MISSISSIPPI DIVISION OF MEDICAID

Pharmacy & Therapeutics Committee Meeting

February 14, 2023

10:00am to 5:00pm

MINUTES

Committee Members Present:

James Benjamin Brock, MD

Brad Gilchrist, PharmD

D. Stanley Hartness, MD

Deborah Minor, PharmD, Co-Chair

Spencer Sullivan, MD

Wilma Wilbanks, RPh, Chair

Committee Members Not Present:

Clyde E. Glenn, MD

Karen Maltby, MD

Kim Rodgers, RPh

Louise Turman, PharmD

Geri Lee Weiland, MD

S. Caleb Williamson, PharmD

Division of Medicaid Staff Present:

Terri Kirby RPh, CPM, Pharmacy Director

Gail McCorkle, RPh, Pharmacy Team Lead

Dennis Smith, RPh, Pharmacy Team Lead

Chris A. Yount, MA, PMP, Program Specialist Team Lead

CHC Staff Present:

Laureen Biczak, DO

Paige Clayton, PharmD

Shannon Hardwick, RPh

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Other Contract Staff Present:

Tricia Banks, PharmD, Gainwell

Jenni Grantham, PharmD, Magnolia

Heather Odem, PharmD, UHC

Buddy Ogletree, PharmD, Aliant

Eric Pittman, PharmD, UM School of Pharmacy

Lew Anne Snow, RN Gainwell

Trina Stewart, PharmD, Molina

Attendance Chart :

Committee Member	Oct 2021	Feb 2022	Aug 2022	Oct 2022	Feb 2023
Brock		X	X		X
Gilchrist	X	X	X	X	X
Glenn		X		X	
Hartness	X	X	X	X	X
Maltby	X		X	X	
Minor	X	X	X	X	X
Rodgers	X	X		X	
Sullivan	X	X	X	X	X
Turman	X	X	X	X	
Weiland		X		X	

Wilbanks	X	X		X	X
Williamson	X	X		X	

I. Call to Order

Ms. Wilbanks, chair, called the meeting to order at 10:02am. Recognizing the lack of a quorum, Ms. Wilbanks instructed the Committee that votes will be taken for each class, but will be considered a "provisionalal recommendation." This set of recommendations will be presented at the next P&T meeting and voted on en bloc for adoption.

II. Welcome and Introductions

Ms. Terri Kirby, Mississippi Division of Medicaid (DOM) Pharmacy Director, welcomed the Pharmacy & Therapeutics (P&T) Committee and all guests in the audience silence their phones. She state that as of the first of February our total beneficiary count was 846, 264 , which means roughly 1 out of 4 Mississippians have Medicaid coverage.

She introduced Change Healthcare, 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. Kirby had DOM contractors in the audience introduce themselves, including Lew Anne Snow and Dr. Tricia Banks from Gainwell, Dr. Jenni Grantham from Magnolia Health Plan, Dr. Heather Odem from United Healthcare, Dr. Trina Stewart from Molina, Dr. Buddy Ogletree from Aliant and Shannon Hardwick from Change Healthcare and Dr. Eric Pittman from UM School of Pharmacy.

III. Administrative Matters

Ms. Kirby reminded guests to register prior to each P&T Committee meeting via the electronic process available through the DOM website (www.medicaid.ms.gov). She stated that copies of the agenda and the public

comment guidelines are available at the industry 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. Kirby 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. Kirby reviewed policies related to food and drink, cell phones and laptop usage, discussions in the hallways, and emergency procedures for the building.

Ms. Kirby stated that DOM aggressively pursues supplemental rebates. Mississippi is part of the Sovereign States Drug Consortium (SSDC) pool.The SSDC is comprised of 14 state Medicaid programs. Change Healthcare is the current vendor for the SSDC and negotiates Supplemental Rebates on its behalf. In addition to supplemental rebates, Change Healthcare factors in the federal rebates paid by all manufacturers of the drugs listed on the PDL to leverage maximum savings for Medicaid. The importance of these federal rebates cannot be stressed enough.

Ms. Kirby 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 March 15,2023. The PDL decisions will be announced no later than March 1, 2023, on the DOM website and will go into effect April 1, 2023.

Ms. Kirby 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.

Ms. Kirby reviewed Committee policies and procedures. She requested that Committee members complete their travel vouchers and reviewed the contents of the folders provided to each Committee member. She reminded Committee members to please be sure to complete all of the enclosed forms and leave them on the table after the meeting. Of particular importance are the confidentiality and Conflict of Interest Forms. All Rebate information found in the cost sheets (in your red folder) is highly confidential per CMS and US Code 1396.

Be mindful that the Conflict-of-Interest forms can be accessed by the public. For example, a true conflict of interest would be a situation where you are a paid speaker by a pharmaceutical manufacturer for a particular drug, --- If this is the case you are not allowed to participate in committee discussions about that drug or participate in any voting involving that drug. Also be aware of any *perceived* conflicts of interest. For example, if you are involved in any studies involving a drug or drug class, DOM's attorney as advised that participation in discussions about that drug or class or voting could be perceived as a conflict of interest and is not recommended.

IV. Approval of October 18, 2022 Meeting Minutes

Ms. Wilbanks asked for additions or corrections to the minutes from the October 18, 2022 meeting. There were no further additions or corrections. The minutes stand approved.

V. PDL Compliance/Generic Percent Report Updates

Dr. Clayton explained the PDL Compliance and Generic Percent reports have not been run due to ongoing claims data transfer to Gainwell. All parties are optimistic that the reports will be ready for presentation at the May meeting.

VI. Drug Class Announcements

Dr. Clayton stated there were no Drug Class Announcements. Ms. Wilbanks asked that the Stimulant Class be added to the agenda. Dr. Sullivan asked that the Antiobesity Class update be added to the agenda for discussion.

VII. Public Comments

1. Andrew Delgado from BMS spoke in favor of Sotyktu.
2. Matt Baker from Axsome spoke in favor of Auvelity.
3. Jigna Bhalia from Astra Zeneca spoke in favor of Lokelma.

4. John Ingram, UMMC Director of Pediatric Comprehensive Epilepsy Center, advocated for a fast track PA process for antiseizure medications when genetic testing identifies the requested agent is the best for the patient in question.

VIII. Therapeutic Class

Potassium Removing Agents

Change Healthcare recommended that the following list be approved. A robust clinical and financial discussion followed. Dr. Brock moved to acc ept the recommendation. Dr. Sullivan seconded. Votes were taken, and the provisional recommendation was made. The recommended category is as follows:

POTASSIUM REMOVING AGENTS		
	LOKELMA (sodium zirconium cyclosilicate)	sodium polystyrene sulfonate SPS ENEMA (sodium polystyrene sulfonate) SPS SUSPENSION (sodium polystyrene sulfonate) VELTASSA (patiromer calcium sorbitex)

IX. New Drug Reviews

a. Anticonvulsants- Zonisade, Ztalmy

Change Healthcare recommended that the following list be approved. A robust clinical and financial discussion followed. Dr. Hartness moved to acc ept the recommendation. Dr. Sullivan seconded. Votes were taken, and the provisional recommendation was made. The recommended category is as follows:

ANTICONVULSANTS DUR+		
	ADJUVANTS	
	carbamazepine carbamazepine suspension carbamazepine ER DEPAKOTE ER (divalproex) DEPAKOTE SPRINKLE (divalproex) divalproex divalproex ER divalproex sprinkle	APTIOM (eslicarbazepine) BANZEL (rufinamide) BRIVIACT (brivaracetam) carbamazepine XR CARBATROL (carbamazepine) DEPAKENE (valproic acid) DEPAKOTE (divalproex) DIACOMIT (stiripentol) ELEPSIA XR (levetiracetam)

	EPIDIOLEX (cannabidiol) EPITOL (carbamazepine) gabapentin GABITRIL (tiagabine) lacosamide lamotrigine levetiracetam levetiracetam ER oxcarbazepine oxcarbazepine suspension topiramate tablet topiramate sprinkle capsule valproic acid zonisamide	EPRONTIA (topiramate solution) EQUETRO (carbamazepine) felbamate FELBATOL (felbamate) FINTEPLA (fenfluramine) FYCOMPA (perampanel) KEPPRA (levetiracetam) KEPPRA XR (levetiracetam) LAMICTAL (lamotrigine) LAMICTAL CHEWABLE (lamotrigine) LAMICTAL ODT (lamotrigine) LAMICTAL XR (lamotrigine) lamotrigine ER/XR lamotrigine ODT NEURONTIN (gabapentin) OXTELLAR XR (oxcarbazepine) QUDEXY XR (topiramate) ROWEEPRA (levetiracetam) SABRIL (vigabatrin) SPRITAM (levetiracetam) STAVZOR (valproic acid) TEGRETOL (carbamazepine) TEGRETOL SUSPENSION (carbamazepine) TEGRETOL XR (carbamazepine) tiagabine TOPAMAX TABLET (topiramate) TOPAMAX Sprinkle (topiramate) topiramate ER (generic Qudexy XR) Step Edit TRILEPTAL Tablets (oxcarbazepine) TRILEPTAL Suspension (oxcarbazepine) TROKENDI XR (topiramate) vigabatrin VIMPAT (lacosamide) XCOPRI (cenobamate) ZONISADE (zonisamide supsension) ZTALMY (ganaxolone)

b. Antidepressants-Auvelity

Change Healthcare recommended that the following list be approved. A robust clinical and financial discussion followed. Dr. Minor moved to accept the recommendation. Dr. Hartness seconded. Votes were taken, and the provisional recommendation was made. The recommended category is as follows:

ANTIDEPRESSANTS, OTHER DUR+

bupropion	APLENZIN (bupropion HBr)
bupropion SR	AUVELITY (dextromethorphan/bupropion)
bupropion XL	desvenlafaxine ER
TRINTELLIX (vortioxetine)	desvenlafaxine fumarate ER
mirtazapine	DESYREL (trazodone)
trazodone	DRIZALMA SPRINKLE (duloxetine DR)
venlafaxine	EFFEXOR (venlafaxine)
venlafaxine ER capsules	EFFEXOR XR (venlafaxine)
VIIBRYD (vilazodone)	EMSAM (selegiline transdermal)
	FETZIMA ER (levomilnacipran)
	FORFIVO XL (bupropion)
	KHEDEZLA ER (desvenlafaxine)
	MARPLAN (isocarboxazid)
	NARDIL (phenelzine)
	nefazodone
	OLEPTRO ER (trazodone)
	PARNATE (tranylcypromine)
	phenelzine
	PRISTIQ (desvenlafaxine)
	REMERON (mirtazapine)
	tranylcypromine
	venlafaxine XR
	venlafaxine ER tablets
	vilazodone
	WELLBUTRIN (bupropion)
	WELLBUTRIN SR (bupropion)
	WELLBUTRIN XL (bupropion HCl)

Ms. Wilbanks call for a short recess at 11:14am
Ms. Wilbanks called the meeting back to order at 11:23am

c. Antifungals (oral)- Vivjoa

Change Healthcare recommended that the following list be approved. A robust clinical and financial discussion followed. Dr. Hartness moved to accept the recommendation. Dr. Sullivan seconded. Votes were taken, and the provisional recommendation was made. The recommended category is as follows:

ANTIFUNGALS (Oral) DUR+		
	clotrimazole	ANCOBON (flucytosine) ^
	fluconazole	BREXAFEMME (ibrexafungerp)
	griseofulvin microsize suspension	CRESEMBA (isavuconazonium)
	nystatin	DIFLUCAN (fluconazole)
	terbinafine	flucytosine
		GRIFULVIN V (griseofulvin, microsize)
		griseofulvin microsize tablets

		griseofulvin ultramicrosize tablet GRIS-PEG (griseofulvin) itraconazole ^ ketoconazole LAMISIL (terbinafine) NOXAFIL (posaconazole) ^ ONMEL (itraconazole) ^ posaconazole^ SPORANOX (itraconazole) ^ TERBINEX Kit (terbinafine/ciclopirox) TOLSURA (itraconazole) VFEND (voriconazole) ^ VIVJOA (oteseconazole) voriconazole ^

d. BPH Agents- Entadfi

Change Healthcare recommended that the following list be approved. A robust clinical and financial discussion followed. Dr. Hartness moved to accept the recommendation. Dr. Gilcrist seconded. Votes were taken, and the provisional recommendation was made. The recommended category is as follows:

BPH AGENTS DUR+	
5-ALPHA-REDUCTASE (5AR) INHIBITORS	
finasteride	AVODART (dutasteride) dutasteride ENTADFI (finasteride/tadalafil) PROSCAR (finasteride)

e. Colony Stimulating Factors- Fylnetra

Change Healthcare recommended that the Fylnetra be preferred. A robust financial discussion followed. Dr. Minor moved to accept the recommendation. Dr. Brock seconded. Dr. Sullivan moved to amend the motion and make Ziextenzo nonpreferred. Dr. Hartness seconded.Votes were taken on both the motion and amendment, and the provisional recommendation was made. The recommended category is as follows:

COLONY STIMULATING FACTORS	
FYLNETRA (pegfilgrastim) NEUPOGEN Syringe (filgrastim)	FULPHILA (pegfilgrastim) GRANIX (tbo-filgrastim)

NEUPOGEN Vial (filgrastim)	LEUKINE (sargramostim) NEULASTA (pegfilgrastim) NIVESTYM (filgrastim-aafi) NYVEPRIA (pegfilgrastim-apgf) RELEUKO (filgrastim) UDENYCA (pegfilgrastim-cbqv) ZARXIO (filgrastim) ZIEXTENZO (pegfilgrastim-bmez)

f. Cytokine & CAM Antagonists- Sotkytu, Spevigo

Change Healthcare recommended that the following list be approved. A robust clinical and financial discussion followed. Dr.Sullivan moved to accept the recommendation. Dr. Brock seconded. Votes were taken, and the provisional recommendation was made. The recommended category is as follows:

CYTOKINE & CAM ANTAGONISTS[DUR+]	
ACTEMRA SYRINGE (tocilizumab) ACTEMRA VIAL(tocilizumab) AVSOLA (infliximab) ENBREL (etanercept) HUMIRA (adalimumab) KINERET (anakinra) methotrexate ORENCIA CLICKJET(abatacept) ORENCIA VIAL(abatacept) OTEZLA (apremilast) SIMPONI (golimumab) TALTZ (ixekizumab) XELJANZ IR (tofacitinib)	ACTEMRA ACTPEN (tocilizumab) ARCALYST (rilonacept) CIMZIA (certolizumab) COSENTYX (secukinumab ENTYVIO (vedolizumab) ILARIS (canakinumab) ILUMYA (tildrakizumab) INFLECTRA (infliximab) KEVZARA (sarilumab) OLUMIANT (baricitinib) ORENCIA SYRINGE (abatacept) OTREXUP (methotrexate) RASUVO (methotrexate) REMICADE (infliximab) RENFLEXIS (infliximab-abda) RHEUMATREX (methotrexate) RINVOQ (upadacitinib) RINVOQ ER (upadacitinib) SILIQ (brodalumab) SKYRIZI (risankizumab) SOTYKTU (deucravacitinib) SPEVIGO (spesolimab) STELARA (ustekinumab) TREMFYA (guselkumab) TREXALL (methotrexate) XELJANZ Oral Solution (tofacitinib) XELJANZ XR (tofacitinib)

g. Intranasal Rhinitis Agents- Ryaltris Nasal

Change Healthcare recommended that the following list be approved. A robust clinical and financial discussion followed. Dr. Hartness moved to accept the recommendation. Dr. Brock seconded. Votes were taken, and the provisional recommendation was made. The recommended category is as follows:

INTRANASAL RHINITIS AGENTS	
ANTIHISTAMINE/CORTICOSTEROID COMBINATION SmartPA	
	DYMISTA (azelastine/fluticasone) RYALTRIS (olopatadine/mometasone) TICALAST (azelastine/fluticasone)

h. Pulmonary Antihypertensives- Tadliq

Change Healthcare recommended that the following list be approved. A robust clinical and financial discussion followed. Dr. Sullivan moved to accept the recommendation. Dr. Brock seconded. Votes were taken, and the provisional recommendation was made. The recommended category is as follows:

PULMONARY ANTIHYPERTENSIVES DUR+	
PDE5's	
sildenafil (generic Revatio) tablet tadalafil	ADCIRCA (tadalafil) REVATIO (sildenafil) tablet REVATIO (sildenafil) suspension sildenafil (generic Revatio) suspension TADLIQ (tadalafil) suspension

i. Stimulants

On behalf of absent Dr. Weiland, Ms. Wilbanks asked if DOM could consider preferring branded Concerta and Adderall XR products and the long acting stimulant, Vyvanse, due to the ongoing supply issues and unavailability of the generics in this class. All members and vendors acknowledge that the FDA limitations placed on the products in the class have caused access issues. DOM stated that there are PA exception steps in place within all 4 program PA units. Committee members stated that their experience is the PA exception process is not working in real time situations and changes in

preferred products are needed, short term, to address this global shortage. Dr. Clayton stated that she could pull cost sheets for the class and work with DOM to make these additions/changes as soon as next week. No motion was made.

j. Antiobesity Agents

Dennis Smith gave the DUR Board findings that were requested by this Committee at the October 2022 meeting. The DUR Board reviewed and discussed the impact of obesity among Mississippi Medicaid beneficiaries with common comorbidities during its December 2022 meeting. The DUR Board voted to encourage DOM to consider changing policies pertaining to medication coverage for the management of obesity and to conduct a review of anti-obesity medications.

X. Other Business

XI. Division of Medicaid Update

Terri Kirby stated in January 2020, the U.S. Department of Health and Human Services (HHS) declared a public health emergency (PHE) in response to the outbreak of COVID-19. In March 2020, Congress passed the Families First Coronavirus Response Act (FFCRA) to help states respond to the COVID-19 pandemic.

Under the FFCRA, the federal government provided states with a 6.2 percentage point increase in Federal Medical Assistance Percentage (FMAP). In exchange, states were prohibited in most circumstances from disenrolling members from Medicaid, even if they were found to be ineligible. This was to ensure members did not lose vital healthcare coverage during the pandemic.

In December 2022, Congress passed the Consolidated Appropriations Act (CAA). Per the CAA, the continuous coverage condition that prohibited states from disenrolling members from Medicaid will expire on March 31, 2023. This means that states will resume routine eligibility operations, and the Mississippi Division of Medicaid (DOM) will begin re-qualifying all Medicaid members this spring.

It’s essential that members update their contact information so they receive and return renewal packets to make sure they keep their Medicaid and CHIP coverage if they are still eligible.

An updated communications toolkit to provide information and guidance for anyone who interacts with Medicaid members will be released in the coming weeks.

The Mississippi Division of Medicaid will take 12 months to initiate renewals and 14 months to complete renewals for each of the approximately 880,000 Mississippians currently enrolled. We need your partnership to ensure eligible members can keep their health coverage and those who no longer qualify know where they can go for affordable coverage resources. Sign up to be a Coverage Champion and help us share important information and resources, including the Stay Covered Flyer. Ask members to update their contact information so we can reach them. Educate yourselves on the renewal process so you can effectively help members. Inform members when they need to take action to keep coverage. Please do not tell members to complete a new application if they already have coverage (unless they are adding someone to their household or wanting to change their category of eligibility). This will bog down the system and may result in the member losing coverage if they are no longer eligible earlier than they otherwise would.

XII. Tentative 2023 Meeting Dates

a. Tuesday, May 9, 2023
b. Tuesday, August 8, 2023
c. Tuesday, October 24, 2023

XIII. Adjournment

The meeting adjourned at 12:22pm.