Division of Medicaid
Office of the Governor
State of Mississippi
Drug Utilization Review (DUR) Board Meeting

MISSISSIPPI DIVISION OF
MEDICAID

May 23, 2019 at 1:00pm

Woolfolk Building, Room 145

Jackson, MS

Prepared by:

MS | DUR Evidence-Based DUR Initiative
The University of Mississippi School of Pharmacy

Drug Utilization Review Board

Lauren Bloodworth, PharmD
University of MS School of Pharmacy
201D Faser Hall
University, MS 38677
Term Expires: June 30, 2021

Beverly Bryant, MD
UMMC, School of Medicine
2500 North State Street
Jackson, MS 39216
Term Expires: June 30, 2021

Rhonda Dunaway, RPh
Coastal Family Health Center
9113 Hwy 49 Suite 200
Gulfport, MS 39503
Term Expires: June 30, 2020

Tanya Fitts, MD
Lafayette Pediatric Clinic
1300 Access Road, Suite 400
Oxford, MS 38655
Term Expires: June 30, 2021

Juanice Glaze, RPh
New Pointe Pharmacy
345 General Robert E Blount Dr.
Bassfield, MS 39421
Term Expires: June 30, 2019

Alice F. Messer, FNP-BC
Newsouth Neurospine
2470 Flowood Drive
Flowood, MS 39232
Term Expires: June 30, 2019

Ray Montalvo, MD
KDMC Specialty Clinic
940 Brookway Boulevard
Brookhaven, MS 39601
Term Expires: June 30, 2020

Holly R. Moore, PharmD
Anderson Regional Medical Center
2124 14th Street
Meridian, MS 39301
Term Expires: June 30, 2020

Janet Ricks, DO
UMMC, Family Medicine
2500 North State Street
Jackson, MS 39216
Term Expires: June 30, 2021

Dennis Smith, RPh
Polk's Discount Drugs
1031 Star Rd
Brandon, MS 39042
Term Expires: June 30, 2020

James Taylor, PharmD **(Chair)**
North MS Medical Center
830 S. Gloster Street
Tupelo, MS 38801
Term Expires: June 30, 2019

Veda Vedanarayanan, MD
Mississippi Center for Advanced Medicine
7731 Old Canton Road, Suite B
Madison, MS 39110
Term Expires: June 30, 2021

2019 DUR Board Meeting Dates

March 7, 2019
May 23, 2019
September 19, 2019
December 5, 2019

As with any analysis, great efforts are made to ensure that the information reported in this document is accurate. The most recent administrative claims data available are being used at the time the reports are generated, which includes the most recent adjudication history. As a result, values may vary between reporting periods and between DUR Board meetings, reflecting updated reversals and claims adjustments.

Unless otherwise indicated, all MS-DUR analyses are conducted for the entire Mississippi Medicaid program including beneficiaries receiving services through the Medicaid fee-for-service (FFS) and the two Mississippi Medicaid Coordinated Care Organizations (CCOs). When dollar figures are reported, the reported dollar figures represent reimbursement amounts paid to providers and are not representative of final Medicaid costs after rebates. Any reported enrollment data presented are unofficial and are only for general information purposes for the DUR Board.

Please refer to the Mississippi Division of Medicaid website for the current official Universal Preferred Drug List (PDL).

http://www.medicaid.ms.gov/providers/pharmacy/preferred-drug-list/

MISSISSIPPI DIVISION OF MEDICAID
OFFICE OF THE GOVERNOR
DRUG UTILIZATION REVIEW BOARD
AGENDA
May 23, 2019

Welcome — James Taylor, PharmD (Chair)

Old Business — James Taylor, PharmD
- Approval of March 2019 Meeting Minutes — page 5

Resource Utilization Review

Feedback and Discussion from the Board

New Business

Pharmacy Program Update — Terri Kirby, RPh; Sara (Cindy) Noble, PharmD, MPH

Next Meeting Information — James Taylor, PharmD

DUR Board Meeting Minutes

MISSISSIPPI DIVISION OF MEDICAID
DRUG UTILIZATION REVIEW (DUR) BOARD
MINUTES OF THE MARCH 7, 2019 MEETING

DUR Board Members:	May 2018	Sep 2018	Dec 2018	Mar 2019
Lauren Bloodworth, PharmD	NA	✓	✓	
Beverly Bryant, MD	NA	✓	✓	✓
Rhonda Dunaway, RPh	✓	✓	✓	✓
Tanya Fitts, MD	NA	✓	✓	✓
Juanice Glaze, RPh	✓	✓	✓	✓
Alice Messer, DNP, FNP-BC	✓			✓
Ray Montalvo, MD	✓		✓	✓
Holly Moore, PharmD		✓	✓	
Janet Ricks, DO		✓	✓	✓
Dennis Smith, RPh	✓	✓	✓	✓
James Taylor, PharmD (Chair)	✓	✓	✓	✓
Veda Vedanarayanan, MD	NA		✓	✓
TOTAL PRESENT	**8****	**9**	**11**	**10**

***Only 10 members were active due to resignations resulting from move and replacements not yet approved by Governor.*

Also Present:

Division of Medicaid (DOM) Staff:
Terri Kirby, RPh, CPM, Pharmacy Director; Cindy Noble, PharmD, MPH, DUR Coordinator; Gail McCorkle, RPh, Clinical Pharmacist; Chris Yount, MA, PMP, Staff Officer – Pharmacy; Carlos Latorre, MD, Medical Director; Sue Reno, RN, Program Integrity; Christy Lyle, RN, Nurse Office Director of Clinical Support Services.

University of Mississippi School of Pharmacy - MS-DUR Staff:
Eric Pittman, PharmD, MS-DUR Project Director; Kaustuv Bhattacharya, MS, MS-DUR Analyst

Conduent Staff:
Leslie Leon, PharmD, Clinical Pharmacist, Mississippi Medicaid Project

Change Healthcare Staff:
Paige Clayton, PharmD, On-Site Clinical Pharmacist; Cheryl Rogers, PharmD, Mississippi PA Pharmacist

Coordinated Care Organization (CCO) Staff:
Heather Odem, PharmD, Director of Pharmacy- Mississippi, UnitedHealthcare Community & State; Jenni Grantham, PharmD, Director of Pharmacy, Magnolia Health; Trina Stewart, PharmD, Pharmacy Manager, Molina Healthcare; Joseph Vazhappilly, PharmD, MBA, Associate Vice President, Pharmacy Services, Molina Healthcare

Visitors:
Phil Hecht, Abbvie; Jason Swartz, Otsuka; Gene Wingo, Biogen; Michele Shirley, Indivior; John Kirby, Indivior; Evelyn Johnson, Capital Resources

Call to Order:
Dr. Taylor, Chair, called the meeting to order at 1:00pm and welcomed everyone. Dr. Pittman recognized Kaustuv Bhattacharya, DUR analyst, for his attendance.

OLD BUSINESS:
Dr. Fitts moved to approve the minutes from the December 2018 DUR Board Meeting, seconded by Dr. Ricks and unanimously approved by the DUR Board.

Resource Utilization Review:
Dr. Pittman informed the Board that Molina claims began appearing in October 2018. Antipsychotics continue to move up in rank in amount paid. This increase in utilization may be attributed to the inclusion of long acting injectable antipsychotics in the Clinician Administered Drugs and Implantable Drug System Devices (CADD) list allowing billing through pharmacy point of sale (POS). Dr. Pittman also noted the absence of neuraminidase inhibitors (antiviral influenza agents) from the resource report. For this same time period in 2017, neuraminidase inhibitors ranked high in both number of claims and dollars spent. This year the apparent decrease in severity of influenza and the utilization of generic products is thought to have contributed to their absence from the report. An increase in hydroxyprogesterone, Makena or 17P, utilization was noted. Dr. Pittman informed the Board that MS-DUR will provide an update at the May 2019 meeting on Makena. It was noted that there are no PA requirements in place in Medicaid for the Makena.

Chronic Obstructive Pulmonary Disease (COPD) Initiatives and Outcomes in CCOs:
One of the recommendations at the December 2018 Board meeting was a request to have the CCOs present any initiatives and outcomes they have in regards to managing beneficiaries with COPD. Pharmacists representing Magnolia Health (Jenni Grantham), Molina Healthcare (Trina Stewart and Joseph Vazhappilly) and UnitedHealthcare Community and State (Heather Odem) presented information on each of their respective programs related to COPD. Each CCO pharmacist provided information on unique programs specific to their organization and the DUR Board members were given the opportunity to ask questions of each CCO's program.

- Magnolia Health's scoring system by which beneficiaries are categorized identifies those with the greatest risk of poor health outcomes related to various disease states, including COPD. Those above a certain threshold are assigned to a case manager (RN) for approximately six months of goal-directed interaction. Case management tasks include developing care plans in which case managers can contact prescribers if they see therapy as inappropriate according to GOLD guidelines. (All case managers have received education on GOLD guidelines recently.) There is also once-weekly contact with beneficiaries to address adherence, smoking cessation, inhaler technique, and importance of long-acting inhaler use. The Outcomes Medication Therapy Management (MTM) program will be used to identify beneficiaries who are not assigned a case manager and who have gaps in coverage (implementation in April, 2019).
- Molina Healthcare provided an overview of one of its corporate initiatives- addressing issues with medication refills and its Medication Therapy Management (MTM) program. The MTM

program uses beneficiary data to identify beneficiaries who did not drop-off first fill prescription or who have any gaps in refill history. When this is discovered, prescribers are informed. The prescriber receives a "missing services" fax for beneficiaries identified with only a short-acting inhaler fill. Following an emergency department visit or inpatient hospitalization, beneficiaries are contacted to discuss adherence and receive medication education. Specific to COPD, Molina's program is designed to address gaps in care, coordination of care, educational needs, comprehensive medication reviews, adherence issues, cost concerns, and consistent follow-up and support. To improve medication adherence and help assure appropriate treatment regimens in line with the GOLD guidelines, Molina's Mississippi pharmacy director works with their care management team to identify COPD patients following an exacerbation event. Medical records are reviewed for COPD including appropriate drug therapy. As this is a new initiative, outcomes will be reported at a later date.

- UnitedHealthcare's clinical programs use detailed data analysis to identify potential problems, implement appropriate interventions, and evaluate the clinical and financial impact of the interventions. One aspect of the program drives quality of care by closing gaps in therapy for members with select chronic disease states. Designed around evidence-based guidelines, the program also incorporates quality measures supported by CMS, HEDI, and Pharmacy Quality Alliance (PQA). UHC's pharmacy benefit manager, OptumRx, manages several retrospective clinical programs. In January 2019, the "Gap In Care" program was expanded to include several new disease states, including COPD. The objective of the COPD program is to optimize the use of long term controller medications and promote the appropriate use of short-acting beta agonists in members with COPD. Algorithms use specific member inclusion and exclusion criteria to identify members with COPD whose pharmacy claims suggest a low controller ratio. This information prompts a report to their prescriber, which introduces the intervention and highlights beneficiaries with potentially suboptimal COPD control. These beneficiaries may benefit from a review of their COPD therapy. To ensure the program is comprehensive, OptumRx will perform a second analysis 120 days after the intervention to determine the impact of the program on physician prescribing to close the identified gaps in care. The analysis takes into account any increase/decrease in drug cost, as well as an extrapolated estimate for total healthcare savings. Measureable results for this program will be available beginning mid-2019. After OptumRx performs this intervention and follow up analysis, UHC's internal Mississippi MTM team reaches out personally to the prescribers whose interventions have been deemed "unsuccessful" to attempt to further close the identified gaps in care. Additionally, the Mississippi care management team reviews a daily report of 30-day hospital re-admits. These members are referred to the pharmacy MTM team for medication reconciliation prior to hospital discharge. The clinical pharmacist will review the member's discharge med list to ensure evidence based guidelines are being followed where indicated.

The Board commended the CCOs for their individual programs, but inquired about the potential for the CCOs to coordinate their programs in an effort to streamline the process for physicians who see beneficiaries from each CCO. Dr. Odem mentioned the advantage of having competition between CCO's. Dr. Bryant acknowledged the healthy competition between the CCOs, but stated, "What we are here to do is to look at the overall health of this population." Dr. Noble recommended that MS-DUR work with the CCOs to assess outcomes and the effectiveness of each program from a DUR perspective. It was suggested that the CCOs share strengths identified from each program. The DUR Board also discussed various ways to potentially increase access to medications for beneficiaries with COPD: adding medications to the 90-day list or increasing the prescription limit. Ms. Kirby informed the Board

that the Division of Medicaid (DOM) is in the process of updating the 90-day list. Additionally, effective July 1, 2019, the prescription limit will increase from 5 to 6 prescriptions monthly.

Multiple Antipsychotic Prior Authorization Rationale:
At the December 2018 Board meeting members voted to expand the prior authorization criteria for concurrent use of multiple antipsychotics from beneficiaries < 18 years of age to also include beneficiaries who are ≥ 18 years. The Board also requested information from prior authorization approvals in the previous 12 months for reasons cited to support concurrent use of multiple antipsychotic medications in the beneficiaries <18 years of age. MS-DUR compiled information submitted by Change Healthcare, Magnolia Health, and UnitedHealthcare. From the information submitted, it was determined that the most common diagnoses associated with the concurrent use of multiple antipsychotics in children were combinations of autism spectrum disorder, oppositional defiant disorder, disruptive mood dysregulation, schizophrenia, and bipolar disorder. It was also noted that most of these prior authorizations were submitted by psychiatrists or other practitioners working in a psychiatric specialty. Dr. Pittman informed the Board that the prior authorization edit for beneficiaries ≥ 18 years of age concurrently receiving multiple antipsychotics will be implemented after DOM has implemented the opioid POS edits in the POS claims system which should occur during the summer of 2019.

Feedback and Discussion from the Board:
Dr. Bryant discussed a potential project she is involved with coordinating the utilization of medication assisted therapy (MAT) for opioid abuse, evidence-based parent training, and court intervention.
Dr. Ricks discussed long-acting reversible contraceptives (LARCs), barriers to access, and training for providers.

NEW BUSINESS

Update on MS-DUR Educational Interventions:
Dr. Pittman reviewed educational mailing statistics for mailings conducted since the previous board meeting.

Special Analysis Projects:
Asthma Overview and Quality Measure Performance
Dr. Pittman provided an overview of asthma and reviewed asthma quality measure performance in Medicaid for beneficiaries during calendar year 2017. Performance was reported on the Centers for Medicare and Medicaid's core set measure" *Asthma Medication Ratio (AMR) for Adults and Children"* and on the Pharmacy Quality Alliance (PQA) measure for *"Medication Therapy for Persons with Asthma"*. Performance on both reported measures indicate there is room for improvement with respect to the management of asthma in Mississippi Medicaid beneficiaries. A robust discussion took place regarding ways to optimize the management of beneficiaries with asthma to improve performance on asthma quality measures and beneficiaries' health.

MS-DUR presented the following recommendations:

1. MS-DUR should design and implement an educational intervention program to educate providers about performance on asthma medication management and to identify beneficiaries who are not meeting quality measure criteria.
2. DOM and the CCOs should identify beneficiaries failing to meet the quality measures' criteria enrolling these identified beneficiaries in management programs designed to educate patients

on the importance of proper treatment for asthma and encourage greater utilization of controller medications.

Mr. Smith made a motion, seconded by Dr. Bryant, to accept the MS-DUR recommendations and additionally to encourage DOM to explore alternative payment options for regarding asthma medications and patient management services performed by pharmacists for Medicaid beneficiaries with asthma. The motion was unanimously approved by the Board.

Opioid Use and COPD Exacerbations

Dr. Pittman presented a summary report to the Board of a study that was conducted by a MS-DUR analyst. The study examined the association of transient opioid use and acute respiratory exacerbations among adults with COPD enrolled in the Mississippi Division of Medicaid. The report was presented primarily for informational purposes to the board. Board members provided feedback on the project and expressed interest in seeing the full report once it is published.

FDA Drug Safety Updates:

Dr. Pittman presented FDA drug safety communications from December 2018 – February 2019. In addition to the fluoroquinolone safety communication presented in the packet, recent safety communications issued for febuxostat (Uloric) on 2-21-2019 and tofacitinib (Xeljanz) on 2-25-2019 were also presented.

Pharmacy Program Update:

Ms. Kirby took this opportunity to inform the Board of the recent initiation of a series of pharmacy stakeholder meetings DOM is hosting. The purpose is to obtain input from various pharmacy organizations and representatives in the state. The intent is to explore potential to reimburse pharmacists for comprehensive patient management services.

In addition to the items already presented, Ms. Kirby updated the Board on the planned implementation of the opioid initiatives targeted for the summer of 2019. She encouraged members to participate in their state professional associations' listserv email list. DOM's Office of Communications will email provider notices to state professional organizations as one method to provide details regarding updates on upcoming opioid initiatives and POS edits.

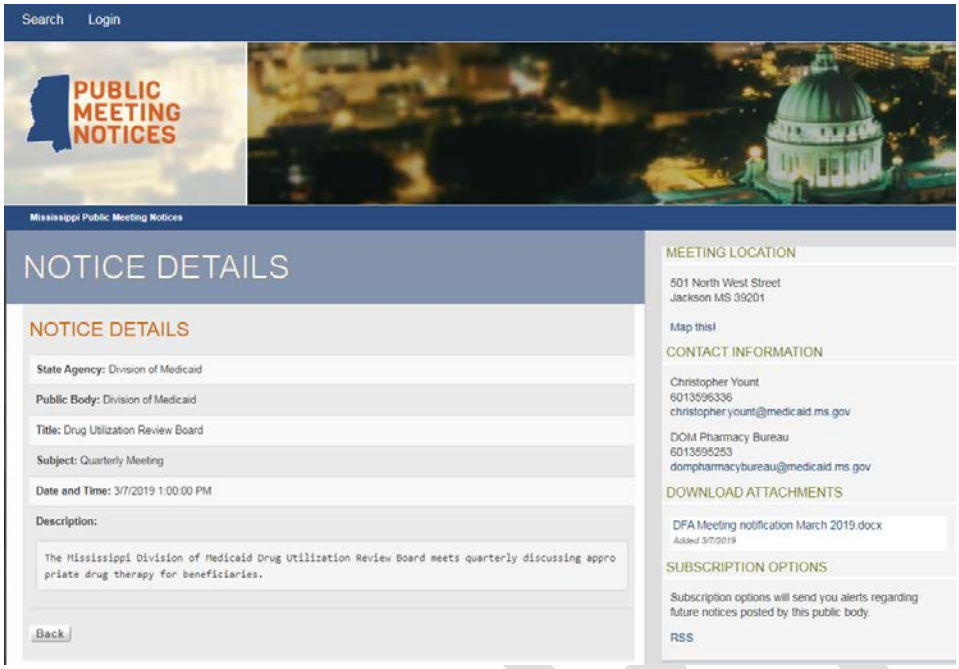
Next Meeting Information:

Dr. Taylor announced that the next meeting of the DUR Board will take place on May 23, 2019 at 1pm.

The meeting adjourned at 3:12 pm.

Submitted,

Eric Pittman, PharmD
Evidence-Based DUR Initiative, MS-DUR



Meeting Location: Woolfolk Building, 501 North West Street, Conference Room 117, Jackson, MS 39201

Contact Information: Pharmacy Bureau:
Chris Yount, 601-359-5253: Christopher.yount@medicaid.ms.gov, or
Jessica Tyson, 601-359-5253; Jessica.Tyson@medicaid.ms.gov

Notice details:

State Agency: MS Division of Medicaid

Public Body: Drug Utilization Board (DUR) Meeting

Subject: Quarterly Meeting

Date and Time: March 7, 2019 at 1PM

Description: The Mississippi Division of Medicaid's Drug Utilization Review (DUR) Board is a quality assurance body which seeks to assure appropriate drug therapy to include optimal beneficiary outcomes and appropriate education for physicians, pharmacists, and the beneficiary. The Drug Utilization Review (DUR) Board is composed of twelve participating physicians and pharmacists who are active MS Medicaid providers and in good standing with their representative organizations.

The Board reviews utilization of drug therapy and evaluates the long-term success of the treatments.

The Drug Utilization Review (DUR) Board meets quarterly.

Resource Utilizaton Review

TABLE 04A: ENROLLMENT STATISTICS FOR LAST 6 MONTHS October 1, 2018 through March 31, 2019							
			Oct-18	Nov-18	Dec-18	Jan-19	Feb-19	Mar-19
Total enrollment			700,512	696,587	694,315	693,667	690,458	685,274
Dual-eligibles			156,975	156,582	154,936	156,153	155,849	155,097
Pharmacy benefits			591,626	587,716	586,123	584,511	580,953	575,644
	LTC		17,171	17,111	17,005	17,150	17,027	16,802
	PLAN %	**FFS**	27.3%	26.5%	25.6%	25.0%	24.8%	24.4%
		MSCAN-UHC	33.3%	32.9%	32.6%	32.3%	31.8%	31.4%
		MSCAN-Magnolia	37.9%	37.7%	37.4%	37.1%	36.6%	36.4%
		MSCAN-Molina	1.5%	2.9%	4.4%	5.6%	6.8%	7.8%

TABLE 04B: PHARMACY UTILIZATION STATISTICS FOR LAST 6 MONTHS October 1, 2018 through March 31, 2019							
		Oct-18	Nov-18	Dec-18	Jan-19	Feb-19	Mar-19
# Rx Fills	**FFS**	115,401	107,786	100,819	111,478	112,088	105,588
	MSCAN-UHC	180,084	172,312	161,765	182,832	181,892	161,183
	MSCAN-Mag	233,688	222,430	211,268	236,428	235,759	213,706
	MSCAN-Mol	6,226	10,688	14,461	21,039	25,979	26,216
# Rx Fills / Bene	**FFS**	0.7	0.7	0.7	0.8	0.8	0.8
	MSCAN-UHC	0.9	0.9	0.8	1.0	1.0	0.9
	MSCAN-Mag	1.0	1.0	1.0	1.1	1.1	1.0
	MSCAN-Mol	0.7	0.6	0.6	0.6	0.7	0.6
$ Paid Rx	**FFS**	$13,285,542	$12,364,520	$11,520,004	$12,567,426	$12,509,011	$12,045,801
	MSCAN-UHC	$15,171,892	$14,516,584	$13,760,044	$16,072,370	$15,402,540	$14,662,418
	MSCAN-Mag	$20,223,058	$18,837,234	$18,656,782	$20,347,101	$20,406,117	$19,822,417
	MSCAN-Mol	$394,473	$705,264	$1,101,314	$1,447,907	$1,759,485	$1,663,235
$ /Rx Fill	**FFS**	$115.13	$114.71	$114.26	$112.73	$111.60	$114.08
	MSCAN-UHC	$84.25	$84.25	$85.06	$87.91	$84.68	$90.97
	MSCAN-Mag	$86.54	$84.69	$88.31	$86.06	$86.55	$92.76
	MSCAN-Mol	$63.36	$65.99	$76.16	$68.82	$67.73	$63.44
$ /Bene	**FFS**	$82.26	$79.39	$76.78	$86.00	$86.82	$85.76
	MSCAN-UHC	$77.01	$75.08	$72.01	$85.13	$83.37	$81.12
	MSCAN-Mag	$90.19	$85.02	$85.11	$93.83	$95.97	$94.60
	MSCAN-Mol	$44.45	$41.38	$42.70	$44.23	$44.54	$37.04

NOTE: Paid amounts represent amount reported on claims as paid to the pharmacy. These amounts do not reflect final actual costs after rebates, etc.

TABLE C: TOP 10 DRUG CATEGORIES BY NUMBER OF CLAIMS IN MAR 2019 (FFS AND CCOs)

Category	Month Year	Rank Volume	# RXs	$ Paid	# Unique Benes
CNS stimulants	Mar 2019	1	26,878	$5,676,225	23,525
	Feb 2019	2	25,972	$5,462,775	22,890
	Jan 2019	1	28,125	$5,886,166	24,408
antihistamines	Mar 2019	2	17,251	$249,889	16,691
	Feb 2019	6	15,613	$228,173	15,169
	Jan 2019	6	16,182	$242,030	15,610
aminopenicillins	Mar 2019	3	16,888	$217,564	16,574
	Feb 2019	3	22,203	$289,148	21,820
	Jan 2019	2	20,528	$264,553	20,155
narcotic analgesic combinations	Mar 2019	4	15,627	$656,233	14,314
	Feb 2019	8	15,202	$639,793	13,923
	Jan 2019	5	16,444	$658,940	14,853
adrenergic bronchodilators	Mar 2019	5	15,530	$939,915	13,596
	Feb 2019	7	15,605	$919,835	13,852
	Jan 2019	4	16,768	$1,004,684	14,739
nonsteroidal anti-inflammatory agents	Mar 2019	6	14,831	$206,798	14,218
	Feb 2019	4	17,636	$243,724	17,061
	Jan 2019	3	17,750	$236,084	16,926
atypical antipsychotics	Mar 2019	7	13,280	$3,037,371	11,581
	Feb 2019	9	12,737	$2,966,671	11,189
	Jan 2019	9	13,331	$2,965,017	11,484
leukotriene modifiers	Mar 2019	8	13,019	$218,248	12,775
	Feb 2019	12	10,731	$179,501	10,583
	Jan 2019	12	11,720	$196,327	11,454
glucocorticoids	Mar 2019	9	11,693	$218,483	11,289
	Feb 2019	10	12,719	$202,769	12,307
	Jan 2019	10	13,002	$230,721	12,559
SSRI antidepressants	Mar 2019	10	11,555	$135,132	10,850
	Feb 2019	11	11,111	$131,079	10,530
	Jan 2019	11	12,115	$139,845	11,255

TABLE D: TOP 10 DRUG CATEGORIES BY DOLLARS PAID IN MAR 2019 (FFS AND CCOs)

Category	Month Year	Rank Paid Amt	# RXs	$ Paid	# Unique Benes
CNS stimulants	Mar 2019	1	26,878	$5,676,225	23,525
	Feb 2019	1	25,972	$5,462,775	22,890
	Jan 2019	1	28,125	$5,886,166	24,408
atypical antipsychotics	Mar 2019	2	13,280	$3,037,371	11,581
	Feb 2019	3	12,737	$2,966,671	11,189
	Jan 2019	2	13,331	$2,965,017	11,484
antiviral combinations	Mar 2019	3	871	$2,913,632	789
	Feb 2019	5	771	$2,587,560	727
	Jan 2019	4	891	$2,741,692	804
insulin	Mar 2019	4	5,082	$2,786,284	3,792
	Feb 2019	4	4,713	$2,602,524	3,635
	Jan 2019	3	5,074	$2,756,509	3,750
TNF alpha inhibitors	Mar 2019	5	338	$1,889,391	319
	Feb 2019	6	322	$1,842,070	308
	Jan 2019	5	332	$1,920,859	304
factor for bleeding disorders	Mar 2019	6	86	$1,389,221	68
	Feb 2019	7	87	$1,511,863	72
	Jan 2019	7	96	$1,346,118	76
bronchodilator combinations	Mar 2019	7	3,799	$1,192,545	3,500
	Feb 2019	9	3,462	$1,071,746	3,237
	Jan 2019	9	3,808	$1,179,968	3,514
gamma-aminobutyric acid analogs	Mar 2019	8	8,921	$1,136,086	8,307
	Feb 2019	8	8,787	$1,201,068	8,296
	Jan 2019	8	9,324	$1,335,248	8,645
adrenergic bronchodilators	Mar 2019	9	15,530	$939,915	13,596
	Feb 2019	10	15,605	$919,835	13,852
	Jan 2019	11	16,768	$1,004,684	14,739
immune globulins	Mar 2019	10	339	$927,619	248
	Feb 2019	11	361	$888,247	259
	Jan 2019	10	446	$1,150,918	274

TABLE E: TOP 25 DRUG MOLECULES
BY NUMBER OF CLAIMS IN MAR 2019 (FFS and CCOs)

Drug Molecule Therapeutic Category	Feb 2019 # Claims	Mar 2019 # Claims	Mar 2019 $ Paid	Mar 2019 # Unique Benes
amoxicillin / aminopenicillins	22,159	16,851	$216,169	16,538
albuterol / adrenergic bronchodilators	15,039	14,893	$746,060	13,114
montelukast / leukotriene modifiers	10,730	13,017	$218,082	12,773
cetirizine / antihistamines	9,995	11,981	$154,764	11,776
azithromycin / macrolides	16,828	10,548	$199,359	10,350
acetaminophen-hydrocodone / narcotic analgesic combinations	10,036	10,462	$142,800	9,811
lisdexamfetamine / CNS stimulants	8,633	8,886	$2,577,775	8,677
fluticasone nasal / nasal steroids	7,203	8,500	$140,462	8,445
gabapentin / gamma-aminobutyric acid analogs	7,336	7,446	$114,457	6,980
ibuprofen / nonsteroidal anti-inflammatory agents	10,359	7,328	$89,058	7,173
oseltamivir / neuraminidase inhibitors	38,295	7,044	$701,707	6,999
ondansetron / 5HT3 receptor antagonists	9,886	6,650	$117,951	6,473
methylphenidate / CNS stimulants	6,297	6,435	$1,413,448	5,834
clonidine / antiadrenergic agents, centrally acting	6,049	6,326	$129,737	6,018
amphetamine-dextroamphetamine / CNS stimulants	5,898	6,234	$304,816	5,420
amlodipine / calcium channel blocking agents	6,001	6,087	$52,672	5,879
cefdinir / third generation cephalosporins	7,104	6,024	$137,436	5,942
amoxicillin-clavulanate / penicillins/beta-lactamase inhibitors	7,183	5,817	$130,633	5,742
prednisolone / glucocorticoids	6,156	5,665	$92,183	5,490
omeprazole / proton pump inhibitors	5,314	5,410	$55,318	5,287
ranitidine / H2 antagonists	4,075	4,338	$54,943	4,191
guanfacine / antiadrenergic agents, centrally acting	3,846	4,192	$117,212	3,949
triamcinolone topical / topical steroids	3,462	4,158	$74,133	4,046
sertraline / SSRI antidepressants	3,823	3,976	$45,959	3,737
atorvastatin / HMG-CoA reductase inhibitors (statins)	3,767	3,884	$43,942	3,693

TABLE F: TOP 25 DRUG MOLECULES
BY DOLLARS PAID IN MAR 2019 (FFS and CCOs)

Drug Molecule Therapeutic Category	Feb 2019 $ Paid	Mar 2019 $ Paid	Mar 2019 # Claims	Mar 2019 # Unique Benes
lisdexamfetamine / CNS stimulants	$2,508,221	$2,577,775	8,886	8,677
methylphenidate / CNS stimulants	$1,335,184	$1,413,448	6,435	5,834
adalimumab / TNF alpha inhibitors	$1,316,129	$1,395,765	233	216
paliperidone / atypical antipsychotics	$1,146,172	$1,118,498	519	480
dexmethylphenidate / CNS stimulants	$926,630	$968,240	3,563	2,996
insulin aspart / insulin	$818,483	$897,219	1,464	1,385
insulin glargine / insulin	$799,039	$808,789	1,782	1,711
deferasirox / chelating agents	$614,035	$802,777	69	66
albuterol / adrenergic bronchodilators	$750,578	$746,060	14,893	13,114
pregabalin / gamma-aminobutyric acid analogs	$724,157	$738,017	1,449	1,399
oseltamivir / neuraminidase inhibitors	$4,077,647	$701,707	7,044	6,999
palivizumab / immune globulins	$711,423	$666,939	304	225
sofosbuvir-velpatasvir / antiviral combinations	$598,673	$655,348	37	35
aripiprazole / atypical antipsychotics	$598,427	$651,104	3,281	3,078
antihemophilic factor / factor for bleeding disorders	$399,696	$638,551	29	19
cobicistat/elvitegravir/emtricitabine/tenofov / antiviral combinations	$503,564	$597,230	207	188
corticotropin / corticotropin	$311,439	$584,044	11	8
lurasidone / atypical antipsychotics	$490,039	$511,932	382	367
hydroxyprogesterone / progestins	$404,979	$507,439	158	148
fluticasone-salmeterol / bronchodilator combinations	$463,426	$506,978	1,323	1,289
somatropin / growth hormones	$495,598	$505,368	130	120
bictegravir/emtricitabine/tenofovir / antiviral combinations	$433,818	$467,928	166	157
budesonide-formoterol / bronchodilator combinations	$414,677	$455,106	1,382	1,357
insulin detemir / insulin	$421,823	$452,767	847	809
etanercept / TNF alpha inhibitors	$469,101	$436,084	94	93

TABLE G: TOP 25 DRUG MOLECULES
BY CHANGE IN NUMBER OF CLAIMS FROM JAN 2019 TO MAR 2019 (FFS and CCOs)

Drug Molecule	Jan 2019 # Claims	Feb 2019 # Claims	Mar 2019 # Claims	Mar 2019 $ Paid	Mar 2019 # Unique Benes
cetirizine / antihistamines	10,324	9,995	11,981	$154,764	11,776
montelukast / leukotriene modifiers	11,719	10,730	13,017	$218,082	12,773
fluticasone nasal / nasal steroids	7,433	7,203	8,500	$140,462	8,445
olopatadine ophthalmic / ophthalmic antihistamines and decongestants	644	620	1,200	$30,713	1,190
polymyxin b-trimethoprim ophthalmic / ophthalmic anti-infectives	869	1,024	1,158	$18,131	1,156
triamcinolone topical / topical steroids	4,034	3,462	4,158	$74,133	4,046
crisaborole topical / miscellaneous topical agents	209	250	321	$199,390	319
mometasone topical / topical steroids	847	727	946	$23,814	928
apixaban / factor Xa inhibitors	510	527	605	$239,416	567
dexamethasone/neomycin/polymyxin b ophthalmic / ophthalmic steroids with anti-infectives	441	489	519	$10,813	511
ciprofloxacin-dexamethasone otic / otic steroids with anti-infectives	1,155	1,138	1,223	$287,468	1,203
mupirocin topical / topical antibiotics	3,115	2,848	3,178	$49,816	3,122
quetiapine / atypical antipsychotics	3,156	3,031	3,219	$57,932	2,876
erythromycin ophthalmic / ophthalmic anti-infectives	416	384	476	$9,631	470
epinephrine / adrenergic bronchodilators	500	490	554	$162,944	548
beclomethasone / inhaled corticosteroids	341	329	395	$81,544	389
rizatriptan / antimigraine agents	401	391	455	$8,919	440
trazodone / phenylpiperazine antidepressants	2,816	2,725	2,863	$32,259	2,721
ofloxacin ophthalmic / ophthalmic anti-infectives	163	200	209	$4,884	207
diclofenac topical / topical non-steroidal anti-inflammatories	391	386	436	$37,797	426
moxifloxacin ophthalmic / ophthalmic anti-infectives	331	351	376	$12,752	371
gentamicin ophthalmic / ophthalmic anti-infectives	567	574	610	$9,033	602
tobramycin ophthalmic / ophthalmic anti-infectives	176	228	217	$3,372	215
cromolyn ophthalmic / ophthalmic antihistamines and decongestants	16	40	54	$869	54
telmisartan / angiotensin II inhibitors	42	41	79	$1,877	76

TABLE H: TOP 25 DRUG MOLECULES
BY CHANGE IN AMOUNT PAID FROM JAN 2019 TO MAR 2019 (FFS and CCOs)

Drug Molecule	Jan 2019 $ Paid	Feb 2019 $ Paid	Mar 2019 $ Paid	Mar 2019 # Claims	Mar 2019 # Unique Benes
corticotropin / corticotropin	$389,278	$311,439	$584,044	11	8
deferasirox / chelating agents	$669,658	$614,035	$802,777	69	66
icatibant / miscellaneous cardiovascular agents	$97,580	$162,517	$227,512	4	2
emicizumab / factor for bleeding disorders	$83,575	$399,402	$213,336	9	9
nusinersen / miscellaneous uncategorized agents	$0	$250,008	$125,008	1	1
glecaprevir-pibrentasvir / antiviral combinations	$257,777	$335,110	$373,777	29	28
crisaborole topical / miscellaneous topical agents	$131,945	$155,022	$199,390	321	319
ivacaftor-tezacaftor / CFTR combinations	$224,799	$202,338	$292,177	14	13
antihemophilic factor / factor for bleeding disorders	$571,691	$399,696	$638,551	29	19
cysteamine / miscellaneous uncategorized agents	$99,780	$104,651	$162,374	2	2
regorafenib / VEGF/VEGFR inhibitors	$40,308	$84,591	$93,079	6	6
sofosbuvir/velpatasvir/voxilaprevir / antiviral combinations	$0	$24,928	$49,857	2	2
immune globulin intravenous / immune globulins	$11,923	$8,833	$61,212	7	4
ixekizumab / interleukin inhibitors	$20,680	$26,262	$69,842	7	6
sofosbuvir-velpatasvir / antiviral combinations	$607,593	$598,673	$655,348	37	35
cannabidiol / miscellaneous anticonvulsants	$52,392	$63,230	$99,939	43	41
immune globulin intravenous and subcutaneous / immune globulins	$118,987	$145,043	$166,527	21	13
lanadelumab / factor for bleeding disorders	$0	$44,198	$44,198	1	1
alpha 1-proteinase inhibitor / miscellaneous respiratory agents	$10,137	$35,547	$50,753	5	4
apixaban / factor Xa inhibitors	$201,298	$211,550	$239,416	605	567
tofacitinib / antirheumatics	$88,005	$83,016	$122,280	28	28
bictegravir/emtricitabine/tenofovir / antiviral combinations	$435,013	$433,818	$467,928	166	157
insulin detemir / insulin	$421,679	$421,823	$452,767	847	809
dupilumab / interleukin inhibitors	$63,001	$76,971	$93,982	32	29
axitinib / multikinase inhibitors	$0	$0	$30,281	2	2

TABLE I: TOP 15 DRUG SOLID DOSAGE FORM HIGH VOLUME (100+ RX FILLS LAST MONTH) PRODUCTS WITH UNIT COST > $1
BY PERCENT CHANGE IN AMOUNT PAID PER UNIT JAN 2019 TO MAR 2019 (FFS and CCOs)

Drug Product Therapeutic Category	Mar 2019 # Claims	Mar 2019 $ Paid	Mar 2019 Avr. Paid Per Rx	Mar 2019 Avr. Units Per Rx	Jan 2019 Paid Per Unit	Feb 2019 Paid Per Unit	Mar 2019 Paid Per Unit	Percent Change
dexmethylphenidate 20 mg capsule, extended release / CNS stimulants (N)	102	$14,485	$142.01	30	$3.81	$4.25	$4.31	13.0%
Entresto (sacubitril-valsartan) 24 mg-26 mg tablet / angiotensin receptor blockers and neprilysin inhibitors (P)	112	$56,131	$501.17	58	$7.49	$8.01	$8.09	8.1%
amphetamine-dextroamphetamine 25 mg capsule, extended release / CNS stimulants (P)	325	$20,976	$64.54	30	$1.63	$1.69	$1.75	7.5%
amphetamine-dextroamphetamine 30 mg capsule, extended release / CNS stimulants (P)	740	$47,652	$64.39	30	$1.66	$1.77	$1.76	6.1%
methylphenidate 36 mg/24 hr tablet, extended release / CNS stimulants (P)	1,157	$298,061	$257.62	38	$6.11	$6.10	$6.45	5.4%
methylphenidate 30 mg/24 hours capsule, extended release / CNS stimulants (P)	108	$11,383	$105.40	30	$2.95	$3.05	$3.10	5.0%
Lyrica (pregabalin) 150 mg capsule / gamma-aminobutyric acid analogs (P)	367	$191,475	$521.73	69	$7.13	$7.40	$7.39	3.7%
amphetamine-dextroamphetamine 20 mg capsule, extended release / CNS stimulants (P)	749	$46,681	$62.32	30	$1.62	$1.68	$1.67	3.5%
Focalin XR (dexmethylphenidate) 40 mg capsule, extended release / CNS stimulants (P)	151	$65,634	$434.66	30	$13.64	$14.11	$14.11	3.5%
Lyrica (pregabalin) 75 mg capsule / gamma-aminobutyric acid analogs (P)	353	$175,778	$497.95	64	$7.13	$7.37	$7.38	3.4%
Lyrica (pregabalin) 100 mg capsule / gamma-aminobutyric acid analogs (P)	268	$142,638	$532.23	72	$7.12	$7.39	$7.36	3.4%
clonidine 0.1 mg/12 hr tablet, extended release / antiadrenergic agents, centrally acting (N)	219	$35,720	$163.10	74	$1.99	$2.03	$2.05	3.2%

Products are only included if 100 or more fills in last month and average cost per unit in reference month was >= $1.

TABLE I: TOP 15 DRUG SOLID DOSAGE FORM HIGH VOLUME (100+ RX FILLS LAST MONTH) PRODUCTS WITH UNIT COST > $1
BY PERCENT CHANGE IN AMOUNT PAID PER UNIT JAN 2019 TO MAR 2019 (FFS and CCOs)

Drug Product Therapeutic Category	Mar 2019 # Claims	Mar 2019 $ Paid	Mar 2019 Avr. Paid Per Rx	Mar 2019 Avr. Units Per Rx	Jan 2019 Paid Per Unit	Feb 2019 Paid Per Unit	Mar 2019 Paid Per Unit	Percent Change
Lyrica (pregabalin) 50 mg capsule / gamma-aminobutyric acid analogs (P)	159	$81,756	$514.19	67	$7.18	$7.37	$7.41	3.2%
Focalin XR (dexmethylphenidate) 25 mg capsule, extended release / CNS stimulants (P)	209	$85,619	$409.66	30	$12.91	$13.32	$13.33	3.2%
colchicine 0.6 mg capsule / antigout agents (P)	127	$20,111	$158.35	35	$3.84	$3.88	$3.96	3.1%

Products are only included if 100 or more fills in last month and average cost per unit in reference month was >= $1.

New Business

Special Analysis Projects

MISSISSIPPI DIVISION OF MEDICAID

MS-DUR INTERVENTION / EDUCATIONAL MAILING UPDATE

FEBRUARY 2019 – APRIL 2019

Ongoing Mailings:

HIGH MEDD (≥90 MEDD) MAILING Initiated Sept 2016			CONCOMITANT BENZODIAZEPINE / OPIOID USE Initiated Feb 2017		PROVIDER SHOPPING FOR OPIOIDS (≥4 Prescribers AND ≥4 Pharmacies) Initiated Nov 2017		
Month	**Prescribers Mailed**	**Benes Addressed**	**Prescribers Mailed**	**Benes Addressed**	**Prescribers Mailed**	**Pharms Mailed**	**Benes Addressed**
18-May	*20	*21	150	*187	48	34	85
18-Jun	*31	*40	150	*283	*31	*18	*53
18-Jul	48	56	150	323	*33	*26	*65
18-Aug	35	53	150	405	48	34	83
18-Sep	41	50	150	292	36	31	67
18-Oct	33	45	150	321	39	30	74
18-Nov	*19	*25	150	*232	43	31	77
18-Dec	-	-	150	338	*21	*17	38
19-Jan	37	48	150	276	28	22	50
19-Feb	21	29	150	267	29	25	56
19-Mar	**68	**89	150	249	27	22	49
19-Apr	45	72	150	252	20	16	36

Notes:
Began excluding sickle cell diagnosis in Oct 2018
* Data for CCOs was incomplete at the time the mailing was run
** Revised and updated MEDD calculation method incorporated into analysis

One-time Mailing:

METABOLIC MONITORING OF CHILDREN AND ADOLESCENTS PRESCRIBED ANTIPSYCHOTICS	
	Prescribers Mailed
19-Apr	116

UPDATE ON MAKENA UTILIZATION IN MISSISSIPPI MEDICAID

BACKGROUND

According to the Mississippi State Department of Health, preterm birth (delivery before 37 weeks of pregnancy) is the leading cause of infant death in Mississippi. Infants born preterm are at an increased risk of breathing complications, infections and brain injury. Preterm labor and prenatal complications from hypertension and other maternal medical conditions are the leading causes of preterm birth in Mississippi. In 2017, 13.6% of infants were born preterm in Mississippi compared to 9.9% for the United States. The average medical cost for a healthy term baby is $4,551, while the average medical cost for a preterm baby is $49,003.[1]

Makena® (hydroxyprogesterone caproate) is a progestin indicated to reduce the risk of preterm birth in women with a history of singleton child spontaneous preterm birth.[2] Makena was approved by the U.S. Food and Drug Administration (FDA) in February 2011.[3] Makena was granted orphan drug exclusivity through February 2018. Prior to its approval, a compounded version of the active ingredient, 17-hydroxyprogesterone caproate (17P), was available to Medicaid beneficiaries whose physician requested the drug through compounding pharmacies. In June 2012, following the release of Makena, the FDA released an updated statement on the compounding of 17P.[4] In its statement, the FDA recommended using an FDA-approved drug product, such as Makena, instead of a compounded drug except when there is a specific medical need (e.g., an allergy) that cannot be met by the approved drug. The FDA is not aware of any scientifically reliable evidence demonstrating that compounding 17P without a preservative or in an oil base different than the one used in Makena produces a significant difference for an identifiable group of patients (aside from the rare patient who is known to be allergic to either the preservative or the oil base). Currently, the MS Division of Medicaid (DOM) does not cover for compounded prescriptions except for hyperalimentation, as defined in DOM's Administrative Code.[5]

From 2011 until early 2018, the only hydroxyprogesterone caproate products commercially available in the U.S. were the Makena 250mg/ml single-dose or multi-dose vials. In February 2018, AMAG pharmaceuticals announced FDA approval of Makena 275mg subcutaneous auto-injector as a ready-to-administer treatment. According to the manufacturer, this new formulation contains a

[1] Mississippi State Department of Health Infant Mortality Report 2018. https://msdh.ms.gov/msdhsite/_static/resources/8015.pdf Accessed April 2019.
[2] Makena [package insert]. AMAG Pharmaceuticals, Waltham, MA; Accessed April 2019.
[3] U.S. Food and Drug Administration. FDA Statement on Makena. March 2011. Accessed March 2018.
[4] U.S. Food and Drug Administration. Updated FDA Statement on Compounded Version of Hydroxyprogesterone Caproate (the Active Ingredient in Makena). https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm402614.htm June 2012. Accessed March 2018.
[5] MS-DOM Administrative Code Part 214. https://medicaid.ms.gov/wp-content/uploads/2014/01/Admin-Code-Part-214.pdf. Accessed May 2018.

short, thin, non-visible needle for subcutaneous use, offering patients and providers a new administration option.[6] In June 2018, American Regent Pharmaceuticals announced the launch of hydroxyprogesterone caproate injection, USP, the first preservative free generic alternative to Makena. It is available in a 250mg single-dose vial.[7] For the purposes of this report and since brand Makena is utilized almost exclusively in Medicaid, the term Makena will be used to refer to all hydroxyprogesterone caproate products.

DOM has taken numerous steps to improve access to Makena. Although Makena has been covered by Medicaid since it was FDA approved, it was listed in the Universal Preferred Drug List (UPDL) starting April 2017 when Makena was added as a preferred product in the Miscellaneous Brand/Generic category to prevent access barriers. Currently brand Makena is still the preferred agent for use on DOM's UPDL. In 2018 DOM took additional steps to improve beneficiary access to Makena and other injectable products by obtaining approval from the Centers for Medicare and Medicaid Services (CMS) to allow certain injectable drugs to be billed and reimbursed as either a medical claim or a point-of-sale (POS) claim. The Clinician Administered Drugs and Implantable Drug System Devices (CADD) list became effective July 1, 2018.

In spring 2018 MS-DUR conducted an evaluation of Makena utilization and potential issues related to access. This analysis was reported at the DUR Board's May 31, 2018 meeting. The report concluded that access delays or difficulties experienced most often occurred during the ordering process. At that time Makena was a limited-distribution specialty pharmaceutical product with a specific process in place for obtaining the product. The manufacturer's program, Makena Care Connection, provides patient support and helps ensure timely access to Makena therapy. One potential barrier to access noted in the report was provider unfamiliarity with the manufacturer's process for obtaining Makena. Another barrier noted by the manufacturer and specialty pharmacies which dispensed Makena was difficulty contacting beneficiaries before approving product shipment. Following the May 2018 Board meeting, the DUR Board Report has been shared both within DOM and externally with the MS State Department of Health. Multiple groups are working to assess and improve beneficiary access to Makena.

For this report, MS-DUR updated the analyses presented in the May 2018 Board report to also include additional data examining the impact of the CADD list on Makena prescribing.

METHODS

MS-DUR conducted a retrospective analysis of Makena utilization among Mississippi Medicaid beneficiaries using Mississippi Medicaid FFS and CCO pharmacy and medical claims from January 1, 2017 through December 31, 2018. This analysis updates the report presented at the May 2018 DUR Board Meeting, and it also specifically examines the impact on Makena access after the July 1, 2018 CADD list implementation.

[6] AMAG Pharmaceuticals Press Release February 14, 2018. Accessed April 2019.
[7] American Regent Press Release Junes 25, 2018. Accessed April 2019.

RESULTS

Table 1 displays the total number of paid claims for Makena by billing type from January 2017 – December 2018.

- Although Makena claims were allowed to be billed as either Medical or POS claims prior to implementation of the CADD List, promotion of the CADD List likely increased awareness surrounding the billing of Makena.
- Average number of monthly paid claims for Makena increased from an average **199** claims monthly before implementation of the CADD List to an average **240** claims monthly after implementation, a **20.6%** increase**.**
- As expected, there has also been a shift in billing type. While Medical claims are still being paid for Makena, average monthly POS claims have increased **50%** since implementation of the CADD list.

TABLE 1: Number of Paid Claims for Makena by Billing Type

Claim Month	TOTAL		Medicaid Program							
			FFS		UHC		MAG		MOL	
	Medical	POS	Medical	POS	Medical	POS	Medical	POS	Medical	POS
Jan 17	121	26	10	0	23	0	88	26	0	0
Feb 17	119	24	7	0	27	0	85	24	0	0
Mar 17	143	26	11	0	51	0	81	26	0	0
Apr 17	101	42	20	1	13	17	68	24	0	0
May 17	98	87	12	5	19	35	67	47	0	0
Jun 17	77	91	10	10	15	42	52	39	0	0
Jul 17	82	90	11	12	13	38	58	40	0	0
Aug 17	84	115	15	20	13	50	56	45	0	0
Sep 17	72	105	12	12	10	55	50	38	0	0
Oct 17	72	116	3	16	5	55	64	45	0	0
Nov 17	88	101	17	16	4	47	67	38	0	0
Dec 17	94	97	9	16	16	43	69	38	0	0
Jan 18	145	95	11	12	57	35	77	48	0	0
Feb 18	136	115	15	17	54	50	67	48	0	0
Mar 18	130	145	17	15	48	63	65	67	0	0
Apr 18	128	148	9	13	52	77	67	58	0	0
May 18	112	141	8	9	40	68	64	64	0	0
Jun 18	103	110	10	14	34	47	59	49	0	0
Jul 18	111	149	20	26	34	60	57	63	0	0
Aug 18	106	145	9	21	40	72	57	52	0	0
Sep 18	104	125	6	11	47	54	51	60	0	0
Oct 18	111	149	15	17	59	61	32	56	5	15
Nov 18	69	139	5	19	38	51	18	47	8	22
Dec 18	99	131	0	9	54	42	29	48	16	32
TOTAL	2505	2512	262	291	766	1062	1448	1090	29	69

* Due to lag in medical claims submission by providers and reporting of medical claims by CCOs, data for November and December may be incomplete.

MS-DUR specifically analyzed new prescriptions written for Makena initiation (new starts) in pregnant women. Table 2 shows the number of beneficiaries initiating Makena therapy since January 2017.

- The number of monthly "new starts" has increased from an average of 44 beneficiaries monthly to an average of 52 beneficiaries monthly since the implementation of the CADD list, representing an **18%** increase in new starts monthly.
- Although during the first 2 months following implementation of the CADD List there was a substantial increase in new starts, numbers appear to have leveled off in later months.
- Due to the lag time in receiving medical claims data, numbers reported for November and December 2018 may be incomplete.

TABLE 2: Number of Beneficiaries Initiating Makena Therapy (January 2107 - December 2018)

Month Initiating Therapy	Medicaid Program				
	Total	FFS	UHC	MAG	MOL
Jan-17	74	5	19	50	0
Feb-17	33	5	12	16	0
Mar-17	40	4	16	20	0
Apr-17	30	8	12	10	0
May-17	44	4	16	24	0
Jun-17	42	14	13	15	0
Jul-17	41	12	11	18	0
Aug-17	53	19	19	15	0
Sep-17	41	10	17	14	0
Oct-17	43	13	10	20	0
Nov-17	49	19	15	15	0
Dec-17	52	12	20	20	0
Jan-18	49	11	17	21	0
Feb-18	50	11	24	15	0
Mar-18	52	13	16	23	0
Apr-18	50	13	26	11	0
May-18	40	8	13	19	0
Jun-18	40	12	14	14	0
Jul-18	60	18	17	25	0
Aug-18	65	19	26	20	0
Sep-18	43	9	15	19	0
Oct-18	57	20	15	14	8
Nov-18	45	10	14	13	8
Dec-18	42	7	6	18	11
Total	***1135***	***276***	***383***	***449***	***27***

Notes:
- There was no look-back into 2016, therefore initiation values for Jan-17 represent all claims for Makena that month.
- Due to the lag time in receiving medical claims data, numbers reported for November and December 2018 may be incomplete.

Table 3 provides utilization data for beneficiaries initiating Makena from June 2017 – August 2018. If treatment is started at the earliest time indicated in Makena labeling (16 weeks) and given for the maximum recommended period of time (through 37weeks), a beneficiary could receive up to 21 doses. As shown in Table 3, women treated with Makena averaged 12.6 weeks of treatment.

TABLE 3: Utilization Summary of Beneficiaries Intiating Treatment in POS With Makena (Initiated from June 2017-August 2018)

		Pharmacy Program				
		FFS	UHC	MAG	MOL	Total
TOTAL number of beneficiaries		33	205	198	1	437
Number of Prescription Fills	1	21	26	43	0	90
	2	7	43	30	0	80
	3	2	44	27	1	74
	4	1	47	52	0	100
	5	2	38	45	0	85
	6+	0	7	1	0	8
Number of Doses Dispensed	3 - 5	21	26	43	0	90
	6 - 10	7	44	30	0	81
	11 - 15	2	47	28	1	78
	16 - 21	3	76	90	0	169
	22 or more	0	12	7	0	19
	Mean	6.8	13.3	12.8	13.2	12.6
Age At Initiation of Makena Therapy	16 - 20 years old	3	14	11	0	28
	21 - 25 years old	16	79	60	0	155
	26 - 30 years old	8	62	70	0	140
	31 - 35 years old	3	37	45	1	86
	36 - 40 years old	2	12	11	0	25
	41 or more years old	1	1	1	0	3

Note: 1. Initiation of Makena was analyzed between June 2017 to August 2018 in order to ensure no Makena use occurred outside of the observation period.
2. The maximum duration for Makena utilization for each beneficiary was 21 weeks after initiation..
3. Beneficiaries with Medical claims for Makena were excluded. Benefeiciaries who had dual Medical and POS claims for Makena were also excluded.
4. Pharmacy program was assigned based on program beneficiary was in at the time of the last fill.

Table 4 shows the dollars paid for Makena claims by payment type from January 2017 – December 2018 and is broken down into 6 month increments.

- Paid claims totals have increased every 6 month period since January 2017.
- Increases in POS paid claims accounted for the majority of total spend increases over the 2 year period.

TABLE 4: Total Paid for Makena Claims by Payment Type

Period	Payment Type		Total
	Medical	POS	
Jan-Jun 2017	$258,419	$908,633	$1,167,052
Jul-Dec 2017	$292,678	$1,924,321	$2,216,998
Jan-Jun 2018	$359,065	$2,397,654	$2,756,720
Jul-Dec 2018	$232,428	$2,678,303	$2,910,731

*Due to the lag time in receiving medical claims data, numbers reported for November and December 2018 may be incomplete.

Tables 5-a/b show the number of prescription claims filled by each pharmacy for 2017 and 2018.

- Noble Health Services, formerly Transcript Pharmacy, filled the vast majority of Makena claims in both years. Noble Health Services has been designated by the manufacturer of Makena, AMAG Pharmaceuticals, as the preferred pharmacy for distributing Makena in Mississippi.
- Comparing pharmacy claims from 2017 to 2018, there were a total of 701 more paid pharmacy claims in 2018, a **75%** increase from the prior year.
- **91%** of paid pharmacy claims during 2017 and 2018 can be attributed to 4 pharmacies (Noble Health Services, BriovaRx, Acariahealth Pharmacy, and F&M Specialty Pharmacy)

TABLE 5-a: Number of Makena Claims Filled by Pharmacies (2017)

	Pharmacy Program				
Pharmacy	FFS	UHC	MAG	MOL	Total
Noble Health Services Inc - Flowood, Ms	85	150	158	0	393
Acariahealth Pharmacy Inc - Slidell, La	3	0	208	0	211
Briovarx Llc - Columbus, Ms	3	197	10	0	210
Caremark Inc - Bartlett, Tn	4	2	17	0	23
Accredo Health Group Inc - Memphis, Tn	4	2	14	0	20
Picayune Drug Co Inc - Picayune, Ms	1	8	0	0	9
Walgreens # 11599 - Columbus, Ms	0	3	6	0	9
Freds Westside Pharmacy Inc - Picayune, Ms	3	1	4	0	8
Walgreens Specialty Pharmacy L - Pitsburgh, Pa	1	0	5	0	6
Medicaid Provider Number 01370783	5	0	0	0	5
Freds Stores Of Tennessee Inc - Poplarville, Ms	0	0	5	0	5
Loves Pharmacy Inc - Ocean Springs, Ms	0	4	0	0	4
Proxsys Rx-Rush, Llc - Ocean Springs, Ms	0	4	0	0	4
Reeves Sain Drug Store Inc - Columbus, Ms	0	3	0	0	3
Polks Crossgates Discounts Dru - Biloxi, Ms	0	2	0	0	2
Wal Mart Pharmacy 10-1346 - Ocean Springs, Ms	0	0	2	0	2
Walgreens Specialty Pharmacy - Frisco, Tx	0	2	0	0	2
Bioscrip Pharmacy Inc - Memphis, Tn	0	1	0	0	1
Wal-Mart Stores East Lp - Picayune, Ms	0	0	1	0	1
Pharmacy ID missing on claim	0	5	11	0	16

TABLE 5-b: Number of Makena Claims Filled by Pharmacies (2018)

	Pharmacy Program				
Pharmacy	FFS	UHC	MAG	MOL	Total
Noble Health Services Inc - Flowood, Ms	170	362	622	70	1224
F And M Specialty Pharmacy, In - Flowood, Ms	2	182	0	0	184
Briovarx Llc - Columbus, Ms	2	120	6	0	128
Freds Westside Pharmacy Inc - Picayune, Ms	2	6	10	0	18
Caremark Inc - Bartlett, Tn	8	3	4	0	15
Walgreens # 11599 - Columbus, Ms	2	5	4	1	12
Acariahealth Pharmacy Inc - Slidell, La	0	0	11	0	11
Medicaid Provider Number 00034747	0	0	5	0	5
Thrift Drugs Inc - Mccomb, Ms	0	5	0	0	5
Accredo Health Group Inc - Memphis, Tn	0	4	0	0	4
Picayune Drug Co Inc - Picayune, Ms	0	0	0	3	3
Wal-Mart Stores East Lp - Picayune, Ms	0	2	1	0	3
Wal-Mart Stores East, Lp - Gulfport, Ms	0	0	3	0	3
Walgreens Specialty Pharmacy - Frisco, Tx	0	3	0	0	3
Magic Mart Pharmacy Inc - Indianola, Ms	0	0	2	0	2
Reeves Sain Drug Store Inc - Columbus, Ms	0	2	0	0	2
Sartin Discount Drug's Inc - Gulfport, Ms	0	2	0	0	2
Fred's Pharmacy #1136 - Batesville, Ms	0	1	0	0	1
Gunn Drug Co Inc - Corinth, Ms	0	1	0	0	1
Polks Crossgates Discounts Dru - Biloxi, Ms	0	1	0	0	1
Wal Mart Pharmacy 10-1346 - Ocean Springs, Ms	0	1	0	0	1
Walgreens #07517 - Jackson, Ms	0	0	1	0	1
Walmart Pharmacy 10-903 - Jackson, Ms	1	0	0	0	1
Pharmacy ID missing on claim	0	0	0	0	5

Figures 1-4 provide a geographical representation of preterm births in MS and Makena utilization.

Figure 1 depicts the number of preterm births in Mississippi for 2017 according to the county level live birth statistics reported by the Mississippi State Department of Health.[8] Exact figures can be found in Appendix A.

- As expected, the most populated counties in Mississippi (Hinds, Rankin, Jackson, Harrison, and Desoto) had the highest total numbers of preterm births.

Figure 2 depicts preterm birth rates by percent of total births for each county.

- The Mississippi average preterm birth rate is 13.6% compared to 9.9% nationally. It should be noted the counties with the highest preterm birth rates, Issaquena (33.3%) and Jefferson (21.65%), both had very low numbers of total births.
- There appears to be clusters in the South-Central, Delta, and Northeast regions with higher preterm birth rates.

Figure 1. Number of Preterm Births in Mississippi in 2017

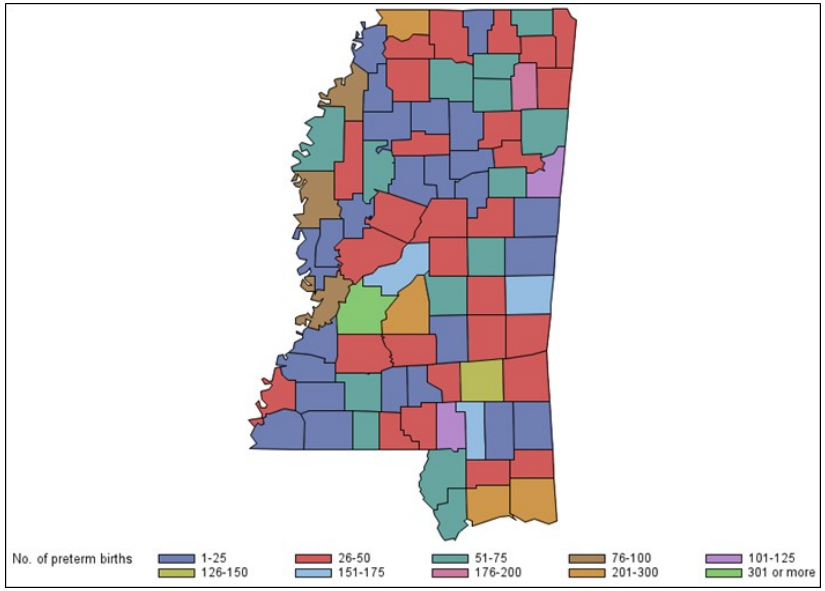
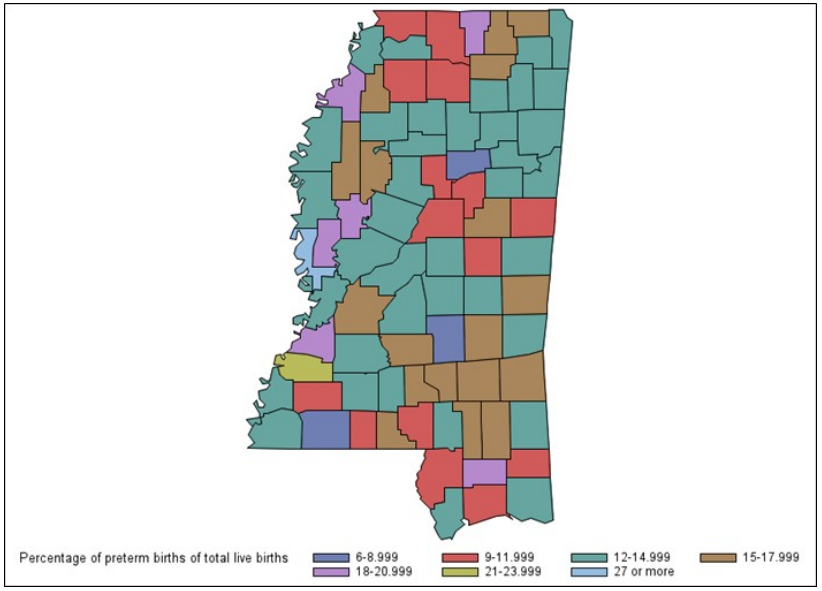


Figure 2. Percent Preterm Births Compared to Total Births in Mississippi in 2017

* No county had a preterm birth rate below 6%



[8] Mississippi State Department of Health. Live Birth Statistics 2017. https://msdh.ms.gov/phs/2017/Summary/bthsumm_cnty_2017.pdf. Accessed April 2019

Figure 3 depicts the number of beneficiaries by county with paid Makena claims between January 2017 and December 2018. This data is taken from Table 1 presented on page 25. These claims include both medical and POS claims. The location of each beneficiary was assigned according the county of residence listed for each beneficiary in claims data.

- Issaquena and Greene counties were the only two counties with no Medicaid beneficiaries having claims for Makena in 2017 and 2018.
- The counties with the highest number of beneficiaries with Makena claims were: Coahoma, Forrest, Harrison, Hinds, and Lee.

Figure 3. Number of Beneficiaries by County with Makena Claims between Jan 2017 - Dec 2018

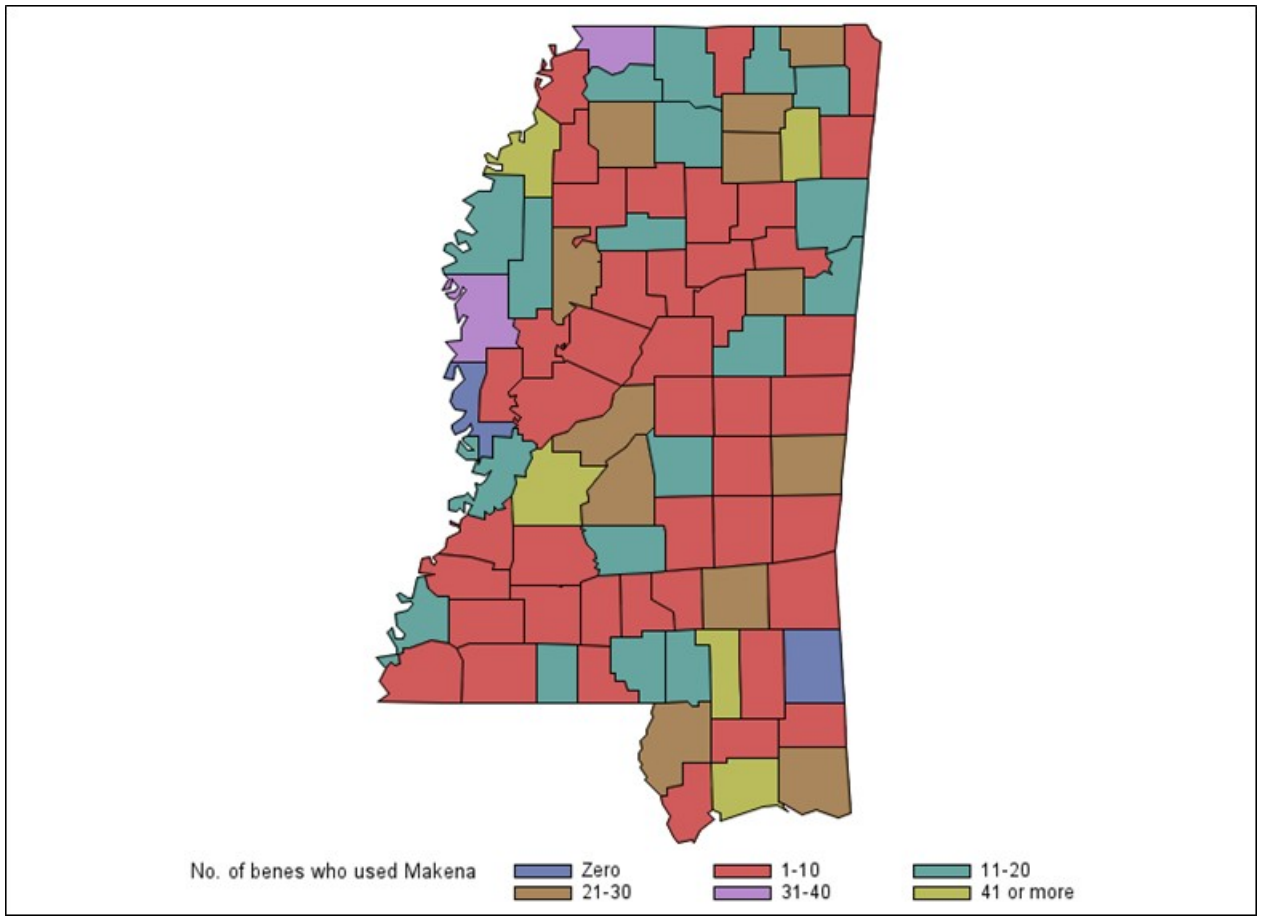


Figure 4 shows the number of beneficiaries initiated on Makena therapy by the county location of their providers between January 2017 and December 2018. This figure does not show where beneficiaries live, but the location of providers who are prescribing Makena. Exact figures are shown in Table 6.

- Forrest county and Hinds county providers initiated the most beneficiaries on Makena.
- **51** counties had no providers initiate Makena therapy.
- Majority of Makena prescribing is associated with larger population counties where specialized healthcare is available.

Figure 4. Number of Beneficiaries Initiated on Makena by County of Provider

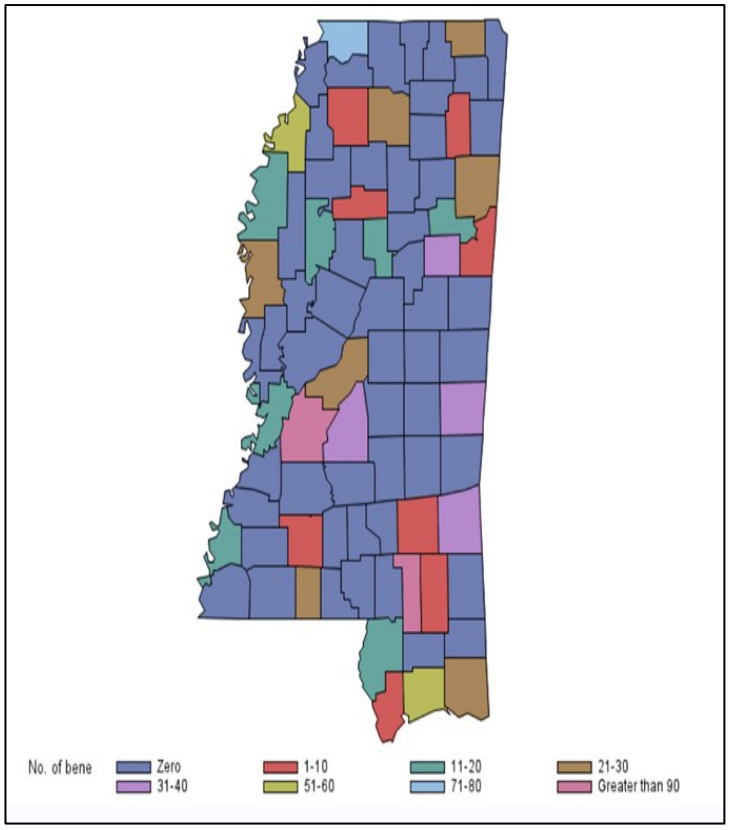


TABLE 6: Total Number of Beneficiaries Initiating Makena by County of Provider (January 1, 2017 – December 31, 2018)

County	Total number of beneficiaries initiating Makena
Hancock	2
Perry	2
Panola	3
Grenada	4
Jones	7
Lowndes	7
Lincoln	8
Lee	9
Pearl river	11
Clay	13
Montgomery	15
Adams	17
Alcorn	17
Bolivar	19
Monroe	19
Warren	19
Leflore	20
Madison	21
Pike	21
Washington	24
Jackson	26
Lafayette	29
Oktibbeha	37
Rankin	37
Lauderdale	38
Wayne	40
Harrison	54
Coahoma	58
Desoto	73
Hinds	97
Forrest	100

**Only POS claims for providers in Mississippi are represented.*

CONCLUSIONS AND RECOMMENDATIONS

Results from this project indicate that the utilization of Makena has increased over the past two years. DOM, the Mississippi State Department of Health, and multiple other agencies continue to work to improve access to Makena. Specifically, DOM initiated the CADD List in 2018 to help increase access to Makena.

With Mississippi leading the nation in preterm birth rates, there is more work that needs to be done. Educating providers and beneficiaries on the potential benefits of Makena is of paramount importance. Data shows all counties in Mississippi have individuals (women) who have experienced a preterm birth in the last 2 years and every county, with the exception of two, have Medicaid beneficiaries who have been prescribed Makena during 2017-2018. However, 51 counties in Mississippi did not have a provider initiate Makena during 2017-2018. This could indicate a potential barrier to Makena access. Another potential barrier to access could be the limited number of pharmacies which account for dispensing the majority of Makena in Mississippi. For providers who may not be familiar with the ordering process for Makena, not having a local pharmacy available to assist the provider in obtaining Makena may pose an additional hurdle.

Recommendations:

1. Results should be shared with other health service office directors within Mississippi Medicaid who are currently working to improve access to Makena and an active task force should be developed to address barriers. The results of this analysis should be presented to the MS State Department of Health's Infant Mortality Committee, other outside agencies, professional associations and healthcare organizations by DOM / MS-DUR.

2. MS-DUR should continue assisting in educating providers and beneficiaries about Makena. The ordering process can be confusing, particularly for those providers who may not routinely prescribe this medication. Provider education should highlight the ordering process and stress the need for patient education. Feedback from the DUR Board is recommended for the types of impactful education.

3. MS-DUR will work with DOM to assess health outcomes associated with beneficiaries who have received Makena. Specifically, beneficiary gestational weeks at delivery will be compared for pregnancy(s) prior to Makena use and pregnancy(s) with Makena use. Healthcare costs associated with each pregnancy will also be compared.

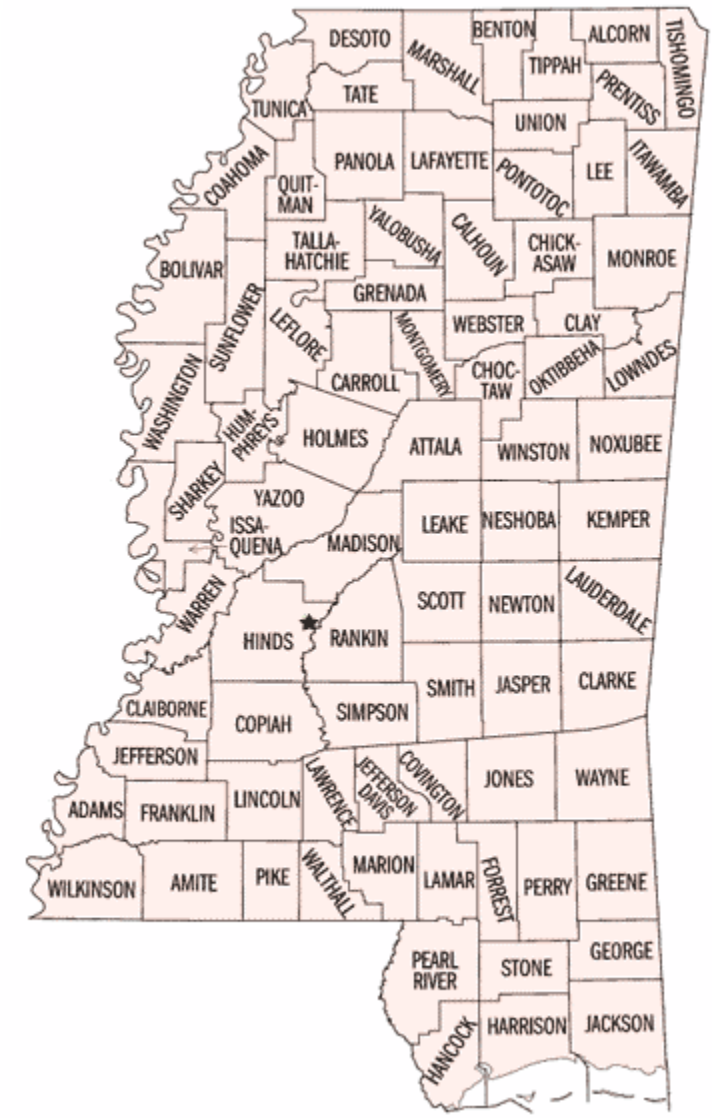
4. CCOs will be invited to present at the next DUR meeting their case management services for Mississippi Medicaid beneficiaries identified as high risk for preterm birth.

APPENDIX A

Mississippi Department of Health - Live Birth Statistics, 2017			
County	Preterm Births (<37 wks)	Total Births	Percent Preterm
Adams	48	358	13.41
Alcorn	65	423	15.37
Amite	8	133	6.02
Attala	28	236	11.86
Benton	20	109	18.35
Bolivar	67	451	14.86
Calhoun	22	159	13.84
Carroll	12	95	12.63
Chickasaw	34	239	14.23
Choctaw	9	92	9.78
Claiborne	23	111	20.72
Clarke	28	201	13.93
Clay	27	220	12.27
Coahoma	76	393	19.34
Copiah	49	333	14.71
Covington	41	261	15.71
Desoto	224	2,130	10.52
Forrest	155	1,014	15.29
Franklin	9	87	10.34
George	38	337	11.28
Greene	19	153	12.42
Grenada	38	261	14.56
Hancock	57	451	12.64
Harrison	285	2,679	10.64
Hinds	505	3,127	16.15
Holmes	31	236	13.14
Humphreys	18	96	18.75
Issaquena	5	15	33.33
Itawamba	30	245	12.24
Jackson	201	1,660	12.11
Jasper	30	188	15.96
Jefferson	21	97	21.65
Jeff Davis	21	127	16.54
Jones	150	863	17.38
Kemper	14	96	14.58
Lafayette	51	539	9.46
Lamar	105	834	12.59
Lauderdale	156	979	15.93
Lawrence	23	170	13.53
Leake	36	286	12.59
Lee	176	1,181	14.90

Mississippi Department of Health - Live Birth Statistics, 2017			
County	Preterm Births (<37 wks)	Total Births	Percent Preterm
Leflore	74	476	15.55
Lincoln	59	422	13.98
Lowndes	110	758	14.51
Madison	166	1,277	13.00
Marion	31	274	11.31
Marshall	45	388	11.60
Monroe	59	419	14.08
Montgome	14	131	10.69
Neshoba	54	451	11.97
Newton	45	312	14.42
Noxubee	20	192	10.42
Oktibbeha	71	591	12.01
Panola	50	493	10.14
Pearl	65	633	10.27
Perry	22	131	16.79
Pike	61	560	10.89
Pontotoc	56	419	13.37
Prentiss	43	295	14.58
Quitman	16	95	16.84
Rankin	232	1,733	13.39
Scott	66	489	13.50
Sharkey	14	72	19.44
Simpson	47	304	15.46
Smith	16	182	8.79
Stone	40	212	18.87
Sunflower	50	298	16.78
Tallahatchi	24	168	14.29
Tate	45	353	12.75
Tippah	46	278	16.55
Tishomingo	26	215	12.09
Tunica	25	181	13.81
Union	60	375	16.00
Walthall	29	178	16.29
Warren	89	610	14.59
Washingto	80	627	12.76
Wayne	41	268	15.30
Webster	9	110	8.18
Wilkinson	12	93	12.90
Winston	30	175	17.14
Yalobusha	23	154	14.94
Yazoo	44	313	14.06
TOTAL	2,955	21,665	13.64

APPENDIX B


DESOTO
MARSHALL
BENTON
ALCORN
TISHOMINGO
TIPPAH
PRENTISS
TUNICA
TATE
UNION
COAHOMA
PANOLA
LAFAYETTE
PONTOTOC
LEE
ITAWAMBA
QUIT-MAN
YALOBUSHA
CALHOUN
CHICK-ASAW
MONROE
TALLA-HATCHIE
BOLIVAR
GRENADA
SUNFLOWER
LEFLORE
MONTGOMERY
WEBSTER
CLAY
WASHINGTON
CARROLL
CHOC-TAW
OKTIBBEHA
LOWNDES
HUM-PHREYS
HOLMES
ATTALA
WINSTON
NOXUBEE
SHARKEY
YAZOO
LEAKE
NESHOBA
KEMPER
ISSA-QUENA
MADISON
SCOTT
NEWTON
LAUDERDALE
WARREN
HINDS
RANKIN
SMITH
JASPER
CLARKE
CLAIBORNE
COPIAH
SIMPSON
JEFFERSON
JEFFERSON DAVIS
COVINGTON
JONES
WAYNE
ADAMS
FRANKLIN
LINCOLN
LAWRENCE
WILKINSON
AMITE
PIKE
WALTHALL
MARION
LAMAR
FORREST
PERRY
GREENE
PEARL RIVER
STONE
GEORGE
HANCOCK
HARRISON
JACKSON

UPDATE ON CGRP INHIBITOR PRESCRIBING IN MISSISSIPPI MEDICAID

BACKGROUND

In 2018, a new class of medications, known as calcitonin gene-related peptide (CGRP) inhibitors, received FDA approval for the prevention of migraine headaches. [1] CGRP inhibitors are the first agents developed specifically for migraine prevention. CGRPs are vasoactive neuropeptides associated with pain whose levels are increased during a migraine. [2, 3] Monoclonal antibodies have been developed that target either CGRP or the CGRP receptor in the prevention migraines. Currently three monoclonal antibody CGRP inhibitors have been approved.

- Aimovig (erenumab-aooe) – approved May 17, 2018
- Ajovy (fremanezumab-vfrm) – approved September 14, 2018
- Emgality (galcanezumab-gnlm) – approved September 27, 2018[4]

With an estimated 39 million migraine sufferers in the U.S. annually, migraines are a serious public health issue. It is estimated that healthcare and lost productivity costs associated with migraines can be as high as $36 billion annually. [5] CGRP inhibitors have the potential to dramatically impact pharmacologic treatment approaches for migraine suffers.

At the September 2018 DUR Board Meeting, MS-DUR presented a report on the introduction of CGRP inhibitors for migraine prevention. The DUR Board provided recommendations for clinical criteria to be utilized by the Mississippi Division of Medicaid (DOM). The Board also recommended MS-DUR revisit this topic to assess the utilization of CGRP inhibitors in the spring of 2019. DOM implemented a manual prior authorization (PA) for CGRPs effective February 1, 2019 that can be found at https://medicaid.ms.gov/manual-prior-authorization-criteria/.

METHODS

A retrospective analysis was conducted using Mississippi Medicaid pharmacy and medical claims data across Fee-For-Service and the three coordinated care organizations [UnitedHealthcare (UHC), Magnolia Health (MAG), and Molina Healthcare (MOL)] for the period of May 2018 through February 2019. Pharmacy claims for three CGRP inhibitor agents [erenumab-aooe (Aimovig), fremanezumab-vfrm (Ajovy), and galcanezumab-gnlm)] were identified using their respective national drug codes (NDCs). For each CGRP inhibitor claim, the provider type was identified and

[1] FDA. FDA approves novel preventive treatment for migraine. May 2018. https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm608120.htm. Accessed April 2019.

[2] Minor, D, et al. Pharmacotherapy: A Pathophysiologic Approach [Internet]. 10th ed. New York (NY): McGraw-Hill; c2017. Chapter 61: Headache Disorders.

[3] Bigal, ME, et al. Migraine in the Triptan Era: Lessons from Epidemiology, Pathophysiology, and Clinical Science. Headache. 2009 Feb;49 Suppl 1:S21-33.

[4] Drugs.com https://www.drugs.com/drug-class/cgrp-inhibitors.html. Accessed April 2019.

[5] Migraine Research Foundation. 2018. Available from: http://migraineresearchfoundation.org/about-migraine/migraine-facts/. Accessed April 2019.

designated as a neurologist, other type of physician, nurse practitioner affiliated with a neurologist, nurse practitioner not affiliated with a neurologist, or other provider. The total cost of each type of CGRP inhibitor treatment was calculated according to each pharmacy program. For beneficiaries with claims for any CGRP inhibitor treatment, their age, gender, and race were also identified.

RESULTS

Table 1 shows the demographic characteristics of beneficiaries with claims for CGRP inhibitors.

- A total of 74 beneficiaries have paid claims for CGRP inhibitors over the ten month period
- 66% of beneficiaries are ages 18-44 years
- 97% of beneficiaries are female and approximately 65% are Caucasian
- Neurologists and NPs associated with a neurologist comprise 78% of prescribers

TABLE 1: Characteristics of Beneficiaries with Claims for CGRP Inhibitors (May 2018 - February 2019)

	FFS	UHC	MAG	MOL	Total
AGE (years)					
18-44	6	14	27	2	49
>44	2	9	14	0	25
Total	*8*	*23*	*41*	*2*	*74*
GENDER					
Male	0	1	1	0	2
Female	8	22	40	2	72
Total	*8*	*23*	*41*	*2*	*74*
RACE					
Caucasian	6	17	23	2	48
Hispanic	0	1	0	0	1
African American	2	4	17	0	23
Other	0	1	1	0	2
Total	*8*	*23*	*41*	*2*	*74*
PROVIDER TYPE					
MD-Neuro	3	12	13	0	28
MD-Other	0	1	6	0	7
NP-Other	1	3	1	0	5
NP-Neuro	3	5	20	2	30
Other Provider	1	2	1	0	4
Total	*8*	*23*	*41*	*2*	*74*

Table 2 shows all paid claims for CGRP inhibitors by plan through February 2019.

- 77% of CGRP inhibitor claims occurred between December 2018 and February 2019

TABLE 2. Number of CGRP Claims (August 2018 - February 2019)			
Month	**Plan**	**Drug**	**Total # of claims**
Aug-18	Magnolia	Aimovig	1
Sep-18	Fee for Service	Aimovig	1
	Magnolia	Aimovig	2
Oct-18	Fee for Service	Aimovig	1
	United Health Care	Aimovig	4
		Ajovy	1
	Magnolia	Aimovig	9
Nov-18	Fee for Service	Aimovig	1
	United Health Care	Aimovig	3
		Ajovy	1
	Magnolia	Aimovig	10
		Ajovy	2
Dec-18	Fee for Service	Aimovig	1
	United Health Care	Aimovig	2
		Ajovy	3
	Magnolia	Aimovig	17
		Ajovy	4
	Molina	Aimovig	1
Jan-19	Fee for Service	Aimovig	3
	United Health Care	Aimovig	6
		Ajovy	5
		Emgality	1
	Magnolia	Aimovig	21
		Ajovy	6
		Emgality	1
Feb-19	Fee for Service	Aimovig	3
		Ajovy	1
	United Health Care	Aimovig	6
		Ajovy	7
		Emgality	1
	Magnolia	Aimovig	20
		Ajovy	7
		Emgality	2
	Molina	Ajovy	1
		Total	**155**

Table 3 shows a claims-level analysis of the total spend associated with each CGRP inhibitor.

- DOM has paid a total of $93,503 in payments to providers for CGRP inhibitors since May 2018; however 77% of claims occurred December 2018 – February 2019.
- The average paid claim for each agent:
    - Aimovig - $612
    - Ajovy - $568
    - Emgality - $681
- The average paid per claim for all CGRP inhibitors combined is $603/claim.

TABLE 3: Claims Level Total Spend by Drug

	FFS	MAG	UHC	MOL	Total Claims	Total Cost
Emgality	0	3	2	0	5	$3,406
Ajovy	1	19	17	1	38	$21,601
Aimovig	10	80	21	1	112	$68,496
TOTAL	11	102	40	2	155	$93,503

In addition to retrospective claims data analysis, MS-DUR compiled data collected from the PA units for FFS and the CCOs for all approvals and denials of manual PAs for CGRP inhibitors through March 2019.

Key Points:

- Manual PAs are required for an initial authorization (12 weeks) and for reauthorization.
- Across all plans (FFS and CCOs), 95 PAs have been approved and 142 have been denied.
- The primary reason noted for PA denials is failure of an appropriate trial of other agents. This was followed distantly by lack of diagnosis and lack in number of headache days.
- PA denials due to lack of approved provider type specified on the PA form for prescribing the CGRP agent does not appear to be a concern.
- There was limited data available to assess appropriateness for reauthorizations as most of the prescriptions are still in the initial authorization phase
    - However, the PA units did note some difficulty documenting *"Verified pharmacy prescription claims history of Aimovig, Ajovy or Emgality and demonstrated adherence"* when reauthorizing PAs due to CGRP samples provided to beneficiaries by their treating providers.

CONCLUSIONS AND RECOMMENDATIONS

With so many migraine sufferers unable to obtain significant symptom relief with prior therapies, CGRP inhibitors have the potential to make a tremendous impact on this segment of pharmacotherapy. Since their release in 2018, CGRP inhibitor utilization in MS Medicaid has been steadily increasing across all pharmacy programs. From data received from the PA units, it does not appear there are issues with beneficiary claims being denied due to lack of approved provider submission. The requirement of a trial of other agents prior to initiating CGRP inhibitors is helping drive appropriate prescribing. With an average cost of $603 per paid claim, it is imperative DOM monitor the utilization and outcomes associated with CGRP inhibitor therapy. At this time it is too early for outcomes to be assessed.

Recommendations:

1. MS-DUR will work with the DOM to assess outcomes associated with CGRP inhibitors. MS-DUR will specifically compare change in hospitalizations, ED visits, and utilization of rescue agents for beneficiaries diagnosed with both episodic and chronic migraine receiving CGRP inhibitors.

CONCURRENT PRESCRIBING OF OPIOIDS AND ANTIPSYCHOTICS

BACKGROUND

Harmful drug interactions may result from the concomitant prescribing of opioids and other central nervous system (CNS) depressants. CNS depression caused by concomitant opioid and CNS depressant use can result in sedation, impaired thoughts, slowed response time, slowed or difficult breathing and death. In 2016 the U.S. Food and Drug Administration issued a drug safety communication warning about serious risks and death when combining opioid pain medicines with other drugs that suppress the CNS. Antipsychotics were listed among the agents associated with potential risk when prescribed along with opioids.[1]

Due to the known potential for abuse associated with opioids, antipsychotics with abuse potential are of particular interest. Among antipsychotics, quetiapine is commonly prescribed off-label to treat sleeplessness or substance abuse withdrawal symptoms. Quetiapine, the most common antipsychotic associated with abuse, has been linked to the street names of "Susie Q," "baby-heroin," and "squirrel." [2] Certain antipsychotics can prolong the QTc interval causing Torsades de Pointes (TdP) which increases the risk of death. These include but are not limited to the antipsychotics aripiprazole, asenapine, chlorpromazine, clozapine, haloperidol, iloperidone, olanzapine, paliperidone, perphenazine, pimavanserin, pimozide, quetiapine, risperidone, thioridazine, and ziprasidone.

During the 2018 federal legislative session, the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act received overwhelming approval by the U.S. Congress and was signed into law. The SUPPORT Act's comprehensive legislation addresses various aspects of the opioid epidemic including treatment, prevention, recovery, and enforcement. Section 1004 of the SUPPORT Act contains the Medicaid provisions that pertain to drug review and utilization. This section requires state Medicaid programs to have drug utilization review safety edits for opioid prescription refills and an automated claims review process to identify refills in excess of state limits, monitor concurrent prescribing of opioids and benzodiazepines or antipsychotics, and require managed care plans to have these automated processes in place effective 10/1/19. States also must have a program to monitor and report annually on antipsychotic prescribing for children and a process to identify potential controlled substance fraud or abuse by Medicaid enrollees, providers or pharmacies. States must submit updated state plan amendments (SPAs) incorporating the new SUPPORT Act

[1] FDA Drug Safety Communication. FDA warns about serious risks and death when combining opioid pain or cough medicines with benzodiazepines; requires its strongest warning. August 31, 2016. https://www.fda.gov/media/99761/download. Accessed April 2019.

[2] Kim S, Lee G, Kim E, Jung H, Chang J. Quetiapine Misuse and Abuse: Is it an Atypical Paradigm of Drug Seeking Behavior?. *J Res Pharm Pract*. 2017;6(1):12–15. doi:10.4103/2279-042X.200987

requirements no later than December 31, 2019.[3] Most of the provisions of the SUPPORT Act pertaining to Medicaid drug review and utilization were already established or in development by many state Medicaid programs. As an initial step towards developing the required automatic claims review described in Section 1004 of the SUPPORT ACT, MS-DUR conducted a claims analysis of concomitant opioid and antipsychotic use for the 2018 calendar year.

METHODS

A retrospective analysis was conducted using Mississippi Medicaid pharmacy claims data across Fee-For-Service (FFS) and the three coordinated care organizations (CCO), UnitedHealthcare (UHC), Magnolia Health (MAG), and Molina Healthcare (MOL), for the period of January 2018 through December 2018. Beneficiaries who had at least one antipsychotic (AP) claim in 2018 were included. Beneficiaries who had a diagnosis for cancer or sickle cell disease in 2017-2018 were excluded. Opioid claims were obtained for these beneficiaries in 2018. Concomitant users were identified as beneficiaries who had at least one day of overlapping use between an AP and an opioid. The number of beneficiaries and claims associated with concomitant use were calculated based on the following AP drug classifications:

- quetiapine (≤200mg),
- quetiapine (>200mg),
- QTc prolonging atypical APs (excluding quetiapine),
- QTc prolonging typical APs
- Other atypical APs
- Other typical APs.

Beneficiaries' enrollment information on the date of AP fill was used to assign the corresponding CCO or FFS plan. Chronic concomitant users were identified as those who had at least one day of overlapping use between an AP and an opioid in three or more consecutive months.

RESULTS

Antipsychotics were grouped into categories by potential drug interactions or relevant adverse event profiles when examining concomitant opioid use. Atypical and typical antipsychotics most commonly correlated with higher risk of QTc prolongation were grouped into individual categories. The remaining atypical and typical antipsychotics were placed into respective categories as well.

[3] Federal Legislation to Address the Opioid Crisis: Medicaid Provisions in the SUPPORT Act. Kaiser Family Foundation. October 5, 2018. https://www.kff.org/medicaid/issue-brief/federal-legislation-to-address-the-opioid-crisis-medicaid-provisions-in-the-support-act/. Accessed April 2019.

Characteristics of beneficiaries who concomitantly received opioids and antipsychotics in 2018 are:

- A total of 3962 unique beneficiaries experienced concomitant use of opioids and antipsychotics.
- 93% of beneficiaries with concomitant opioid and antipsychotic use were between the ages of 18-65 years.
- Only 7% of beneficiaries below 18 years of age and < 1% of those beneficiaries > 65 years of age received opioids and antipsychotics concomitantly. These age groups are potentially at higher risk for adverse events due to concomitant use.
- 71% of concomitant use occurred in females.

TABLE 1. Charactersitics of Beneficiaries with Concomitant Use of Antipsychotics and Opioids in Mississippi Medicaid by Plan January 2018 - December 2018

Characteristic	Pharmacy Plan				
	FFS	UHC	Mag	Mol	Total
Age group					
0 to 17 years	80 (10.90%)	88 (6.20%)	114 (6.40%)	1 (3.33%)	283 (7.14%)
18 to 35 years	173 (23.57%)	370 (26.06%)	488 (27.45%)	15 (50.00%)	1046 (26.40%)
36 to 65 years	472 (64.30)	961 (67.68%)	1175 (66.09%)	14 (46.67%)	2622 (66.18%)
66+ years	9 (1.23%)	1 (0.06%)	1 (0.06%)	0 (0.00%)	11 (0.28%)
Gender					
Female	459 (62.53%)	1019 (71.76%)	1325 (74.52%)	23 (76.67%)	2826 (71.33%)
Male	275 (37.47%)	401 (28.24%)	453 (25.48%)	7 (23.33%)	1136 (28.67%)
Race					
Caucasian	410 (55.86%)	690 (48.59%)	835 (46.96%)	13 (43.33%)	1948 (49.16%)
African American	274 (37.33%)	590 (41.55%)	799 (44.94%	16 (53.34%)	1679 (42.38%)
Other	50 (6.81%)	140 (9.86%)	144 (8.10%)	1 (3.33%)	335 (8.46%)

Note:
FFS = Fee-for-service, UHC = United Health Care, Mag = Magnolia, Mol = Molina.
Plan is based on beneficiary enrollment as of the date of antipsychotic fill.

A summary of concomitant use of antipsychotics and opioids in Mississippi Medicaid between January 2018 and December 2018 from Table 2 below is:

- Beneficiaries prescribed multiple antipsychotics who had a concomitant opioid claim could be present in multiple categories.
- A total of 9083 instances of concomitant opioid and antipsychotic use occurred in 2018 impacting 3962 unique beneficiaries.
- Concomitant use of opioids and quetiapine comprised approximately 42% of concomitant events.
- QTc prolonging antipsychotics and opioids accounted for approximately 90% of concomitant claims.

Table 2. Concomitant Use of Antipsychotics (APs) and Opioids in Mississippi Medicaid - Claims and Benes by Plan
January 2018 - December 2018

Drug type	FFS		UHC		Mag		Mol	
	Benes	Claims	Benes	Claims	Benes	Claims	Benes	Claims
Quetiapine (<200mg)	189	323	324	653	392	794	7	10
Quetiapine (>=200mg)	121	244	282	772	361	972	6	7
QTc prolonging atypical APs (excluding quetiapine)	383	789	696	1440	862	1652	13	14
QTc prolonging typical APs	48	100	86	203	96	203	1	2
Other atypical APs	36	93	138	301	151	342	3	3
Other typical APs	16	29	40	52	60	84	0	0

Note:
AP = Antipsychotic, FFS = Fee-for-service, UHC = United Health Care, Mag = Magnolia, Mol = Molina.
Plan is based on beneficiary enrollment as of the date of AP fill.
QTc prolonging atypical APs (excluding quetiapine) include aripiprazole, asenapine, clozapine, iloperidone, olanzapine, paliperidone, pimavanserin, risperidone, ziprasidone.
QTc prolonging typical APs include chlorpromazine, haloperidol, perphenazine, pimozide, thioridazine.
Other atypical APs include brexpiprazole, cariprazine, lurasidone.
Other typical APs include fluphenazine, loxapine, prochlorperazine, thiothixene, trifluoperazine.

References for AP classification:
1. https://www.accessdata.fda.gov/scripts/cder/daf/
2. https://crediblemeds.org/index.php/drugsearch

Table 3 illustrates claims level analysis of days of overlap in concomitant use of opioids and antipsychotics. This table shows the number of claims and the individual durations of overlap for concomitant use of antipsychotics and opioids.

- 57% of concomitant overlap was for short-term use of opioids defined by ≤ 14 days.
- 43% of overlap occurred for ≥15 days.
- MS-DUR calculated the number of beneficiaries with chronic concomitant use (identified as beneficiaries who had at least one overlapping day of use of opioids and antipsychotics for three or more consecutive months) and identified **258** beneficiaries as chronic concomitant users in 2018.

Table 3. Days of Concomitant Use of Antipsychotics and Opioids in Mississippi Medicaid
January 2018 - December 2018

Drug type	Number of claims				
	Less than 3 days	4 to 7 days	8 to 14 days	15 to 30 days	31+ days
Quetiapine (<200mg)	308	312	297	855	8
Quetiapine (>=200mg)	328	386	332	946	3
QTc prolonging atypical APs (excluding quetiapine)	902	846	635	1499	13
QTc prolonging typical APs	116	99	87	206	0
Other atypical APs	136	124	121	358	0
Other typical APs	47	61	24	33	0

Note:
QTc prolonging atypical APs (excluding quetiapine) include aripiprazole, asenapine, clozapine, iloperidone, olanzapine, paliperidone, pimavanserin, risperidone, ziprasidone.
QTc prolonging typical APs include chlorpromazine, haloperidol, perphenazine, pimozide, thioridazine.
Other atypical APs include brexpiprazole, cariprazine, lurasidone.
Other typical APs include fluphenazine, loxapine, prochlorperazine, thiothixene, trifluoperazine.
31+ days category was created based on trends observed in data. Corresponding AP claims had greater than 30 days of supply.

References for AP classification:
1. https://www.accessdata.fda.gov/scripts/cder/daf/
2. https://crediblemeds.org/index.php/drugsearch

CONCLUSIONS AND RECOMMENDATIONS

The concomitant use of opioids and antipsychotics may place beneficiaries at higher risk of harmful effects. With the approval of the SUPPORT Act and implementation deadline October 1, 2019, Mississippi DOM plans to establish an automatic claims review process to monitor the concomitant use of opioids and antipsychotics. The MS-DUR claims data indicates nearly 4,000 beneficiaries experienced concomitant therapy with opioids and antipsychotics in 2018. One option is a prospective DUR edit alerting pharmacists of the potential risks associated with concomitant use. Alternatively, a retrospective DUR approach could entail educational mailings to providers targeting all concomitant prescribing, concomitant prescribing of antipsychotics associated with abuse, sedation, CNS depression and /or QTc prolongation. DOM must determine what type of automatic claims monitoring is most appropriate for MS Medicaid beneficiaries.

Recommendations:

1. MS-DUR should work with the DOM to develop an automatic claims review process to monitor concomitant use of opioids and antipsychotics and implement the process prior to October 1, 2019.

2. MS-DUR should implement an educational initiative to notify providers and/or pharmacists, depending on the review process being initiated.

FDA DRUG SAFETY COMMUNICATIONS

March & April 2019

- 4/30/2019 FDA adds Boxed Warning for risk of serious injuries caused by sleepwalking with certain prescription insomnia medicines

- 4/9/2019 FDA identifies harm reported from sudden discontinuation of opioid pain medicines and requires label changes to guide prescribers on gradual, individualized tapering

APPENDIX

AWP	Any Willing Provider, Average Wholesale Price
BENE	Beneficiary
CAH	Critical Access Hospital
CCO	Coordinated Care Organization
CDC	Centers for Disease Control
CHIP	Children's Health Insurance Program
CMS	Center for Medicare and Medicaid Services
COB	Coordination of Benefits
CPC	Complex Pharmaceutical Care
DME	Durable Medical Equipment
DOC	Department of Corrections
DOM	Division of Medicaid
DUR	Drug Utilization Review
EOB	Explanation of Benefits
EPSDT	Early and Periodic Screening, Diagnosis and Treatment
FA	Fiscal Agent
FFS	Fee For Service
FPW	Family Planning Waiver
FQHC	Federally Qualified Health Clinic
FY	Fiscal Year
HB	House Bill
HCPCS/ HEIDIS	Health Plan Employer Data and Information Set
HHS	Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability
IDD	Intellectual and Developmental Disabilities
LTC	Long Term Care
MAG	Magnolia Health
MEDD	Morphine Equivalent Daily Dose
MSCAN	Mississippi Coordinated Access Network
MSDH	Mississippi State Department of Health
NADAC	National Average Drug Acquisition Cost
NDC	National Drug Code
P&T	Pharmacy and Therapeutics
PA	Prior Authorization
PBM	Pharmacy Benefit Manager
PDL	Preferred Drug List
PI	Program Integrity
PIP	Performance Improvement Program
POS	Point of Sale, Place of Service, Point of Service
Pro-DUR	Prospective Drug Use Review
OTC	Over the Counter
QI	Quality Indicator
QIO	Quality Improvement Organization
QM	Quality Management
RA	Remittance Advise
REOMB	Recipient's Explanation of Medicaid Benefits
Retro-DUR	Retrospective Drug Utilization Review
RFI	Request for Information
RFP	Request for Proposal
RHC	Rural Health Clinic
SB	Senate Bill
SCHIP	State Child Health Insurance Program
SMART PA	Conduent's Pharmacy Application (SmartPA) is a proprietary electronic prior authorization system used for Medicaid fee for service claims
SPA	State Plan Amendment
UHC	United Healthcare
UM/QIO	Utilization Management and Quality Improvement Organization
UPDL	Universal Preferred Drug List
UR	Utilization Review
VFC	Vaccines for Children
WAC	Wholesale Acquisition Cost
WIC	Women, Infants, Children
340B	Federal Drug Discount Program