STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

Bob Wise
Governor

Paul L. Nusbaum
Secretary

West Virginia Department of Health and Human Resources
Bureau for Medical Services
Pharmaceutical and Therapeutics (P & T) Committee
March 9, 2005 – 9:00 a.m.
The Diamond Building – 350 Capitol Street
Rooms B10 and B11
Charleston, West Virginia

M I N U T E S

Members Present:
David Avery, M.D.
John D. Justice, M.D.
Steven R. Matulis, M.D.
Barbara Koster, MSN, RNC-ANP
Kristy H. Lucas, PharmD
Harriet Nottingham, R. Ph.
Kevin W. Yingling, R.Ph., M.D.
Michael Grome, PA-C
Teresa Dunsworth, PharmD
James Bartsch, R.Ph.

Members Not Present
Thomas L. Gilligan, R.Ph., D.O.

DHHR/BMS Staff Present
Nora Antlake, Counsel
Sandra J. Joseph, M.D., Medical Director
Peggy King, Pharmacy Director
Gail Goodnight, Rebate Coordinator
Randy Myers, Deputy Commissioner
Lynda Edwards, Secretary

Contract Staff/Provider Synergies Present:
Steve Liles, PharmD
Dan Kincaid, Vice President, Finance & Operations

Other Contract Staff/State Staff Present:
Stephen Small, RDTP
Scott Brown, R.Ph., Pharmaceutical Advocate

Present:

Alcon: Bradley Fuller, Matthew Murphy
Alpharma: Michael Rankin
Amgen: Barry Tucker, Francine Dumhart
Ashfield: Kathleen Garcia
AstraZeneca: Frank Salopek, Joann Shoup
Bill Crouch & Assoc.: Raymona Kinneberg
Biovial: Joseph Brann, Maureen Stasi, Gary Starr
Boehringer Ingelheim: Leslie McLaughlin
Bristol-Myers Squibb: Cindy Kraus, Michael Kennedy
Eisai: George Thomas
Elan: Cathy Gore, Johnathan Williams
Genentech: Tony La Mantia
Genzyme: Rob Lanham, Gregory Madison
GlaxoSmithKline: Steve Mitchell, Gary Browning, Marc Canterbury, Carol May, David Casarona, Talbert Turner
Indevus: Mike Wernicke, Joni Casebolt
InterMune: Alex Lopez
Ivax Labs: Michael O'Leary, James M. Daddio, Fred Honeycutt
Janssen: Bobbi Simmers, Michelle Regalla Casto, Stephen Morris, Mark Akers
Johnson & Johnson: Thomas Lambert, Chris Barnowski, Bobbi Summers
King Pharmaceuticals: Steven James, Matthew Hughes
Lilly: Steven M. Babineaux, Darrell Evans, Shonda Foster, John Young, Ronald H. Hart, Nick Alvaro, Terry Hotsinpiller, Michael Murray, Todd Bledsoe
McNeil: Chris Barnowski
Merck: Emmanuel Mahlis, Robert Kelly
Nabi: Mace Whiting, Ray Rutz
Novartis: Cathy McGeehan
Novo Nordisk: Clint Houck, Scott Coleman
Organon: Tim Stanley, Craig Gelband, Mike Roth
Ortho McNeil: Stephen Morris, Edwin Morgan, Casey Frey, Terri Cunningham, Tammy Shidler, Christopher Barnowski
P & G Pharmaceuticals: Michael Valle
Pfizer: Darren Ray, Shawnee Lewis, Pamela Smith, Richard Booth, Charles Dent, Todd Dawson, James Davis, Brian Adams, Sally Swisher, Edgar Hines, Mark Hahn, Amber Willis, Daniel Moore, James Woods, Glenna Bianchin
Purdue Pharma: Brian Rosen
Reliant: Lawrence Stack, Kevin Paul, William Gergely
Roche: Brian Caldwell, Archie Shew
Sanofi: John Snodgrass, George Aiello, Gerry Crowley, Kimberly Eskridge-Rose, Richard Bowman, Dev Rellan, Walter Gose, Jeffrey Hartness
Santarus: Doug Shilling, William Hickman, Angela Clay
Schering-Plough: Gokul Gopalan, Linda Neuman, Robert Cortes, Robert Fonte, Norman Craig, James Harper, Margaret Savage, Ronnie Coleman, Robert Marsh, Feng Ho

Schwarz Pharma: Peter Bohn
Sepracor: William Caldwell, Larry Green, Melissa Kay, Keith Pearson, Sue Shrout
Takeda: Paul Moss, Jeffrey Sheetz, Charlie Kelly, Bill Hollyfield, Charles Fussenegger
TAP: Stacey Poole, James Knott
UCB Pharmaceuticals: Michael Bullock
University of Cincinnati: Guy Neff
WVU: John Young, Richard Granese
Wyeth: Tim Atchison, Lori Kelly, Benjamin Marsh, Mark Reed, Scott Cullins
Other: Hussein Elkhatib, Joseph Anderson, Matthew Wilson, Julian Espiritu, William Wesryn

I. Call to Order

Dr. Steven Matulis, Chairperson, called the meeting to order at 9:30 a.m.

II. Housekeeping

Peggy King, R.Ph., Pharmacy Director, was recognized, and she advised the audience on how the meeting would be conducted. She introduced Lynda Edwards, who would be serving as fire marshal and gave the audience exit instructions in case the fire alarm sounded. She told the audience that when they needed to leave the meeting that they needed to be escorted out of the building for the security of the building. She informed the audience that the sign-up sheet posted by an audience member outside the door was not the official sign-up sheet for the meeting and that people do not officially sign-up until 8:00 a.m. at the table inside.

III. Introductions

All parties seated at the table introduced themselves and gave a brief statement about their professional credentials and affiliations.

IV. Approval of Minutes of November 10, 2004 Meeting

Chairman Matulis asked for approval of the minutes from the last meeting. A motion was made and seconded, votes were taken and the motion carried to approve the minutes as submitted.

V. Public Comment Period

Ms. King stated that this meeting was the first meeting of the multi-state purchasing pool made up of Louisiana, Maryland, and West Virginia. She read the basic information about TOP$ to the audience. (Attachment 1) She informed the Committee that if they had questions about TOP$ Dan Kincaid, Vice President, Finance and Operations, and Steve Liles, PharmD, of Provider Synergies were there to answer them. She also stated that the Centers for Medicare and Medicaid Services (CMS) has not approved the plan and the decisions made at this meeting will be held until CMS has given their approval.

Dr. Liles said that the states will review all the same classes at the same time, manufacturers were asked to have their rebate proposal for all states, and the contracted rebates will run for the same time period for all states.

He said that the recommendations are the same for all states, except for unique situations where West Virginia would want to do something different. He said that one of the hallmarks of the multi-state pool required by CMS is that each state maintains its independence and act on its own.

Ms. King explained that the public comment period would be a 45-minute session. She explained the speaker sign-up. The sign-up is at 8:00 a.m. and there will be three minutes to speak.

She also stated that the session is not interactive and that no slide presentations or handouts would be distributed during the meeting. She informed the audience that materials they wanted to be submitted to the Committee had to be submitted to Lynda Edwards after the comment period and she would distribute them to the Committee. The following individuals took the floor:

Richard Bowman, M.D., Sanofi: Dr. Bowman said that he was with the Center for Pain Relief in Charleston and spoke about Ambien. He stated that there was there were three reasons he wanted the Committee to keep Ambien on the formulary: mechanism of action, utilization and half-life. He stated that this drug was good for patients with pain and that these patients use less narcotic medications. He also said that Ambien will be available generically in December.

Dev Rellan, M.D.,Sanofi: Dr. Rellan, Nephrologist, Marshall University, discussed Type II diabetics, high blood pressure and kidney disease in these patients. He talked about the benefits of Avapro in these populations.

Shonda Foster, Lilly: Ms. Foster said that she was with Eli Lilly and spoke about Cymbalta. She said that Cymbalta was the first in its class to have an indication for diabetic neuropathy. She stated that it was a safe and well tolerated medication with mild to moderate side effects.

Richard Booth, M.D., Pfizer: Dr. Booth, Assistant Professor, Obstetrics and Gynecology, Marshall University School of Medicine and general OB/GYN physician at Valley Health, talked about Detrol LA. He stated that he has found Detrol LA to have the best side-effect profile of the group of overactive bladder medications and that approximately 80% of his patients are using this drug. He said that it works very well for nocturnal incontinence as well as urgency symptoms. He stated that a switch to oxybutynin with its worse side-effect profile would not be cost effective.

John Young, M.D., Lilly: Dr. Young, Associate Professor, WVU and neuropsychiatrist spoke about the benefits of Cymbalta and why he thought it should be included on the PDL. He said patients who do not respond well to SSRIs need to have alternative classes of

medications available to them. He stated its unique effectiveness was in treating diabetic neuropathy. He said that physicians rely heavily on narcotics to treat chronic pain in these patients. Therefore, it is worthwhile to have a medication that patients can take once-a-day and is a non-controlled, non-narcotic that is helpful in relieving their misery.

Hussein Elkhatib, M.D.: Dr. Elkhatib, Clinical Assistant Professor, WVU, spoke about Cymbalta and making it a first choice for treatment of depression. He stated that depression is a leading cause of health related disability. He said that one out of six patients may experience a depression related episode and it is a potentially fatal disorder. He explained that depression may increase the risk of morbidity, stroke, diabetes, myocardial infarction and congestive heart failure. He said that duloxetine and venlafaxine are in a unique class of antidepressants. He stated that duloxetine actually offers a cost saving measure for the state because of the titration required to reach a maximum effective dose and quicker onset of action.

Lawrence Stack, R.Ph., Reliant: Mr. Stack spoke about the studies and benefits of Antara. He said that Antara is second to none in decreasing triglycerides at the lowest available dose, and is available in capsules.

Linda Neuman, M.D., Schering-Plough: Dr. Neuman wanted to speak about PegIntron. She discussed the studies where PegIntron had statistical significant improvement over Intron A and Ribaviron and had no adverse events reported. She explained the Ideal Study.

Margaret Savage, M.D., Merck-Schering-Plough: Dr. Savage spoke about Zetia and Vytorin. She stated that Zetia used as monotherapy significantly lowered total cholesterol, LDL cholesterol, triglycerides, and increased HDL cholesterol. She explained that Vytorin was effective at lowering cholesterol and triglycerides.

Gokul H. Gopalan, M.D., Schering-Plough: Dr. Gopalan spoke about Clarinex and Clarinex syrup. He said that Clarinex is not affected by food. He stated that patients switched from Claritin to Clarinex showed a significant decrease in symptoms within 24 hours. He said the syrup was approved last year and is the only non-sedating antihistamine syrup. He also stated that Nasonex is an aqueous and scent-free formulation.

Robert C. Cortes, M.D., Schering-Plough: Mr. Cortes explained the efficacy of PegIntron and studies in which it was included. He stated that PegIntron was beneficial for addicts because it came in pen dosage instead of syringe.

Kimberly D. Eskridge-Rose, Sanofi: Ms. Eskridge-Rose spoke about Uroxatrol or alfuzosin. She said that Uroxatral is to be given with food because absorption is decreased to about 50% in the fasting state. She said that its efficacy has been proved in three trials. She stated that Uroxatral has a very low incidence of cardiovascular side effects making it a safe alternative.

Barry Tucker, Amgen: Mr. Tucker discussed darbepoetin alfa and epoetin alfa. He mentioned that darbepoetin has a half-life three times longer than epoetin alfa. He said that

what separates the products across all indications is that darbepoetin is dosed less frequently than epoetin, which results in decreased visits to the physicians. He wanted the Committee to consider keeping it on the formulary.

Darren T. Ray, Associate Area Manager, Pfizer: Mr. Ray commented about Provider Synergies and the multi-state pool contracts. He said that Pfizer wanted the State to extend the terms for existing contracts.

Gerald Crowley, M.D., Respiratory Specialist, Sanofi: Dr. Crowley spoke about non-sedating antihistamines, specifically Allegra. He stated that Allegra appears to offer the best combination of efficacy and safety when compared to the other available agents, and he wanted the Committee to select Allegra as the preferred branded agent for those patients who fail the over-the-counter products.

Richard Granese, M.D., WVU: Dr. Granese said he was a psychiatrist at WVU and was representing the West Virginia Psychiatry Association. He spoke about the SSRIs. He stated that patients who suffer from acute psychiatry illness are suicidal. He said that Effexor XR and Cymbalta are two of the antidepressants that are efficacious in difficult depression and chronic pain. He explained that Cymbalta has an FDA indication for diabetic neuropathy. He said that his experience with prescribing these medications for his patients, Cymbalta use resulted in more tolerance to pain and a better quality of life.

Sally Swisher, M.D., Neurologist, Pfizer: Dr. Swisher spoke about Relpax and the efficacy of this drug when treating migraine headaches. She said she really would appreciate the Committee to consider keeping it on the formulary and being able to treat her patients with this drug.

Emmanuel Mahlis, M.D., Medical Director, Merck: Dr. Mahlis wanted the Committee to include Zocor on the Preferred Drug List (PDL). He said that Zocor is the only statin to reduce the risk of major coronary events and stroke in diabetic patients. He stated that Zocor will become generic in June 2006 saving more for patients and entities providing the drug.

Mrs. King, advised the audience that the public comment section had ended.

VI. Executive Session

A motion was made to move to the Executive Session. The motion was seconded and carried. The Committee adjourned to Executive Session at 10:30 a.m. Dr. Matulis stated that another Executive Session/Lunch will be from 1:00 p.m. to 2:00 p.m.

VII. Old Business

No old business was discussed.

VIII. Therapeutic Category Reviews

There were 25 categories of drugs scheduled for review. Steve Liles gave an overview at the beginning of each category. The Committee reviewed and discussed each category and made the following recommendations:

A. Antihistamines, Minimally Sedating

Steve Liles recommended the following list be approved. A motion was made to accept the recommendations of Provider Synergies. The motion was seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED
ANTIHISTAMINES, MINIMALLY SEDATING	**ANTIHISTAMINES**	
	loratadine **CLARINEX Syrup (desloratadine)**	ALAVERT (loratadine) ALLEGRA (fexofenadine) CLARINEX tablets (desloratadine) CLARITIN (loratadine) TAVIST-ND (loratadine) ZYRTEC (cetirizine)
	ANTIHISTAMINE/DECONGESTANT COMBINATIONS	
	loratadine/pseudoephedrine	ALLEGRA-D (fexofenadine/pseudoephedrine) CLARITIN-D (loratadine/pseudoephedrine) ZYRTEC-D (cetirizine/pseudoephedrine)

B. Analgesics, Narcotic

Steve Liles recommended the following list for PDL inclusion. A Committee member made a motion to accept the recommendations with the exclusion of butalbital with codeine, propoxyphene, meperidine, and propoxyphene combination. The motion was seconded. Votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED
ANALGESICS, NARCOTIC (Non-parenteral)	**SHORT ACTING**	
	acetaminophen/codeine aspirin/codeine codeine hydrocodone/APAP hydrocodone/ibuprofen hydromorphone levorphanol methadone morphine oxycodone oxycodone/APAP oxycodone/aspirin pentazocine/APAP pentazocine/naloxone propoxyphene/APAP tramadol	ACTIQ (fentanyl) ANEXSIA (hydrocodone/APAP) BANCAP HC (hydrocodone/APAP) butalbital/APAP/caffeine/codeine butalbital/ASA/caffeine/codeine DARVOCET (propoxyphene/APAP) DARVON (propoxyphene) DEMEROL (meperidine) DILAUDID (hydromorphone) FIORICET W/ CODEINE (butalbital/APAP/caffeine/codeine) FIORINAL W/ CODEINE (butalbital/ASA/caffeine/codeine) LORCET, LORTAB (hydrocodone/APAP) MAXIDONE (hydrocodone/APAP) meperidine MSIR (morphine)

DRUG CLASS	PREFERRED	NON-PREFERRED
	ULTRACET (tramadol/APAP)	NORCO (hydrocodone/APAP) OXYFAST, OXYIR (oxycodone) PANLOR (dihydrocodeine/APAP/caffeine) PERCOCET (oxycodone/APAP) PERCODAN (oxycodone/aspirin) PERCOLONE (oxycodone) PHRENILIN W/ CAFFEINE AND CODEINE (butalbital/ASA/caffeine/codeine) propoxyphene propoxyphene/ASA/caffeine REPREXAIN (hydrocodone/ibuprofen) SYNALGOS-DC (dihydrocodeine/ASA/caffeine) TALACEN (pentazocine/APAP) TALWIN NX (pentazocine/naloxone) TYLENOL W/CODEINE (APAP/codeine) ULTRAM (tramadol) VICODIN (hydrocodone/APAP) VICOPROFEN (hydrocodone/ibuprofen) ZYDONE (hydrocodone/APAP)
	LONG-ACTING	
	DURAGESIC (fentanyl) KADIAN (morphine) morphine SR	AVINZA (morphine) MS CONTIN (morphine) ORAMORPH SR (morphine) oxycodone ER OXYCONTIN (oxycodone) PALLADONE (hydromorphone ER)

C. Antimigraine Agents, Triptans

Steve Liles made recommendations for the list. A motion was made to accept the recommendations of Provider Synergies with the addition of Imitrex, subcutanenous. The motion was seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED
ANTIMIGRAINE AGENTS, TRIPTANS	AXERT (almotriptan) IMITREX Injection (sumatriptan) MAXALT (rizatriptan) ZOMIG (zolmitriptan)	AMERGE (naratriptan) FROVA (frovatriptan) IMITREX Nasal (sumatriptan) IMITREX Tablets (sumatriptan) RELPAX (eletriptan)

D. Proton Pump Inhibitors

Steve Liles recommended the following drugs for the Preferred Drug List. A motion was made to accept the recommendations of Provider Synergies. The motion was seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED
PROTON PUMP INHIBITORS (Oral)	PREVACID (lansoprazole)	ACIPHEX (rabeprazole) NEXIUM (esomeprazole) omeprazole PRILOSEC (omeprazole) PRILOSEC OTC (omeprazole) PROTONIX (pantoprazole) ZEGERID (omeprazole)

E. Ulcerative Colitis Agents

Steve Liles recommended the following list be approved. A motion was made to accept the recommendations of Provider Synergies. The motion was seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED
ULCERATIVE COLITIS AGENTS	**ORAL**	
	COLAZAL (balsalazide) PENTASA (mesalamine) sulfasalazine	ASACOL (mesalamine) AZULFIDINE (sulfasalazine) DIPENTUM (olsalazine)
	RECTAL	
	mesalamine	CANASA (mesalamine) ROWASA (mesalamine)

F. Bladder Relaxant Preparations

Dr. Liles recommended the following drugs for the Preferred Drug List. A short discussion ensued explaining that urologists were accepting of the choices for the Preferred Drug List. A Committee member said that these drugs are used in the elderly population. He had concerns about oxybutynin. Another discussion ensued about Detrol and new drugs on the market. Dr. Matulis made a motion to table the vote on this class until after the Executive Session. The motion was seconded, votes were taken and the motion carried.

When the Committee returned from the Executive Session, Steve Liles recommended the following list be approved. A motion was made to accept the recommendations of Provider Synergies. The motion was seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED
BLADDER RELAXANT PREPARATIONS	DITROPAN XL (oxybutynin) ENABLEX (darifenacin) oxybutynin OXYTROL (oxybutynin)	DETROL (tolterodine) DETROL LA (tolterodine) DITROPAN (oxybutynin) SANCTURA (trospium) VESICARE (solifenacin)

G. BPH Treatments

Steve Liles recommended the following list be approved. A motion was made to accept the recommendations of Provider Synergies. The motion was seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED
BPH AGENTS	**ALPHA BLOCKERS**	
	doxazosin FLOMAX (tamsulosin) trazosin UROXATRAL (alfuzosin**)**	CARDURA (doxazosin) HYTRIN (terazosin)
	5-ALPHA-REDUCTASE (5AR) INHIBITORS	
	PROSCAR (finasteride)	AVODART (dutasteride)

H. Beta Blockers

Steve Liles recommended the following drugs for inclusion on the Preferred Drug List. A Committee member suggested that patients already on Coreg be maintained on Coreg. A motion was made to accept the recommendations of Provider Synergies with the addition of Coreg. The motion was seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED
BETA BLOCKERS (Oral)	**BETA BLOCKERS**	
	atenolol INDERAL LA (propranolol) INNOPRAN XL (propranolol) metoprolol nadolol propranolol sotalol timolol TOPROL XL (metoprolol)	acebutolol BETAPACE (sotalol) betaxolol bisoprolol BLOCADREN (timolol) CARTROL (carteolol) CORGARD (nadolol) INDERAL (propranolol) KERLONE (betaxolol) LEVATOL (penbutolol) LOPRESSOR (metoprolol) pindolol SECTRAL (acebutolol) TENORMIN (atenolol) ZEBETA (bisoprolol)
	BETA- AND ALPHA- BLOCKERS	
	COREG (carvedilol) labetalol	NORMODYNE (labetalol) TRANDATE (labetalol)

I. Angiotensin II Receptor Blockers

Steve Liles recommended the following drugs for the Preferred Drug List. A motion was made to add Avapro. The motion was seconded. Some discussion ensued about diabetic neuropathy in this class. Dr. Matulis stated that a motion was made to accept the

recommendations of Provider Synergies with the addition of Avapro. Votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBs)	**ANGIOTENSIN RECEPTOR BLOCKERS**	
	AVAPRO (irbesartan) COZAAR (losartan) DIOVAN (valsartan) MICARDIS (telmisartan)	ATACAND (candesartan) BENICAR (olmesartan) TEVETEN (eprosartan)
	ARB/DIURETIC COMBINATIONS	
	AVALIDE (irbesartan/HCTZ) DIOVAN-HCT (valsartan/HCTZ) HYZAAR (losartan/HCTZ) MICARDIS-HCT (telmisartan/HCTZ)	ATACAND-HCT (candesartan/HCTZ) BENICAR-HCT (olmesartan/HCTZ) TEVETEN-HCT (eprosartan/HCTZ)

J. Calcium Channel Blockers

Steve Liles recommended the following drugs for the Preferred Drug List. A motion was made to accept the recommendations of Provider Synergies. The motion was seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED
CALCIUM CHANNEL BLOCKERS (Oral)	**SHORT-ACTING**	
	diltiazem verapamil	ADALAT (nifedipine) CALAN (verapamil) CARDENE (nicardipine) CARDIZEM (diltiazem) DYNACIRC (isradipine) nicardipine nifedipine NIMOTOP (nimodipine) PROCARDIA (nifedipine)
	LONG-ACTING	
	CARDIZEM LA (diltiazem) diltiazem DYNACIRC CR (isradipine) felodipine nifedipine SULAR (nisoldipine) verapamil VERELAN PM (verapamil)	ADALAT CC (nifedipine) CALAN SR (verapamil) CARDENE SR (nicardipine) CARDIZEM CD (diltiazem) CARDIZEM SR (diltiazem) COVERA-HS (verapamil) DILACOR XR (diltiazem) ISOPTIN SR (verapamil) NORVASC (amlodipine) PLENDIL (felodipine) PROCARDIA XL (nifedipine) TIAZAC (diltiazem) VERELAN (verapamil)

K. ACE Inhibitor/CCB Combinations

Steve Liles recommended the following drugs for the Preferred Drug List. A motion was made to accept the recommendations of Provider Synergies. The motion was seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED
ACE INHIBITOR/CALCIUM CHANNEL BLOCKER COMBINATIONS	LOTREL (benazepril/amlodipine) TARKA (trandolapril/verapamil)	LEXXEL (enalapril/felodipine)

L. Lipotropics, Other

Steve Liles recommended the following list be approved. A motion was made to accept the recommendations of Provider Synergies. The motion was seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED
LIPOTROPICS, OTHER (non-statins)	**BILE ACID SEQUESTRANTS**	
	cholestyramine COLESTID (colestipol)	QUESTRAN (cholestyramine) WELCHOL (colesevalam)
	CHOLESTEROL ABSORPTION INHIBITORS	
		ZETIA (ezetimibe)
	FIBRIC ACID DERIVATIVES	
	gemfibrozil TRICOR (fenofibrate)	ANTARA (fenofibrate) LOFIBRA (fenofibrate) LOPID (gemfibrozil)
	NIACIN	
	niacin NIASPAN (niacin)	NIACELS (niacin) NIADELAY (niacin) SLO-NIACIN (niacin)

M. Lipotropics, Statins

Steve Liles recommended the following list be approved. A motion was made to accept the recommendations of Provider Synergies. The motion was seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED
LIPOTROPICS, STATINS	**STATINS**	
	ALTOPREV (lovastatin) CRESTOR (rosuvastatin) LESCOL (fluvastatin) LESCOL XL (fluvastatin) ZOCOR (simvastatin)	LIPITOR (atorvastatin) lovastatin MEVACOR (lovastatin) PRAVACHOL (pravastatin)
	STATIN COMBINATIONS	
	ADVICOR (lovastatin/niacin) VYTORIN (ezetimibe/simvastatin)	CADUET (atorvastatin/amlodipine) PRAVIGARD PAC (pravastatin/ASA)

A motion was made to move to the Executive Session/Lunch, motion was seconded, votes were taken and the motion.

After the Executive Session, Dr. Matulis once again called the session to order. He stated that one of the topics at the Executive Session was the information in the Committee members' meeting packets. He said that some of the data was getting out to the public. It was suggested to make it a policy of the Committee that when they receive the data they do

not discuss this information with drug companies. A motion was made to accept the suggestion. The motion was seconded. Dr. Matulis said that the Committee was being overwhelmed with requests for information. It was stated that samples from pharmaceutical companies could be left with someone other than the physician in their offices. A motion was made to strongly recommend that the Committee abstain from contact with pharmaceutical representatives after receiving the confidential information in the packets. Motion was seconded, votes were taken and the motion carried.

Lynda Edwards made an announcement that people were standing in the stairwells and letting people from the outside street inside the building. She said that this was a security risk to the people inside the building and this was not allowed. She also stated that the audience was not allowed to follow employees into the building from the employee entrance on Washington Street. All visitors need to enter through the Capitol Street entrance.

The Committee returned to discussion of the Bladder Relaxant Class. (See results posted with that class above.)

N. Anticoagulants, Injectable

Steve Liles recommended the following list be approved. A motion was made to accept the recommendations of Provider Synergies. The motion was seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED
ANTICOAGULANTS, INJECTABLE[CL]	FRAGMIN (dalteparin) LOVENOX (enoxaparin)	ARIXTRA (fondaparinux) INNOHEP (tinzaparin)

CL– Requires Clinical PA

O. Erythropoiesis Stimulating Proteins

Steve Liles recommended the following list be approved. A motion was made to accept the recommendations of Provider Synergies. The motion was seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED
ERYTHROPOIESIS STIMULATING PROTEINS[CL]	ARANESP (darbepoetin) PROCRIT (rHuEPO)	EPOGEN (rHuEPO)

CL – Requires Clinical PA

P. Phosphate Binders

Steve Liles recommended the following drugs for the Preferred Drug List. A motion was made to add Renagel to the list and have a review of this class again in six months. The motion was seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED
PHOSPHATE BINDERS	FOSRENOL (lanthanum)	

DRUG CLASS	PREFERRED	NON-PREFERRED
	MAGNEBIND 400 (magnesium/calcium carbonate) PHOSLO (calcium acetate) RENAGEL (sevelamer)	

Q. Estrogen Agents, Combination

Steve Liles recommended the following list be approved. A motion was made to accept the recommendations of Provider Synergies. The motion was seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED
ESTROGENS, COMBINATIONS	**ORAL**	
	ACTIVELLA (17ß-estradiol/norethindrone acetate) FEMHRT (EE/norethindrone acetate) PREFEST (17ß-estradiol/norgestimate) PREMPHASE (CE/MPA) PREMPRO (CE/MPA)	
	TOPICAL	
	COMBIPATCH (17ß-estradiol/norethindrone acetate)	CLIMARA PRO (estradiol/levonorgestrel)

R. Hypoglycemics, Meglitinides

Steve Liles recommended the following list be approved. A motion was made to accept the recommendations of Provider Synergies. The motion was seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED
HYPOGLYCEMICS, MEGLITINIDES	STARLIX (nateglinide)	PRANDIN (repaglinide)

S. Hypoglycemics, TZD

Steve Liles recommended the following list be approved. A motion was made to accept the recommendations of Provider Synergies. The motion was seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED
HYPOGLYCEMICS, TZDS	ACTOS (pioglitazone)	AVANDIA (rosiglitazone)

T. Multiple Sclerosis Agents

Steve Liles recommended the following list be approved. A motion was made to accept the recommendations of Provider Synergies. The motion was seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED
MULTIPLE SCLEROSIS AGENTS[CL]	AVONEX (interferon beta-1a) BETASERON (interferon beta-1b) REBIF (interferon beta-1a)	COPAXONE (glatiramer)

CL – Requires Clinical PA

U. Hepatitis C Agents

Steve Liles recommended the following list be approved. A short discussion ensued about the Hepatitis C Agents. A Committee member questioned whether patients already on Pegasys and Copegus would be grandfathered. It was agreed that would be the case. It was questioned about the prior authorization process for Infergen with a non-responder and Ms. King said that if the patient did not respond to the preferred products, they could be approved for the non-preferred ones. A motion was made to accept the recommendations of Provider Synergies with grandfathering. The motion was seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED
HEPATITIS C TREATMENTS[CL]	PEG-INTRON (pegylated IFN) PEG-INTRON Redipen(pegylated IFN) REBETOL (ribavirin)	COPEGUS (ribavirin) INFERGEN (consensus IFN) PEGASYS (pegylated IFN) REBETRON (IFNα/ribavirin) ribavirin

CL- Requires Clinical PA

V. Otic Antibiotic Preparations

Steve Liles recommended the following list be approved. A motion was made to accept the recommendations of Provider Synergies. The motion was seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED
OTIC ANTIBIOTIC PREPARATIONS	CIPRODEX (ciprofloxacin / dexamethasone) COLY-MYCIN S (neomycin / hydrocortisone) FLOXIN (ofloxacin) neomycin / polymyxin / hydrocortisone	CIPRO HC (ciprofloxacin / hydrocortisone) CORTISPORIN (neomycin / polymyxin / hydrocortisone) CORTISPORIN TC (neomycin / hydrocortisone) PEDIOTIC (neomycin / polymyxin / hydrocortisone)

W. Sedative Hypnotics

Steve Liles recommended the following list be approved. A member said that they would like to see removed from the list, estazolam or Prosom. Some discussion ensued about Ambien and its abuse potential and limiting it to 14 pills a month, similar to what insurance companies are requesting for limits on dosing. Another member agreed that Prosom should be off the preferred list and that Ambien is overused. It was agreed that grandfathering would not be appropriate, but that tapering off would be more effective with plenty of notice. Another member asked if it could be used for a one-month time period, and then prior authorized

afterwards. Ms. King said that the Bureau could take this recommendation into consideration. In the past with other drugs that were highly utilized, Heritage Information Systems sent letters to physicians informing them of their patients taking certain drugs and that prior authorization would soon be required for those patients/drugs. The physicians could then get prior authorizations or change the patients' treatments. Ms. King said that the Bureau could delay prior authorization for thirty days and send out notices. A motion was made to accept the recommendations of Provider Synergies, with the additional of the removal of Prosom and have the DUR handle the prior authorization procedure. The motion was seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED
SEDATIVE HYPNOTICS	**BENZODIAZEPINES**	
	RESTORIL 7.5 mg (temazepam) temazepam	DALMANE (flurazepam) DORAL (quazepam) estazolam flurazepam HALCION (triazolam) PROSOM (estazolam) RESTORIL 15, 22.5, 30 mg (temazepam) triazolam
	OTHERS	
	SONATA (zaleplon)	AMBIEN (zolpidem) AQUA CHLORAL (chloral hydrate) chloral hydrate SOMNOTE (chloral hydrate)

X. Antidepressants, Other

Steve Liles recommended the following drugs for the Preferred Drug List. A Committee member said that they would like to have Cymbalta put on the Preferred Drug List but require prior authorization at doses greater than 60mg. Some discussion ensued about Cymbalta and Effexor. A member mentioned a six-month review of the class again. A motion was made accept the recommendations of Provider Synergies and add Cymbalta with a review in six months. The motion was seconded. Votes were taken and the motion carried.

A member said that bupropion IR should be excluded from the Preferred Drug List due to its risk of seizures. A motion was made to exclude bupropion IR, the motion was seconded. Votes were taken and the motion carried. (This action was taken at the end of meeting during other business).

DRUG CLASS	PREFERRED	NON-PREFERRED
ANTIDEPRESSANTS, OTHER (non-SSRI)	bupropion SR CYMBALTA (duloxetine) EFFEXOR XR (venlafaxine) mirtazapine mirtazapine soltabs trazodone	bupropion IR DESYREL (trazodone) EFFEXOR (venlafaxine) nefazodone REMERON (mirtazapine) REMERON Soltabs(mirtazapine) SERZONE (nefazodone)

DRUG CLASS	PREFERRED	NON-PREFERRED
		WELLBUTRIN (bupropion) WELLBUTRIN SR (bupropion) WELLBUTRIN XL (bupropion)

Y. Growth Hormone

Steve Liles recommended the following list be approved. A motion was made to accept the recommendations of Provider Synergies. The motion was seconded, votes were taken and the motion carried.

DRUG CLASS	PREFERRED	NON-PREFERRED
GROWTH HORMONE[CL]	NORDITROPIN (somatropin) NUTROPIN AQ (somatropin) TEV-TROPIN (somatropin)	GENOTROPIN (somatropin) HUMATROPE (somatropin) NUTROPIN (somatropin) SAIZEN (somatropin) SEROSTIM (somatropin)

IX. Next Meeting Date

The next meeting date of the P & T Committee will be September 14, 2005. **(This date has now been changed to August 17, 2005.)**

X. Other Business

Ms. King said that recommendations would be effective when approval has been given by CMS (Centers for Medicare and Medicaid Services) for the State Plan Amendment and proper notice has been given to providers. She told the audience to check the website for notices.

Dr. Matulis suggested that the Preferred Drug List should only change yearly like other insurance companies. Dr. Liles said that there were some problems inherent with negotiations when using a yearly model. He said that even though meetings are held every six months, and changes would be recommended every six months, the classes could only be changed once a year if that was the Bureau's preference.

A member asked about information being sent out to providers, such as notices. Ms. King explained the process of the Program Instructions and paper overload. She explained that now the Bureau uses the Pharmacy Manual and changes are made on the web or providers can get their information from the Bureau's Provider Services if they do not have web access.

XI. Adjournment

A motion was made, was seconded, votes were taken and the motion carried to adjourn the meeting of the Pharmaceutical and Therapeutics Committee.

Attachment 1

TOP$ [SM] Discussion for P&T Committee

TOP$ [SM] Definition

- TOP$ [SM] stands for The Optimal PDL $olution.
- TOP$[SM] is a State Medicaid Pharmaceutical Purchasing Pool administered by Provider Synergies
- As of March 2005, three states are participating: Louisiana, Maryland, and West Virginia, representing 1.5 million lives

Why Participate in TOP$ [SM]

- CMS letter to State Medicaid Directors in Sept 2004 encouraged states to consider joining purchasing pools in order to garner better rebates
- CMS approved Medicaid pooling initiative in the spring 2004
- Strengthens negotiating position with manufacturers presently and in the future when dual eligibles leave Medicaid for MMA in 2006
- Increased size by negotiating for more than one state increases value of negotiation for manufacturers as long as states continue to control market share as they have in the past

State Benefits by Participation in TOP$ [SM]

- Increase PDL savings
- Learn best practices from other states
- Strengthen negotiating position in 2006 even though dual eligibles will move to Medicare

Impact on Supplemental Rebate Negotiations

- If TOP$ states P&T Committees continue to accept Provider Synergies PDL recommendations 95% of the time as they have done so in the past, then manufacturers will view the pool as a coordinated effort with consistent PDL recommendation approval amongst participating states. This coordinated effort is of greater value to a manufacturer then compared to a single state.
- Rebate bids are more aggressive then if compared to a single state bid

Impact on P&T Process

- States will maintain their own P&T Committees
- P&T Process will not change
- Provider Synergies will continue to provide balanced clinical and financial information in support of PDL recommendations
- Savings forecasts will be based in PDL recommendations impact on that individual state

Miscellaneous

- Each state submitted their State Plan Amendment to CMS in December 2004
- Additional states are expected to join TOP$ [SM]