

MISSISSIPPI DIVISION OF MEDICAID

Pharmacy & Therapeutics Committee Meeting

February 15, 2022

10:00am to 5:00pm

MINUTES

Committee Members Present:

James Benjamin Brock, MD

Brad Gilchrist, PharmD

Clyde E. Glenn, MD

D. Stanley Hartness, MD

Deborah Minor, PharmD, Co-Chair

Kim Rodgers, RPh

Spencer Sullivan, MD

Louise Turman, PharmD

Geri Lee Weiland, MD

Wilma Wilbanks, RPh, Chair

Committee Members Not Present:

Karen Maltby, MD

S. Caleb Williamson, PharmD

Division of Medicaid Staff Present:

Terri Kirby RPh, CPM, Pharmacy

Director

Gail McCorkle, RPh, Pharmacist III

Dennis Smith, RPh, Pharmacist III

Chris A. Yount, MA, PMP, Staff Officer III

CHC Staff Present:

Laureen Biczak, DO

Paige Clayton, PharmD

Shannon Hardwick, RPh

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Other Contract Staff Present:

Jenni Grantham, PharmD, Magnolia

Heather Odem, PharmD, UHC

Buddy Ogletree, PharmD, Alliant

Lew Anne Snow, RN Gainwell

Trina Stewart, PharmD, Molina

Attendance Chart for State Fiscal Year 2022:

Committee Member	Aug 2021	Oct 2021	Feb 2022	May 2022
Brock			Х	
Gilchrist	Х	X	Х	
Glenn	X		X	
Hartness	X	X	X	
Maltby	X	X		
Minor	X	X	X	
Rodgers	Х	X	X	
Sullivan	X	X	X	
Turman		X	X	
Weiland			X	
Wilbanks	X	X	X	
Williamson	X	X		

I. Call to Order

Ms. Wilbanks, chair, called the meeting to order at 10:04am

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 and reminded everyone in the room to wear their masks and silence their phones.

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 introduced DOM staff members Chris Yount, Dennis Smith, and Gail McCorkle. Ms. Kirby recognized DOM contractors in the audience, including Lew Anne Snow from Gainwell, Dr. Jenni Grantham from Magnolia Health Plan, Dr. Heather Odem from United Healthcare, Dr. Trina Stewart from Molina, Dr. Buddy Ogletree from Alliant and Shannon Hardwick from Change Healthcare.

Ms. Kirby recognized Wilma Wilbanks and her husband Bob on their impending honor by the University of Mississippi School of Pharmacy as the 2022 Distinguished Alumni of the Year at the upcoming Alumni Weekend in April. She continued to thank Mrs. Wilbanks for her dedicated service and congratulated her on this well-deserved honor.

III. Administrative Matters

Ms. Kirby reminded guests to register prior to each P&T Committee meeting via the electronic available process 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 12 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 P&T Committee meeting are posted to the DOM each (www.medicaid.ms.gov) within 30 days of the meeting. The meeting minutes will be posted no later than March 15,2022. The PDL decisions will be announced no later than March 1, 2022, on the DOM website and will go into effect April 1, 2022.

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 19, 2021 Meeting Minutes

Ms. Wilbanks asked for additions or corrections to the minutes from the October 19, 2021 meeting. There were no further additions or corrections. The minutes stand approved.

v. PDL Compliance/Generic Percent Report Updates

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

- A. Dr. Clayton reviewed the PDL Compliance Report; overall compliance for 4q21 was 97%.
- B. Dr. Clayton reviewed the Generic Percent Report; overall generic utilization for 4q21 was 89.5%.

VI. Drug Class Announcements

Dr. Clayton recommended the addition of Carbaglu and its generic to the Miscellaneous Class on the PDL. The net cost to the State for the branded product is less than the generic and should be preferred over the generic at this time. Dr. Weiland made the motion to accept the recommendation. Dr. Hartness seconded. Votes were taken, and the motion was adopted.

VII. Public Comments

- 1. Bradford Loo from Intra-Cellular Therapies spoke in favor of Caplyta.
- David McCullough from Mirum Pharmaceuticals spoke in favor of Livmarli.
- 3. Irina Smith from AbbVie spoke in favor of Qulipta.
- 4. Tim Birner from Alkermes spoke in favor of Lybalvi.
- Naji Braich from Janssen Scientific Affairs spoke in favor of Invega Hafyera.

VIII. Therapeutic Class- New Drug Reviews

a. Acne Topical - Winlevi (clascoterone)

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

THERAPEUTIC DRUG CLASS	PREFERRED AGENTS	NON-PREFERRED AGENTS
ACNE AGENTS		
		ANTI-INFECTIVE
	clindamycin gel (generic Cleocin-T) clindamycin lotion clindamycin solution	ACZONE (dapsone) AKNE-MYCIN (erythromycin) azelaic acid AMZEEQ FOAM (minocycline) AZELEX (azelaic acid) CLEOCIN-T (clindamycin) CLINDAMYCIN PAC (clindamycin) CLINDAGEL (clindamycin) clindamycin foam clindamycin gel daily (generic Clindagel) dapsone ERY (erythromycin) ERYGEL (erythromycin) erythromycin gel, swabs, solution EVOCLIN (clindamycin) KLARON (sulfacetamide) sulfacetamide WINLEVI(clascoterone)

b. Antibiotics, GI- Aemcolo (rifamycin)

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

ANTIBIOTICS (GI)	
FIRVANQ (vancomycin)	AEMCOLO (rifaximin)
metronidazole	DIFICID (fidaxomicin)
neomycin	FLAGYL (metronidazole)
tinidazole	FLAGYL ER (metronidazole)
	paromomycin
	TINDAMAX (tinidazole)

VANCOCIN (vancomycin) vancomycin XIFAXAN (rifaximin)

c. Antineoplastics - Selected Systemic Enzyme Inhibitors Exkivity (mobocertinib) and Welireg (belzutifan)

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

*ANTINEOPLASTICS – SELECTED SYSTEMIC ENZYME			
INHIBITORS			
	AFINITOR (everolimus)	ALECENSA (alectinib)	
	BOSULIF (bosutinib)	ALUNBRIG (brigatnib)	
	CAPRELSA (vandetanib)	AYVAKIT (avapritinib)	
	COMETRIQ (cabozantinib)	BALVERSA (erdafitinib)	
	COTELLIC (cobimetinib)	BRAFTOVI (encorafenib)	
	GILOTRIF (afatanib)	BRUKINSA (zanubrutinib)	
	ICLUSIG (ponatinib)	CABOMETYX (cabozantinib s-	
	imatinib mesylate	malate)	
	IMBRUVICA (ibrutnib)	CALQUENCE (acalabrutinib)	
	INLYTA (axitinib)	COPIKTRA (duvelisib)	
	IRESSA (gefitinib)	DAURISMO (glasdegib)	
	JAKAFI (ruxolitinib)	ERIVEDGE (vismodegib)	
	MEKINIST (trametinib dimethyl	ERLEADA (apalutamide)	
	sulfoxide)	erlotinib	
	NEXAVAR (sorafenib)	everolimus	
	ROZLYTREK (entrectinib)	EXKIVITY (mobocertinib)	
	SPRYCEL (dasatinib)	FARYDAK (panobinostat)	
	STIVARGA (regorafenib)	FOTIVDA (tivozanib)	
	SUTENT (sunitinib)	GAVRETO (pralsetinib)	
	TAFINLAR (dabrafenib)	GLEEVEC (imatinib mesylate)	
	TARCEVA (erlotinib)	GLEOSTINE (lomustine)	
	TASIGNA (nilotinib)	IBRANCE (palbociclib) SmartPA	
	TURALIO (pexidartinib)	IDHIFA (enasidenib)	
	TYKERB (lapatinib ditosylate)	INQOVI	
	vandetanib	(cedazuridine/decitabine)	
	VOTRIENT (pazopanib)	INREBIC (fedratinib)	
	XALKORI (crizotinib)	KISQALI (ribociclib)	
	XTANDI (enzalutamide)	KOSELUGO (selumetinib)	

ZELBORAF (vemurafenib) ZYDELIG (idelalisib) ZYKADIA (ceritnib) lapatinib ditosylate LENVIMA (lenvatinib) SmartPA LORBRENA (Iorlatinib) LUMAKRAS (sotorasib) LYNPARZA (olaparib) ŚmartPA MEKTOVI (binimetnib) NERLYNX (neratinib maleate) NUBEQA (darolutamide) ODOMZO (sonidegib) ONUREG (azacitidine) ORGOVYX (relugolix) PEMAZYRE (pemigatinib) PIQRAY (alpelisib) QINLOCK (ripretinib) RETEVMO (selpercatinib) RUBRACA (rucaparib) RYDAPT (midostaurin) TABRECTA (capmatinib) TAGRISSO (osimertinib) TALZENNA (talazoparib) TAZVERIK (tazemetostat) TEPMETKO (tepotinib) TIBSOVO (ivosidenib) TRUSELTIQ (infigratinib) TUKYSA (tucatinib) **UKONIQ** (umbralisib) VERZENIO (abemaciclib) VITRAKVI (larotrectinib) VIZIMPRO (dacomitinib) WELIREG (belzutifan) XATMEP (methotrexate) XOSPATA (gilteritinib) XPOVIO (selinexor) ZEJULA (niraparib)

d. Antimigraine, Preventative- Qulipta (atogepant)

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

ANTIMIGRAINE AGENTS, ACUTE TREATMENT		
CGRP ORAL		
NURTEC ODT (rimegepant)	UBRELVY (ubrogepant) QULIPTA (atogepant)	

e. Antipsychotics- Invega Hafyera (paliperidone) and Lybalvi (olanzapine/samidorphan)

Change Healthcare recommended that the following list be approved. A robust clinical and financial discussion followed. Dr. Minor moved to accept the recommendation for Lybalvi. Dr. Weiland seconded. Votes were taken, and the motion was adopted. Dr. Minor moved to accept the recommendation

for Invega Hafyera with the understanding that as soon as the coding freeze is lifted, Invega Hafyera will be preferred when it is added to the current Smart PA rule. Dr. Sullivan seconded. Votes were taken, and the motion was adopted. The approved category is as follows:

ANTIPSYCHOTICS SmartPA		
	ORAL	
amitriptyline/perphenazine aripiprazole clozapine fluphenazine haloperidol olanzapine ODT perphenazine quetiapine XR risperidone risperidone ODT SAPHRIS (asenapine) thioridazine thiothixene trifluoperazine ziprasidone	ABILIFY (aripiprazole) ABILIFY MYCITE (aripiprazole) ADASUVE (loxapine) aripiprazole solution aripiprazole ODT asenapine CAPLYTA (lumateperone) chlorpromazine clozapine ODT CLOZARIL (clozapine) FANAPT (iloperidone) FAZACLO (clozapine) GEODON (ziprasidone) HALDOL (haloperidol) INVEGA ER (paliperidone) LATUDA (lurasidone) LYBALVI (olanzapine/samidorphan) NUPLAZID (pimavanserin) olanzapine/fluoxetine paliperidone ER REXULTI (brexpiprazole) RISPERDAL (risperidone) SEROQUEL (quetiapine) SEROQUEL XR (quetiapine) SYMBYAX (olanzapine/fluoxetine) VERSACLOZ (clonazpine) VRAYLAR (cariprazine) ZYPREXA (olanzapine)	
INJECTABLE	ATYPICALS SmartPA	
ABILIFY MAINTENA (aripirazole) ARISTADA ER (aripiprazole lauroxil) ARISTADA INITIO (aripiprazole lauroxil) INVEGA SUSTENNA (paliperidone palmitate) INVEGA TRINZA (paliperidone)	ABILIFY (aripiprazole) GEODON (ziprasidone) INVEGA HAFYEARA (paliperidone) olanzapine ZYPREXA (olanzapine)	

PERSERIS (risperidone)
RISPERDAL CONSTA (risperidone)

ZYPREXA RELPREVV (olanzapine)

f. Atopic Dermatitis- Opzelura (ruxolitinib)

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

ATOPIC DERMATITIS SmartPA	
DUPIXENT (dupilumab) ELIDEL (pimecrolimus) PROTOPIC (tacrolimus) tacrolimus	EUCRISA (crisaborole) OPZELURA (ruxolitinib) pimecrolimus

g. Bile Salts- Bylvay (odevixibat) and Livmarli (maralixibat) Change Healthcare recommended that the following list be approved. A robust clinical and financial discussion followed. Dr. Glenn moved to accept the recommendation. Mr. Rogers seconded. Votes were taken, and the motion was adopted. The approved category is as follows:

BILE SALTS		
ursodiol	ACTIGALL (ursodiol)	
	BYLVAY (odevixibat)	
	CHENODAL (chenodiol)	
	CHOLBAM (cholic acid)	
	LIVMARLI (maralixibat)	
	OCALIVA (obeticholic acid)	
	URSO (ursodiol)	
	URSO FORTE (ursodiol)	

h. Dry Eye Agents, Nasal-Tyrvaya (varenicline)

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

OPHTHALMIC, DRY EYE AGENTS

RESTASIS droperette (cyclosporine)	CEQUA (cyclosporine 0.09%)
	EYSUVIS (loteprednol etabonate)
	RESTASIS Multidose (cyclosporine)
	TYRVAYA (varaenicline) Nasal
	XIIDRA (lifitegrast) ^{Smart PA}

i. Immunosuppressants- Rezurock (belumosudil)

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

IMMUNOSUPPRESSIVE (ORAL) SmartPA AZASAN (azathioprine) ASTAGRAF XL (tacrolimus) azathioprine **ENVARSUS XR (tacrolimus)** CELLCEPT (mycophenolate) **HECORIA** (tacrolimus) cyclosporine MYFORTIC (mycophenolic acid) PROGRAF (tacrolimus) cyclosporine modified **GENGRAF** (cyclosporine) **REZUROCK** (belumosudil) IMURAN (azathioprine) mycophenolic acid mycophenolate mofetil **NEORAL** (cyclosporine) **RAPAMUNE** (sirolimus) SANDIMMUNE (cyclosporine) sirolimus tacrolimus **ZORTRESS** (everolimus)

j. Stimulants and Related Agents- Azstarys (serdexmethylphenidate/dexmethylphenidate)

Change Healthcare recommended that the following list be approved. A robust clinical and financial discussion followed. Dr. Weiland stated that Vyvanse moving to nonpreferred on January 1, 2022, had caused some disruption in her practice. While she understood the move and appreciated the 105 day look back grandfathering, the pandemic has caused a lot of children to be medication free during virtual learning. These children do not have a recent claim, but as students are returning to live classroom learning, there is a need to resume medication and she knows this drug works well.

Paige Clayton recommended to include that rationale on the prior authorization and she felt certain that would be a valid reason to approve the PA. Dr. Weiland moved to accept the recommendation. Dr. Glenn seconded. Votes were taken, and the motion was adopted. The approved category is as follows:

STIMULANTS AND RELATED AGENTS SmartPA

LONG-ACTING

amphetamine salt combination ER dexmethylphenidate ER dextroamphetamine ER DYANAVEL XR (amphetamine) methylphenidate CD (generic Metadate CD) methylphenidate ER (generic Concerta) methylphenidate ER Tabs (generic Ritalin SR) methylphenidate ER/LA Caps (generic Ritalin LA)

QUILLICHEW (methylphenidate) QUILLIVANT XR (methylphenidate) ADDERALL XR (amphetamine salt combination) ADHANSIA XR (methylphenidate) ADZENYS XR ODT (amphetamine)

ADZENYS ER SUSPENSION (amphetamine) amphetamine susp 24 hr (generic ADZENYS ER)

APTENSIO XR (methylphenidate)

AZSTARYS (serdexmethylphen/dexmethylphen) CONCERTA (methylphenidate)

COTEMPLA XR-ODT (methylphenidate)

DAYTRANA (methylphenidate)

DEXEDRINE (dextroamphetamine)

FOCALIN XR (dexmethylphenidate)

JORNAY PM (methylphenidate)

methylphenidate ER caps (generic Aptensio XR)

methylphenidate ER (generic Relexxi)

MYDAYIS (amphetamine salt combination)

RELEXXI (methylphenidate)

RITALIN LA (methylphenidate)

RITALIN SR (methylphenidate)

VYVANSE (lisdexamfetamine)*

VYVANSE CHEWABLE (lisdexamfetamine)*

Other Business IX.

Dr. Laureen Biczak presented a COVID update including the latest pharmacological therapies and pipeline products.

X. **Division of Medicaid Update**

Terri Kirby stated there were two DOM updates. On February 14th, roughly 63 more physician administered drugs began requiring prior approval in the FFS population. Alliant is the vendor responsible for handling these PA requests. A list of all PADs requiring PA is posted on the Medicaid pharmacy PA page. Secondly, a reminder that DOM is in the process of actively transitioning to a new fiscal agent. DOM is moving from Conduent to Gainwell Technologies. This transition is set to take place in 2022. Be mindful and careful to read any news

from us regarding the transfer of fiscal agents. A wide variety of pharmacy testers are needed to test the Gainwell system prior to go-live. Please contact the Office of Pharmacy if you are interested.

On another note, the Office of Pharmacy has recently received the SPA template to allow reimbursement for OTC home Covid tests. Be looking for more information to come out on that soon.

XI. Tentative 2022 Meeting Dates

- **a.** Tuesday, May 10, 2022
- **b.** Tuesday, August 9, 2022

XII. Adjournment

The meeting adjourned at 12:17pm