment G

VI. OTHER BUSINESS

No other business was discussed.

VII. OPEN TO THE FLOOR

Joseph Whalen, M.D., a psychiatrist, distributed a short report and a curriculum vitae. He said that there needed to be a carve-out for drugs prescribed by psychiatrists. He also wanted Zyprexa and Abilify to be available without PA.

See Attachment H

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, May 21, 2003, from 4:00 p.m. to 6:00 p.m.

Respectfully submitted,

Lynda L. Edwards
Secretary