Drug Utilization Review Board Meeting Minutes
November 19, 2003

The forty-second 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.
Myra Chiang, M.D.
John R. Vanin, M.D.
Dan Dickman, M.D.
David Elliott, PharmD.
Mitch Shaver, M.D.
Kevin Yingling, R.Ph., M.D.
Bernie Smith, R.Ph., M.B.A., M.H.A.
Mary Nemeth-Pyles, M.S.N., R.N., C.S.
Pat Regan, PharmD.
Matthew Watkins, D.O.
Kerry Stitzinger, R.Ph.

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

DHHR/BMS Staff Present:
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

Other State Agency Staff Present:
Felice Joseph, PEIA

Interested Parties Present:
Amgen: Francine Galante
Astra Zeneca: Tom Farrah
Aventis: Walter Gose
Bristol Myers Squibb: Karen Brett Long, Cindy Kraus
Cephalon: Deborah Bearer
Genentech: Bob McConnell
Government Relations Specialist: Thom Stevens
Janssen: Todd Houldsworth, Mark Akers, Bert Wickey
Johnson & Johnson: Raymona Kinneberg
Merck: Bob Kelley, Larry Swann, Ed Davis
Novartis: Cathi McGeehan, Michael Beatty
Novo Nordisk: Patrick Baird
Schering: Feng Ho
Sepracor: Sue Ellen Shrout, Tony Severoni
TAP: Stacey Poole

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 17, 2003, MINUTES

A motion was made to accept the minutes of the September 17, 2003, DUR Board meeting as written. The motion was seconded and passed unanimously.

III. OLD BUSINESS

A. Prior Authorization Criteria for Xolair®(omalizumab)

Ms. Reed read the proposed criteria for Xolair. The FDA approved indication is for the treatment of moderate to severe persistent asthma in children 12 or over and in adults. COPD, acute bronchospasms, or status asthmaticus are not approved indications. The prior authorization criteria was approved as presented. A motion was made and seconded, votes were taken and the motion carried. (*See Attachment))*

B. Review of PA Form for Xolair®

Ms. Reed stated that the prior authorization form included in the packet would not be acted upon until Steve Small has had the opportunity to review it. *(See Attachment)*

IV. NEW BUSINESS

A. Approval of Meeting Dates for 2004

Ms. Reed read the proposed meeting dates for 2004: February 18, 2004, May 19, 2004, September 15, 2004 and November 17, 2004 from 4:00 p.m. to 6:00 p.m. A motion was made to accept these dates for 2004, motion was seconded, votes were taken and the motion carried.

B. Nominating Committee selection of 3 members to choose nominees for Chairman and Vice-Chairman for 2004

Ms. Reed asked for volunteers to serve on the nominating committee for Chairman and Vice-Chairman for 2004. Steve Judy, David Elliott and Chris Terpening volunteered to serve in this capacity. Their nominations will be voted upon at the next meeting.

C. Review of actions taken at October 29, 2003, Pharmacy and Therapeutics Committee

Vicki Cunningham reported on the actions taken by the Pharmacy & Therapeutics Committee during the first phase of their annual review of the Preferred Drug List.

DRUG CLASS	PREFERRED	NON-PREFERRED	CRITERIA
PROTON PUMP INHIBITORS	lansoprazole (Prevacid)** rabeprazole (AcipHex)** Prilosec OTC**	esomeprazole (Nexium) omeprazole (Prilosec) pantoprazole (Protonix)	***PA Criteria: Both of the preferred drugs must be tried before a non-preferred agent will be approved, unless one of the exceptions on the PA form is present.*** Review of this class will be continued at the January meeting.

The changes made in the PPI class and a short discussion ensued about the efficacy of the PPIs. Two proposals were presented for changes in prior authorization criteria for the PPI class.

Proposal:

1. Remove prior authorization criteria from Prilosec OTC and make it the first-line preferred agent.

2. In order to receive prior authorization for the second-line preferred agent (which will require prior authorization), there must be a two-week trial of Prilosec OTC unless one of the exceptions on the PA form is present. (These include an allergy to the preferred agent, intolerable side effects from the preferred agent, a previous trial of the preferred agent, or the possibility of an adverse drug-drug or drug-disease interaction.)

3. Patients that already have prior authorizations for PPI's will be allowed to continue on them until the PA expires. (Many are good for one year.) At that time, they will be required to switch to OTC Prilosec, unless one of the exceptions of the PA form is present.

OR

1. Remove the prior authorization requirement from Prilosec OTC and make it the first-line preferred agent.

2. Send letters to physicians of recipients on Aciphex and Prevacid explaining the current prior authorization will be expire in three months. After that, their patients will need a prescription for OTC Prilosec. Letters will also be sent to physicians of patients on Prilosec with a legend status to inform them that their patients will need a new prescription for the OTC Prilosec.

3. After a two-week trial of OTC Prilosec, if the outcome is not acceptable, the second-line PPI (which will require a PA) can be approved. We can also send letters to prescribers with patients on Protonix and Nexium to inform them of the addition of a PPI which does not require a PA to the preferred list and ask them to voluntarily switch therapies. If their patients have had a trial of Prilosec in the past, then the PA for the non-preferred agent will remain in place until it expires.

The second proposal was chosen. A motion was made and seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED	CRITERIA
BETA AGONISTS (INHALED & PERORAL)	albuterol/ipratropium MDI (Combivent) albuterol HFA MDI (Proventil HFA) albuterol syrup, tablets, CFC MDI, inhalation solution # metaproterenol syrup, tablets, inhalation solution # ***formoteral MDI (Foradil)*** salmeterol (Serevent, Serevent Diskus) terbutaline # levalbuterol inhalation solution (Xopenex)	albuterol/ipratropium inhalation solution (Duoneb) albuterol HFA MDI (Ventolin HFA) albuterol inhalation solution (Accuneb) albuterol SR tablets (Volmax) metaproterenol MDI (Alupent) ***pirbuterol MDI (Maxair, Maxair Autohaler)***	***PA Criteria: The preferred agents must be tried before non-preferred agents will be authorized, unless one of the exceptions on the PA form is present.*** Maxair Autohaler was removed from the list and Foradil was added to the list.

No changes were made to the prior authorization (PA) criteria for the inhaled and peroral class.

DRUG CLASS	PREFERRED	NON-PREFERRED	CRITERIA
GLUCO-CORTICOIDS, INHALED	beclomethasone CFC (Vanceril) fluticasone (Flovent, Flovent Rotadisk) fluticasone/salmeterol (Advair) ***triamcinolone (Azmacort)***	beclomethasone HFA (QVAR) budesonide (Pulmicort Turbuhaler) budesonide (Pulmicort Respules)*** ***flunisolide (Aerobid, Aerobid M)*** The Committee asked that Provider Synergies return to the company for further negotiations about Advair.	***PA Criteria: All of the preferred agents (in one dosage form) must be tried before a non-preferred agent will be authorized, unless one of the exceptions on the PA form is present.*** <u>A recommendation was made to remove Advair from the PDL, but the committee asked Provider Synergies to go back to the company for negotiations. If it is removed, would you recommend grandfathering those patients already on Advair?</u>

Ms. Cunningham asked the Board their opinion on grandfathering Advair if it was no longer on the preferred list. A motion was made to grandfather Advair for patients already on therapy, the motion was seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED	CRITERIA
CORTI-COSTEROIDS, NASAL	flunisolide (Nasalide)# fluticasone (Flonase) mometasone (Nasonex) ***flunisolide (Nasarel)*** ***triamcinolone AQ (Nasacort AQ)***	beclomethasone (Beconase, Vancenase) beclomethasone AQ (Beconase AQ, Vancenase AQ) budesonide (Rhinocort) budesonide aqua (Rhinocort Aqua) triamcinolone (Nasacort)	***PA Criteria: All 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 in the PA criteria for the nasal corticosteroid class.

DRUG CLASS	PREFERRED	NON-PREFERRED	CRITERIA
CALCIUM CHANNEL BLOCKERS	diltiazem (Cardizem)# diltiazem SR (Cardizem SR, Cardizem CD, Dilacor XR)# felodipine (Plendil) isradipine (Dynacirc) isradipine SR (Dynacirc CR) nicardipine (Cardene)# nifedipine SR (Adalat CC, Procardia XL)# nimodipine (Nimotop) nisoldipine (Sular) verapamil (Calan, Isoptin)# verapamil ER (Verelan PM) verapamil SR (Calan SR, Isoptin SR)#	amlodipine (Norvasc) bepridil (Vascor) nicardipine SR (Cardene SR) nifedipine (Adalat, Procardia) generic and brand verapamil ER (Covera-HS) verapamil SR (Verelan) diltiazem SR (Tiazac) nimodipine (Nimotop) ***nicardipine (IR) generic and brand***	***PA Criteria: If one of the preferred agents on the list has already been tried or if one of the exceptions on the PA form is present, a non-preferred agent will be authorized.*** <u>The Committee asked Provider Synergies to return to the company for further negotiations on Norvasc.</u>

No changes were made in the PA criteria for the Calcium Channel blocker class.

DRUG CLASS	PREFERRED	NON-PREFERRED	CRITERIA
ANGIOTENSIN II RECEPTOR BLOCKERS	eprosartan (Teveten) losartan (Cozaar) losartan/HCTZ (Hyzaar) olmesartan (Benicar) telmisartan (Micardis) telmisartan/HCTZ (Micardis HCT) valsartan (Diovan) valsartan/HCTZ (Diovan HCT)	candesartan (Atacand) candesartan/HCTZ (Atacand HCT) irbesartan (Avapro) irbesartan/HCTZ (Avalide)	***PA Criteria: Five of the agents must be tried, for at least two weeks each, before one of the non-preferred agents will be authorized. Exceptions to this criteria are those listed on the PA form.*** No change.

No changes were made in the PA criteria for the angiotensin II receptor blockers.

DRUG CLASS	PREFERRED	NON-PREFERRED	CRITERIA
ANTIFUNGALS, TOPICAL	clotrimazole/betameth-asone (Lotrisone)# ketoconazole (Nizoral)# Nizoral Shampoo naftifine (Naftin) nystatin (Mycostatin)# nystatin/triamcinolone (Mycolog)# sulconazole (Exelderm) ciclopirox (Loprox)	butenafine (Mentax) ciclopirox (Penlac) econazole (Spectazole) oxiconazole (Oxistat) terbinafine (Lamisil) Loprox Shampoo	***PA Criteria: Three of the preferred agents must be tried for at least two weeks each before one of the non-preferred agents will be authorized, unless one of the exceptions on the PA form is present.***

No changes were made in the PA criteria for the topical antifungals.

DRUG CLASS	PREFERRED	NON-PREFERRED	CRITERIA
ANTIFUNGALS, ORAL	clotrimazole (Mycelex Troche) fluconazole (Diflucan) ***(Quantity limits still apply)***† ketoconazole (Nizoral)#** nystatin# terbinafine (Lamisil)** ***Grifulvin V Suspension*** ***(PA after 12 years of age)***	flucytosine (Ancobon) itraconazole (Sporanox) griseofulvin (brand & generic)	***PA Criteria: Non-preferred agents will be authorized only if one of the exceptions on the PA form is present for the appropriate preferred agent's use.***

No changes were made in the PA criteria for the oral antifungals, although Grifulvin V was added to the PDL and does not require a PA for children under 12 years of age.

DRUG CLASS	PREFERRED	NON-PREFERRED	CRITERIA
ACE INHIBITOR/ CALCIUM CHANNEL BLOCKER, COMBINATIONS	amlodipine/benazepril (Lotrel) verapamil SR/ trandolapril (Tarka)	felodipine/enalapril (Lexxel)	***PA Criteria: A thirty day trial of both of the preferred agents is required before a non-preferred agent will be authorized.*** No change.

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

DRUG CLASS	PREFERRED	NON-PREFERRED	CRITERIA
ACE INHIBITORS	benazepril (Lotensin) benazepril/HCTZ (Lotensin HCT) captopril (Capoten)# captopril/HCTZ (Capozide)# enalapril (Vasotec)# enalapril/HCTZ (Vasoretic)# fosinopril (Monopril) fosinopril/HCTZ (Monopril HCT) lisinopril (Prinivil/Zestril)# lisinopril/HCTZ (Prinzide/Zestoretic) moexipril (Univasc) moexipril/HCTZ (Uniretic) quinapril (Accupril) quinapril/HCTZ (Accuretic) trandolapril (Mavik)	perindopril (Aceon) ramipril (Altace)	***PA Criteria: Four of the preferred agents must be tried, for at least 30 days each, before a non-preferred agent will be authorized, unless one of the exceptions on the PA form is present.*** No change.

No changes were made in the PA criteria for the ACE inhibitors.

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) Paxil®	***PA Criteria: None of the non-preferred agents will be authorized unless there is a documented allergic reaction to all of the preferred agents.*** Committee asked that Provider Synergies return to company for further negotiations about Zoloft.

It was stated that paroxetine, the recently introduced generic for Paxil, is not preferred. Vicki Cunningham explained that, in many instances, the generic form costs more than the brand during its first six months on the market because it is a single source product. Ms. Cunningham said that Zoloft has been referred back to Provider Synergies to return to the manufacturer for further negotiations.

Note: The generic was reported as non-preferred in error. Paroxetine will be a preferred agent.

DRUG CLASS	PREFERRED	NON-PREFERRED	CRITERIA
ANTI-INCONTINENCE AGENTS	flavoxate (Urispas) oxybutynin (Ditropan)# tolterodine (Detrol) tolterodine LA (Detrol LA)	oxybutynin XL (Ditropan XL) oxybutynin transdermal (Oxytrol)	***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.*** A decision on this class as postponed until the January meeting.

There were no changes in the PA criteria for this class.

DRUG CLASS	PREFERRED	NON-PREFERRED	CRITERIA
ANXIOLYTICS (First review of this class)	alprazolam# buspirone# chlordiazepoxide# diazepam# lorazepam# oxazepam#	alprazolam ER (Xanax XR) meprobamate chlorazepate	PA Criteria: All of the preferred agents in the class must be tried before a non-preferred agent will be authorized, unless one of the exceptions on the PA form is present. Xanax XR will only be approved for patients with a documented diagnosis of panic disorder and for whom compliance is an issue.

Ms. Reed presented the PA criteria for Xanax XR, which is non-preferred. The suggestion was that it only be approved for patients with a documented diagnosis of panic disorder for whom compliance is an issue. A Board member asked if clonazepam had been discussed. Ms. Cunningham stated that it was listed under anticonvulsants. It was stated that it is approved for panic disorder. There are no restrictions on Klonopin other than a requirement to use the generic form, when appropriate. The newest form, the Klonopin Wafer has not been discussed because Klonopin is included in the anti-convulsant class. There was some discussion about Klonopin also being an anxiolytic and whether it should be listed in this class, also. A motion was made to accept the proposed criteria, motion was seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED	CRITERIA
BETA-ADRENERGIC RECEPTOR BLOCKING AGENTS	acebutolol (Sectral)# atenolol (Tenormin)# betaxolol (Kerlone)# bisoprolol (Zebeta)# carvedilol (Coreg) labetalol (Normodyne, Trandate)# metoprolol (Lopressor)# metoprolol XL (Toprol XL) nadolol (Corgard)# pindolol (Visken)# propranolol (Inderal)# propranolol LA (Inderal LA) sotalol (Betapace)# timolol (Blocadren)#	carteolol (Cartrol) penbutolol (Levatol) sotalol (Betapace AF) No change.	***PA Criteria: If one of the exceptions on the PA form is present or if the physician feels that the patient cannot be stabilized with any of the preferred agents, one of the non-preferred agents will be approved.*** No change.

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

DRUG CLASS	PREFERRED	NON-PREFERRED	CRITERIA
LEUKOTRIENE RECEPTOR AGONISTS	montelukast (Singulair)	zafirlukast (Accolate) zileuton (Zyflo)	***PA Criteria: The preferred agent must be tried before the non-preferred agents will be approved, unless one of the exceptions on the PA form is present.*** <u>No change.</u>

No changes were made in this category.

D. Report from Dr. Sandra Joseph – Update on the prophylactic use of azithromycin in children with cystic fibrosis

Dr. Joseph reported on requests for the use of azithromycin as a prophylactic agent in children with cystic fibrosis and on a study that she had found about this. She presented the data from the report and the criteria used for the study. Members of the Board discussed the information available and the difficulty encountered in treating patients these patients. A motion was made to approve azithromycin for prophylaxis for a six month trial in patients with cystic fibrosis, if requested. It was stated that the criteria for approval of this therapy should be the same criteria that was used in the study presented by Dr. Joseph. The criteria for inclusion in the study were: (1) patients were older than six years of age and weighed 55 pounds of more, (2) had mild to moderate lung disease, (3) had Pseudomonas aeruginosa in their sputum for at least one year, (4) had not had a sputum culture of tuberculous mycobacteria in the past two years, and (5) did not have liver or kidney disease.

E. Diabetes Disease Management Program – *Insulin Sooner* – Patrick Baird – Novo Nordisk Pharmaceuticals

Presentation was given (See Attachment).

V. <u>REPORTS</u>

A. Heritage Information Systems (See Attachment)

Due to time constraints, Robert Berringer, Heritage Information Systems, asked that the Board refer to the written report that had been distributed.

B. Rational Drug Therapy Program (See Attachment)

An oral report was given by Steve Small, Rational Drug Therapy Program Director.

C. ACS Third Quarter Report (See Attachment)

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

VI. <u>OTHER BUSINESS</u>

Steve Judy stated that pharmacists needed to be notified when generics should not be dispensed in lieu of the brand. He said that it seemed that the State was violating their own policy when they state that the brand should be used instead of the brand. Vicki Cunningham

explained to them that it was a matter of the cost. Ms. Cunningham suggested that a Program Instruction could be sent out to pharmacists to notify them when a generic is not to be substituted.

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, February 18th, 2004 from 4:00-6:00 pm.

Respectfully submitted,

Lynda L. Edwards
Secretary