

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



MISSISSIPPI DIVISION OF
MEDICAID

September 16, 2021 at 1:00pm

ZOOM Meeting

Prepared by:



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

Drug Utilization Review Board

Lauren Bloodworth, PharmD

University of MS School of Pharmacy
201D Faser Hall
University, MS 38677
Term Expires: June 30, 2024

Ray Montalvo, MD

KDMC Specialty Clinic
940 Brookway Boulevard
Brookhaven, MS 39601
Term Expires: June 30, 2023

Terrence Brown, PharmD

GA Carmichael Family Health Center
1668 West Peace Street
Canton, MS 39046
Term Expires: June 20, 2023

Holly R. Moore, PharmD

Anderson Regional Medical Center
2124 14th Street
Meridian, MS 39301
Term Expires: June 30, 2023

Patrick Bynum, MD

MEA Vicksburg Ambulatory Care Clinic
4204 Clay Street
Vicksburg, MS 39183
Term Expires: June 30, 2022

Janet Ricks, DO

UMMC, Family Medicine
2500 North State Street
Jackson, MS 39216
Term Expires: June 30, 2024

Rhonda Dunaway, RPh

Coastal Family Health Center
9113 Hwy 49 Suite 200
Gulfport, MS 39503
Term Expires: June 30, 2023

Cheryl Sudduth, RPh

Funderburk's Pharmacy
134 West Commerce Street
Hernando, MS 38632
Term Expires: June 30, 2022

Tanya Fitts, MD

Lafayette Pediatric Clinic
1300 Access Road, Suite 400
Oxford, MS 38655
Term Expires: June 30, 2024

James Taylor, PharmD (Chair)

North MS Medical Center
830 S. Gloster Street
Tupelo, MS 38801
Term Expires: June 30, 2022

Alan Torrey, MD

Merit Health Medical Group
Pain Management
2080 South Frontage Road
Vicksburg, MS 39180
Term Expires: June 30, 2022

2021 DUR Board Meeting Dates

March 4, 2021
June 10, 2021

September 16, 2021
December 9, 2021

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

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

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

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

**MISSISSIPPI DIVISION OF MEDICAID
OFFICE OF THE GOVERNOR
DRUG UTILIZATION REVIEW BOARD
AGENDA
September 16, 2021**

Welcome

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Pharmacy Program Update Terri Kirby, RPh

Next Meeting Information

Remaining 2021 Meeting Date: December 9

DUR Board Meeting Minutes

**MISSISSIPPI DIVISION OF MEDICAID
DRUG UTILIZATION REVIEW (DUR) BOARD
MINUTES OF THE JUNE 10, 2021 MEETING**

DUR Board Roster: State Fiscal Year 2021 (July 1, 2020 – June 30, 2021)	Sep 2020	Dec 2020	Mar 2021	Jun 2021
Lauren Bloodworth, PharmD (Chair)	✓	✓	✓	✓
Terrence Brown, PharmD	NA	NA	✓	
Patrick Bynum, MD	NA	NA	✓	✓
Rhonda Dunaway, RPh	✓	✓	✓	✓
Tanya Fitts, MD	✓	✓	✓	
Philip Merideth	NA	NA	✓	✓
Ray Montalvo, MD	✓	✓		✓
Holly Moore, PharmD	✓		✓	
Janet Ricks, DO	✓		✓	
Cheryl Sudduth, RPh	✓	✓		✓
James Taylor, PharmD	✓	✓	✓	
Alan Torrey, MD		✓		✓
TOTAL PRESENT**	9	7	9	7

*** 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, Research Assistant Professor; Yiran Rong, DUR Analyst;

Conduent Staff:

Leslie Leon, PharmD, Clinical Pharmacist, Mississippi Medicaid Project; Lew Anne Snow, RN, BSN, Pharmacy Services Sr. Analyst, Mississippi Medicaid Project;

Change Healthcare Staff:

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

Coordinated Care Organization (CCO) Staff:

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

Visitors:

Kimberly Clark, Viiv Healthcare; Jill Gran, Otsuka; Justin Simmons, Abbvie; Jim Chapman, Abbvie; Nole Mangine, Abbvie; Jenna Ferrara, Abbvie; Julie Young, Abbvie; Natasha Dowd, Alkermes; Tracey Smalley, Amgen; Shauna Williams, Bayer; Robert Greely, Biogen; David Large, Biohaven; Brian Berhow, Sunovion; Andrew Delgado, BMS; Jeff Knappen, Spark Therapeutics; Martin McNulty, Pfizer; Cathy Prine-Eagle, Merck; Wendy Williams, Supernaus; Tony Bucalo, EMD Serono; Brount Young, Global Blood Therapeutics; Michelle Shirley, Indivior; Mike Peoples, Lilly; Steve Isaki, Lundbeck; John Schillo, Lundbeck; Paula Whatly, Novo Nordisk; April Gault, Takeda; Carley Riehle, Takeda; Steve Patterson, Zealand Pharma; Shawn Headley; Hope Ladner; Russell Smith;

Call to Order:

Dr. Pittman called the meeting to order at 1:01pm and welcomed everyone to the meeting via Zoom.

OLD BUSINESS:

Dr. Bloodworth moved to approve the minutes from the March 2021 DUR Board Meeting, seconded by Ms. Sudduth, and unanimously approved by the DUR Board.

Resource Utilization Review:

Dr. Pittman presented the resource utilization report for March 2021. Enrollment numbers continued to climb. The number of beneficiaries with pharmacy benefits was up 14.1% compared to March 2020. While enrollment numbers increased, the number of prescription fills decreased 4.8% compared to March 2020. The total dollars paid for prescriptions was slightly increased compared to that paid in March 2020. One other item of note was the substantial increase in paid claims for the administration of COVID-19 vaccines that occurred during the first quarter of 2021.

Feedback and Discussion from Board:

Dr. Pittman informed the Board that the work of DUR around HPV vaccination rates has generated exposure among other organizations around MS involved in improving vaccination rates. The MS HPV Roundtable along with the American Cancer Society is sponsoring 2 upcoming webinars targeting pharmacists' involvement in HPV vaccinations.

NEW BUSINESS:

Update on MS-DUR Educational Interventions:

Dr. Pittman provided an overview of all DUR mailings and educational notices that occurred March 2021 – May 2021.

Special Analysis Projects:

Review of the Current State of Migraine Treatment among Medicaid Beneficiaries

MS-DUR presented 3 reports centered on migraine treatment among Medicaid beneficiaries. Each report focused on different aspects of migraine treatment. The landscape of migraine treatment has been rapidly changing since calcitonin gene-related peptide inhibitor therapies entered the market in 2018. With the changes occurring in this space, MS-DUR felt it was appropriate to conduct an in-depth examination of prescribing patterns.

Report 1: Overall trends in the utilization of medications for the treatment of migraine

Total spending on migraine-related medications showed a consistent increase since 2018. This increase was primarily attributed to the utilization of calcitonin gene-related peptide (CGRP) inhibitor products. There were no formal recommendations as a result of this report.

Report 2: Calcitonin gene-related peptide inhibitor utilization trends and outcomes assessment

This report aimed to establish if CGRP inhibitor medications were being utilized within the Mississippi Division of Medicaid in a cost-effective manner and to determine if current utilization strategies, including prior authorization, were being optimized to encourage appropriate CGRP inhibitor utilization among this population. The report showed that of the beneficiaries that received CGRP inhibitor therapy, the majority received injectable products as compared to the oral products. Approximately 5% had claims for the concurrent use of oral and injectable CGRP inhibitor products. Outcomes associated with CGRP inhibitor use were assessed through claims data and included healthcare resource utilization and opioid use. Outcomes were stratified by those that were classified as ‘early discontinuers’ or ‘continuers’ of CGRP inhibitor therapy. Results were mixed when comparing outcomes pre- and post-CGRP inhibitor initiation. It was noted that outcomes assessed through claims data may not present a true picture of clinical effectiveness. The following recommendations were discussed:

1. Medicaid should consider reassessing their UPDL and prior authorization requirements to ensure the most appropriate utilization of CGRP inhibitors occurs. Items for consideration:

- UPDL requirement prohibiting concurrent use of oral CGRP inhibitor agents with another CGRP inhibitor agent.

MS-DUR recommended defining parameters for concurrent use such as a minimum length of trial of a preventive CGRP inhibitor agent prior to adding a second agent, dose maximization of preventive agent prior to adding a second agent, trial of a different preventive agent prior adding a second agent, or verification of adherence to preventive agent prior to adding a second agent.

- Manual PA requirements for reauthorization.
MS-DUR recommended defining parameters for reauthorization criteria. Current language in the manual PA document is vague and may benefit from the incorporation of measurable thresholds. These thresholds should be based on evidence in literature and would help identify those patients in which continued CGRP inhibitor therapy is most beneficial.

Following discussion, Ms. Dunaway made a motion, seconded by Dr. Bloodworth, and unanimously approved by the Board to accept the recommendations presented.

Report 3: Utilization of preventive therapy for migraine among Medicaid beneficiaries

Results from this report confirmed national trends for the underdiagnosis and undertreatment of migraine. Among Medicaid beneficiaries, only 52% of those determined as eligible for preventive migraine treatment had a diagnosis for migraine in claims data pointing to underdiagnosis. Related to undertreatment, only 52.4% of those determined eligible to receive preventive therapy actually had claims for preventive therapy during the study period. While it was shown that certain sociodemographic factors (age, CCI index score, distance traveled to provider, and pharmacy plan) significantly impacted beneficiary use of preventive treatment, overall social determinants of health factors did not appear to have a significant impact on the odds of beneficiaries receiving preventive migraine treatment. The following recommendation was discussed:

1. DOM may consider strategies to improve the rates of preventive migraine diagnosis and treatment among Medicaid beneficiaries, especially targeting those in the FFS program

Following a discussion, Dr. Bloodworth made a motion, seconded by Dr. Montalvo, and unanimously approved by the Board to accept the recommendation presented.

FDA Drug Safety Updates:

Dr. Pittman presented FDA drug safety communications for March 2021 – May 2021.

Pharmacy Program Update:

Ms. Kirby provided a brief pharmacy program update informing everyone that the upcoming September 2021 DUR Board Meeting and the October 2021 P&T Board Meetings are both tentatively scheduled to be held in-person in the Woolfolk Building in Jackson, MS.

Mr. Yount informed guests that beginning with the next DUR Board Meeting, guests would be required to register in advance to attend. The process for registration will be similar to that utilized for P&T meetings

Miscellaneous:

Remaining 2021 Meeting Dates/Times

September 16, 2021

December 9, 2021

**Meeting time will remain at 1 pm.*

Next Meeting Information:

Dr. Pittman announced that the next meeting of the DUR Board will take place on September 16, 2021 at 1pm in-person at the Woolfolk Building.

Dr. Bloodworth motioned to adjourn the meeting at 2:34 pm, seconded by Dr. Montalvo, and unanimously approved by the Board.

Submitted,

Eric Pittman, PharmD

Evidence-Based DUR Initiative, MS-DUR

DRAFT

Meeting Location: Meetings will be held virtually until further notice. Please visit [Medicaid.ms.gov](https://www.Medicaid.ms.gov) and click on the Pharmacy Information link for further information.

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

Date and Time: March 4, 2021; June 10, 2021; September 16, 2021; and December 9, 2021 at 1PM

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

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

The Drug Utilization Review (DUR) Board meets quarterly.

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Mississippi Public Meeting Notices

NOTICE DETAILS

NOTICE DETAILS

State Agency: Division of Medicaid

Public Body: Division of Medicaid

Title: Drug Utilization Review Board Meeting

Subject: Drug Utilization Review Board Meeting

Date and Time: 6/10/2021 1:00:00 PM

Description:

The Drug Utilization Review Board reviews utilization of drug therapy and evaluates the long term success of the treatments.

Back

MEETING LOCATION

501 N. West Street
Jackson MS 39201

Map this!

CONTACT INFORMATION

Chris Yount
6013596336
christopher.yount@medicaid.ms.gov

DOWNLOAD ATTACHMENTS

DFA Meeting notification DUR 2021.docx
Added 1/14/2021

SUBSCRIPTION OPTIONS

Subscription options will send you alerts regarding future notices posted by this public body.

RSS

Resource Utilization Review

TABLE 04A: ENROLLMENT STATISTICS FOR LAST 6 MONTHS**January 1, 2021 through June 30, 2021**

		Jan-21	Feb-21	Mar-21	Apr-21	May-21	Jun-21
Total enrollment		758,588	763,044	768,273	772,663	776,410	780,002
Dual-eligibles		164,756	164,307	164,259	164,413	164,411	164,432
Pharmacy benefits		644,950	649,479	654,908	658,924	662,086	664,346
PLAN %	LTC	14,892	14,705	14,828	14,865	14,857	14,770
	FFS	25.5%	25.6%	25.9%	26.3%	26.2%	26.2%
	MSCAN-UHC	28.4%	28.4%	28.3%	28.2%	28.2%	28.2%
	MSCAN-Magnolia	30.9%	30.7%	30.5%	30.3%	30.2%	30.1%
	MSCAN-Molina	15.2%	15.3%	15.3%	15.2%	15.4%	15.5%

TABLE 04B: PHARMACY UTILIZATION STATISTICS FOR LAST 6 MONTHS**January 1, 2021 through June 30, 2021**

		Jan-21	Feb-21	Mar-21	Apr-21	May-21	Jun-21
# Rx Fills	FFS	104,639	94,982	114,008	119,984	114,035	119,014
	MSCAN-UHC	137,276	119,682	142,778	160,579	159,074	163,604
	MSCAN-Mag	157,105	143,159	168,471	174,865	163,154	167,099
	MSCAN-Mol	48,809	44,938	54,213	59,703	58,562	61,375
# Rx Fills / Bene	FFS	0.6	0.6	0.7	0.7	0.7	0.7
	MSCAN-UHC	0.7	0.6	0.8	0.9	0.9	0.9
	MSCAN-Mag	0.8	0.7	0.8	0.9	0.8	0.8
	MSCAN-Mol	0.5	0.5	0.5	0.6	0.6	0.6
\$ Paid Rx	FFS	\$12,875,993	\$11,435,092	\$14,041,988	\$13,855,461	\$13,778,115	\$14,592,770
	MSCAN-UHC	\$15,269,459	\$13,149,300	\$15,493,207	\$19,009,236	\$18,948,501	\$20,098,916
	MSCAN-Mag	\$16,912,132	\$15,791,600	\$18,079,366	\$17,857,195	\$16,690,256	\$18,138,698
	MSCAN-Mol	\$4,621,066	\$4,258,673	\$4,916,148	\$4,962,232	\$4,652,546	\$4,972,890
\$ /Rx Fill	FFS	\$123.05	\$120.39	\$123.17	\$115.48	\$120.82	\$122.61
	MSCAN-UHC	\$111.23	\$109.87	\$108.51	\$118.38	\$119.12	\$122.85
	MSCAN-Mag	\$107.65	\$110.31	\$107.31	\$102.12	\$102.30	\$108.55
	MSCAN-Mol	\$94.68	\$94.77	\$90.68	\$83.12	\$79.45	\$81.02
\$ /Bene	FFS	\$78.29	\$68.78	\$82.78	\$79.95	\$79.43	\$83.84
	MSCAN-UHC	\$83.36	\$71.29	\$83.59	\$102.30	\$101.49	\$107.28
	MSCAN-Mag	\$84.86	\$79.20	\$90.51	\$89.44	\$83.47	\$90.71
	MSCAN-Mol	\$47.14	\$42.86	\$49.06	\$49.54	\$45.63	\$48.29

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 made a change to their claims reporting procedure. This change impacted the calculation of amounts paid for certain claims resulting in inflated values. A procedure is in the process of development to correct this issue.

TABLE C: TOP 10 DRUG CATEGORIES BY NUMBER OF CLAIMS IN JUN 2021 (FFS AND CCOs)

Category	Month Year	Rank Volume	# RXs	\$ Paid	# Unique Benes
CNS stimulants	Jun 2021	1	21,812	\$3,915,755	18,111
	May 2021	1	23,063	\$4,256,112	19,593
	Apr 2021	1	26,724	\$4,962,000	22,551
adrenergic bronchodilators	Jun 2021	2	15,357	\$965,471	13,008
	May 2021	3	14,744	\$903,506	12,570
	Apr 2021	3	15,241	\$948,363	12,880
antihistamines	Jun 2021	3	15,306	\$220,599	14,441
	May 2021	2	16,049	\$232,656	15,206
	Apr 2021	2	17,456	\$254,732	16,625
nonsteroidal anti-inflammatory agents	Jun 2021	4	15,146	\$224,130	14,192
	May 2021	5	14,285	\$210,181	13,463
	Apr 2021	4	14,844	\$219,434	14,025
atypical antipsychotics	Jun 2021	5	14,802	\$4,323,466	12,213
	May 2021	6	14,116	\$4,200,428	11,860
	Apr 2021	5	14,488	\$4,081,009	12,241
SSRI antidepressants	Jun 2021	6	14,693	\$177,832	13,358
	May 2021	7	13,732	\$168,576	12,644
	Apr 2021	6	14,371	\$175,825	13,259
aminopenicillins	Jun 2021	7	13,771	\$178,033	13,282
	May 2021	4	14,546	\$189,435	14,089
	Apr 2021	7	13,933	\$179,450	13,566
narcotic analgesic combinations	Jun 2021	8	13,471	\$556,126	12,119
	May 2021	9	12,668	\$514,660	11,575
	Apr 2021	8	12,935	\$546,177	11,658
proton pump inhibitors	Jun 2021	9	12,575	\$436,795	11,742
	May 2021	10	12,120	\$428,770	11,422
	Apr 2021	9	12,522	\$447,257	11,816
glucocorticoids	Jun 2021	10	12,289	\$267,960	11,627
	May 2021	8	12,750	\$258,671	12,045
	Apr 2021	10	11,704	\$226,121	11,117

TABLE D: TOP 10 DRUG CATEGORIES BY DOLLARS PAID IN JUN 2021 (FFS AND CCOs)

Category	Month Year	Rank Paid Amt	# RXs	\$ Paid	# Unique Benes
atypical antipsychotics	Jun 2021	1	14,802	\$4,323,466	12,213
	May 2021	2	14,116	\$4,200,428	11,860
	Apr 2021	2	14,488	\$4,081,009	12,241
TNF alpha inhibitors	Jun 2021	2	610	\$4,077,870	478
	May 2021	3	496	\$3,488,564	425
	Apr 2021	3	533	\$3,697,501	439
CNS stimulants	Jun 2021	3	21,812	\$3,915,755	18,111
	May 2021	1	23,063	\$4,256,112	19,593
	Apr 2021	1	26,724	\$4,962,000	22,551
antiviral combinations	Jun 2021	4	969	\$3,092,329	850
	May 2021	4	896	\$3,026,013	797
	Apr 2021	4	909	\$3,028,707	816
insulin	Jun 2021	5	5,904	\$2,714,340	4,185
	May 2021	5	5,412	\$2,470,986	3,910
	Apr 2021	5	5,614	\$2,600,825	4,098
interleukin inhibitors	Jun 2021	6	492	\$2,421,830	367
	May 2021	6	422	\$2,222,224	330
	Apr 2021	6	403	\$2,069,568	322
CFTR combinations	Jun 2021	7	100	\$2,144,454	64
	May 2021	9	70	\$1,472,562	59
	Apr 2021	7	77	\$1,604,110	62
miscellaneous uncategorized agents	Jun 2021	8	175	\$1,468,483	148
	May 2021	7	180	\$1,723,762	153
	Apr 2021	8	191	\$1,450,320	173
bronchodilator combinations	Jun 2021	9	4,279	\$1,311,407	3,767
	May 2021	10	4,185	\$1,304,830	3,688
	Apr 2021	9	4,300	\$1,320,152	3,856
factor for bleeding disorders	Jun 2021	10	118	\$1,119,578	102
	May 2021	8	135	\$1,681,914	105
	Apr 2021	10	106	\$1,304,526	89

**TABLE E: TOP 25 DRUG MOLECULES
BY NUMBER OF CLAIMS IN JUN 2021 (FFS and CCOs)**

Drug Molecule Therapeutic Category	May 2021 # Claims	Jun 2021 # Claims	Jun 2021 \$ Paid	Jun 2021 # Unique Benes
albuterol / adrenergic bronchodilators	13,938	14,414	\$678,804	12,383
amoxicillin / aminopenicillins	14,526	13,737	\$177,318	13,252
cetirizine / antihistamines	11,456	10,691	\$141,744	10,240
montelukast / leukotriene modifiers	9,996	9,594	\$151,790	9,121
azithromycin / macrolides	9,848	8,680	\$148,578	8,389
gabapentin / gamma-aminobutyric acid analogs	8,104	8,576	\$133,545	7,857
acetaminophen-hydrocodone / narcotic analgesic combinations	8,074	8,479	\$111,068	7,850
fluticasone nasal / nasal steroids	8,138	7,429	\$112,107	7,183
sars-cov-2 (covid-19) mna bnt-162b2 vaccine / viral vaccines	4,226	6,921	\$222,492	5,966
ibuprofen / nonsteroidal anti-inflammatory agents	6,469	6,818	\$83,015	6,569
clonidine / antiadrenergic agents, centrally acting	6,489	6,712	\$90,041	6,083
amlodipine / calcium channel blocking agents	6,443	6,677	\$80,304	6,260
prednisolone / glucocorticoids	6,511	6,254	\$92,921	5,940
lisdexamfetamine / CNS stimulants	6,705	6,252	\$2,042,730	5,855
omeprazole / proton pump inhibitors	5,813	6,041	\$66,189	5,756
ondansetron / 5HT3 receptor antagonists	6,714	6,029	\$89,114	5,680
amphetamine-dextroamphetamine / CNS stimulants	6,062	5,956	\$183,518	5,017
sertraline / SSRI antidepressants	5,024	5,400	\$65,701	4,928
methylphenidate / CNS stimulants	5,693	5,247	\$800,019	4,521
cefdinir / third generation cephalosporins	5,678	5,211	\$116,958	5,069
triamcinolone topical / topical steroids	4,444	5,026	\$91,036	4,781
amoxicillin-clavulanate / penicillins/beta-lactamase inhibitors	4,974	4,972	\$107,853	4,767
atorvastatin / HMG-CoA reductase inhibitors (statins)	4,530	4,703	\$53,364	4,374
hydroxyzine / miscellaneous anxiolytics, sedatives and hypnotics	3,979	4,296	\$65,828	4,042
guanfacine / antiadrenergic agents, centrally acting	4,150	4,207	\$108,474	3,876

**TABLE F: TOP 25 DRUG MOLECULES
BY DOLLARS PAID IN JUN 2021 (FFS and CCOs)**

Drug Molecule Therapeutic Category	May 2021 \$ Paid	Jun 2021 \$ Paid	Jun 2021 # Claims	Jun 2021 # Unique Benes
adalimumab / antirheumatics	\$2,718,559	\$3,182,141	436	344
lisdexamfetamine / CNS stimulants	\$2,192,468	\$2,042,730	6,252	5,855
paliperidone / atypical antipsychotics	\$1,757,237	\$1,756,050	685	614
elixacaftor/ivacaftor/tezacaftor / CFTR combinations	\$886,672	\$1,622,496	73	50
bictegravir/emtricitabine/tenofovir / antiviral combinations	\$1,334,891	\$1,410,173	416	381
dupilumab / interleukin inhibitors	\$968,284	\$1,143,820	359	263
aripiprazole / atypical antipsychotics	\$1,010,000	\$1,044,513	4,020	3,631
insulin glargine / insulin	\$894,091	\$974,024	2,116	1,965
etanercept / antirheumatics	\$720,829	\$835,082	160	120
carglumic acid / miscellaneous uncategorized agents	\$1,028,226	\$822,581	4	2
liraglutide / GLP-1 receptor agonists	\$761,969	\$812,980	986	920
methylphenidate / CNS stimulants	\$901,886	\$800,019	5,247	4,521
somatropin / growth hormones	\$633,472	\$683,437	162	139
albuterol / adrenergic bronchodilators	\$655,424	\$678,804	14,414	12,383
insulin aspart / insulin	\$544,523	\$618,804	1,570	1,415
lacosamide / miscellaneous anticonvulsants	\$599,302	\$609,833	634	545
dexmethylphenidate / CNS stimulants	\$624,480	\$585,711	2,743	2,188
budesonide-formoterol / bronchodilator combinations	\$541,308	\$561,989	1,773	1,679
deferasirox / chelating agents	\$343,321	\$560,168	94	66
emicizumab / factor for bleeding disorders	\$781,552	\$534,566	23	20
empagliflozin / SGLT-2 inhibitors	\$427,988	\$517,368	680	629
lurasidone / atypical antipsychotics	\$435,908	\$499,184	351	308
cobicistat/elvitegravir/emtricitabine/tenofovir / antiviral combinations	\$500,540	\$484,841	142	124
insulin detemir / insulin	\$471,137	\$478,884	901	833
apixaban / factor Xa inhibitors	\$432,165	\$460,469	1,034	925

**TABLE G: TOP 25 DRUG MOLECULES
BY CHANGE IN NUMBER OF CLAIMS FROM APR 2021 TO JUN 2021 (FFS and CCOs)**

Drug Molecule	Apr 2021 # Claims	May 2021 # Claims	Jun 2021 # Claims	Jun 2021 \$ Paid	Jun 2021 # Unique Benes
sars-cov-2 (covid-19) mna bnt-162b2 vaccine / viral vaccines	2,806	4,226	6,921	\$222,492	5,966
prednisolone / glucocorticoids	4,976	6,511	6,254	\$92,921	5,940
ciprofloxacin-dexamethasone otic / otic steroids with anti-infectives	835	993	1,773	\$393,060	1,598
mupirocin topical / topical antibiotics	3,440	3,560	4,169	\$62,522	4,017
ofloxacin otic / otic anti-infectives	503	599	936	\$24,670	898
nystatin topical / topical antifungals	1,818	1,897	2,183	\$39,611	2,032
acetaminophen-hydrocodone / narcotic analgesic combinations	8,135	8,074	8,479	\$111,068	7,850
cephalexin / first generation cephalosporins	2,696	2,736	2,992	\$53,747	2,901
triamcinolone topical / topical steroids	4,758	4,444	5,026	\$91,036	4,781
budesonide / inhaled corticosteroids	1,548	1,683	1,804	\$206,425	1,677
fluconazole / azole antifungals	3,530	3,310	3,780	\$51,290	3,514
hydroxyzine / miscellaneous anxiolytics, sedatives and hypnotics	4,054	3,979	4,296	\$65,828	4,042
sulfamethoxazole-trimethoprim / sulfonamides	3,679	3,469	3,914	\$64,299	3,758
clindamycin / lincomycin derivatives	2,287	2,245	2,516	\$68,414	2,416
amoxicillin-clavulanate / penicillins/beta-lactamase inhibitors	4,751	4,974	4,972	\$107,853	4,767
metronidazole / miscellaneous antibiotics	2,620	2,498	2,839	\$33,463	2,739
gabapentin / gamma-aminobutyric acid analogs	8,389	8,104	8,576	\$133,545	7,857
bupropion / smoking cessation agents	1,887	1,852	2,068	\$42,257	1,900
acetaminophen-oxycodone / narcotic analgesic combinations	2,550	2,504	2,731	\$43,583	2,548
nitrofurantoin / urinary anti-infectives	1,770	1,780	1,947	\$76,048	1,864
quetiapine / atypical antipsychotics	3,207	3,230	3,383	\$54,043	2,889
buspirone / miscellaneous anxiolytics, sedatives and hypnotics	2,748	2,690	2,919	\$37,850	2,713
polymyxin b-trimethoprim ophthalmic / ophthalmic anti-infectives	402	496	563	\$8,748	552
metformin / biguanides	3,705	3,639	3,858	\$43,003	3,610
levothyroxine / thyroid hormones	3,237	3,231	3,389	\$75,064	3,072

**TABLE H: TOP 25 DRUG MOLECULES
BY CHANGE IN AMOUNT PAID FROM APR 2021 TO JUN 2021 (FFS and CCOs)**

Drug Molecule	Apr 2021 \$ Paid	May 2021 \$ Paid	Jun 2021 \$ Paid	Jun 2021 # Claims	Jun 2021 # Unique Benes
elexacaftor/ivacaftor/tezacaftor / CFTR combinations	\$1,102,309	\$886,672	\$1,622,496	73	50
dupilumab / interleukin inhibitors	\$880,683	\$968,284	\$1,143,820	359	263
adalimumab / antirheumatics	\$2,963,326	\$2,718,559	\$3,182,141	436	344
ciprofloxacin-dexamethasone otic / otic steroids with anti-infectives	\$184,539	\$219,232	\$393,060	1,773	1,598
c1 esterase inhibitor, human / hereditary angioedema agents	\$121,119	\$230,622	\$319,474	10	7
paliperidone / atypical antipsychotics	\$1,562,701	\$1,757,237	\$1,756,050	685	614
corticotropin / corticotropin	\$199,494	\$279,281	\$359,015	4	4
deferasirox / chelating agents	\$419,971	\$343,321	\$560,168	94	66
ixekizumab / interleukin inhibitors	\$158,923	\$207,246	\$297,677	29	22
sars-cov-2 (covid-19) mrna bnt-162b2 vaccine / viral vaccines	\$89,598	\$136,526	\$222,492	6,921	5,966
etanercept / antirheumatics	\$724,282	\$720,829	\$835,082	160	120
bictegravir/emtricitabine/tenofovir / antiviral combinations	\$1,301,159	\$1,334,891	\$1,410,173	416	381
immune globulin intravenous and subcutaneous / immune globulins	\$188,420	\$271,174	\$296,452	24	16
cysteamine / miscellaneous uncategorized agents	\$82,943	\$178,502	\$178,502	2	2
asfotase alfa / miscellaneous metabolic agents	\$199,239	\$0	\$285,101	4	3
palbociclib / CDK 4/6 inhibitors	\$249,470	\$210,080	\$328,250	25	18
everolimus / mTOR inhibitors	\$297,990	\$225,395	\$373,485	35	28
dapagliflozin / SGLT-2 inhibitors	\$327,757	\$368,940	\$402,322	619	596
lenalidomide / other immunosuppressants	\$291,222	\$263,198	\$358,431	21	19
insulin aspart / insulin	\$555,499	\$544,523	\$618,804	1,570	1,415
ofatumumab / CD20 monoclonal antibodies	\$20,758	\$6,925	\$83,050	6	4
empagliflozin / SGLT-2 inhibitors	\$455,722	\$427,988	\$517,368	680	629
liraglutide / GLP-1 receptor agonists	\$753,256	\$761,969	\$812,980	986	920
emicizumab / factor for bleeding disorders	\$480,006	\$781,552	\$534,566	23	20
selexipag / agents for pulmonary hypertension	\$67,514	\$86,809	\$118,721	7	3

**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 APR 2021 TO JUN 2021 (FFS and CCOs)**

Drug Product Therapeutic Category	Jun 2021 # Claims	Jun 2021 \$ Paid	Jun 2021 Avr. Paid Per Rx	Jun 2021 Avr. Units Per Rx	Apr 2021 Paid Per Unit	May 2021 Paid Per Unit	Jun 2021 Paid Per Unit	Percent Change
dexmethylphenidate 15 mg capsule, extended release / CNS stimulants (N)	134	\$10,606	\$79.15	30	\$1.26	\$1.94	\$2.28	80.6%
methylphenidate 36 mg/24 hr tablet, extended release / CNS stimulants (P)	920	\$61,216	\$66.54	37	\$1.29	\$1.32	\$1.46	13.2%
atomoxetine 18 mg capsule / CNS stimulants (P)	135	\$6,795	\$50.33	30	\$1.28	\$1.39	\$1.33	4.1%
atomoxetine 25 mg capsule / CNS stimulants (P)	218	\$11,801	\$54.13	30	\$1.36	\$1.33	\$1.41	3.8%
buprenorphine-naloxone 8 mg-2 mg film / narcotic analgesic combinations (N)	853	\$169,744	\$199.00	49	\$3.66	\$3.69	\$3.77	3.1%
Vimpat (lacosamide) 200 mg tablet / miscellaneous anticonvulsants (P)	188	\$185,106	\$984.61	63	\$15.17	\$15.15	\$15.45	1.8%
Saphris (asenapine) 5 mg tablet / atypical antipsychotics (P)	154	\$117,589	\$763.57	39	\$18.68	\$19.06	\$18.99	1.7%
Eliquis (apixaban) 5 mg tablet / factor Xa inhibitors (P)	890	\$402,775	\$452.56	56	\$7.69	\$7.74	\$7.82	1.7%
Januvia (sitagliptin) 50 mg tablet / dipeptidyl peptidase 4 inhibitors (P)	103	\$68,138	\$661.53	44	\$15.51	\$15.81	\$15.75	1.6%
methylphenidate 54 mg/24 hr tablet, extended release / CNS stimulants (P)	622	\$32,874	\$52.85	30	\$1.37	\$1.38	\$1.39	1.5%
Focalin XR (dexmethylphenidate) 10 mg capsule, extended release / CNS stimulants (P)	266	\$98,773	\$371.33	30	\$12.03	\$12.06	\$12.19	1.3%
Genvoya (cobicistat/elvitegravir/emtricitabine/tenofovir) 150 mg-150 mg-200 mg-10 mg tablet / antiviral combinations (P)	142	\$484,841	\$3,414.38	35	\$104.48	\$104.84	\$105.69	1.2%
methylphenidate 27 mg/24 hr tablet, extended release / CNS stimulants (P)	513	\$24,038	\$46.86	30	\$1.18	\$1.15	\$1.19	1.0%

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 APR 2021 TO JUN 2021 (FFS and CCOs)**

Drug Product Therapeutic Category	Jun 2021 # Claims	Jun 2021 \$ Paid	Jun 2021 Avr. Paid Per Rx	Jun 2021 Avr. Units Per Rx	Apr 2021 Paid Per Unit	May 2021 Paid Per Unit	Jun 2021 Paid Per Unit	Percent Change
Vimpat (lacosamide) 100 mg tablet / miscellaneous anticonvulsants (P)	159	\$165,001	\$1,037.74	71	\$14.27	\$14.43	\$14.40	0.9%
Focalin XR (dexamethylphenidate) 20 mg capsule, extended release / CNS stimulants (P)	233	\$92,022	\$394.94	30	\$12.47	\$12.56	\$12.58	0.9%

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
JUNE 2021 – AUGUST 2021

Ongoing Intervention(s):

PROVIDER SHOPPING FOR OPIOIDS (≥4 Prescribers AND ≥4 Pharmacies)			
Month	Prescribers Mailed	Pharms Mailed	Benes Addressed
20-Sep	10	8	18
20-Oct	8	6	14
20-Nov	6	4	10
20-Dec	5	4	9
21-Jan	3	3	6
21-Feb	5	4	9
21-Mar	6	5	11
21-Apr	6	6	12
21-May	3	3	6
21-Jun	4	4	8
21-Jul	3	2	5
21-Aug	6	4	10

CONCOMITANT USE OF OPIOIDS AND ANTIPSYCHOTICS		
Month	Prescribers Mailed	Benes Addressed
21-May	74	94
21-Jun	60	80
21-Jul	44	48
21-Aug	45	47

IMMUNE GLOBULIN UTILIZATION

BACKGROUND

Immune globulin (IG) products are agents derived from human plasma that are administered in order to improve a patient's humoral immune response. Through passive immunity, immune globulin products boost the immune response by increasing the body's concentrations of antibodies.¹ In addition to being a benchmark treatment for individuals with primary immunodeficiency of the humoral immune system, immune globulins can be used in the treatment of a myriad of other conditions due to their anti-inflammatory and immunomodulating effects.^{1,2} Immune globulin products are primarily administered via intravenous (IV) or subcutaneous (SC) routes, but intramuscular (IM) administration is available in some instances such as in the treatment of antibody deficiencies.¹

Figure 1 displays the products currently listed under Medicaid's Universal Preferred Drug List (UPDL) under the immune globulin category along with their FDA approved indications.³⁻²²

Figure 1: UPDL Immune Globulin Products and FDA Approved Indication(s)								
Brand Name	FDA Indication							
	PI	ITP	CIDP	KS	MMN	CLL	VPPX	aTTP
<i>Asceniv</i>	x							
<i>Bivigam</i>	x							
<i>Cablivi †</i>								x
<i>Carimune NF *</i>	x	x						
<i>Cutaquig</i>	x							
<i>Cuvitru</i>	x							
<i>Flebogamma DIF *</i>	x	x						
<i>Gamastan/</i> <i>Gamastan S/D *</i>							x	
<i>Gammagard *</i>	x				x			
<i>Gammagard S/D</i>	x	x		x		x		
<i>Gammaked *</i>	x	x	x					
<i>Gammaplex</i>	x	x						
<i>Gamunex-C *</i>	x	x	x					
<i>Hizentra *</i>	x		x					
<i>HyQvia *</i>	x							
<i>Octagam *</i>	x	x						
<i>Panzyga *</i>	x	x	x					
<i>Privigen</i>	x	x	x					
<i>Xembify *</i>	x							
Notes: PI = primary humoral immunodeficiency; ITP = idiopathic thrombocytopenic purpura; CIDP = chronic inflammatory demyelinating polyneuropathy; KS = Kawasaki syndrome; MMN = multifocal motor neuropathy; CLL = B-cell chronic lymphocytic leukemia; VPPX = viral prophylaxis (for hepatitis A, measles, varicella, rubella); aTTP = acquired thrombotic thrombocytopenic purpura. † Not specifically classified as an immune globulin but included on the UPDL with this class. * Preferred product per UPDL version 2021.13.								

Along with their FDA approved indications, immune globulin products may be utilized in treating a plethora of other conditions related to immune deficiency states, autoimmune and inflammatory disorders.²³ The clinical circumstances and evidence supporting non-FDA-approved use of these products varies across disease states.

Considering the breadth of potential uses for immune globulin products coupled with an increased spending trend among products in this category, the Division of Medicaid in collaboration with the coordinated care organizations (CCOs) requested MS-DUR conduct an analysis of the utilization trends for IG products among Medicaid beneficiaries.

METHODS

A retrospective database analysis of Mississippi Medicaid beneficiaries was conducted. Pharmacy and medical claims for fee-for-service (FFS) and CCOs [United Healthcare (UHC), Magnolia Health (MAG) and Molina Healthcare (MOL)] from January 1, 2017 to December 31, 2020 were reviewed. The first claim for an immune globulin product was considered as the index event. Demographics and health plan enrollment of the beneficiaries at the index event were assessed. Quarterly trends in claims and spending utilization of IG products were assessed. In medical claims, specific brands of IG products were identified using NDC codes and J codes. Where NDC codes were not available, J codes under the 'procedure code' variable were used to identify the prescribed IG product. If multiple IG brands had same J code, a specific IG brand was assigned using the following algorithm. If a beneficiary had a medical claim(s) for a specific IG brand with overlapping J code, the same brand was assigned to medical claims with missing NDC codes but having same J code. If all medical claims were missing NDC codes, and only J codes were available then the brand was assigned as 'Not Specified'. A total of 164 claims (2.8% of total claims) were classified as 'Not Specified' using this methodology.

FDA-approved and supported non-FDA-approved diagnoses associated with IG use were evaluated for the period July 2016 – December 2020 using the International Classification of Diseases (ICD)-10 codes from medical, outpatient, and inpatient claims. Identification of FDA-approved diagnosis was IG-brand specific. A bene was considered to have a FDA-approved diagnosis if they were prescribed a specific IG product and had a claim for an associated FDA-approved indication during the identification period. Determination of supported non-FDA-approved use was not IG brand-specific. A beneficiary was considered to have supported non-FDA-approved use of IGs if they were prescribed any IG and had a claim for any supported non-FDA-approved indication(s) during the above time period. For instances where a specific IG brand could not be identified, all FDA-approved indications for brands having same J code were evaluated. For e.g. 'Not specified' (J Code 1561) included Gammunex-C and Gammaked, both of which are approved for treating primary immunodeficiency, immune thrombocytopenia purpura, and chronic inflammatory demyelinating polyneuropathy.

To determine supported non-FDA-approved use, MS-DUR compiled a list of indications supported across compendia, primary literature and health plan policies.^{24–32}

RESULTS

Table 1 details demographic characteristics for beneficiaries prescribed IG therapy between January 2017 and December 2020.

- A total of 378 beneficiaries received IG therapy during the study period.
- Beneficiaries under the age of 18 years were the largest group treated with IG products (35.7%).
- 62.2% of those treated with IG products were women.

Table 1. Demographic Characteristics of Beneficiaries Prescribed Immune Globulin Products (January 2017 - December 2020)									
Variable	FFS		UHC		Magnolia		Molina		Total
Age Category (yrs)									
0 - 17	43	26.5%	42	60.0%	43	35.2%	7	29.2%	135
18 - 25	14	8.6%	7	10.0%	22	18.0%	10	41.7%	53
26 - 44	30	18.5%	16	22.9%	37	30.3%	7	29.2%	90
45 - 64	61	37.7%	5	7.1%	20	16.4%	0	0.0%	86
65 and above	14	8.6%	0	0.0%	0	0.0%	0	0.0%	14
Total	162		70		122		24		378
Gender									
Female	97	59.9%	33	47.1%	86	70.5%	19	79.2%	235
Male	65	40.1%	37	52.9%	36	29.5%	5	20.8%	143
Total	162		70		122		24		378
Race									
Caucasian	94	58.0%	41	58.6%	55	45.1%	11	45.8%	201
African American	61	37.7%	23	32.9%	44	36.1%	11	45.8%	139
Other	7	4.3%	6	8.6%	23	18.9%	2	8.3%	38
Total	162		70		122		24		378

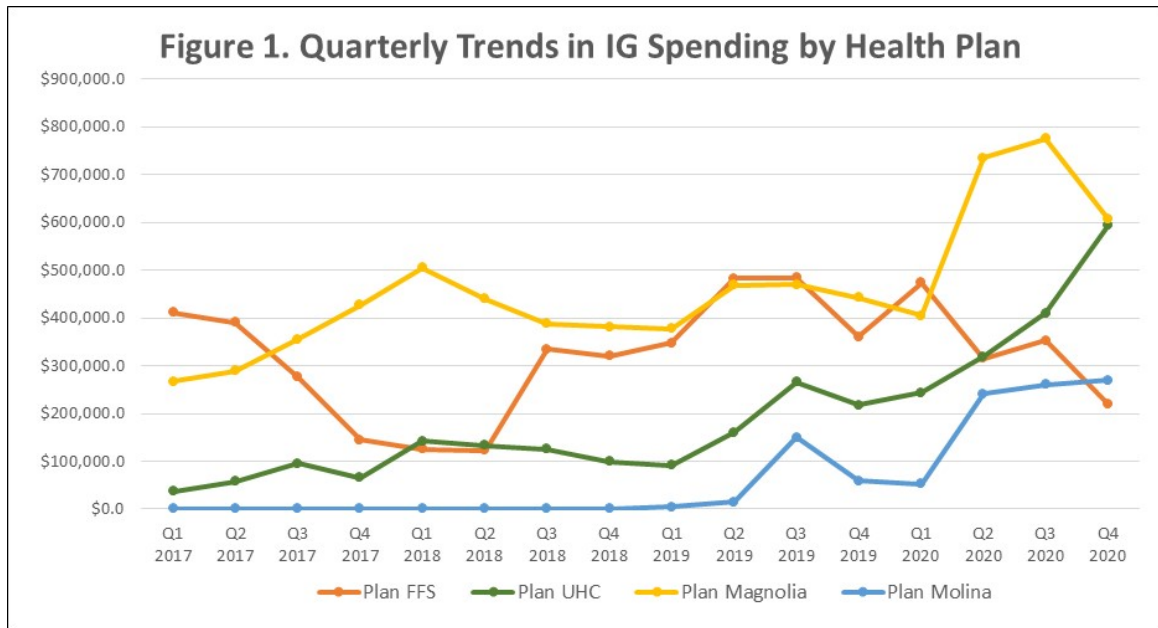
NOTE: Age and health plan were assessed at the first IG product claim referred to as the index date.

Although the utilization of IG products has seen a slight increase since 2017, spending has risen substantially.

- The number of claims for IG products increased 8% in 2020 compared 2017. (Table 2a)
- Spending associated with IG products increased **123%** over the same period. (Table 2b)
- Spending trends across the CCOs have seen more consistent increases as compared to FFS. (Figure 1)

Table 2a. Quarterly Trends in IG Utilization by Health Plan and Claims* (January 2017 - December 2020)					
Month	Plan				Total
	FFS	UHC	Magnolia	Molina	
Q1 2017	144	71	224	0	439
Q2 2017	117	97	111	0	325
Q3 2017	134	75	112	0	321
Q4 2017	102	63	143	0	308
Q1 2018	147	100	177	0	424
Q2 2018	99	108	168	0	375
Q3 2018	101	71	129	0	301
Q4 2018	79	66	139	1	285
Q1 2019	112	69	174	10	365
Q2 2019	117	86	130	7	340
Q3 2019	112	80	131	13	336
Q4 2019	94	70	182	14	360
Q1 2020	124	94	180	16	414
Q2 2020	85	90	158	18	351
Q3 2020	92	106	143	34	375
Q4 2020	70	122	137	36	365
Total	1,729	1,368	2,438	149	5,684
*Includes both pharmacy and medical claims.					

Table 2b. Quarterly Trends in IG Spending by Health Plan (January 2017 - December 2020)							
Month	# of claims*	# of benes**	Plan				Total
			FFS	UHC	Magnolia	Molina	
Q1 2017	439	177	\$410,968.0	\$37,375.1	\$267,224.3	\$0.0	\$715,567.4
Q2 2017	325	178	\$390,218.1	\$57,493.5	\$288,757.6	\$0.0	\$736,469.2
Q3 2017	321	172	\$276,514.9	\$94,915.8	\$355,787.5	\$0.0	\$727,218.3
Q4 2017	308	181	\$145,080.3	\$65,756.2	\$426,362.9	\$0.0	\$637,199.5
Q1 2018	424	225	\$124,914.1	\$142,133.0	\$504,577.3	\$0.0	\$771,624.4
Q2 2018	375	218	\$123,060.3	\$133,072.0	\$439,644.4	\$0.0	\$695,776.7
Q3 2018	301	192	\$334,501.6	\$124,968.9	\$387,387.9	\$0.0	\$846,858.4
Q4 2018	285	189	\$320,370.6	\$99,637.8	\$381,404.2	\$783.0	\$802,195.6
Q1 2019	365	213	\$348,076.3	\$91,434.1	\$377,134.8	\$3,965.0	\$820,610.2
Q2 2019	340	216	\$483,322.9	\$159,960.7	\$467,867.8	\$14,972.4	\$1,126,123.7
Q3 2019	336	224	\$483,836.9	\$265,129.3	\$469,163.8	\$149,536.6	\$1,367,666.6
Q4 2019	360	221	\$361,178.0	\$216,996.7	\$443,005.4	\$59,653.5	\$1,080,833.6
Q1 2020	414	241	\$473,167.1	\$243,857.9	\$405,186.6	\$51,933.5	\$1,174,145.0
Q2 2020	351	213	\$314,699.3	\$319,244.8	\$734,725.1	\$240,415.1	\$1,609,084.3
Q3 2020	375	234	\$353,019.3	\$410,412.9	\$775,530.9	\$260,122.2	\$1,799,085.4
Q4 2020	365	236	\$219,385.3	\$594,401.4	\$606,425.0	\$270,189.6	\$1,690,401.3
Total	5,684	3,330	\$4,942,927.8	\$3,056,790.0	\$7,330,185.3	\$1,051,571.0	\$16,381,474.1
*Includes both pharmacy and medical claims.							
**Does not represent unique beneficiaries.							



When examining diagnoses associated with IG use, MS-DUR categorized use by FDA-approved use, supported non-FDA-approved use, and use outside of these two scenarios. As stated in the methods section, a bene was considered to have an FDA-approved diagnosis if they were prescribed a specific IG product and had a claim for an FDA-approved indication associated with that product during the identification period. Determination of supported non-FDA-approved use was not IG brand-specific. A beneficiary was considered to have supported non-FDA-approved use of IGs if they were prescribed any IG and had a claim for any supported non-FDA-approved indication(s) during the above time period. Determining diagnoses associated with supported non-FDA-approved use was not a simple, clear-cut process. This determination was made based on a combination of compendia support, evidence in primary literature, and health plan policies. ICD-10 codes utilized in identifying diagnoses associated with FDA-approved and supported non-FDA-approved use can be found in Appendix A. A wide net was cast to include as many supported diagnoses as possible. It should be noted, however, that when considering supported diagnoses, there are disease state specific considerations regarding when the use of IG products are warranted.

Table 3 provides a summary of IG use by beneficiary diagnoses. We found:

- 63% of beneficiaries had a brand-specific FDA-approved diagnosis on record.
- 15.3% did not have an FDA-approved or supported diagnosis on record.
- *Note: If the IG-brand specific requirement for FDA-approved indication was relaxed for the analysis, only 5.6% of beneficiaries had no FDA-approved or supported diagnosis present in claims data.*

Table 3. Summary of FDA-Approved and Supported Non-FDA-Approved Use of IG Products (July 2016 - December 2020)						
supported non-FDA diagnosis**	FDA-approved diagnosis*				Total	
	Present		Absent			
	n	%	n	%	n	%
Present	94	24.9%	82	21.7%	176	46.6%
Absent	144	38.1%	58	15.3%	202	53.4%
Total	238	63.0%	140	37.0%	378	100.0%
NOTE: Percentages are based on total no. of benes (N=378).						
NOTE 1: Identification of diagnosis was conducted using medical, outpatient, and inpatient claims for the period July 2016 to December 2020.						
*Identification of FDA-approved diagnosis was IG-brand specific. A bene was considered to have a FDA-approved diagnosis if they were prescribed a specific IG product and had a claim for an associated FDA-approved indication during the above time period.						
**Identification of supported non-FDA-approved use was not IG brand-specific. A bene was considered to have a supported use of IGs if they were prescribed any IG and had a claim for any supported indications during the above time period.						
NOTE 2: 323/378 (85.5%) had some FDA-approved diagnosis when the the IG brand restriction was relaxed.						
NOTE 3: For where IG brand could not be identified, following diagnoses were evaluated based on FDA-approved indications: Not specified (J Code 1561): Primary Immunodeficiency, Immune Thrombocytopenia Purpura, and Chronic Inflammatory Demyelinating Polyneuropathy Not specified (J Code 1566): Primary Immunodeficiency and Immune Thrombocytopenia Purpura						
NOTE 4: Of the highlighted 58 beneficiaries, 37 beneficiaries had some FDA-approved diagnosis irrespective of IG brand during the study period. Remaining 21/378 (5.6%), truly had no supported or FDA-approved indication.						

Another issue to consider in intravenous immunoglobulin (IVIG) therapy is a lack of consensus on appropriate dosing practices.³³ Package inserts for IVIG medications provide mg/kg dosing recommendations, however, they do not specify a preferred patient dosing weight to use.³³ This is significant in that IVIGs are high-cost, resource-intensive medications. Dosing optimization by using alternate dosing weights such as ideal body weight (IBW) or adjusted body weight (AdjBW) instead of actual body weight (ABW) may lead to improved resource efficiency. This has led to a divergence of dosing strategies in clinical practice, including varied preferred dosing weights and

rounding practices.³³ While there is limited research in this area, improved resource efficiency through use of alternative IVIG dosing strategies has been demonstrated within literature. A five-year retrospective study from the University of Texas MD Anderson Cancer Center found that if IBW were used in place of ABW, the Center's five-year use of IVIG could decrease by almost 36%, leading to an annual cost savings of \$3.89 million and a cumulative 1,366-hour/year decrease in infusion time.³⁴ A separate single-year retrospective study at a tertiary care hospital in the northeastern United States found that use of alternative dosing strategies, including using IBW or AdjBW for obese patients, could have led to annual savings ranging from approximately \$20,000 to \$159,000.³⁵

Importantly, however, both of these studies lack insight into safety or effectiveness of using alternative dosing weights for IVIG therapy. While literature examining outcomes of alternative IVIG dosing strategies is especially scarce, a recent study performed across the Sanford Health System shows promise for these approaches. Using a pre-post sequential period analysis, authors found that the use of IBW-based IVIG dosing showed significantly reduced median grams per dose utilization with no significant differences in key clinical outcomes, including 30-day hospital readmission, hospital mortality, and hospital length of stay.³⁶ A subgroup analysis of obese individuals found no differences in these outcomes, indicating that IBW may be appropriate to use in these patients as well.³⁶ Finally, use of IBW was found to be associated with improved safety outcomes, including incidence of acute kidney injury and infection.³⁶ Notably, however, the study failed to meet desired power indicating that while these results are encouraging, they should be interpreted with caution and further studies should be awaited to determine the impact of alternative IVIG dosing strategies on outcomes.³⁶

CONCLUSIONS

Immune globulin products are effective in treating a myriad of health conditions. Although there is limited use of IG products in Medicaid, these products are high-cost. Costs associated with the use of IG products have increased 123% from 2017 to 2020. The place in therapy for IG products is also unique for each condition where their use is supported. In addition to disease state specific considerations, appropriate patient dosing weight is another factor that should be addressed with IVIG products. Considering the complexities associated with IG product use, close management of this drug class may be warranted.

RECOMMENDATIONS

1. MS-DUR recommends the Division of Medicaid consider moving all IG products on the UPDL to a manual prior authorization process.

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Appendix A: List of FDA-approved and supported non-FDA-approved indications with ICD-10 codes included in the analyses

Immune Globulin FDA approved indications:		
Primary Humoral Immunodeficiency (PID)	D80.0	Hereditary hypogammaglobulinemia (applicable to X-linked agammaglobulinemia [Bruton])
	D80.2	Selective deficiency of immunoglobulin A
	D80.5	Immunodeficiency with increased immunoglobulin M [IgM]
	D81.9	Combined immunodeficiency, unspecified
	D83.9	Common variable immunodeficiency, unspecified
	D84.9	Immunodeficiency, unspecified
	D84.81	Immunodeficiency due to conditions classified elsewhere
Idiopathic Thrombocytopenia Purpura, Acute/chronic (ITP)	D69.3	Immune thrombocytopenic purpura
	D69.51	Posttransfusion purpura
Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)	G61.81	Chronic inflammatory demyelinating polyneuritis
	G61.89	Other inflammatory polyneuropathies
	G61.9	Inflammatory polyneuropathy, unspecified
	G62.89	Other specified polyneuropathies
	G62.9	Polyneuropathy, unspecified
Kawasaki Syndrome (KS)	M30.3	
Multifocal motor neuropathy (MMN)	G60.0	Hereditary motor and sensory neuropathy
	G61.82	Multifocal motor neuropathy
	G12.20	Motor neuron disease, unspecified
	G12.29	Other motor neuron disease
Chronic Lymphocytic Leukemia (B-cell CLL)	C91.10	Chronic lymphocytic leukemia of B-cell type not having achieved remission
	C91.11	Chronic lymphocytic leukemia of B-cell type in remission
	C91.12	Chronic lymphocytic leukemia of B-cell type in relapse
Acquired thrombotic thrombocytopenic purpura (aTTP)	D69.3	
Viral Prophylaxis (Hep A, measles, varicella, rubella) (VPPX)	Z20.5	Contact with and (suspected) exposure to viral hepatitis
	Z20.828	Contact with and (suspected) exposure to other viral communicable diseases
	Z23	Encounter for immunization
	Z29.1	Encounter for prophylactic immunotherapy
	Z29.8	Encounter for other specified prophylactic measures
	Z29.13	Encounter for prophylactic Rho(D) immune globulin

Common supported non-FDA-approved indications		
Autoimmune bullous disease	L13.8	
Bullous pemphigoid	L12.0	
Dermatomyositis , polymyositis	M33.00	Juvenile dermatomyositis, organ involvement unspecified
	M33.01	Juvenile dermatomyositis with respiratory involvement
	M33.02	Juvenile dermatomyositis with myopathy
	M33.03	Juvenile dermatomyositis without myopathy
	M33.09	Juvenile dermatomyositis with other organ involvement
	M33.10	Other dermatomyositis, organ involvement unspecified
	M33.11	Other dermatomyositis with respiratory involvement
	M33.12	Other dermatomyositis with myopathy
	M33.13	Other dermatomyositis without myopathy
	M33.19	Other dermatomyositis with other organ involvement
	M33.20	Polymyositis, organ involvement unspecified
	M33.21	Polymyositis with respiratory involvement
	M33.22	Polymyositis with myopathy
	M33.29	Polymyositis with other organ involvement
	M33.90	Dermatopolymyositis, unspecified, organ involvement unspecified
	M33.91	Dermatopolymyositis, unspecified with respiratory involvement
	M33.92	Dermatopolymyositis, unspecified with myopathy
	M33.93	Dermatopolymyositis, unspecified without myopathy
	M33.99	Dermatopolymyositis, unspecified with other organ involvement
Epidermolysis bullosa (aquired, unspecified)	L12.30	
Epidermolysis bullosa (other acquired)	L12.35	
Feto-neonatal alloimmune thrombocytopenia	P61.0	
Sequele of Guillain-Barre syndrome	G65.0	
Guillain-Barre syndrome/ AIDP	G61.0	
Multiple Sclerosis	G35	
Mucous membrane pemphigoid	L12.1	
Multiple myeloma infection prophylaxis (see the following ICD codes)		
Multiple myeloma not having achieved remission	C90.00	
Multiple myeloma in remission	C90.01	
Multiple myeloma in relapse	C90.02	

Myasthenia gravis/LEMS	G70.0
Myasthenia gravis without acute exacerbation	G70.00
Myasthenia gravis with acute exacerbation	G70.01
Paraneoplastic neurological syndrome	G13.0
Pediatric HIV infection prophylaxis	Z20.6
Pemphigus foliaceus	L10.2
Pemphigus vulgaris	L10.0
Stiff-person syndrome	G25.82
Autoimmune hemolytic anemia	D59.1, D59.0
Autoimmune neutropenia	D70.8
Autoimmune uveitis (Acute and subacute iridocyclitis)	H20.0x
Bone marrow transplant; (Transplant complication)	T86.0x
Cytomegalovirus	B25.xx
Renal marrow transplant; (Transplant complication)	T86.1x
Neonatal jaundice	P58.xx, P59.xx
RSV (Respiratory syncytial virus)	B97.4
Toxic Shock Syndrome	A48.3
von Willebrand disorder	D68.0
Other disorders involving the immune mechanism, not elsewhere classified	D89.xx
Other immune deficiencies	D84.0, D84.1, D84.821, D84.822, D84.89

INFLUENZA VACCINATION AND TREATMENT UPDATE 2020-2021 SEASON

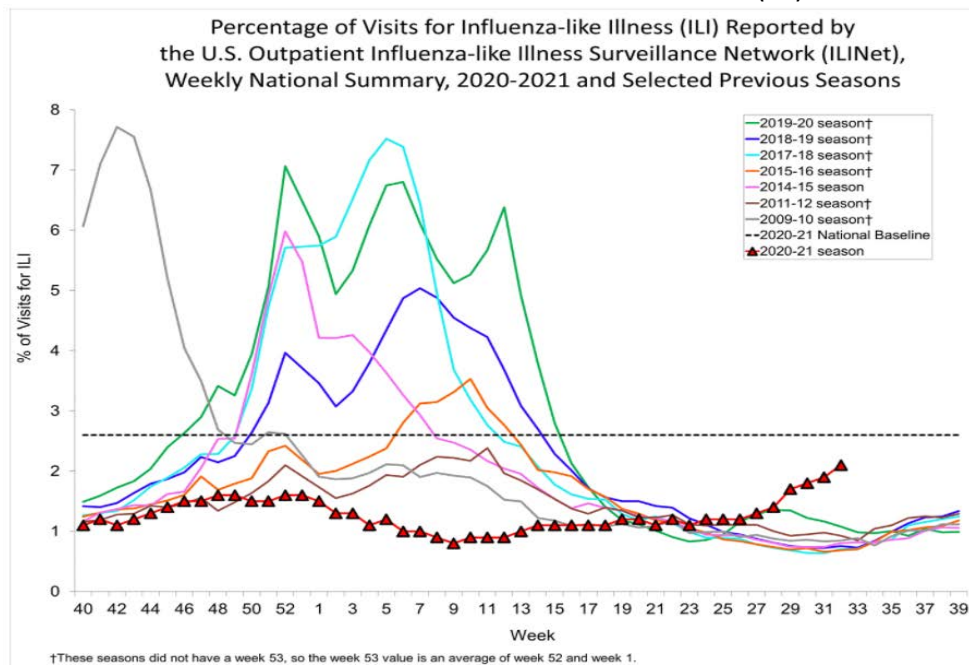
BACKGROUND

Influenza (Flu) is a contagious respiratory illness that can cause mild to severe illness and can even lead to death. While infection from the influenza virus can occur at any time, influenza viruses typically circulate in the United States (US) from late fall through early spring. The 2020-2021 flu season was unusually low. Rather than attributing the unusually low flu activity to one specific cause, multiple factors potentially contributed to the sharp decline in flu activity during the 2020-2021 flu season. A combination of factors including COVID-19 risk mitigation measures and a record number of influenza vaccine doses are thought to have contributed to the unusually low flu activity.¹

For the 2020-2021 flu season in the US:¹

- Only 0.2% of respiratory specimens tested were positive for an influenza virus compared to positive testing levels during the previous three seasons which peaked at around 30%.
- The rate of laboratory-confirmed influenza-associated hospitalizations during the 2020-2021 season was the lowest recorded since this type of data collection began in 2005.
- Only one pediatric flu death was reported during the 2020-2021 flu season.
- Nationwide weekly summary of the percent of visits for influenza-like illness for 2020-2021 season was very low compared to previous seasons.

Figure 1: Nationwide Percent of Visits for Influenza Like-Illness (ILI) 2009-2021²



METHODS

Pharmacy and medical claims from fee-for-service and all CCOs[United Healthcare (UHC), Magnolia Health (MAG) and Molina Healthcare (MOL)] for influenza vaccines and anti-influenza agents were extracted for state fiscal year (SFY) 2021 (July 1, 2020 to June 30, 2021). The analysis included prescriptions for influenza vaccines and all anti-influenza agents listed on MS Division of Medicaid's Universal Preferred Drug List (Tamiflu®, oseltamivir, Flumadine®, rimantadine, Rapivab®, Relenza®, Xofluza®). The number of beneficiaries taking these agents, the number of prescriptions filled and the amounts paid for these claims were determined for SFY 2021.

RESULTS

In Table 1 the number of Medicaid beneficiaries with documented influenza vaccination for SFY 2021 is displayed.

- 73,349 beneficiaries had documentation of receiving flu vaccination during SFY 2021. *{It should be noted that vaccination claims with a paid reimbursement amount of zero dollars were not included in this analysis. This could include vaccine claims through the Vaccines for Children (VFC) Program or bundled payment claims such as those through Federally Qualified Health Centers (FQHCs).}*

Table 1: Influenza Vaccination Utilization in Mississippi Medicaid for State Fiscal Year 2021 (July 1, 2020 - June 30, 2021)								
Age at index flu vaccination	Plan at index flu vaccination	Number of beneficiaries receiving flu vaccines*	Amount paid Pharmacy Claim		Amount paid Medical Claim**			
			# of Benes	Cost/Bene	Flu Vaccine		Vaccine Administration	
< 19	FFS	3,300	30	\$35.3	219	\$15.8	1,990	\$16.4
	UHC	19,422	84	\$29.6	816	\$19.8	14,148	\$17.3
	MAG	21,698	1	\$11.3	2,050	\$19.0	15,088	\$16.9
	Mol	7,507	1	\$28.7	574	\$19.3	5,627	\$22.3
	Total	51,927	116	\$30.9	3,659	\$19.0	36,853	\$17.8
≥ 19	FFS	5,432	859	\$35.4	2,438	\$22.4	1,940	\$13.5
	UHC	5,939	1,440	\$32.8	3,053	\$22.5	2,664	\$13.3
	MAG	7,977	1,824	\$28.9	3,819	\$22.2	3,283	\$13.4
	Mol	2,074	386	\$33.5	1,299	\$21.3	1,081	\$13.9
	Total	21,422	4,509	\$31.8	10,609	\$22.2	8,968	\$13.5
Total (across all plans and age groups)		73,349	4,625	\$31.7	14,268	\$21.4	45,821	\$17.0

Note: FFS = Fee-for-service, UHC = United Health Care, MAG = Magnolia, MOL = Molina

* Beneficiaries with medical or pharmacy claims were identified. These totals do not represent unique beneficiaries.

** Only medical claims for flu vaccination or vaccine administration with paid amount > \$0.01 were included in the analysis;

CPT codes for influenza vaccines included: 90630, 90685-90688, 90654-90658, 90660-90662, 90653, 90666, 90668, 90664, 90672-90674, 90756, 90682, 90686, 90682, Q2035. A beneficiary with both a claim for a flu vaccine and vaccine administration was counted under each column and therefore would be represented twice in the total.

CPT codes for vaccine administration included: 90460-90461, 90471-90474

References:

- www.immunize.org/catg.d/p4072.pdf
- <https://www.aapc.com/blog/44189-code-the-shots-for-flu-vaccine/>

Table 2 displays the number of anti-influenza prescriptions filled, beneficiaries treated and the amounts paid for each antiviral agent during SFY 2021.

- Reflective of the unusually low flu activity during the 2020/2021 season, the use of anti-influenza prescription products was extremely low this past year.
- Compared to SFY 2019, during SFY 2021:
 - The number of prescriptions filled was down 95.5%;
 - The number of beneficiaries treated was down 95.5%;
 - Total spend on anti-influenza prescriptions was down 98%.

Table 2. Utilization of Anti-Influenza Agents in Mississippi Medicaid SFY 2021 (July 1, 2020 - June 30, 2021)				
Drug	Plan	Prescriptions filled	Beneficiaries	Paid Amount
Oseltamivir Phosphate	FFS	502	484	\$21,989.15
	UHC	938	886	\$44,516.21
	MAG	1107	1,077	\$53,958.61
	MOL	481	467	\$22,723.85
	Total	3,028	2,914	\$143,187.82
Tamiflu	FFS	2	2	\$175.54
	UHC	4	4	\$673.36
	MAG	2	2	\$600.86
	Total	8	8	\$1,449.76
Xofluza	UHC	2	2	\$312.48
	MAG	1	1	\$51.17
	MOL	1	1	\$151.10
	Total	4	4	\$514.75
Grand total (across all plans and drugs)		3,040	2,926	\$145,152.33
Note: FFS = Fee-for-Service, UHC = United HealthCare, MAG = Magnolia, MOL = Molina Other anti-influenza agents, namely Rapivab (peramivir), Flumadine (rimantadine), and Relenza did not have any pharmacy or medical claims during the study period. Paid amounts represent amount reported on claims as paid to pharmacy. These amounts do not reflect final actual costs after rebates etc.				

Table 3 displays anti-influenza drug utilization in Mississippi Medicaid for SFY 2021. The total number of unique beneficiaries receiving drugs is shown by health plan and number of prescription fills.

- Majority of beneficiaries receiving anti-influenza drugs received one prescription fill (n=2,837, 97%).
- Only 4 beneficiaries received ≥ 3 prescription fills of anti-influenza drugs.
- 14.1% (n=412) beneficiaries had documentation of receiving flu vaccination prior to filling a prescription for an anti-influenza drug.

Table 3. Anti-influenza Drug Utilization in Mississippi Medicaid for SFY 2021 (July 1, 2020 - June 30, 2021)						
Plan	Total number of beneficiaries	Number of beneficiaries by the number of fills received			# Beneficiaries who received flu vaccines*	# Beneficiaries who received flu vaccine prior to antiviral rx fill
		1	2	3 or more		
FFS	486	473	12	1	34	28
UHC	892	859	31	2	177	147
MAG	1,080	1,052	28	-	205	160
MOL	466	453	12	1	92	77
Total	2,924	2,837	83	4	508	412
<p>Note: FFS = Fee-for-service, UHC = United Health Care, MAG = Magnolia, MOL = Molina</p> <p>Numbers represent beneficiaries who had pharmacy claims only. No beneficiaries with anti-influenza drug related medical claims were identified in the study period.</p> <p>* Beneficiaries with medical or pharmacy claims were identified.</p> <p>CPT codes for influenza vaccines included: 90630, 90685-90688, 90654-90658, 90660-90662, 90653, 90666, 90668, 90664, 90672-90674, 90756, 90682, 90686, 90682, Q2035.</p> <p>References:</p> <p>1. www.immunize.org/catg.d/p4072.pdf</p> <p>2. https://www.aapc.com/blog/44189-code-the-shots-for-flu-vaccine/</p>						

CONCLUSIONS AND RECOMMENDATIONS

This report for the DUR Board on influenza and treatment utilization trends in the four pharmacy programs is for information and discussion purposes only. No action is being sought at this time.

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2. Weekly U.S. Influenza Surveillance Report | CDC. Published August 23, 2021. Accessed August 27, 2021. <https://www.cdc.gov/flu/weekly/index.htm>

PALIVIZUMAB UTILIZATION UPDATE: 2020-2021 SEASON

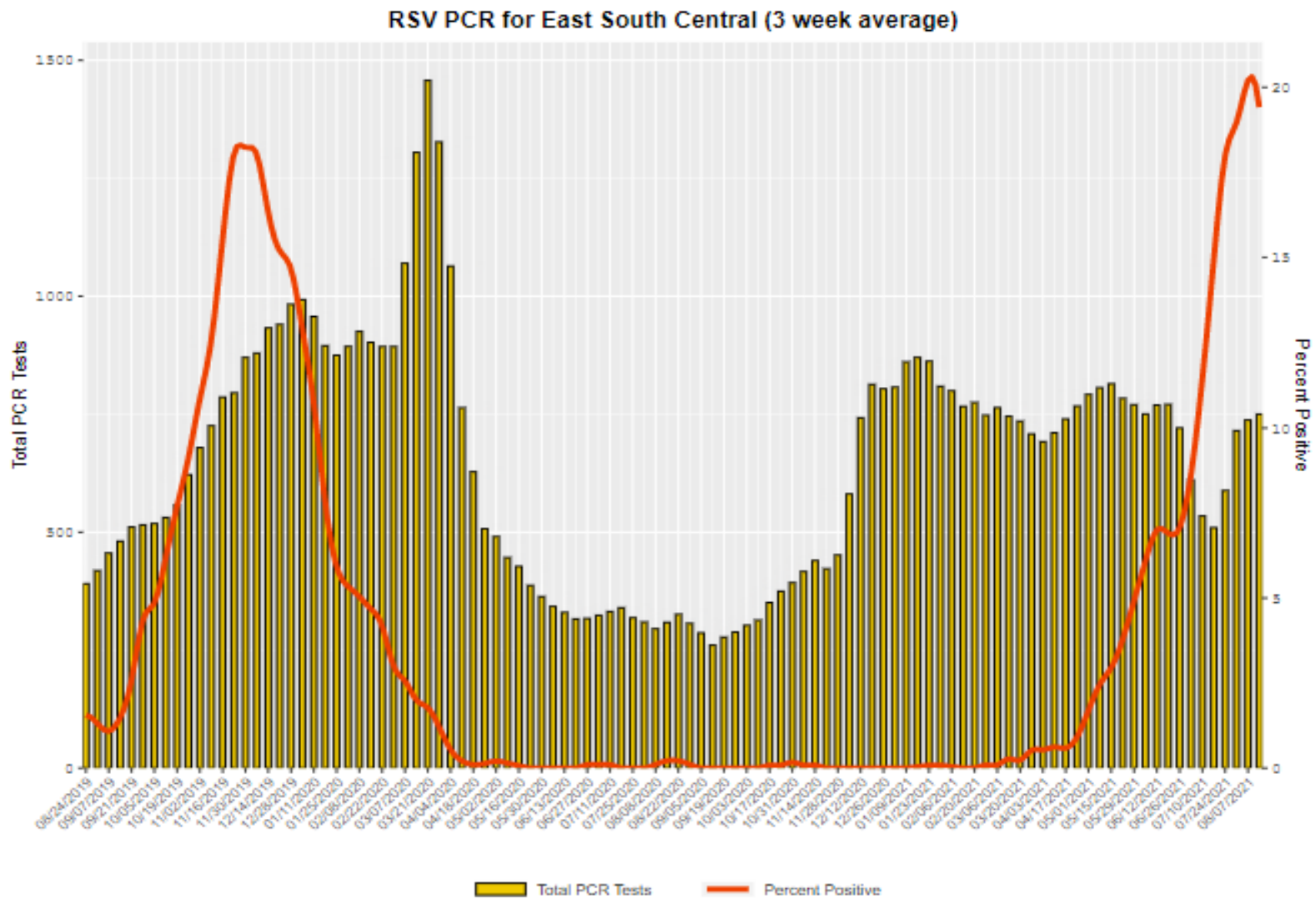
BACKGROUND

Respiratory syncytial virus (RSV) is a common respiratory virus that typically causes mild, cold-like symptoms, but RSV can be serious for infants and older adults. RSV can lead to the development of bronchiolitis and pneumonia in young children. Annually in the United States (US), it is estimated that RSV leads to 58,000 hospitalizations among children under 5 years of age.¹ Palivizumab (Synagis®) was licensed in June 1998 by the Food and Drug Administration for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in children at increased risk of severe disease.² The Mississippi Division of Medicaid (DOM) supports the administration of palivizumab for children meeting the American Academy of Pediatrics (AAP) criteria for RSV immunoprophylaxis. On July 28, 2014, the AAP published their policy statement, “Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection,” on-line in *Pediatrics*.³ At the August 2014 DUR Board Meeting the board voted to adopt the new guidelines as the criteria to be used by DOM for the 2014-15 Season, and DOM has continued following those guidelines. The AAP Committee on Infectious Diseases and the Subcommittee on Bronchiolitis regularly review and evaluate all data as they become available.

In the US, RSV infections typically occur during the fall and winter cold and flu season. The beginning and ending of RSV season has been relatively consistent in the past. However, the 2020-2021 season was atypical. RSV activity remained low during fall 2020 through spring 2021. For example, the RSV polymerase chain reaction (PCR) percent positive for the division that includes Mississippi shows virtually no positive PCR tests during the fall and winter months of 2020-2021. (Figure 1).⁴

Although RSV infections remained low in fall 2020, states opened access to palivizumab in line with previous seasons. In MS, access to palivizumab for the 2020/2021 season ran from October 2020 through March 2021. With the unusual rise in RSV infections during early summer 2021, MS Medicaid issued guidance allowing additional palivizumab doses during the summer months leading up to the typical season in fall 2021. Additionally, in response to atypically low RSV activity in fall of 2020 and an interseasonal increase in activity in spring of 2021, the AAP also issued “*Interim Guidance for Use of Palivizumab Prophylaxis to Prevent Hospitalization From Severe Respiratory Syncytial Virus Infection During the Current Atypical Interseasonal RSV Spread*” in August 2021 to guide practitioners.⁵ This guidance stated, “*Given the current atypical interseasonal change in RSV epidemiology, which may represent a delayed onset of the 2020-2021 season, the AAP strongly supports consideration for use of palivizumab in patients who would be candidates per current eligibility recommendations. This recommendation applies to regions experiencing high rates of RSV circulation, consistent with a typical fall-winter season.*”⁵

FIGURE 1: East South Central Division Percent Positive PCR Tests



PALIVIZUMAB UTILIZATION

Table 1 displays a summary of beneficiaries and claims associated with palivizumab utilization during state fiscal year (SFY) 2021 (July 1, 2020 – June 30, 2021). A total of 1,471 claims representing 321 unique beneficiaries occurred during SFY 2021.

Table 1. Demographic Summary of Beneficiaries and Claims Associated with Palivizumab Utilization State Fiscal Year 2021 (July 1, 2020 - June 30, 2021)					
	FFS	UHC	MAG	MOL	Total
Beneficiaries*	22	108	78	131	321
POS Claims	89	470	344	568	1,471
Age at fill (in months)					
<6	1	99	90	127	317
6-12	21	248	173	245	687
13-18	21	97	65	145	328
19-24	36	26	15	44	121
>24	10	-	1	7	18
Race					
Caucasian	20	110	82	171	383
African American	12	238	206	217	673
Other	57	122	56	180	415
Sex					
Female	42	276	159	303	780
Male	47	194	185	265	691
* Some beneficiaries may be enrolled in multiple plans during the analysis period; The sum of beneficiaries in each plan may not be equal to total number of unique beneficiaries with palivizumab utilization. FFS = Fee for Service; UHC = United HealthCare; MAG = Magnolia; MOL = Molina					

As seen in Table 2, claims for palivizumab began appearing in October 2020 which coincided with the typical season. In line with the unusual increase in RSV infections in early summer, claims for palivizumab reappeared in May/June 2021.

Table 2. Utilization and Paid Amounts for Palivizumab during State Fiscal Year 2021 (July 1, 2020 - June 30, 2021)										
	FFS		UHC		MAG		MOL		Total	
Fill month	#Claims	Paid	#Claims	Paid	#Claims	Paid	#Claims	Paid	#Claims	Paid
Oct-20	10	\$31,855	48	\$133,653	44	\$122,572	82	\$219,875	184	\$507,955
Nov-20	11	\$44,670	63	\$166,177	55	\$140,221	92	\$254,885	221	\$605,953
Dec-20	10	\$38,211	83	\$215,007	61	\$159,346	95	\$253,683	249	\$666,248
Jan-21	21	\$74,205	101	\$271,907	67	\$173,030	106	\$280,733	295	\$799,875
Feb-21	19	\$65,470	96	\$254,397	59	\$159,620	104	\$283,428	278	\$762,916
Mar-21	18	\$59,222	77	\$205,379	56	\$162,741	88	\$245,465	239	\$672,807
May-21	0	\$0	0	\$0	1	\$3,136	0	\$0	1	\$3,136
Jun-21	0	\$0	2	\$4,825	1	\$3,136	1	\$3,318	4	\$11,279
Total	89	\$313,633	470	\$1,251,345	344	\$923,802	568	\$1,541,387	1,471	\$4,030,169
FFS = Fee for Service; UHC = United HealthCare; MAG = Magnolia; MOL = Molina										

Table 3 shows a summary of palivizumab utilization for the last four seasons. The total number of beneficiaries treated dropped slightly last year although there were virtually no RSV infections reported during the typical season. The average paid amount per beneficiary treated was the highest it has been at \$11,888 last season. The total dollars paid for 2020-2021 season was the highest of the past four seasons at \$4,030,169.

Table 3. Palivizumab Utilization Summary by Season and Pharmacy Program					
Season	Pharmacy Program				
	FFS	UHC	MAG	MOL	Total
	Number of unique beneficiaries				
2017-18	18	164	165	0	347
2018-19	34	155	175	27	391
2019-20	22	108	105	149	384
2020-21	22	108	78	131	339
	Total Dollars Paid				
2017-18	\$93,812	\$1,283,588	\$1,725,471	\$0	\$3,102,871
2018-19	\$270,004	\$1,385,769	\$2,079,138	\$123,795	\$3,858,706
2019-20	\$230,222	\$883,547	\$1,056,784	\$1,494,942	\$3,665,495
2020-21	\$313,633	\$1,251,346	\$923,802	\$1,541,388	\$4,030,169
	Mean Number of Claims/Beneficiary				
2017-18	3.3	3.6	4.2	0	3.7
2018-19	4.1	4	4.9	2.3	3.8
2019-20	4.3	3.6	4.3	4.3	4.1
2020-21	4	4.4	4.4	4.3	4.3
	Dollars Paid/Beneficiary				
2017-18	\$5,212	\$7,827	\$10,457	\$0	\$8,942
2018-19	\$7,941	\$8,940	\$11,881	\$4,585	\$9,869
2019-20	\$10,465	\$8,181	\$10,065	\$10,033	\$9,546
2020-21	\$14,256	\$11,587	\$11,844	\$11,766	\$11,888
FFS = Fee for Service; UHC = United HealthCare; MAG = Magnolia; MOL = Molina					

NO ACTION NEEDED: This report for the DUR Board on palivizumab (Synagis®) utilization trends in the four pharmacy programs is for information and discussion purposes only. No action is being sought at this time.

REFERENCES

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2. SYNAGIS (palivizumab) Health Care Professional Website. Accessed August 19, 2021. <https://synagishcp.com/index.html>
3. Committee C on ID and BG. Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection. *Pediatrics*. 2014;134(2):415-420. doi:10.1542/peds.2014-1665
4. RSV State Trends - NREVSS | CDC. Published August 9, 2021. Accessed August 18, 2021. <https://www.cdc.gov/surveillance/nrevss/rsv/state.html>
5. Interim Guidance for Use of Palivizumab Prophylaxis to Prevent Hospitalization From Severe Respiratory Syncytial Virus Infection During the Current Atypical Interseasonal RSV Spread. Accessed August 18, 2021. <http://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/clinical-guidance/interim-guidance-for-use-of-palivizumab-prophylaxis-to-prevent-hospitalization/>

FDA DRUG SAFETY COMMUNICATIONS

June 2021 – August 2021

- 9/01/2021 FDA requires warnings about increased risk of serious heart-related events, cancer, blood clots, and death for JAK inhibitors that treat certain chronic inflammatory conditions
- 7/20/2021 FDA requests removal of strongest warning against using cholesterol-lowering statins during pregnancy; still advises most pregnant patients should stop taking statins
- 6/16/2021 FDA warns that vapors from alcohol-based hand sanitizers can have side effects

APPENDIX



MISSISSIPPI DIVISION OF
MEDICAID

**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.

DUR Bylaws V2= updated 12/06/2018

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

DUR Bylaws V2= updated 12/06/2018

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

Section 7 - Board Officers

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

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

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

Section 8 – Reimbursement

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

Article III. Meetings

Section 1 – Frequency

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

Section 2 – Regular Meetings

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

Section 3 – Special Meetings

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

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

Section 4 – Meeting Notice

DUR Board members will be notified of the location for the meeting a minimum of ten (10) days in advance. Notification may include one or a combination of the following methods: 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.

DUR Bylaws V2= updated 12/06/2018

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

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

Section 5 – Meeting Sign-In

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

Section 6 – Quorum

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

Section 7 – Voting

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

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

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

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

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 move to close 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 declare 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

