MISSISSIPPI DIVISION OF MEDICAID

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Pharmacy & Therapeutics Committee Meeting

Woolfolk Building
Conference Center East, Room 145
Jackson, MS 39201-1399

August 13, 2013
10:00am to 5:00pm

MINUTES

Committee Members Present:
Anne A. Norwood, FNP, PhD
Billy Ray Brown, Pharm.D.
Carol Tingle, M.D.
D. Stanley Hartness, M.D.
Deborah Minor, Pharm.D.
Geri Lee Weiland, M.D.
John W. Gaudet, M.D.
Maretta M. Walley, R.Ph., J.D.
Ryan Harper, Pharm.D.
Wilma Johnson Wilbanks, R.Ph.

Committee Members Not Present:
Lee Voulters, M.D.
Sharon R. Dickey, Pharm.D.

Division of Medicaid Staff Present:
Judith Clark, R.Ph., Pharmacy Director
William Thompson, Pharmacy Deputy Director
Terri Kirby, R.Ph., Pharmacist III
Shannon Hardwick, R.Ph., Pharmacist III
Jessica Tyson, Pharmacy Technician
Dell Williams, Operation Management Analyst
Delvin Taylor, Operation Management Analyst

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

Other Contract Staff Present:
Leslie Leon, Pharm.D., ACS-Xerox
Kyle Null, Pharm.D., Ph.D., University of Mississippi School of Pharmacy
Ben Banahan, Ph.D., University of Mississippi School of Pharmacy

I. Call to Order

Ms. Wilma Wilbanks, R.Ph., Vice-Chairperson, called the meeting to order at 10:05 a.m.

II. Introductions

Ms. Judith Clark, Mississippi Department of Medicaid (DOM) Pharmacy Bureau Director welcomed the Pharmacy & Therapeutics (P&T) Committee and all guests in the audience. She recognized returning members Dr. Billy Ray Brown, Dr. Geri Lee Weiland, and Ms. Wilma Wilbanks. She introduced Goold Health Systems, DOM's Preferred Drug List (PDL) and Supplemental Rebate (SR) vendor. All parties seated at the table introduced themselves and gave a brief statement about their professional credentials and affiliations.

Ms. Clark expressed DOM's appreciation to the Committee members for their voluntary service to the P&T Committee.

Ms. Clark introduced DOM staff members Jessica Tyson, Billy Thompson, Dell Williams, and Delvin Taylor. She thanked her entire staff for their dedication, compassion, flexibility, and their tireless work as advocates for the Medicaid client community.

Ms. Clark recognized DOM contractors in the audience, including Dr. Leslie Leon from Xerox, and Drs. Ben Banahan and Kyle Null from the University of the Mississippi School of Pharmacy's MS-DUR Program.

III. Administrative Matters

Ms. Clark reviewed Committee policies and procedures. She reminded the Committee and the audience that the PDL is posted several weeks prior to P&T meetings.

Ms. Clark reminded guests to sign in via the electronic process available through the DOM website (www.medicaid.ms.gov) prior to the meeting. She stated that copies of the agenda and the public comment guidelines are available at the sign-in table. She stated that there is a separate sign in sheet for advocates and reminded guests that advocate presenters are limited to 3 minutes of general comment about a disease, not specific to a drug. She noted that industry presenters must provide their full name, drug name, identification, and company affiliation when signing in. She stated that industry presenters are allowed 3 minutes per drug and that no handouts are permitted. Presenters are requested to sign in at least 10 minutes prior to start of meeting.

Ms. Clark stated that any documents used in the meeting that are not marked confidential and proprietary will be posted on DOM's website (www.medicaid.ms.gov) after the meeting.

Ms. Clark called for nominations for Chairperson and Vice-Chairperson. Dr. Weiland nominated Ms. Wilbanks for Chairperson. Dr. Minor seconded. Votes were taken, and the motion was adopted. Dr. Weiland nominated Dr. Harper for Vice-Chairman. Dr. Norwood seconded. Votes were taken, and the motion was adopted.

Ms. Clark reviewed policies related to food and drink, cell phones and pagers, discussions in the hallways, and emergency procedures for the building.

Ms. Clark requested that Committee members complete their travel vouchers and reviewed the contents of the folders provided to each Committee member.

Ms. Clark stated that DOM aggressively pursues supplemental rebates. Implementation for classes discussed at the annual October meeting when the full PDL is reviewed is January 1, 2014. Mississippi is part of the Sovereign States Drug Consortium (SSDC) pool.

Ms. Clark reviewed the voting procedure and reminded the Committee that, in accordance with the Mississippi Open Meetings Act, the minutes reflect each person's vote. She requested that the Chair announce the recommendation, motions, and the names of committee members making motions. The minutes for each P&T Committee meeting are posted to the DOM website (www.medicaid.ms.gov) within 30 days of the meeting. The meeting minutes will be posted no later than September 13, 2013. Decisions will be announced no later than September 1, 2013 on the DOM website (www.medicaid.ms.com).

Ms. Clark stated that the P&T Committee works in an advisory capacity and that DOM is responsible for final decisions related to the PDL. She reviewed the meeting process. She stated that DOM takes into account recommendations from both the P&T Committee and the clinical contractor before making a final decision. She stated that the PDL is completely updated once per year; quarterly updates are implemented throughout the year.

IV. Division of Medicaid Update

Ms. Clark noted that provider notices regarding ketoconazole, doxycycline, and hurricane preparedness are available on the DOM website (www.medicaid.ms.com).

V. Approval of April 9, 2013 Meeting Minutes

Ms. Wilbanks asked for approval of the minutes from the April 9, 2013 meeting. Ms. Wilbanks declared that there being no further discussion, the minutes would stand accepted.

VI. PDL Compliance/Generic Percent Report Updates

Dr. Biczak provided an explanation of the PDL Compliance and Generic Percent reports.

A. Dr. Biczak reviewed the PDL Compliance Report; overall compliance for Q2 2013 was 95%.

B. Dr. Biczak reviewed the Generic Percent Report; overall generic utilization for Q2 2013 was 79.1%.

VII. Drug Class Announcements

Dr. Bissell stated that two new categories are recommended for addition to the PDL: Antineoplastics, Selected Systemic Enzyme Inhibitors and Irritable Bowel Syndrome/Short Bowel (IBS/SB).

Dr. Bissell stated that oral ketoconazole was moved to non-preferred on the PDL based on an FDA warning released on July 26, 2013. The FDA's concerns included severe adrenal gland and liver complications. GHS recommended granting a two week grace period for existing users of the drug before the PA criteria take effect so that patients have time to switch therapies before refill requests are rejected at the pharmacy.

Dr. Bissell noted that October meeting will be full review of every category on the PDL. MS DOM attended the June SSDC meeting to review manufacturer offers. DOM is currently making final decisions for 2014. The Committee will consider all of the offers in October.

GHS recommended starting the October meeting at 9:00 a.m. Dr. Harper moved to accept the recommendation. Dr. Weiland seconded. Votes were taken, and the motion was adopted.

Ms. Clark reviewed the 2 brand/5 generic drug policy.

VIII. First Round of Extractions

GHS recommended that the following classes be extracted:

- IBS/SBS
- Antineoplastics, Selected Systemic Enzyme Inhibitors

IX. Public Comments

Ms. Clark reviewed the public comment process.

Julia Compton, Novartis, spoke in favor of TOBI Podhaler. A robust clinical discussion followed.

Jerrica Dodd, Biogen Idec, spoke in favor of Tecfidera.

Kimberly Hughes, American Cancer Society Cancer Action Network, spoke in favor of adding oral oncology agents to the PDL as preferred products .

Laura Moseley, Bristol Myers Squibb, spoke in favor of Sprycel.

Kara Sperandeo, Forest Research Institute, spoke in favor of Linzess.

Megan Jones, Johnson & Johnson, spoke in favor of Invokana.

X. Second Round of Extractions

No other categories were recommended for extraction.

XI. Non-Extracted Categories

All classes were recommended for extraction.

XII. Extracted Therapeutic Class Reviews

A. IBS/SBS

GHS recommended that the following list be approved; existing users of Amitiza, Fulyzaq, Gattex, Linzess, Lotronex, and NutreStore should be grandfathered where there are existing users. Zorbtive is currently non-preferred in the Growth Hormone Category and is being moved to this category. A robust clinical discussion followed. Dr. Minor moved to accept the recommendation. Dr. Tingle seconded. Votes were taken, and the motion was adopted. The approved category is below.

PREFERRED AGENTS	NON-PREFERRED AGENTS
dicyclomine hyoscyamine	AMITIZA (lubiprostone) BENTYL (dicyclomine) FULYZAQ (crofelemer) GATTEX (teduglutide) LEVSIN (hyoscyamine) LEVSIN-SL (hyoscyamine) LINZESS (linaclotide) LOTRONEX (alosetron) NUTRESTORE POWDER PACK (glutamine) ZORBTIVE (somatropin)

B. Antineoplastics – Selected Systemic Enzyme Inhibitors

GHS recommended that the following list be approved. Dr. Bissell stated that the Antineoplastics category has been added to give Committee a sense of overall use and cost of drugs in the class. All drugs are recommended to be preferred. GHS recommends that the DUR review PA criteria or clinical edits. Dr. Harper moved to accept the recommendation. Dr. Weiland seconded. Votes were taken, and the motion was adopted. The approved category is below.

PREFERRED AGENTS	NON-PREFERRED AGENTS
AFINITOR (everolimus) BOSULIF (bosutinib) CAPRELSA (vandetanib) COMTRIQ (cabozantinib) GLEEVEC (imatinib mesylate) ICLUSIG (ponatinib) INLYTA (axitinib) IRESSA (gefitinib) JAKAFI (ruxolitinib) KYPROLIS (carfilzomib) NEXAVAR (sorafenib) SPRYCEL (dasatinib) STIVARGA (regorafenib) SUTENT (sunitinib) TARCEVA (erlotinib) TASIGNA (nilotinib)	

PREFERRED AGENTS	NON-PREFERRED AGENTS
TORISEL (temsirolimus) TYKERB (lapatinib ditosylate) vandetanib VELCADE (bortezomib) VOTRIENT (pazopanib) XALKORI (crizotinib) ZELBORAF (vemurafenib)	

XIII. New Drug/New Generic Reviews

A. TOBI Podhaler

GHS recommended that TOBI Podhaler be made a non-preferred drug in the Cystic Fibrosis Agents category and that a manual PA be required. Dr. Weiland moved to accept the recommendation, including the requirement of a manual PA. Dr. Brown seconded. Votes were taken, and the motion was adopted. The approved category is below.

PREFERRED AGENTS	NON-PREFERRED AGENTS
	CAYSTON (aztreonam)** COLY-MYCIN M (colistimethate sodium)** KALYDECO (ivacaftor) PULMOZYME (dornase alfa)** TOBI (tobramycin)** TOBI PODHALER (tobramycin)

B. Tecfidera

GHS recommended that Tecfidera be made a non-preferred drug in the Multiple Sclerosis Agents category. Dr. Norwood moved to accept the recommendation. Ms. Walley seconded. Votes were taken, and the motion was adopted. The approved category is below.

PREFERRED AGENTS	NON-PREFERRED AGENTS
AVONEX (interferon beta-1a) COPAXONE (glatiramer) REBIF (interferon beta-1a)	AMPYRA (dalfampridine) AUBAGIO (teriflunomide) BETASERON (interferon beta-1b) EXTAVIA (interferon beta-1b) GILENYA (fingolimod) TECFIDERA (dimethyl fumarate)

C. Kynamro

GHS recommended that Kynamro be made a non-preferred drug in the Lipotropics, Other (Non-statins) category. Dr. Minor moved to accept the recommendation. Dr. Weiland seconded. Votes were taken, and the motion was adopted. The approved category is below.

PREFERRED AGENTS	NON-PREFERRED AGENTS
BILE ACID SEQUESTRANTS	
cholestyramine colestipol	COLESTID (colestipol) QUESTRAN (cholestyramine) WELCHOL (colesevelam)

PREFERRED AGENTS	NON-PREFERRED AGENTS
OMEGA-3 FATTY ACIDS	
LOVAZA (omega-3-acid ethyl esters)	VASCEPA (icosapent ethyl)
CHOLESTEROL ABSORPTION INHIBITORS	
	ZETIA (ezetimibe)
FIBRIC ACID DERIVATIVES	
ANTARA (fenofibrate, micronized) gemfibrozil TRICOR (fenofibrate nanocrystallized) TRILIPIX (fenofibric acid)	fenofibrate, micronized fenofibrate nanocrystallized 145mg fenofibric acid FENOGLIDE (fenofibrate) FIBRICOR (fenofibric acid) LIPOFEN (fenofibrate) LOFIBRA (fenofibrate) LOPID (gemfibrozil) TRIGLIDE (fenofibrate)
MTP INHIBITOR	
	JUXTAPID (lomitapide)
APOLIPOPROTEIN B-100 SYNTHESIS INHIBITOR	
	KYNAMRO (mipomersen)
NIACIN	
NIACOR (niacin) NIASPAN (niacin)	

D. Diclegis

GHS recommended that Diclegis be made a non-preferred drug in the Antiemetics category and that over-the-counter options be preferred for women of childbearing age. A robust clinical discussion followed. Dr. Minor moved to accept the recommendation. Dr. Harper seconded. Votes were taken, and the motion was adopted. The approved category is below.

PREFERRED AGENTS	NON-PREFERRED AGENTS
5HT3 RECEPTOR BLOCKERS	
ondansetron ondansetron solution	ANZEMET (dolasetron) granisetron GRANISOL (granisetron) ondansetron ODT SANCUSO (granisetron) ZOFRAN (ondansetron) ZOFRAN ODT (ondansetron) ZUPLENZ (ondansetron)
ANTIEMETIC COMBINATIONS	
	DICLEGIS (doxylamine/pyridoxine)
CANNABINOIDS	
	CESAMET (nabilone) MARINOL (dronabinol) dronabinol
NMDA RECEPTOR ANTAGONIST	
	EMEND (aprepitant)

E. Invokana

GHS recommended that Invokana be made a non-preferred drug in the Hypoglycemics, Sodium Glucose Cotransporter-2 Inhibitors category. Dr. Weiland moved to accept the recommendation. Dr. Minor seconded. Votes were taken, and the motion was adopted. The approved category is below.

PREFERRED AGENTS	NON-PREFERRED AGENTS
	INVOKANA (canagliflozin)

F. Prolensa

GHS recommended that Prolensa be made a non-preferred drug in the Ophthalmic Anti-inflammatories category. Dr. Weiland moved to accept the recommendation. Dr. Tingle seconded. Votes were taken, and the motion was adopted. The approved category is below.

PREFERRED AGENTS	NON-PREFERRED AGENTS
dexamethasone	ACULAR LS (ketorolac)
diclofenac	ACUVAIL (ketorolac)
FLAREX (fluorometholone)	BROMDAY (bromfenac)
flurbiprofen	bromfenac
FML FORTE (fluorometholone)	DUREZOL (difluprednate)
FML SOP (fluorometholone)	OCUFEN (flurbiprofen)
ILEVRO (nepafenac)	PROLENSA (bromfenac)
MAXIDEX (dexamethasone)	PRED MILD (prednisolone)
NEVANAC (nepafenac)	PRED FORTE (prednisolone)
prednisolone acetate	VOLTAREN (diclofenac)
prednisolone NA phosphate	
VEXOL (rimexolone)	

Dr. David Dzielak, Executive Director and Will Crump, Deputy Director, joined the meeting and were introduced.

G. Simbrinza

GHS recommended that Simbrinza be made a non-preferred drug in the Ophthalmics, Glaucoma Agents category. A robust clinical discussion followed. Dr. Tingle moved to table discussion on the category until the October meeting. Dr. Weiland seconded. Votes were taken, and the motion was adopted.

PREFERRED AGENTS	NON-PREFERRED AGENTS
BETA BLOCKERS	
betaxolol	BETAGAN (levobunolol)
BETIMOL (timolol)	BETOPTIC S (betaxolol)
carteolol	OPTIPRANOLOL (metipranolol)
ISTALOL (timolol)	timolol gel
levobunolol	TIMOPTIC (timolol)
metipranolol	
timolol solution	
CARBONIC ANHYDRASE INHIBITORS	
AZOPT (brinzolamide)	
dorzolamide	
TRUSOPT (dorzolamide)	
COMBINATION AGENTS	
COMBIGAN (brimonidine/timolol)	COSOPT PF(dorzolamide/timolol)
COSOPT (dorzolamide/timolol)	SIMBRINZA (brinzolamide/brimonidine)
dorzolamide/timolol	

PREFERRED AGENTS	NON-PREFERRED AGENTS
PARASYMPATHOMIMETICS	
pilocarpine	CARBOPTIC (carbachol) ISOPTO CARBACHOL (carbachol) ISOPTO CARPINE (pilocarpine) PHOSPHOLINE IODIDE (echothiophate iodide) PILOPINE HS (pilocarpine)
PROSTAGLANDIN ANALOGS	
latanoprost TRAVATAN Z (travoprost)	LUMIGAN (bimatoprost) RESCULA (unoprostone)[NR] travoprost XALATAN (latanoprost) ZIOPTAN (tafluprost)
SYMPATHOMIMETICS	
ALPHAGAN P 0.15% (brimonidine) brimonidine	ALPHAGAN P 0.1% (brimonidine) dipivefrin PROPINE (dipivefrin)

XIV. Miscellaneous Brand/Generic Additions

A. alprazolam/alprazolam ER

GHS recommended that alprazolam be made a preferred drug and that alprazolam ER be made a non-preferred drug in the Miscellaneous Brand/Generic category. Existing users of alprazolam ER should be grandfathered as part of this recommendation. Dr. Minor moved to accept the recommendation Dr. Tingle seconded. Votes were taken, and the motion was adopted. The approved category is below.

PREFERRED AGENTS	NON-PREFERRED AGENTS
CLONIDINE	
CATAPRES-TTS (clonidine) clonidine tablets	clonidine patches CATAPRES (clonidine)
MISCELLANEOUS	
alprazolam CARAFATE SUSPENSION (sucralfate) MEGACE ES (megestrol) SUBOXONE (buprenorphine/naloxone)	alprazolam ER KORLYM (mifepristone) megestrol suspension 625mg/5mL sucralfate suspension
SUBLINGUAL NITROGLYCERIN	
nitroglycerin lingual 12gm nitroglycerin sublingual NITROLINGUAL PUMPSPRAY (nitroglycerin) 12gm NITROSTAT SUBLINGUAL (nitroglycerin)	nitroglycerin lingual 4.9gm NITROLINGUAL (nitroglycerin) 4.9gm NITROMIST (nitroglycerin)

B. Carafate/sucralfate suspension

GHS recommended that carafate/sucralfate suspension be made a preferred drug and sucralfate suspension be made a non-preferred drug in the Miscellaneous Brand/Generic category. A robust clinical discussion followed. Dr. Brown moved to accept the recommendation. Dr. Norwood seconded. Votes were taken, and the motion carried. The approved category is below.

PREFERRED AGENTS	NON-PREFERRED AGENTS
CLONIDINE	
CATAPRES-TTS (clonidine) clonidine tablets	clonidine patches CATAPRES (clonidine)
MISCELLANEOUS	
alprazolam CARAFATE SUSPENSION (sucralfate) MEGACE ES (megestrol) SUBOXONE (buprenorphine/naloxone)	alprazolam ER KORLYM (mifepristone) megestrol suspension 625mg/5mL sucralfate suspension
SUBLINGUAL NITROGLYCERIN	
nitroglycerin lingual 12gm nitroglycerin sublingual NITROLINGUAL PUMPSPRAY (nitroglycerin) 12gm NITROSTAT SUBLINGUAL (nitroglycerin)	nitroglycerin lingual 4.9gm NITROLINGUAL (nitroglycerin) 4.9gm NITROMIST (nitroglycerin)

XV. Other Business

Dr. Dzielak thanked the Committee, Ms. Clark and her staff, and Mr. Crump for their hard work on behalf of Medicaid clients.

XVI. Next Meeting Date

The next meeting of the Pharmacy & Therapeutics Committee will be held on October 22, 2013 at 9:00 a.m. in the Woolfolk Building, Conference Center East, Room 145, in Jackson, Mississippi.

XVII. Adjournment

The meeting adjourned at 12:07 p.m.