

# Drug Utilization Review Board Meeting Minutes

## May 19, 2004

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.  
Dan Dickman, 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.

### **Members Absent:**

James Bennett, M.D.  
David Elliott, PharmD.  
Kevin Yingling, R.Ph., M.D.  
Steve Judy, R.Ph.  
Pat Regan, PharmD.  
Kerry Stitzinger, R.Ph.

### **DHHR/BMS Staff Present:**

Randy Myers, Deputy Commissioner  
Sandra Joseph, M.D., Medical Director  
Gail Goodnight, R.Ph., Rebate Coordinator  
Vicki Cunningham, R.Ph., DUR Coordinator  
Lynda Edwards, Secretary

### **Contract Staff:**

Steve Small, Rational Drug Therapy Program  
Rob Berringer, Heritage Information Systems

### **Interested Parties Present:**

**Athlon:** Jennifer Howard  
**Aventis:** Walter Gose  
**Berlex:** Cathy Gore  
**Boehringer Ingelheim:** Devin Tubert  
**Bristol Myers Squibb:** Funmi Oduolowu,  
Steve Long, Deidra Montague, John  
Hymen  
**GSK:** Carol May, Gary Browning  
**Janssen:** Bert Wickey  
**Johnson & Johnson:** James F. Cannon,  
Raymona Kinneberg  
**Lilly:** Ron Hart  
**Merck:** Bob Kelley  
**Medimmune:** Colleen Bimle, Tammi Moore  
**Pfizer:** Gary Mueller, Kent Hunter, Pamela  
Smith  
**Schering:** Feng Ho  
**Serono Inc.:** David Shirkey  
**TAP:** Stacey Poole, Jim Knott  
**Wyeth:** Philip A. Reale

## **I. INTRODUCTIONS**

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

## **II. APPROVAL OF THE FEBRUARY 18, 2004, MINUTES**

A motion was made to accept the minutes of the February 18, 2004 DUR Board meeting as written. The motion was seconded and passed unanimously.

### **III. OLD BUSINESS**

#### **A. Coverage of Selected Cough and Cold Preparations**

Ms. Cunningham stated that covering agents in the Cough and Cold Class would require an amendment to the State Plan. Because many of the drugs in this class are also used to treat allergies, there have been numerous requests from providers to include them in the list of covered drugs. She said that it is possible that the change in the State Plan could be approved by the Center for Medicare and Medicaid (CMS) by September. The agents added would only include selected products with generic equivalents. She also added that Rynatan, or its generic equivalent, was the drug most often requested. There are no long acting liquid antihistamine-decongestant preparations covered at the present time. The ENT specialists have requested an antihistamine-decongestant combination with a drying agent, as well. The suggested list for coverage includes an agent that satisfies both of these requests and was approved for coverage by the Board.

#### **B. Covered Over-the-Counter Preparations**

Ms. Cunningham stated that a list of currently covered over-the-counter medications had been provided at the last meeting. She asked the Board if they had any suggestions for the list. It was noted by a Board member that a cough medication with codeine or dextromethorphan should be added to the list. It was stated that the over-the-counter medications would require a prescription written by the physician. Mrs. Reed asked the Board if they wanted to approve the list with the removal of mineral oil (which had been discussed at the previous meeting) and the addition of a generic formulation of Robitussin DM, with a quantity limit of four ounces per prescription. A motion was made, seconded, votes were taken and the motion carried.

### **IV. NEW BUSINESS**

#### **A. Presentation by Wayne Atkinson, R.Ph. – Pharmacist Specific Guidelines for Medication Therapy Management – Dementia and Alzheimer’s Disease**

Mr. Atkinson discussed the information in the handouts provided to the Board on Medication Therapy Management for Dementia and Alzheimer’s Disease. He said that he wanted to explore the possibility of forming a multi-disciplinary group to work with pharmacists on medication therapy management services and being specialty consultants to physicians. He discussed the need for developing a standard for these services provided by pharmacists. He also inquired about physicians or pharmacists interested in medication management in the geriatric population. Some discussion ensued about whether or not this was a federal directive. Mr. Atkinson stated that some requirements had been set by a consensus panel for Medicare in regard to Pharmacy Benefit Managers who provide medication management services for the elderly. He said that all of the elderly could benefit from this service, including those who had no prescription insurance coverage. He stated that the Board would be able to make a positive impact in this area, because no standards are currently available.

Ms. Cunningham said that this was technically not a function of the DUR Board, but that their function may change as the new Medicare Legislation comes into law. She said that the Board should consider this an opportunity to set standards, develop protocols, and implement disease management programs wherever possible. Current legislation only requires that Medicare recipients have a choice of two Prescription Benefit Managers (PBM’s) for processing their prescriptions. Counseling patients and monitoring therapy are very important services for the elderly. It is an opportunity to make sure that these

services are included in pharmacy care. Programs such as the one provided by Mr. Atkinson provide the opportunity to establish standards for providing medication management during the program development.

Ms. Cunningham said she would be able to assist in forming a sub-committee to research the possibility of developing standards and would contact the Board of Pharmacy for their input. A Board member said that some quality parameters for pharmacy directed medication therapy management services should be developed, no matter how they are implemented. Ms. Cunningham stated that a collaborative practice act for physicians and pharmacists is being proposed in West Virginia and standards such as these would be an integral part of that type of collaboration.

See Attachment A

#### **B. Growth Hormone – PA Criteria for Non-Growth Hormone Deficient Patients**

Ms. Reed asked the Board if they felt that Medicaid should cover growth hormone for non-growth hormone deficient children. Some discussion ensued about the genetics of height in children and coverage of growth hormone by other insurance companies. Some Board members stated that it should not be covered in this instance because it is being used cosmetically. The Board reviewed the proposed criteria for use when there is no growth hormone deficiency and suggested some changes. The Board will vote on the amended criteria at the September meeting.

See Attachment B

#### **C. Provigil – Review of New Indications and Criteria for Approval**

Ms. Reed read the proposed criteria for a new indication, excessive sleepiness due to shift work, for Provigil. Some discussion ensued as to whether patients that are fatigued because of shift work should be evaluated to rule out medical problems before beginning Provigil therapy. Dr. Sandra Joseph expressed her concerns that patients with C-PAP machines may stop using them if they are taking Provigil. It was also noted that there was no inclusion criteria for the diagnosis. Several suggestions were made for amending the proposed prior authorization criteria for this indication. Ms. Cunningham stated that she would make the suggested changes and that the criteria could be voted on at the next meeting.

See Attachment C

#### **D. Risperdal Consta – Approval Criteria**

Ms. Reed read the proposed criteria for Risperdal Consta. A Board member stated that sometimes psychiatrists may initiate the therapy, but physicians in primary care are the ones who continue it. It was suggested that patients see their psychiatrist annually for a review of therapy. A discussion about the shortage of psychiatrists followed and it was recommended that the drug should only be initially prescribed by Board certified or Board-eligible psychiatrists. It was asked if there were any exclusions for patients in long-term residential care settings, since supervision there eliminates most compliance issues with oral medications. Steve Small stated that if patients are taking other oral medications, a justification for an injectable form is required. It was pointed out that there were no age restrictions included in the criteria. Ms. Cunningham said that it was not indicated for use in patients under the age of eighteen and that the criteria would be amended to reflect this. The amended criteria will be voted on at the next meeting.

See Attachment D

#### **E. Enbrel – Review of New FDA Indication and Approval Criteria**

Ms. Reed read the criteria for Enbrel for the treatment of Psoriasis. It was stated that the criteria should read psoriasis involving either five or ten percent of the body, but not a range between them, and include the age limitation of 18 years or older for use. Ms. Cunningham stated that some advocacy groups objected to requiring failure of treatment with phototherapy before Enbrel will be approved. A Board member stated he felt that this was appropriate, because patients who “crash” on Enbrel suffer some serious side effects and are often left with multiple medical problems. Dr. Joseph asked about the treatment duration and it was stated that the treatment was indefinite. It was asked if criteria for approval should include initiation of therapy by a dermatologist. Arthritis was discussed as an underlying problem with this diagnosis and that it was recommended that rheumatologists be included as specialists who could initiate therapy with this agent. Ms. Cunningham stated that Enbrel is usually billed by physician’s (with a J Code) and that we have been asked to develop this criteria for use by both the outpatient pharmacy program and the medical policy program. The Board recommended that the prior approval criteria require that therapy with Enbrel must be initiated by a dermatologist or a rheumatologist. Ms. Cunningham stated that she would amend the criteria and that it would be voted on at the next meeting.

See Attachment E

#### **F. Review of PDL Changes from April 21, 2004 P & T Meeting**

Ms. Cunningham stated that there would not be a review of changes made to the Preferred Drug List, since the recommendation from the last meeting P&T meeting had not been signed by the Secretary of Health and Human Resources. Most changes that were made expanded the list and did not require any changes in prior authorization criteria. However, there will be a review at the September meeting. She also stated that, with the date of implementation of the Unisys MMIS so close, it has become impractical to request that ACS make any more coding changes for the Bureau. No recent changes have been implemented, with the exception of preparing to end the prior authorizations of Prevacid. Prilosec OTC is now available without a PA. Protonix is the second-line agent, but will still require a PA. Physicians will get a letter alerting them to patients who need prior authorizations for PPI agents.

#### **3-Day Emergency Supply Policy**

Ms. Cunningham reported that members of the P & T Committee felt that the 3-day emergency supply did not work well with the PDL. Many times the patient will get a new prescription on Friday and only be able to get a 3-day emergency supply of a non-preferred drug. Often they run out of the medication before approval could be obtained on Monday. Much of the research and communication necessary for a PA cannot be accomplished over the week-end. It was suggested that we expand the period covered by the emergency supply to five or seven days. She said that she wanted the Boards’ comments on this. A member said that in discussions several years ago, the 3-day supply was only intended for life-threatening drugs. The cost would have to be evaluated and the benefit of increasing the emergency supply should be carefully considered. Ms. Cunningham stated that changing the policy would require a change in the State Plan Amendment and a cost study. She requested a recommendation from the Board in regard to this proposal. Steve Small stated that the turn-around time for a PA is usually two and a half hours for requests by fax and one day for those that come in by phone. Some discussion ensued about the providers who were not available to provide needed

information requested for prior authorization requests in a timely manner. Mr. Small said in those instances that a week's supply of medication is approved. An extended supply is also given to recipients whose prescribers are on vacation or unavailable for other reasons. Ms Cunningham said that she would report to the P & T Committee that the Board recommended keeping the 3-day emergency supply policy, since the "kinder, gentler Rational Drug Therapy Program" has the situation under control.

## **V. REPORTS**

### **A. Rational Drug Therapy Program (See Attachment)**

There were no comments from the Board regarding the Report.

Steve Small reported that many patients on COX-II Inhibitors are also on Proton Pump Inhibitors. He suggested that criteria for approving or not approving a COX-II Inhibitor could include concurrent use of PPI's, Mr. Small also suggested that the use of aspirin and COX-II Inhibitors is important to consider. If patients are at a low risk of a GI bleed, are on a PPI for other reasons, and are taking aspirin daily, then a traditional NSAID would be considered appropriate therapy, because of the GI protection that is offered by the PPI. For patients needing both cardioprotective and anti-inflammatory therapy, the GI protective effects of a COX-II agent are lost by taking aspirin and don't justify their expense. Mr. Small asked if the Board would be willing to review some criteria concerning the use of aspirin, anti-inflammatory therapy and PPI's. The Board agreed to consider criteria concerning concurrent use of these agents.

Ms. Cunningham told Steve Small that some prior authorization criteria may be sent to him to review for Crestor before the next meeting.

### **B. Heritage Information Systems**

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

Rob Berringer presented proposed population-based interventions on diabetes therapy, asthma therapy, stroke prevention, and dose optimization therapy.

Ms. Cunningham asked the Board to choose two interventions for the next quarter. A discussion of the management of diabetes followed, and Ms. Cunningham reported on the revitalization of the West Virginia Health Initiative Program (WVHIPS) for diabetes disease state management. Ms. Cunningham stated that WVHIPS was not widely adopted initially for several reasons. Providers are required to complete a training program for enrollment, and no training program has been available since the inception of the program and the live training that was offered initially. She said that the Diabetes Control Network had offered funding for a complete educational program and that Dr. Dickman had been working with them to provide the educational modules. Providers will receive six hours of continuing education for their participation and can be enrolled in the Disease Management Program upon completion. Access will be provided via the web and providers will be able to bill for extended visits with diabetic patients and contract with Diabetes Educators for teaching self-management skills to their patients. The Bureau is also proposing a change in the State Plan to allow Diabetes Educators to bill directly for diabetes management services. Dr. Dickman stated that he felt that it was a valuable program and that the compensation provided by Medicaid was very fair. Ms. Cunningham said that the program would begin on August 1, 2004, and that there would be a link to the educational modules on the DHHR website and, hopefully, on the CAMC website. For providers without internet access, the program will be available on a CD.

The Board voted to adopt Diabetes Care Guidelines and Stroke Prevention as the population-based interventions for the next quarter.

**C. ACS First Quarter Report (See Attachment)**

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

**VI. OTHER BUSINESS**

No other business was discussed.

**VII. OPEN TO THE FLOOR**

No remarks from the floor.

**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, September 15, 2004 from 4:00 p.m. - 6:00 pm.

Respectfully submitted,

Lynda L. Edwards  
Secretary

**Criteria of Coverage of Growth Hormone  
In Non-Growth Hormone Deficient Children**

- A. We can elect not to cover this in any way if they are not growth hormone deficient, because it is cosmetic
  
- B. We can cover with the following criteria:
  - 1. There is a standard deviation of 2.25 or more below mean height for chronological age.
  - 2. No expanding intracranial lesion or tumor diagnosed.
  - 3. Growth rate is below five centimeters per year.
  - 4. Bone age is 14-15 years or less in females and 15-16 years or less in males and epiphyses are open.
  - 5. There is a mixed or normal response to any two stimuli tests in raising serum growth hormone above 10 nanograms/milliliter.
  - 6. The child is proportionally shorter than the predicted rate of growth from the parent's height.
  - 7. Request must come from a pediatric endocrinologist.

**Prior Authorization Criteria for Coverage of Growth Hormone  
In Non-Growth Hormone Deficient Children  
(Amended Draft)**

Growth Hormone will be approved for use in children with non-growth hormone deficiency if the following criteria are met:

- 1. There is a standard deviation of 2.25 or more below mean height for chronological age.
- 2. No expanding intracranial lesion or tumor diagnosed.
- 3. Growth rate is below five centimeters per year.
- 4. Bone age is 14-15 years or less in females and 15-16 years or less in males and epiphyses are open.
- 5. There is a mixed or normal response to any two stimuli tests in raising serum growth hormone above 10 nanograms/milliliter.
- 6. The child is proportionally shorter than the predicted rate of growth from the parent's height.
- 7. Requests must come from a pediatric endocrinologist.

**Criteria for Coverage of Modafinil (Provigil)**

Prescriptions for Modafinil (Provigil) require prior authorization for all age groups. Authorization will only be given for FDA approved indications and meeting the following criteria:

- Patients > 16 years of age
- Diagnosis of narcolepsy
- Shift work disorder in patients working at least 5 or more overnight shifts per month and the patient has a score of at least 10 on the EPWORTH Sleepiness Scale.
- Diagnosis of excessive sleepiness associated with obstructive sleep apnea or hypopnea syndrome, if
  - Patient has had a sleep study and diagnosis is confirmed by a sleep specialist physician; and
  - Patient is compliant with Continuous Positive Airway Pressure (CPAP) or Bi-level Positive Airway Pressure (BiPAP) device and meets the criteria for Medicaid coverage of CPAP and/or BiPAP device; and
  - Other medications used by the patient have been reviewed by the prescribing physician. Sedating medications should be discontinued if possible.
- All other requests will be reviewed on a case-by-case basis by the Medicaid Medical Director

**Criteria for Coverage of Modafinil (Provigil)  
(Amended Draft)**

Prescriptions for Modafinil (Provigil) require prior authorization for all age groups. Authorization will only be given for FDA approved indications and meeting the following criteria:

- Patients > 16 years of age
- Diagnosis of narcolepsy
- Shift work disorder in patients working at least 5 or more overnight shifts per month and the patient has a score of at least 10 on the EPWORTH Sleepiness Scale and the reason for excessive somnolence is ruled out.
- Diagnosis of excessive sleepiness associated with obstructive sleep apnea or hypopnea syndrome, if
  - Patient has had a sleep study and diagnosis is confirmed by a sleep specialist physician; and
  - Patient is compliant with Continuous Positive Airway Pressure (CPAP) or Bi-level Positive Airway Pressure (BiPAP) device and meets the criteria for Medicaid coverage of CPAP and/or BiPAP device; and
  - Other medications used by the patient have been reviewed by the prescribing physician. Sedating medications should be discontinued if possible.
- All other requests will be reviewed on a case-by-case basis by the Medicaid Medical Director

**Prior Authorization Criteria  
Risperdal Consta**

1. Patient has diagnosis of schizophrenia or schizoaffective disorder.
2. Prescriber is a psychiatrist.
3. Patient has had at least a three day prior exposure to risperdone, with no hypersensitivity reaction.
4. Initial dose is 25 mg. every two weeks adjusted  $\geq 4$  weeks. (Maximum dose=50 mg.)
5. Carbamazepine stopped prior to beginning injection and all other antipsychotic medications will be tapered off after 3 weeks.
6. Justification for use of injectable in place of oral form.

**Prior Authorization Criteria  
Risperdal Consta  
(Amended Draft)**

1. Patient has diagnosis of schizophrenia or schizoaffective disorder.
2. Initiation of therapy is by a psychiatrist or in consultation with a psychiatrist.
3. Patient has had at least a three day prior exposure to risperdone, with no hypersensitivity reaction.
4. Initial dose is 25 mg. every two weeks adjusted  $\geq 4$  weeks. (Maximum dose=50 mg.)
5. Carbamazepine stopped prior to beginning injection and all other antipsychotic medications will be tapered off after 3 weeks.
6. Justification for use of injectable in place of oral form.
7. Patient must be at least 18 years old.

**Enbrel for Psoriasis  
Prior Authorization Criteria**

1. Psoriasis affects  $\geq$  5-10% of body surface area (moderate to severe psoriasis).
2. Psoriasis has significant impact on the patient's quality of life and/or is disabled or has psoriatic arthritis.
3. Systemic treatment has been previously required.
4. Phototherapy is contraindicated, unavailable, or psoriasis is resistant to phototherapy.
5. Documentation of previous treatment is present.

**Enbrel for Psoriasis  
Prior Authorization Criteria  
(Amended Draft)**

1. Psoriasis affects  $\geq$  10% of body surface area (moderate to severe psoriasis).
2. Psoriasis has significant impact on the patient's quality of life and/or patient is disabled or has psoriatic arthritis.
3. Systemic treatment has been previously required.
4. Phototherapy is contraindicated, unavailable, or psoriasis is resistant to phototherapy.
5. Documentation of previous treatment is present.
6. Patient must be 18 years or older.
7. Initial treatment plan must be done in consultation with a dermatologist or rheumatologist.