Drug Utilization Review Board Meeting Minutes
February 18, 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
Steve Judy, R.Ph.
Lester Labus, M.D.
Chris Terpening, PharmD., Ph.D.
John R. Vanin, M.D.
Dan Dickman, M.D.
David Elliott, PharmD.
Kevin Yingling, R.Ph., M.D.
Bernie Smith, R.Ph., M.B.A., M.H.A.
James Bennett, M.D.
George Bryant, PA-C
Mary Nemeth-Pyles, M.S.N., R.N., C.S.
Pat Regan, PharmD.
Matthew Watkins, D.O.
Kerry Stitzinger, R.Ph.

Members Absent:
Ernest Miller, D.O.
Mitch Shaver, M.D.
Myra Chiang, M.D.

DHHR/BMS Staff Present:
Nancy V. 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 Small, Rational Drug Therapy Program
Ona Dingess, Rational Drug Therapy Program

Interested Parties Present:
Altana: Rachel Bove
Astra Zeneca: Mark DiMaio
Aventis: Walter Gose
Berle: Cathy Gore
Boehringer Ingelheim: Dan Ingram, Cindy Kraus
Janssen: Bert Wickey
Johnson & Johnson: James F. Cannon
Merck: Preston Collier, Bob Kelley, Allen Goldberg, Michael Tu
Novartis: Cathi McGeehan
Novo Nordisk: Patrick Baird, Clint Houck, Angela Asom
Pfizer: Gary Mueller
Schering: Feng Ho, Ronnie Coleman
TAP: Stacey Poole, Jim Knott
Wyeth: Tim Atchison
WVU Nursing: Kevin (?)

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 19, 2003, MINUTES

A motion was made to accept the minutes of the November 19, 2003, DUR Board meeting as written. The motion was seconded and passed unanimously.

III. OLD BUSINESS

A. Election of Officer for 2004 - 2005

Chris Terpening presented the slate of officers for the 2004-2005 term. The nominees proposed by the Nominating Committee were: Dan Dickman, Karen Reed, and Bernie Smith.

Vicki Cunningham asked that members vote for only one person and that the nominee with the highest number of votes would serve as Chairperson and with the second highest number would serve as Co-Chairperson. The Co-Chairperson would serve when the Chairperson was unable to attend the meeting. Gail Goodnight was asked to be in charge of counting the votes. After two ballots, Karen Reed was re-elected to serve as Chairperson and Dan Dickman as Co-Chairperson.

B. Report from Dr. Joseph on long-term use of macrolides

Dr. Joseph gave a follow-up report on requests for the use of azithromycin as a prophylactic agent in pediatric patients with cystic fibrosis. The study that she had cited at the September meeting has since been published in *JAMA* (October 2003). She reported that she had received several requests from physicians who wished to implement this therapy for their patients. Physicians making the request have cited this study. It was done over a period of two years and was a randomized double-blind placebo controlled trial. There was 241 patients screened, but only 87 were eligible for the study. Although this is an off-label use for this drug, the results of the study were published in a peer-reviewed journal.

Members of the Board agreed that azithromycin should be approved for use in pediatric patients with cystic fibrosis, in accordance with the criteria that had been adopted at the previous meeting. Those criteria are: (1) patients must be older than six years of age and weigh 55 pounds or more, (2) have mild to moderate lung disease, (3) have Pseudomonas aeruginosa in sputum for at least one year (4) have not had the presence of tuberculosis mycobacteria in the past two years, and (5) have no presence of liver or kidney disease. This criteria will be used by the Rational Drug Therapy Program when requests of this nature are made.

C. Diabetes Disease Management Program – *Protocol for Insulin Sooner* – Patrick Baird and Dr. Asom - NovoNordisk

The protocol for the Diabetes Disease Management Program, “Insulin Sooner”, was explained by Dr. Angela Asom of NovoNordisk. A discussion ensued regarding the advantages and drawbacks of initiating this Program with a small number of patients. Vicki Cunningham stated that she would like the Board’s feedback on the feasibility of introducing this program through Medicaid and if busy practitioners like themselves would consider participating. Questions about who would pay for a dietician, a Certified Diabetes Educator, and the extra lab work that it would require arose. One of the Board members inquired whether this would be a study or a trial. He also stated any practitioner would want to have all of these extra resources available to their patients, but was concerned about the financial aspects and who would be responsible. Ms. Cunningham explained that the proposal was to initiate the Program with 60-80 patients and measure the outcomes. If significant savings could be shown through better glucose control for these patients, then there would be a possibility of offering the Program statewide. Patrick Baird, a representative of NovoNordisk, stated that his company would consider providing dieticians and Certified Diabetic Educators for patients in the Program at no cost to the

State. Ms. Cunningham reported that this disease management program was recommended by Provider Synergies to be used in conjunction with the Preferred Drug List. She also added that she felt that members of the Board would be the best judge of whether or not a program would be appropriate to use in busy practices. More discussion about the Program followed and no recommendations were made at the time. The Board suggested that this would be a decision that should be made by the Bureau. Ms. Cunningham thanked the Board members, Patrick Baird and Dr. Asom for their input.

IV. NEW BUSINESS

A. Presentation by Schering Representative on the use of Zetia when combined with HMG CoA Reductase Inhibitors

Ms. Cunningham stated that the statins and other lipotropics were reviewed and some physicians were uncomfortable with criteria asking patients to try a maximum dose of a statin for 12 weeks before Zetia could be added. As a result of some of the discussion at the P & T meeting, an e-mail was sent out to see if Board members would like more information about Zetia presented at the meeting.

A presentation was given by Dr. Allen Goldberg on the use of Zetia. Some discussion ensued about maximum dosage of statins and if better results could be reached sooner by adding a second agent.

B. Review of actions taken at the January 21, 2004 Pharmaceutical and Therapeutics Committee Meeting – Review of PA Criteria

Ms. Cunningham asked the Board to turn to the Lipotropics, Other section in their notebooks. She stated that the PA criteria for this category was approved last year after the first meeting of the P & T Committee. She read the criteria for the category. The question that came up for discussion was the maximum tolerable dose of statins, and she wanted to know if they wanted to change the criteria. A Board member discussed the costs of Zetia being allowed before maximum dosage of a statin was reached. The members were concerned that Zetia would be used as first line instead of trying statins. A motion was made to accept the criteria as it was previously, motion was seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED	CRITERIA
LIPOTROPICS, OTHER	cholestyramine (Questran)# cholestyramine light (Questran Light)# colestipol (Colestid) fenofibrate (Tricor) gemfibrozil (Lopid)# niacin ER (Niaspan or generic) niacin ER/lovastatin (Advicor)	colesevelam (WelChol) ezetimibe (Zetia) fenofibrate (Lofibra)	*PA Criteria: The preferred agents must be tried before a non-preferred agent will be authorized, unless one of the exceptions on the PA form is present. Zetia, as monotherapy, will only be approved for patients who cannot take statins or other available agents. Zetia and Welchol will be approved for add-on therapy only after an insufficient response to the maximum tolerable dose of a statin for 12 weeks of therapy.*

Ms Cunningham stated that the Pharmaceutical and Therapeutics Committee had met in January to continue their review of the Preferred Drug List. The following therapeutic classes were reviewed and changes to the status of the drugs in them are listed below.

Ms. Cunningham stated that Avodart is now non-preferred. Changes were made in the PA criteria and modified as follows:

DRUG CLASS	PREFERRED	NON-PREFERRED	CRITERIA
BENIGN PROSTATIC HYPERPLASIA (BPH)/MICTURITION AGENTS	doxazosin (Cardura)# tamsulosin (Flomax) terazosin (Hytrin)# finasteride (Proscar)	alfuzosin (Uroxatral) dutasteride (Avodart)	*PA Criteria: One of the preferred agents must be tried before a non-preferred agent will be authorized, unless one of the exceptions on the PA form is present.*

No changes were made to the Ulcerative Colitis Agents.

DRUG CLASS	PREFERRED	NON-PREFERRED	CRITERIA
AMINOSALICYLATES FOR ULCERATIVE COLITIS	balsalazide (Colazal) mesalamine (Asacol) mesalamine (Canasa) suppositories mesalamine (Rowasa) enemas olsalazine (Dipentum) sulfasalazine# sulfasalazine EC#	mesalamine (Pentasa)	*PA Criteria: The preferred agents, (one dosage form of each chemical entity), must be tried before a non-preferred agent will be authorized, unless one of the exceptions on the PA form is present.*

Ms. Cunningham stated that Lexapro was added to the SSRIs as a preferred drug.

DRUG CLASS	PREFERRED	NON-PREFERRED	CRITERIA
ANTIDEPRESSANTS, SELECTIVE SEROTONIN REUPTAKE INHIBITORS (SSRIs)	citalopram (Celexa) fluoxetine (Prozac)# fluvoxamine (Luvox)# paroxetine (Paxil)# paroxetine CR (Paxil CR) sertraline (Zoloft) escitalopram (Lexapro)	fluoxetine ER (Prozac Weekly) fluoxetine (Sarafem) paroxetine suspension (Paxil)	*PA Criteria: None of the non-preferred dosage forms will be authorized unless there is documentation showing that the preferred dosage forms of the corresponding agents are inappropriate for the patient.*

No changes were made to the Antiemetics/Antivertigo class.

DRUG CLASS	PREFERRED	NON-PREFERRED	CRITERIA
ANTIEMETICS/ ANTIVERTIGO AGENTS	**ANTIEMETIC** hydroxyzine# metoclopramide# ondansetron (Zofran)(Quantity limits apply) ondansetron orally dissolving tablets (Zofran ODT) (Quantity limits apply) prochlorperazine# promethazine# **ANTIVERTIGO** meclizine# scopolamine, oral (Scopace) scopolamine, transdermal (Transderm Scop)	**ANTIEMETIC** aprepitant (Emend) dolasetron (Anzemet) dronabinol (Marinol) granisetron (Kytril) thiethylperazine maleate (Torecan)	*PA Criteria: A trial of the preferred agents (with corresponding routes of administration and for appropriate diagnoses) is required before non-preferred agents will be approved, unless one of the exceptions on the PA form is present. For chemotherapy or radiation- induced nausea, a trial of Zofran is adequate for approval of the 5 HT-3 agents.*

Ms. Cunningham stated that Detrol LA was added to the Preferred Drug List. She also stated that there was not much controversy about this class, since almost all agents are preferred.

One of the Board members asked about how the criteria was written for different classes. He wanted to know if patients were required to try one or all of the preferred agents. Vicki Cunningham stated that the criteria was specific for each class and the Board members had articulated that in their work on the criteria the past year. The Board member felt that the criteria should be consistent, with either all preferred agents required for a trial or only one for each class.

DRUG CLASS	PREFERRED	NON-PREFERRED	CRITERIA
ANTIINCONTINENCE AGENTS	oxybutynin (Ditropan)# oxybutynin XL (Ditropan XL) oxybutynin transdermal (Oxytrol) flavoxate (Urispas)# tolterodine LA (Detrol LA)	tolterodine (Detrol)	*PA Criteria: All of the preferred agents in this category must be tried before a non-preferred agent will be authorized, unless one of the exceptions on the PA form is present.*

Ms. Cunningham stated that, in the Calcium Channel Blockers category that if one of the agents was tried in the preferred group and the results were not acceptable, then they could have a non-preferred agent. A Board member emphasized that the Calcium Channel Blockers should be broken down into two categories, dihydropyridines and non-dihydropyridines. A motion was made to accept the PA criteria and apply it to each category, requiring a trial of one agent in a category before a non-preferred one would be authorized. The motion was seconded, votes taken and motion carried.

The PA criteria should reflect that a trial of one agent within a category would be required before a non-preferred agent in that category could be authorized.

DRUG CLASS	PREFERRED	NON-PREFERRED	CRITERIA
CALCIUM CHANNEL BLOCKERS	diltiazem (Cardizem)# diltiazem SR (Cardizem SR, Cardizem CD, Dilacor XR)# diltiazem LA (Cardizem LA) verapamil (Calan, Isoptin)# verapamil ER (Verelan PM) verapamil SR (Calan SR, Isoptin SR)# **Dihydropyridines** felodipine (Plendil) isradipine (Dynacirc) isradipine SR (Dynacirc CR) nifedipine SR (Adalat CC, Procardia XL)# nisoldipine (Sular)	diltiazem SR (Tiazac) verapamil SR (Verelan) verapamil ER (Covera-HS) **Dihydropyridines** nifedipine capsules (Adalat, Procardia and generic) nicardipine IR (Cardene and generic) amlodipine (Norvasc) bepridil (Vascor) nicardipine SR (Cardene SR) nimodipine (Nimotop)	*PA Criteria: One of the preferred dosage forms must be tried before a non-preferred dosage form of the corresponding agent will be authorized.* ***Dihydropyridines*** *PA Criteria: One of the preferred agents must be tried before a non-preferred agent will be authorized, unless one of the exceptions on the PA form is present. §(Nimodipine will be approved with the appropriate diagnosis.)*

No changes were made in the PA criteria for this class.

DRUG CLASS	PREFERRED	NON-PREFERRED	CRITERIA
ATOPIC DERMATITIS IMMUNE MODULATORS	pimecrolimus (Elidel)	tacrolimus (Protopic)	*PA Criteria: The preferred agent must be tried, for at least 30 days, before a non-preferred agent will be authorized.*

No changes were made in the PA criteria for this class.

DRUG CLASS	PREFERRED	NON-PREFERRED	CRITERIA
MACROLIDES	azithromycin (Zithromax) clarithromycin (Biaxin) clarithromycin (Biaxin XL) erythromycin (base, ethylsuccinate)	cinoxacin (Cinobac) dirithromycin (Dynabac) erythromycin estolate troleandomycin (Tao)	*PA Criteria: No non-preferred agents will be authorized unless one of the exceptions on the PA form is present for all of the preferred agents.*

No changes were made in the PA criteria for this class. Cefzil, Vantin and Cedax have been added to the Preferred Drug List.

DRUG CLASS	PREFERRED	NON-PREFERRED	CRITERIA
CEPHALOSPORINS AND RELATED ANTIBIOTICS	**First Generation** cefadroxil (Duricef)# cephalexin (Keflex)# cephradine (Velosef)# **Second Generation** cefaclor (Ceclor)# cefprozil (Cefzil) cefuroxime axetil (Ceftin)# **Third Generation** cefdinir (Omnicef) cefditoren pivoxil (Spectracef) cefpodoxime proxetil (Vantin) ceftibuten (Cedax) cefixime (Suprax)# **Penicillin/Beta Lactamase Inhibitor** amoxicillin/clavulanate (Augmentin)# amoxicillin/clavulanate (Augmentin ES-600) amoxicillin/clavulanate (Augmentin XR)	**Second Generation** loracarbef (Lorabid)	*PA Criteria: The preferred agents must be tried before a non-preferred agent will be authorized, unless one of the exceptions on the PA form is present.*

No changes were made for the Intermittent Claudication class.

DRUG CLASS	PREFERRED	NON-PREFERRED	CRITERIA
INTERMITTENT CLAUDICATION AGENTS	cilostazol (Pletal) pentoxifylline (Trental)#		

No changes were made in the PA criteria for the Estrogen class.

DRUG CLASS	PREFERRED	NON-PREFERRED	CRITERIA
ESTROGEN AGENTS, COMBINATION	17ß-estradiol/norethindrone acetate (Activella) 17ß-estradiol/norethindrone acetate (Combipatch) 17ß-estradiol/norgestimate (Prefest) conjugated estrogens/ medroxyprogesterone acetate (Premphase)	conjugated estrogens/ medroxyprogesterone acetate (Prempro) ethinyl estradiol/ norethindrone acetate (Femhrt)	*PA Criteria: The preferred agents must be tried for at least 90 days before a non-preferred agent will be authorized, unless one of the exceptions on the PA form is present. Estratest has been classified as a desi-drug and therefore, can no longer be covered by Medicaid.*

There were no changes in the PA criteria for this class. Ms. Cunningham stated that last year patients already on non-preferred agents received authorization for that agent for one year. She asked the Board if they wanted to continue this criteria indefinitely. The Board said that it wanted to continue the criteria. Ms. Cunningham said that she would change it to say that they would receive authorization for that agent.

DRUG CLASS	PREFERRED	NON-PREFERRED	CRITERIA
IMMUNOMODULATORY AGENTS FOR MULTIPLE SCLEROSIS	interferon beta-1a (Rebif)** interferon beta-1b (Betaseron)**	glatiramer (Copaxone) interferon beta-1a (Avonex)	*PA Criteria: Patients starting therapy in this class will be required to try the preferred agents, unless one of the exceptions on the PA form is present. Patients already on non-preferred agents will receive prior authorization for that agent for one year.*

Celebrex has been added to the preferred list, although it does require prior authorization. Mobic was added to the preferred list and will be treated as a COXII Inhibitor, because that is the way it was marketed. Ms. Cunningham asked if there were any objections. A Board member asked how Mobic compared in cost to Celebrex and Bextra and the rest of the category. It was stated that there wasn't much of a difference. No changes were made in the PA criteria for the NSAIDS class.

DRUG CLASS	PREFERRED	NON-PREFERRED	CRITERIA
NONSTEROIDAL ANTIINFLAMMATORY DRUGS (NSAIDS)	celecoxib (Celebrex)** diclofenac (Voltaren)# etodolac (Lodine)# flurbiprofen (Ansaid)# ibuprofen (Motrin)# indomethacin (Indocin)# ketoprofen (Oruvail)# ketorolac (Toradol)# meloxicam (Mobic)** naproxen (Naprosyn, Anaprox)# oxaprozin (Daypro)# piroxicam (Feldene)# rofecoxib (Vioxx)** sulindac (generic)# valdecoxib (Bextra)**	diclofenac/misoprostol (Arthrotec) meclofenamate # mefenamic acid (Ponstel) nabumetone (Relafen and generic) tolmetin (Tolectin and generic	*PA Criteria: Non-preferred agents will only be approved after the preferred non-selective NSAIDS and the COX-II agents, when appropriate, have been tried unless one of the exceptions on the PA form is present.*

There is an opportunity for some educational intervention about Persantine this year. Ticlid is now non-preferred and the PA criteria was changed to reflect this.

DRUG CLASS	PREFERRED	NON-PREFERRED	CRITERIA
PLATELET AGGREGATION INHIBITORS	aspirin (OTC)# aspirin/dipyridamole ER (Aggrenox) clopidogrel (Plavix) dipyridamole (Persantine)#	ticlopidine (Ticlid and generic)	*PA Criteria: The non-preferred agent will only be approved after a two-week trial of clopidogrel, when appropriate.*

Discussion about the Proton Pump Inhibitor (PPI) class was continued at the last P & T Committee Meeting. The Board members set criteria for one preferred PPI and decided not to require a PA for Prilosec OTC. We believed at the time that the second-line agent would be Prevacid. It is now Protonix. It was decided that the prior authorizations that are in effect would be given a few more months and then terminated. Since both of the preferred agents are tablets, Ms. Cunningham asked if the Board wanted to work out

dosing for children or make any special provisions. It was agreed that Prevacid Suspension would not require a PA for children up to 12 years of age. A PA would be required for adults with swallowing difficulty for the suspension. An adhoc study was included for the Board to inform them that a change will be required for about 11, 000 patients on Prevacid and 5,870 on AcipHex. The PA will continue for three months and then they will be required to change to the preferred drug. The physicians will be notified about their patients who need new prescriptions. The PA criteria for this class will stay the same with the exception that no prior authorization will be required for children up to the age of 12 for Prevacid Suspension. The motion was seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED	CRITERIA
PROTON PUMP INHIBITORS	omeprazole (Prilosec OTC) (No PA required) pantoprazole (Protonix)**	esomeprazole (Nexium) omeprazole (Prilosec and generic) lansoprazole (Prevacid)(No PA required for children up to 12 years of age for Suspension.) rabeprazole (AcipHex)	*PA Criteria: Both of the preferred agents must be tried before a non-preferred agent will be approved, unless one of the exceptions on the PA form is present.*

\# Generic forms only.
** Prior authorization required.

C. Review of Over-the-Counter Medications covered by Medicaid

Ms. Reed stated that a list had been provided of currently covered over-the-counter medications by West Virginia Medicaid and a list of OTC drugs that are currently covered by the Missouri Medicaid Program. It was noted that generic Claritin was not on the list. Peggy King said that the price on the brand name Claritin is lower than generic. She stated that it would be discussed in the P & T Committee Meeting when that category comes up for review again. Ms. Cunningham wanted to know if the Board wanted to make any recommendations for changes to the list. It was decided to carry this over to the next meeting. She asked that the Board keep and review the list to see if they wanted to make any recommendations.

D. Discussion of Cough and Cold Products for Coverage

It was stated that, although we do not cover cough and cold medications, they are often requested. Under the State Plan the cough and cold medications are not covered. Drugs like Rynatan and some decongestants and antihistamines are classified as cough and cold products. Some physicians have requested them for treatment of allergies and pointed out that it would be much less expensive to use generic forms than non-sedating antihistamines. Ms. Cunningham stated that this would require a change in our State Plan, which would take some time. She asked for recommendations to the list of cough and cold preparations that should be covered.

V. REPORTS

A. Rational Drug Therapy Program (See Attachment)

There were no comments from the Board regarding the Report.

B. ACS Fourth 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 5:45 p.m. The next meeting will be held on Wednesday, May 19, 2004 from 4:00 p.m. - 6:00 pm.

Respectfully submitted,

Lynda L. Edwards
Secretary