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



December 8, 2022 at 1:00pm
Woolfolk Building, Room 145
Jackson, MS

Prepared by:



#### **Drug Utilization Review Board**

Joseph Austin, MD

Vicksburg Women's Care 100 Maxwell Drive Vicksburg, MS 39180

Term Expires: June 30, 2025

Lauren Bloodworth, PharmD

MS State Department of Health 3212 Hwy 51 S Hernando, MS 38632

Term Expires: June 30, 2024

Terrence Brown, PharmD

BioScrip Infusion Services 187 Country Place Pkwy, Suite C

Pearl, MS 39208

Term Expires: June 20, 2023

Patrick Bynum, MD

MEA Vicksburg Ambulatory Care Clinic 4204 Clay Street Vicksburg, MS 39183

Term Expires: June 30, 2025

Chrysanthia Davis, PharmD

Omnicare Pharmacy 100 Business Park Dr, Ste D Ridgeland, MS 39157

Term Expires: June 30, 2025

Tanya Fitts, MD

Lafayette Pediatric Clinic 1300 Access Road, Suite 400

Oxford, MS 38655

Term Expires: June 30, 2024

Jahanzeb Khan, MD

University Hospital 2500 N. State Street Jackson, MS 39216

Term Expires: June 30, 2024

Ray Montalvo, MD

KDMC Specialty Clinic 940 Brookway Boulevard Brookhaven, MS 39601

Term Expires: June 30, 2023

Holly R. Moore, PharmD

Anderson Regional Medical Center 2124 14<sup>th</sup> Street

Meridian, MS 39301

Term Expires: June 30, 2023

Kristi Phelps, RPh

Burnham Drugs 12500 Hwy 57 Gautier, MS 39553

Term Expires: June 30, 2023

Joshua Pierce, PharmD

McGuffee Drugs 102 Main St.

Magee, MS 39111

Term Expires: June 30, 2024

Bobbie West, MD

MEA Medical Clinic 342 Gilchrist Drive Pearl, MS 39208

Term Expires: June 30, 2025

#### **Proposed 2023 DUR Board Meeting Dates**

March 2, 2023 June 1, 2023 September 7, 2023 December 7, 2023 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

#### **December 8, 2022**

#### Welcome

Old Business	
Approval of September 2022 Meeting Minutes	page 5
Resource Utilization Review	
Enrollment Statistics	page 13
Pharmacy Utilization Statistics	page 13
Top 10 Drug Categories by Number of Claims	page 14
Top 10 Drug Categories by Amount Paid	page 15
Top 25 Drug Molecules by Number of Claims	page 16
Top 25 Drug Molecules by Dollars Paid	page 17
Top 25 Drug Molecules by Change in Number of Claims	page 18
Top 25 Drug Molecules by Change in Dollars Paid	page 19
Top 15 Solid Dosage Form High Volume Products By Percent Change In	
Amount Paid Per Unit	page 20
Follow-up and Discussion from the Board	
New Business	
MS-DUR Educational Interventions	page 22
Special Analysis Projects	
Assessment of Predictors of Severe Maternal Morbidity	page 23
COVID-19 Overview Among Medicaid Beneficiaries	page 33
Impact of Obesity Among Medicaid Beneficiaries	page 40
FDA Drug Safety Updates	page 50
Pharmacy Program Update	Terri Kirby, RPh

#### **Next Meeting Information**

Proposed 2023 DUR Board Meeting Dates:

March 2, 2023; June 1, 2023; September 7, 2023; December 7, 2023

**DUR Board Meeting Minutes** 

## MISSISSIPPI DIVISION OF MEDICAID DRUG UTILIZATION REVIEW (DUR) BOARD MINUTES OF THE SEPTEMBER 15, 2022 MEETING

DUR Board Roster: State Fiscal Year 2023	Dec 2021	Mar 2022	Jun 2022	Sep 2022
(July 1, 2022 – June 30, 2023)				
Joseph Austin, MD	NA	NA	NA	✓
Lauren Bloodworth, PharmD	✓	✓		
Terrence Brown, PharmD	✓	✓	✓	✓
Patrick Bynum, MD	✓	✓	✓	✓ ✓
Chrysanthia Davis, PharmD	NA	NA	NA	1
Tanya Fitts, MD		✓	~	✓
Jahanzeb Khan, MD	NA	NA	NA	✓
Ray Montalvo, MD	✓			✓
Holly Moore, PharmD			<b>1</b>	✓
Kristi Phelps, RPh	NA	NA	NA	✓
Joshua Pierce, PharmD	~	✓	<b>✓</b>	<b>✓</b>
Bobbie West, MD	NA	NA	NA	<b>✓</b>
TOTAL PRESENT**	7	9	7	11

<sup>\*\*</sup> Total Present may not be reflected by individual members marked as present above due to members who either resigned or whose terms expired being removed from the list.

#### **Also Present:**

#### **Division of Medicaid (DOM) Staff:**

Terri Kirby, RPh, CPM, Pharmacy Director; Dennis Smith, RPh, DUR Coordinator; Gail McCorkle, RPh, Clinical Pharmacist; Chris Yount, MA, PMP, Staff Officer – Pharmacy;

#### University of Mississippi School of Pharmacy - MS-DUR Staff:

Eric Pittman, PharmD, MS-DUR Project Director; Kaustuv Bhattacharya, PhD, Research Assistant Professor;

#### **Change Healthcare Staff:**

Paige Clayton, PharmD, On-Site Clinical Pharmacist; Shannon Hardwick, RPh, CPC Pharmacist;

#### **Coordinated Care Organization (CCO) Staff:**

Jenni Grantham, PharmD, Director of Pharmacy, Magnolia Health; Heather Odem, PharmD, Director of Pharmacy - Mississippi, UnitedHealthcare Community & State; Trina Stewart, PharmD, Pharmacy Manager, Molina Healthcare;

#### **Gainwell Staff:**

Ashleigh Holeman, MS Pharmacy Services Manager; Tricia Banks, PharmD, MS Clinical Pharmacist; Lew Anne Snow, RN, Advisor Business Analyst;

#### Alliant Health Staff:

Catherine Brett, MD, Quality Director, MS UM/QIO; Buddy Ogletree, PharmD, Pharmacist;

#### **Visitors:**

Floyd Holmes, Lilly; Cathy Prine-Eagle, Merck; Ryan Bucalo, Insulet Corporation; Bridget Gipson, UCB; Paula Whatley, Novo Nordisk; Julie Young, Abbvie; Shawn Headley, Gilead.

#### Call to Order/Welcome:

Dr. Montalvo called the meeting to order at 1:04 pm.

Mr. Smith welcomed the new members, Dr. Joseph Austin, Dr. Chrysanthia Davis, Dr. Jahanzeb Khan, Ms. Kristi Phelps, and Dr. Bobbie West. Mr. Smith took some time to provide an overview of the functions of the DUR Board for the new members.

#### **OLD BUSINESS:**

Dr. Fitts moved to approve the minutes from the June 2022 DUR Board Meeting, seconded by Dr. Bynum, and unanimously approved by the DUR Board.

#### **Resource Utilization Review:**

Dr. Pittman presented the resource utilization report for June 2022. Dr. Pittman oriented the new board members to the information contained in the resource utilization report. He spent some additional time providing background for each section of the resource report.

#### **NEW BUSINESS:**

#### **Appointment of Officers:**

The positions of Board Chair and Vice-Chair were vacant. Dr. Terrence Brown volunteered to become Chair and Dr. Tanya Fitts volunteered to become Vice-Chair. Dr. Austin moved to approve Dr. Brown and Dr. Fitts for these positions, seconded by Dr. Moore, and unanimously approved by the DUR Board.

#### **Update on MS-DUR Educational Interventions:**

Dr. Pittman provided an overview of all DUR mailings and educational notices that occurred between June 2022 – August 2022. Dr. Pittman provided a brief historical review of each mailing and noted how these educational efforts have impacted prescribing practices.

#### **Special Analysis Projects:**

## Assessment of Predictors of Severe Maternal Morbidity (SMM) Among Pregnant Medicaid Beneficiaries

Improving maternal health is a primary focus area for the Division of Medicaid. This study examining the relationship between risk factors and severe maternal morbidity events among Medicaid beneficiaries will help inform DOM on which risk factors are most closely associated with SMM events and can help guide the development of future interventions aimed at

improving overall maternal health. From this model, the Maternal Comorbidity Index (MCI), distance from the delivery center, age, and race were found to be significantly associated with SMM events.

The following recommendations were presented:

- 1. MS-DUR should conduct an extension study of this analysis further examining MCI and distance from the delivery center:
  - a. Determine which MCI factors or cut-off points for MCI are most associated with SMM events.
  - b. Determine if there is a relationship between the distance to different types of delivery centers and SMM events.
- 2. DOM should explore opportunities to utilize findings from this analysis to inform the development of future services targeted toward improving maternal outcomes.
- 3. DOM and MS-DUR should seek opportunities to disseminate insights gained from this analysis into the broader public domain.

Following a robust discussion, Dr. Brown made a motion to accept the recommendations as presented, seconded by Dr. Austin, and unanimously approved by the Board.

#### **Utilization Trends of Immunomodulators Among Medicaid Beneficiaries**

Immunomodulator utilization among Medicaid beneficiaries has seen a significant increase in recent years. Dose escalations above FDA labeling were common among many agents examined in the Medicaid population. Dose escalation with immunomodulators has been explored in the literature with many of these studies focusing on patients with an inadequate initial response or those experiencing loss of response over time. In these studies, clinical criteria were established to determine the need for dose escalation, and disease activity measures were assessed to evaluate outcomes experienced.

The following recommendations were presented:

- DOM should work to establish detailed clinical criteria for immunomodulators defining circumstances when dose escalation is appropriate and detailing monitoring parameters for determining outcomes associated with immunomodulating agents.
- DOM should work to strengthen the electronic PA criteria for various immunomodulating agents focusing on appropriate diagnosis-based dosing.

Following a robust discussion, Dr. Moore made a motion to accept the recommendations as presented, seconded by Dr. Fitts, and unanimously approved by the Board.

#### **Palivizumab Utilization Update**

MS-DUR presented a report detailing the utilization of palivizumab for the prevention of serious lower respiratory tract disease caused by the respiratory syncytial virus (RSV) in children at high risk of severe disease during the 2021/2022 RSV season. Once again, this past year brought an atypical RSV season prompting Medicaid to reopen access to palivizumab outside of the typical season parameters. This report for the DUR Board was for informational purposes only.

No action was sought as a result of this report.

#### **Influenza Vaccination and Treatment Update**

MS-DUR presented a report summarizing influenza vaccination and treatment among Medicaid beneficiaries during the 2021/2022 influenza season. The report detailed flu vaccinations by age group, pharmacy plan, and place of service for vaccine administration (pharmacy or medical setting). The report also detailed the use of anti-influenza therapeutic agents. This report was for informational purposes only.

No action was sought as a result of this report.

#### **FDA Drug Safety Updates:**

Dr. Pittman presented FDA drug safety communications for June 2022 – August 2022.

#### **Pharmacy Program Update:**

Ms. Kirby provided a pharmacy program update highlighting the upcoming transition to their new fiscal agent, Gainwell. Ms. Kirby provided the Board with a copy of a provider notice DOM was preparing to send out with details on the upcoming transition.

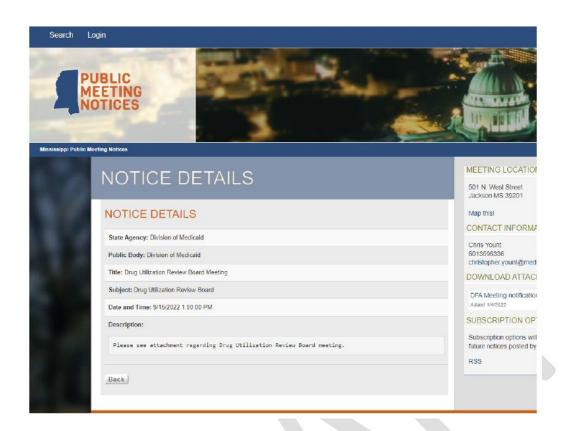
#### **Next Meeting Information:**

The next meeting is scheduled for December 8, 2022.

Dr. Pierce motioned to adjourn the meeting at 2:46 pm, seconded by Dr. Fitts, and unanimously approved by the Board.

Submitted,

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



Important Updates: Beginning October 1, 2021, pharmaceutical and industry members, vendors, and general public must register to attend. Registration will open thirty (30) days prior to the meeting date. Registration will close at 12pm (noon) the day before the meeting. Due to the ongoing pandemic, only one representative per company may register/attend. Public speaking is not allowed at DUR meetings unless called on by the Board.

Parking: parking may be found on the perimeter of the Woolfolk Building, on the north side of the Woolfolk Building located at the old Wright and Ferguson building (yellow/brown building), and at the Division of Medicaid and First Baptist Church main parking lots at the corner of High Street and North President Street. Guests may not park at the Woolfolk Building or in any parking space marked "Reserved".



NOTE: Registration is required for all pharmaceutical industry and advocacy representatives to be able to attend DUR Board meetings. Registration closes at 12:00 pm on September 14.

Organizations that have met the one rep per company limit (as of 7:45 am, September 15, 2022):

- 1. Abbott
- 2. AbbVie
- 3. Alliant
- 4. Bayer
- 5. Blogen
- 6. Capitol Resources
- 7. Centene
- 8. Change Healthcare
- 9. GBT 10. Gilead
- 11. GlaxoSmithKline
- 12. Insulet Corp.
- 13. Kite Pharma
- 14. Lilly
- 15. Merck
- 16. Mississippi State Dept. of Health
- 17. Molina
- 18. Novartis
- 19. Novo Nordisk
- 20. SOBI
- 21. Tolmar Pharmaceuticals
- 22. UCB
- 23. United Healthcare
- 24. Viiv

Meeting Location: Woolfolk Building, 501 North West Street, Conference Room 145, Jackson, MS 39201, unless otherwise noted by the corresponding date of the meeting listed below.

**Contact Information:** Office of Pharmacy:

Chris Yount, 601-359-5253: Christopher.yount@medicaid.ms.gov, or Jessica Tyson, 601-359-5253; <a href="mailto:lessica.Tyson@medicaid.ms.gov">lessica.Tyson@medicaid.ms.gov</a>

Notice details:

State Agency: MS Division of Medicaid

Public Body: Drug Utilization Board (DUR) Meeting

**Subject:** Quarterly Meeting

#### **Dates and Times:**

#### 2022 dates:

- March 3, 2022 (1-3pm; Room 117, Woolfolk Building)
- June 9, 2022 (1-3pm; Room 145)
- September 15, 2022 (1-3pm; Room 145)
- December 8, 2022 (1-3pm; Room 145)

**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 February 1, 2022 through July 31, 2022											
			Feb-22	Mar-22	Apr-22	May-22	Jun-22	Jul-22				
To	otal eni	rollment	855,336	858,028	860,566	863,355	866,574	869,341				
D	ual-elig	ibles	166,586	166,627	166,755	166,953	167,293	167,453				
Pl	harmad	y benefits	740,204	742,955	745,503	748,234	751,448	754,202				
	LTC		14,936	15,069	15,139	15,191	15,237	15,187				
	0	FFS	46.3%	47.4%	49.3%	50.2%	51.1%	51.3%				
	% N	MSCAN-UHC	20.9%	20.5%	19.8%	19.4%	19.0%	19.0%				
	PLAN	MSCAN-Magnolia	22.0%	21.5%	20.8%	20.4%	20.1%	19.9%				
	1	MSCAN-Molina	10.8%	10.6%	10.1%	10.0%	9.8%	9.8%				

	TABLE 04B: PHARMACY UTILIZATION STATISTICS FOR LAST 6 MONTHS												
		Febi	ruary 1, 2022	2 through Jul	y 31, 2022								
	Feb-22         Mar-22         Apr-22         May-22         Jun-22         Jul-22												
	FFS	151,771	173,958	175,572	175,949	170,267	163,448						
#	MSCAN-UHC	140,639	152,245	146,594	142,503	133,848	129,615						
Rx Fills	MSCAN-Mag	137,639	149,506	144,272	139,334	131,503	118,640						
	MSCAN-Mol	48,046	52,862	49,675	48,600	45,038	44,030						
#	FFS	0.4	0.5	0.5	0.5	0.4	0.4						
Rx Fills	MSCAN-UHC	0.9	1.0	1.0	1.0	0.9	0.9						
/ Bene	MSCAN-Mag	0.8	0.9	0.9	0.9	0.9	0.8						
/ Delle	MSCAN-Mol	0.6	0.7	0.7	0.6	0.6	0.6						
Ś	FFS	\$17,482,455	\$19,744,541	\$18,755,378	\$20,384,649	\$20,170,018	\$18,622,834						
ې Paid	MSCAN-UHC	\$18,515,288	\$20,787,523	\$19,401,752	\$19,547,373	\$19,170,380	\$18,855,950						
Rx	MSCAN-Mag	\$15,288,757	\$16,986,859	\$15,842,931	\$15,487,708	\$16,136,476	\$14,240,616						
KX	MSCAN-Mol	\$4,679,905	\$5,474,048	\$4,808,987	\$4,682,130	\$4,843,059	\$4,620,439						
	FFS	\$115.19	\$113.50	\$106.82	\$115.86	\$118.46	\$113.94						
\$	MSCAN-UHC	\$131.65	\$136.54	\$132.35	\$137.17	\$143.23	\$145.48						
/Rx Fill	MSCAN-Mag	\$111.08	\$113.62	\$109.81	\$111.16	\$122.71	\$120.03						
	MSCAN-Mol	\$97.40	\$103.55	\$96.81	\$96.34	\$107.53	\$104.94						
	FFS	\$51.01	\$56.07	\$51.03	\$54.27	\$52.53	\$48.13						
\$	MSCAN-UHC	\$119.68	\$136.49	\$131.44	\$134.66	\$134.27	\$131.59						
/Bene	MSCAN-Mag	\$93.89	\$106.34	\$102.17	\$101.47	\$106.84	\$94.88						
	MSCAN-Mol	\$58.54	\$69.51	\$63.87	\$62.58	\$65.76	\$62.51						

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

In April 2021, UHC changed their claims reporting procedure, and the estimates presented in these tables may be slightly higher than the amount actually paid by UHC

TABLE C: TOP 10 DRUG CATEGORIES BY NUMBER OF CLAIMS IN JUL 2022 (FFS AND CCOs)

Category	Month Year	Rank Volume	#RXs	\$ Paid	# Unique Benes
CNS stimulants	Jul 2022	1	20,170	\$2,985,094	17,119
	Jun 2022	1	20,075	\$3,000,468	16,859
	May 2022	1	22,867	\$3,521,864	19,309
SSRI antidepressants	Jul 2022	2	14,110	\$171,853	12,954
	Jun 2022	2	15,004	\$185,119	13,576
	May 2022	3	14,884	\$184,814	13,577
nonsteroidal anti-inflammatory agents	Jul 2022	3	13,745	\$185,992	12,994
	Jun 2022	3	14,438	\$203,910	13,574
	May 2022	4	14,693	\$213,626	13,775
atypical antipsychotics	Jul 2022	4	13,652	\$4,533,682	11,431
	Jun 2022	4	14,355	\$4,412,298	11,812
	May 2022	5	14,505	\$4,551,028	11,973
adrenergic bronchodilators	Jul 2022	5	12,863	\$958,861	10,844
	Jun 2022	5	13,118	\$921,430	11,041
	May 2022	2	14,891	\$948,576	12,561
narcotic analgesic combinations	Jul 2022	6	11,772	\$639,692	10,772
	Jun 2022	6	12,439	\$719,031	11,290
	May 2022	10	12,130	\$670,966	11,065
proton pump inhibitors	Jul 2022	7	11,584	\$376,197	10,935
	Jun 2022	7	12,143	\$403,941	11,349
	May 2022	9	12,309	\$418,467	11,545
antihistamines	Jul 2022	8	11,031	\$163,577	10,280
	Jun 2022	8	11,483	\$170,564	10,376
	May 2022	7	13,567	\$198,335	12,232
antiadrenergic agents, centrally acting	Jul 2022	9	10,071	\$196,868	9,052
	Jun 2022	10	10,387	\$206,785	9,187
	May 2022	11	10,633	\$204,594	9,498
aminopenicillins	Jul 2022	10	9,631	\$124,020	9,390
	Jun 2022	9	11,303	\$145,559	10,999
	May 2022	6	14,142	\$185,579	13,752

TABLE D: TOP 10 DRUG CATEGORIES BY DOLLARS PAID IN JUL 2022 (FFS AND CCOs)

Category	Month Year	Rank Paid Amt	#RXs	\$ Paid	# Unique Benes
atypical antipsychotics	Jul 2022	1	13,652	\$4,533,682	11,431
	Jun 2022	1	14,355	\$4,412,298	11,812
	May 2022	1	14,505	\$4,551,028	11,973
interleukin inhibitors	Jul 2022	2	699	\$3,781,972	535
	Jun 2022	3	669	\$3,589,814	513
	May 2022	2	654	\$3,664,833	486
TNF alpha inhibitors	Jul 2022	3	435	\$3,418,246	365
	Jun 2022	2	495	\$3,928,975	388
	May 2022	4	460	\$3,473,210	371
CNS stimulants	Jul 2022	4	20,170	\$2,985,094	17,119
	Jun 2022	5	20,075	\$3,000,468	16,859
	May 2022	3	22,867	\$3,521,864	19,309
antiviral combinations	Jul 2022	5	1,361	\$2,835,056	1,282
	Jun 2022	4	1,145	\$3,093,836	1,040
	May 2022	5	940	\$2,930,060	851
insulin	Jul 2022	6	5,110	\$2,254,693	3,719
	Jun 2022	7	5,481	\$2,481,588	3,919
	May 2022	6	5,317	\$2,370,829	3,824
CFTR combinations	Jul 2022	7	81	\$1,798,145	70
	Jun 2022	6	115	\$2,558,420	80
	May 2022	7	99	\$2,121,836	80
factor for bleeding disorders	Jul 2022	8	148	\$1,635,970	104
	Jun 2022	8	183	\$1,855,356	134
	May 2022	8	152	\$2,113,759	116
miscellaneous uncategorized agents	Jul 2022	9	150	\$1,493,260	133
	Jun 2022	14	150	\$968,234	141
	May 2022	9	165	\$1,415,961	141
antirheumatics	Jul 2022	10	588	\$1,430,124	488
	Jun 2022	10	594	\$1,312,304	495
	May 2022	11	605	\$1,313,335	514

## TABLE E: TOP 25 DRUG MOLECULES BY NUMBER OF CLAIMS IN JUL 2022 (FFS and CCOs)

Drug Molecule Therapeutic Category	Jun 2022 # Claims	Jul 2022 # Claims	Jul 2022 \$ Paid	Jul 2022 # Unique Benes
albuterol / adrenergic bronchodilators	12,203	11,807	\$657,466	10,177
amoxicillin / aminopenicillins	11,274	9,592	\$123,258	9,351
azithromycin / macrolides	7,767	8,185	\$124,273	7,990
gabapentin / gamma-aminobutyric acid analogs	8,330	8,002	\$120,531	7,390
montelukast / leukotriene modifiers	8,830	7,859	\$118,437	7,571
acetaminophen-hydrocodone / narcotic analgesic combinations	7,522	7,160	\$91,806	6,702
cetirizine / antihistamines	7,165	7,033	\$97,892	6,600
amphetamine-dextroamphetamine / CNS stimulants	6,320	6,358	\$168,096	5,449
ibuprofen / nonsteroidal anti-inflammatory agents	6,483	6,252	\$72,680	6,058
clonidine / antiadrenergic agents, centrally acting	6,382	6,210	\$74,470	5,824
amlodipine / calcium channel blocking agents	6,320	6,053	\$68,429	5,703
fluticasone nasal / nasal steroids	6,825	5,947	\$87,996	5,808
ondansetron / 5HT3 receptor antagonists	6,313	5,871	\$83,797	5,621
methylphenidate / CNS stimulants	5,645	5,743	\$899,672	5,057
omeprazole / proton pump inhibitors	5,559	5,261	\$58,702	5,106
sertraline / SSRI antidepressants	5,552	5,180	\$62,459	4,729
triamcinolone topical / topical steroids	5,069	4,767	\$77,338	4,503
atorvastatin / HMG-CoA reductase inhibitors (statins)	4,497	4,412	\$48,450	4,072
lisdexamfetamine / CNS stimulants	4,483	4,383	\$1,502,561	4,186
hydroxyzine / miscellaneous anxiolytics, sedatives and hypnotics	4,301	4,361	\$66,786	4,117
pantoprazole / proton pump inhibitors	4,362	4,187	\$46,195	3,940
famotidine / H2 antagonists	3,986	4,004	\$113,708	3,804
amoxicillin-clavulanate / penicillins/beta-lactamase inhibitors	4,576	3,891	\$80,683	3,776
guanfacine / antiadrenergic agents, centrally acting	4,003	3,861	\$122,398	3,575
cefdinir / third generation cephalosporins	4,563	3,811	\$80,321	3,716

## TABLE F: TOP 25 DRUG MOLECULES BY DOLLARS PAID IN JUL 2022 (FFS and CCOs)

Drug Molecule Therapeutic Category	Jun 2022 \$ Paid	Jul 2022 \$ Paid	Jul 2022 # Claims	Jul 2022 # Unique Benes
adalimumab / TNF alpha inhibitors	\$3,634,633	\$3,143,158	384	320
paliperidone / atypical antipsychotics	\$1,725,804	\$1,851,774	650	596
elexacaftor/ivacaftor/tezacaftor / CFTR combinations	\$2,450,692	\$1,688,368	76	66
dupilumab / interleukin inhibitors	\$1,519,439	\$1,643,858	499	375
lisdexamfetamine / CNS stimulants	\$1,504,917	\$1,502,561	4,383	4,186
bictegravir/emtricitabine/tenofovir / antiviral combinations	\$1,527,323	\$1,414,533	392	374
aripiprazole / atypical antipsychotics	\$1,211,527	\$1,214,072	3,701	3,393
liraglutide / GLP-1 receptor agonists	\$990,170	\$1,044,454	1,165	1,100
methylphenidate / CNS stimulants	\$886,625	\$899,672	5,743	5,057
ustekinumab / interleukin inhibitors	\$804,218	\$851,996	38	29
insulin glargine / insulin	\$939,106	\$840,095	1,833	1,727
emicizumab / factor for bleeding disorders	\$717,810	\$734,970	33	24
somatropin / growth hormones	\$658,352	\$721,984	169	135
etanercept / antirheumatics	\$658,392	\$721,552	118	94
empagliflozin / SGLT-2 inhibitors	\$615,107	\$662,281	838	779
albuterol / adrenergic bronchodilators	\$659,797	\$657,466	11,807	10,177
carglumic acid / miscellaneous uncategorized agents	\$205,592	\$635,269	3	2
ixekizumab / interleukin inhibitors	\$520,512	\$596,148	78	57
antihemophilic factor / factor for bleeding disorders	\$642,222	\$544,386	34	17
budesonide-formoterol / bronchodilator combinations	\$558,685	\$544,056	1,555	1,498
apixaban / factor Xa inhibitors	\$545,504	\$522,286	1,082	968
insulin aspart / insulin	\$558,064	\$514,244	1,359	1,230
cannabidiol / miscellaneous anticonvulsants	\$522,881	\$511,288	152	137
buprenorphine-naloxone / narcotic analgesic combinations	\$571,194	\$501,759	1,387	1,167
dapagliflozin / SGLT-2 inhibitors	\$563,176	\$491,915	761	736

## TABLE G: TOP 25 DRUG MOLECULES BY CHANGE IN NUMBER OF CLAIMS FROM MAY 2022 TO JUL 2022 (FFS and CCOs)

Drug Molecule	May 2022 # Claims	Jun 2022 # Claims	Jul 2022 # Claims	Jul 2022 \$ Paid	Jul 2022 # Unique Benes
ciprofloxacin-dexamethasone otic / otic steroids with anti-infectives	1,127	1,878	1,687	\$416,459	1,587
nirmatrelvir-ritonavir / antiviral combinations	39	224	484	\$4,402	475
epinephrine / adrenergic bronchodilators	646	853	993	\$285,214	866
hydrocortisone/neomycin/polymyxin b otic / otic steroids with anti-infectives	424	759	731	\$48,231	710
hydroxyzine / miscellaneous anxiolytics, sedatives and hypnotics	4,132	4,301	4,361	\$66,786	4,117
ofloxacin otic / otic anti-infectives	736	971	963	\$26,101	925
sars-cov-2 mma (tozinameran 5y-11y) vaccine / viral vaccines	280	316	464	\$15,512	429
tetanus/diphth/pertuss (tdap) adult/adol / vaccine combinations	82	116	221	\$12,557	218
sars-cov-2 mrna (tozinameran-tris-sucrose) vaccine / viral vaccines	948	933	1,062	\$35,001	1,032
ofloxacin ophthalmic / ophthalmic anti-infectives	260	343	374	\$7,752	363
dexamethasone / glucocorticoids	453	547	564	\$7,181	548
chlorhexidine topical / mouth and throat products	623	775	711	\$7,574	699
naloxone / antidotes	97	124	172	\$15,921	161
clindamycin / lincomycin derivatives	2,116	2,189	2,177	\$52,801	2,091
tretinoin topical / topical acne agents	640	688	700	\$42,729	651
mupirocin topical / topical antibiotics	3,538	3,739	3,595	\$53,049	3,461
molnupiravir / miscellaneous antivirals	5	21	60	\$525	60
dupilumab / interleukin inhibitors	447	472	499	\$1,643,858	375
spinosad topical / topical anti-infectives	346	371	398	\$110,441	352
acetaminophen-oxycodone / narcotic analgesic combinations	2,536	2,730	2,587	\$39,299	2,428
clindamycin topical / vaginal anti-infectives	799	816	847	\$35,445	804
sars-cov-2 (covid-19) mrna-1273 vaccine / viral vaccines	292	288	339	\$11,776	332
viloxazine / noradrenergic uptake inhibitors for ADHD	133	148	177	\$71,254	151
sars-cov-2 mrna (tozinameran 6m-4y) vaccine / viral vaccines	0	5	43	\$1,321	36
pimecrolimus topical / miscellaneous topical agents	391	415	432	\$138,533	380

## TABLE H: TOP 25 DRUG MOLECULES BY CHANGE IN AMOUNT PAID FROM MAY 2022 TO JUL 2022 (FFS and CCOs)

Drug Molecule	May 2022 \$ Paid	Jun 2022 \$ Paid	Jul 2022 \$ Paid	Jul 2022 # Claims	Jul 2022 # Unique Benes
dupilumab / interleukin inhibitors	\$1,402,991	\$1,519,439	\$1,643,858	499	375
emtricitabine/rilpivirine/tenofovir / antiviral combinations	\$118,453	\$189,044	\$260,021	63	52
ciprofloxacin-dexamethasone otic / otic steroids with anti-infectives	\$279,265	\$463,528	\$416,459	1,687	1,587
antihemophilic factor / factor for bleeding disorders	\$412,595	\$642,222	\$544,386	34	17
mifepristone / uterotonic agents	\$148,541	\$166,658	\$259,654	8	3
etanercept / antirheumatics	\$623,153	\$658,392	\$721,552	118	94
epinephrine / adrenergic bronchodilators	\$187,058	\$246,785	\$285,214	993	866
deflazacort / glucocorticoids	\$57,227	\$125,700	\$149,256	17	6
liraglutide / GLP-1 receptor agonists	\$952,939	\$990,170	\$1,044,454	1,165	1,100
somatropin / growth hormones	\$650,737	\$658,352	\$721,984	169	135
guselkumab / interleukin inhibitors	\$133,347	\$183,068	\$201,461	16	16
enzalutamide / antineoplastic hormones	\$128,318	\$221,788	\$193,980	17	15
apremilast / antirheumatics	\$139,312	\$141,879	\$203,052	50	36
voxelotor / miscellaneous uncategorized agents	\$107,221	\$162,829	\$168,294	18	16
macitentan / agents for pulmonary hypertension	\$95,833	\$107,026	\$156,704	14	11
coagulation factor ix / factor for bleeding disorders	\$271,867	\$258,472	\$326,400	8	6
paliperidone / atypical antipsychotics	\$1,798,359	\$1,725,804	\$1,851,774	650	596
abatacept / antirheumatics	\$120,282	\$106,207	\$169,309	33	30
empagliflozin / SGLT-2 inhibitors	\$617,514	\$615,107	\$662,281	838	779
tafamidis / transthyretin stabilizers	\$0	\$131,308	\$40,000	2	1
abemaciclib / CDK 4/6 inhibitors	\$98,738	\$143,774	\$136,720	11	11
pancrelipase / digestive enzymes	\$398,684	\$411,125	\$436,665	196	171
nilotinib / BCR-ABL tyrosine kinase inhibitors	\$40,335	\$40,807	\$77,907	6	5
alpelisib / PI3K inhibitors	\$51,242	\$69,972	\$88,702	4	4
calcium/magnesium/potass/sodium oxybates / miscellaneous anxiolytics, sedatives and hypnotics	\$12,787	\$15,342	\$49,894	3	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 MAY 2022 TO JUL 2022 (FFS and CCOs)

Drug Product Therapeutic Category	Jul 2022 # Claims	Jul 2022 \$ Paid	Jul 2022 Avr. Paid Per Rx	Jul 2022 Avr. Units Per Rx	May 2022 Paid Per Unit	Jun 2022 Paid Per Unit	Jul 2022 Paid Per Unit	Percent Change
Entresto (sacubitril-valsartan) 97 mg-103 mg tablet / angiotensin receptor blockers and neprilysin inhibitors (P)	201	\$135,974	\$676.49	66	\$9.28	\$9.51	\$9.92	6.9%
Nurtec ODT (rimegepant) 75 mg tablet, disintegrating / CGRP inhibitors (P)	130	\$115,977	\$892.13	9	\$97.91	\$100.39	\$102.92	5.1%
Entresto (sacubitril-valsartan) 49 mg-51 mg tablet / angiotensin receptor blockers and neprilysin inhibitors (P)	174	\$112,036	\$643.89	66	\$9.39	\$9.49	\$9.84	4.8%
Spiriva HandiHaler (tiotropium) 18 mcg capsule / anticholinergic bronchodilators (P)	299	\$144,495	\$483.26	30	\$15.02	\$15.14	\$15.73	4.7%
Vraylar (cariprazine) 3 mg capsule / atypical antipsychotics (N)	119	\$148,599	\$1,248.73	30	\$39.88	\$40.97	\$41.71	4.6%
Vyvanse (lisdexamfetamine) 30 mg tablet, chewable / CNS stimulants (N)	148	\$50,686	\$342.47	30	\$10.59	\$10.88	\$11.04	4.3%
Vyvanse (lisdexamfetamine) 40 mg capsule / CNS stimulants (N)	909	\$312,112	\$343.36	30	\$10.64	\$10.83	\$11.09	4.2%
Vyvanse (lisdexamfetamine) 50 mg capsule / CNS stimulants (N)	778	\$265,893	\$341.76	30	\$10.60	\$10.79	\$11.04	4.2%
Vyvanse (lisdexamfetamine) 20 mg capsule / CNS stimulants (N)	399	\$137,055	\$343.50	30	\$10.67	\$10.91	\$11.11	4.1%
Entresto (sacubitril-valsartan) 24 mg-26 mg tablet / angiotensin receptor blockers and neprilysin inhibitors (P)	279	\$178,182	\$638.64	64	\$9.34	\$9.53	\$9.73	4.1%
Vyvanse (lisdexamfetamine) 70 mg capsule / CNS stimulants (N)	424	\$145,522	\$343.21	30	\$10.68	\$10.82	\$11.09	3.9%
Vyvanse (lisdexamfetamine) 20 mg tablet, chewable / CNS stimulants (N)	154	\$52,585	\$341.46	30	\$10.59	\$10.84	\$11.00	3.8%
Trintellix (vortioxetine) 20 mg tablet / miscellaneous antidepressants (P)	186	\$88,504	\$475.83	34	\$13.49	\$13.75	\$14.00	3.8%
Vyvanse (lisdexamfetamine) 30 mg capsule / CNS stimulants (N)	845	\$290,217	\$343.45	30	\$10.68	\$10.85	\$11.07	3.7%
Vyvanse (lisdexamfetamine) 60 mg capsule / CNS stimulants (N)	448	\$152,064	\$339.43	30	\$10.55	\$10.67	\$10.94	3.6%

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 INITIATIVE UPDATE

#### September 2022 – November 2022

#### Ongoing Intervention(s):

		PPING FOR OP		COMITANT U		
Month	Prescribers	Pharms	Benes	Month	Prescribers	Benes
WOITE	Mailed	Mailed	Addressed	WIOIR	Mailed	Addressed
21-Dec	4	2	6	21-Dec	54	66
22-Jan	4	2	6	22-Jan	28	34
22-Feb	6	5	11	22-Feb	63	71
22-Mar	6	4	10	22-Mar	39	41
22-Apr	3	2	5	22-Apr	42	47
22-May	4	3	7	22-May	42	48
22-Jun	4	4	8	22-Jun	39	43
22-Jul	3	2	5	22-Jul	46	55
22-Aug	3	2	5	22-Aug	48	58
22-Sep	2	1	3	22-Sep	49	56
22-Oct	3	2	5	22-Oct	34	39
22-Nov	2	2	4	22-Nov	41	43

#### SEVERE MATERNAL MORBIDITY FOLLOW-UP

#### **BACKGROUND**

In the United States (US), maternal health is a huge health problem. The US has the highest maternal mortality rate among developed countries with approximately 700 maternal deaths occurring annually due to pregnancy or its complications. Alternal health problems are significantly concerning in the southern region of US. The statistics are particularly grave in Mississippi where the maternal mortality rate is one of the highest in the country at 22.1 per 100,000 live births which is well higher than the national average of 17.4 per 100,000 live births. The alarming high rate of maternal mortality despite huge investment in technology and services for maternal health highlights the need to better understand maternal morbidities and their risk factors.

In recent years, as a measure for preventing maternal mortality and addressing maternal health disparities, severe maternal morbidity (SMM) has been utilized as a significant indicator. According to the Centers for Disease Control and Prevention (CDC), SMM is defined as "an unexpected outcome of labor and delivery that adversely impacts a woman's health". Since 1993, the annual rate of severe maternal morbidity in the US has increased by twofold, from 49.5 in 1993 to 144 in 2014 per 10,000 births. Although the CDC and the American College of Obstetricians and Gynecologists (ACOG) have offered detailed recommendations for monitoring and reviewing severe pregnancy and delivery complications, Ti is estimated that more than 60,000 incidences of SMM occur every year. Mississippi also reported the highest SMM rate out of 26 states that reported such data. More than 60% of pregnant women are covered by Medicaid in Mississippi. Has been found that SMM occurs more frequently among Medicaid-insured women as compared to commercially insured patients. Data from maternal mortality review committees in 35 US states from 2017 to 2019 show that over 80% of pregnancy-related deaths in the U.S. are preventable, but inadequate treatment and identification of health risks contribute to hundreds of maternal deaths annually.

#### Our previous study findings:<sup>13</sup>

- The incidence of SMM among MS Medicaid women with live birth or stillbirth between 2018 2021 was 3.22%.
- The most common SMMs observed were sepsis 23.1%, pulmonary edema and acute heart failure 23.1%; followed by adult respiratory distress syndrome 14.8%, puerperal cerebrovascular disorders 13.6%, eclampsia 11.4%, acute renal failure 11.4%, and air and thrombotic embolism 11.1%. (Table 1)
- This study also reported that Maternal Comorbidity Index (MCI), distance from delivery center, age, and race were found to be significantly associated with SMM events among beneficiaries enrolled in Mississippi Medicaid. (Table 2)

TABLE 1. Severe Maternal Morbidity Conditions Among Medicaid  Beneficiaries with Live Birth or Stillbirth					
Conditions	Total				
	N	%			
Any SMM**	359				
1. Acute myocardial infarction	9	2.50%			
2. Aneurysm	2	0.60%			
3. Acute renal failure	41	11.40%			
4. Adult respiratory distress syndrome	53	14.80%			
5. Amniotic fluid embolism	4	1.10%			
6. Cardiac arrest/ventricular fibrillation	4	1.10%			
7. Conversion of cardiac rhythm	0	0.00%			
8. Disseminated intravascular coagulation	26	7.20%			
9. Eclampsia	41	11.40%			
10. Heart failure/arrest during surgery or procedure	0	0.00%			
11. Puerperal cerebrovascular disorders	49	13.60%			
12. Pulmonary edema and acute heart failure	83	23.10%			
13. Severe anesthesia complications	0	0.00%			
14. Sepsis	83	23.10%			
15. Shock	23	6.40%			
16. Sickle cell disease with crisis	9	2.50%			
17. Air and thrombotic embolism	40	11.10%			
18. Blood products transfusion	0	0.00%			
19. Hysterectomy	0	0.00%			
20. Temporary tracheostomy	0	0.00%			
21. Ventilation	0	0.00%			

TABLE 2. Results from Logistic Regression Model Examining the Relationship between Risk Factors and SMM Events (January 1, 2018 - December 31, 2020)					
Characteristics	Adjusted OR	p value			
MCI	1.31 (1.18 - 1.45)	<0.001			
Distance from delivery center	1.12 (1.06 - 1.17)	<0.001			
Age					
<18	1.15 (0.67 - 1.96)	0.43			
18-34	Reference				
>=35	2.07 (1.26 - 3.40)	0.02			
Race					
White	Reference				
African American	1.40 (1.01 - 1.93)	0.047			
Others	0.83 (0.39 - 1.77)	0.34			
Pregnancy-related visit	0.93 (0.71-1.22)	0.59			
Postpartum care visit	0.81 (0.60 - 1.09)	0.17			
Prenatal vitamin use	1.02 (0.76 -1.36)	0.91			
Prenatal low dose aspirin use	2.59 (0.68 - 10.63)	0.19			
SVI					
Least vulnerable	Reference				
Moderately vulnerable	0.71 (0.51 - 0.99)	0.27			
Mosts vulnerable	0.69 (0.44 - 1.06)	0.27			
SVI - Social Vulnerability Index, MCI - Maternal Comorbidity Index					
Distance from delivery center expressed per 100 miles					

#### Major focus for current study: Maternal comorbidity Index (MCI)

Maternal Comorbidity Index is a simple measure which captures the burden of chronic, behavioral, and pregnancy-induced conditions at an individual level (Figure 1). It was developed and validated to predict the occurrence of acute maternal end-organ injury and mortality.

**FIGURE 1. Maternal Comorbidity Index** 

Condition	Weight	ICD-10 Codes
Severe preeclampsia	5	014.1
Chronic congestive	5	150.22, 150.23, 150.32, 150.33, 150.42, 150.43
heart failure		
Congenital heart	4	Q20, Q21, Q22, Q23, Q24, Q25, Q26
disease		
Sickle cell disease	3	D57.00 , D57.01, D57.02, D57.211, D57.212,
		D57.219, D57.411, D57.412, D57.419, D57.811,
		D57.812, D57.819, (5th digit: unspecified, acute
		chest syndrome or splenic sequestration)
Multiple gestations	2	030
Cardiac valvular	2	105.0, 105.1, 105.2, 105.8
disease		
Systemic lupus	2	M32
erythematosus		
Human	2	B20, Z21
immunodeficiency		
virus		
Mild preeclampsia or	2	014.0, 014.9
unspecified		
preeclampsia		
Drug abuse	2	F11.1, F12.1, F13.1, F14.1, F15.1, F16.1, F18.1,
		F19.1
Placenta previa	2	O44
Chronic renal disease	1	N26.9, N18
Preexisting	1	010
hypertension		
Previous cesarean	1	034.21, 034.22
birth		
Gestational	1	013
hypertension		
Alcohol abuse	1	F10.1
Asthma	1	J45
Preexisting diabetes	1	024.0, 024.1, 024.3, 024.8
mellitus		

Maternal Age		-
35-39 years	1	-
40-44 years	2	-
45-49 years	3	-

A higher MCI score has been linked to higher risks of SMM in the real world. MCI was originally developed and validated also in a Medicaid population. In that study, for each unit increase in MCI score, the odds of maternal end-organ injury or death increased by 37% in the 30 days following delivery. As demonstrated by Salahuddin et al. after reviewing delivery-related hospitalization data in Texas from 2011-2014, increased MCI scores were associated with a higher risk of SMM during the delivery hospitalization [Adjusted odds ratio (OR): 1.42, 95% confidence interval (CI): 1.41-1.43]. Additionally, a recent study of California's delivery hospital discharge data by Main et al revealed that certain medical conditions within MCI were associated with a higher risk of developing SMM events. In line with these studies, our study indicates a single point increase in MCI was associated with a 31% increase in odds of SMM (adjusted OR: 1.31, 95% confidence interval: 1.18 – 1.45). (Table 2)

Following the presentation of these findings at the September 2022 DUR Board meeting, it was recommended that MS-DUR conduct an extension study further examining MCI and the distance from the delivery center measure.

#### **METHODS**

A descriptive analysis was conducted comparing the occurrence of the different conditions classified under the MCI across individuals that experienced SMM events compared to those that did not experience SMM events. Additionally, to assess whether beneficiaries traveled the same amount for delivery as their usual prenatal care, the distance from the delivery center to usual pregnancy related care provided in the prenatal period was determined to ascertain if the significantly different distance measure was attributable to traveling greater distances for delivery or if it is an indication of access inequity where the beneficiaries reside. The usual pregnancy related provider was identified based on the provider with the greatest number of pregnancy related visits for each beneficiary. In the case of multiple providers having the same number of visits in the prenatal period for a beneficiary, the provider with the most recent visit prior to delivery was identified as the usual prenatal care provider.

#### **ROC Curve Analysis**<sup>17,18</sup>

A final step will be conducted to identify the optimal MCI cut-off that separates those who are at risk of SMM events among pregnant beneficiaries enrolled in Medicaid. The receiver operator characteristic (ROC) curve analysis will be used to select the clinically relevant cut-off score for MCI. The ROC curve shows the tradeoff between sensitivity and specificity as one changes the cut-off values for positivity. Hence, the sensitivity versus 1-specificity plot in ROC space is called ROC curve.

Sensitivity: the proportion of positive observations that are measured as positive, i.e. true positive rate (TPR)

Specificity: the proportion of negative observations that are measured as negative, i.e. true negative (TNR)

The area under the curve (AUC) will be used to measure accuracy of the plot. The closer the curve follows the left-upper corner of the plot, the more accurate the test. Likewise, Youden's index will be used to quantify the optimal cut-off MCI score. Youden's index maximizes the vertical line between the ROC curve and diagonal line (i.e. chance level) which is defined as sensitivity – false positive error fraction.

Youden's Index: (sensitivity + specificity) - 1

#### RESULTS

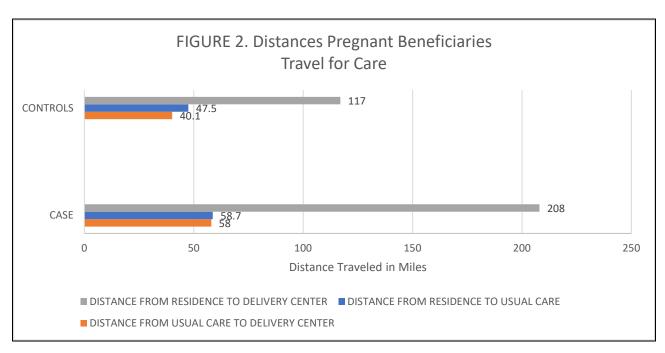
Table 3 presents the prevalence of the different MCI conditions across the two groups – cases (pregnant beneficiaries who experienced an SMM event) and controls (pregnant beneficiaries who did not experience an SMM event). From the descriptive analysis we can see the major drivers of MCI in cases (relative to controls) were:

- Pre-existing hypertension and previous cesarean birth;
- Followed by pre-existing diabetes mellitus, drug abuse, gestational hypertension, and asthma.

Condition	Matched Cases and controls (N = 1077)	Cases (N = 359)	Controls (N = 718)	
Previous cesarean birth	160 (14.86 %)	67 (18.66 %)	93 (12.95 %)	
Preexisting hypertension	128 (11.88 %)	67 (18.66 %)	61 (8.50 %)	
Gestational hypertension	77 (7.15 %)	31 (8.64 %)	46 (6.41 %)	
Asthma	77 (7.15 %)	31 (8.64 %)	46 (6.41 %)	
Placenta previa	44 (4.09 %)	16 (4.46 %)	28 (3.90 %)	
Drug abuse	43 (3.99 %)	23 (6.41 %)	20 (2.79 %)	
Preexisting diabetes mellitus	40 (3.71 %)	26 (7.24 %)	14 (1.95 %)	
Multiple gestation	28 (2.6 %)	12 (3.34 %)	16 (2.23 %)	
Mild preeclampsia or unspecified preeclampsia	22 (2.04 %)	12 (3.34 %)	10 (1.39 %)	
Systemic lupus erythematosus	11 (1.02 %)	7 (1.95 %)	4 (0.56 %)	
Sickle cell disease	9 (0.84 %)	9 (2.51 %)	0 (0.00 %)	
Congenital heart disease	7 (0.65 %)	2 (0.56 %)	5 (0.70 %)	
Chronic renal disease	6 (0.56 %)	4 (1.11 %)	2 (0.28 %)	
Human immunodeficiency virus	5 (0.46 %)	5 (1.39 %)	0 (0.00 %)	
Chronic congestive heart failure	3 (0.28 %)	3 (0.84 %)	0 (0.00 %)	
Severe preeclampsia	2 (0.19 %)	1 (0.28 %)	1 (0.14 %)	
Alcohol abuse	2 (0.19 %)	1 (0.28 %)	1 (0.14 %)	
Cardiac valvular disease	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	
Maternal Age				
35-39 years	26 (2.41 %)	14 (3.90 %)	12 (1.67 %)	
40-44 years	4 (0.37 %)	3 (0.84 %)	1 (0.14 %)	
>45 years	4 (0.37 %)	3 (0.84 %)	1 (0.14 %)	

Table 4 and Figure 2 present a more detailed description of the distances pregnant beneficiaries travel for care. In our previous study, it was found that the distance from a beneficiary's residence to their delivery center was significantly associated with their likelihood of experiencing an SMM event. During discussions, a question was raised regarding the distances beneficiaries were traveling for usual prenatal care. In our follow-up analysis, we examined the distance from a beneficiary's residence to their usual prenatal care. We also examined the distance from their usual prenatal care to the delivery center. It was found that the distances between beneficiaries' residence and their usual prenatal care as well as the distance between their usual prenatal care and their delivery center were different when comparing cases and controls. This indicates that beneficiaries experiencing SMM events traveled further for both usual prenatal care and delivery with the difference traveled for delivery being substantially further for those experiencing SMM events than for those not experiencing SMM events.

TABLE 4. Distance Pregnant Beneficiaries Travel for Care							
	Mean (Standard error)	Median	Lower quartile	Upper quartile			
Distance between beneficiary residence and delivery center(in 100 miles)							
Full cohort (N = 11,119)	1.16 (0.02)	0.347	0.093	1.048			
Cases (N = 359)	2.08 (0.19)	0.654	0.167	2.62			
Controls (N = 718)	1.17 (0.08)	0.369	0.101	1.049			
Distance between beneficiary residence and usual prenatal care (in 100 miles)							
Full cohort (N = 11,119)	0.609 (0.01)	0.193	0.05	0.424			
Cases (N = 359)	0.587 (0.08)	0.202	0.057	0.418			
Controls (N = 718)	0.475 (0.04)	0.192	0.05	0.406			
Distance between usual prental care and delivery center (in 100 miles)							
Full cohort (N = 11,119)	0.459 (0.04)	0.093	0	0.493			
Case (N = 359)	0.580 (0.08)	0.16	0.004	0.663			
Control (N = 718)	0.401 (0.03)	0.07	0	0.45			



#### CONCLUSIONS

From our follow-up analysis we found the driving MCI conditions among pregnant beneficiaries experiencing SMM events as compared to those that did not experience SMM events included pre-existing hypertension and previous cesarean birth, followed by pre-existing diabetes mellitus, drug abuse, gestational hypertension, and asthma. We also found that pregnant beneficiaries experiencing SMM events traveled further distances for both usual prenatal care and delivery compared to those that did not experience SMM events. These findings can be used to help Medicaid provide improved maternal care and reduce instances of SMM.

#### RECOMMENDATIONS

- 1. MS-DUR should complete the ROC curve analysis to determine an MCI cut-off score.
- DOM is encouraged to seek opportunities to disseminate findings from this study and to collaborate with other stakeholders in maternal health across Mississippi such as the MSDH and the March of Dimes.

#### REFERENCES

- 1. Severe Maternal Morbidity in the United States: A Primer. doi:10.26099/r43h-vh76
- 2. Maternal Mortality Maternity Care US Compared 10 Other Countries | Commonwealth Fund. Accessed October 11, 2022. https://www.commonwealthfund.org/publications/issue-briefs/2020/nov/maternal-mortality-maternity-care-us-compared-10-countries
- 3. Snyder JE, Stahl AL, Streeter RA, Washko MM. Regional Variations in Maternal Mortality and Health Workforce Availability in the United States. *Ann Intern Med*. 2020;173(11 Suppl):S45-S54. doi:10.7326/M19-3254
- 4. Hoyert DL, Miniño AM. Maternal Mortality in the United States: Changes in Coding, Publication, and Data Release, 2018. *Natl Vital Stat Rep Cent Dis Control Prev Natl Cent Health Stat Natl Vital Stat Syst*. 2020;69(2):1-18.
- 5. Severe Maternal Morbidity in the United States | Pregnancy | Reproductive Health | CDC. Published February 2, 2021. Accessed October 11, 2022. https://www.cdc.gov/reproductivehealth/maternalinfanthealth/severematernalmorbidity.html
- 6. State Strategies for Preventing Pregnancy-Related Deaths: A Guide for Moving Maternal Mortality Review Committee Data to Action. :89.
- 7. Severe Maternal Morbidity: Screening and Review. Accessed October 11, 2022. https://www.acog.org/en/clinical/clinical-guidance/obstetric-care-consensus/articles/2016/09/severe-maternal-morbidity-screening-and-review
- 8. Postpartum Medicaid Addressing Gaps in Coverage to Improve Maternal Health. Center for Mississippi Health Policy; 2021:4. https://mshealthpolicy.com/wp-content/uploads/2021/02/Post-Partum-Medicaid-Feb-2021.pdf
- 9. Natality Birth Records Documentation. Accessed October 19, 2022. https://wonder.cdc.gov/wonder/help/natality.html
- 10. Chen LY, Crum RM, Strain EC, Alexander GC, Kaufmann C, Mojtabai R. Prescriptions, nonmedical use, and emergency department visits involving prescription stimulants. *J Clin Psychiatry*. 2016;77(3):e297-304. doi:10.4088/JCP.14m09291
- 11. Mississippi State Department of Health. *Mississippi Marternal Mortality Report 2013 2016.*; 2021.
- 12. Pregnancy-Related Deaths: Data from Maternal Mortality Review Committees in 36 US States, 2017–2019 | CDC. Published September 26, 2022. Accessed October 24, 2022. https://www.cdc.gov/reproductivehealth/maternal-mortality/erase-mm/data-mmrc.html

- 13. Drug Utilization Review Board Mississippi Division of Medicaid. Published April 3, 2014. Accessed November 28, 2022. https://medicaid.ms.gov/drug-utilization-review-dur-board/
- 14. Bateman BT, Mhyre JM, Hernandez-Diaz S, et al. Development of a comorbidity index for use in obstetric patients. *Obstet Gynecol*. 2013;122(5):957-965. doi:10.1097/AOG.0b013e3182a603bb
- 15. Salahuddin M, Mandell DJ, Lakey DL, et al. Maternal comorbidity index and severe maternal morbidity during delivery hospitalizations in Texas, 2011-2014. *Birth Berkeley Calif*. 2020;47(1):89-97. doi:10.1111/birt.12465
- Main EK, Leonard SA, Menard MK. Association of Maternal Comorbidity With Severe Maternal Morbidity: A Cohort Study of California Mothers Delivering Between 1997 and 2014. *Ann Intern Med*. 2020;173(11 Suppl):S11-S18. doi:10.7326/M19-3253
- 17. Florkowski CM. Sensitivity, Specificity, Receiver-Operating Characteristic (ROC) Curves and Likelihood Ratios: Communicating the Performance of Diagnostic Tests. *Clin Biochem Rev*. 2008;29(Suppl 1):S83-S87.
- 18. Hajian-Tilaki K. Receiver Operating Characteristic (ROC) Curve Analysis for Medical Diagnostic Test Evaluation. *Casp J Intern Med.* 2013;4(2):627-635.

#### **COVID-19 OVERVIEW AMONG MEDICAID BENEFICIARIES**

#### **BACKGROUND**

Beginning March 2020, the novel coronavirus, COVID-19, was declared a global pandemic by the World Health Organization and a national emergency was declared in the United States.¹ Since that time, almost 98 million cases of COVID-19 have been reported in the United States with over 935,000 cases being reported in Mississippi.² COVID-19 has had a significant impact on public health with nearly 5.4 million hospitalizations and over 1 million deaths associated with the virus in the US.² To help combat the COVID-19 pandemic, vaccines and therapeutic agents were developed in record setting time. The first COVID-19 vaccine received Emergency Use Authorization in the United States in December 2020.³ The Centers for Disease Control and Prevention (CDC) reports that over 650 million vaccine doses have been administered in the US since 2020 with approximately 68.7% of the US population having completed the primary series.² In Mississippi, just over 4 million vaccine doses have been administered with 52% of the population being fully vaccinated with the primary series.⁴ Among the COVID-19 therapeutic agents, nearly 8 million doses have been administered in the US with just over 50,000 doses administered in Mississippi.⁵

For this report, MS-DUR set out to describe characteristics of Medicaid beneficiaries diagnosed with COVID-19 and report trends in COVID-19 vaccinations and therapeutic agents administered.

#### **METHODS**

A retrospective analysis was conducted using Mississippi Medicaid medical and point of sale (POS) pharmacy claims for fee-for-service (FFS) and coordinated care organization [CCOs: UnitedHealthcare (UHC), Magnolia (MAG), and Molina (MOL)] claims for the period of March 11, 2020 to June 30, 2022. The analysis was comprised of three aims: identify and provide descriptive characteristics of beneficiaries diagnosed with COVID-19, provide utilization trends of COVID-19 vaccinations, and provide utilization trends in the utilization of COVID-19 therapeutic agents.

Beneficiaries with a diagnosis of COVID-19 were identified in the period between March 11, 2020 and June 30, 2022 using the International Classification of Diseases (ICD-10) codes. The first claim with a COVID-19 diagnosis for a beneficiary was considered as the "index date". Demographic characteristics such as age, sex, and race were reported at baseline (index date). The pharmacy plan for each beneficiary with COVID-19 was identified based on the plan at the index diagnosis date. Comorbidities for these beneficiaries were assessed in the 12-month period prior to the index COVID-19 diagnosis date. Comorbidities included in this analysis included cardiovascular disease, heart failure, asthma, COPD, diabetes, depression, hypertension, stroke, and tobacco use. For beneficiaries with COVID-19, COVID-19 related hospitalizations, ICU admissions, and all-cause death were reported. All-cause deaths were assessed from the index date through the end of the study period (June 30, 2022). COVID-19 related hospitalizations were defined as those that had a

primary diagnosis code for COVID-19. For those beneficiaries that had COVID-19 related hospitalizations, ICU admissions were identified based on revenue center codes for ICU stay.

Monthly trends in COVID-19 vaccinations were assessed between December 2020 (the first COVID-19 vaccine was approved by the FDA for immediate use on December 11, 2020)<sup>6</sup> and June 2022 (end of state fiscal year 2022). COVID-19 vaccinations in this period were identified from both pharmacy claims and medical claims using national drug codes (NDC) and procedure codes.<sup>7</sup> The pharmacy plan was determined based on the beneficiary plan as of the claim date for the vaccination.

Additionally, monthly trends in utilization of COVID-19 therapeutics (monoclonal antibodies and antiviral agents) were assessed using both medical and pharmacy claims data. Monoclonal antibodies included in this trend analysis were Bebtelovimab IV, Etesevimab IV, Regen-Cov (casirivimab and imdevimab) IV, Sotrovimab IV, Bamlanivimab IV (used with etesevimab), and Evusheld (tixagevimab and cilgavimab) IM. Antiviral agents in this trend analysis included Veklury (remdesivir) IV, Paxlovid (nirmatrelvir tablets and ritonavir tablets) oral (PO), and Lagevrio (molnupiravir) PO. Pharmacy plan for both trend analyses were determined based on the claim date.

#### **RESULTS**

Table 1 describes the demographic characteristics of those Medicaid beneficiaries with a COVID-19 diagnosis in claims data from March 2020 through June 2022.

- 135,990 Medicaid beneficiaries had a diagnosis of COVID-19;
- 62.9% were female;
- 54.6% were Black;
- The most common comorbid conditions present were:
  - Hypertension 15%,
  - Depression 11.3%;
- 5.7% (7,798) of those with a COVID-19 diagnosis in claims data had a COVID-related hospitalization with 18% (1,405) of those hospitalized involving an ICU admission;
- Of those with a COVID-19 diagnosis in claims data, 2.9% had an **all-cause death** between their index date and the end of the study period. As a frame of reference, Table 1a displays the all-cause death rate during the reporting period for beneficiaries without a diagnosis of COVID-19. This rate was 4%, higher than the 2.9% for beneficiaries with COVID-19. The higher non-COVID death rate during the pandemic is in line with current literature with studies reporting markedly decreased rates for hospital admissions and increased rates for mortality from non-COVID diseases since the beginning of the pandemic.<sup>8,9</sup>

TABLE 1. Demographics of Beneficiaries with a COVID-19 Diagnosis										
(March, 2020 - June, 2022)										
V - 11	Fee-for	-Service	United HealthCare		Mag	nolia	Мо	lina	To	tal
Variable	N	%	N	%	N	%	N	%	N	%
Age Category (yrs)										
0-5	3,569	8.3%	7,318	20.0%	7,481	19.2%	4,987	28.1%	23,355	17.2%
6-11	3,816	8.9%	7,344	20.1%	8,132	20.9%	2,988	16.9%	22,280	16.4%
12-17	4,722	11.0%	9,956	27.3%	10,669	27.4%	3,438	19.4%	28,785	21.2%
18-25	9,164	21.4%	3,236	8.9%	3,103	8.0%	1,971	11.1%	17,474	12.8%
26-44	9,512	22.2%	5,875	16.1%	6,186	15.9%	3,548	20.0%	25,121	18.5%
45-64	5,890	13.8%	2,780	7.6%	3,332	8.6%	791	4.5%	12,793	9.4%
65+	6,151	14.4%	13	0.0%	18	0.0%	0	0.0%	6,182	4.5%
Total	42,824		36,522		38,921		17,723		135,990	
Sex										
Female	28,937	67.6%	22,013	60.3%	23,461	60.3%	11,191	63.1%	85,602	62.9%
Male	13,884	32.4%	14,509	39.7%	15,460	39.7%	6,532	36.9%	50,385	37.1%
Unknown	3	0.0%	-	0.0%	-	0.0%	-	0.0%	3	0.0%
Total	42,824		36,522		38,921		17,723		135,990	
Race			•				•			
White	15,463	36.1%	13,181	36.1%	12,317	31.6%	6,506	36.7%	47,467	34.9%
Other	4,030	9.4%	4,330	11.9%	4,063	10.4%	1,790	10.1%	14,213	10.5%
Black	23,331	54.5%	19,010	52.1%	22,539	57.9%	9,425	53.2%	74,305	54.6%
Total	42,824		36,521		38,919		17,721		135,985	
Comorbidities								ı	,	
Cardiovascular disease	2,319	5.4%	707	1.9%	821	2.1%	226	1.3%	4,073	3.0%
Heart failure	2,284	5.3%	566	1.5%	696	1.8%	170	1.0%	3,716	2.7%
Asthma	2,751	6.4%	3,221	8.8%	3,907	10.0%	1,251	7.1%	11,130	8.2%
COPD	2,496	5.8%	1,282	3.5%	1,516	3.9%	512	2.9%	5,806	4.3%
Diabetes	4,799	11.2%	1,917	5.2%	2,420	6.2%	620	3.5%	9,756	7.2%
Depression	6,250	14.6%	3,625	9.9%	4,031	10.4%	1,526	8.6%	15,432	11.3%
Hypertension	9,547	22.3%	4,215	11.5%	5,064	13.0%	1,582	8.9%	20,408	15.0%
Stroke	1,535	3.6%	218	0.6%	232	0.6%	90	0.5%	2,075	1.5%
Tobacco use	1,852	4.3%	1,308	3.6%	1,498	3.8%	584	3.3%	5,242	3.9%
COVID-related										
hospitalizations	4,867	11.4%	1,135	3.1%	1,242	3.2%	554	3.1%	7,798	5.7%
ICU admissions	600	1.4%	326	0.9%	376	1.0%	103	0.6%	1,405	1.0%
Death (all cause)	3,200	7.5%	285	0.8%	318	0.8%	86	0.5%	3,889	2.9%

Note: Plan determined as of the first COVID 19-related medical claim; age calculated as of first COVID-19 related medical claim ICU admissions were flagged among beneficiaries that had any COVID-related hospitalizations; COVID-related hospitalizations were defined as those that had a primary diagnosis code for COVID-19

TABLE 1a. Death Rates among Beneficiaries without COVID-19 Alive as of Report Start Date with at Least One Month Eligibility During the Reporting Period: March 2020 - June 2022

Plan	#Eligible Beneficiaries	# Beneficiaries who died	Death Rate
FFS	442,445	27,480	6.2%
UHC	127,831	1,165	0.9%
MAG	132,428	1,372	1.0%
MOL	68,104	558	0.8%
Total	770,828	30,595	4.0%

FFS: Fee-for-Service, UHC: United HealthCare, MAG: Magnolia, MOL: Molina Pharmacy program determined as of beneficiary's last month of enrollment.

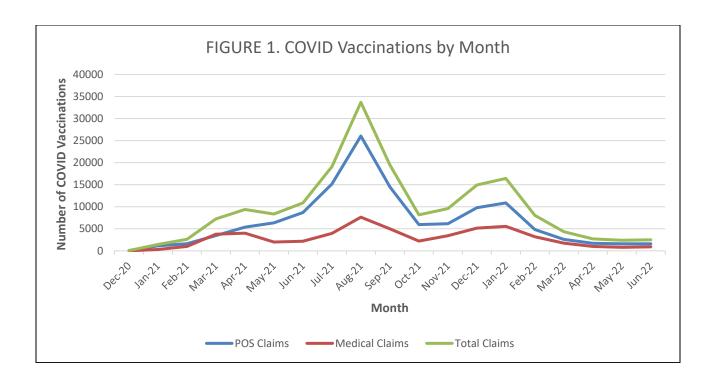
Table 2 and Figure 1 display trends in COVID-19 vaccine administration between December 2020 and June 2022. Vaccine administration was identified through claims data using the Current Procedural Terminology (CPT) codes approved for COVID-19 vaccinations.

- A total of 181,221 vaccine administration claims were identified. Of these, 70.3% (127,440) were submitted by pharmacies through point-of-sale (POS).
- July through September 2021 were the months with the largest number of vaccinations administered. This timeframe is indicative of the second wave of COVID-19 vaccine administration. Vaccines administered during the initial vaccination wave were primarily provided through sites set up by the Mississippi State Department of Health.
- There was another bump in claims in December 2021 and January 2022 corresponding to the first appearance of the Omicron variant in the US.<sup>10</sup>

	TABLE 2. COVID-19 Vaccinations by Month and Pharmacy Plan									
	(December 2020 - June 2022)									
					Pharmacy F	rogram				
Month	Tot	al		FFS	U	нс	N	1AG	MOL	
	POS	Medical	POS	Medical	POS	Medical	POS	Medical	POS	Medical
Dec-20	48	8	47	5	1	1	0	2	0	0
Jan-21	1,147	301	1,023	112	54	61	38	105	32	23
Feb-21	1,618	996	1,140	368	193	256	220	309	65	63
Mar-21	3,465	3,774	998	1,205	967	1,041	1,237	1,295	263	233
Apr-21	5,374	4,005	1,389	1,180	1,626	1,139	1,846	1,421	513	265
May-21	6,356	1,986	1,595	598	2,022	527	1,983	720	756	141
Jun-21	8,684	2,177	2,246	568	2,782	634	2,672	805	984	170
Jul-21	15,138	3,951	3,957	802	5,001	1,289	4,464	1,468	1,716	392
Aug-21	26,039	7,630	7,181	1,738	8,381	2,345	7,426	2,702	3,051	845
Sep-21	14,485	4,988	4,226	1,240	4,478	1,534	4,014	1,676	1,767	538
Oct-21	5,956	2,211	1,933	652	1,719	648	1,616	686	688	225
Nov-21	6,154	3,421	1,931	1,034	1,919	923	1,693	1,165	611	299
Dec-21	9,768	5,158	3,072	1,300	3,172	1,541	2,503	1,855	1,021	462
Jan-22	10,872	5,550	3,676	1,385	3,549	1,640	2,428	1,945	1,219	580
Feb-22	4,829	3,197	1,651	763	1,487	974	1,123	1,117	568	343
Mar-22	2,598	1,734	1,031	447	721	501	527	595	319	191
Apr-22	1,712	991	709	316	439	276	390	292	174	107
May-22	1,594	797	659	282	442	211	322	246	171	58
Jun-22	1,603	906	699	314	453	248	272	275	179	69
Total	127,440	53,781	39,163	14,309	39,406	15,789	34,774	18,679	14,097	5,004

FFS: Fee-for-Service, UHC: United HealthCare, MAG: Magnolia, MOL: Molina

COVID vaccinations were identified using CPT codes (reference: American Medical Association. COVID-19 CPT vaccine and immunization codes https://www.ama-assn.org/practice-management/cpt/covid-19-cpt-vaccine-and-immunization-codes#unique-cpt-codes-approved-for-covid-19-immunizations)



Although there are currently four therapeutic agents available for use in the US to prevent or treat eligible patients<sup>11</sup>, additional therapeutic agents that have previously been used to treat COVID-19 were included in this analysis. Below is a listing of the included agents along with their initial Emergency Use Authorization (EUA) and FDA approval date if applicable:

- Monoclonal antibodies
  - Bebtelovimab IV EUA 2/2022,
  - Etesevimab and Bamlanivimab IV EUA 5/2021,
  - o Regen-COV (casirivimab/imdevimab) IV EUA 11/2020,
  - Sotrovimab IV, EUA 5/2021,
  - Bamlanivimab IV EUA 11/2020,
  - Evushield (tixagevimab/cilgavimab) IM EUA 12/2021; (prophylaxis)
- Antivirals
  - Veklury (remdesivir) IV EUA 5/2020, FDA approval 10/2020,
  - o Paxlovid (nirmatrelvir/ritonavir) PO EUA 12/2021,
  - Lagevrio (molnupiravir) PO EUA 12/2021.

<sup>\*</sup>Italics – not currently available for use

TABLE 3. Monthly Utilization Trends of Monoclonal Antibody Therapeutics for COVID-19								
Month	FFS	UHC	MAG	MOL	Total			
Apr-21	0	1	3	0	4			
May-21	0	0	1	0	1			
Jun-21	0	1	0	0	1			
Jul-21	5	3	6	1	15			
Aug-21	120	118	141	57	436			
Sep-21	104	89	108	34	335			
Oct-21	26	12	23	8	69			
Nov-21	35	15	23	5	78			
Dec-21	106	60	63	29	258			
Jan-22	26	23	19	11	79			
Feb-22	5	1	1	2	9			
Mar-22	1	1	0	0	2			
Apr-22	0	1	0	0	1			
May-22	2	3	0	0	5			
Jun-22	10	1	3	1	15			
Total	440	329	391	148	1308			

FFS: Fee-for-Service, U	HC: United HealthCa	re, MAG: Magnolia,
NACL - NA-E		

Monoclonal antibodies included in this analysis: Bebtelovimab IV, Etesevimab IV, Regen-Cov (casirivimab and imdevimab) IV, Sotrovimab IV,Bamlanivimab IV (used with etesevimab)

Evusheld (tixagevimab and cilgavimab) IM

No claims were found for these products prior to April 2021

	TABLE 4. Monthly Utilization Trends of Antiviral Therapeutics for COVID-19								
Month	FFS	UHC	MAG	MOL	Total				
Jan-22	2	0	8	3	13				
Feb-22	3	8	0	0	11				
Mar-22	0	1	1	0	2				
Apr-22	1	0	1	0	2				
May-22	13	15	13	3	44				
Jun-22	64	91	73	21	249				
Total	83	115	96	27	321				

FFS: Fee-for-Service, UHC: United HealthCare, MAG: Magnolia, MOL: Molina

Antiviral agents included in this analysis: Veklury (remdesivir) IV, Paxlovid (nirmatrelvir tablets and ritonavir tablets) PO, Lagevrio (molnupiravir) PO

No claims were found for these products prior to January 2022

- The submission of claims for the administration of monoclonal antibodies to Medicaid beneficiaries first appeared in April 2021, however, limited utilization was seen until August 2021. The majority of claims for monoclonal antibody agents occurred between August 2021 and January 2022. (Table 3)
- The first claims for the antivirals appeared in January 2022, but remained limited until June 2022. (Table 4)
- Pharmacists received FDA authorization to prescribe Paxlovid beginning July 2022.<sup>12</sup>

#### **CONCLUSIONS**

The COVID-19 global pandemic has had a tremendous impact on healthcare around the world. In Mississippi, many Medicaid beneficiaries have been infected with the virus. This report provides baseline descriptive characteristics of Medicaid beneficiaries diagnosed with COVID-19 and trends in the uptake of COVID-19 vaccines and therapeutic agents.

#### **RECOMMENDATIONS**

This report for the DUR Board on COVID-19 is for information and discussion purposes only. No action is being sought at this time.

#### REFERENCES

- 1. A Timeline of COVID-19 Developments in 2020. AJMC. Accessed November 11, 2022. https://www.ajmc.com/view/a-timeline-of-covid19-developments-in-2020
- 2. CDC. COVID Data Tracker. Centers for Disease Control and Prevention. Published March 28, 2020. Accessed November 11, 2022. https://covid.cdc.gov/covid-data-tracker
- 3. Coronavirus: Timeline. U.S. Department of Defense. Accessed November 11, 2022. https://www.defense.gov/Explore/Spotlight/Coronavirus-DOD-Response/Timeline/
- 4. COVID-19 Data Reports Mississippi State Department of Health. Accessed November 11, 2022. https://msdh.ms.gov/msdhsite/ static/14,23549,420,971.html
- 5. Cumulative COVID-19 Therapeutics Delivered and Administered Amounts by Jurisdiction. Accessed November 21, 2022. https://aspr.hhs.gov/COVID-19/Therapeutics/Orders/Documents/state-data.pdf
- 6. FDA Approves First COVID-19 Vaccine. FDA. Published August 23, 2021. Accessed November 23, 2022. https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine
- 7. COVID-19 CPT vaccine and immunization codes | American Medical Association. Accessed November 23, 2022. https://www.ama-assn.org/practice-management/cpt/covid-19-cpt-vaccine-and-immunization-codes#unique-cpt-codes-approved-for-covid-19-immunizations
- 8. Dang A, Thakker R, Li S, Hommel E, Mehta HB, Goodwin JS. Hospitalizations and Mortality From Non–SARS-CoV-2 Causes Among Medicare Beneficiaries at US Hospitals During the SARS-CoV-2 Pandemic. *JAMA Netw Open*. 2022;5(3):e221754. doi:10.1001/jamanetworkopen.2022.1754
- 9. Cronin CJ, Evans WN. Excess mortality from COVID and non-COVID causes in minority populations. *Proc Natl Acad Sci.* 2021;118(39):e2101386118. doi:10.1073/pnas.2101386118
- 10. Omicron and the BQs: A Guide to What We Know. Yale Medicine. Accessed November 23, 2022. https://www.yalemedicine.org/news/5-things-to-know-omicron
- 11. Emergency Use Authorization. *FDA*. Published online December 1, 2022. Accessed December 1, 2022. https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
- 12. Coronavirus (COVID-19) Update: FDA Authorizes Pharmacists to Prescribe Paxlovid with Certain Limitations. FDA. Published July 7, 2022. Accessed December 1, 2022. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-pharmacists-prescribe-paxlovid-certain-limitations

#### IMPACT OF OBESITY ON MISSISSIPPI MEDICAID

#### **BACKGROUND**

Obesity is a common, chronic disease with a complex pathophysiology that increases the risks of other conditions such as hypertension, diabetes, and cardiovascular disease. Obesity is defined by the Centers for Disease Control and Prevention (CDC) as "weight that is higher than what is considered healthy for a given height." A milestone in the movement establishing obesity as a chronic disease came in 2013 when the American Medical Association formally recognized "obesity as a disease state with multiple pathophysiological aspects requiring a range of interventions to advance obesity treatment and prevention."

Body Mass Index (BMI) is the primary screening tool for identifying overweight and obesity. BMI is calculated by dividing a person's weight in kilograms by the square of height in meters. Figure 1 displays overweight and obesity classifications as determined by BMI.

Figure 1: Overweight and Obesity Classifications by BMI.<sup>3</sup>



According to the World Health Organization (WHO), obesity worldwide has almost tripled since 1975. In 2016, 1.9 billion adults worldwide were overweight, with 650 million classified as obese translating into 39% of the world's adult population being overweight and 13% have obesity. In the US, the prevalence of obesity is higher with the National Health and Nutrition Examination Survey (NHANES) pre-pandemic estimating 41.9% (108 million) of adults experienced obesity between 2017-March 2020. The same study, the prevalence of obesity in children and adolescents aged 2-19 years was 19.7%. These figures are projected to continue to increase. It is predicted that by 2030, nearly 1 in 2 adults in the US will have obesity. In Mississippi, the prevalence of adult obesity is projected to be 58.2% by 2030. The prevalence of obesity has been found to vary across racial and ethnic groups with it being highest among non-Hispanic Black women.

Obesity has been shown to be associated with over 60 comorbidities that include hypertension, type 2 diabetes, coronary artery disease, depression, osteoarthritis, and certain cancers. Additionally, the impact of obesity on the development of comorbidities has been shown to increase over time. In

Obesity has also been found to increase mortality risks. Studies have shown that weight gain throughout early adulthood to midlife is associated with increased mortality. However, a study by Xie et al<sup>16</sup> found that individuals that lost weight going from an obese body mass in early adulthood to overweight by midlife had a 54% reduction in mortality risk compared to those who remained obese.

With the increased health burden associated with obesity also comes an increased economic burden. In a 10-year health expenditures simulation study, Su et al demonstrated that the obese population annually averaged \$3,900 in higher medical expenditures in the initial year compared to normal weight population. This annual difference increased to \$4,600 by year 10. The impact of obesity on medical expenditures varied according to the obesity category. Over 10 years, the difference in medical expenditures compared to the normal weight population for those in obesity class I averaged \$2,820 annually, \$5,100 annually for those in obesity class II, and \$8,710 annually for those in obesity class III. A retrospective claims study by Cawley et al found that adults with obesity experienced higher annual medical costs by \$2,505 compared to normal weight adults. This study also found that costs increased significantly as the class of obesity increased with annual expenditures associated with class III obesity climbing to \$5,850. A separate study found that individuals with BMI  $\geq$  35 kg/m2 (class II and above) cost state Medicaid programs nearly \$8 billion in medical costs in 2013. This study calculated that Mississippi Medicaid had \$69 million in obesity attributable medical expenditures in 2013.

Obesity has a complex pathophysiology with factors such as genetic, metabolic, behavioral, and environmental all playing a role. Although decreased caloric intake and increased physical activity may initially lead to weight loss, a cascade of metabolic and hormonal adaptations make weight loss difficult to sustain.<sup>19</sup> To aid in the achievement of greater weight loss and weight loss maintenance, the American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE) Comprehensive Clinical Practice Guidelines recommend the addition of pharmacotherapy to lifestyle therapy.<sup>20</sup> Additionally the guidelines recommend the chronic use of pharmacotherapy when potential benefits outweigh the risks.

With recent advances in the pharmacotherapeutic agents indicated for obesity management and promising therapies under development, there is renewed interest in this drug category. The drugs in this therapeutic class include amphetamine sulfate (Evekeo®), benzphetamine, diethylpropion, liraglutide (Saxenda®), orlistat (Xenical®), naltrexone and bupropion (Contrave®), phendimetrazine, phentermine, phentermine and topiramate (Qsymia®), semaglutide (Wegovy®), and setmelanotide (Imcivree®). Currently, the Mississippi Division of Medicaid's State Plan Amendment (SPA) prohibits coverage of pharmacotherapy for obesity management. At the request of the Pharmacy and Therapeutics Committee, MS-DUR was asked to present a report describing the impact of obesity among Medicaid beneficiaries with common comorbidities present.

#### **METHODS**

A retrospective observational cohort study was conducted to examine the impact of obesity on allcause healthcare costs for beneficiaries with at least one of the five high-risk conditions – diabetes, coronary artery disease, hyperlipidemia, nonalcoholic steatohepatitis (NASH), and hypertension. Medical claims for beneficiaries enrolled in Fee-for-Service (FFS) and the coordinated care organizations [CCOs: UnitedHealthcare (UHC), Magnolia (MAG), and Molina (MOL)] were assessed for the period from January 1, 2016 to June 30, 2022. A beneficiary was included in the study cohort if they had at least one medical claim with an International Classification of Diseases (ICD-10) diagnosis code, in any position, for one of the five conditions mentioned above. The date of the first diagnosis claim was flagged as the index date. Eligible beneficiaries were also required to have at least 12 months of pre-index and post-index continuous enrollment thereby restricting the identification period to January 1, 2017 to June 30, 2021. Dual eligible beneficiaries and those without full pharmacy/medical benefits during the study period were excluded from the study population.

The presence of obesity was ascertained for the beneficiaries included in the study cohort using ICD-10 diagnoses codes (E66.xx and Z68.xx). A beneficiary was considered to have an obesity diagnosis if they had a medical claim with an obesity diagnosis code, in any position, anytime in the entire study period. Three groups were created based on the presence and timing of the obesity diagnosis: beneficiaries with no obesity (reference group), beneficiaries with obesity in the pre-index period (regardless of their obesity diagnosis in the post-index period), and those with post-index obesity diagnosis only (as long as they were continuously enrolled). A sub cohort based on beneficiaries with class III obesity was created using the same three-group approach described above. Class III obesity was defined per CDC classification of having a BMI of 40 kg/m² or higher. This approach to assessing the impact of obesity was chosen partially because of the difficulty in identifying obesity in claims data due to it being undercoded.<sup>21</sup>

To measure costs, all available follow-up months for a beneficiary until the end of their continuous enrollment were considered. Total, medical, and pharmacy all-cause costs were calculated and adjusted for inflation to June 2022 using the Consumer Price Index – Medical Component.<sup>22</sup> All costs were standardized to the per-member-per-year (PMPY) metric.

Univariate cost comparisons were conducted using the Wilcoxon rank sum test. Generalized linear models with gamma distribution and log link were used to estimate mean adjusted all-cause costs after accounting for the following baseline covariates – age and health plan (as of the index date), sex, race/ethnicity, modified Elixhauser-van Walraven Comorbidity Index score, and diagnoses of prediabetes, obstructive sleep apnea, and/or polycystic ovarian syndrome.<sup>23</sup> Modified Elixhauser-van Walraven Comorbidity Index score was calculated by excluding obesity, hypertension, diabetes from the original index.

In addition to describing the impact of obesity on beneficiaries with comorbid conditions, MS-DUR also examined utilization trends among two classes of diabetes medications, sodium-glucose cotransporter-2 (SGLT2) inhibitors and glucagon-like peptide 1 (GLP-1) receptor agonists (RA), which have been shown to cause weight loss. MS-DUR identified new starts of therapy with these diabetes medications during the time frame between April 2019 through June 2022. New starts were defined as initial prescriptions for a class of a product preceded by at least 180 days without a prescription claim for that class of product. As patients with diabetes should receive routine

medical care for managing and monitoring their condition, MS-DUR checked for medical claims with diagnostic codes for diabetes during the two-year period prior to each index date for new starts.

#### **RESULTS**

Table 1 describes the number of beneficiaries having one or more medical claims with a diagnosis code for diabetes, coronary artery disease, hypertension, NASH, or hyperlipidemia during the study period. There were 160,025 beneficiaries with at least one medical claim for one of these diagnoses between January 1, 2017 and June 30, 2021. Of these, 77, 083 met the criteria for inclusion in the study.

TABLE 1. Attrition Table for the Study Population - Main Group An Obesity)	alysis (Overall			
Inclusion/Exclusion Criteria	# of beneficiaries			
Beneficiaries having ≥1 medical claim with a diagnosis code for diabetes, coronary artery disease, hypertension, NASH, or hyperlipidemia between January 1, 2017 to June 30, 2021	160,025			
Excluding beneficiaries without full medical or pharmacy benefits, and those without at least 12-month pre-index and post-index continuous enrollment (n=81,713)	78,312			
Excluding beneficiaries who had their first obesity diagnosis after the end of their continuous enrollment (n=39)	78,273			
Excluding beneficiaries who had their first obesity diagnosis prior to the 12-month pre-index period with no obesity record at a later time (n=1,190)	77,083			
Final sample for main group analysis	77,083			
NASH - Non-alcoholic steatohepatitis Index date was defined as the date of first diagnosis of one of the five disorders mentioned above.				

Table 2 displays the baseline characteristics of those beneficiaries included in the study population.

- Of the 77,083 beneficiaries included in the study, 34,564 (44.8%) had an obesity diagnosis in claims data.
- For the 34,564 beneficiaries that had an obesity diagnosis, 20,484 (59.3%) had the diagnosis prior to their index claim for one of the qualifying health conditions.
- Those most likely to experience obesity were female, Black, age 44-64 years, and in a CCO plan.
- 54.6% of obese patients in the study sample had two or more high-risk conditions present.

TA									
Beneficiary	<i>i</i>	TOTA	ΔI			Obesit	y Group		
Characteristic	cs	1012	<b>1</b> L	No Obe	esity	Pre-index C	Obesity*	Post-Index Obes	sity Only
TOTAL		77,08	33	42,51	اوا	20,48	4	14,080	
Demographics									
	0 - 17 years	7,434	9.6%	3,198	7.5%	3,093	15.1%	1,143	8.1%
Ago	18 - 44 years	17,444	22.6%	6,221	14.6%	7,309	35.7%	3,914	27.8%
Age	44 - 64 years	35,188	45.6%	18,368	43.2%	9,144	44.6%	7,676	54.5%
	65+ years	17,017	22.1%	14,732	34.6%	938	4.6%	1,347	9.6%
Gender**	Female	50,291	65.2%	25,112	59.1%	15,163	74.0%	10,016	71.1%
Gender***	Male	26,787	34.8%	17,404	40.9%	5,320	26.0%	4,063	28.9%
	White	24,933	32.3%	14,887	35.0%	5,842	28.5%	4,204	29.9%
Daga	Black	44,173	57.3%	22,938	53.9%	12,794	62.5%	8,441	60.0%
Race	Hispanic	557	0.7%	243	0.6%	212	1.0%	102	0.7%
	Other	7,420	9.6%	4,451	10.5%	1,636	8.0%	1,333	9.5%
	FFS	34,100	44.2%	25,336	59.6%	4,341	21.2%	4,423	31.4%
Medicaid Program	UHC	18,363	23.8%	7,650	18.0%	6,604	32.2%	4,109	29.2%
Medicaid Program	MAG	23,433	30.4%	9,008	21.2%	9,064	44.2%	5,361	38.1%
	MOL	1,187	1.5%	525	1.2%	475	2.3%	187	1.3%
Clinical Covariates									
Polycystic ovary syndrome	Yes	321	0.4%	41	0.1%	227	1.1%	53	0.4%
(PCOS)	No	76,762	99.6%	42,478	99.9%	20,257	98.9%	14,027	99.6%
Obstructive sleep apnea	Yes	4,737	6.1%	725	1.7%	3,197	15.6%	815	5.8%
(OSA)	No	72,346	93.9%	41,794	98.3%	17,287	84.4%	13,265	94.2%
D	Yes	3,501	4.5%	971	2.3%	1,883	9.2%	647	4.6%
Prediabetes	No	73,582	95.5%	41,548	97.7%	18,601	90.8%	13,433	95.4%
Elixhauser Comorbidity Index (ECI)***	Mean, SD	3.82	7.11	3.81	6.87	4.24	7.83	3.23	6.65
	1	40,903	53.1%	25,205	59.3%	9,999	48.8%	5,699	40.5%
Number of High-Risk	2	21,975	28.5%	11,546	27.2%	5,799	28.3%	4,630	32.9%
Conditions Present	3	9,889	12.8%	4,431	10.4%	2,969	14.5%	2,489	17.7%
Conditions Present	4	4,246	5.5%	1,330	3.1%	1,673	8.2%	1,243	8.8%
	5	70	0.1%	7	0.0%	44	0.2%	19	0.1%

#### Notes

The study includes all Medicaid beneficiaries with a diagnosis of any of the following diseases: diabetes, hypertension, hyperlipidemia, coronary artery disease, NASH between January 1, 2017 and June 30,2021

Beneficiaries are required to be continuously enrolled for 12 months prior to the diagnosis (index date) and at least 12 months post-index. Therefore the entire study period is from January 1, 2016 - June 30, 2022

Age, gender, race and Medicaid program are assessed on the index date.

Polycystic ovary syndrome (PCOS), obstructive sleep apnea (OSA), prediabetes and Elixhauser Comorbidity Index (ECI) are assessed during the 12 months pre-index period

From this study population, adjusted healthcare costs associated with beneficiaries in each category (no obesity, pre-index obesity, and post-index obesity) were calculated from their index date through the end of their continuous enrollment. Total, medical, and pharmacy all-cause costs were calculated, adjusted for inflation to June 2022, and standardized to per-member-per-year (PMPY). Adjusted costs were calculated after accounting for the following baseline characteristics: age, health plan as of index date, race, sex, ECI score, and baseline diagnoses of prediabetes, obstructive sleep apnea, or polycystic ovarian syndrome. Table 3 provides a summary of adjusted costs stratified by category.

<sup>\*</sup>Pre-index obesity group includes beneficiaries who had an obesity diagnosis only in the pre-index period, as well as beneficiaries with obesity diagnosis during the pre- and post-index periods

<sup>\*\*</sup>Gender was unknown for 5 beneficiaries, 3 in the "No obesity" group, 1 in each of the other two groups

<sup>\*\*\*</sup>ECI weighted using the van Walraven methodology

	TABLE 3. Summary of <u>Adjusted</u> Costs* Stratified by Obesity Group									
	All-cause Total Costs (PMPY)			All-cause Medical Costs (PMPY)			All-cause Pharmacy cos	ts (PMPY)		
Obesity Group	Mean (95% CI)	Difference in mean costs	p-value	Mean (95% CI)	Difference in mean costs	p-value	Mean (95% CI)	Difference in mean costs	p-value	
No Obesity (Reference)	\$11,520 (\$10,803 - \$12,285)	-	-	\$8,974 (\$8,413 - \$9,571)	-	-	\$790 (\$741 - \$842)	-	-	
Pre-index Obesity**	\$11,791 (\$11,069 - \$12,561)	\$271	0.018	\$8,904 (\$8,357 - \$9,487)	-\$70	0.430	\$1,134 (\$1,065 - \$1,208)	\$344	< 0.001	
Post-index Obesity Only	\$12,827 (\$12,014 - \$13,695)	\$1,307	< 0.001	\$9,650 (\$9,037 - \$10,304)	\$676	< 0.001	\$1,247 (\$1,168 - \$1,331)	\$457	< 0.001	

NOTES: PMPY - Per Member Per Year; CI - Confidence Interval

#### From Table 3:

- Compared to the reference group (no obesity), there was a significant difference across all three cost categories (total, medical, and pharmacy all-cause costs) for those in the post-index obesity group.
- For those in the pre-index obesity group, only all-cause pharmacy costs were significantly different compared to the no obesity group.

	TABLE 4. Summary of <u>Adjusted</u> Costs* Stratified by Class III <sup>a</sup> Obesity Subgroup								
	All-cause Total Costs (PMPY)		All-cause Medical Costs (PMPY)		s (PMPY)		All-cause Pharmacy costs (PMPY)		
Obesity Subgroup	Mean (95% CI)	Difference in	p-value	Mean (95% CI)	Difference in	p-value	Mean (95% CI)	Difference in	p-value
	, ,	mean costs		, ,	mean costs		,	mean costs	
No Obesity (Reference)	\$11,463 (\$10,646 - \$12,343)	-	-	\$8,625 (\$8,009 - \$9,288)	-	-	\$876 (\$813 - \$943)	-	-
Pre-index Obesity**	\$13,263 (\$12,321 - \$14,278)	\$1,800	< 0.001	\$9,594 (\$8,911 - \$10,330)	\$969	< 0.001	\$1,476 (\$1,371 - \$1,589)	\$600	< 0.001
Post-index Obesity Only	\$14,036 (\$13,020 - \$15,133)	\$2,573	< 0.001	\$10,222 (\$9,481- \$11,021)	\$1,597	< 0.001	\$1,388 (\$1,287 - \$1,497)	\$512	< 0.001

NOTES: PMPY - Per Member Per Year; CI - Confidence Interval

In much of the literature examining the economic burden of obesity, results were stratified by obesity categories with those experiencing class III obesity having the largest economic burden. In our study, we conducted a subgroup analysis comparing those beneficiaries with class III obesity to those without obesity.

<sup>\*</sup>Adjusted costs were calculated after accounting for the following baseline characteristics of the beneficiaries - age and health plan as of the index date, race, sex, Elixhauser Comorbidity Index Score, baseline diagnoses of prediabetes, obstructive sleep apnea, or polycystic ovarian syndrome. 5 beneficiaries with unknown sex were excluded from the analytical model.

<sup>\*</sup>All costs were adjusted to the first half of 2022 using Medical component of the Consumer Price Index.

<sup>\*\*</sup>Pre-index obesity group includes beneficiaries who had an obesity diagnosis only in the pre-index period, as well as beneficiaries with obesity diagnosis during the pre- and post-index periods.

<sup>&</sup>lt;sup>a</sup> Class III obesity was defined based on the CDC obesity classification.

<sup>\*</sup>Adjusted costs were calculated after accounting for the following baseline characteristics of the beneficiaries - age and health plan as of the index date, race, sex, Elixhauser Comorbidity Index Score, baseline diagnoses of prediabetes, obstructive sleep apnea, or polycystic ovarian syndrome. 4 beneficiaries with unknown sex were excluded from the analytical model.

<sup>\*</sup>All costs were adjusted to the first half of 2022 using Medical component of the Consumer Price Index.

<sup>\*\*</sup>Pre-index Class III obesity group includes beneficiaries who had a Class III obesity diagnosis only in the pre-index period, as well as beneficiaries with Class III obesity diagnosis during the pre- and post-index periods.

Table 4 displays those results.

- Compared to those with no obesity, beneficiaries with class III obesity (pre-index or post-index) had significantly greater all-cause healthcare costs across every category.
- The mean difference in all-cause total costs for those with class III pre-index obesity and post-index obesity were \$1,800 PMPY and \$2,573 PMPY, respectively.

As part of a DUR report reviewing diabetes treatment patterns in 2019, MS-DUR assessed trends in new starts for the major classes of hypoglycemic agents utilized between January 2016 and March 2019. With that analysis, MS-DUR further examined certain glucose-lowering classes (SGLT2 inhibitors and GLP-1 RAs) that are associated with weight loss for their potential use in beneficiaries without a diabetes diagnosis for weight loss. An update of that analysis was included in this report.

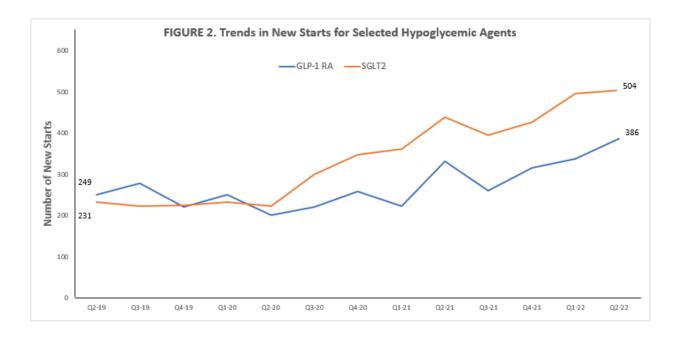


Figure 2 displays trends in the new starts for selected hypoglycemic agents. Quarterly new starts for SGLT2 inhibitors increased 118% and GLP-1 RAs increased 55% between April 2019 and June 2022. When examining the proportion of beneficiaries with new starts for these agents that had a diabetes diagnosis in claims data within 2 years prior to their index prescription date (Table 5), 11.2% of GLP-RA new starts and 11.6% of SGLT2 inhibitor new starts did not have a diabetes diagnosis in claims data. These numbers are similar to those that were found in our previous board report for GLP-RAs but is higher than what we found for SGLT2 inhibitors. The increase in the number of new starts for these agents along with the proportion of new starts without a diagnosis for diabetes could indicate that a small proportion of beneficiaries are being prescribed these agents for reasons other than diabetes, such as weight loss.

TABLE 5: Perce	TABLE 5: Percent of GLP-1 RA and SGLT2 Inhibitor New Starts Having Documented Diabetes  During Two Years Prior to Start of Therapy (Q2-19 to Q2-22)								
Dhawaaa	GLP-	1 RA New Sta	arts	SGLT2 I	nhibitor Nev	v Starts			
Pharmacy Program	Document	ed Diabetes I	Diagnosis	Document	ed Diabetes	Diagnosis			
Program	Yes	N	0	Yes	No				
FFS	783	99	11.2%	1,051	211	16.7%			
UHC	1,023	146	12.5%	1,257	145	10.3%			
MAG	1,362	136	9.1%	1,601	142	8.2%			
MOL	321	61	15.9%	367	64	14.9%			
All Programs	3,489	442	11.2%	4,276	562	11.6%			

#### **CONCLUSIONS**

Obesity is a common, chronic disease with a complex pathophysiology that impacts an increasing proportion of the U.S. population. By 2030, adult obesity is projected to affect 58.2% of the population in Mississippi. Common comorbidities associated with obesity such as hypertension, diabetes, coronary artery disease, osteoporosis, and others contribute to the enormous health and economic burdens attributed to obesity. The burdens associated with obesity coupled with recent changes in the pharmacotherapeutic landscape of obesity management present an opportunity for the Division of Medicaid to examine its current policies regarding obesity management.

#### **RECOMMENDATIONS**

- 1. DOM is encouraged to consider changing policies pertaining to medication coverage for the management of obesity.
- 2. DOM is encouraged to ask the P&T Committee to conduct a therapeutic class review of anti-obesity medications.
- 3. DOM is encouraged to consider conducting a detailed economic impact evaluation to determine the impact of coverage of anti-obesity medications.
- 4. DOM should consider a phased-in approach to medication coverage exploring options based on data presented in the report. This approach could be developed around factors such as obesity classification, age, or presence of comorbidities.

#### REFERENCES

- CDC. Defining Adult Overweight and Obesity. Centers for Disease Control and Prevention. Published June 3, 2022. Accessed November 1, 2022. https://www.cdc.gov/obesity/basics/adult-defining.html
- 2. Kyle TK, Dhurandhar EJ, Allison DB. Regarding Obesity as a Disease: Evolving Policies and Their Implications. *Endocrinol Metab Clin North Am.* 2016;45(3):511. doi:10.1016/j.ecl.2016.04.004
- 3. CDC. CDC Overweight & Obesity. Centers for Disease Control and Prevention. Published September 27, 2022. Accessed October 25, 2022. https://www.cdc.gov/obesity/index.html
- 4. WHO. Obesity. Accessed November 1, 2022. https://www.who.int/health-topics/obesity
- 5. Bryan S, Afful J, Carroll M, et al. *NHSR 158. National Health and Nutrition Examination Survey 2017—March 2020 Pre-Pandemic Data Files*. National Center for Health Statistics (U.S.); 2021. doi:10.15620/cdc:106273
- CDC. Obesity is a Common, Serious, and Costly Disease. Centers for Disease Control and Prevention. Published July 20, 2022. Accessed November 22, 2022. https://www.cdc.gov/obesity/data/adult.html
- 7. U.S. Census Bureau QuickFacts: United States. Accessed November 22, 2022. https://www.census.gov/quickfacts/fact/table/US/PST0452219
- 8. Ward ZJ, Bleich SN, Cradock AL, et al. Projected U.S. State-Level Prevalence of Adult Obesity and Severe Obesity. *N Engl J Med*. 2019;381(25):2440-2450. doi:10.1056/NEJMsa1909301
- 9. Hales CM, Carroll MD, Fryar CD, Ogden CL. Prevalence of Obesity and Severe Obesity Among Adults: United States, 2017-2018. *NCHS Data Brief*. 2020;(360):1-8.
- 10. What Is Obesity? | Obesity Medicine Association. Published December 4, 2018. Accessed November 23, 2022. https://obesitymedicine.org/what-is-obesity/
- 11. Su W, Huang J, Chen F, et al. Modeling the clinical and economic implications of obesity using microsimulation. *J Med Econ*. 2015;18(11):886-897. doi:10.3111/13696998.2015.1058805
- 12. Zheng Y, Manson JE, Yuan C, et al. Associations of Weight Gain From Early to Middle Adulthood With Major Health Outcomes Later in Life. *JAMA*. 2017;318(3):255-269. doi:10.1001/jama.2017.7092
- 13. Shimazu T, Kuriyama S, Ohmori-Matsuda K, Kikuchi N, Nakaya N, Tsuji I. Increase in body mass index category since age 20 years and all-cause mortality: a prospective cohort study (the Ohsaki Study). *Int J Obes* 2005. 2009;33(4):490-496. doi:10.1038/ijo.2009.29

- 14. Adams KF, Leitzmann MF, Ballard-Barbash R, et al. Body mass and weight change in adults in relation to mortality risk. *Am J Epidemiol*. 2014;179(2):135-144. doi:10.1093/aje/kwt254
- 15. Chen C, Ye Y, Zhang Y, Pan XF, Pan A. Weight change across adulthood in relation to all cause and cause specific mortality: prospective cohort study. *BMJ*. 2019;367:l5584. doi:10.1136/bmj.l5584
- 16. Xie W, Lundberg DJ, Collins JM, et al. Association of Weight Loss Between Early Adulthood and Midlife With All-Cause Mortality Risk in the US. *JAMA Netw Open*. 2020;3(8):e2013448. doi:10.1001/jamanetworkopen.2020.13448
- 17. Cawley J, Biener A, Meyerhoefer C, et al. Direct medical costs of obesity in the United States and the most populous states. *J Manag Care Spec Pharm*. 2021;27(3):354-366. doi:10.18553/jmcp.2021.20410
- 18. Wang YC, Pamplin J, Long MW, Ward ZJ, Gortmaker SL, Andreyeva T. Severe Obesity In Adults Cost State Medicaid Programs Nearly \$8 Billion In 2013. *Health Aff (Millwood)*. 2015;34(11):1923-1931. doi:10.1377/hlthaff.2015.0633
- 19. Sumithran P, Prendergast LA, Delbridge E, et al. Long-term persistence of hormonal adaptations to weight loss. *N Engl J Med*. 2011;365(17):1597-1604. doi:10.1056/NEJMoa1105816
- 20. Garvey WT, Mechanick JI, Brett EM, et al. American Association of Clinical Endocrinologists and American College of Endocrinology Comprehensive Clinical Practice Guidelines For Medical Care of Patients with Obesity. *Endocr Pract*. 2016;22:1-203. doi:10.4158/EP161365.GL
- 21. Quan H, Li B, Duncan Saunders L, et al. Assessing Validity of ICD-9-CM and ICD-10 Administrative Data in Recording Clinical Conditions in a Unique Dually Coded Database. *Health Serv Res.* 2008;43(4):1424-1441. doi:10.1111/j.1475-6773.2007.00822.x
- 22. Consumer Price Index (CPI) Databases: U.S. Bureau of Labor Statistics. Accessed November 29, 2022. https://www.bls.gov/cpi/data.htm
- 23. van Walraven C, Austin PC, Jennings A, Quan H, Forster AJ. A modification of the Elixhauser comorbidity measures into a point system for hospital death using administrative data. *Med Care*. 2009;47(6):626-633. doi:10.1097/MLR.0b013e31819432e5

# FDA DRUG SAFETY COMMUNICATIONS

# September 2022 – November 2022

•	11/22/2022 FDA investigating risk of severe hypocalcemia in patients on dialysis
	receiving osteoporosis medicine Prolia (denosumab).

# **APPENDIX**



# Division of Medicaid Drug Utilization Review Board By-Laws

# Article I. Purpose

The Drug Utilization Review Board (DUR) is a requirement of the Social Security Act, Section 1927. The purpose of the DUR Board is to provide clinical guidance to the Division of Medicaid (DOM) regarding the utilization of pharmaceutical products within the Mississippi Medicaid program. The DUR Board makes recommendations to DOM to promote patient safety and cost effective care in the Mississippi Medicaid program. The DUR Board shall advise DOM with respect to the content of medical criteria and standards for utilization management strategies including prospective drug prior authorization (PA), concurrent patient management, retrospective drug utilization review, and educational intervention programs. DOM retains the authority to accept or reject the recommendations by the DUR Board.

# Article II. Membership

## Section 1 - Board Composition

- A. The DUR Board will consist of not less than twelve (12) voting members.
- B. The DUR Board voting members will be comprised of at least one-third (1/3), but no more than fifty-one percent (51%), licensed and actively practicing physicians and at least one-third (1/3) licensed and actively practicing pharmacists. Voting members may consist of health care professionals with knowledge/expertise in one or more of the following:
  - 1) Prescribing of drugs,
  - 2) Dispensing and monitoring of drugs,
  - 3) Drug use review, evaluation, and intervention,
  - 4) Medical quality assurance.
- C. Non-voting board members consist of the Division of Medicaid (DOM) Executive Director, Office of Pharmacy pharmacists, DUR Coordinator, the DUR contractor and Medical Director.

## Section 2 - Appointment selection methodology

- A. DOM's Office of Pharmacy in consultation with officially recognized state professional healthcare associations recommends potential, qualified new candidates for appointment or reappointment of existing board members to DOM's Executive Director.
- B. Nominations are considered internally and appointments are given final approval by the DOM Executive Director.
- C. Board members are appointed by the Governor of the State of Mississippi, or Governor's designee, pursuant to state law.

#### Section 3 - Term of Office

- A. All members are appointed for three year terms following a staggered appointment fulfillment as follows: one-third of DUR Board members shall be appointed each term. All subsequent appointments shall be for terms of three years from the expiration date of the previous term.
- B. Members may serve up to three consecutive three-year terms (for a total of nine consecutive years).
- C. Members may serve for either an extended term or a fourth consecutive term at the discretion of the Executive Director and by recommendation of both the DUR Coordinator and Division of Medicaid Office of Pharmacy in the event that no qualified, willing candidate is found in sufficient time. Members, including those filling vacated positions, may be re-appointed by the Executive Director for a subsequent term.
- D. In the event of an unexpected or expected vacancy, the DUR Coordinator and Office of Pharmacy may recommend a qualified replacement candidate to DOM's Executive Director for emergency approval.
- E. The Executive Director shall fill any vacancy before the end of the term, and the person appointed to fill the vacancy shall serve for the remainder of the unexpired term. Members, including those filling vacated positions, may be reappointed by the Executive Director for a subsequent term.

#### **Section 4 - Attendance**

- A. Members are required to attend at least fifty percent of the meetings per year. Failure to attend meetings without an explanation of extenuating circumstances will result in the termination of the member's appointment.
- B. Members are asked to give advance notice regarding any planned absences so that a quorum may be determined prior to meetings.

#### **Section 5 - Resignation**

A member of the DUR Board may resign by giving a 30 day written advance notice to the DUR Board Chair and DUR Coordinator.

#### **Section 6 - Removal**

A member of the DUR Board may be removed by either the DUR Board Chair or majority vote of the DUR Board for good cause. Good cause may be defined as one or more of the following conditions:

- A. Lack of attendance –failure to attend at least 50% of the scheduled DUR meetings shall constitute a resignation by said DUR Board member,
- B. Identified misconduct or wrongdoing during any DUR Board term, or

DUR Bylaws V2= updated 12/06/2018

C. Not disclosing a conflict of interest either upon initial disclosure or throughout the rest of the term.

#### Section 7 - Board Officers

At the first meeting of the state fiscal year, which constitutes July 1 through June 30, board members shall select two members to serve as Chair and Chair-Elect of the board, respectively. The Chair and Chair-Elect shall both serve one year terms. At the end of the serving year, the Chair-Elect assumes the role of Chair, and a new Chair-Elect will be chosen.

If the persons serving as Chair and Chair-Elect have either previously served as Chair or Chair-Elect, that person may be reelected to either posting.

The Chair-Elect will serve as Chair in absentia of the Chair or by the Chair's request.

#### **Section 8 - Reimbursement**

The Division of Medicaid will reimburse DUR Board members for travel related expenses.

# Article III. Meetings

#### Section 1 - Frequency

The DUR Board shall meet at least quarterly, and may meet at other times as necessary for the purpose of conducting business that may be required. The DUR Board Chair, a majority of the members of the board, or the Division of Medicaid Office of Pharmacy and DUR Coordinator, shall maintain the authority of calling DUR meetings.

## **Section 2 - Regular Meetings**

The DUR Board will hold regular quarterly meetings in the city of Jackson, Mississippi. Meetings will occur at the predesignated time and place. Dates for the upcoming year's quarterly meetings will be posted before the first quarterly meeting of the upcoming year.

#### **Section 3 - Special Meetings**

The DUR Board may meet at other times other than regular quarterly meetings as deemed necessary and appropriate. The DUR Coordinator and Office of Pharmacy must notify DUR Board members of any special meeting at least two weeks, i.e., ten (10) days, prior to the requested meeting date. Special meetings may be requested by the following officials:

- A. Division of Medicaid Executive Director,
- B. DUR Coordinator and Office of Pharmacy,
- C. DUR Board Chair, or
- D. Majority of DUR Board members via communication to DUR Coordinator and/or DUR Board Chair.

#### **Section 4 - Meeting Notice**

DUR Board members will be notified of the location for the meeting a minimum of ten (10) days in advance. Notification may include one or a combination of the following methods: email, fax, or other written communication. DUR Board members are required to keep on file

DOM Office of Pharmacy his or her address, primary phone number, alternate phone number (i.e., cell), fax number, and email address to which notices and DUR related communications may be submitted.

DUR Bylaws V2= updated 12/06/2018

Meetings may be cancelled due to lack of quorum, severe inclement weather, or other reasons as determined by the DUR Coordinator and Office of Pharmacy. In the event of a cancellation, the DUR Coordinator and DOM Pharmacy staff will communicate with DUR Board members regarding the meeting cancellation as soon as circumstances permit. Notifications shall also be posted with DFA and on DOM's website to ensure that the public is notified of any meeting cancellation.

DUR Board Meetings shall be open to the public and conducted in accordance with state law, specifically the Open Meetings Act. Notice of any meetings held shall be provided at least five (5) days in advance of the date scheduled for the meeting. The notice shall include the date, time, place and purpose for the meeting and shall identify the location of the meeting to the general public.

### **Section 5 - Meeting Sign-In**

All meeting attendees will be required to sign-in at the meeting entrance for DUR meetings. Sign-in sheets will be logged, scanned and transferred to electronic medium for official records. All attendees shall include participant's name and entity represented (as applicable).

#### Section 6 - Quorum

A simple majority of voting board members shall constitute a quorum and must be present for the transaction of any business of the board. For a fully-appointed 12-person DUR Board as required by state law, seven voting board members constitutes a quorum. If a quorum is not present, the Chair, Chair-Elect or DUR Coordinator maintains the responsibility to conclude meeting proceedings. Meeting minutes shall reflect that a quorum was not present.

#### **Section 7 - Voting**

The voting process shall be conducted by the Chair or the Chair-Elect in absentia of the Chair.

All board recommendations shall begin with a motion by a voting board member. The motion may then be seconded by a voting board member. If a recommendation does not receive a second motion, the motion shall not pass. If a recommendation receives a second motion, then the board shall vote on the motion. A motion shall be considered as passed if the motion carries a majority of votes if a quorum of the board is present.

In the event that a motion receives a tie vote in the presence of a quorum, the motion shall not pass. The motion can be brought up for further discussion after which a subsequent motion may be made to vote on the issue again during the same meeting, or a motion can be made to table the issue and discussion until the next quarterly DUR Board meeting.

A vote abstention occurs when a voting member is present for the meeting and the action but has chosen not to vote on the current motion. An abstention is a vote with the majority on the measure. A recusal, on the other hand, is necessitated when a voting member has a conflict of interest or potential pecuniary benefit resulting from a particular measure. In order to properly and completely recuse oneself from a matter, the DUR Board member must leave the room or area where discussions, considerations, or other actions take place

DUR Bylaws V2= updated 12/06/2018

*before* the matter comes up for discussion. The member must remain absent from the meeting until the vote is concluded. The minutes will state the recusing member left the room before the matter came before the DUR Board and did not return until after the vote.

#### Section 8 – Minutes

A public body speaks only through its minutes. State law, specifically the Open Meetings Act, requires minutes be kept of all meetings of a public body, whether in open or executive session, showing the following:

- A. Members present or absent,
- B. Date, time and place of meeting,
- C. Accurate recording of any final actions taken,
- D. Record, by individual member, of how s/he voted on any final action, and
- E. Any other information that the public body requests is reflected in the minutes.

The minutes shall be finalized no later than thirty (30) days after the adjournment of the DUR Board meeting and shall be made available for public inspection. DOM Office of Pharmacy posts all DUR Board Minutes on the DUR webpage.

#### Section 9 - Speakers & Special Topics

DUR Board members may request various healthcare, industry, or specialized professionals to present at DUR meetings regarding a posted topic on an upcoming DUR agenda.

- A. The DUR Board may allow up to 20 minutes for topic presentation by an invited speaker.
- B. DUR Board Members may ask a member of the audience to provide information on a topic being discussed by the Board. Invited participants may be asked to disclose any potential conflicts of interests if applicable. (See Article IV, Section 1).
- C. Members of the audience may not speak unless so designated at the appropriate time by a DUR Board member.
- D. DUR Board Members, both voting and non-voting, maintain speaking privileges at DUR meetings.
- E. Contracted employees of DOM and employees of other DOM vendors are considered members of the audience.

#### **Section 10 - Executive Session**

During special circumstances, the DUR Board may go into executive session at the conclusion of normal meeting proceedings; however, all DUR Board meetings must commence as an open meeting. In order for executive session to be called, the following procedure must be followed in accordance with the Open Meetings Act:

- A. A member may <u>move to close</u> the meeting to determine whether board needs to go into executive session; vote in open meeting with vote recorded in minutes, majority rules.
- B. Closed meeting: vote taken on whether to <u>declare</u> executive session, requires 3/5 of all members present.
- C. Board comes back into open session and states statutory reason for executive session. The reason for the executive session shall be recorded in the meeting minutes.
- D. Board members then will go into executive session where action may be taken on stated subject matter only.

E. Minutes must be kept in accordance with the Open Meetings Act.

#### Section 11 - Conduct of Participants

Pursuant to state law, specifically the Open Meetings Act, the DUR Board may make and enforce reasonable rules and regulations for the conduct of persons attending the DUR meetings. The following is a non-exhaustive list of rules for DUR Board meetings:

- A. Attendees should please remain silent and allow for the efficient transaction of business.
- B. Cell phones should be placed on silent or vibrate.
- C. Laptop computers are discouraged from being utilized during meetings as frequent typing may distract board members.
- D. Food and drink are not allowed in the meeting room.
- E. Security is provided by the state. Guests not following proper decorum may be asked to leave by security.

# Article IV. Public Participation

#### Section 1 - Disclosure of Persons Appearing Before DUR Board

The DUR Board may ask individuals appearing before the board to disclose either in writing or verbally their relationship, as applicable, including but not limited to pharmaceutical companies or special interest groups. Any such disclosures should be recorded as a matter of public record in the documented meeting minutes.

#### Article V. Conflicts of Interest

DUR Board members are expected to maintain the highest professional, ethical standards. A conflict of interest may exist when a DUR Board member maintains a financial/pecuniary, personal, or professional interest that may compete or interfere with the DUR Board member's ability to act in a fair, impartial manner while acting in the best interests of the Division of Medicaid and the beneficiaries that it serves.

As such, DUR Board members are required to complete and submit annually a Conflict of Interest disclosure statement with the DOM Office of Pharmacy and DUR Coordinator. Statements shall be maintained by the Office of Pharmacy. Members have an ongoing responsibility to update and revise said statements, disclosing any new conflicts of interest to the DUR Coordinator and DOM Office of Pharmacy.

It is the sole responsibility and requirement of each board member to review the agenda of each forthcoming board meeting to determine any if any potential conflicts of interest exist. If so, an aforementioned Disclosure statement must be updated indicating the conflict of interest. The board member should notify the Chair or Chair-Elect of the conflict of interest prior to the meeting.

A DUR Board member shall recuse himself/herself from any vote, action, or discussion pertaining to any product or product class if there is documentation stating an actual or perceived conflict of interest. Please refer to the procedure outlined in Article III, Section 7.

# Article VI. Confidentiality

DUR Board members are required to safeguard all confidential and proprietary information, including but not limited to pricing information, which is disclosed by the Mississippi Division of Medicaid for purposes of conducting DUR Board activities. Any provider or patient specific information discussed by the DUR Board shall also be kept strictly confidential in accordance with state and federal law.

#### Article VII. Amendments

## **Proposed Amendments of By-Laws**

- A. Proposed amendments must be submitted to the DUR Coordinator at least thirty (30) days prior to the next scheduled DUR meeting and the proposed amendments will be disseminated to the DUR Board en masse for consideration at said DUR Board meeting.
- B. Proposed amendments will be distributed to board members no less than five (5) business days prior to next DUR Board meeting.
- C. Proposed amendments will be initiated by the Chair, or the Chair-Elect in absentia of the Chair, prior to Next Meeting Information announcements.
- D. Proposed amendments will be voted upon at the next scheduled DUR Board meeting. If majority of DUR Board votes to ratify amendment, the amendment will take effect immediately at the conclusion of the meeting.

# MS-DUR BOARD COMMON ABBREVIATIONS

ANAID	A . MOHE D
AWP	Any Willing Provider, Average
DENIE	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
СОВ	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
НВ	House Bill
HCPCS/	Health Plan Employer Data and
HEIDIS	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
MOL	Molina Healthcare
MPR	Medication Possession Ratio
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
PDC	Proportion of Days Covered
PDC	•
	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-	Retrospective Drug Utilization
DUR	Review
RFI	Request for Information
RFP	Request for Proposal
RHC	Rural Health Clinic
SB	Senate Bill
SCHIP	State Child Health Insurance
	Program
SMART	Conduent's Pharmacy Application
PA	(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
3400	I reactal blug biscoullt Plogram