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

MISSISSIPPI DIVISION OF
MEDICAID

September 15, 2022 at 1:00pm

Woolfolk Building, Room 145

Jackson, MS

Prepared by:

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

Drug Utilization Review Board

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

2022 DUR Board Meeting Dates

March 3, 2022
June 9, 2022
September 15, 2022
December 8, 2022

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 15, 2022

Welcome

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Remaining 2022 DUR Board Meeting Date: December 8, 2022

DUR Board Meeting Minutes

MISSISSIPPI DIVISION OF MEDICAID
DRUG UTILIZATION REVIEW (DUR) BOARD
MINUTES OF THE JUNE 9, 2022 MEETING

DUR Board Roster: State Fiscal Year 2022 (July 1, 2021 – June 30, 2022)	Sep 2021	Dec 2021	Mar 2022	Jun 2022
Lauren Bloodworth, PharmD	✓	✓	✓	
Terrence Brown, PharmD	✓	✓	✓	✓
Patrick Bynum, MD	✓	✓	✓	✓
Rhonda Dunaway, RPh	✓	✓	✓	✓
Tanya Fitts, MD	✓		✓	✓
Ray Montalvo, MD	✓	✓		
Holly Moore, PharmD	✓			✓
Joshua Pierce, PharmD	NA	✓	✓	✓
Cheryl Sudduth, RPh			✓	
James Taylor, PharmD (Chair)	✓		✓	✓
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, 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;

Alliant Health Staff:
Catherine Brett, MD, Quality Director, MS UM/QIO; Buddy Ogletree, PharmD, Pharmacist;

Visitors:

Eric Berthelot, Sobi – North America; Brandon Cope, Otsuka Pharmaceuticals; Tanner DeYoung, Capital Resources; Bridget Gipson, UCB; Shawn Headley, Gilead; Floyd Holmes, Lilly; Lawanda Lewis, Sanofi Specialty Care Market Access; Lisa Tracz, Global Blood Therapeutics; Shauna Williams, Bayer; Gene Wingo, Biogen.

Call to Order/Welcome:
Dr. Taylor called the meeting to order at 1:05 pm.

OLD BUSINESS:
Dr. Fitts moved to approve the minutes from the December 2021 DUR Board Meeting, seconded by Ms. Dunaway, and unanimously approved by the DUR Board.

Resource Utilization Review:
Dr. Pittman presented the resource utilization report for March 2022. Enrollment numbers continued to climb but at a slower rate. Dr. Pittman continued the review by walking board members through the resource report pointing out drug classes where utilization trends have consistently been increasing in recent months.

NEW BUSINESS:

Update on MS-DUR Educational Interventions:
Dr. Pittman provided an overview of all DUR mailings and educational notices that occurred between March 2022 – June 2022 including the one-time asthma education that recently occurred. This education is the first step in a larger provider education effort to increase awareness around recent asthma management recommendations focusing on single maintenance and reliever therapy. The board recommended including this education in a future provider bulletin.

Special Analysis Projects:

Metabolic Monitoring of Children and Adolescents Prescribed Antipsychotics
The use of antipsychotic medications in children and adolescents can increase a child's risk of developing serious metabolic issues. It is recommended that glucose and lipid monitoring occur prior to and routinely throughout treatment with these medications in children and adolescents. The National Committee for Quality Assurance (NCQA) has developed a Healthcare Effectiveness Data and Information Set (HEDIS) measure that assesses the percentage of children and adolescents with ongoing antipsychotic medication use that had metabolic testing during the year. MS-DUR has conducted multiple educational initiatives in the past to improve performance on this measure. Upon running the quality measure for calendar year 2020 and comparing MS' rate to other states, it was determined that MS ranks in the bottom quartile. Although performance has improved over previous years, continued work is needed.

The following recommendation was presented:

1. MS-DUR recommends DOM work the MCOs to develop innovative, targeted intervention(s) for improving metabolic monitoring for children and adolescents prescribed antipsychotics.

During the discussion, board members suggested DOM look into increasing access to point-of-care testing for beneficiaries. Opportunities could include ensuring community mental health centers have point-of-care testing available or allowing pharmacists the ability to conduct point-of-care testing. It was also suggested that DOM explore what other states are doing to increase performance on this rate.

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

Adherence to Antipsychotic Medications for Individuals with Schizophrenia

Medication non-adherence is a major concern for individuals being treated for schizoaffective disorder or schizophrenia as it has been found to be a major cause of relapse and hospital readmission. When running the SAA quality measure, we found that 53.9% of the eligible beneficiaries had 80% or more adherence to antipsychotic medications during the measurement period, which is lower than the national median (62.5%) for other Medicaid programs that reported this measure. While bivariate associations between adherence and outcomes of interest were statistically significant, significant associations were only observed for all-cause ER visits when outcomes were assessed in the adjusted analysis. This points toward the need to explore the impact of adherence on outcomes among vulnerable individuals (i.e. those with comorbidities, previous hospitalizations or ED visits, etc.) and to develop targeted interventions.

The following recommendation was presented:

1. DOM should work with the MCOs to develop interventions that can improve performance on the SAA measure and bring Mississippi's rate in line with the national median. Interventions may look to specifically target vulnerable individuals.

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

Utilization of Smoking Cessation Therapy

Smoking is a major health concern with many negative effects associated with its use. Smoking rates have been found to be higher among Medicaid populations compared to the general population. Although smoking cessation medications are currently available on the UPDL, limited utilization has occurred in recent years. Currently, through Medicaid, smoking cessation counseling is only available to pregnant beneficiaries and utilization exceeds that of medication therapy in this population. Medicaid should seek opportunities to increase beneficiary uptake of smoking cessation therapy.

The following recommendation was presented:

1. DOM should conduct educational interventions to increase the awareness of smoking cessation services offered and the products covered. These interventions should target prescribers, pharmacists, and beneficiaries.

The Board held a lengthy discussion around ways to increase beneficiary uptake of smoking cessation services. In addition to the recommendation presented by MS-DUR, the Board included 2 additional recommendations.

2. *DOM should expand coverage eligibility for cessation counseling from only pregnant beneficiaries to all Medicaid beneficiaries.*
3. *DOM should explore a collaborative opportunity with the MS State Department of Health to establish a statewide standing order allowing pharmacists to prescribe OTC nicotine products.*

Following discussion, Dr. Bynum made a motion to accept all three recommendations, seconded by Dr. Fitts, and unanimously approved by the Board.

Assessment of Predictors of Severe Maternal Morbidity

Improving maternal morbidity and overall maternal health is a priority focus area for DOM. MS-DUR presented a project proposal to the Board that will assess the relationship between risk factors and severe maternal morbidity events among pregnant Medicaid beneficiaries in Mississippi. Board members provided input on the study design.

No formal recommendations occurred as a result of this report.

FDA Drug Safety Updates:

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

Pharmacy Program Update:

Ms. Kirby provided a pharmacy program update highlighting the following areas:

1) Ms. Kirby thanked the Board members whose terms are expiring for their service to Medicaid.
2) Medicaid will be changing its fiscal agent to Gainwell. Implementation is planned for October 2022.
3) Ms. Kirby recognized Ms. Dunaway as our incoming DUR Board Chair and thanked the outgoing chair, Dr. Taylor, for his service.

Next Meeting Information:

The next meeting is scheduled for September 15, 2022.

Dr. Pierce motioned to adjourn the meeting at 2:54 pm, seconded by Dr. Moore, and unanimously approved by the Board.

Submitted,

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

Meetings

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

- ~~March 3, 2022;~~
- June 9, 2022;
- September 15, 2022; and,
- December 8, 2022

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.

The following companies have met the registration limit as of June 8, 2022:

1. Bayer
2. Biogen
3. Capitol Resources
4. Change Healthcare
5. Chiesi
6. Gene
7. Gilead
8. Global Blood Therapeutics
9. Indivior
10. Lilly
11. Otsuka
12. Regeneron
13. Sanofi
14. Sarepta
15. Sobi
16. UCB
17. United Healthcare


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PUBLIC MEETING NOTICES
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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
Date and Time: 6/9/2022 1:00:00 PM
Description:
Please see attachment regarding Drug Utilization Review Board meeting.
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 2022.docx
Added 1/4/2022
SUBSCRIPTION OPTIONS
Subscription options will send you alerts regarding future notices posted by this public body.
RSS

Resource Utilizaton Review

TABLE 04A: ENROLLMENT STATISTICS FOR LAST 6 MONTHS
January 1, 2022 through June 30, 2022

			Jan-22	Feb-22	Mar-22	Apr-22	May-22	Jun-22
Total enrollment			810,339	812,199	814,834	816,901	818,843	820,828
Dual-eligibles			166,781	166,499	166,518	166,594	166,687	166,881
Pharmacy benefits			695,086	697,028	699,710	701,780	703,654	705,553
	LTC		15,007	14,940	15,058	15,089	15,068	14,968
	PLAN %	**FFS**	41.7%	42.9%	44.2%	46.1%	47.0%	47.9%
		MSCAN-UHC	22.7%	22.2%	21.7%	21.0%	20.7%	20.3%
		MSCAN-Magnolia	23.8%	23.3%	22.8%	22.1%	21.7%	21.4%
		MSCAN-Molina	11.8%	11.6%	11.3%	10.8%	10.6%	10.4%

TABLE 04B: PHARMACY UTILIZATION STATISTICS FOR LAST 6 MONTHS
January 1, 2022 through June 30, 2022

		Jan-22	Feb-22	Mar-22	Apr-22	May-22	Jun-22
# Rx Fills	**FFS**	164,070	151,260	173,376	174,898	175,237	169,470
	MSCAN-UHC	159,166	140,647	152,246	146,597	142,486	133,828
	MSCAN-Mag	153,083	137,641	149,517	144,280	139,460	120,781
	MSCAN-Mol	53,306	48,047	52,863	49,673	48,599	45,048
# Rx Fills / Bene	**FFS**	0.6	0.5	0.6	0.5	0.5	0.5
	MSCAN-UHC	1.0	0.9	1.0	1.0	1.0	0.9
	MSCAN-Mag	0.9	0.8	0.9	0.9	0.9	0.8
	MSCAN-Mol	0.6	0.6	0.7	0.7	0.7	0.6
$ Paid Rx	**FFS**	$16,958,955	$16,909,690	$19,103,161	$18,142,709	$19,735,549	$19,512,665
	MSCAN-UHC	$20,298,720	$18,513,748	$20,784,420	$19,400,236	$19,544,544	$19,167,102
	MSCAN-Mag	$16,257,744	$15,290,143	$16,994,598	$15,836,818	$15,504,576	$14,812,238
	MSCAN-Mol	$5,071,980	$4,679,676	$5,473,605	$4,808,468	$4,680,470	$4,843,106
$ /Rx Fill	**FFS**	$103.36	$111.79	$110.18	$103.73	$112.62	$115.14
	MSCAN-UHC	$127.53	$131.63	$136.52	$132.34	$137.17	$143.22
	MSCAN-Mag	$106.20	$111.09	$113.66	$109.76	$111.18	$122.64
	MSCAN-Mol	$95.15	$97.40	$103.54	$96.80	$96.31	$107.51
$ /Bene	**FFS**	$58.51	$56.55	$61.77	$56.08	$59.67	$57.74
	MSCAN-UHC	$128.65	$119.64	$136.89	$131.64	$134.18	$133.82
	MSCAN-Mag	$98.28	$94.15	$106.53	$102.11	$101.54	$98.10
	MSCAN-Mol	$61.84	$57.88	$69.23	$63.44	$62.75	$66.00

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

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

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

Category	Month Year	Rank Volume	# RXs	$ Paid	# Unique Benes
CNS stimulants	Jun 2022	1	20,155	$2,996,488	16,927
	May 2022	1	22,978	$3,520,610	19,401
	Apr 2022	1	25,433	$3,958,986	21,504
SSRI antidepressants	Jun 2022	2	15,022	$184,876	13,597
	May 2022	3	14,916	$184,800	13,611
	Apr 2022	5	15,064	$186,560	13,819
nonsteroidal anti-inflammatory agents	Jun 2022	3	14,452	$203,832	13,592
	May 2022	4	14,696	$213,310	13,780
	Apr 2022	4	15,081	$218,603	14,212
atypical antipsychotics	Jun 2022	4	14,345	$4,378,071	11,807
	May 2022	5	14,495	$4,517,218	11,965
	Apr 2022	6	14,537	$4,242,697	12,160
adrenergic bronchodilators	Jun 2022	5	13,156	$922,217	11,073
	May 2022	2	14,933	$948,206	12,596
	Apr 2022	3	15,301	$971,065	12,907
narcotic analgesic combinations	Jun 2022	6	12,435	$715,866	11,295
	May 2022	10	12,135	$669,341	11,073
	Apr 2022	10	12,218	$634,457	11,138
proton pump inhibitors	Jun 2022	7	12,154	$403,066	11,362
	May 2022	9	12,326	$418,032	11,563
	Apr 2022	9	12,405	$412,446	11,716
antihistamines	Jun 2022	8	11,534	$171,088	10,417
	May 2022	7	13,625	$198,939	12,280
	Apr 2022	2	17,034	$245,257	15,978
aminopenicillins	Jun 2022	9	11,342	$145,649	11,044
	May 2022	6	14,199	$185,974	13,813
	Apr 2022	7	13,870	$180,906	13,493
antiadrenergic agents, centrally acting	Jun 2022	10	10,419	$203,625	9,214
	May 2022	11	10,666	$200,728	9,526
	Apr 2022	12	10,883	$220,178	9,762

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

Category	Month Year	Rank Paid Amt	# RXs	$ Paid	# Unique Benes
TNF alpha inhibitors	Jun 2022	1	614	$4,534,252	478
	May 2022	2	582	$4,057,643	465
	Apr 2022	2	566	$4,088,957	457
atypical antipsychotics	Jun 2022	2	14,345	$4,378,071	11,807
	May 2022	1	14,495	$4,517,218	11,965
	Apr 2022	1	14,537	$4,242,697	12,160
interleukin inhibitors	Jun 2022	3	669	$3,559,865	513
	May 2022	3	658	$3,648,534	489
	Apr 2022	4	627	$3,370,129	472
antiviral combinations	Jun 2022	4	1,143	$3,067,084	1,038
	May 2022	5	939	$2,903,245	850
	Apr 2022	5	881	$2,956,268	796
CNS stimulants	Jun 2022	5	20,155	$2,996,488	16,927
	May 2022	4	22,978	$3,520,610	19,401
	Apr 2022	3	25,433	$3,958,986	21,504
CFTR combinations	Jun 2022	6	105	$2,523,486	71
	May 2022	7	89	$2,095,235	71
	Apr 2022	7	92	$2,179,547	70
insulin	Jun 2022	7	5,479	$2,480,177	3,917
	May 2022	6	5,314	$2,369,825	3,824
	Apr 2022	6	5,347	$2,422,797	3,864
factor for bleeding disorders	Jun 2022	8	185	$1,806,087	136
	May 2022	8	152	$2,058,552	116
	Apr 2022	8	147	$1,854,606	114
bronchodilator combinations	Jun 2022	9	4,061	$1,360,708	3,627
	May 2022	10	4,176	$1,392,072	3,726
	Apr 2022	9	4,174	$1,380,781	3,688
GLP-1 receptor agonists	Jun 2022	10	1,517	$1,282,399	1,388
	May 2022	11	1,510	$1,233,628	1,390
	Apr 2022	10	1,527	$1,272,726	1,427

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

Drug Molecule Therapeutic Category	May 2022 # Claims	Jun 2022 # Claims	Jun 2022 $ Paid	Jun 2022 # Unique Benes
albuterol / adrenergic bronchodilators	14,212	12,231	$657,834	10,449
amoxicillin / aminopenicillins	14,158	11,312	$145,061	11,015
montelukast / leukotriene modifiers	10,206	8,857	$137,573	8,429
gabapentin / gamma-aminobutyric acid analogs	8,185	8,326	$125,134	7,612
azithromycin / macrolides	9,832	7,789	$122,079	7,591
acetaminophen-hydrocodone / narcotic analgesic combinations	7,443	7,520	$97,783	7,034
cetirizine / antihistamines	9,163	7,209	$100,319	6,430
fluticasone nasal / nasal steroids	8,603	6,850	$104,609	6,684
ibuprofen / nonsteroidal anti-inflammatory agents	6,699	6,488	$77,173	6,279
clonidine / antiadrenergic agents, centrally acting	6,541	6,405	$82,584	5,918
amphetamine-dextroamphetamine / CNS stimulants	6,876	6,332	$179,049	5,361
ondansetron / 5HT3 receptor antagonists	7,400	6,329	$91,067	6,033
amlodipine / calcium channel blocking agents	6,181	6,303	$72,442	5,881
methylphenidate / CNS stimulants	6,506	5,674	$887,899	4,937
sertraline / SSRI antidepressants	5,513	5,562	$69,473	5,015
omeprazole / proton pump inhibitors	5,671	5,559	$65,355	5,334
triamcinolone topical / topical steroids	5,026	5,082	$82,009	4,813
amoxicillin-clavulanate / penicillins/beta-lactamase inhibitors	5,507	4,598	$98,226	4,452
cefdinir / third generation cephalosporins	5,823	4,593	$101,859	4,450
lisdexamfetamine / CNS stimulants	5,288	4,511	$1,498,438	4,292
atorvastatin / HMG-CoA reductase inhibitors (statins)	4,524	4,479	$49,502	4,133
prednisolone / glucocorticoids	6,296	4,382	$67,455	4,227
pantoprazole / proton pump inhibitors	4,321	4,364	$48,594	4,057
hydroxyzine / miscellaneous anxiolytics, sedatives and hypnotics	4,136	4,298	$68,040	4,037
guanfacine / antiadrenergic agents, centrally acting	4,125	4,012	$117,689	3,668

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

Drug Molecule Therapeutic Category	May 2022 $ Paid	Jun 2022 $ Paid	Jun 2022 # Claims	Jun 2022 # Unique Benes
adalimumab / TNF alpha inhibitors	$3,135,648	$3,581,573	432	339
elexacaftor/ivacaftor/tezacaftor / CFTR combinations	$1,990,582	$2,416,784	100	67
paliperidone / atypical antipsychotics	$1,789,641	$1,717,390	662	592
bictegravir/emtricitabine/tenofovir / antiviral combinations	$1,367,589	$1,510,787	420	397
dupilumab / interleukin inhibitors	$1,395,580	$1,508,863	472	351
lisdexamfetamine / CNS stimulants	$1,727,381	$1,498,438	4,511	4,292
aripiprazole / atypical antipsychotics	$1,205,035	$1,204,369	3,867	3,491
liraglutide / GLP-1 receptor agonists	$942,189	$980,012	1,154	1,066
insulin glargine / insulin	$916,235	$939,254	2,022	1,884
methylphenidate / CNS stimulants	$1,044,463	$887,899	5,674	4,937
ustekinumab / interleukin inhibitors	$901,691	$790,443	35	29
emicizumab / factor for bleeding disorders	$996,994	$701,517	33	23
albuterol / adrenergic bronchodilators	$734,313	$657,834	12,231	10,449
somatropin / growth hormones	$647,504	$654,594	159	131
etanercept / TNF alpha inhibitors	$617,796	$651,749	119	91
antihemophilic factor / factor for bleeding disorders	$399,363	$622,913	40	16
empagliflozin / SGLT-2 inhibitors	$611,253	$608,707	804	743
lacosamide / miscellaneous anticonvulsants	$657,972	$601,150	672	567
buprenorphine-naloxone / narcotic analgesic combinations	$527,248	$569,014	1,513	1,206
dapagliflozin / SGLT-2 inhibitors	$539,103	$558,519	826	781
insulin aspart / insulin	$513,782	$558,053	1,463	1,306
budesonide-formoterol / bronchodilator combinations	$581,066	$557,033	1,640	1,570
apixaban / factor Xa inhibitors	$496,689	$531,238	1,123	1,016
ixekizumab / interleukin inhibitors	$661,375	$514,544	74	54
cannabidiol / miscellaneous anticonvulsants	$467,707	$506,664	166	140

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

Drug Molecule	Apr 2022 # Claims	May 2022 # Claims	Jun 2022 # Claims	Jun 2022 $ Paid	Jun 2022 # Unique Benes
ciprofloxacin-dexamethasone otic / otic steroids with anti-infectives	993	1,130	1,894	$467,621	1,795
mupirocin topical / topical antibiotics	2,983	3,550	3,752	$54,841	3,654
hydrocortisone/neomycin/polymyxin b otic / otic steroids with anti-infectives	294	424	767	$50,660	750
ofloxacin otic / otic anti-infectives	584	739	983	$26,170	951
cephalexin / first generation cephalosporins	2,518	2,910	2,849	$47,156	2,784
hydroxyzine / miscellaneous anxiolytics, sedatives and hypnotics	3,968	4,136	4,298	$68,040	4,037
sulfamethoxazole-trimethoprim / sulfonamides	3,318	3,568	3,638	$54,527	3,526
hydrocortisone topical / topical steroids	1,788	2,012	2,019	$43,781	1,909
medroxyprogesterone / contraceptives	2,929	2,989	3,160	$115,012	3,104
triamcinolone topical / topical steroids	4,855	5,026	5,082	$82,009	4,813
nirmatrelvir-ritonavir / antiviral combinations	1	39	224	$1,965	219
epinephrine / adrenergic bronchodilators	662	653	863	$249,568	762
polymyxin b-trimethoprim ophthalmic / ophthalmic anti-infectives	844	1,206	1,044	$16,624	1,006
clindamycin / lincomycin derivatives	2,036	2,121	2,193	$55,024	2,098
acetaminophen-oxycodone / narcotic analgesic combinations	2,575	2,536	2,732	$41,712	2,562
folic acid / vitamins	2,202	2,270	2,359	$18,846	1,790
nystatin topical / topical antifungals	1,909	1,950	2,065	$37,095	1,947
fluconazole / azole antifungals	3,745	3,745	3,901	$49,744	3,672
gabapentin / gamma-aminobutyric acid analogs	8,182	8,185	8,326	$125,134	7,612
trazodone / phenylpiperazine antidepressants	3,639	3,645	3,782	$43,350	3,493
metronidazole / miscellaneous antibiotics	2,865	2,848	3,004	$34,024	2,930
ethinyl estradiol-norelgestromin / contraceptives	1,721	1,809	1,847	$249,178	1,671
bupropion / smoking cessation agents	2,011	2,088	2,109	$42,193	1,961
dexamethasone / glucocorticoids	456	453	548	$6,766	534
cyclobenzaprine / skeletal muscle relaxants	2,982	2,952	3,072	$30,444	2,958

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

Drug Molecule	Apr 2022 $ Paid	May 2022 $ Paid	Jun 2022 $ Paid	Jun 2022 # Claims	Jun 2022 # Unique Benes
elexacaftor/ivacaftor/tezacaftor / CFTR combinations	$2,095,825	$1,990,582	$2,416,784	100	67
adalimumab / TNF alpha inhibitors	$3,263,646	$3,135,648	$3,581,573	432	339
ciprofloxacin-dexamethasone otic / otic steroids with anti-infectives	$244,840	$280,015	$467,621	1,894	1,795
corticotropin / corticotropin	$318,953	$558,143	$489,594	7	5
antihemophilic factor / factor for bleeding disorders	$467,028	$399,363	$622,913	40	16
bictegravir/emtricitabine/tenofovir / antiviral combinations	$1,363,361	$1,367,589	$1,510,787	420	397
everolimus / mTOR inhibitors	$319,301	$418,763	$461,854	39	32
cysteamine / miscellaneous uncategorized agents	$203,893	$356,818	$344,071	5	4
tafamidis / transthyretin stabilizers	$0	$0	$131,308	7	1
interferon gamma-1b / interferons	$0	$0	$120,700	2	1
leuprolide / antineoplastic hormones	$194,308	$207,111	$310,303	38	34
immune globulin intravenous and subcutaneous / immune globulins	$271,317	$353,818	$372,292	51	22
paliperidone / atypical antipsychotics	$1,624,760	$1,789,641	$1,717,390	662	592
ustekinumab / interleukin inhibitors	$705,147	$901,691	$790,443	35	29
mifepristone / progesterone receptor modulators	$82,533	$148,541	$165,860	6	3
buprenorphine-naloxone / narcotic analgesic combinations	$490,977	$527,248	$569,014	1,513	1,206
deferiprone / antidotes	$24,361	$89,328	$101,883	4	3
somatropin / growth hormones	$578,172	$647,504	$654,594	159	131
dapagliflozin / SGLT-2 inhibitors	$486,735	$539,103	$558,519	826	781
teriflunomide / selective immunosuppressants	$257,631	$261,930	$329,132	40	30
c1 esterase inhibitor, human / hereditary angioedema agents	$79,813	$74,860	$150,549	6	4
dupilumab / interleukin inhibitors	$1,439,901	$1,395,580	$1,508,863	472	351
azacitidine / miscellaneous antineoplastics	$0	$42,333	$64,451	3	2
coagulation factor ix / factor for bleeding disorders	$191,414	$263,951	$251,043	9	7
voxelotor / miscellaneous uncategorized agents	$103,729	$107,221	$162,829	18	16

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 2022 TO JUN 2022 (FFS and CCOs)

Drug Product Therapeutic Category	Jun 2022 # Claims	Jun 2022 $ Paid	Jun 2022 Avr. Paid Per Rx	Jun 2022 Avr. Units Per Rx	Apr 2022 Paid Per Unit	May 2022 Paid Per Unit	Jun 2022 Paid Per Unit	Percent Change
buprenorphine-naloxone 8 mg-2 mg tablet / narcotic analgesic combinations (P)	149	$12,455	$83.59	48	$1.28	$1.36	$1.43	11.8%
Nurtec ODT (rimegepant) 75 mg tablet, disintegrating / CGRP inhibitors (P)	144	$129,060	$896.25	9	$95.63	$97.53	$99.96	4.5%
Jardiance (empagliflozin) 10 mg tablet / SGLT-2 inhibitors (P)	377	$280,734	$744.65	40	$16.71	$17.00	$17.35	3.8%
Vyvanse (lisdexamfetamine) 30 mg tablet, chewable / CNS stimulants (N)	153	$51,199	$334.63	30	$10.42	$10.48	$10.78	3.5%
Vraylar (cariprazine) 3 mg capsule / atypical antipsychotics (N)	115	$141,021	$1,226.27	30	$39.34	$39.58	$40.64	3.3%
Linzess (linaclotide) 290 mcg capsule / guanylate cyclase-C agonists (P)	102	$50,297	$493.10	35	$14.50	$14.61	$14.98	3.3%
Eliquis (apixaban) 2.5 mg tablet / factor Xa inhibitors (P)	157	$67,497	$429.92	53	$7.64	$7.76	$7.87	2.9%
Biktarvy (bictegravir/emtricitabine/tenofovir) 50 mg-200 mg-25 mg tablet / antiviral combinations (P)	420	$1,510,787	$3,597.11	35	$101.15	$103.03	$103.97	2.8%
dexmethylphenidate 20 mg capsule, extended release / CNS stimulants (P)	376	$21,629	$57.52	30	$1.50	$1.49	$1.54	2.8%
Entresto (sacubitril-valsartan) 49 mg-51 mg tablet / angiotensin receptor blockers and neprilysin inhibitors (P)	186	$120,250	$646.50	67	$9.09	$9.16	$9.33	2.7%
Vyvanse (lisdexamfetamine) 20 mg capsule / CNS stimulants (N)	393	$131,430	$334.43	30	$10.56	$10.58	$10.81	2.3%
Genvoya (cobicistat/elvitegravir/emtricitabine/tenofov) 150 mg-150 mg-200 mg-10 mg tablet / antiviral combinations (P)	107	$383,466	$3,583.80	34	$106.40	$107.54	$108.80	2.3%
Januvia (sitagliptin) 100 mg tablet / dipeptidyl peptidase 4 inhibitors (P)	349	$249,162	$713.93	45	$15.49	$15.63	$15.81	2.1%

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 2022 TO JUN 2022 (FFS and CCOs)

Drug Product Therapeutic Category	Jun 2022 # Claims	Jun 2022 $ Paid	Jun 2022 Avr. Paid Per Rx	Jun 2022 Avr. Units Per Rx	Apr 2022 Paid Per Unit	May 2022 Paid Per Unit	Jun 2022 Paid Per Unit	Percent Change
Vimpat (lacosamide) 200 mg tablet / miscellaneous anticonvulsants (P)	204	$210,218	$1,030.48	63	$15.66	$15.72	$15.95	1.8%
Vyvanse (lisdexamfetamine) 40 mg capsule / CNS stimulants (N)	960	$319,186	$332.49	30	$10.53	$10.52	$10.72	1.8%

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 2022 – August 2022

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
21-Sep	5	4	9	21-Sep	46	50
21-Oct	5	1	6	21-Oct	51	88
21-Nov	4	3	7	21-Nov	43	49
21-Dec	4	2	6	21-Dec	54	66
22-Jan	4	2	6	22-Jan	28	34
22-Feb	6	5	11	22-Feb	63	71
22-Mar	6	4	10	22-Mar	39	41
22-Apr	3	2	5	22-Apr	42	47
22-May	4	3	7	22-May	42	48
22-Jun	4	4	8	22-Jun	39	43
22-Jul	3	2	5	22-Jul	46	55
22-Aug	3	2	5	22-Aug	48	58

ASSESSMENT OF PREDICTORS OF SEVERE MATERNAL MORBIDITY AMONG PREGNANT MEDICAID BENEFICIARIES

BACKGROUND

Maternal health can be considered a key indicator of the overall health of a society. The United States has the highest maternal mortality rate among developed countries with approximately 700 maternal deaths occurring annually.[1,2] Additionally, it is estimated that as many as 60,000 incidences of severe maternal morbidity (SMM) occur annually.[1] SMM is defined by the CDC as "unexpected outcomes of labor and delivery that result in significant short- or long-term consequences to a woman's health."[3] The annual rate of severe maternal morbidity per 10,000 delivery hospitalizations in the US has consistently increased over the years from 49.5 in 1993 to 144 in 2014.[4] Improving maternal morbidity and overall maternal health is a priority focus area for the Mississippi Division of Medicaid.

Several risk factors associated with severe maternal morbidity and mortality have been identified in the literature. Factors such as increased maternal age, certain racial/ethnic minorities, pre-pregnancy obesity, preexisting chronic medical conditions, and cesarean delivery have all been potentially associated with increased maternal morbidity and mortality.[5–12] In addition to these risk factors, social determinants of health, such as unmarried status, lower education, and rural residence, have also been found to be associated with higher maternal mortality.[12,13]

The objective of this project is to assess the relationship between risk factors and severe maternal morbidity events among pregnant Medicaid beneficiaries in Mississippi. For this report, MS-DUR is presenting a project proposal along with descriptive characteristics of the study sample identified in claims data.

METHODS

A retrospective analysis was conducted using Mississippi Medicaid fee-for-service (FFS) and coordinated care organization [CCOs: UnitedHealthcare (UHC), Magnolia (MAG), and Molina (MOL)] claims for the period of January 1, 2018 to December 31, 2021 to assess predictors of Severe Maternal Morbidity (SMM). Medicaid beneficiaries between the ages of 12-55 years with a pregnancy episode were identified between January 1, 2018 to December 31, 2020 (identification period).

Beneficiaries with pregnancy episodes were identified using the ICD 10 codes for live birth (Z37.0, Z37.2, Z37.50, Z37.51, Z37.52, Z37.53, Z37.54, Z37.59, Z37.3, Z37.60, Z37.61, Z37.62, Z37.63, Z37.64, Z37.69, O80) or stillbirth (Z37.1, Z37.4, Z37.7, O36.4XX0, O36.4XX1, O36.4XX2, O36.4XX3, O36.4XX4, O36.4XX5, O36.4XX9) from any diagnosis field in medical claims (Inpatient, Outpatient and Medical files) as per the criteria used by Moll et.al.[14] The date of service for the claim for live or stillbirth thus identified was assigned as the pregnancy end date. The type of term associated with the delivery was determined using ICD-10-CM codes for preterm status (O6010X0-9,

O6012X0-9, O6013X0-9, O6014X0-9, O42011-9, O42111-9, O42911-9) or full-term status (O6020X0-9, O6022X0-9, O6023X0-9, O4202, O4292, O471, O80). Only the first pregnancy episode within the identification period was included in this analysis. The start date of each pregnancy event was determined using the criteria of 245 days before the pregnancy end date for pregnancies that were identified as preterm and 270 days before the pregnancy end date for all other pregnancies.[15] For those pregnancy end dates for which the term could not be identified using the previous step, the week of gestation associated with the end date was determined using ICD codes Z3A01-42 and the start date was calculated using the formula: (pregnancy end date - week of gestation*7 +1) following the methodology of Moll et.al.[14] Finally, those individuals that were not continuously enrolled during the pregnancy episode, were age less than 12 years or more than 55 years, or had missing plan information were excluded from the final sample. Due to a very low number of beneficiaries who died within 365 days following the cohort entry date, this outcome could not be analyzed. Therefore, beneficiaries who died were excluded from the cohort.

Predictor Variables

Sociodemographics:

Sociodemographic predictors such as age as of cohort entry date and race were included in the regression analysis as maternal characteristics associated with SMM such as higher maternal age at delivery and race, especially Black women and women residing in the southern region, have been reported to have a higher likelihood of experiencing SMM after delivery.[16]

Social Determinants of Health

Social determinants, such as unmarried status, lower education, and rural residence, have been reported in the literature to be associated with worse maternal outcomes.[12,13] To account for the physical environment of the patient, their 5-digit Federal Information Processing System (FIPS) code for their county of residence will be mapped to the CDC's Social Vulnerability Index (SVI) for counties in Mississippi in 2018, which summarizes the socioeconomic status, disability, transportation, housing conditions, etc. in a community. County-level factors will be assessed and categorized.[18] Additionally, since food environment is not summarized in the SVI, the Food Environment Index from County Health Rankings for all counties in Mississippi in the year 2018 will be used to summarize this factor.[19]

Care-related/Access-related Factors

Several factors associated with maternal care were included in the regression model. Pregnancy-related visits during the first trimester and postpartum care visits during the two-week period following delivery were assessed for their association with SMM. The use of both prenatal vitamins and low-dose aspirin among pregnant beneficiaries was included in the model. Another potential risk factor for maternal outcomes identified by the DUR board was the distance a mother must travel to deliver. Distance to the delivery center was calculated based on the distance from the home zip code for the mother and the zip code for the delivery center.

Clinical Characteristics

The Maternal Comorbidity Index was measured and the association between the Maternal Comorbidity Index and study outcomes was assessed. The Maternal Comorbidity Index is a simple measure that captures the burden of chronic, behavioral, and pregnancy-induced conditions at an individual level.[20] (Figure 1) It was developed and validated to predict the occurrence of acute maternal end-organ injury and mortality.[20] It has been found that Maternal Comorbidity Index is associated with an increased risk of SMM and delivery-related mortality.[21,22]

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	-

The Centers for Disease Control and Prevention (CDC)'s Maternal Mortality Review Committees (MMRCs) have identified a series of critical underlying causes of pregnancy-related death.[23] The underlying cause of death is the disease or injury that initiated the chain of events leading to death or the circumstances of the accident or violence which produced the fatal injury. The diseases or injuries that are listed on the MMRC Decision form and not included in the Maternal Comorbidity Index were also captured. Both Maternal Comorbidity Index and underlying cause of pregnancy-related death were identified in the medical claims (from pregnancy start to occurrence of 1st SMM episode) for each study subject.

Case and control definitions

Cases were defined as beneficiaries who had any severe maternal morbidity (SMM) - identified in accordance with the criteria put forth by the Centers for Disease Control Prevention (CDC), which defines SMM as one of the 21 conditions in Figure 2. [24] The ICD-10-CM diagnosis and procedure codes were used to identify SMM in the 365 days post the cohort entry date (date of delivery) which is the outcome identification period. Controls were defined as beneficiaries from the study cohort who did not have any SMM at the time of matching. Two controls were identified for each case using risk set sampling. This method allowed for random sampling from eligible controls, such that each control had an equal or greater time at risk of SMM as compared to the matched case. This approach further allowed for controls to serve as future cases and for one beneficiary to serve as a control for more than one case. Cases and controls were matched on the time of cohort entry, and controls were assigned by the matched case index date.

Logistic regression

Adjusted conditional logistic regression analysis was used to assess the relationship between risk factors and SMM events.

Figure 2: Severe Maternal Morbidity Indicators

1. Acute myocardial infarction	I21.01, I21.02, I21.09, I21.11, I21.19, I21.21, I21.29, I21.3, I21.4, I21.9, I21.A1 and I21.A9, I22.0, I22.1, I22.2, I22.8, I22.9
2. Aneurysm	I71.00 – I71.03, I71.1, I71.2, I71.3, I71.4, I71.5, I71.6, I71.8, I71.9, I79.0
3. Acute renal failure	N17.0, N17.1, N17.2, N17.8, N17.9, O90.4
4. Adult respiratory distress syndrome	J80, J95.1, J95.2, J95.3, J95.821, J95.822, J96.00, J96.01, J96.02, J96.20, J96.21, J96.22, R09.2
5. Amniotic fluid embolism	O88.11x*, O88.12 (childbirth), O88.13 (puerperium) * x=1st, 2nd and 3rd trimester
6. Cardiac arrest/ventricular fibrillation	I46.2, I46.8, I46.9, I49.01*, I49.02**; * Ventricular fibrillation, ** Ventricular flutter

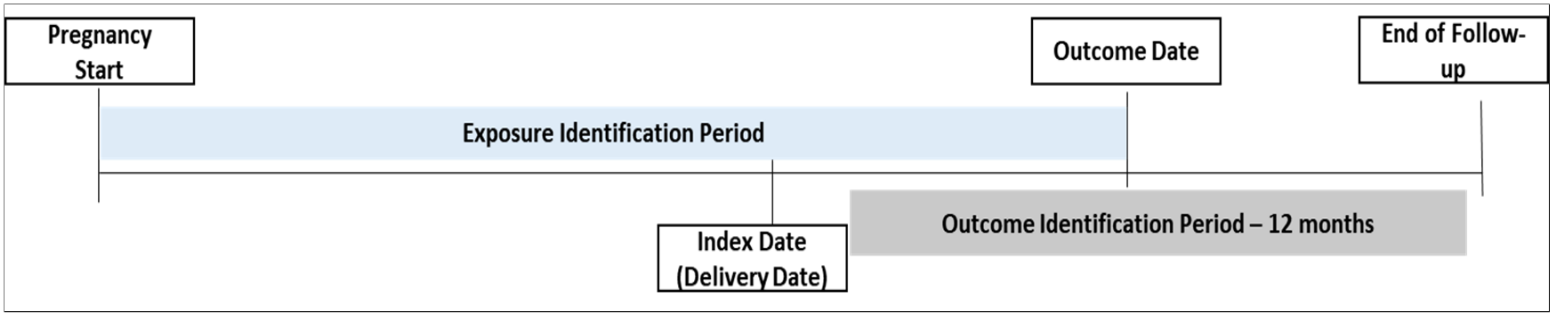
7. Conversion of cardiac rhythm	5A2204Z, 5A12012
8. Disseminated intravascular coagulation	D65, D68.8, D68.9, O72.3* *see comments for pregnancy-related codes
9. Eclampsia	O15.00, O15.02, O15.03, O15.1, O15.2, O15.9, O14.22 – HELLP syndrome (HELLP), second trimester, O14.23 – HELLP syndrome (HELLP), third-trimester HELLP syndrome is not included currently (ranges in severity, more research is needed)
10. Heart failure/arrest during surgery or procedure	I97.120, I97.121, I97.130, I97.131, I97.710, I97.711
11. Puerperal cerebrovascular disorders	- I60.0x, I60.1x, I60.2, I60.3x, I60.4, I60.5x, I60.6, I60.7, I60.8, I60.9; I61.1, I61.2, I61.3, I61.4, I61.5, I61.6, I61.8, I61.9; I62.0x, I62.1, I62.9;I63.0xx, I63.1xx, I63.2xx, I63.3xx, I63.4xx , I63.5xx, I63.6, I63.8, I63.9; I65.0x, I65.1, I65.2x, I65.8, I65.9; I66.0x, I66.1x, I66.2x, I66.3, I66.8, I66.9; I67.0, I67.1, I67.2, I67.3, I67.4, I67.5, I67.6, I67.7, I67.8xx, I67.9; I68.0, I68.2, I68.8; O22.51, O22.52, O22.53, I97.810, I97.811, I97.820, I97.821, O87.3 674.0x – no crosswalk
12. Pulmonary edema and acute heart failure	J81.0, I50.1, I50.20, I50.21, I50.23, I50.30, I50.31, I50.33, I50.40, I50.41, I50.43, I50.9; (-) Add 5th character: 0=unspecified 1=acute 2=chronic 3=acute on chronic 0=unspecified – keep since it is commonly used among health care providers terminology in medical records
13. Severe anesthesia complications	O74.0 , O74.1, O74.2, O74.3, O89.01*, O89.09, O89.1, O89.2 *O89.01 Aspiration – decided to keep due to difficulties of separation from "Aspiration Pneumonitis"
14. Sepsis	- O85, O86.04, T80.211A, T81.4XXA, T81.44, T81.44XA, T81.44XD, T81.44XS Or severity: R65.20, or A40.0, A40.1 , A40.3 , A40.8, A40.9, A41.01, A41.02, A41.1, A41.2, A41.3, A41.4, A41.50, A41.51, A41.52, A41.53, A41.59, A41.81, A41.89, A41.9, A32.7
15. Shock	O75.1, R57.0, R57.1, R57.8, R57.9, R65.21, T78.2XXA, T88.2XXA , T88.6XXA, T81.10XA, T81.11XA, T81.19XA
16. Sickle cell disease with crisis	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)
17. Air and thrombotic embolism	I26.01, I26.02, I26.09, I26.90, I26.92, I26.99 O88.011-O88.019, 088.02, O88.03, O88.211-O88.219, O88.22, O88.23, O88.311-O88.319, O88.32, O88.33, O88.81, O88.82, O88.83 * I26.0 – Pulmonary embolism with acute cor pulmonale external icon (acute right ventricle heart failure)
18. Blood products transfusion	99.0x à 160 ICD-10-PCS codes The most common, •30233H1 Transfusion of Nonautologous Whole Blood into Peripheral Vein, Percutaneous Approach •30233K1 Transfusion of Nonautologous Frozen Plasma into Peripheral Vein, Percutaneous Approach

	•30233L1 Transfusion of Nonautologous Fresh Plasma into Peripheral Vein, Percutaneous Approach •30233M1 Transfusion of Nonautologous Plasma Cryoprecipitate into Peripheral Vein, Percutaneous Approach •30233N1 Transfusion of Nonautologous Red Blood Cells into Peripheral Vein, Percutaneous Approach •30233P1 Transfusion of Nonautologous Frozen Red Cells into Peripheral Vein, Percutaneous Approach •30233R1 Transfusion of Nonautologous Platelets into Peripheral Vein, Percutaneous Approach •30233T1 Transfusion of Nonautologous Fibrinogen into Peripheral Vein, Percutaneous Approach •30240H1 Transfusion of Nonautologous Whole Blood into Central vein, open approach •30240K1 Transfusion of Nonautologous Frozen Plasma into Central vein, open approach •30240L1 Transfusion of Nonautologous Fresh Plasma into Central vein, open approach •30240M1 Transfusion of Nonautologous Plasma Cryoprecipitate into Central vein, open approach •30240N1 Transfusion of Nonautologous Red Blood Cells into Central vein, open approach •30240P1 Transfusion of Nonautologous Frozen Red Cells into Central vein, open approach •30240R1 Transfusion of Nonautologous Platelets into Central vein, open approach •30240T1 Transfusion of Nonautologous Fibrinogen into Central vein, open approach •30243H1 Transfusion of Nonautologous Whole Blood into Central vein, percutaneous approach •30243K1 Transfusion of Nonautologous Frozen Plasma into Central vein, percutaneous approach •30243L1 Transfusion of Nonautologous Fresh Plasma into Central vein, percutaneous approach •30243M1 Transfusion of Nonautologous Plasma Cryoprecipitate into Central vein, percutaneous approach •30243N1 Transfusion of Nonautologous Red Blood Cells into Central vein, percutaneous approach •30243P1 Transfusion of Nonautologous Frozen Red Cells into Central vein, percutaneous approach •30243R1 Transfusion of Nonautologous Platelets into Central vein, percutaneous approach •30243T1 Transfusion of Nonautologous Fibrinogen into Central vein, percutaneous approach •30233N0 Transfusion of Autologous Red Blood Cells into Peripheral Vein, Percutaneous Approach

	•30233P0 Transfusion of Autologous Frozen Red Cells into Peripheral Vein, Percutaneous Approach •30240N0 Transfusion of Autologous Red Blood Cells into Central vein, open approach •30240P0 Transfusion of Autologous Frozen Red Cells into Central vein, open approach •30243N0 Transfusion of Autologous Red Blood Cells into Central vein, percutaneous approach •30243P0 Transfusion of Autologous Frozen Red Cells into Central vein, percutaneous approach
19. Hysterectomy	0UT90ZZ, 0UT94ZZ, 0UT97ZZ, 0UT98ZZ, 0UT9FZZ
20. Temporary tracheostomy	0B110Z4, 0B110F4, 0B113Z4, 0B113F4, 0B114Z4, 0B114F4
21. Ventilation	5A1935Z, 5A1945Z, 5A1955Z

Figure 3 provides a visual model of the study design.

Figure 3: Study Design



RESULTS

Beneficiary information such as age, race, and plan (FFS/MAG/UHC/MOL) for each pregnancy episode was captured in Table 1. Age and plan were determined as of the start date of the pregnancy episode.

- The majority of beneficiaries in the study sample were in the 18-30 years age group (75.3%), African American (64.4%), and enrolled in fee-for-service (52.4%).

Table 1: Demographics of Beneficiaries Enrolled in Mississippi Medicaid with a Pregnancy Episode January 1, 2018 - December 31, 2020

Characteristics	Total		Plan at Pregnancy Start							
			FFS		UHC		MAG		MOL	
	N	%	N	%	N	%	N	%	N	%
Age Category										
12-18	881	7.9%	136	2.3%	288	14.3%	403	15.0%	54	9.1%
18-30	8,375	75.3%	4,813	82.6%	1,356	67.6%	1,776	65.9%	430	72.5%
31-40	1,798	16.2%	847	14.5%	351	17.5%	492	18.3%	108	18.2%
41-55	65	0.6%	30	0.5%	12	0.6%	22	0.8%	1	0.2%
Total	**11,119**		**5,826**		**2,007**		**2,693**		**593**	
Race										
Caucasian	3,553	32.0%	2,020	34.7%	636	31.7%	740	27.5%	157	26.48%
African American	7,158	64.4%	3,580	61.4%	1,303	64.9%	1,866	69.3%	409	69.0%
Hispanic	120	1.1%	50	0.9%	32	1.6%	30	1.1%	8	1.3%
American Indian	68	0.6%	62	1.1%	-	0.0%	3	0.1%	3	0.5%
Other	220	2.0%	114	2.0%	36	1.8%	54	2.0%	16	2.7%
Total	**11,119**		**5,826**		**2,007**		**2,693**		**593**	

Note: *FFS - Fee-for-Service; UHC - UnitedHealthcare; MAG - Magnolia Health; MOL - Molina Healthcare; *Pregnancy episodes included were live birth and still births and only the 1st pregnancy episode was included.

Table 2 describes the SMM conditions identified for the included pregnancy episodes, stratified by plan.

- 359 (3.2%) beneficiaries had any severe maternal morbidity.
- The most common SMMs observed were sepsis (N=83, 23.1%), pulmonary edema, and acute heart failure (N=83, 23.1%). These were followed by adult respiratory distress syndrome (N=53, 14.8%), puerperal cerebrovascular disorders (N=49, 13.6%), acute renal failure (N=41, 11.4%), eclampsia (N=41, 11.4%), and air and thrombotic embolism (N=40, 11.1%).

Table 2: Description of Severe Maternal Morbidity among Beneficiaries Enrolled in Mississippi Medicaid with a Pregnancy Episode January 1, 2018 - December 31, 2020

Conditions	Total		Plan at Pregnancy Start							
			FFS		UHC		MAG		MOL	
	N	%	N	%	N	%	N	%	N	%
Any SMM**	**359**		**157**		**83**		**97**		**22**	
1. Acute myocardial infarction	9	2.5%	5	3.2%	2	2.4%	2	2.1%	0	0.0%
2. Aneurysm	2	0.6%	2	1.3%	0	0.0%	0	0.0%	0	0.0%
3. Acute renal failure	41	11.4%	23	14.6%	7	8.4%	10	10.3%	1	4.5%
4. Adult respiratory distress syndrome	53	14.8%	31	19.7%	10	12.0%	11	11.3%	1	4.5%
5. Amniotic fluid embolism	4	1.1%	0	0.0%	2	2.4%	1	1.0%	1	4.5%
6. Cardiac arrest/ventricular fibrillation	4	1.1%	1	0.6%	2	2.4%	1	1.0%	0	0.0%
7. Conversion of cardiac rhythm	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
8. Disseminated intravascular coagulation	26	7.2%	9	5.7%	6	7.2%	10	10.3%	1	4.5%
9. Eclampsia	41	11.4%	18	11.5%	13	15.7%	8	8.2%	2	9.1%
10. Heart failure/arrest during surgery or procedure	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
11. Puerperal cerebrovascular disorders	49	13.6%	20	12.7%	10	12.0%	18	18.6%	1	4.5%
12. Pulmonary edema and acute heart failure	83	23.1%	39	24.8%	16	19.3%	23	23.7%	5	22.7%
13. Severe anesthesia complications	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
14. Sepsis	83	23.1%	38	24.2%	19	22.9%	21	21.6%	5	22.7%
15. Shock	23	6.4%	11	7.0%	5	6.0%	3	3.1%	4	18.2%
16. Sickle cell disease with crisis	9	2.5%	2	1.3%	5	6.0%	2	2.1%	0	0.0%
17. Air and thrombotic embolism	40	11.1%	21	13.4%	9	10.8%	9	9.3%	1	4.5%
18. Blood products transfusion	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
19. Hysterectomy	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
20. Temporary tracheostomy	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
21. Ventilation	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%

Note: *FFS - Fee-for-Service; UHC - UnitedHealthcare; MAG - Magnolia Health; MOL - Molina Healthcare; *Pregnancy episodes included were live birth and stillbirths, only the first pregnancy was considered for analysis. **SMM (Severe Maternal Morbidity) conditions were identified using ICD Codes in the 365 days following the end date of the pregnancy episode. SMM was identified using ICD-10-CM diagnosis and procedure codes as defined by CDC. ** Individuals could have multiple SMMs, therefore, the total percentage will add up to more than 100%.

Table 3 describes the age and race distribution among the cases and matched controls, stratified by plan.

Table 3: Demographics of Cases and Matched Controls Enrolled in Mississippi Medicaid with Pregnancy Episodes January 1, 2018 - December 31, 2020

Characteristics	Plan at Pregnancy Start									
	Total		FFS		UHC		MAG		MOL	
	Cases	Controls	Cases	Controls	Cases	Controls	Cases	Controls	Cases	Controls
Age Category										
12-18	24	53	2	11	9	15	10	25	3	2
18-30	239	542	116	300	49	95	59	138	15	9
31-40	88	120	37	46	21	33	26	37	4	4
41-64	8	3	2	0	4	0	2	3	0	0
Total	**359**	**718**	**157**	**357**	**83**	**143**	**97**	**203**	**22**	**15**
Race										
Caucasian	99	234	43	133	31	41	16	57	9	3
African American	249	453	106	209	49	96	0	137	13	11
Hispanic	0	15	0	6	0	3	0	6	0	0
American Indian	4	4	4	3	0	0	81	1	0	0
Other	7	12	4	6	3	3	0	2	0	1
Total	**359**	**718**	**157**	**357**	**83**	**143**	**97**	**203**	**22**	**15**

Note: *Cases were beneficiaries with with any SMM (Severe Maternal Morbidity) conditions . Controls were beneficiaries with no SMM and were matched to the cases in 2:1 ratio based on index date (delivery date) using incidence density sampling. *FFS - Fee-for-Service; UHC - UnitedHealthcare; MAG - Magnolia Health; MOL - Molina Healthcare .

Table 4: Cases and Matched Controls Descriptive Statistics					
Characteristics	**Measurement time**	**Full cohort**	**Case**	**Control**	***p* value**
			(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%)	
>=35		695 (6.25%)	45 (12.53%)	35 (4.87%)	
Race	Cohort entry				0.1
White		3553 (31.95%)	99 (27.58%)	234 (32.59%)	
African American		7158 (64.38%)	249 (69.36%)	453 (63.09%)	
Others		408 (3.67%)	11 (3.06%)	31 (4.32%)	
Pregnancy-related visit	First trimester of pregnancy	4957 (44.58%)	166 (46.24 %)	317 (44.15%)	0.52
Distance from delivery center (100 miles)	Delivery date	1.16 (2.29)	1.98 (3.08)	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				0.32
Least vulnerable		2776 (25.01%)	102 (28.41%)	174 (24.23%)	
Moderately vulnerable		6056 (54.56 %)	188 (52.37%)	399 (55.57%)	
Mosts vulnerable		2268 (20.43%)	69 (19.22%)	145 (20.19%)	
MCI	Pregnancy start to index date	N/A	1.10 (1.69)	0.51 (1.13)	**<0.001**
Notes: SVI - Social Vulnerability Index, MCI - Maternal Comorbidity Index					

Table 4 compares the descriptive characteristics of those in the case and control cohorts.

- Those in the case cohort had a larger proportion of individuals in the ≥ 35 years of age category.
- Those in the case cohort lived further away from their delivery center compared to those in the control cohort (mean of 198 miles for cases vs 117 miles for controls).
- Those in the case cohort had a higher MCI score compared to those in the control group.

Results of the adjusted conditional logistic regression analysis are presented in Table 5. Controlling for other covariates, MCI, distance from delivery center, age, and race were found to be significantly associated with severe maternal morbidity (SMM).

- A single point increase in MCI was associated with a 31% increase in odds of SMM [odds ratio (OR): 1.31, 95% confidence interval (CI): 1.18 – 1.45].
- A 100-mile increase in distance from the delivery center was associated with a 12% increase in odds of SMM (OR: 1.12, 95% CI: 1.06-1.17).
- Beneficiaries who were 35 years old or older at the time of delivery had more than twice the odds of SMM as compared to those who were 18-34 years old (OR: 2.07, 95% CI: 1.26 – 3.40).
- African American beneficiaries had 40% greater odds of SMM (OR: 1.40, 95% CI: 1.01-1.93) as compared to white beneficiaries.
- No statistically significant associations were found between any other covariate and the outcome of interest.

Table 5: Results from Logistic Regression Model Examining the Relationship between Risk Factors and SMM Events (January 1, 2018 - December 31, 2020)		
Characteristics	**Adjusted OR**	***p value***
MCI	1.31 (1.18 - 1.45)	**<0.001**
Distance from delivery center	1.12 (1.06 - 1.17)	**<0.001**
Age		
<18	1.15 (0.67 - 1.96)	0.43
18-34	Reference	
>=35	2.07 (1.26 - 3.40)	**0.02**
Race		
White	Reference	
African American	1.40 (1.01 - 1.93)	**0.047**
Others	0.83 (0.39 - 1.77)	0.34
Pregnancy-related visit	0.93 (0.71-1.22)	0.59
Postpartum care visit	0.81 (0.60 - 1.09)	0.17
Prenatal vitamin use	1.02 (0.76 -1.36)	0.91
Prenatal low dose aspirin use	2.59 (0.68 - 10.63)	0.19
SVI		
Least vulnerable	Reference	
Moderately vulnerable	0.71 (0.51 - 0.99)	0.27
Mosts vulnerable	0.69 (0.44 - 1.06)	0.27
SVI - Social Vulnerability Index, MCI - Maternal Comorbidity Index		
Distance from delivery center expressed per 100 miles		

CONCLUSIONS

Improving maternal health is a primary focus area for the Division of Medicaid. This study examining the relationship between risk factors and severe maternal morbidity events among Medicaid beneficiaries will help inform DOM on which risk factors are most closely associated with SMM events and can help guide the development of future interventions aimed at improving overall maternal health. From this model, MCI, distance from delivery center, age, and race were found to be significantly associated with SMM events.

RECOMMENDATIONS

1. MS-DUR should conduct an extensive study of this analysis further examining MCI and distance from delivery center:

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

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UTILIZATION TRENDS OF IMMUNOMODULATORS AMONG MEDICAID BENEFICIARIES

BACKGROUND

Immunomodulators can be broadly defined as agents that interact with the body's immune response to help the body fight diseases. Immunomodulating agents encompass a wide variety of pharmacologic agents including monoclonal antibodies, cytokines antagonists, and cell adhesion molecules (CAM) antagonists. Because of their impact on the body's immune response, immunomodulators are utilized as treatments across a broad spectrum of diseases. Many of these agents have transformed the treatment landscape for patients suffering from chronic inflammatory conditions such as rheumatic, skin, respiratory, and gastrointestinal diseases; and their indications for use are continuously expanding. As a result of their broad and expanding indications for use, the utilization of immunomodulators has increased in recent years. While these agents have been shown to be highly effective, in some patients their effectiveness may be limited or diminish over time leading prescribers to consider dose escalations above FDA-labeled dosing regimens. Multiple studies have examined scenarios where dose escalations with these agents may be considered.[1–4,4,5,5–9,9–18]

To assess prescribing practices for immunomodulators among Medicaid beneficiaries, MS-DUR examined trends in the utilization of immunomodulators with a focus on utilization for FDA-labeled indications and dosing regimens. A list of immunomodulators included in this report is provided in Figure 1.

Figure 1: Immunomodulator Drugs Included in Review

Actemra (tocilizumab)		Nucala (mepolizumab)
Arcalyst (rilonacept)		Olumiant (baricitinib)
Avsola (infliximab)		Orencia (abatacept)
Cibinqo (abrocitinib)		Otezla (apremilast)
Cimzia (certolizumab)		Remicade (infliximab)
Cosentys (secukinumab)		Renflexis (infliximab)
Dupixent (dupilumab)		Rinvoq (upadacitinib)
Enbrel (etanercept)		Siliq (brodalumab)
Enspryng (satralizumab)		Simponi (golimumab)
Entyvio (vedolizumab)		Skyrizi (risankizumab)
Fasenra (benralizumab)		Stelara (ustekinumab)
Humira (adalimumab)		Taltz (ixekizumab)
Ilaris (canakinumab)		Tremfya (guselkumab)
Ilumya (tildrakizumab)		Tezspire (tezepelumab)
Inflectra (infliximab)		Uplizna (inebilizumab)
Kevzara (sarilumab)		Xeljanz (tofacitinib)
Kineret (anakinra)		Xolair (omalizumab)

METHODS

A retrospective analysis was conducted using Mississippi Medicaid medical and point of sale (POS) pharmacy claims for fee-for-service (FFS) and coordinated care organization [CCOs: UnitedHealthcare (UHC), Magnolia (MAG), and Molina (MOL)] claims for the period of July 1, 2019 to June 30, 2022 (study period) to assess the utilization of immunomodulators. For each immunomodulator included, the International Classification of Diseases (ICD) diagnosis codes in claims data corresponding to FDA-labeled indications for each agent (Figure 2) were assessed for a lookback period of two years prior to the first claim during the study period. From this, the proportion of claims for each agent with an FDA-labeled indication present in claims data throughout the study period was calculated. To demonstrate utilization changes in this group of medications, a comparison between the total number of claims and dollars paid for the agents included in this analysis in July 2019 and June 2022 was presented.

A more in-depth analysis was conducted for four agents in this group: adalimumab (Humira), dupilumab (Dupixent), infliximab (Avsola, Inflectra, Remicade, Renflexis), and ustekinumab (Stelara). Along with examining FDA-approved indications present in claims data for these agents, demographic characteristics of beneficiaries receiving these agents and dosing patterns were also assessed. Dosing thresholds corresponding with FDA-labeled dosing recommendations were established and the proportion of claims exceeding these thresholds was calculated to determine instances of dose escalation. For all beneficiaries prescribed adalimumab, dupilumab, infliximab, and ustekinumab, diagnoses by dosing were captured for claims exceeding the dosing thresholds in an attempt to assess which indications were driving these dose escalations.

Figure 2: Immunomodulators and FDA-Approved Indications																													
Drug Name	FDA-Approved Indications*																												
	RA	*Crohn's*	*UC*	*AS*	PsO	*PsA*	*JIA*	*Asthma*	*CAPS*	*AD*	*NP*	*NMOSD*	*CRS*	*SSc-ILD*	*GCA*	*DIRA*	*RP*	*ERA*	*EE*	*JRA*	*HS*	*NIU*	*TRAPS*	*HES*	*EGP*	*AA*	*GVHD*	*OU*	*CIU*
Actemra	x						x						x	x	x														
Arcalyst									x							x	x												
Avsola	x	x	x	x	x	x																							
Cibinqo										x																			
Cimzia	x	x		x	x	x																							
Cosentys				x	x	x												x											
Dupixent								x		x	x								x										
Enbrel	x			x	x	x	x													x									
Enspryng												x																	
Entyvio		x	x																										
Fasenra								x																					
Humira	x	x	x	x	x	x	x														x	x							
Ilaris							x		x														x						
Ilumya					x																								
Inflectra	x	x	x	x		x																							
Kevzara	x																												
Kineret	x								x																				
Nucala								x			x													x	x				
Olumiant	x																									x			
Orencia	x					x	x																				x		
Otezla					x	x																						x	
Remicade	x	x	x	x	x	x																							
Renflexis	x	x	x	x	x	x																							
Rinvoq	x		x	x		x				x																			
Siliq					x																								
Simponi	x		x	x		x	x																						
Skyrizi		x			x	x																							
Stelara		x	x		x	x																							
Taltz				x	x	x																							
Tremfya					x	x																							
Tezspire								x																					
Uplizna												x																	
Xeljanz	x		x	x		x	x																						
Xolair								x			x																		x
* Only FDA approved indications included. See Appendix 1 for glossary of indications.																													

RESULTS

Tremendous growth has occurred among immunomodulators in recent years. Comparing utilization numbers in Mississippi Medicaid from July 2019 to June 2022, this group of medications has experienced a 127% increase in the number of claims and a 141% increase in the amount paid monthly. (Table 1)

Table 1. Comparison of Immunomodulator Utilization and Spend July 2019 vs June 2022

Month	#claims	Amount paid
19-Jul	616	$ 2,505,773.22
22-Jun	1,396	$ 6,027,648.61
Change	***127%***	***141%***

** Paid amounts referenced in this report reflect gross paid amounts and do not take into account rebates.*

This group of immunomodulator agents makes up a substantial portion of Medicaid's monthly spend on medications. In July 2019, these agents composed 5.2% of the paid amounts for pharmacy claims while in June 2022 that proportion had risen to 10.3%. Several of these agents are routinely among Medicaid's top drugs by dollars paid on the monthly resource utilization review reports and use continues to grow. It should be noted that paid amounts referenced in this report reflect gross paid amounts and do not take into account rebates.

Part of the review of these agents examined prescribing patterns as they related to FDA-approved indications. A two-year lookback period from the initial claim during the study period was utilized to assess for the presence of an FDA-approved indication. Table 2 displays claims for immunomodulators by the percent with FDA-approved indications present in claims data.

- Overall, 90.0% of claims had an FDA-approved or on-label indication present in claims data.
- 6 drugs had less than 50% of claims with on-label use.
- 4 drugs had between 50%-75% of claims with on-label use.
    - These 10 drugs made up only 6.8% of total claims.

Table 2. Total Claims for Immunomodulator Agents by FDA-Approved Indication (July 1, 2019 - June 30, 2022)			
Drug Name	**Total Claims**	**On-Label Claims**	**Percent On-Label Claims**
Actemra (tocilizumab)	543	527	97.1%
Arcalyst (rilonacept)	NA	NA	NA
Avsola (infliximab)	45	32	71.1%
Cibinqo (abrocitinib)	NA	NA	NA
Cimzia (certolizumab)	478	446	93.3%
Cosentyx (secukinumab)	1,053	592	56.2%
Dupixent (dupilumab)	8,403	7,518	89.5%
Enbrel (etanercept)	5,972	5,124	85.8%
Enspryng (satralizumab)	10	10	100.0%
Entyvio (vedolizumab)	593	592	99.8%
Fasenra (benralizumab)	387	376	97.2%
Humira (adalimumab)	11,883	11,333	95.4%
Ilaris (canakinumab)	299	299	100.0%
Ilumya (tildrakizumab)	6	0	0.0%
Inflectra (infliximab)	235	213	90.6%
Kevzara (sarilumab)	87	87	100.0%
Kineret (anakinra)	109	0	0.0%
Nucala (mepolizumab)	1,792	1,789	99.8%
Olumiant (baricitinib)	9	6	66.7%
Orencia (abatacept)	1,072	1,012	94.4%
Otezla (apremilast)	874	412	47.1%
Remicade (infliximab)	1,539	1,321	85.8%
Renflexis (infliximab)	429	363	84.6%
Rinvoq (upadacitinib)	465	455	97.8%
Siliq (brodalumab)	2	0	0.0%
Simponi (golimumab)	297	292	98.3%
Skyrizi (risankizumab)	22	9	40.9%
Stelara (ustekinumab)	846	826	97.6%
Taltz (ixekizumab)	868	410	47.2%
Tremfya (guselkumab)	169	100	59.2%
Tezspire (tezepelumab)	2	2	100.0%
Uplizna (inebilizumab)	NA	NA	NA
Xeljanz (tofacitinib)	1,213	1,118	92.2%
Xolair (omalizumab)	6,707	6,460	96.3%
Total	***46,409***	***41,724***	***89.9%***
Notes: Red highlight - Below 50%; Yellow highlight - 50-75%;			

Of the drugs included in this review, DOM requested MS-DUR conduct a more extensive analysis of four agents: adalimumab (Humira), dupilumab (Dupixent), infliximab (Avsola, Inflectra, Remicade, Renflexis), and ustekinumab (Stelara).

Adalimumab (Humira):

Humira consistently ranks as one of the top drugs by dollars paid by Medicaid monthly. In June 2022, Medicaid paid more than $3.5 million for claims attributed to Humira. Between July 2019

and June 2022, beneficiaries prescribed Humira were predominantly African American, female, and in the 21-44 yrs age category. (Table 3a)

Table 3a. Demographic Characteristics of Beneficiaries Prescribed Humira (July 2019 - June 2022)

	FFS		UHC		MAG		MOL		Total*	
Age Category (yrs)										
0 - 20	65	26.5%	94	29.0%	79	23.4%	24	22.4%	262	25.9%
21 - 44	85	34.7%	132	40.7%	135	40.1%	59	55.1%	411	40.6%
45 - 64	93	38.0%	98	30.2%	123	36.5%	24	22.4%	338	33.4%
65+	2	0.8%	0	0.0%	0	0.0%	0	0.0%	2	0.2%
Total	***245***		***324***		***337***		***107***		***1,013***	
Gender										
Female	195	79.6%	258	79.6%	268	79.5%	87	81.3%	808	79.8%
Male	50	20.4%	66	20.4%	69	20.5%	20	18.7%	205	20.2%
Total	***245***		***324***		***337***		***107***		***1,013***	
Race										
Caucasian	107	43.7%	144	44.4%	130	38.6%	46	43.0%	427	42.2%
African American	118	48.2%	149	46.0%	177	52.5%	51	47.7%	495	48.9%
Other	20	8.2%	31	9.6%	30	8.9%	10	9.3%	91	9.0%
Total*	***245***		***324***		***337***		***107***		***1,013***	

Note: Age and health plan were assessed at the first Humira claim during the study period

**1,015 beneficiaries were prescribed Humira. 2 beneficiaries did not have demographic and plan information*

Figure 3 shows the monthly trends in Humira claims during the study period. Comparing July 2019 to June 2022, the number of monthly Humira claims increased 64% from 258 to 423.

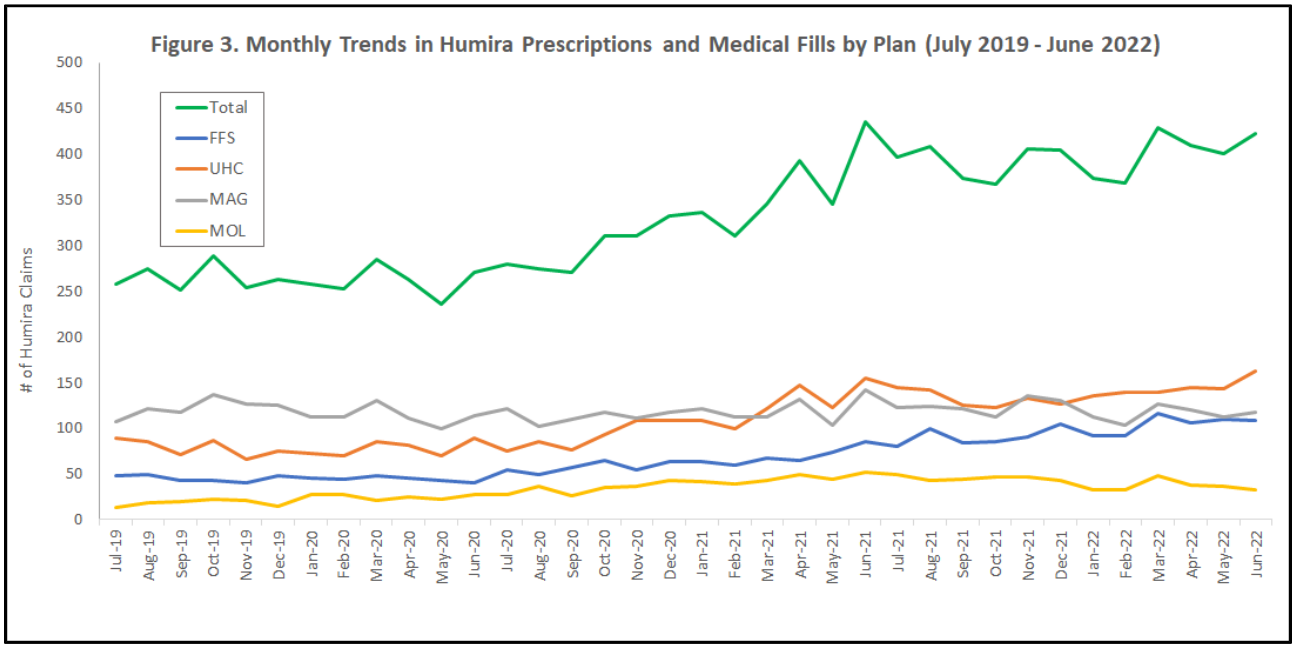


Table 3b presents monthly trends in Humira utilization by FDA-approved indications. Overall 95.4% of claims had an FDA-approved indication associated with that claim in the data. The top 4 indications associated with Humira claims were rheumatoid arthritis, Crohn's disease, plaque psoriasis, and hidradenitis suppurativa.

Table 3b. Monthly Trends in Humira Utilization by FDA-approved Indications (July 2019 - June 2022)

Month	Total	Claims with on-label use*	Percent on-label claims	On-label use by indication								
				Ankylosing spondylitis	Crohn's disease	Hidradenitis suppurativa	Plaque psoriasis	Polyarticular juvenile idiopathic arthritis	Psoriatic arthritis	Rheumatoid arthritis	Ulcerative colitis	Uveitis
Jul-19	259	250	96.5%	12	62	34	57	11	32	81	32	14
Aug-19	276	264	95.7%	8	66	40	68	16	42	83	33	10
Sep-19	252	238	94.4%	8	60	36	56	22	33	73	22	11
Oct-19	290	276	95.2%	10	75	34	62	26	33	84	35	12
Nov-19	256	246	96.1%	11	53	32	59	23	30	73	27	17
Dec-19	263	254	96.6%	10	62	41	59	22	30	79	22	11
Jan-20	259	243	93.8%	7	63	28	60	24	30	74	27	13
Feb-20	255	245	96.1%	7	70	27	54	31	32	74	27	14
Mar-20	285	273	95.8%	11	67	36	69	28	36	85	29	15
Apr-20	265	251	94.7%	8	65	29	61	25	32	83	29	14
May-20	237	230	97.0%	3	71	28	51	23	27	69	19	14
Jun-20	272	264	97.1%	12	76	33	62	25	33	81	28	11
Jul-20	280	269	96.1%	12	70	40	62	29	32	73	28	16
Aug-20	274	265	96.7%	14	73	34	63	32	39	73	21	15
Sep-20	270	264	97.8%	11	69	39	57	28	34	79	22	18
Oct-20	311	299	96.1%	8	85	45	62	32	37	88	28	18
Nov-20	311	298	95.8%	13	78	43	68	37	42	84	30	22
Dec-20	332	318	95.8%	11	82	55	65	36	41	93	26	21
Jan-21	336	320	95.2%	13	85	47	69	37	40	88	31	20
Feb-21	312	295	94.6%	14	71	47	66	35	43	92	24	19
Mar-21	345	328	95.1%	11	88	55	74	30	47	93	31	15
Apr-21	394	377	95.7%	27	99	61	69	37	42	102	33	26
May-21	346	331	95.7%	19	72	70	65	30	42	97	24	29
Jun-21	437	415	95.0%	22	108	71	83	44	49	108	32	34
Jul-21	398	372	93.5%	17	92	75	84	42	52	101	34	25
Aug-21	409	388	94.9%	16	94	80	84	39	50	111	30	25
Sep-21	375	358	95.5%	19	91	79	67	41	40	89	35	28
Oct-21	368	352	95.7%	17	93	71	72	36	47	87	30	32
Nov-21	406	388	95.6%	19	96	88	77	41	45	99	40	34
Dec-21	405	383	94.6%	13	93	80	93	35	55	105	35	30
Jan-22	373	360	96.5%	13	98	78	60	37	39	97	38	26
Feb-22	368	350	95.1%	10	98	80	64	26	40	90	34	26
Mar-22	429	409	95.3%	12	118	82	82	38	45	99	39	33
Apr-22	410	381	92.9%	13	98	91	73	28	50	95	44	30
May-22	402	380	94.5%	14	107	83	71	34	39	96	43	33
Jun-22	423	399	94.3%	17	101	106	69	34	38	96	37	26
Total	***11,883***	***11,333***	***95.4%***	***462***	***2,949***	***1,998***	***2,417***	***1,114***	***1,418***	***3,174***	***1,099***	***757***

**On-label use was described as having a diagnosis for FDA-approved indications - Ankylosing spondylitis, Crohn's disease, Hidradenitis suppurative, Plaque psoriasis, Polyarticular juvenile idiopathic arthritis, Psoriatic arthritis, Rheumatoid arthritis, Ulcerative colitis, or Uveitis on or in a 2-year period prior to the first fill date of Humira.*

Note: A beneficary could have more than one clinical indication mentioned above. Hence, the summed total of claims for individual indications will not be equal to total number on on-label claims.

FDA-labeled dosing for Humira varies across indications. For most indications, FDA-labeled adult maintenance dosing is 40mg subcutaneously (SQ) every 2 weeks. For patients with hidradenitis suppurativa, FDA-labeled maintenance dosing is 40mg SQ every week or 80mg SQ every 2 weeks. Additionally, for those with moderate to severe rheumatoid arthritis not taking methotrexate, the dose can also be increased to 40mg SQ every week or 80mg SQ every 2 weeks.[19] The most commonly prescribed Humira dosage forms for maintenance dosing in Medicaid are the 40mg or 80mg injection pens. To assess dosing, three maintenance dosing thresholds were set: beneficiaries with > 2 vials per month for 40mg, beneficiaries with > 4 vials per month for 40mg, and beneficiaries with > 2 vials per month for 80mg. (Table 3c)

- > 2 vials per month for 40mg – According to FDA-approved dosing regimens, only beneficiaries being treated for hidradenitis suppurativa or RA not taking methotrexate should exceed 2 vials per month. The proportion of beneficiaries with > 2 vials per month for 40mg has risen over the course of the study period from 27.1% in the last half of 2019 to 33.7% in the first half of 2022.
- > 4 vials per month for 40mg and > 2 vials per month for 80mg – Dosages exceeding these levels are above any FDA-approved dosing regimens. Although claims exceeding these thresholds were low, the numbers and proportions increased throughout the study period.

Table 3c. Monthly Trends in Humira Dosing by Strength								
Month	Total # of Humira claims	Number of vials per month for maintenance claims*	Number of vials >2 per month for 40mg	Proportion of vials >2 per month for 40mg	Number of vials >4 per month for 40mg	Proportion of vials >4 per month for 40mg	Number of vials >2 per month for 80mg	Proportion of vials >2 per month for 80mg
Jul-19	259	25	5	20.0%	0	*0.0%*	0	*0.0%*
Aug-19	276	193	66	34.2%	2	*1.0%*	0	*0.0%*
Sep-19	252	206	59	28.6%	4	*1.9%*	0	*0.0%*
Oct-19	290	228	69	30.3%	6	*2.6%*	0	*0.0%*
Nov-19	256	219	53	24.2%	2	*0.9%*	0	*0.0%*
Dec-19	263	221	56	25.3%	8	*3.6%*	1	*0.5%*
Jan-20	259	213	57	26.8%	7	*3.3%*	3	*1.4%*
Feb-20	255	208	52	25.0%	2	*1.0%*	0	*0.0%*
Mar-20	285	238	71	29.8%	9	*3.8%*	2	*0.8%*
Apr-20	265	225	67	29.8%	4	*1.8%*	0	*0.0%*
May-20	237	205	54	26.3%	6	*2.9%*	2	*1.0%*
Jun-20	272	225	72	32.0%	5	*2.2%*	2	*0.9%*
Jul-20	280	230	68	29.6%	7	*3.0%*	2	*0.9%*
Aug-20	274	229	66	28.8%	6	*2.6%*	2	*0.9%*
Sep-20	270	234	67	28.6%	6	*2.6%*	0	*0.0%*
Oct-20	311	252	67	26.6%	5	*2.0%*	1	*0.4%*
Nov-20	311	265	69	26.0%	7	*2.6%*	1	*0.4%*
Dec-20	332	274	87	31.8%	6	*2.2%*	2	*0.7%*
Jan-21	336	282	89	31.6%	7	*2.5%*	1	*0.4%*
Feb-21	312	278	71	25.5%	5	*1.8%*	1	*0.4%*
Mar-21	345	282	87	30.9%	11	*3.9%*	4	*1.4%*
Apr-21	394	301	109	36.2%	19	*6.3%*	3	*1.0%*
May-21	346	279	98	35.1%	10	*3.6%*	2	*0.7%*
Jun-21	437	329	123	37.4%	26	*7.9%*	3	*0.9%*
Jul-21	398	313	105	33.5%	21	*6.7%*	5	*1.6%*
Aug-21	409	323	119	36.8%	14	*4.3%*	9	*2.8%*
Sep-21	375	314	97	30.9%	11	*3.5%*	3	*1.0%*
Oct-21	368	311	102	32.8%	8	*2.6%*	3	*1.0%*
Nov-21	406	311	114	36.7%	22	*7.1%*	6	*1.9%*
Dec-21	405	313	111	35.5%	17	*5.4%*	5	*1.6%*
Jan-22	373	298	102	34.2%	22	*7.4%*	6	*2.0%*
Feb-22	368	293	92	31.4%	11	*3.8%*	3	*1.0%*
Mar-22	429	328	119	36.3%	17	*5.2%*	9	*2.7%*
Apr-22	410	309	108	35.0%	17	*5.5%*	9	*2.9%*
May-22	402	324	107	33.0%	13	*4.0%*	12	*3.7%*
Jun-22	423	331	106	32.0%	21	*6.3%*	14	*4.2%*
Total	***11883***	***9409***	***2964***	***31.5%***	***364***	***3.9%***	***116***	***1.2%***

**For each beneficiary, the first claim during the study period is considered the induction claim, all other claims are treated as maintenance claims.*

Table 3d provides diagnostic characteristics for beneficiaries receiving Humira above each dosing threshold.

- 58.2% (591) of beneficiaries received > 2 vials per month of the 40mg injections. For those beneficiaries, the most common diagnoses found in claims data were rheumatoid arthritis, hidradenitis suppurativa, Crohn's disease, and plaque psoriasis.
- For the 16.5% (167) beneficiaries with claims for >4 vials per month for the 40 mg vials, hidradenitis suppurativa was the most common indication followed by Crohn's disease.
- For the 7.7% (78) beneficiaries with claims for >2 vials per month for the 80mg vials, again hidradenitis suppurativa was the most common indication followed by Crohn's disease.

Table 3d. Clinical Characteristics of Humira Users								
	Total # of beneficiaries		Total # of beneficiaries with >2 vials per month for 40mg		Total # of beneficiaries with >4 vials per month for 40mg		Total # of beneficiaries with >2vials per month for 80mg	
	N	%	N	%	N	%	N	%
All Humira Users	***1015***	***100.0%***	***591***	***100.0%***	***167***	***100.0%***	***78***	***100.0%***
# of Unique Humira Users with FDA-approved Diagnoses*	*955*	*94.1%*	*556*	*94.1%*	*157*	*94.0%*	*70*	*89.7%*
Ankylosing spondylitis	52	*5.1%*	26	*4.4%*	4	*2.4%*	0	*0.0%*
Crohn's disease	193	*19.0%*	116	*19.6%*	31	*18.6%*	23	*29.5%*
Hidradenitis suppurativa	173	*17.0%*	135	*22.8%*	79	*47.3%*	30	*38.5%*
Plaque psoriasis	217	*21.4%*	107	*18.1%*	20	*12.0%*	12	*15.4%*
Polyarticular juvenile idiopathic arthritis	81	*8.0%*	48	*8.1%*	15	*9.0%*	0	*0.0%*
Psoriatic arthritis	132	*13.0%*	60	*10.2%*	10	*6.0%*	6	*7.7%*
Rheumatoid arthritis	299	*29.5%*	164	*27.7%*	23	*13.8%*	4	*5.1%*
Ulcerative colitis	91	*9.0%*	52	*8.8%*	9	*5.4%*	10	*12.8%*
Uveitis	58	*5.7%*	34	*5.8%*	7	*4.2%*	1	*1.3%*

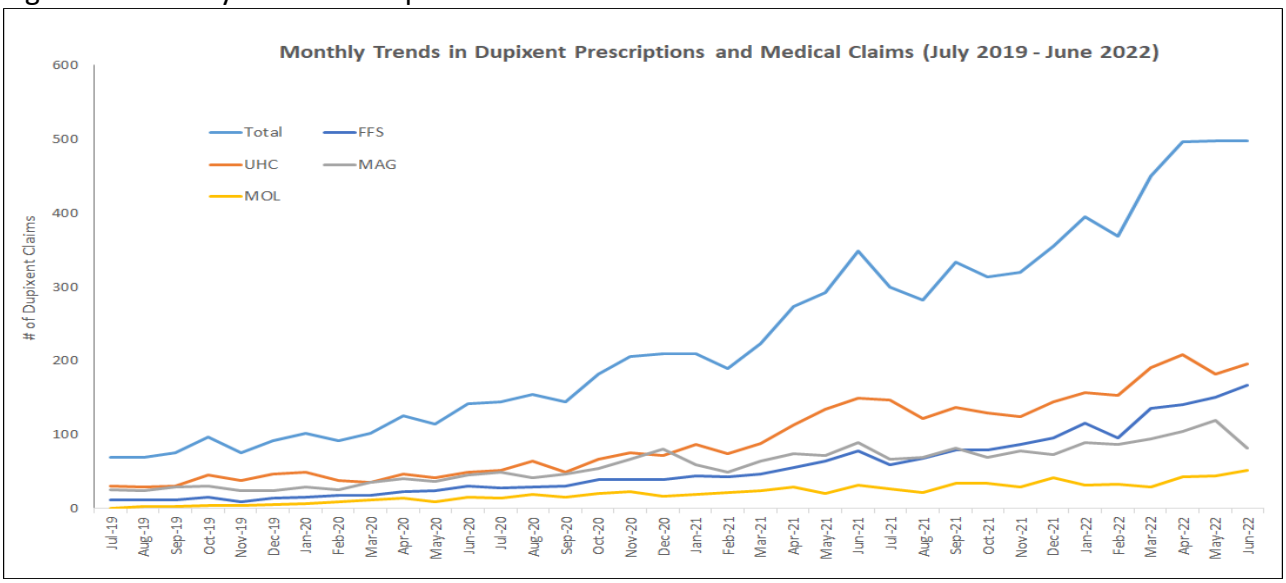
**Beneficiaries were considered to have a diagnosis for FDA-approved indications if they had a claim for the above conditions on or in a 2-year period prior to their first fill of Humira. Out of the 9409 vials for maintenance claims, 185 vials had a fill dose of 20mg. Since no clinical threshold was established for 20mg, these vials were excluded from the analysis*

Tables 3c and 3d provide evidence to suggest there are circumstances where Medicaid beneficiaries are receiving Humira at doses exceeding FDA labeling. In the literature supporting such dose escalations for Humira, defined clinical criteria or disease activity measures were utilized to establish criteria for dose escalations and evaluate outcomes. [1,2,5,6,8,10,12,15,16] Currently, according to Medicaid's Universal Preferred Drug List, products classified under cytokine and CAM antagonists (the drug category Humira is classified) are subject to approved age and documented diagnosis for appropriate indication requirements.[20] There are no current maximum dose criteria or criteria requiring justification for dose escalations.

Dupilumab (Dupixent):

Dupixent has experienced tremendous growth in utilization over the study period. Monthly utilization of Dupixent has increased by over 600% comparing the number of claims in July 2019 and June 2022.

Figure 4: Monthly Trends in Dupixent Utilization



Examining the demographic characteristics of those receiving Dupixent shows that they were predominantly younger than 18 years, female, and African American. (Table 4a)

Table 4a. Demographic Characteristics of Beneficiaries Prescribed Dupixent (July 2019 - June 2022)

	FFS		UHC		Magnolia		Molina		Total*
Age Category (yrs)									
0 - 12	66	38.8%	94	40.3%	91	43.3%	35	43.2%	286
13 - 17	47	27.6%	76	32.6%	59	28.1%	13	16.0%	195
18 - 44	49	28.8%	47	20.2%	37	17.6%	28	34.6%	161
45 - 64	7	4.1%	16	6.9%	23	11.0%	5	6.2%	51
65 and above	1	0.6%	0	0.0%	0	0.0%	0	0.0%	1
Total	***170***		***233***		***210***		***81***		***694***
Gender									
Female	113	66.5%	156	67.0%	132	62.9%	58	71.6%	459
Male	57	33.5%	77	33.0%	78	37.1%	23	28.4%	235
Total	***170***		***233***		***210***		***81***		***694***
Race									
Caucasian	42	24.7%	58	24.9%	44	21.0%	19	23.5%	163
African American	117	68.8%	153	65.7%	156	74.3%	56	69.1%	482
Other	11	6.5%	22	9.4%	10	4.8%	6	7.4%	49
Total*	***170***		***233***		***210***		***81***		***694***

NOTE: Age and health plan were assessed at the first Dupixent claim during the study period.

As displayed in Table 4b, 89.5% of claims had an FDA-approved indication for treatment in claims data. The primary indication associated with Dupixent claims was atopic dermatitis.

Table 4b. Monthly Trends in Dupixent Utilization by FDA-approved Indications (July 2019 - June 2022)							
Month	Total	Claims with on-label use*	Percent on-label claims	On-label use by indication			
				Moderate to severe Asthma	Atopic dermatitis	Nasal polyps	Eosinophilic esophagitis
Jul-19	70	65	92.9%	20	61	0	0
Aug-19	70	66	94.3%	19	62	1	0
Sep-19	76	71	93.4%	21	67	2	0
Oct-19	97	88	90.7%	29	83	3	0
Nov-19	76	69	90.8%	19	66	2	0
Dec-19	92	85	92.4%	24	81	2	0
Jan-20	103	93	90.3%	27	86	5	0
Feb-20	93	83	89.2%	29	74	4	0
Mar-20	103	89	86.4%	28	84	3	0
Apr-20	128	116	90.6%	33	108	6	0
May-20	114	96	84.2%	26	90	4	0
Jun-20	144	130	90.3%	45	119	4	1
Jul-20	145	130	89.7%	43	117	5	0
Aug-20	155	140	90.3%	45	129	4	0
Sep-20	145	129	89.0%	44	116	5	0
Oct-20	183	164	89.6%	58	147	8	0
Nov-20	207	186	89.9%	57	167	8	0
Dec-20	211	194	91.9%	65	177	8	0
Jan-21	211	188	89.1%	66	170	9	0
Feb-21	190	172	90.5%	54	158	8	0
Mar-21	225	206	91.6%	66	186	11	0
Apr-21	275	250	90.9%	93	223	16	0
May-21	294	262	89.1%	86	240	12	0
Jun-21	351	318	90.6%	96	283	22	0
Jul-21	303	277	91.4%	105	253	12	0
Aug-21	285	257	90.2%	87	233	16	0
Sep-21	334	302	90.4%	102	277	15	0
Oct-21	316	281	88.9%	86	258	14	0
Nov-21	322	289	89.8%	85	268	15	0
Dec-21	357	316	88.5%	108	283	22	0
Jan-22	399	352	88.2%	124	323	19	0
Feb-22	372	332	89.2%	104	307	17	0
Mar-22	454	402	88.5%	121	374	16	1
Apr-22	500	432	86.4%	137	405	15	1
May-22	501	448	89.4%	135	418	16	1
Jun-22	502	440	87.6%	115	409	15	2
Total	***8,403***	***7,518***	***89.5%***	***2,402***	***6,902***	***344***	***6***

*On-label use was described as having a diagnosis for FDA-approved indications - Moderate to severe asthma, Atopic dermatitis, Nasal polyps, or Eosinophilic esophagitis on or in a 2-year period prior to the first fill of Dupixent.

NOTE: A beneficiary could have more than one clinical indication mentioned above. Hence, the summed total of claims for individual indications will not be equal to total number on on-label claims.

Dupixent's FDA-recommended maintenance dosing is every 2 or 4 weeks, depending on a patient's age or weight, for atopic dermatitis, asthma, and nasal polyps. For eosinophilic esophagitis, Dupixent is recommended to be administered weekly.[21] To assess dosing, a threshold of 2 maintenance doses per month was established. In Table 4c, a very small proportion of claims exceeded the threshold of 2 doses per month, however, that proportion began increasing in March 2022.

Table 4c. Monthly Trends in Dupixent Maintenance Claims Occurring at > 2 Maintenance Doses per Month (July 2019 - June 2022)

Month	Total # of Dupixent claims	Induction claims	Maintenance claims	Maintenance claims with > 2 doses/month	*Proportion of maintenance claims with > 2 doses/month*
Jul-19	70	61	9	0	*0.0%*
Aug-19	70	14	56	0	*0.0%*
Sep-19	76	9	67	4	*6.0%*
Oct-19	97	15	82	0	*0.0%*
Nov-19	76	6	70	0	*0.0%*
Dec-19	92	7	85	3	*3.5%*
Jan-20	103	14	89	0	*0.0%*
Feb-20	93	10	83	3	*3.6%*
Mar-20	103	7	96	0	*0.0%*
Apr-20	128	13	115	3	*2.6%*
May-20	114	6	108	0	*0.0%*
Jun-20	144	20	124	3	*2.4%*
Jul-20	145	21	124	0	*0.0%*
Aug-20	155	16	139	0	*0.0%*
Sep-20	145	13	132	0	*0.0%*
Oct-20	183	22	161	6	*3.7%*
Nov-20	207	28	179	3	*1.7%*
Dec-20	211	14	197	9	*4.6%*
Jan-21	211	16	195	3	*1.5%*
Feb-21	190	18	172	0	*0.0%*
Mar-21	225	15	210	0	*0.0%*
Apr-21	275	20	255	15	*5.9%*
May-21	294	20	274	31	*11.3%*
Jun-21	351	30	321	21	*6.5%*
Jul-21	303	10	293	34	*11.6%*
Aug-21	285	13	272	16	*5.9%*
Sep-21	334	17	317	37	*11.7%*
Oct-21	316	27	289	24	*8.3%*
Nov-21	322	17	305	16	*5.2%*
Dec-21	357	25	332	17	*5.1%*
Jan-22	399	25	374	40	*10.7%*
Feb-22	372	26	346	15	*4.3%*
Mar-22	454	34	420	59	*14.0%*
Apr-22	500	29	471	90	*19.1%*
May-22	501	32	469	77	*16.4%*
Jun-22	502	28	474	90	*19.0%*
Total	***8,403***	***698***	***7,705***	***619***	***8.0%***

Table 4d. Clinical Characteristics of Dupixent Users				
	Total # of beneficiaries		Total # of beneficiaries with > 2 maintenance doses/month	
	N	%	N	%
All Dupixent Users	***698***	***100.0%***	***103***	***100.0%***
# of Unique Dupixent Users with FDA-approved Diagnoses	*623*	*89.3%*	*90*	*87.4%*
Atopic dermatitis	573	*82.1%*	87	*84.5%*
Moderate to severe Asthma	179	*25.6%*	23	*22.3%*
Nasal polyps	22	*3.2%*	2	*1.9%*
Eosinophilic esophagitis	3	*0.4%*	0	*0.0%*
*Beneficiaries were considered to have a diagnosis for FDA-approved indications if they had a claim for the above conditions on or in a 2-year period prior to their first fill of Dupixent.				

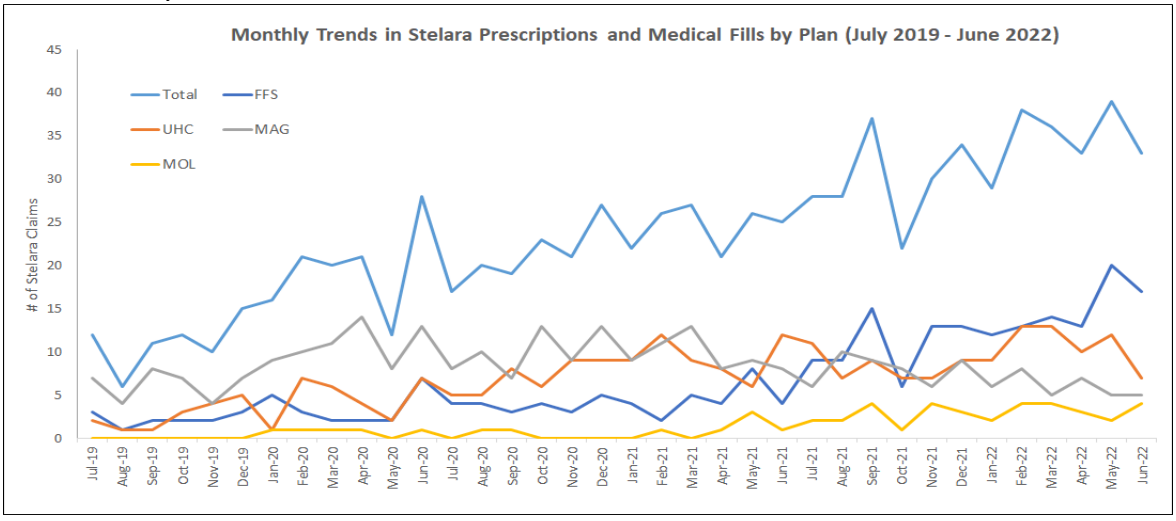
Atopic dermatitis was the most common indication present for any beneficiary receiving Dupixent, regardless of the number of vials they received monthly. For those beneficiaries with claims for more than 2 doses/month, eosinophilic esophagitis was not present in records as an indication for use. (Table 4d)

When referencing Medicaid's manual prior authorization (PA) criteria for Dupixent, available online, there are criteria stating that maintenance dosing will not exceed every other week dosing. These criteria apply to those receiving Dupixent for atopic dermatitis, asthma, and nasal polyps. Published literature examining escalated dosing for Dupixent is sparse at this time.

Ustekinumab (Stelara):

Stelara is a nonpreferred agent on the UPDL but has shown a 175% increase in utilization comparing July 2019 and June 2022. (Figure 5)

Figure 5: Monthly trends in Stelara Utilization



Beneficiaries that received Stelara during the study period were predominantly between the ages of 18-44 yrs, female, and African American. (Table 5a)

Table 5a. Demographic Characteristics of Beneficiaries Prescribed Stelara (July 2019 - June 2022)

	FFS		UHC		Magnolia		Molina		Total*
Age Category (yrs)									
0 - 17	8	23.5%	6	18.8%	9	21.4%	1	11.1%	24
18 - 44	20	58.8%	16	50.0%	25	59.5%	6	66.7%	67
45 - 64	6	17.6%	10	31.3%	8	19.0%	2	22.2%	26
Total	***34***		***32***		***42***		***9***		***117***
Gender									
Female	24	70.6%	26	81.3%	33	78.6%	6	66.7%	89
Male	10	29.4%	6	18.8%	9	21.4%	3	33.3%	28
Total	***34***		***32***		***42***		***9***		***117***
Race									
Caucasian	13	38.2%	14	43.8%	20	47.6%	4	44.4%	51
African American	19	55.9%	17	53.1%	18	42.9%	4	44.4%	58
Other	2	5.9%	1	3.1%	4	9.5%	1	11.1%	8
Total*	***34***		***32***		***42***		***9***		***117***

NOTE: Age and health plan were assessed at the first Stelara claim during the study period.

*118 beneficiaries were prescribed Stelara. 1 beneficiary did not have demographic and plan information.

When examining the trends in Stelara utilization by FDA-approved indications, 97.6% of claims for Stelara had an FDA-approved indication on record. (Table 5b) Crohn's disease was the most common indication associated with Stelara claims.

Table 5b. Monthly Trends in Stelara Utilization by FDA-approved Indications (July 2019 - June 2022)							
Month	Total	Claims with on-label use*	Percent on-label claims	On-label use by indication			
				Psoriatic arthritis	Plaque psoriasis	Crohn's disease	Ulcerative colitis
Jul-19	12	12	100.0%	3	4	8	1
Aug-19	6	6	100.0%	1	2	4	1
Sep-19	11	11	100.0%	4	5	6	1
Oct-19	12	12	100.0%	2	6	6	1
Nov-19	10	10	100.0%	2	5	4	3
Dec-19	15	15	100.0%	2	5	11	1
Jan-20	16	16	100.0%	3	5	8	6
Feb-20	21	21	100.0%	2	6	14	3
Mar-20	20	20	100.0%	4	6	12	4
Apr-20	21	21	100.0%	2	5	17	4
May-20	12	12	100.0%	1	4	8	2
Jun-20	28	28	100.0%	6	9	19	4
Jul-20	17	17	100.0%	6	8	8	2
Aug-20	20	20	100.0%	1	8	14	2
Sep-20	19	18	94.7%	2	4	14	6
Oct-20	23	23	100.0%	5	6	16	3
Nov-20	21	21	100.0%	3	7	11	5
Dec-20	27	27	100.0%	7	10	17	6
Jan-21	22	21	95.5%	2	6	14	7
Feb-21	26	25	96.2%	6	10	14	3
Mar-21	27	27	100.0%	3	9	16	11
Apr-21	22	22	100.0%	4	6	16	5
May-21	26	25	96.2%	1	8	16	6
Jun-21	25	24	96.0%	1	10	13	9
Jul-21	28	28	100.0%	3	8	19	6
Aug-21	28	27	96.4%	0	7	19	9
Sep-21	37	36	97.3%	3	13	23	9
Oct-21	22	22	100.0%	3	6	16	5
Nov-21	30	29	96.7%	2	9	22	5
Dec-21	34	33	97.1%	1	9	25	10
Jan-22	29	28	96.6%	2	5	25	5
Feb-22	38	36	94.7%	1	9	28	8
Mar-22	36	34	94.4%	2	7	28	8
Apr-22	33	33	100.0%	4	10	27	8
May-22	39	36	92.3%	0	9	25	11
Jun-22	33	30	90.9%	1	9	21	10
Total	***846***	***826***	***97.6%***	***95***	***255***	***564***	***190***

*On-label use was described as having a diagnosis for FDA-approved indications - Psoriasis, Psoriatic arthropathy, Crohn's disease, or Ulcerative colitis on or in a 2-year period prior to the first fill date of Stelara.

NOTE: A beneficiary could have more than one clinical indication mentioned above. Hence, the summed total of claims for individual indications will not be equal to total number on on-label claims.

Stelara has indications for psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis. The FDA-labeled maintenance dosing regimen for psoriasis and psoriatic arthritis is every 12 weeks. The recommended maintenance dosing regimen for Crohn's disease and ulcerative colitis is every 8 weeks.[22] Based on these dosing regimens, a threshold of 8 weeks was established to determine the frequency of dosing that exceeded FDA-labeled dosing. (Table 5c)

Table 5c. Monthly Trends in Stelara Maintenance Claims Occuring at < 8 Week Dosing Intervals					
Month	**Total # of Stelara claims**	**Induction claims**	**Maintenance claims**	**Maintenance claims occuring at < 8-week intervals**	***Proportion of maintence claims with < 8-week intervals***
Jul-19	12	12	0	0	*0.0%*
Aug-19	6	1	5	5	*100.0%*
Sep-19	11	4	7	3	*42.9%*
Oct-19	12	3	9	4	*44.4%*
Nov-19	10	4	6	2	*33.3%*
Dec-19	15	4	11	5	*45.5%*
Jan-20	16	4	12	5	*41.7%*
Feb-20	21	6	15	7	*46.7%*
Mar-20	20	5	15	11	*73.3%*
Apr-20	21	1	20	10	*50.0%*
May-20	12	1	11	6	*54.5%*
Jun-20	28	5	23	6	*26.1%*
Jul-20	17	1	16	10	*62.5%*
Aug-20	20	2	18	7	*38.9%*
Sep-20	19	5	14	8	*57.1%*
Oct-20	23	2	21	11	*52.4%*
Nov-20	21	5	16	9	*56.3%*
Dec-20	27	3	24	11	*45.8%*
Jan-21	22	2	20	11	*55.0%*
Feb-21	26	3	23	8	*34.8%*
Mar-21	27	2	25	12	*48.0%*
Apr-21	22	2	20	10	*50.0%*
May-21	26	4	22	10	*45.5%*
Jun-21	25	3	22	15	*68.2%*
Jul-21	28	2	26	10	*38.5%*
Aug-21	28	3	25	14	*56.0%*
Sep-21	37	3	34	21	*61.8%*
Oct-21	22	1	21	11	*52.4%*
Nov-21	30	3	27	14	*51.9%*
Dec-21	34	4	30	13	*43.3%*
Jan-22	29	3	26	15	*57.7%*
Feb-22	38	5	33	14	*42.4%*
Mar-22	36	3	33	24	*72.7%*
Apr-22	33	1	32	17	*53.1%*
May-22	39	6	33	19	*57.6%*
Jun-22	33	0	33	19	*57.6%*
Total	***846***	***118***	***728***	***377***	***51.8%***
NOTE: For 377 claims with <8 week interval dosing, average difference between two Stelara claims was 34.05 days (SD: 14.48), Median: 32 days (lower quartile: 27 days; upper quartile: 48 days) indicating a probable every 4-5 week dosing interval.					

According to the results in Table 5c, 51.8% (377) of claims for Stelara were less than 8 weeks apart. For these 377 claims, the average length of time between two Stelara claims was just over

34 days indicating a probable dosing frequency of every 4-5 weeks. The most common diagnosis associated with Stelara claims, regardless of dosing frequency, was Crohn's disease. (Table 5d)

Table 5d. Clinical Characteristics of Stelara Users

	Total # of beneficiaries		Total # of beneficiaries with <8-wk dosing	
	N	%	N	%
All Stelara Users	***118***	***100.0%***	***87***	***100.0%***
# of Unique Stelara Users with FDA-approved Diagnoses	*113*	*95.8%*	*85*	*97.7%*
Crohn's disease	71	*60.2%*	53	*60.9%*
Plaque psoriasis	39	*33.1%*	31	*35.6%*
Ulcerative colitis	30	*25.4%*	21	*24.1%*
Psoriatic arthritis	18	*15.3%*	13	*14.9%*

*Beneficiaries were considered to have a diagnosis for FDA-approved indications if they had a claim for the above conditions on or in a 2-year period prior to their first fill of Stelara.

There is literature supporting escalated dosing of Stelara in patients with suboptimal response after an initial trial or loss of response.[4,7,11,23] In these studies various disease activity measures were utilized to establish criteria for enrollment and assess outcomes. Currently, DOM requires a clinical review for Stelara to be approved, but no defined clinical criteria are established to determine when escalated dosing is appropriate.

Infliximab (Avsola, Inflectra, Remicade, Renflexis):

Prior to January 2022, all forms of infliximab were classified as nonpreferred on Medicaid's UPDL. Beginning January 2022, Avsola became preferred. For the purposes of this portion of the report, Avsola was presented separately while the other agents were combined for analyses.

When combining the demographic information for all four agents together we found that the majority of beneficiaries that received infliximab products were between the ages of 18-44 years, female, and African American. (Tables 6a and 7a)

Table 6a. Demographic Characteristics of Beneficiaries Prescribed Avsola (July 2019 - June 2022)									
	FFS		UHC		Magnolia		Molina		Total*
Age Category (yrs)									
0 - 17	2	50.0%	2	33.3%	1	33.3%	1	50.0%	6
18 - 44	2	50.0%	2	33.3%	2	66.7%	1	50.0%	7
45 - 64	0	0.0%	2	33.3%	0	0.0%	0	0.0%	2
Total	***4***		***6***		***3***		***2***		***15***
Gender									
Female	1	25.0%	5	83.3%	2	66.7%	1	50.0%	9
Male	3	75.0%	1	16.7%	1	33.3%	1	50.0%	6
Total	***4***		***6***		***3***		***2***		***15***
Race									
Caucasian	2	50.0%	1	16.7%	0	0.0%	2	100.0%	5
African American	2	50.0%	3	50.0%	3	100.0%	0	0.0%	8
Other	0	0.0%	2	33.3%	0	0.0%	0	0.0%	2
Total	***4***		***6***		***3***		***2***		***15***

Table 7a. Demographic Characteristics of Beneficiaries Prescribed Inflectra, Remicade or Renflexis (July 2019 - June 2022)									
	FFS		UHC		Magnolia		Molina		Total*
Age Category (yrs)									
0 - 17	14	20.9%	29	44.6%	32	38.6%	2	12.5%	77
18 - 44	31	46.3%	26	40.0%	38	45.8%	8	50.0%	103
45 - 64	19	28.4%	10	15.4%	13	15.7%	6	37.5%	48
65 and above	3	4.5%	0	0.0%	0	0.0%	0	0.0%	3
Total	***67***		***65***		***83***		***16***		***231***
Gender									
Female	45	67.2%	42	64.6%	57	68.7%	12	75.0%	156
Male	22	32.8%	23	35.4%	26	31.3%	4	25.0%	75
Total	***67***		***65***		***83***		***16***		***231***
Race									
Caucasian	18	26.9%	27	41.5%	26	31.3%	4	25.0%	75
African American	44	65.7%	33	50.8%	50	60.2%	10	62.5%	137
Other	5	7.5%	5	7.7%	7	8.4%	2	12.5%	19
Total*	***67***		***65***		***83***		***16***		***231***
NOTE: Age and health plan were assessed at the first claim during the study period.									
*234 beneficiaries were prescribed Inflectra, Remicade or Renflexis. 3 beneficiaries did not have demographic and plan information.									

Tables 6b and 7b show that the number of monthly claims for infliximab products has not increased during the study period similar to that of many other immunomodulators. Monthly claims were at 71 in July 2019, peaked at 98 in August 2021, and were at 32 in June 2022. Although Avsola became the preferred product in January 2022, the nonpreferred agents continued to make up the largest portion of infliximab claims. The leading indications associated with claims for infliximab products were Crohn's disease and Ulcerative colitis. The proportion of claims with an FDA-labeled indication in claims data was 71.1% for Avsola and 86.1% for the nonpreferred agents (Inflectra, Remicade, and Renflexis).

Table 6b. Monthly Trends in Avsola Utilization by FDA-approved Indications (July 2019 - June 2022)

Month	Total	Claims with on-label use*	Percent on-label claims	On-label use by indication					
				Rheumatoid arthritis	Psoriatic arthritis	Ankylosing spondylitis	Plaque psoriasis	Crohn's disease	Ulcerative colitis
Jul-19	0	0		0	0	0	0	0	0
Aug-19	0	0		0	0	0	0	0	0
Sep-19	0	0		0	0	0	0	0	0
Oct-19	0	0		0	0	0	0	0	0
Nov-19	0	0		0	0	0	0	0	0
Dec-19	0	0		0	0	0	0	0	0
Jan-20	0	0		0	0	0	0	0	0
Feb-20	0	0		0	0	0	0	0	0
Mar-20	0	0		0	0	0	0	0	0
Apr-20	0	0		0	0	0	0	0	0
May-20	0	0		0	0	0	0	0	0
Jun-20	0	0		0	0	0	0	0	0
Jul-20	0	0		0	0	0	0	0	0
Aug-20	0	0		0	0	0	0	0	0
Sep-20	0	0		0	0	0	0	0	0
Oct-20	0	0		0	0	0	0	0	0
Nov-20	0	0		0	0	0	0	0	0
Dec-20	0	0		0	0	0	0	0	0
Jan-21	0	0		0	0	0	0	0	0
Feb-21	0	0		0	0	0	0	0	0
Mar-21	0	0		0	0	0	0	0	0
Apr-21	0	0		0	0	0	0	0	0
May-21	0	0		0	0	0	0	0	0
Jun-21	0	0		0	0	0	0	0	0
Jul-21	0	0		0	0	0	0	0	0
Aug-21	0	0		0	0	0	0	0	0
Sep-21	2	2	100.0%	0	0	2	0	0	0
Oct-21	1	1	100.0%	0	0	1	0	0	0
Nov-21	2	2	100.0%	0	2	0	2	0	0
Dec-21	2	2	100.0%	1	0	1	0	0	0
Jan-22	5	0	0.0%	0	0	0	0	0	0
Feb-22	1	1	100.0%	0	0	0	0	0	1
Mar-22	3	0	0.0%	0	0	0	0	0	0
Apr-22	4	2	50.0%	0	0	0	0	1	2
May-22	12	10	83.3%	1	0	0	0	8	5
Jun-22	13	12	92.3%	1	0	0	0	8	5
Total	***45***	***32***	***71.1%***	***3***	***2***	***4***	***2***	***17***	***13***

*On-label use was described as having a diagnosis for FDA-approved indications - Rheumatoid arthritis, Psoriasis, Ankylosing spondylitis, Psoriatic arthropathy, Crohn's disease, or Ulcerative colitis on or in a 2-year period prior to the first fill date of Avsola.

NOTE: A beneficiary could have more than one clinical indication mentioned above. Hence, the summed total of claims for individual indications will not be equal to total number on on-label claims.

Table 7b. Monthly Trends in Inflectra, Remicade and Renflexis Utilization by FDA-approved Indications (July 2019 - June 2022)									
Month	Total	Claims with on-label use*	Percent on-label claims	On-label use by indication					
				Rheumatoid arthritis	Psoriatic arthritis	Ankylosing spondylitis	Plaque psoriasis	Crohn's disease	Ulcerative colitis
Jul-19	71	65	91.5%	12	4	3	4	40	19
Aug-19	52	45	86.5%	8	5	2	6	27	15
Sep-19	64	59	92.2%	12	5	3	4	36	20
Oct-19	68	61	89.7%	8	5	3	4	42	21
Nov-19	44	38	86.4%	5	2	1	1	26	15
Dec-19	66	59	89.4%	14	5	3	5	33	22
Jan-20	57	53	93.0%	7	3	1	4	35	17
Feb-20	48	39	81.3%	10	5	4	5	23	14
Mar-20	63	55	87.3%	6	5	2	6	38	16
Apr-20	61	52	85.2%	11	2	3	3	36	19
May-20	61	54	88.5%	8	4	1	4	37	19
Jun-20	59	51	86.4%	12	2	2	3	32	20
Jul-20	58	50	86.2%	8	2	1	2	34	20
Aug-20	59	49	83.1%	11	4	2	4	34	13
Sep-20	72	61	84.7%	13	3	1	2	40	22
Oct-20	59	50	84.7%	7	1	3	1	36	20
Nov-20	70	58	82.9%	12	4	2	3	43	20
Dec-20	75	62	82.7%	11	3	1	2	43	21
Jan-21	73	61	83.6%	12	2	4	2	39	24
Feb-21	66	55	83.3%	11	2	2	1	42	16
Mar-21	80	66	82.5%	11	2	2	1	43	26
Apr-21	88	76	86.4%	12	3	4	2	55	33
May-21	79	66	83.5%	8	3	2	1	45	25
Jun-21	92	80	87.0%	13	4	3	1	55	26
Jul-21	83	73	88.0%	8	2	4	1	51	25
Aug-21	98	86	87.8%	10	4	3	4	64	35
Sep-21	81	67	82.7%	9	1	3	1	50	26
Oct-21	77	67	87.0%	8	2	3	3	48	25
Nov-21	87	75	86.2%	8	2	1	1	57	31
Dec-21	79	70	88.6%	11	2	4	0	53	22
Jan-22	17	14	82.4%	1	1	0	0	14	3
Feb-22	19	15	78.9%	1	1	0	0	13	5
Mar-22	23	19	82.6%	1	1	0	0	17	6
Apr-22	15	13	86.7%	1	1	0	0	13	1
May-22	20	17	85.0%	1	0	0	0	14	6
Jun-22	19	16	84.2%	2	2	0	0	14	3
Total	***2203***	***1897***	86.1%	***303***	***99***	***73***	***81***	***1322***	***671***

*On-label use was described as having a diagnosis for FDA-approved indications - Rheumatoid arthritis, Psoriasis, Ankylosing spondylitis, Psoriatic arthropathy, Crohn's disease, or Ulcerative colitis on or in a 2-year period prior to the respective first fill date of Inflectra, Remicade and Renflexis. However, Psoriasis is not included for Inflectra.

NOTE: A beneficiary could have more than one clinical indication mentioned above. Hence, the summed total of claims for individual indications will not be equal to total number on on-label claims.

FDA-labeled dosing regimens for infliximab products are:

- Every 8 weeks for Crohn's disease, ulcerative colitis, psoriatic arthritis, and plaque psoriasis;
- Every 6 weeks for ankylosing spondylitis;
- Every 8 weeks for rheumatoid arthritis but may increase to every 4 weeks in some patients.[24–27]

Based on these recommendations, a threshold of every 8 weeks was established to examine maintenance dosing frequency. In Tables 6c and 7c, it can be seen that 93.3% of claims for Avsola and 65.7% of the claims for the other infliximab agents were at less than 8-week intervals. For all agents, Crohn's disease and ulcerative colitis were the most common indications for use associated with claims. (Tables 6d and 7d) Both of these indications have recommended dosing at 8-week intervals. Similar to other immunomodulators assessed in this project, the literature supporting dose escalation with infliximab includes criteria for determining the appropriateness of dose escalation and disease activity measures to assess outcomes.[1,3,5] Currently DOM does not have defined clinical criteria established to determine when escalated dosing is appropriate.

Table 6c. Monthly Trends in Avsola Maintenance Claims Occurring at < 8 Week Dosing Intervals					
Month	**Total # of Avsola claims**	**Induction claims**	**Maintenance claims**	**Maintenance claims occurring at < 8-week intervals**	***Proportion of maintenance claims with < 8-week intervals***
Jul-19	0	0	0	0	
Aug-19	0	0	0	0	
Sep-19	0	0	0	0	
Oct-19	0	0	0	0	
Nov-19	0	0	0	0	
Dec-19	0	0	0	0	
Jan-20	0	0	0	0	
Feb-20	0	0	0	0	
Mar-20	0	0	0	0	
Apr-20	0	0	0	0	
May-20	0	0	0	0	
Jun-20	0	0	0	0	
Jul-20	0	0	0	0	
Aug-20	0	0	0	0	
Sep-20	0	0	0	0	
Oct-20	0	0	0	0	
Nov-20	0	0	0	0	
Dec-20	0	0	0	0	
Jan-21	0	0	0	0	
Feb-21	0	0	0	0	
Mar-21	0	0	0	0	
Apr-21	0	0	0	0	
May-21	0	0	0	0	
Jun-21	0	0	0	0	
Jul-21	0	0	0	0	
Aug-21	0	0	0	0	
Sep-21	2	1	1	1	
Oct-21	1	0	1	1	*100.0%*
Nov-21	2	1	1	1	*100.0%*
Dec-21	2	1	1	1	*100.0%*
Jan-22	5	1	4	4	*100.0%*
Feb-22	1	1	0	0	
Mar-22	3	0	3	3	*100.0%*
Apr-22	4	1	3	2	*66.7%*
May-22	12	6	6	6	*100.0%*
Jun-22	13	3	10	9	*90.0%*
Total	***45***	***15***	***30***	***28***	***93.3%***

NOTE: For 28 claims with <8 week interval dosing, average difference between two Avsola claims was 18.25 days (SD: 13.37), Median: 16 days (lower quartile: 7 days, upper quartile: 28 days).

Table 7c. Monthly Trends in Inflectra, Remicade, Renflexis Maintenance Claims Occurring at < 8 Week Dosing Intervals					
Month	**Total # of Inflectra, Remicade, and Renflexis claims**	**Induction claims**	**Maintenance claims**	**Maintenance claims occurring at < 8-week intervals**	***Proportion of maintenance claims with < 8-week intervals***
Jul-19	71	65	6	6	*0.0%*
Aug-19	52	24	28	24	*85.7%*
Sep-19	64	9	55	39	*70.9%*
Oct-19	68	5	63	46	*73.0%*
Nov-19	44	2	42	29	*69.0%*
Dec-19	66	5	61	38	*62.3%*
Jan-20	57	9	48	31	*64.6%*
Feb-20	48	5	43	29	*67.4%*
Mar-20	63	7	56	35	*62.5%*
Apr-20	61	9	52	31	*59.6%*
May-20	61	3	58	34	*58.6%*
Jun-20	59	7	52	36	*69.2%*
Jul-20	58	4	54	37	*68.5%*
Aug-20	59	10	49	30	*61.2%*
Sep-20	72	7	65	43	*66.2%*
Oct-20	59	5	54	35	*64.8%*
Nov-20	70	8	62	46	*74.2%*
Dec-20	75	5	70	44	*62.9%*
Jan-21	73	5	68	41	*60.3%*
Feb-21	66	5	61	35	*57.4%*
Mar-21	80	10	70	39	*55.7%*
Apr-21	88	11	77	46	*59.7%*
May-21	79	7	72	47	*65.3%*
Jun-21	92	8	84	56	*66.7%*
Jul-21	83	9	74	48	*64.9%*
Aug-21	98	14	84	53	*63.1%*
Sep-21	81	4	77	51	*66.2%*
Oct-21	77	6	71	43	*60.6%*
Nov-21	87	3	84	56	*66.7%*
Dec-21	79	8	71	44	*62.0%*
Jan-22	17	2	15	13	*86.7%*
Feb-22	19	1	18	14	*77.8%*
Mar-22	23	0	23	18	*78.3%*
Apr-22	15	0	15	14	*93.3%*
May-22	20	1	19	14	*73.7%*
Jun-22	19	0	19	17	*89.5%*
Total	***2203***	***283***	***1920***	***1262***	***65.7%***

NOTE: For 1262 claims with <8 week interval dosing, average difference between two same drug claims was 34.58 days (SD: 10.94), Median: 34 days (lower quartile: 28 days, upper quartile: 42 days).

Table 6d. Clinical Characteristics of Avsola Users				
	Total # of beneficiaries		Total # of beneficiaries with <8-wk dosing	
	N	%	N	%
All Avsola Users	***15***	***100.0%***	***11***	***100.0%***
# of Unique Avsola Users with FDA-approved Diagnoses	*14*	*93.3%*	*10*	*90.9%*
Crohn's disease	8	*53.3%*	6	*54.5%*
Ulcerative colitis	5	*33.3%*	4	*36.4%*
Rheumatoid arthritis	2	*13.3%*	1	*9.1%*
Psoriatic arthritis	1	*6.7%*	1	*9.1%*
Plaque psoriasis	1	*6.7%*	1	*9.1%*
Ankylosing spondylitis	1	*6.7%*	1	*9.1%*

*Beneficiaries were considered to have a diagnosis for FDA-approved indications if they had a claim for the above conditions on or in a 2-year period prior to their first fill of Avsola.

Table 7d. Clinical Characteristics of Inflectra, Remicade, Renflexis Users				
	Total # of beneficiaries		Total # of beneficiaries with <8-wk dosing	
	N	%	N	%
All Inflectra, Remicade, Renflexis Users	***234***	***100.0%***	***183***	***100.0%***
# of Unique Users with FDA- approved Diagnoses	*201*	*85.9%*	*158*	*86.3%*
Crohn's disease	132	*56.4%*	109	*59.6%*
Ulcerative colitis	75	*32.1%*	60	*32.8%*
Rheumatoid arthritis	35	*15.0%*	24	*13.1%*
Psoriatic arthritis	11	*4.7%*	7	*3.8%*
Plaque psoriasis	11	*4.7%*	6	*3.3%*
Ankylosing spondylitis	5	*2.1%*	4	*2.2%*

*Beneficiaries were considered to have a diagnosis for FDA-approved indications if they had a claim for the above conditions on or in a 2-year period prior to their respective first fill.

CONCLUSIONS

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

RECOMMENDATIONS

1. DOM should work to establish detailed clinical criteria for immunomodulators defining circumstances when dose escalation is appropriate and detailing monitoring parameters for determining outcomes associated with immunomodulator agents.

2. DOM should work to strengthen the electronic PA criteria for various immunomodulator agents focusing on appropriate diagnosis-based dosing.

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APPENDIX

Appendix 1: FDA-Approved Indications	
Abbreviation	***Description***
AA	Alopecia areata
AD	Atopic dermatitis
AS	Ankylosing spondylitis
CAPS	cryopyrin-associated periodic syndromes (FCAS and MWS)
CIU	Chronic idiopathic urticaria
CRS	CAR T cell-induced cytokine release syndrome
DIRA	Deficiency of interleukin-a receptor antagonist
EE	Eosinophilic esophagitis
EGP	Eosinophilic granulomatosis with polyangiitis
ERA	Enthesitis-related arthritis
GCA	Giant cell arteritis (temporal arteritis)
GVHD	Acute graft-versus-host disease
HES	Hypereosinophilic syndrome
HS	Moderate to severe hidradenitis suppurativa
JIA	Juvenile idiopathic arthritis
JRA	Juvenile rheumatoid arthritis
NIU	Non-infectious uveitis
NMOSD	Anti-aquaporin-4 (AQP4) antibody positive neuromyelitis optica spectrum disorder
NP	Nasal polyps (chronic rhinosinusitis w/ nasal polyps - CRwNP)
OU	Oral ulcers associated with Bechet's syndrome
PsA	Psoriatic arthritis
PsO	Plaque psoriasis
RA	Rheumatoid arthritis
RP	Recurrent pericarditis
SSc-ILD	Systemic sclerosis-associated interstitial lung disease
TRAPS	TNF receptor associated periodic syndrome
UC	Ulcerative colitis

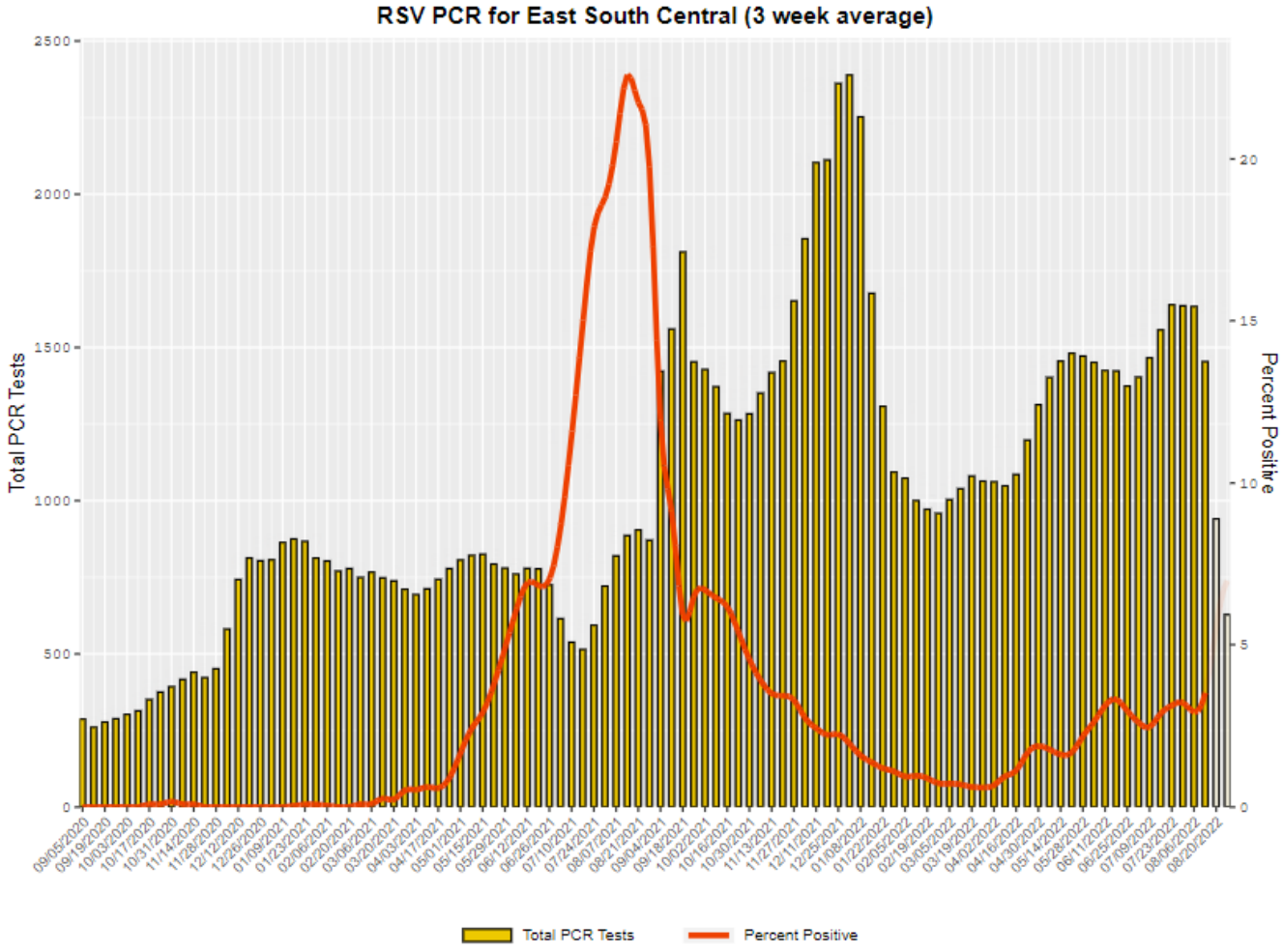
PALIVIZUMAB UTILIZATION UPDATE: 2021-2022 SEASON

BACKGROUND

Respiratory syncytial virus (RSV) is a common respiratory virus typically causing 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 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" online 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 have traditionally occurred during the fall and winter months concurrently with cold and flu season. The beginning and ending of RSV season has been relatively consistent in the past. However, since the COVID-19 pandemic began, this trend has changed. The 2020-2021 season was atypical. RSV activity remained low during fall 2020 through much of spring 2021. An unusual interseasonal rise in RSV began in late spring through summer and early fall 2021.[4] Because of the interseasonal RSV activity during the summer months, the Division of Medicaid allowed the utilization of palivizumab outside of the typical RSV season. The typical RSV season for 2021/2202 began in October 2021 and ran through March 2022. By November 2021, however, the RSV test positivity rate fell below the 5% threshold for the division that includes Mississippi. (Figure 1) Once again during summer 2022, RSV cases were reported outside of the typical season prompting the Division of Medicaid to offer guidance allowing the prescribing of palivizumab outside of the usual timeframe.

FIGURE 1: East South Central Division Percent Positive PCR Tests[4]



PALIVIZUMAB UTILIZATION

Table 1 displays a summary of beneficiaries and claims associated with palivizumab utilization during state fiscal year (SFY) 2022 (July 1, 2021 – June 30, 2022). A total of 1,605 claims representing 371 unique beneficiaries occurred during SFY 2022.

Table 1. Demographic Summary of Beneficiaries and Claims Associated with Palivizumab Utilization State Fiscal Year 2022 (July 1, 2021 - June 30, 2022)

	FFS	UHC	MAG	MOL	*Total*
Beneficiaries*	25	126	117	119	***371***
POS Claims	93	497	486	529	***1,605***
Age at fill (in months)					
<6	8	159	162	125	***454***
6-12	23	226	238	271	***758***
13-18	37	78	65	121	***301***
19-24	21	28	18	8	***75***
>24	4	6	3	4	***17***
Race					
Caucasian	34	108	111	169	***422***
African American	20	273	300	270	***863***
Other	39	116	75	90	***320***
Sex					
Female	50	223	208	293	***774***
Male	43	274	278	236	***831***

* 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 beneficiaries with synagis utilization

FFS = Fee for Service; UHC = United HealthCare; MAG = Magnolia; MOL = Molina

As seen in Table 2, claims for palivizumab began appearing in July 2021 as a result of the interseasonal rise in RSV reported during summer 2021. Palivizumab claims continued through the typical end of RSV season in March 2022.

Table 2. Utilization and Paid Amounts for Palivizumab during State Fiscal Year 2022 (July 1, 2021 - June 30, 2022)

	FFS		UHC		MAG		MOL		*Total*	
Fill month	#Claims	Paid	#Claims	Paid	#Claims	Paid	#Claims	Paid	***#Claims***	***Paid***
Jul-21	0	$0	3	$7,811	3	$7,993	0	$0	***6***	***$15,805***
Aug-21	0	$0	26	$66,135	23	$58,141	17	$48,486	***66***	***$172,761***
Sep-21	6	$23,219	37	$94,476	29	$78,285	24	$67,195	***96***	***$263,175***
Oct-21	1	$3,086	44	$113,003	40	$109,493	36	$89,580	***121***	***$315,163***
Nov-21	13	$40,481	102	$281,144	100	$285,071	142	$374,026	***357***	***$980,723***
Dec-21	11	$31,187	66	$184,332	63	$194,241	80	$218,857	***220***	***$628,618***
Jan-22	21	$55,002	76	$212,481	77	$221,359	103	$270,758	***277***	***$759,600***
Feb-22	20	$51,917	74	$218,426	83	$232,985	84	$241,690	***261***	***$745,017***
Mar-22	21	$47,867	69	$194,499	68	$184,543	43	$127,819	***201***	***$554,729***
Total	***93***	***$252,759***	***497***	***$1,372,307***	***486***	***$1,372,111***	***529***	***$1,438,411***	***$1,605***	***$4,435,591***

FFS = Fee for Service; UHC = United HealthCare; MAG = Magnolia; MOL = Molina

Table 3 shows a summary of palivizumab utilization for the last five SFYs. The total number of beneficiaries treated during SFY 2022 rose compared to the previous year. The average paid amount per beneficiary treated dropped slightly compared to SFY 2021 to $11,956. However, the total dollars paid for SFY 2022 was the highest of the past five years at $4,435,591.

Table 3. Palivizumab utilization summary by Season and Pharmacy Program

Season	Pharmacy Program				
	FFS	UHC	MAG	MOL	*Total*
	Number of unique beneficiaries*				
SFY 2018	18	164	165	0	***333***
SFY 2019	34	155	168	27	***367***
SFY 2020	22	108	101	150	***370***
SFY 2021	22	109	79	131	***323***
SFY 2022	25	126	117	119	***371***
	Total Dollars Paid				
SFY 2018	$93,812	$1,283,588	$1,725,471	$0	***$3,102,871***
SFY 2019	$270,004	$1,385,769	$2,018,792	$123,795	***$3,798,360***
SFY 2020	$230,222	$883,547	$1,023,409	$1,494,976	***$3,632,335***
SFY 2021	$314,219	$1,262,651	$925,021	$1,542,600	***$4,044,491***
SFY 2022	$252,758	$1,372,309	$1,372,113	$1,438,411	***$4,435,591***
	Mean Number of Claims/Beneficiary				
SFY 2018	3.3	3.6	4.2	0	***3.7***
SFY 2019	4.1	4	4.8	2.3	***3.8***
SFY 2020	4.3	3.6	4.1	4.3	***4.1***
SFY 2021	4	4.4	4.4	4.3	***4.3***
SFY 2022	3.7	3.9	4.2	4.4	***4.1***
	Dollars Paid/Beneficiary				
SFY 2018	$5,212	$7,827	$10,457	$0	***$9,318***
SFY 2019	$7,941	$8,940	$12,017	$4,585	***$10,350***
SFY 2020	$10,473	$8,181	$10,133	$9,967	***$9,817***
SFY 2021	$14,283	$11,584	$11,709	$11,776	***$12,522***
SFY 2022	$10,110	$10,891	$11,727	$12,087	***$11,956***

FFS = Fee for Service; UHC = United HealthCare; MAG = Magnolia; MOL = Molina
SFY - state fiscal year
*Some beneficiaries may be enrolled in multiple plans in a particular season; the sum of beneficiaries in each plan may not be equal to total number of beneficiaries with Synagis utilization.

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.

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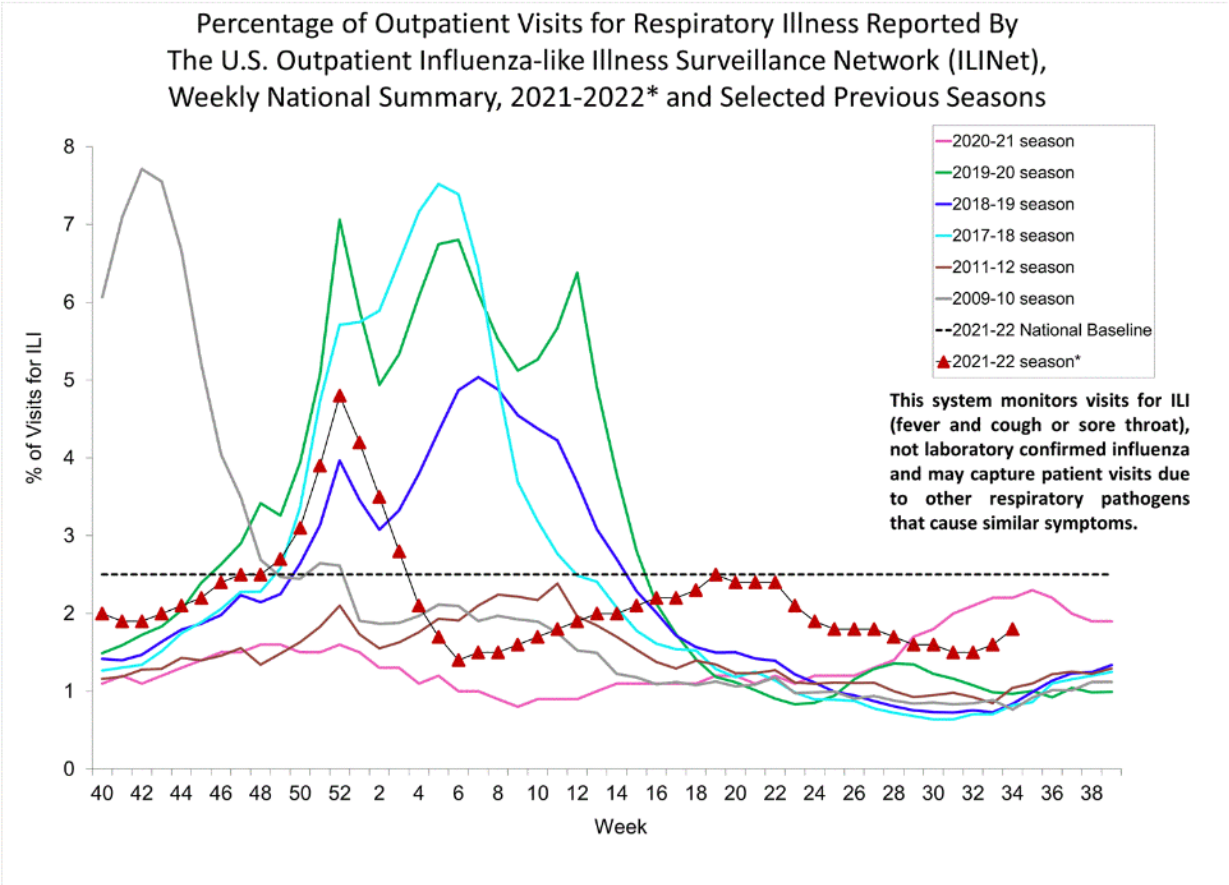
INFLUENZA VACCINATION AND TREATMENT UPDATE
2021-2022 SEASON

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 2021-2022 influenza season did not follow this pattern. Influenza activity began increasing in November 2021 and consisted of two distinct waves of infection that resulted in elevated levels remaining through June 2022.[1] Laboratory-confirmed influenza-associated hospitalizations during the first wave occurred around the beginning of January 2022 and the second, slightly higher peak in hospitalizations occurred at the end of April 2022. Although activity remained elevated for a prolonged period compared to prior seasons, the severity was considered mild.[2]

Figure 1: Nationwide Percent of Visits for Influenza Like-Illness (ILI)[1]



METHODS

Pharmacy and medical claims from fee-for-service and all CCOs[UnitedHealthcare (UHC), Magnolia Health (MAG) and Molina Healthcare (MOL)] for influenza vaccines and anti-influenza agents were extracted for state fiscal year (SFY) 2022 (July 1, 2021 to June 30, 2022). The analysis included prescriptions for influenza vaccines and all anti-influenza agents listed on the 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 2022.

RESULTS

In Table 1 the number of Medicaid beneficiaries with documented influenza vaccination for SFY 2022 is displayed.

- 57,139 beneficiaries had documentation of receiving flu vaccination during SFY 2022. This number was lower than that reported for 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 2022 (July 1, 2021 - June 30, 2022)

Age at index flu vaccination	Plan at index flu vaccination	Number of beneficiaries who received flu vaccines*	Amount paid Rx**		Amount paid Medical**			
					Flu Vaccine		Vaccine Administration	
			# of Benes	Cost/Bene	# of Benes	Cost/Bene	# of Benes	Cost/Bene
< 19	FFS	6,726	160	$36.3	296	$14.2	4,204	$17.9
	UHC	12,672	65	$37.6	294	$20.9	8,862	$18.1
	MAG	14,044	93	$31.0	1,030	$19.8	9,141	$17.4
	Mol	5,449	-	-	321	$19.9	3,956	$20.6
	Total	38,891	318	$35.0	1,941	$19.1	26,163	$18.2
≥ 19	FFS	6,317	986	$36.9	2,646	$22.3	2,185	$14.5
	UHC	4,604	1,168	$38.1	2,285	$23.2	2,001	$14.3
	MAG	5,820	1,421	$36.5	2,813	$23.1	2,390	$14.9
	Mol	1,507	364	$34.9	848	$21.8	726	$14.9
	Total	18,248	3,939	$36.9	8,592	$22.8	7,302	$14.6
Total (across all plans and age groups)		**57,139**	**4,257**	**$36.8**	**10,533**	**$22.1**	**33,465**	**$17.4**

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, 90653-90658, 90660-90662, 90664, 90666-90668, 90672-90674, 90756, 90682, 90686, 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:

1. www.immunize.org/catg.d/p4072.pdf
2. 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 2022.

- Numbers for SFY were up compared to numbers reported for the unusually low influenza rates reported in SFY 2021. However, these numbers were still below those reported in recent years before SFY 2021 which may be a reflection of the relatively mild severity of this past year's flu season.
- Generic oseltamivir made up over 99% of claims for anti-influenza agents.

Table 2. Utilization of Anti-Influenza Agents in Mississippi Medicaid (July 1, 2021 - June 30, 2022)

Drug	Plan	Prescriptions filled	Beneficiaries	Paid Amount
Oseltamivir Phosphate	FFS	7,723	7,323	$322,414.36
	UHC	7,355	6,332	$309,455.41
	MAG	6,043	5,913	$249,799.98
	MOL	2,973	2,873	$117,374.14
Rimantadine Hydrochloride	FFS	-	-	$0.00
	UHC	1	1	$23.20
	MAG	-	-	$0.00
	MOL	-	-	$0.00
Tamiflu	FFS	-	-	$0.00
	UHC	1	1	$56.85
	MAG	-	-	$0.00
	MOL	-	-	$0.00
Xofluza	FFS	3	3	$636.48
	UHC	22	19	$3,567.42
	MAG	4	4	$310.76
	MOL	4	4	$509.03
Grand total (across all plans and drugs)		**24,129**	**22,372**	**$1,004,147.63**

Note: FFS = Fee-for-Service, UHC = United HealthCare, MAG = Magnolia, MOL = Molina
Other anti-influenza agents, namely Rapivab (peramivir) 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.
Total number of beneficiaries may not equal sum of beneficiaries for each product and plan, since certain beneficiaries may have had utilization of multiple products or enrolled in multiple pharmacy plans during the analysis period.

Table 3 displays anti-influenza drug utilization in Mississippi Medicaid for SFY 2022. 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=21,208, 94.8%).
- Only 0.5% of beneficiaries treated with anti-influenza drugs received ≥3 prescription fills.
- 7.3% (n=1,711) beneficiaries had documentation of receiving flu vaccination before filling a prescription for an anti-influenza drug.

Table 3: Anti-influenza drug utilization in Mississippi Medicaid for State Fiscal Year 2022 (July 1, 2021 - June 30, 2022)

Plan	Total number of beneficiaries with antiviral rx fills	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	7,257	6,980	250	27	406	350
UHC	6,342	5,709	556	77	734	576
MAG	5,903	5,757	133	13	720	560
MOL	2,870	2,762	104	4	298	225
Total	22,372	21,208	1,043	121	2,158	1,711

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

Numbers represent beneficiaries who had pharmacy claims only. No beneficiaries with anti-influenza drug related medical claims were identified in the study period.

* Beneficiaries with medical or pharmacy claims were identified.

CPT codes for influenza vaccines included: 90630, 90685-90688, 90654-90658, 90660-90662, 90653, 90666, 90668, 90664, 90672-90674, 90756, 90682, 90686, 90682, Q2035.

References:

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

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.

REFERENCES

1. CDC. Weekly U.S. Influenza Surveillance Report. Centers for Disease Control and Prevention. Published September 2, 2022. Accessed September 6, 2022. https://www.cdc.gov/flu/weekly/index.htm

2. Merced-Morales A. Influenza Activity and Composition of the 2022–23 Influenza Vaccine — United States, 2021–22 Season. *MMWR Morb Mortal Wkly Rep*. 2022;71. doi:10.15585/mmwr.mm7129a1

FDA DRUG SAFETY COMMUNICATIONS

June 2022 – August 2022

- 6/30/2022 FDA warns about possible increased risk of death and serious side effects with cancer drug Copiktra (duvelisib)

- 6/1/2022 FDA approval of lymphoma medicine Ukoniq (umbralisib) is withdrawn due to safety concerns

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