STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
Bureau for Medical Services
Office of Pharmacy Services
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Earl Ray Tomblin
Governor

Michael J. Lewis, M.D., Ph.D.
Cabinet Secretary

Pharmaceutical and Therapeutics (P&T) Committee
Charleston Civic Center
Charleston, West Virginia
January 26, 2011

MINUTES

Members Present:
David Avery, M.D.
Rodney L. Fink, D.O.
Scott Brown, R.Ph.
Steven R. Matulis, M.D
Jeffrey V. Ashley, M.D.
Harriet Nottingham, R.Ph.

Members Present via Teleconference:
Robert Stanton, Pharm.D.
Teresa Dunsworth, Pharm.D.
Michael Grome, PA-C

Members Not Present:
Teresa Frazer, M.D., FAAP
James D. Bartsch, R.Ph.
Barbara Koster, N.P.

DHHR/BMS Staff Present:
Peggy King, R.Ph., Pharmacy Director
Vicki Cunningham, R.Ph., DUR Coordinator
William Hopkins, Pharmacy Operations Manager
Lynda Ahmad, Secretary

Contract Staff/GHS Staff Present:
Laureen Biczak, D.O.
Chad Bissell, Pharm.D.
Tina Hisel, Pharm.D.
Shelagh Harvard

Other Contract Staff/State Staff Present:
Eric Sears, R.Ph., Molina

I. Call to Order

Dr. David Avery, M.D., Chairperson, called the meeting to order at 2:12 p.m.

II. Welcome and Introductions

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

III. Housekeeping Items/Updates

A. Approval of the October 27, 2010 Minutes

Chairman Avery asked for approval of the minutes from the October 27, 2010 meeting. A motion was made and seconded; the motion carried to approve the minutes as submitted.

B. PDL Compliance/Generic Percent Report Updates

Dr. Biczak reviewed the PDL Compliance Report; overall compliance for Q3 2010 was 97.1%.

Dr. Biczak reviewed the Generic Utilization Report; overall generic utilization for Q3 2010 was 73.9%.

IV. Public Comments

Ms. King explained the public comment process.

Melanie Funke, URL Pharma, spoke in favor of Colcrys.

Tanner Odom, Novartis, spoke in favor of Gilenya.

Tanner Odom, Novartis, spoke in favor of Tekamlo.

Dr. Michael Bottorff, University of Charleston (Boehringer Ingelheim), spoke in favor of Pradaxa.

Dr. Jane Ruby, Reckitt Benckiser, spoke in favor of Suboxone.

V. Executive Session

The Committee adjourned to Executive Session at 2:29. The Committee returned from Executive Session at 3:10.

VI. Old Business

A. Ophthalmic Fluoroquinolones and Macrolides for Bacterial Conjunctivitis

Dr. Bissell provided an update to the Committee on Ophthalmic Fluoroquinolones, including the impact of the clinical PA criteria on prescribing practices and the Medicaid budget. GHS made the original recommendation in October 2009 for a prior authorization to be required for all prescriptions for ophthalmic fluoroquinolones for members under 21 years of age, and the criteria became effective on January 1, 2010. GHS reviewed the number of prescriptions and cost for the first three quarters of 2009 and then compared it to the first three quarters of 2010, after the edit was in place. The clinical PA criteria are consistent with guidelines of the American Academy of Ophthalmology in regard to treating bacterial conjunctivitis.

In 2010, claims for Ophthalmic Fluoroquinolones and Macrolides dropped by about 80% from the 2009 baseline. The number of prescriptions for members over the age of 21 declined by 3.5%, while utilization by members under 21 dropped roughly 95%. Pre-rebate dollars spent on this class of drugs decreased by about 75%. The total pre-rebate, federal and state savings for this PA criteria equaled roughly $270K for the 3 quarters studied.

GHS reviewed claim level detail for those prescribers who submitted more than 30 claims for either quinolones or azithromycin drops for patients under 21 years of age; most prescriptions were written by optometrists and ophthalmologists, one OB-GYN and 2 to 3 pediatricians. Dr. Bissell concluded by stating that this was a very effective edit in controlling both utilization and cost.

B. Cough & Cold Products

Dr. Biczak provided information on the type of evidence available for some of the products included on the cough and cold list. She noted that since GHS began managing the list, it has decreased in size significantly. While evidence exists for the products in this class, it is not of the best quality and some of it is quite old. There is some evidence for non-cough and -cold indications, such as rhinitis, for which some of the drugs on the list are utilized.

There is mild to moderate evidence of decent quality that combination 1st generation antihistamines and decongestants, topical decongestants (nasal sprays), oral decongestants, (particularly pseudoephedrine) and dextromethorphan provide modest symptom relief. The

evidence recommended that these products be used for symptomatic relief, with the best evidence pointing to the topical decongestants, oral decongestants, and combination products. There is no evidence that the 1st generation antihistamines work alone for cough and cold symptoms, and no evidence that the new non-sedating antihistamines work for cough and nasal symptoms due to upper respiratory infection. There is also evidence regarding non-cough and -cold indications for 1st generation antihistamines and guaifenesin, particularly for COPD, chronic bronchitis or allergic rhinitis indications.

GHS included consideration for special requests from providers or Committee members in the past, which has led to the recommendation for at least one drug containing an anticholinergic, and a pediatric product with promethazine. Some of the multiple combination categories were eliminated. The evidence for codeine as a cough suppressant is very small, so GHS recommended dropping all codeine containing products.

Dr. Biczak noted a recent FDA warning for Tessalon and related generic products due to the danger of overdose in children because the drug looks like candy. Tessalon is widely used in West Virginia due to its low cost. The evidence is very poor for efficacy.

The recommended list provides a variety of the drugs proven to give at least modest symptomatic relief to people with cough and cold and the other illnesses for which some of these drugs are indicated.

Ms. King noted that she sent an email to GHS regarding a large chain that requested that BMS add additional NDCs to the PDL since they did not warehouse the preferred NDCs for those drugs. She asked that those NDCs be included in the motion if they are cost effective. Dr. Biczak stated that if the drugs in question are in categories that are retained for coverage, GHS will ensure the NDCs involved are added to the list if they are found to be reasonably cost effective relative to current options on the list.

Dr. Stanton asked if a vote was being requested on cough and cold products at the meeting. Dr. Fink stated that the Committee had previously rejected drugs with proven efficacy, therefore, he proposed rejecting any drugs without proven efficacy. He moved that the Committee accept the recommendation of GHS, with the addition of excluding the generic and brand Tessalon. The motion was seconded. Dr. Dunsworth and Dr. Stanton requested that the list of products be read; Dr. Bissell read the list. Dr. Biczak added that categories recommended for deletion made up 20% of spending in the category, but that savings would be more modest as many of the prescriptions would switch to other products that remained available. Mr. Brown amended the motion to add Delsym to the preferred list. The motion to amend was seconded, votes were taken and the motion carried. Ms. King inquired as to the price of Delsym. Mr. Brown stated that a 4-ounce bottle would cost $4-6 over the counter, in line with similar products in the category. He noted that Delsym provides 12-hour relief. Dr. Biczak stated that GHS will provide net cost information at the next meeting. Dr. Stanton asked if hydrocodone products had been removed from the list. Dr. Biczak confirmed that they had been removed during a previous iteration. The motion was seconded, votes were taken and the motion carried.

VII. New Business

A. New Class Reviews

i. Hyperuricemia & Gout Agents

GHS recommended that a new Hyperuricemia & Gout Agents class be added to the PDL and that all generics be listed as preferred; all brand name products should be added as non-preferred. The motion was seconded, votes were taken and the motion carried.

PREFERRED AGENTS	NON-PREFERRED AGENTS
ANTIMITOTICS	
	COLCRYS (colchicine)
ANTIMITOTIC-URICOSURIC COMBINATION	
colchicine/probenecid	
URATE-OXIDASE ENZYME	
	KRYSTEXXA (pegloticase)
URICOSURIC	
probenecid	
XANTHINE OXIDASE INHIBITORS	
allopurinol	ULORIC (febuxostat) ZYLOPRIM (allopurinol)

B. New Drug Reviews

The following new drugs were called for extraction:

A. Pradaxa
B. Tekamlo
C. Suboxone film

Dr. Avery called for a motion on those drugs that were not extracted. A motion was made to accept all non-extracted drugs as recommended by GHS. The motion was seconded and passed.

i. Atelvia

GHS recommended that Atelvia be made a non-preferred drug in the Bone Resorption Suppression and Related Agents, Bisphosphonates category. The approved list is below.

PREFERRED AGENTS	NON-PREFERRED AGENTS
BISPHOSPHONATES	
alendronate FOSAMAX SOLUTION (alendronate)	ACTONEL (risedronate) ACTONEL WITH CALCIUM (risedronate/ calcium)

PREFERRED AGENTS	NON-PREFERRED AGENTS
	ATELVIA (risedronate) BONIVA (ibandronate) DIDRONEL (etidronate) FOSAMAX TABLETS (alendronate) FOSAMAX PLUS D (alendronate/vitamin D)

ii. Avar Gel

GHS recommended that Avar Gel be made a non-preferred drug in the Acne Agents, Combinations category. The approved list is below.

PREFERRED AGENTS	NON-PREFERRED AGENTS
COMBINATION AGENTS	
benzoyl peroxide/urea erythromycin/benzoyl peroxide sulfacetamide sodium/sulfur wash/cleanser	ACANYA (clindamycin phosphate/benzoyl peroxide) AVAR (sulfur/sulfacetamide) BENZACLIN GEL (benzoyl peroxide/ clindamycin) BENZAMYCIN PAK (benzoyl peroxide/ erythromycin) benzoyl peroxide/clindamycin gel CLENIA (sulfacetamide sodium/sulfur) DUAC CS (benzoyl peroxide/ clindamycin) EPIDUO (adapalene/benzoyl peroxide) INOVA 4/1 (benzoyl peroxide/salicylic acid) NUOX (benzoyl peroxide/sulfur) PLEXION (sulfacetamide sodium/sulfur) PRASCION (sulfacetamide sodium/sulfur) ROSAC (sulfacetamide sodium/avobenzone/sulfur) ROSADERM (sulfacetamide sodium/sulfur) ROSANIL (sulfacetamide sodium/sulfur) ROSULA (sulfacetamide sodium/sulfur/ urea) sulfacetamide sodium/sulfur lotion, gel, pad sulfacetamide sodium/sulfur/ urea SULFOXYL (benzoyl peroxide/sulfur) SULFATOL (sulfacetamide sodium/sulfur/urea) VELTIN (clindamycin/tretinoin) ZENCIA WASH (sulfacetamide sodium/sulfur) ZIANA (clindamycin/tretinoin)

iii. Beyaz

GHS recommended that Beyaz be made a non-preferred drug in the Miscellaneous Brand/Generic, Oral Contraceptives category. The motion was seconded, votes were taken and the motion carried. The approved list is below.

PREFERRED AGENTS	NON-PREFERRED AGENTS
ORAL CONTRACEPTIVES	
LO SEASONIQUE (ethinyl estradiol/levonorgestrel) SEASONIQUE (ethinyl estradiol/levonorgestrel) YASMIN (ethinyl estradiol/drospirenone)	BEYAZ (ethinyl estradiol/drospirenone/levomefolate) Gianvi (ethinyl estradiol/drospirenone) Ocella (ethinyl estradiol/drospirenone) YAZ (ethinyl estradiol/drospirenone)

iv. Bromday

GHS recommended that Bromday be made a non-preferred drug in the Ophthalmic Anti-Inflammatories category. The approved list is below.

PREFERRED AGENTS	NON-PREFERRED AGENTS
flurbiprofen ketorolac 0.4% NEVANAC (nepafenac)	ACULAR LS (ketorolac) ACUVAIL 0.45% (ketorolac tromethamine) AP BROMDAY (bromfenac) diclofenac AP DUREZOL (difluprednate) AP XIBROM (bromfenac)

v. Gilenya

GHS recommended that Gilenya be made a non-preferred drug in the Multiple Sclerosis Agents, Non-Interferons category. The approved list is below.

PREFERRED AGENTS	NON-PREFERRED AGENTS
NON-INTERFERONS	
COPAXONE (glatiramer)	AMPYRA (dalfampridine) CL* GILENYA (fingolimod) TYSABRI (natalizumab)

vi. Granisol

GHS recommended that Granisol be made a non-preferred drug in the Antiemetics, 5HT3 Receptor Blockers category. The approved list is below.

PREFERRED AGENTS	NON-PREFERRED AGENTS
5HT3 RECEPTOR BLOCKERS	
ondansetron ondansetron ODT	ANZEMET (dolasetron) KYTRIL (granisetron) granisetron GRANISOL (granisetron) SANCUSO (granisetron) ZOFRAN (ondansetron) ZOFRAN ODT (ondansetron) ZUPLENZ (ondansetron)

vii. Ketocon Plus

GHS recommended that Ketocon Plus be made a non-preferred drug in the Antifungals (Topical), Antifungal/Steroid Combinations category. The approved list is below.

PREFERRED AGENTS	NON-PREFERRED AGENTS
ANTIFUNGAL/STEROID COMBINATIONS	
clotrimazole/betamethasone nystatin/triamcinolone	KETOCON PLUS (ketoconazole/hydrocortisone) LOTRISONE (clotrimazole/betamethasone) AP MYCOLOG (nystatin/triamcinolone) AP

viii. Kombiglyze XR

GHS recommended that Kombiglyze XR be made a preferred drug in the Hypoglycemics, Incretin Mimetics/Enhancers, Oral category. The approved list is below.

PREFERRED AGENTS	NON-PREFERRED AGENTS
ORAL[AP]	
JANUMET (sitagliptin/metformin) JANUVIA (sitagliptin) KOMBIGLYZE XR (saxagliptin/metformin) ONGLYZA (saxagliptin)	

ix. Lodosyn

GHS recommended that Lodosyn be made a non-preferred drug in the Antiparkinson's Agents (Oral), Other category. The approved list is below.

PREFERRED AGENTS	NON-PREFERRED AGENTS
OTHER ANTIPARKINSON'S AGENTS	
amantadine[AP] bromocriptine carbidopa/levodopa selegiline STALEVO (levodopa/carbidopa/entacapone)	AZILECT (rasagiline) ELDEPRYL (selegiline) levodopa/carbidopa ODT LODOSYN (carbidopa) PARCOPA (levodopa/carbidopa) SINEMET (levodopa/carbidopa) ZELAPAR (selegiline)

x. Veltin

GHS recommended that Veltin be made a non-preferred drug in the Acne Agents (Topical), Combination category. The approved list is below.

PREFERRED AGENTS	NON-PREFERRED AGENTS
COMBINATION AGENTS	
benzoyl peroxide/urea erythromycin/benzoyl peroxide sulfacetamide sodium/sulfur wash/cleanser	ACANYA (clindamycin phosphate/benzoyl peroxide) AVAR (sulfur/sulfacetamide) BENZACLIN GEL (benzoyl peroxide/ clindamycin) BENZAMYCIN PAK (benzoyl peroxide/ erythromycin) benzoyl peroxide/clindamycin gel CLENIA (sulfacetamide sodium/sulfur) DUAC CS (benzoyl peroxide/ clindamycin) EPIDUO (adapalene/benzoyl peroxide) INOVA 4/1 (benzoyl peroxide/salicylic acid) NUOX (benzoyl peroxide/sulfur) PLEXION (sulfacetamide sodium/sulfur) PRASCION (sulfacetamide sodium/sulfur) ROSAC (sulfacetamide sodium/avobenzone/sulfur) ROSADERM (sulfacetamide sodium/sulfur) ROSANIL (sulfacetamide sodium/sulfur) ROSULA (sulfacetamide sodium/sulfur/ urea) sulfacetamide sodium/sulfur lotion, gel, pad sulfacetamide sodium/sulfur/ urea

PREFERRED AGENTS	NON-PREFERRED AGENTS
	SULFOXYL (benzoyl peroxide/sulfur) SULFATOL (sulfacetamide sodium/sulfur/urea) VELTIN (clindamycin/tretinoin) ZENCIA WASH (sulfacetamide sodium/sulfur) ZIANA (clindamycin/tretinoin)

xi. Zencia Wash

GHS recommended that Zencia Wash be made a non-preferred drug in the Acne Agents (Topical), Combination category. The approved list is below.

PREFERRED AGENTS	NON-PREFERRED AGENTS
COMBINATION AGENTS	
benzoyl peroxide/urea erythromycin/benzoyl peroxide sulfacetamide sodium/sulfur wash/cleanser	ACANYA (clindamycin phosphate/benzoyl peroxide) AVAR (sulfur/sulfacetamide) BENZACLIN GEL (benzoyl peroxide/ clindamycin) BENZAMYCIN PAK (benzoyl peroxide/ erythromycin) benzoyl peroxide/clindamycin gel CLENIA (sulfacetamide sodium/sulfur) DUAC CS (benzoyl peroxide/ clindamycin) EPIDUO (adapalene/benzoyl peroxide) INOVA 4/1 (benzoyl peroxide/salicylic acid) NUOX (benzoyl peroxide/sulfur) PLEXION (sulfacetamide sodium/sulfur) PRASCION (sulfacetamide sodium/sulfur) ROSAC (sulfacetamide sodium/avobenzone/sulfur) ROSADERM (sulfacetamide sodium/sulfur) ROSANIL (sulfacetamide sodium/sulfur) ROSULA (sulfacetamide sodium/sulfur/ urea) sulfacetamide sodium/sulfur lotion, gel, pad sulfacetamide sodium/sulfur/ urea SULFOXYL (benzoyl peroxide/sulfur) SULFATOL (sulfacetamide sodium/sulfur/urea) VELTIN (clindamycin/tretinoin) ZENCIA WASH (sulfacetamide sodium/sulfur) ZIANA (clindamycin/tretinoin)

Dr. Avery called for a review of the extracted drugs. The following extracted drugs were reviewed and discussed by the Committee members:

i. Pradaxa

GHS recommended that Pradaxa be made a non-preferred drug in the Anticoagulants, Oral category and that the DUR Committee consider clinical PA criteria for the drug. Dr. Avery stated that other formularies in the State have added Pradaxa as a preferred drug and that the Committee should maintain vigilance regarding Pradaxa in terms of utilization and budget for a possible future move to the preferred list. Dr. Matulis stated that many cardiologists are switching their patients to Pradaxa because of the complications and cost-of-care related to other drugs, particularly Coumadin. He recommended tabling the discussion until more

information is available. Dr. Stanton stated that the strength approved for patients with renal insufficiency was not based on clinical trial data; the Food and Drug Administration (FDA) recommendation was based on drug level data, but renal insufficiency patients were excluded from the trial. Dr. Stanton stated that the Committee should not include the half-strength dose if the drug is made preferred since there is no clinical data.

Dr. Matulis stated that as a GI doctor, he frequently sees evidence of complications from Coumadin in his practice. Dr. Biczak stated that some patients stabilize quickly on warfarin and their dose does not change; those patients represent lower cost and morbidity rates. Others do not stabilize on the drug, leading many other States' P&T Committees to limit approval for the use of Pradaxa to those patients who are not quickly stabilized. Dr. Avery stated that all of the costs associated with care of these patients should be considered. Mr. Brown stated that the drug does show some promise, but was studied in a very narrowly focused group of patients, is very expensive, and does not have a supplemental rebate offer attached to it. Mr. Brown suggested that, based on the way it was studied and approved, the drug be available to patients through prior authorization (PA) until more data becomes available. Dr. Ashley asked Mr. Brown how he would word the criteria. Mr. Brown stated that he would follow the indications and approval set forth by the FDA.

Dr. Matulis offered an anecdote regarding a local practice, which employs two people full time to handle their caseload of warfarin patients; another cost beyond those mentioned.

Mr. Brown shared his concern that some patients would skip to Pradaxa if it was preferred, including those who might actually tolerate warfarin. Dr. Ashley asked if the PA would include only atrial fibrillation. Mr. Brown stated that the DUR board is responsible for writing criteria.

Dr. Dunsworth stated that while it takes a lot of time and effort to manage patients on warfarin, without PA criteria, the new drug could be used for many things for which it is not indicated, which is a concern.

Dr. Biczak stated that the study was limited to people with specific risk factors such as age > or equal to 75 or age > or equal to 65 and one of several other risk factors, such as diabetes, coronary artery disease or hypertension. Dr. Avery stated that the PDL contains many drugs for which step edits have been written; the same could be done for Pradaxa.

Mr. Brown made a motion to accept as recommended, with DUR PA criteria follow up, and GHS to provide more data as it becomes available. The motion was seconded.

Dr. Stanton stated that he would like to see one strength preferred and one strength non-preferred. Dr. Avery stated that the PA criteria could address that issue. A discussion regarding the Auto PA process was held. The motion was restated. The motion was seconded, votes were taken and the motion did not pass.

Dr. Matulis moved that Pradaxa be made preferred for its indicated use. Dr. Stanton made an amendment that only the highest strength be preferred and that the strength recommended for renal insufficiency, with creatinine clearances between 15 and 30, not be considered for any indication. The amendment was not seconded. Mr. Brown restated his objections to Pradaxa gaining preferred status. Dr. Fink requested a roll call vote. The motion was seconded, votes were taken and the motion carried. GHS was charged with reviewing the drug in six months.

PREFERRED AGENTS	NON-PREFERRED AGENTS
ORAL	
PRADAXA (dabigatran) AP warfarin	

ii. Suboxone Film

GHS recommended that Suboxone Film be made a preferred drug in the Miscellaneous Brand/Generic category. Mr. Brown requested that GHS and the Bureau move actively and aggressively to remove tablets from the PDL to cut back on diversion of the drug. A motion was made to accept the recommendation of GHS. The motion was seconded, votes were taken and the motion carried.

PREFERRED AGENTS	NON-PREFERRED AGENTS
SUBSTANCE ABUSE TREATMENTS	
SUBOXONE (buprenorphine) CL	

iii. Tekamlo

GHS recommended that Tekamlo be made a preferred drug in the Angiotensin Modulators, Direct Renin Inhibitors category. Dr. Bissell clarified that the initial recommendation was for the drug to be non-preferred, but GHS was now recommending the drug be preferred. He further recommended that the DUR consider removing the existing PA criteria and changing to the criteria used for Tekturna and Valturna. A motion was made to accept the recommendation of GHS. The motion was seconded, votes were taken and the motion carried.

PREFERRED AGENTS	NON-PREFERRED AGENTS
DIRECT RENIN INHIBITORS	
TEKAMLO (aliskiren/amlodipine) AP TEKTURNA (aliskiren) AP TEKTURNA HCT (aliskiren/HCTZ) AP VALTURNA (aliskiren/valsartan) AP	

VIII. Next Meeting Date

The next meeting of the P&T Committee will be held on April 27, 2011 at 2:00 p.m. in the Diamond Building, Charleston, WV.

IX. Other Business

There was no other business.

X. Election of Officers

Dr. Matulis was nominated as Committee Chairman. A motion was made, was seconded, votes were taken and the motion carried. Mr. Brown was nominated for Committee Vice Chairperson. A motion was made, was seconded, votes were taken and the motion carried.

Dr. Avery was thanked by the Committee for his years of service.

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.