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

MISSISSIPPI DIVISION OF
MEDICAID

March 2, 2023 at 1:00pm

Woolfolk Building, Room 117

Jackson, MS

Prepared by:

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

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 14th 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

2023 DUR Board Meeting Dates

March 2, 2023
June 15, 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 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
March 2, 2023

Welcome

Old Business

Resource Utilization Review

Follow-up and Discussion from the Board

New Business

Pharmacy Program Update Dennis Smith, RPh

Next Meeting Information
Remaining 2023 DUR Board Meeting Dates:
June 15, 2023; September 7, 2023; December 7, 2023

DUR Board Meeting Minutes

MISSISSIPPI DIVISION OF MEDICAID
DRUG UTILIZATION REVIEW (DUR) BOARD
MINUTES OF THE DECEMBER 8, 2022 MEETING

DUR Board Roster: State Fiscal Year 2023 (July 1, 2022 – June 30, 2023)	Mar 2022	Jun 2022	Sep 2022	Dec 2022
Joseph Austin, MD	NA	NA	✓	✓
Lauren Bloodworth, PharmD	✓			
Terrence Brown, PharmD	✓	✓	✓	✓
Patrick Bynum, MD	✓	✓	✓	✓
Chrysanthia Davis, PharmD	NA	NA	✓	✓
Tanya Fitts, MD	✓	✓	✓	
Jahanzeb Khan, MD	NA	NA	✓	✓
Ray Montalvo, MD			✓	
Holly Moore, PharmD		✓	✓	✓
Kristi Phelps, RPh	NA	NA	✓	✓
Joshua Pierce, PharmD	✓	✓	✓	✓
Bobbie West, MD	NA	NA	✓	
TOTAL PRESENT**	**9**	**7**	**11**	**8**

** *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:
Keana Dandridge, Novartis; Shawn Headley, Gilead; Cathy Prine-Eagle, Merck; Paula Whatley, Novo Nordisk; Daniel Field, Capital Resources.

Call to Order/Welcome:
Dr. Brown called the meeting to order at 1:00 pm.

OLD BUSINESS:
Dr. Bynum moved to approve the minutes from the September 2022 DUR Board Meeting, seconded by Dr. Davis, and unanimously approved by the DUR Board.

Resource Utilization Review:
Dr. Pittman presented the resource utilization report for July 2022. Dr. Pittman provided an overview of the resource utilization report and highlighted trends identified in each section.

NEW BUSINESS:

Update on MS-DUR Educational Interventions:
Dr. Pittman provided an overview of all DUR mailings and educational notices that occurred between September 2022 – November 2022.

Special Analysis Projects:

Assessment of Predictors of Severe Maternal Morbidity (SMM) Among Pregnant Medicaid Beneficiaries – Follow-up Analysis

From the follow-up analysis it was 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. It was 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.

The following recommendations were presented:

1. MS-DUR should complete the ROC curve analysis to determine an MCI cut-off score.
2. MS-DUR should further examine differences in provider types, types of transportation services provided, and care provided during the first trimester between cases and controls.

3. 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.

Following a robust discussion, Dr. Bynum made a motion to accept the recommendations, seconded by Dr. Pierce, and unanimously approved by the Board.

COVID-19 Overview Among Medicaid Beneficiaries

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 provided baseline descriptive characteristics of Medicaid beneficiaries diagnosed with COVID-19 and trends in the uptake of COVID-19 vaccines and therapeutic agents.

This report for the DUR Board on COVID-19 was for information and discussion purposes only. No action was sought as a result of this report.

Impact of Obesity Among Medicaid Beneficiaries

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.

The following recommendations were presented:

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.
5. MS-DUR is encouraged to examine trends in healthcare utilization costs for those individuals initiated on GLP1-RAs and SGLT2 Inhibitors without a diagnosis of diabetes present in claims data.

Following a robust discussion, Dr. Pierce made a motion to accept the recommendations, seconded by Ms. Phelps, and unanimously approved by the Board.

FDA Drug Safety Updates:
Dr. Pittman presented FDA drug safety communications for September 2022 – November 2022.

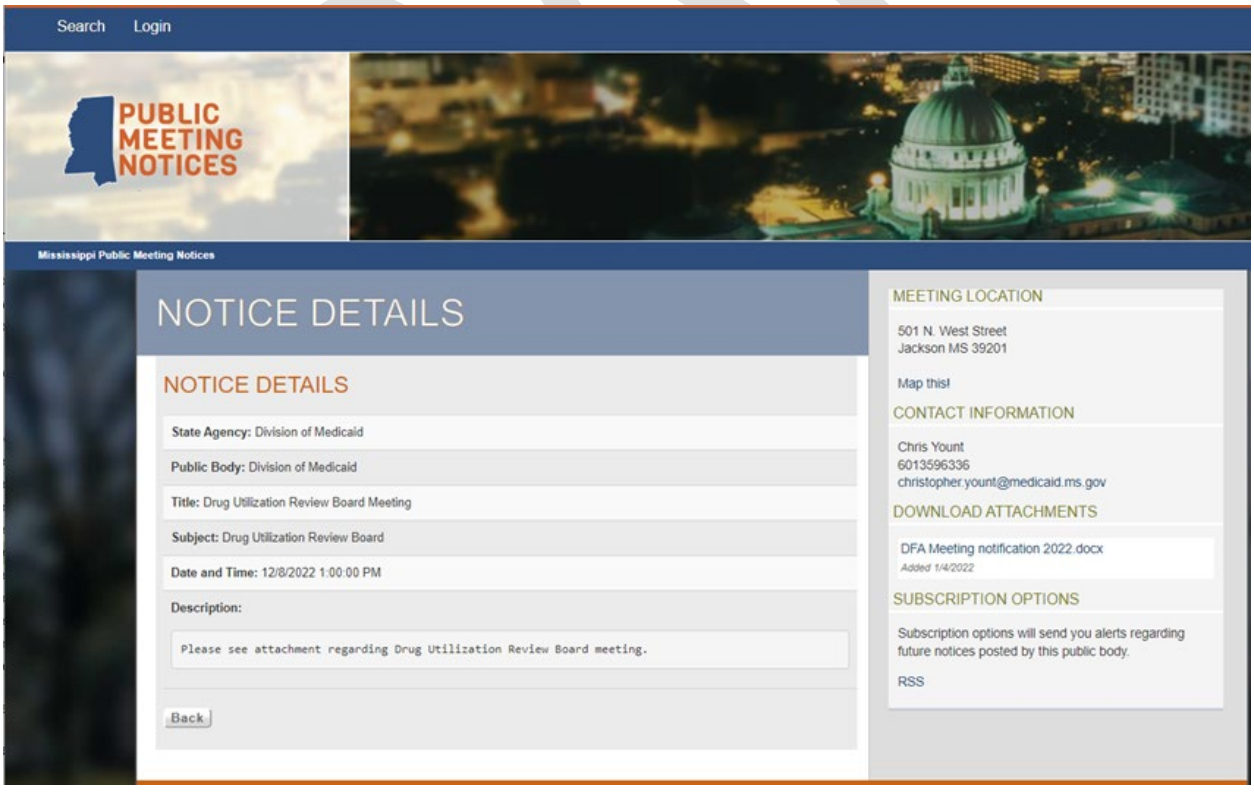
Pharmacy Program Update:
Ms. Kirby provided a pharmacy program update highlighting the recent transition to their new fiscal agent, Gainwell. Ms. Kirby encouraged the Board to provide feedback regarding any issues they may encounter and to be aware of pharmacy updates that occur.

Next Meeting Information:
The Board was presented with potential 2023 meeting dates. They were asked to review those dates for possible conflicts. A follow-up email will be sent out to the Board confirming the 2023 dates.

Dr. Pierce motioned to adjourn the meeting at 2:35 pm, seconded by Dr. Moore, and unanimously approved by the Board.

Submitted,

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



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; Jessica.Tyson@medicaid.ms.gov

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.

DUR Board Registration for December 8, 2022 now open (live meeting, no virtual options)

Registration for the December 8, 2022 Drug Utilization Review board meeting is now open. Registration is limited to one representative per company. Agenda will be posted approximately one week prior to event date. Meeting information and registration link are provided below. Please email DOMPharmacyOffice@medicaid.ms.gov with any questions.

Meetings

Meetings will be held at 1:00 pm in Woolfolk Building Room 145 unless otherwise noted. 2022 dates are as follows:

- ~~March 3, 2022;~~
- ~~June 9, 2022;~~
- ~~September 15, 2022 (1pm); and,~~
- December 8, 2022 (1pm)

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".*

CLICK HERE to register online! You must register to attend DUR Board meetings.

NOTE: Registration is **required** for all pharmaceutical industry and advocacy representatives to be able to attend DUR Board meetings.

Companies that have meet the one rep per company registration limit as of December 1, 2022:

1. Alliant
2. American Cancer Society
3. Biogen
4. Gilead
5. Grifols
6. Merck
7. Novartis
8. Novo Nordisk
9. Vertex

Resource Utilizaton Review

TABLE 04A: ENROLLMENT STATISTICS FOR LAST 6 MONTHS
July 1, 2022 through December 31, 2022

			Jul-22	Aug-22	Sep-22	Oct-22	Nov-22	Dec-22
Total enrollment			873,076	877,014	879,628	882,151	885,116	886,577
Dual-eligibles			167,023	167,243	167,562	167,551	167,374	167,239
Pharmacy benefits			758,072	761,953	764,296	766,469	769,148	770,356
	LTC		15,263	15,344	15,340	15,313	15,110	14,872
	PLAN %	**FFS**	51.5%	52.3%	52.3%	52.0%	51.7%	49.9%
		MSCAN-UHC	18.9%	18.6%	18.5%	18.6%	18.7%	19.3%
		MSCAN-Magnolia	19.8%	19.5%	19.5%	19.5%	19.6%	20.2%
		MSCAN-Molina	9.8%	9.6%	9.7%	9.9%	10.0%	10.6%

TABLE 04B: PHARMACY UTILIZATION STATISTICS FOR LAST 6 MONTHS
July 1, 2022 through December 31, 2022

		Jul-22	Aug-22	Sep-22	Oct-22	Nov-22	Dec-22
# Rx Fills	**FFS**	164,707	207,426	186,143	185,333	195,780	163,857
	MSCAN-UHC	129,561	157,195	46,861	188	136	126
	MSCAN-Mag	118,601	291	222	204	180	172
	MSCAN-Mol	44,005	56,045	17,135	203	214	178
# Rx Fills / Bene	**FFS**	0.4	0.5	0.5	0.5	0.5	0.4
	MSCAN-UHC	0.9	1.1	0.3	0.0	0.0	0.0
	MSCAN-Mag	0.8	0.0	0.0	0.0	0.0	0.0
	MSCAN-Mol	0.6	0.8	0.2	0.0	0.0	0.0
$ Paid Rx	**FFS**	$18,757,096	$22,039,039	$19,079,029	$20,896,115	$22,185,250	$20,583,279
	MSCAN-UHC	$18,849,628	$20,985,002	$5,090,365	$88,810	$22,704	$35,427
	MSCAN-Mag	$14,233,094	$23,147	$18,120	$14,337	$15,725	$13,593
	MSCAN-Mol	$4,618,547	$5,211,511	$1,522,797	$11,738	$11,511	$10,641
$ /Rx Fill	**FFS**	$113.88	$106.25	$102.50	$112.75	$113.32	$125.62
	MSCAN-UHC	$145.49	$133.50	$108.63	$472.39	$166.94	$281.17
	MSCAN-Mag	$120.01	$79.54	$81.62	$70.28	$87.36	$79.03
	MSCAN-Mol	$104.96	$92.99	$88.87	$57.82	$53.79	$59.78
$ /Bene	**FFS**	$48.04	$55.30	$47.73	$52.43	$55.79	$53.55
	MSCAN-UHC	$131.56	$148.07	$36.00	$0.62	$0.16	$0.24
	MSCAN-Mag	$94.83	$0.16	$0.12	$0.10	$0.10	$0.09
	MSCAN-Mol	$62.17	$71.25	$20.54	$0.15	$0.15	$0.13

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

***Complete claim information not available for Magnolia starting August 2022 and all MSCAN plans starting September 2022.*

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

Category	Month Year	Rank Volume	# RXs	$ Paid	# Unique Benes
contraceptives	Dec 2022	1	7,183	$395,453	6,106
	Nov 2022	2	7,150	$391,463	6,043
	Oct 2022	1	7,413	$418,094	6,216
CNS stimulants	Dec 2022	2	5,570	$718,948	4,388
	Nov 2022	3	6,319	$844,266	5,047
	Oct 2022	2	6,336	$839,277	5,144
SSRI antidepressants	Dec 2022	3	5,393	$64,873	4,541
	Nov 2022	7	5,798	$69,814	4,850
	Oct 2022	5	5,696	$73,698	4,842
nonsteroidal anti-inflammatory agents	Dec 2022	4	4,972	$62,907	4,492
	Nov 2022	4	6,265	$80,610	5,686
	Oct 2022	4	5,801	$74,721	5,260
macrolides	Dec 2022	5	4,549	$89,985	4,330
	Nov 2022	5	6,224	$120,876	5,902
	Oct 2022	8	4,845	$98,591	4,591
vitamins	Dec 2022	6	4,179	$38,026	3,018
	Nov 2022	12	4,187	$37,768	3,043
	Oct 2022	12	3,959	$39,128	2,986
aminopenicillins	Dec 2022	7	4,081	$54,657	3,804
	Nov 2022	6	6,023	$80,218	5,592
	Oct 2022	3	6,080	$80,806	5,779
atypical antipsychotics	Dec 2022	8	4,035	$966,913	3,042
	Nov 2022	11	4,530	$1,015,329	3,323
	Oct 2022	10	4,509	$1,033,647	3,313
adrenergic bronchodilators	Dec 2022	9	3,888	$232,653	3,151
	Nov 2022	9	4,914	$280,662	3,938
	Oct 2022	7	4,868	$293,853	3,994
glucocorticoids	Dec 2022	10	3,783	$105,281	3,490
	Nov 2022	8	5,012	$111,897	4,609
	Oct 2022	9	4,817	$107,541	4,447

TABLE D: TOP 10 DRUG CATEGORIES BY DOLLARS PAID IN DEC 2022 (FFS)

Category	Month Year	Rank Paid Amt	# RXs	$ Paid	# Unique Benes
interleukin inhibitors	Dec 2022	1	250	$1,422,239	155
	Nov 2022	1	277	$1,692,949	163
	Oct 2022	2	249	$1,517,125	150
antirheumatics	Dec 2022	2	231	$1,407,043	160
	Nov 2022	2	245	$1,498,571	164
	Oct 2022	1	247	$1,532,783	172
CFTR combinations	Dec 2022	3	52	$1,192,074	26
	Nov 2022	5	48	$1,032,465	25
	Oct 2022	7	38	$708,869	25
factor for bleeding disorders	Dec 2022	4	95	$1,160,738	77
	Nov 2022	3	112	$1,333,276	84
	Oct 2022	3	108	$1,466,684	85
antiviral combinations	Dec 2022	5	296	$1,018,673	259
	Nov 2022	4	294	$1,069,091	238
	Oct 2022	5	283	$970,693	236
atypical antipsychotics	Dec 2022	6	4,035	$966,913	3,042
	Nov 2022	6	4,530	$1,015,329	3,323
	Oct 2022	4	4,509	$1,033,647	3,313
CNS stimulants	Dec 2022	7	5,570	$718,948	4,388
	Nov 2022	7	6,319	$844,266	5,047
	Oct 2022	6	6,336	$839,277	5,144
selective immunosuppressants	Dec 2022	8	161	$706,164	109
	Nov 2022	9	167	$684,976	119
	Oct 2022	9	173	$691,464	124
insulin	Dec 2022	9	1,831	$684,623	1,171
	Nov 2022	8	1,820	$693,682	1,176
	Oct 2022	8	1,833	$703,066	1,203
miscellaneous uncategorized agents	Dec 2022	10	52	$640,598	43
	Nov 2022	11	47	$436,491	41
	Oct 2022	13	45	$396,618	38

TABLE E: TOP 25 DRUG MOLECULES
BY NUMBER OF CLAIMS IN DEC 2022 (FFS)

Drug Molecule Therapeutic Category	Nov 2022 # Claims	Dec 2022 # Claims	Dec 2022 $ Paid	Dec 2022 # Unique Benes
azithromycin / macrolides	6,072	4,396	$66,072	4,199
amoxicillin / aminopenicillins	5,998	4,057	$51,887	3,783
albuterol / adrenergic bronchodilators	4,763	3,720	$187,669	3,042
ondansetron / 5HT3 receptor antagonists	4,635	2,992	$41,120	2,823
gabapentin / gamma-aminobutyric acid analogs	2,701	2,686	$36,565	2,128
oseltamivir / neuraminidase inhibitors	10,660	2,589	$94,422	2,455
ibuprofen / nonsteroidal anti-inflammatory agents	3,419	2,410	$27,480	2,261
amoxicillin-clavulanate / penicillins/beta-lactamase inhibitors	2,737	2,399	$49,745	2,232
amlodipine / calcium channel blocking agents	2,130	2,187	$27,906	1,766
acetaminophen-hydrocodone / narcotic analgesic combinations	2,214	2,137	$27,576	1,891
amphetamine-dextroamphetamine / CNS stimulants	2,288	2,042	$52,970	1,605
sertraline / SSRI antidepressants	2,128	1,986	$23,221	1,657
ergocalciferol / vitamins	1,947	1,985	$14,937	1,502
ethinyl estradiol-norgestimate / contraceptives	1,869	1,920	$32,034	1,654
montelukast / leukotriene modifiers	2,191	1,879	$27,219	1,709
fluticasone nasal / nasal steroids	2,256	1,844	$27,231	1,766
medroxyprogesterone / progestins	1,712	1,758	$64,262	1,678
atorvastatin / HMG-CoA reductase inhibitors (statins)	1,780	1,723	$17,379	1,309
fluconazole / azole antifungals	1,757	1,699	$18,947	1,539
cefdinir / third generation cephalosporins	2,815	1,613	$34,465	1,433
omeprazole / proton pump inhibitors	1,659	1,599	$16,520	1,421
metronidazole / miscellaneous antibiotics	1,601	1,535	$18,126	1,425
folic acid / vitamins	1,510	1,530	$11,137	1,047
pantoprazole / proton pump inhibitors	1,570	1,519	$17,058	1,269
methylphenidate / CNS stimulants	1,741	1,505	$236,269	1,189

TABLE F: TOP 25 DRUG MOLECULES BY DOLLARS PAID IN DEC 2022 (FFS)

Drug Molecule Therapeutic Category	Nov 2022 $ Paid	Dec 2022 $ Paid	Dec 2022 # Claims	Dec 2022 # Unique Benes
adalimumab / antirheumatics	$1,296,964	$1,195,131	131	89
elexacaftor/ivacaftor/tezacaftor / CFTR combinations	$918,027	$1,036,832	45	24
dupilumab / interleukin inhibitors	$557,518	$574,191	176	107
bictegravir/emtricitabine/tenofovir / antiviral combinations	$554,975	$505,863	122	108
ustekinumab / interleukin inhibitors	$352,782	$403,385	18	12
emicizumab / factor for bleeding disorders	$581,813	$350,757	21	21
paliperidone / atypical antipsychotics	$329,569	$348,382	123	112
lisdexamfetamine / CNS stimulants	$374,209	$322,098	966	878
cannabidiol / miscellaneous anticonvulsants	$316,638	$306,924	90	66
antihemophilic factor / factor for bleeding disorders	$440,742	$296,073	11	8
liraglutide / GLP-1 receptor agonists	$275,659	$286,778	343	292
insulin glargine / insulin	$271,318	$266,040	632	527
everolimus / selective immunosuppressants	$242,862	$250,357	14	12
somatropin / growth hormones	$322,473	$242,832	46	31
aripiprazole / atypical antipsychotics	$250,263	$239,168	1,001	838
methylphenidate / CNS stimulants	$278,909	$236,269	1,505	1,189
ixekizumab / interleukin inhibitors	$401,831	$219,839	30	20
empagliflozin / SGLT-2 inhibitors	$208,757	$215,051	301	248
carglumic acid / miscellaneous uncategorized agents	$0	$211,758	1	1
interferon gamma-1b / interferons	$422,438	$211,236	5	2
antihemophilic factor-von willebrand factor / factor for bleeding disorders	$31,864	$209,833	12	5
apixaban / factor Xa inhibitors	$201,095	$204,460	503	373
albuterol / adrenergic bronchodilators	$241,620	$187,669	3,720	3,042
buprenorphine-naloxone / narcotic analgesic combinations	$192,763	$187,455	521	413
dapagliflozin / SGLT-2 inhibitors	$176,491	$174,602	247	214

TABLE G: TOP 25 DRUG MOLECULES
BY CHANGE IN NUMBER OF CLAIMS FROM OCT 2022 TO DEC 2022 (FFS)

Drug Molecule	Oct 2022 # Claims	Nov 2022 # Claims	Dec 2022 # Claims	Dec 2022 $ Paid	Dec 2022 # Unique Benes
benzonatate / antitussives	573	955	787	$9,391	734
folic acid / vitamins	1,367	1,510	1,530	$11,137	1,047
ergocalciferol / vitamins	1,863	1,947	1,985	$14,937	1,502
codeine-guaifenesin / upper respiratory combinations	80	164	151	$2,037	136
cefprozil / second generation cephalosporins	155	215	223	$7,607	201
doxycycline / tetracyclines	910	1,037	976	$12,393	919
valacyclovir / purine nucleosides	682	672	736	$13,793	648
norethindrone / contraceptives	478	515	526	$8,254	454
cefuroxime / second generation cephalosporins	123	143	171	$2,942	164
levofloxacin / quinolones	195	235	239	$3,297	222
acetaminophen-oxycodone / narcotic analgesic combinations	787	850	829	$12,937	745
levothyroxine / thyroid hormones	1,133	1,157	1,173	$17,529	967
medroxyprogesterone / progestins	1,720	1,712	1,758	$64,262	1,678
nirmatrelvir-ritonavir / antiviral combinations	8	14	43	$401	42
lisinopril / angiotensin converting enzyme (ACE) inhibitors	905	912	936	$10,247	789
furosemide / loop diuretics	810	792	841	$7,169	666
oxycodone / narcotic analgesics	216	245	247	$3,869	210
amitriptyline / tricyclic antidepressants	448	477	476	$4,407	408
multivitamin, prenatal / vitamin and mineral combinations	314	355	341	$6,482	303
scopolamine / anticholinergics/antispasmodics	88	107	113	$9,928	97
dexamethasone / glucocorticoids	175	215	199	$3,049	183
nystatin-triamcinolone topical / topical steroids with anti-infectives	79	82	101	$1,994	85
amlodipine / calcium channel blocking agents	2,166	2,130	2,187	$27,906	1,766
insulin detemir / insulin	260	280	279	$136,772	237
polymyxin b-trimethoprim ophthalmic / ophthalmic anti-infectives	281	348	299	$4,536	287

TABLE H: TOP 25 DRUG MOLECULES
BY CHANGE IN AMOUNT PAID FROM OCT 2022 TO DEC 2022 (FFS)

Drug Molecule	Oct 2022 $ Paid	Nov 2022 $ Paid	Dec 2022 $ Paid	Dec 2022 # Claims	Dec 2022 # Unique Benes
elexacaftor/ivacaftor/tezacaftor / CFTR combinations	$638,342	$918,027	$1,036,832	45	24
carglumic acid / miscellaneous uncategorized agents	$0	$0	$211,758	1	1
antihemophilic factor-von willebrand factor / factor for bleeding disorders	$37,526	$31,864	$209,833	12	5
osimertinib / EGFR inhibitors	$15,673	$31,346	$165,340	9	2
anti-inhibitor coagulant complex / factor for bleeding disorders	$0	$132,375	$133,769	1	1
ivacaftor-lumacaftor / CFTR combinations	$0	$43,911	$131,733	6	1
cysteamine / miscellaneous uncategorized agents	$0	$229,383	$127,439	2	2
glecaprevir-pibrentasvir / antiviral combinations	$21,754	$64,213	$128,433	10	7
lenalidomide / miscellaneous antineoplastics	$35,012	$46,685	$128,386	8	5
enzalutamide / antineoplastic hormones	$77,010	$116,034	$168,067	13	8
teduglutide / miscellaneous GI agents	$85,849	$85,849	$171,699	4	3
corticotropin / corticotropin	$0	$124,394	$82,926	1	1
tucatinib / HER2 inhibitors	$0	$43,169	$75,557	5	3
risdiplam / miscellaneous uncategorized agents	$82,206	$58,723	$140,941	10	5
deutetrabenazine / VMAT2 inhibitors	$50,447	$72,451	$104,967	17	10
paliperidone / atypical antipsychotics	$294,503	$329,569	$348,382	123	112
immune globulin intravenous / immune globulins	$33,664	$30,404	$83,834	8	5
leuprolide / antineoplastic hormones	$40,462	$50,300	$86,799	15	11
interferon beta-1a / interferons	$45,899	$38,521	$91,699	12	6
ribociclib / CDK 4/6 inhibitors	$39,022	$30,341	$81,113	8	3
regorafenib / multikinase inhibitors	$20,461	$20,461	$61,382	3	2
vedolizumab / selective immunosuppressants	$38,608	$46,332	$77,215	10	7
diroximel fumarate / selective immunosuppressants	$7,756	$7,834	$42,437	6	2
risankizumab / interleukin inhibitors	$54,846	$144,823	$89,125	6	4
pazopanib / VEGF/VEGFR inhibitors	$0	$3,481	$34,212	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 OCT 2022 TO DEC 2022 (FFS)

Drug Product Therapeutic Category	Dec 2022 # Claims	Dec 2022 $ Paid	Dec 2022 Avr. Paid Per Rx	Dec 2022 Avr. Units Per Rx	Oct 2022 Paid Per Unit	Nov 2022 Paid Per Unit	Dec 2022 Paid Per Unit	Percent Change
Vyvanse (lisdexamfetamine) 50 mg capsule / CNS stimulants (N)	168	$55,654	$331.27	30	$10.34	$10.40	$10.72	3.7%
Vyvanse (lisdexamfetamine) 70 mg capsule / CNS stimulants (N)	101	$34,586	$342.43	30	$10.87	$11.01	$11.03	1.5%
Farxiga (dapagliflozin) 10 mg tablet / SGLT-2 inhibitors (Y)	204	$142,156	$696.85	40	$16.84	$17.09	$17.06	1.4%
Jardiance (empagliflozin) 10 mg tablet / SGLT-2 inhibitors (Y)	154	$107,790	$699.93	38	$17.69	$17.90	$17.92	1.3%
Biktarvy (bictegravir/emtricitabine/tenofovir) 50 mg-200 mg-25 mg tablet / antiviral combinations (Y)	122	$505,863	$4,146.42	37	$107.84	$108.81	$108.92	1.0%
Suboxone (buprenorphine-naloxone) 8 mg-2 mg film / narcotic analgesic combinations (Y)	419	$176,783	$421.92	47	$8.46	$8.51	$8.50	0.5%
QuilliChew ER (methylphenidate) 20 mg/24 hr tablet, chewable, extended release / CNS stimulants (Y)	186	$67,457	$362.67	30	$11.86	$11.81	$11.92	0.4%
Vyvanse (lisdexamfetamine) 60 mg capsule / CNS stimulants (N)	135	$43,538	$322.51	30	$10.33	$10.46	$10.37	0.4%
Jardiance (empagliflozin) 25 mg tablet / SGLT-2 inhibitors (Y)	147	$107,262	$729.67	43	$17.44	$17.78	$17.43	(0.0%)
ethinyl estradiol-norethindrone with iron 20 mcg-1 mg capsule / sex hormone combinations (Y)	124	$8,611	$69.44	36	$1.54	$1.69	$1.54	(0.2%)
Vyvanse (lisdexamfetamine) 40 mg capsule / CNS stimulants (N)	196	$66,274	$338.13	30	$10.93	$10.94	$10.90	(0.2%)
Xulane (ethinyl estradiol-norelgestromin) 35 mcg-150 mcg/24 hr film, extended release / contraceptives (Y)	1,269	$168,769	$132.99	3	$38.30	$38.24	$38.20	(0.3%)
QuilliChew ER (methylphenidate) 30 mg/24 hr tablet, chewable, extended release / CNS stimulants (Y)	131	$48,967	$373.79	30	$11.93	$11.90	$11.85	(0.7%)

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

TABLE I: TOP 15 DRUG SOLID DOSAGE FORM HIGH VOLUME (100+ RX FILLS LAST MONTH) PRODUCTS WITH UNIT COST > $1
BY PERCENT CHANGE IN AMOUNT PAID PER UNIT OCT 2022 TO DEC 2022 (FFS)

Drug Product Therapeutic Category	Dec 2022 # Claims	Dec 2022 $ Paid	Dec 2022 Avr. Paid Per Rx	Dec 2022 Avr. Units Per Rx	Oct 2022 Paid Per Unit	Nov 2022 Paid Per Unit	Dec 2022 Paid Per Unit	Percent Change
Eliquis (apixaban) 5 mg tablet / factor Xa inhibitors (Y)	405	$166,371	$410.79	48	$8.27	$8.17	$8.20	(0.8%)
Vyvanse (lisdexamfetamine) 30 mg capsule / CNS stimulants (N)	177	$59,322	$335.15	30	$10.92	$10.89	$10.81	(1.0%)

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

December 2022 – February 2023

Ongoing Intervention(s):

PROVIDER SHOPPING FOR OPIOIDS (≥4 Prescribers AND ≥4 Pharmacies)				CONCOMITANT USE OF OPIOIDS AND ANTIPSYCHOTICS		
Month	Prescribers Mailed	Pharms Mailed	Benes Addressed	Month	Prescribers Mailed	Benes Addressed
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
22-Dec	3	3	6	22-Dec	27	28
23-Jan	1	1	2	23-Jan	19	19
23-Feb	4	4	8	23-Feb	14	17

Note: Beginning with December's mailing, CCO data was not included due to issues receiving encounter claims.

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.[1,2] Maternal health problems are significantly concerning in the southern region of US.[3] 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.[4] 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".[5] 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.[5] 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,[5–7] it is estimated that more than 60,000 incidences of SMM occur every year.[1] Mississippi also reported the highest SMM rate out of 26 states that reported such data.[8] More than 60% of pregnant women are covered by Medicaid in Mississippi.[9,10] It has been found that SMM occurs more frequently among Medicaid-insured women as compared to commercially insured patients.[11] 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.[12]

Our previous study findings:[13]

- A total of 359 cases of SMM were identified among MS Medicaid women with live birth or stillbirth between 2018 – 2020.
- 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)

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%

- A nested case control study was conducted to determine the association between risk factors and SMM events. Between 2018 and 2020, 11,119 eligible beneficiaries were identified for the cohort. The majority of eligible beneficiaries were in the 18-34 years age group (85.83 %), Black (64.38%) with a mean age of 24.84 (SD = 5.71) years. The highest proportion of the study cohort was found to be in the moderately vulnerable group (54.56 %) on the Social Vulnerability Index and the mean distance of beneficiaries from the delivery center in 100 miles was determined to be 1.16 (SD = 2.29). In terms of clinical factors, 44.58 % of the study cohort had pregnancy-related visits to a provider during their first trimester, and 29.66 % had postpartum care visits within two weeks of delivery. Additionally, only 3.30% had prenatal vitamin use and 0.11 % had low-dose aspirin use documented in claims data during the prenatal period. (Table 2)

TABLE 2. Cases and Matched Controls Descriptive Statistics					
Characteristics	**Measurement time**	**Full cohort**	**Case**	**Control**	***p* value**
		(N = 11,119)	(N = 359)	(N =718)	
Age Mean (SD)	Cohort entry	24.84 (5.71)	26.65 (6.55)	25.08 (5.47)	**<0.001**
<18		881 (7.92%)	24 (6.69%)	53 (7.38%)	
18-34		9543 (85.83%)	290 (80.78%)	630 (87.74%)	**<0.001**
>=35		695 (6.25%)	45 (12.53%)	35 (4.87%)	
Race	Cohort entry				**0.04**
White		3553 (31.95%)	99 (27.58%)	234 (32.59%)	
African American		7158 (64.38%)	253 (70.47%)	457 (63.65%)	
Others		408 (3.67%)	7 (1.95%)	27 (3.76%)	
Pregnancy-related visit	First trimester of pregnancy	4957 (44.58%)	165 (46.96 %)	317 (44.15%)	0.58
Distance from delivery center(100 miles)	Delivery date	1.16 (2.29)	2.08 (3.65)	1.17 (2.26)	**<0.001**
Postpartum care visit	Two weeks post delivery date	3298 (29.66%)	110 (30.64%)	202 (28.13%)	0.39
Prenatal vitamin use	Prenatal period	367 (3.30%)	131 (36.49%)	261 (36.35 %)	0.96
Prenatal low dose aspirin use	Prenatal period	12 (0.11%)	3 (0.84%)	9 (1.25%)	0.54
SVI	Cohort entry				0.3
Least vulnerable		2776 (25.01%)	103 (28.69%)	175 (24.37%)	
Moderately vulnerable		6056 (54.56 %)	187 (52.09%)	399 (55.71%)	
Mosts vulnerable		2268 (20.43%)	69 (19.22%)	143 (19.92%)	
MCI	Pregnancy start to index date	N/A	1.28 (1.75)	0.64 (1.19)	**<0.001**
*SVI - Social Vulnerability Index, MCI - Maternal Comorbidity Index					

- Results from the adjusted logistics regression model showed 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 3)

TABLE 3. 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	
Black	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		

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	O14.1
Chronic congestive heart failure	5	I50.22, I50.23, I50.32, I50.33, I50.42, I50.43
Congenital heart disease	4	Q20, Q21, Q22, Q23, Q24, Q25, Q26
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	O30
Cardiac valvular disease	2	I05.0, I05.1, I05.2, I05.8
Systemic lupus erythematosus	2	M32
Human immunodeficiency virus	2	B20, Z21
Mild preeclampsia or unspecified preeclampsia	2	O14.0, O14.9
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 hypertension	1	O10
Previous cesarean birth	1	O34.21, O34.22
Gestational hypertension	1	O13
Alcohol abuse	1	F10.1
Asthma	1	J45
Preexisting diabetes mellitus	1	O24.0, O24.1, O24.3, O24.8
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.[14] 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].[15] 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.[16]

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 3)

Table 4 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.

TABLE 4. Maternal Comordity Index Conditions Present in Study Sample

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 %)

Following the presentation of these findings at the December 2022 DUR Board meeting, MS-DUR set out to determine an optimal MCI cut score separating those at risk of experiencing an SMM event.

METHODS

ROC Curve Analysis[17,18]

The receiver operator characteristic (ROC) curve analysis was used to select clinically relevant cut-off score for MCI. The ROC curve shows the trade-off 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) was 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 was used to quantify the optimal cut-off MCI score. Youden's index maximizes the vertical line between ROC curve and diagonal line (i.e. chance level) which is defined as sensitivity – false positive error fraction.

Youden's Index: (sensitivity + specificity) – 1.

Plot ROC curve with cut-point labeling and optimal cut-point analysis SAS macro was used for the analysis.[19]

RESULTS

Figure 2 depicts the ROC curve with Youden's index identified. The optimal threshold for the prediction of risk of SMM was identified to be at an MCI score of 1. Accordingly, categorizing pregnant women with any maternal comorbidity condition included in the MICI as being at high risk of SMM yielded a sensitivity of 50.7 % and specificity of 67.5 %.

Table 5 shows the distribution of MCI scores across cases and controls. The majority of cases and controls (61.47%) had an MCI score of zero with controls (67.55 %) having a higher percentage compared to cases (49.30 %). It also shows that as the MCI score increases, the percentage is comparatively higher in cases.

FIGURE 2: ROC Curve and Youden's Index

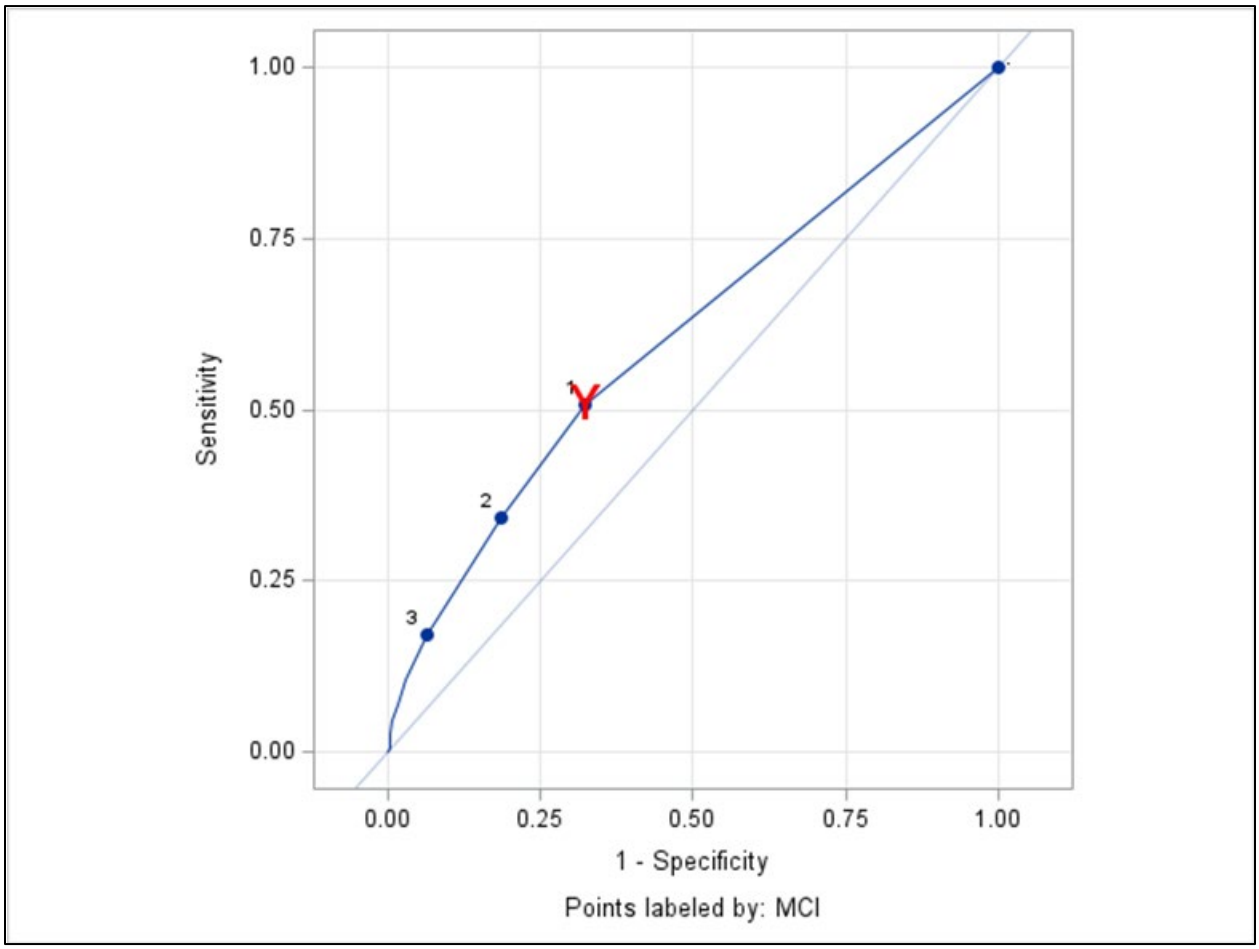


TABLE 5. MCI Distribution Among Cases and Controls			
MCI score	**Control**	**Cases**	**Total**
0	485 (67.55 %)	177 (49.30 %)	662 (61.47 %)
1	99 (13.79 %)	59 (16.43 %)	158 (14.67 %)
2	87 (12.12 %)	61 (16.99 %)	148 (13.74 %)
3	26 (3.62 %)	24 (6.69 %)	50 (4.64 %)
4	9 (1.25 %)	13 (3.62 %)	22 (2.04 %)
5	6 (0.84 %)	8 (2.23 %)	14 (1.3 %)
6	2 (0.28 %)	8 (2.23 %)	10 (0.93 %)
7	2 (0.28 %)	7 (1.95 %)	9 (0.84 %)
8	1 (0.14 %)	2 (0.56 %)	3 (0.28 %)
10	1 (0.14 %)	0 (0%)	1 (0.09%)
Total	**718**	**359**	**1077**

To further support this finding, we reran the adjusted logistics regression model utilizing MCI as a dichotomous (0/1) variable assigning individuals with an MCI score of zero a value of zero and those with a score ≥ 1 a value of 1. The results revealed that individuals with an MCI score ≥ 1 had nearly twice the odds of experiencing an SMM event, even after accounting for potential confounders in the model as shown in Table 6.

Table 6. Results from Adjusted Logistic Regression Model Examining the Relationship between Risk Factors and SMM Events Utilizing Dichotomized MCI (January 1, 2018 - December 31, 2020)

Characteristics	Adjusted OR	*p value*
MCI		
0	Reference	
≥ 1	1.99 (1.49 - 2.67)	**<0.001**
Distance from delivery center	1.12 (1.06 - 1.17)	**<0.001**
Age		
<18	1.21 (0.71 - 2.06)	0.56
18-34	Reference	
>=35	2.05 (1.25 - 3.34)	**0.02**
Race		
White	Reference	
African American	1.39 (1.01 - 1.93)	0.06
Others	0.86 (0.40 - 1.85)	0.4
Pregnancy-related visit	0.99 (0.75 - 1.30)	0.93
Postpartum care visit	0.71 (0.52 - 0.97)	**0.03**
Prenatal vitamin use	1.03 (0.77 - 1.38)	0.83
Prenatal low dose aspirin use	2.90 (0.72 - 11.75)	0.14
SVI		
Least vulnerable	Reference	
Moderately vulnerable	0.74 (0.54 - 1.03)	0.32
Mosts vulnerable	0.73 (0.47 - 1.12)	0.35

SVI - Social Vulnerability Index, MCI - Maternal Comorbidity Index

Distance from delivery center expressed per 100 miles

CONCLUSIONS

Multiple factors have been shown to be associated with negative maternal outcomes. Specifically, from our studies in the Mississippi Medicaid population, we found that MCI, distance to delivery center, age, and race were all significantly associated with SMM events. This follow-up analysis determined that a pregnant beneficiary with a score of one or higher on the MCI was at a significantly greater risk of experiencing an SMM event.

RECOMMENDATIONS

1. MS-DUR recommends DOM encourage providers utilize the MCI as a screening tool to help identify pregnant beneficiaries at risk of experiencing SMM events.
2. DOM is encouraged to explore opportunities to provide additional maternal care to those beneficiaries identified as being at an increased risk of experiencing SMM events.

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GENE THERAPY AGENTS AND IDENTIFICATION OF POTENITAL ELIGIBLE BENEFICIARIES

BACKGROUND

Gene therapy can be broadly defined as the modification or manipulation of genetic material to treat or prevent disease. Gene therapy utilizes a vector to deliver new genetic material into a cell. Vectors can be delivered in one of two ways: ex-vivo or in-vivo. Ex-vivo treatment involves removing a patient's own cells from their body, altering the cells in a lab, and returning the modified cells to the patient's body. With in-vivo treatment, the new genetic material is delivered directly into the patient's body. Once the modified genetic material is delivered to the patient, changes occur to how proteins are produced in the cell. These changes could involve replacing a disease causing gene with a healthy copy of the gene, inactivating a disease-causing gene, or introducing a new or modified gene to help treat a disease.[1,2] Although the process for developing gene therapies is lengthy and complex, gene therapies have shown promise in treating rare diseases where effective therapeutic options have traditionally been limited.

Gene therapy products are regulated by the U.S. Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) and have slowly begun entering the U.S. market since the approval of the first gene therapy in 2017. As these products enter the market, payers are tasked with not only identifying patients eligible to receive these therapies but also appropriately allocating budget dollars to pay for these agents. It is estimated that the annual spend by Medicaid programs on gene therapy products will be $5.44 billion by 2030.[3]

There are multiple gene therapy products on the horizon for conditions impacting Mississippi Medicaid beneficiaries such as sickle cell disease (SCD), beta thalassemia, and hemophilia B. Sickle cell disease and beta thalassemia are both inherited blood disorders that affect hemoglobin. Lovotibeglogene autotemcel (lovo-cel) is an experimental gene therapy designed as a one-time treatment for sickle cell disease (SCD) utilizing a modified β-globin gene to produce anti-sickling hemoglobin in a patient.[4] Bluebird Bio, the manufacturer of lovo-cel, expects to submit a Biologics License Application (BLA) to the FDA in the first quarter of 2023.[5] Exagamglogene autotemcel (exa-cel), a joint venture between Vertex Pharmaceuticals and CRISPR Therapeutics, is a treatment for sickle cell disease and transfusion-dependent beta thalassemia (TBT). It works to reduce or eliminate vaso-occlusive crises for patients with SCD and to eliminate transfusion requirements for patients with TBT by editing a patient's own hematopoietic stem cells by utilizing clustered regularly interspaced short palindromic repeat (CRISPR)/Cas9 gene-editing technology to produce high levels of fetal hemoglobin.[6] The manufacturer expects to complete the BLA submission by the end of the first quarter of 2023.[6] Betibeglogene autotemcel (beti-cel, Zynteglo®) is an autologous hematopoietic stem cell-based gene therapy approved by the FDA in August 2022 for the treatment of adult and pediatric patients with beta thalassemia who require regular red blood cell transfusions. Hemophilia B is a genetic bleeding disorder caused by insufficient levels of blood clotting protein Factor IX. Hemophilia B is less prevalent than hemophilia A (15% of all hemophilia patients) and occurs in approximately 1 in 40,000 individuals, with males being those primarily

impacted.[7] Etranacogene dezaparvovec-drlb (Hemgenix®) is an adeno-associated virus vector-based gene therapy indicated for the treatment of adults with hemophilia B (congenital Factor IX deficiency) who use Factor IX prophylaxis therapy, have a history of life-threatening hemorrhage, or have had repeated, serious spontaneous bleeding episodes.[8] Hemgenix® is a one-time single dose IV infusion that received FDA approval in November 2022.[7]

Using criteria defined in published clinical trial data and available prescribing information, MS-DUR built models identifying Medicaid beneficiaries that would potentially be eligible for gene therapies in each of the following areas: SCD, beta thalassemia, and hemophilia B.

METHODS

A retrospective claims 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)] to identify Medicaid beneficiaries who satisfy eligibility criteria for gene therapies for sickle cell disease, beta thalassemia, and hemophilia B. In all analyses, individuals were identified for the disease of interest (e.g., hemophilia B) between July 1, 2019 and June 30, 2022. No continuous enrollment was required during this time period, and the index date was the last occurrence of a diagnosis during the identification period. Eligibility for a gene therapy of interest was guided by clinical trials inclusion and exclusion criteria, prior authorization criteria, and prescribing information, where available, recognizing the limitations of administrative claims data.

Sickle Cell Disease (SCD)
SCD was identified based on ICD-10 diagnosis codes D57.0x, D57.1x, D57.2x, D57.8x in any position during the identification period. For SCD, the two gene therapies under consideration were lovotibeglogene autotemcel (lovo-cel) and exagamglogene autotemcel (exa-cel). Trials for these therapies included individuals ranging in age from 2 years and older, with the upper limit for lovo-cel at 50 years and 35 years for exa-cel.[4,9–13] For the current study, no age criteria were specified, rather, results were stratified by various age groups. In addition, trials for both treatments required individuals to have experienced 2 or more vaso-occlusive crises (VOCs) each year during the two years prior to enrollment in the clinical trials. The current study examined three VOCs scenarios – 4, 6, and 8 VOCs over a 2-year period, stratified by any VOCs and severe VOCs (i.e., VOCs resulting in an inpatient admission or emergency room visit lasting for 24 hours or more). VOCs were based on ICD-10 diagnosis codes D57.21x and D57.81x and considered unique events if they occurred at least 7 days apart. The study also examined the occurrence of acute chest syndrome (ACS). ACS events were identified as the presence of an ACS diagnosis (ICD-10 codes D57.01, D57.211, D57.811) with pneumonia (ICD-10 codes J13-J18) and pulmonary infiltrate (ICD-10 code R91.8). ACS events were counted as unique if they occurred at least 7 days apart. Finally, in addition to VOCs and ACS events, lovo-cel trials required individuals to have experienced hydroxyurea (HU) treatment failure or intolerance any time prior to enrollment in the clinical trial. HU treatment failure in the current study was operationalized as ≥ 2 VOCs during the period an individual was persistent to HU therapy. Persistence to HU therapy was defined as having no more

than 15 days gap between fills for HU, with a total days' supply of 84 days or more, and included data from July 2017 to June 2022. As such, individuals could contribute up to five years of data to the HU analysis.

Beta Thalassemia

An individual was included in the beta thalassemia population if they had at least one diagnosis with ICD-10 code D57.4x between July 2019 and June 2022. Identification of Medicaid beneficiaries eligible for beta thalassemia gene therapy was based on inclusion and exclusion criteria for clinical trials and available prior authorization criteria for betibeglogene autotemcel (Zynteglo®).[14–17] As with SCD, although clinical trials included an age requirement (≤50, with specific criteria for individuals <5 years), the current study included no age criteria, however, results were stratified by various age groups. In addition, although red blood cell (RBC) transfusion was an inclusion criterion in clinical trials, rather than exclude Medicaid beneficiaries with beta thalassemia who did not satisfy the transfusion criteria (i.e., ≥ 8 RBC transfusions in the last year), the current analyses are stratified by transfusion status. Transfusions were counted as unique events if they occurred at least 3 days apart. For all exclusion criteria (i.e., liver impairment (includes hepatitis B, hepatitis C, cirrhosis, and fatty liver), haematopoietic stem cell transplantation (HSCT) and human immunodeficiency virus (HIV), beneficiaries were flagged, but not excluded from the analysis.

Hemophilia B

Hemophilia B was identified using ICD-10 code D67.x in any position during the identification period. Inclusion and exclusion for hemophilia gene therapy were guided by clinical trials and etranacogene dezaparvovec-drlb (Hemgenix®) prescribing information.[8,18,19] As with SCD and beta thalassemia, although gene therapy for hemophilia B included an age requirement in the prescribing information (i.e., ≥18 years), the current study did not apply any age criteria, and stratified study results by various age groups. In addition, instead of applying inclusion criteria such as ≥ 4 bleeding events in the past year, or exclusion criteria such as factor IX use, factor IX inhibitor use, HIV, hepatitis B or hepatitis C, given the small sample size, beneficiaries were flagged if they satisfied these criteria.

RESULTS

Sickle Cell Disease

Baseline descriptive statistics are provided in Table 1.1

- Between July 2019 and June 2022, 2,378 Medicaid beneficiaries had a diagnosis for SCD.
- Most Medicaid beneficiaries with SCD were 50 years and younger, with 36.5% (869) of beneficiaries aged 18-35 years.
- A majority of beneficiaries were female, and this was consistent across plan types (about 60%).
- In terms of race, overall, 88.6% were Black, with White beneficiaries accounting for only 1.6% of the SCD population.

- Distribution of SCD beneficiaries by plan type were as follows: 805 (33.9%) fee-for-service (FFS), 587 (24.7%) United Health Care (UHC), 709 (29.8%) Magnolia (MAG) and 277 (11.6%) Molina (MOL).

TABLE 1.1. Baseline Demographics for Sickle Cell Disease Population

Beneficiary Characteristics		TOTAL		Program							
				FFS		UHC		MAG		MOL	
TOTAL		2,378		805		587		709		277	
Age	0 - 1 years	114	4.8%	14	1.7%	33	5.6%	37	5.2%	30	10.8%
	2 - 11 years	520	21.9%	117	14.5%	150	25.6%	184	26.0%	69	24.9%
	12 - 17 years	346	14.6%	97	12.0%	107	18.2%	118	16.6%	24	8.7%
	18 - 35 years	869	36.5%	312	38.8%	204	34.8%	232	32.7%	121	43.7%
	36 - 50 years	336	14.1%	156	19.4%	74	12.6%	81	11.4%	25	9.0%
	51 - 64 years	157	6.6%	76	9.4%	19	3.2%	54	7.6%	8	2.9%
	65+ years	36	1.5%	33	4.1%	0	0.0%	3	0.4%	0	0.0%
Gender	Female	1,440	60.6%	489	60.7%	350	59.6%	424	59.8%	177	63.9%
	Male	938	39.4%	316	39.3%	237	40.4%	285	40.2%	100	36.1%
Race	White	37	1.6%	13	1.6%	8	1.4%	10	1.4%	6	2.2%
	Black	2,106	88.6%	724	89.9%	523	89.1%	612	86.3%	247	89.2%
	Other	235	9.9%	68	8.4%	56	9.5%	87	12.3%	24	8.7%

Notes:

The study includes all Medicaid beneficiaries with a diagnosis sickle cell disease (ICD-10 codes: D57.0x, D57.1x, D57.2x, D57.8x) between July 1, 2019 and June 30, 2022.

Age, gender, race and program were assessed on the index date. The index date was the last occurrence of an SCD diagnosis.

Baseline demographics were missing for 2 beneficiaries. Other race includes 3 Hispanic beneficiaries.

Based on clinical trial inclusion criteria[4,9], the presence of vaso-occlusive crises (VOCs) were determined in claims data in the 2 years prior to the index date. VOCs distribution, stratified by number of VOCs, is provided in Table 1.2. VOCs were categorized as any VOCs and severe VOCs (i.e., VOCs resulting in an inpatient admission or emergency room visit lasting for 24 hours or more). Trial criteria required a history of 2 or more severe VOCs in each of the previous 2 years for inclusion. Based on these requirements:

- **A total of 171 beneficiaries (7.2% of the study population) experienced ≥ 4 severe VOCs in the 2 years prior to their index date.** This most closely mirrors clinical trial criteria for exa-cel.
- Across age groups, beneficiaries aged 18 – 50 years consistently had the highest proportion of VOCs with 130 of those experiencing ≥ 4 severe VOCs.
- Males and individuals classified as 'Other' race also had the highest VOCs, although in those with ≥ 4 severe VOCs, Black and 'Other' race groups were similar.
- In terms of pharmacy program, VOCs were highest in UHC and MAG and lowest in MOL and FFS.

TABLE 1.2. Vaso-occlusive Crises Among Sickle Cell Disease Population

Beneficiary Characteristics		Study population*	Any VOCs						Severe VOCs					
			4 VOCs or More		6 VOCs or More		8 VOCs or More		4 VOCs or More		6 VOCs or More		8 VOCs or More	
			# of SCD Patients	Percent	# of SCD Patients	Percent	# of SCD Patients	Percent	# of SCD Patients	Percent	# of SCD Patients	Percent	# of SCD Patients	Percent
TOTAL		**2380**	631	26.5%	439	18.4%	334	14.0%	171	7.2%	109	4.6%	80	3.4%
Age	0 - 1 years	114	2	1.8%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
	2 - 11 years	520	103	19.8%	47	9.0%	27	5.2%	9	1.7%	2	0.4%	0	0.0%
	12 - 17 years	346	87	25.1%	50	14.5%	32	9.2%	22	6.4%	9	2.6%	6	1.7%
	18 - 35 years	869	286	32.9%	223	25.7%	174	20.0%	90	10.4%	57	6.6%	44	5.1%
	36 - 50 years	336	112	33.3%	86	25.6%	74	22.0%	40	11.9%	34	10.1%	24	7.1%
	51 - 64 years	157	38	24.2%	30	19.1%	25	15.9%	8	5.1%	6	3.8%	5	3.2%
	65+ years	36	2	5.6%	2	5.6%	1	2.8%	2	5.6%	1	2.8%	1	2.8%
Gender	Female	1440	321	22.3%	227	15.8%	175	12.2%	92	6.4%	60	4.2%	44	3.1%
	Male	938	309	32.9%	211	22.5%	158	16.8%	79	8.4%	49	5.2%	36	3.8%
Race	White	37	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
	Black	2106	550	26.1%	386	18.3%	290	13.8%	154	7.3%	97	4.6%	70	3.3%
	Other	235	80	34.0%	52	22.1%	43	18.3%	17	7.2%	12	5.1%	10	4.3%
Pharmacy Program	FFS	805	185	23.0%	113	14.0%	79	9.8%	35	4.3%	20	2.5%	15	1.9%
	UHC	587	188	32.0%	128	21.8%	100	17.0%	51	8.7%	28	4.8%	23	3.9%
	MAG	709	213	30.0%	167	23.6%	131	18.5%	73	10.3%	54	7.6%	38	5.4%
	MOL	277	44	15.9%	30	10.8%	23	8.3%	12	4.3%	7	2.5%	4	1.4%

Notes

VOCs were identified using ICD-10 codes D57.0x, D57.21, and D57.81. VOCs were counted as unique events if they occurred at least 7 days apart.

Severe VOCs were inpatient and emergency department visits where the admission and discharge were on different dates.

**Total row includes 2 beneficiaries with missing demographics.*

Other Race includes 3 Hispanic beneficiaries.

Trial criteria for lovo-cel also allowed for inclusion of individuals with a history of acute chest syndrome (ACS) (at least 2 total episodes in the prior 2 years, with at least one episode in the past year) defined as an acute event with pneumonia-like symptoms and the presence of a new pulmonary infiltrate. With either a history of VOCs or ACS, the lovo-cel criteria also required a failure or intolerance to hydroxyurea (HU).

TABLE 1.3. Vaso-occlusive Crises, Acute Chest Syndrome and Hydroxyurea Treatment Failure Among Sickle Cell Disease Population

Beneficiary Characteristics		Hydroxyurea Treatment Failure		ACS/Any VOCs + Hydroxyurea Treatment Failure						ACS/Severe VOCs + HU Tx failure					
				HU Tx failure + ≥ 4 VOCs OR ≥ 2 ACS		HU Tx failure + ≥ 6 VOCs OR ≥ 2 ACS		HU Tx failure + ≥ 8 VOCs OR ≥ 2 ACS		HU Tx failure + ≥ 4 VOCs OR ≥ 2 ACS		HU Tx failure + ≥ 6 VOCs OR ≥ 2 ACS		HU Tx failure + ≥ 8 VOCs OR ≥ 2 ACS	
		# of SCD Patients	Percent	# of SCD Patients	Percent	# of SCD Patients	Percent	# of SCD Patients	Percent	# of SCD Patients	Percent	# of SCD Patients	Percent	# of SCD Patients	Percent
TOTAL		204	100.0%	163	79.9%	128	62.7%	109	53.4%	60	29.4%	41	20.1%	32	15.7%
Age	0 - 1 years	1	0.5%	1	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
	2 - 11 years	53	26.0%	34	64.2%	20	37.7%	13	24.5%	4	7.5%	1	1.9%	1	1.9%
	12 - 17 years	35	17.2%	24	68.6%	15	42.9%	14	40.0%	10	28.6%	4	11.4%	4	11.4%
	18 - 35 years	76	37.3%	69	90.8%	61	80.3%	54	71.1%	32	42.1%	24	31.6%	19	25.0%
	36 - 50 years	28	13.7%	26	92.9%	24	85.7%	23	82.1%	12	42.9%	11	39.3%	7	25.0%
	51 - 64 years	11	5.4%	9	81.8%	8	72.7%	5	45.5%	2	18.2%	1	9.1%	1	9.1%
Gender	Female	93	45.6%	76	81.7%	62	66.7%	54	58.1%	37	39.8%	25	26.9%	20	21.5%
	Male	111	54.4%	87	78.4%	66	59.5%	55	49.5%	23	20.7%	16	14.4%	12	10.8%
Race	Black	171	83.8%	135	78.9%	109	63.7%	96	56.1%	52	30.4%	35	20.5%	28	16.4%
	Other*	33	16.2%	28	84.8%	19	57.6%	13	39.4%	8	24.2%	6	18.2%	4	12.1%
Pharmacy Program	FFS	44	21.6%	30	68.2%	18	40.9%	13	29.5%	9	20.5%	5	11.4%	4	9.1%
	UHC	57	27.9%	49	86.0%	38	66.7%	34	59.6%	18	31.6%	9	15.8%	8	14.0%
	MAG	87	42.6%	70	80.5%	62	71.3%	53	60.9%	29	33.3%	24	27.6%	17	19.5%
	MOL	16	7.8%	14	87.5%	10	62.5%	9	56.3%	4	25.0%	3	18.8%	3	18.8%

Notes:

Hydroxyurea treatment failure was operationalized as having 2 or more vaso-occlusive crisis or 1 or more acute chest syndrome (ACS) during the time the individual was treatment persistent to hydroxyurea (persistence was defined as staying on HU therapy for 84 days or longer with an allowable gap of no more than 15 days.

VOCs were identified using ICD-10 codes D57.0x, D57.21, and D57.81. VOCs were counted as unique events if they occurred at least 7 days apart.

Severe VOCs were inpatient and emergency department visits where the admission and discharge were on different dates.

ACS events were identified as the presence of an ACS diagnosis (ICD-10 codes D57.01, D57.211, D57.811) with pneumonia (ICD-10 codes J13-J18) and pulmonary infiltrate (ICD-10 code R91.8). ACS events were counted as unique if they occurred at least 7 days apart.

Total row includes 2 beneficiaries with missing demographics.

There were no beneficiaries aged 65 years and older or who identified as White with hydroxyurea treatment failure.

**Other Race includes 3 Hispanic beneficiaries.*

Table 1.3 shows beneficiaries that would be eligible for lovo-cel based on those criteria.

- A total of 204 (8.6%) of beneficiaries with SCD population experienced HU treatment failure.
- Of these 204 beneficiaries, the highest rate of HU treatment failure was observed in beneficiaries aged 18 – 35 years (37.3%), males (54.4%), Black (83.8%) and beneficiaries enrolled in MAG (42.6%).
- Following the criteria in the lovo-cel trials, a total of **60 beneficiaries had hydroxyurea treatment failure and had ≥ 4 Severe VOCs or ≥ 2 ACS episodes.**

Beta Thalassemia

Baseline descriptive statistics are provided in Table 2.1

- 321 Medicaid beneficiaries had a diagnosis for beta thalassemia between July 2019 and June 2022.
- Most of the beneficiaries (81.3%) were aged 5 – 50 years, and a large proportion of beneficiaries were female (60.1%) and Black (89.1%). Only one beneficiary was White, and there were no Hispanic beneficiaries in the study population.
- 55 of the 322 beneficiaries with beta thalassemia had at least one RBC transfusion.
- Modeling inclusion criteria from Zynteglo® trials, we determined the number of beneficiaries that received ≥ 8 transfusions in the year prior to the index date. Twelve beneficiaries (3.7%) met this criterion, with baseline demographics missing for 1 beneficiary. All 11 beneficiaries with demographic information present were aged 5 – 50 years, and 9 (81.8%) were Black.

TABLE 2.1. Baseline Demographics for Beta Thalassemia Population

		Overall										Beneficiaries with ≥ 8 Transfusions							
Beneficiary Characteristics		TOTAL		Medicaid Program								TOTAL*		Program					
				FFS		UHC		MAG		MOL				FFS		UHC		MAG	
TOTAL		321		88		101		99		33		11		3		3		5	
Age	0 - 4 years	45	14.0%	10	11.4%	10	9.9%	12	12.1%	13	39.4%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
	5 - 50 years	261	81.3%	67	76.1%	89	88.1%	85	85.9%	20	60.6%	11	100.0%	3	100.0%	3	100.0%	5	100.0%
	51 - 64 years	12	3.7%	8	9.1%	2	2.0%	2	2.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
	65+ years	3	0.9%	3	3.4%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Gender	Female	193	60.1%	50	56.8%	63	62.4%	56	56.6%	24	72.7%	5	45.5%	1	33.3%	1	33.3%	3	60.0%
	Male	128	39.9%	38	43.2%	38	37.6%	43	43.4%	9	27.3%	6	54.5%	2	66.7%	2	66.7%	2	40.0%
Race	Black	286	89.1%	82	93.2%	94	93.1%	79	79.8%	31	93.9%	9	81.8%	3	100.0%	3	100.0%	3	60.0%
	Other	35	10.9%	6	6.8%	7	6.9%	20	20.2%	2	6.1%	2	18.2%	0	0.0%	0	0.0%	2	40.0%

Notes

The study includes all Medicaid beneficiaries with a diagnosis of beta thalassemia (ICD-10 codes: D57.4x) between July 1, 2019 and June 30, 2022.

Overall includes all beneficiaries with beta thalassemia. Beneficiaries with ≥ 8 transfusions are those with beta thalassemia who received 8 or more red blood cell transfusions during the year prior to the last beta thalassemia diagnosis. Transfusions were identified as the presence of any of the following: ICD-10 procedure codes 30233H1, 30243H1, 30233N1, 30233P1, 30243N1, 30243P1, 6A550Z0, HCPCS/CPT codes S3906, P9016, P9010, P9021, P9022, 09882, 36430, 36440, 09883, 36450, 36455, 36512, 36456, and revenue center code 0381.

Age, gender, race and program were assessed on the index date. The index date was the last occurrence of a beta thalassemia diagnosis

*Baseline demographic information was missing for 1 beneficiary. For the overall population, other includes 1 White beneficiary. In addition, there were no Hispanic beneficiaries in the population. For the subgroup with 8 transfusions or more, there were 12 beneficiaries, with 1 beneficiary having no baseline demographics. In addition, there were no White beneficiaries in this subgroup and no beneficiaries enrolled in Molina.

TABLE 2.2. Inclusion and Exclusion Flags for Beta Thalassemia Gene Therapy Eligibility															
		Overall							Beneficiaries with ≥ 8 Transfusions						
Beneficiary Characteristics		Study Population	Liver Impairment		HSCT		HIV		Study Population*	Liver Impairment		HSCT		HIV	
TOTAL		321	37	11.5%	1	0.3%	4	1.2%	12	3	25.0%	0	0.0%	1	8.3%
Age	0 - 4 years	45	1	0.3%	0	0.0%	1	0.3%	0	0	0.0%	0	0.0%	0	0.0%
	5 - 50 years	261	32	10.0%	1	0.3%	2	0.6%	11	2	16.7%	0	0.0%	0	0.0%
	51 - 64 years	12	3	0.9%	0	0.0%	0	0.0%	0	0	0.0%	0	0.0%	0	0.0%
	65+ years	3	0	0.0%	0	0.0%	0	0.0%	0	0	0.0%	0	0.0%	0	0.0%
Gender	Female	193	21	6.5%	0	0.0%	2	0.6%	5	1	8.3%	0	0.0%	0	0.0%
	Male	128	15	4.7%	1	0.3%	1	0.3%	6	1	8.3%	0	0.0%	0	0.0%
Race	Black	286	32	10.0%	1	0.3%	2	0.6%	9	1	8.3%	0	0.0%	0	0.0%
	Other	35	4	1.2%	0	0.0%	1	0.3%	2	1	8.3%	0	0.0%	0	0.0%
Pharmacy Program	FFS	88	7	2.2%	0	0.0%	0	0.0%	3	1	8.3%	0	0.0%	0	0.0%
	UHC	101	11	3.4%	0	0.0%	1	0.3%	3	0	0.0%	0	0.0%	0	0.0%
	MAG	99	17	5.3%	1	0.3%	1	0.3%	5	1	8.3%	0	0.0%	0	0.0%
	MOL	33	1	0.3%	0	0.0%	1	0.3%	0	0	0.0%	0	0.0%	0	0.0%

Notes:

The study includes all Medicaid beneficiaries with a diagnosis of beta thalassemia (ICD-10 codes: D57.4x) between July 1, 2019 and June 30, 2022.

Overall includes all beneficiaries with beta thalassemia. Beneficiaries with ≥ 8 transfusions are those with beta thalassemia who received 8 or more red blood cell transfusions during the year prior to the last beta thalassemia diagnosis. Transfusions were identified as the presence of any of the following: ICD-10 procedure codes 30233H1, 30243H1, 30233N1, 30233P1, 30243N1, 30243P1, 6A550Z0, HCPCS/CPT codes S3906, P9016, P9010, P9021, P9022, 09882, 36430, 36440, 09883, 36450, 36455, 36512, 36456, and revenue center code 0381.

Baseline demographic information was missing for 1 beneficiary. For the overall population, other includes 1 White beneficiary. In addition, there were no Hispanic beneficiaries in the population.

*For the subgroup with 8 transfusions or more, there were 12 beneficiaries, with 1 beneficiary having no baseline demographics. In addition, there were no White beneficiaries in that subgroup and no beneficiaries enrolled in Molina.

Baseline demographic information was missing for one beneficiary with HSCT and HIV.

Liver impairment, HSCT and HIV were identified between July 2017 and June 2022; as such, an individual could contribute up to 5 years of data to this analysis. Liver impairment includes a diagnosis for any of the following: Hepatitis B (ICD-10 codes B18.0x, B.18.1x, B19.1x), hepatitis C (ICD-10 codes B17.10, B17.11, B18.2, V02.62, Z22.52), cirrhosis (ICD-10 codes K74.0x, I85.0x, K74.60, K74.69, R18.0, R18.8, K76.6, K65.0, K65.1, K65.2, K65.8, K65.9) or fatty liver (ICD-10 codes K74.0x, K74.6x, K75.81, K76.0, K76.9). HIV was identified using ICD-10 codes B20 , B97.35, O98.72, O98.73, R75, Z21, O98.71x). Finally, HSCT was identified using ICD-10 procedure codes 30230G2, 30233G2, 30230G3, 30233G3, 30230G4, 30233G4, 30240G2, 30243G2, 30240G3, 30243G3, 30240G4, 30243G4, 30250G1, 30253G1, 30260G1 , 30263G1 , 30230Y2 , 30233Y2 , 30230Y3 , 30233Y3 , 30230Y4 , 30233Y4 , 30240Y2 , 30243Y2 , 30240Y3 , 30243Y3 , 30240Y4 , 30243Y4 , 30250Y1 , 30253Y1, 30260Y1, 30263Y , 30230X2, 30233X2, 30230X3, 30233X3, 30230X4 , 30233X4, 30240X2, 30243X2, 30240X3, 30243X3, 30240X4, 30243X4, 30250X1, 30253X1, 30260X1, 30263X1, 30230G0, 30233G0, 30240G0, 30243G0, 30250G0, 30253G0, 30260G0, 30263G0, 30230X0, 30233X0, 30240X0, 30243X0, 30250X0, 30253X0, 30260X0, 30263X0, 30230Y0, 30233Y0, 30240Y0, 30243Y0, 30250Y0, 30253Y0, 30260Y0, 30263Y0, and HCPCS/CPT codes S2142, 38240, 38243, 38241.

Table 2.2 presents beneficiary-specific information related to inclusion and exclusion criteria outlined in Zynteglo® trials that can be determined through claims data. This information is presented for the overall group identified as having beta thalassemia and those with beta thalassemia that had ≥ 8 transfusions. Exclusion criteria flagged were liver impairment (includes hepatitis B, hepatitis C, cirrhosis, and fatty liver), haematopoietic stem cell transplantation (HSCT) and human immunodeficiency virus (HIV).

- Of the 321 beneficiaries with beta thalassemia, 37 (11.5%) had a liver impairment, 1 (0.3%) had HSCT and 4 (1.2%) had HIV.
- **Of the subgroup of 12 beneficiaries with ≥ 8 transfusions, 3 had liver impairment and 1 of those also had HIV. There were no beneficiaries in this subgroup who received HSCT**.

Hemophilia B

Baseline demographics for Medicaid beneficiaries with Hemophilia B between July 2019 and June 2022 are provided in Table 3.1.

- There were 29 Medicaid beneficiaries with a diagnosis for hemophilia B during the identification period.
- Most of the beneficiaries (n = 18, 62.1%) were <18 years, a majority were male (79.3%), and White (69.2%).
- Although the table indicates 3 beneficiaries were enrolled in CCO plans (2 MAG and 1 UHC) at the index date, those beneficiaries moved into FFS in subsequent months.

TABLE 3.1. Baseline Demographics for Hemophilia B Population

Beneficiary Characteristics		TOTAL		Program					
				FFS		UHC*		MAG*	
TOTAL		29		26		1		2	
Age	0 - 17 years	18	62.1%	17	65.4%	1	100.0%	0	0.0%
	18 - 64 years	9	31.0%	7	26.9%	0	0.0%	2	100.0%
	65+ years	2	6.9%	2	7.7%	0	0.0%	0	0.0%
Gender	Female	6	20.7%	4	15.4%	0	0.0%	2	100.0%
	Male	23	79.3%	22	84.6%	1	100.0%	0	0.0%
Race	White	20	69.0%	19	73.1%	1	100.0%	0	0.0%
	Black	6	20.7%	4	15.4%	0	0.0%	2	100.0%
	Other	3	10.3%	3	11.5%	0	0.0%	0	0.0%

Notes

The study includes all Medicaid beneficiaries with a diagnosis of hemophilia B (ICD-10 codes: D67.x) between July 1, 2019 and June 30, 2022.

Age, gender, race and Medicaid program were assessed on the index date. The index date was the last occurrence of a hemophilia B diagnosis.

* Medicaid program was assigned at index date. The beneficiaries attributed to UHC and MAG were moved to FFS in subsequent months.

TABLE 3.2. Inclusion and Exclusion Flags for Hemophilia B Gene Therapy Eligibility													
Beneficiary Characteristics		**Study Population**	**≥4 Bleeding Events**		**Factor IX Use**		**Factor IX Inhibitor Use**		**HIV**		**Hepatitis B**		**Hepatitis C**	
TOTAL		**29**	**0**	0.0%	**15**	51.7%	**0**	0.0%	**0**	0.0%	**0**	0.0%	**0**	0.0%
Age	0 - 17 years	18	0	0.0%	11	61.1%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
	18 - 64 years	9	0	0.0%	3	33.3%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
	65+ years	2	0	0.0%	1	50.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Gender	Female	6	0	0.0%	1	16.7%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
	Male	23	0	0.0%	14	60.9%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Race	White	20	0	0.0%	11	55.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
	Black	6	0	0.0%	2	33.3%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
	Other	3	0	0.0%	2	66.7%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Pharmacy Program*	FFS	26	0	0.0%	15	57.7%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
	UHC	1	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
	MAG	2	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%

Notes

The study includes all Medicaid beneficiaries with a diagnosis of hemophilia B (ICD-10 codes: D67.x) between July 1, 2019 and June 30, 2022.

* Pharmacy program was assigned at index date. The beneficiaries attributed to UHC and MAG were moved to FFS in subsequent months.

Bleeding events were identified using ICD-10 diagnosis codes M25.0x, R58, I62.1, I62.00, I62.01, I62.02, I62.03, I62.9, R04.0, R04.1, K92.2, M79.81, K13.70, K13.79, K62.5, H11.30, H11.31, H11.32, H11.33, H02.89. Bleeding events were assessed during the 1 year period prior to the index date, and events were considered unique if they occurred at least 3 days apart.

Factor IX use was identified using generic name "coagulation factor ix and the corresponding NDCs (pharmacy claims) and J-codes (medical claims) in the year prior to the index date.

Factor IX inhibitor use was identified using generic names prothrombin complex and coagulation factor viia and the corresponding NDCs (pharmacy claims) and J-codes (medical claims) with at least two unique fills for factor IX inhibitors at any time between July 2017 and June 2022.

HIV (B20 , B97.35, O98.72, O98.73, R75, Z21, O98.71x), hepatitis B (B18.0x, B.18.1x, B19.1x), and hepatitis C (ICD-10 codes B17.10, B17.11, B18.2, V02.62, Z22.52) were assessed at anytime between July 2017 and June 2022.

Results for hemophilia inclusion and exclusion flags are provided in Table 3.2.

- **6 Medicaid beneficiaries had at least one bleeding event; however, <u>no</u> beneficiary had ≥ 4 bleeding events in the year prior to the index date.** *The 4 bleeding event criteria was drawn from inclusion criteria in the phase 1/2 trials for Hemgenix®.*[20] *This criterion was not spelled out in the phase 3 trial, but the participants in that trial had a mean adjusted annualized bleeding rate during a lead-in period calculated at 4.1 events.*[8,19]
- **15 beneficiaries (51.7%) had one or more claims for factor IX in the year prior to the index date**. The highest use of factor IX was observed in the <18 years group, where 11 out of 18 beneficiaries (i.e., 61.1%) had at least one claim for factor IX.
- No Medicaid beneficiaries with hemophilia B had any claims for factor IX inhibitors, or diagnosis for HIV, hepatitis B or hepatitis C during the study period that would exclude them from receiving Hemgenix®.

CONCLUSIONS

Gene therapies offer much needed treatment options in the rare disease landscape where effective treatments have been limited in the past. In light of the groundbreaking treatment advances, payers are tasked with identifying appropriate individuals eligible of receiving these therapies. Although the number of individuals identified as being eligible to receive these therapies may be small, the cost of some of these gene therapies can be astronomical requiring payers to plan and appropriately allocate resources to cover these products.

RECOMMENDATIONS

This report is presented for informational purposes with no formal recommendations included.

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AMCP Annual Meeting – March 21-24, 2023 – San Antonio, TX

***Silver Ribbon Winner**

Title: Assessment of Predictors of Severe Maternal Morbidity among Beneficiaries with Live Birth or Stillbirth in Mississippi Medicaid

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Background: Mississippi (MS) has one of the highest rates of severe maternal morbidity (SMM) rates in the US. Additionally, SMMs are found to be more frequent among Medicaid-insured women. A significant proportion of pregnant women in the state are covered by Medicaid and hence demand the need for the identification of potential risk factors. This study aimed to assess the association between risk factors and SMM events among beneficiaries with a live birth or stillbirth enrolled in MS Medicaid.

Methods: A nested case-control study was conducted using 2018 – 2021 MS Medicaid fee-for-service and coordinated care organization claims database. Medicaid beneficiaries between the ages of 12-55 years with a live birth or stillbirth were required to be continuously enrolled throughout the pregnancy period and 12 months post-delivery date without any missing demographic information. Cases were defined as beneficiaries who had SMM events during 12 months post delivery date and were matched with controls in a 1:2 ratio based on time of cohort entry (delivery date) using risk set sampling. The association between the sociodemographic and clinical predictors and SMM were tested using conditional logistic regression.

Results: A total of 11,119 MS Medicaid beneficiaries with a live birth or stillbirth were eligible for the study. Among them, 359 beneficiaries were identified as cases. The results showed that a single point increase in the Maternal Comorbidity Index (MCI) was associated with a 31% increase in the odds of experiencing SMM (aOR: 1.31, 95% CI: 1.18 – 1.45). Likewise, a 100-mile increase in distance from beneficiary's residence to the delivery center was associated with greater odds of experiencing SMM (aOR: 1.12, 95% CI: 1.06-1.17). Beneficiaries 35 years old or older at the time of delivery had more than twice the odds of experiencing SMM as compared to those who were 18-34 years old (aOR: 2.03, 95% CI: 1.23 – 3.35). Additionally, African American pregnant women had 40% greater odds of experiencing SMM (aOR: 1.40, 95% CI: 1.01-1.94) as compared to White pregnant women.

Conclusion: Maternal health care policies focusing on improving health care coverage and increasing access to high-quality and equitable maternity care should be implemented in MS to mitigate disparities in maternal health. Results from this study will help identify individuals enrolled in MS Medicaid who are risk for severe maternal morbidity and aid development targeted multicomponent, multilevel interventions for improving maternal health outcomes in this highly vulnerable population.

Statement to be included on poster

Acknowledgement: The work reported was conducted by the MS-DUR program in the Center for Pharmaceutical Marketing and Management as part of the retrospective drug use analysis activities conducted under contract with the Mississippi Division of Medicaid. The views expressed are those of the authors and do not necessarily reflect those of Mississippi Division of Medicaid or the University of Mississippi.

Empirical Validity of the Quality Measure 'Adherence to Antipsychotic Medications for Individuals With Schizophrenia' Among Medicaid Beneficiaries

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BACKGROUND

Nonadherence to antipsychotic medication is a major concern among the schizophrenia population. The HEDIS quality measure 'Adherence to Antipsychotic Medications for individuals with Schizophrenia' (SAA-AD) measures adherence using Proportion of Days Covered (PDC). Previous research has suggested nonadherence to antipsychotic medication among schizophrenia patients is associated with increased healthcare resource use.

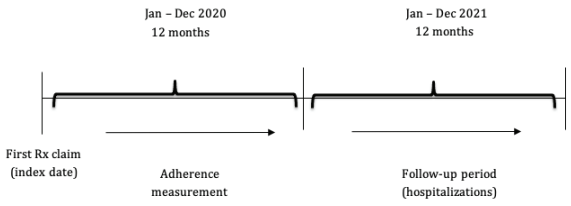
This study aimed to estimate the performance on the SAA-AD quality measure and examine the association between the SAA-AD measure performance and healthcare resource utilization in Mississippi Medicaid.

METHODS

A retrospective study was conducted using Mississippi Medicaid medical and pharmacy claims for the period January 1st,2020 – December 31st, 2021. The analysis included data from the fee-for-service (FFS) and coordinated care organizations (CCOs).

Beneficiaries aged 18 years and older with a diagnosis of schizophrenia and schizoaffective disorder were identified. SAA-AD measure, assessed in calendar year 2020, reports the percentage of beneficiaries who were dispensed and remained on antipsychotics for at least 80% of the treatment period.

Figure 1. Description of study design for patients with schizophrenia on antipsychotics



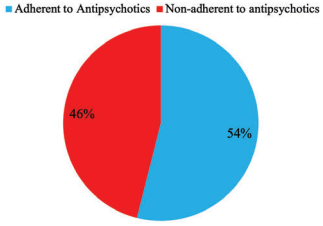
Calendar year 2021 was used to identify outcomes: mental health-related hospitalization, all-cause hospitalization, mental health-related ER visits and all-ER visits. Age, sex, race, previous hospitalization, previous ER visit, treatment period and Deyo-Charlson comorbidity index were included as covariates. Multivariable logistic regression was conducted to explore the association of adherence to antipsychotic medications and mental health-related and all-cause hospitalizations and ER visits.

RESULTS

A total of 3,722 beneficiaries had a diagnosis of schizophrenia and schizoaffective disorders. 54% (N=2,008) were considered adherent. Among those who were adherent:

- 7.6% had a mental-health hospitalization and 18% had an all-cause hospitalization during measurement year.
- 4.3% had mental-health related ER visits and 36% had an all-cause ER visit during measurement year.

Figure 2- Adherent v Non-adherent



After controlling for covariates:

- Significant association between adherence to antipsychotics and mental heath related hospitalization. (OR = 0.577, 95% CI: 0.412, 0.807)
- Significant association between adherence to antipsychotics and all-cause ER visits (OR=0.790, 95% CI: 0.645, 0.968)
- Non-significant associations between adherence to antipsychotics and any-cause hospitalization (OR=1.094, 95% CI: 0.846, 1.413) and mental health-related ER visit (OR=0.736, 95% CI: 0.483, 1.123).

American Drug Utilization Review Society Annual Meeting – February 2023

Table 1: Association between Adherence to Antipsychotic medication and mental health related Hospitalization and ER

Mental Health Hospitalization			
	OR	95% Wald CI	
Adherence	0.577	0.412	0.807
Age	0.988	0.979	0.998
Sex (ref = Female)			
Male	1.796	1.394	2.314
Race (ref = African Amer)			
Caucasian	0.53	0.384	0.733
Other	0.747	0.523	1.066
Previous Hospitalization	1.114	0.963	1.288
Previous ER Visit	1.536	1.321	1.786
Comorbidity Index	0.971	0.883	1.069
Treatment period	1.289	1.091	1.523
Mental health ER Visit			
	OR	95% Wald CI	
Adherence	0.736	0.483	1.123
Age	0.987	0.975	0.999
Sex (ref = Female)			
Male	1.77	1.28	2.447
Race (ref = African Amer)			
Caucasian	0.473	0.307	0.729
Other	0.713	0.452	1.125
Previous Hospitalization	1.449	1.197	1.755
Previous ER Visit	1.12	0.931	1.347
Comorbidity Index	0.956	0.843	1.084
treatment period	1.052	0.862	1.284

Table 2: Association between Adherence to Antipsychotic medication and All-cause Hospitalization and ER visits

All-cause Hospitalization			
	OR	95% Wald CI	
Adherence	1.094	0.846	1.413
Age	1.004	0.996	1.011
Sex (ref = Female)			
Male	0.796	0.662	0.957
Race (ref = African Amer)			
Caucasian	1.631	1.33	2.001
Other	1.067	0.809	1.409
Previous Hospitalization	2.554	2.284	2.856
Previous ER Visit	1.117	0.997	1.251
Comorbidity Index	1.1	1.035	1.169
Treatment period	1.101	1.037	1.17
All-cause ER Visit			
	OR	95% Wald CI	
Adherence	0.79	0.645	0.968
Age	1	0.994	1.005
Sex (ref = Female)			
Male	0.647	0.56	0.747
Race (ref = African Amer)			
Caucasian	1.333	1.125	1.579
Other	1.116	0.904	1.377
Previous Hospitalization	1.163	1.06	1.275
Previous ER Visit	1.783	1.644	1.934
Comorbidity Index	1.1	1.035	1.164
Treatment period	0.909	0.826	1

CONCLUSIONS

This study found that the SAA measure did significantly predict both mental health-related hospitalizations and any-cause ER visit among Medicaid beneficiaries with schizophrenia treated with antipsychotics. However, the SAA measure did not significantly predict either all-cause hospitalization or mental health related ER visits among the study population. Further research is needed to estimate the empirical validity of the measure with additional outcomes (i.e., healthcare cost) and in more states.

Acknowledgments and Disclosures

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FDA DRUG SAFETY COMMUNICATIONS

December 2022 – February 2023

- No new safety communications were posted by the FDA.

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 re-appointed 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

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: e-mail, fax, or other written communication. DUR Board members are required to keep on file with
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.

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

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

AWP	Any Willing Provider, Average Wholesale Price
BENE	Beneficiary
CAH	Critical Access Hospital
CCO	Coordinated Care Organization
CDC	Centers for Disease Control
CHIP	Children's Health Insurance Program
CMS	Center for Medicare and Medicaid Services
COB	Coordination of Benefits
CPC	Complex Pharmaceutical Care
DME	Durable Medical Equipment
DOC	Department of Corrections
DOM	Division of Medicaid
DUR	Drug Utilization Review
EOB	Explanation of Benefits
EPSDT	Early and Periodic Screening, Diagnosis and Treatment
FA	Fiscal Agent
FFS	Fee For Service
FPW	Family Planning Waiver
FQHC	Federally Qualified Health Clinic
FY	Fiscal Year
HB	House Bill
HCPCS/ HEIDIS	Health Plan Employer Data and Information Set
HHS	Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability
IDD	Intellectual and Developmental Disabilities
LTC	Long Term Care
MAG	Magnolia Health
MEDD	Morphine Equivalent Daily Dose
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
PDL	Preferred Drug List
PI	Program Integrity
PIP	Performance Improvement Program
POS	Point of Sale, Place of Service, Point of Service
Pro-DUR	Prospective Drug Use Review
OTC	Over the Counter
QI	Quality Indicator
QIO	Quality Improvement Organization
QM	Quality Management
RA	Remittance Advise
REOMB	Recipient's Explanation of Medicaid Benefits
Retro-DUR	Retrospective Drug Utilization Review
RFI	Request for Information
RFP	Request for Proposal
RHC	Rural Health Clinic
SB	Senate Bill
SCHIP	State Child Health Insurance Program
SMART PA	Conduent's Pharmacy Application (SmartPA) is a proprietary electronic prior authorization system used for Medicaid fee for service claims
SPA	State Plan Amendment
UHC	United Healthcare
UM/QIO	Utilization Management and Quality Improvement Organization
UPDL	Universal Preferred Drug List
UR	Utilization Review
VFC	Vaccines for Children
WAC	Wholesale Acquisition Cost
WIC	Women, Infants, Children
340B	Federal Drug Discount Program