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



June 10, 2021 at 1:00pm

ZOOM Meeting

Prepared by:



2021 DUR Board Meeting Dates

March 4, 2021 June 10, 2021 September 16, 2021 December 9, 2021 As with any analysis, great efforts are made to ensure that the information reported in this document is accurate. The most recent administrative claims data available are being used at the time the reports are generated, which includes the most recent adjudication history. As a result, values may vary between reporting periods and between DUR Board meetings, reflecting updated reversals and claims adjustments.

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

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

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

MISSISSIPPI DIVISION OF MEDICAID OFFICE OF THE GOVERNOR DRUG UTILIZATION REVIEW BOARD AGENDA June 10, 2021

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Next Meeting Information

Remaining 2021 Meeting Dates: September 16, and December 9

DUR Board Meeting Minutes

MISSISSIPPI DIVISION OF MEDICAID DRUG UTILIZATION REVIEW (DUR) BOARD MINUTES OF THE MARCH 4, 2021 MEETING

DUR Board Roster:	Jun	Sep	Dec	Mar
State Fiscal Year 2021	2020	2020	2020	2021
(July 1, 2020 – June 30, 2021)				
Lauren Bloodworth, PharmD	✓	\checkmark	✓	✓
(Chair)				
Terrence Brown, PharmD	NA	NA	NA	\checkmark
Patrick Bynum, MD	NA	NA	NA	\checkmark
Rhonda Dunaway, RPh	√	✓	×	\sim
Tanya Fitts, MD	√	✓	\checkmark	✓
Philip Merideth	NA	NA	NA	\checkmark
Ray Montalvo, MD	√	\checkmark	~	
Holly Moore, PharmD	√	\checkmark		✓
Janet Ricks, DO	√	✓		\checkmark
Cheryl Sudduth, RPh	\checkmark	✓	\checkmark	
James Taylor, PharmD	\checkmark	\checkmark	~	\checkmark
Alan Torrey, MD	\checkmark		~	
TOTAL PRESENT**	11	9	7	9

** 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; Mason Frantom, Data and Compliance Officer;

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

Eric Pittman, PharmD, MS-DUR Project Director;

Conduent Staff:

Leslie Leon, PharmD, Clinical Pharmacist, Mississippi Medicaid Project;

Change Healthcare Staff:

Paige Clayton, PharmD, On-Site Clinical Pharmacist; Sarah Boydstun, PharmD, PA Pharmacist;

Coordinated Care Organization (CCO) Staff:

Heather Odem, PharmD, Director of Pharmacy - Mississippi, UnitedHealthcare Community & State; Jenni Grantham, PharmD, Director of Pharmacy, Magnolia Health;

Visitors:

Kimberly Clark, Viiv Healthcare; Brandon Cope, Otsuka; Jill Gran, Otsuka; Justin Simmons, Abbvie; Jason Swartz, Otsuka; Gene Wingo, Biogen; Stephanie Arnold, Greenwich Biosciences; Brian Berhow, Sunovion; Michelle Bessett, Biocodex; John Churnetski, Alexion; Kendra Davies, Greenwich Biosciences; Andrew Delgado, BMS; Todd Dickerson, Jazz Pharmaceuticals; Stanley Ferrell, SeaGen; Sharron Glass, Alimera Sciences; Chris Hartmann, Jazz Pharmaceuticals; Steve Kohn, Sobi; Anabelle Keohane, Sanofi Genzyme; Jeff Knappen, Spark Therapeutics; David Large, Biohaven; Chris Lauhoff, Genentech; Martin McNulty, Pfizer; Robert Pedrazza, Vertex; Cathy Prine-Eagle, Merck; Taryn Stinson, Jazz Pharmaceuticals; Wendy Williams, Supernaus; Diana Sedgwick; Dr. James Brock, UMC (guest presenter).

Call to Order:

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

OLD BUSINESS:

Dr. Fitts moved to approve the minutes from the December 2020 DUR Board Meeting, seconded by Dr. Bloodworth, and unanimously approved by the DUR Board.

Resource Utilization Review:

Dr. Pittman presented the resource utilization report for October 2020 – December 2020. Enrollment numbers continued to climb. The number of beneficiaries with pharmacy benefits was up 10.4% compared to December 2019. While enrollment numbers increased, the number of prescription fills decreased 13.6% compared to December 2019. The total dollars paid for prescriptions was slightly increased compared to that paid in December 2019. One other item of note was the substantial decrease in the utilization of neuraminidase inhibitors for the treatment of flu compared to prior years.

Feedback and Discussion from Board:

Dr. Pittman informed the Board that implementation of the proton pump inhibitor maximum days supply edit has been postponed due to supply concerns for alternative agents. Once supplies are stable, the edit will be implemented. However, an educational piece is still scheduled to be in DOM's upcoming March Provider Bulletin in anticipation of the edit.

NEW BUSINESS:

Update on MS-DUR Educational Interventions:

Dr. Pittman provided an overview of all DUR mailings and educational notices that occurred December 2020 – February 2021.

Special Analysis Projects:

HIV Pre-Exposure Prophylaxis (PrEP)

Dr. James Brock provided an overview of HIV PrEP to the Board. Following Dr. Brock's presentation, Dr. Pittman reviewed the MS-DUR analysis of PrEP utilization in Medicaid between 2014 and 2020. It was noted that PrEP therapy is covered under Medicaid's UPDL and as part of the Family Planning Waiver for both males and females. Even with no restrictions to access, only 159 beneficiaries have been initiated on PrEP therapy since January 2014. In order for PrEP therapy to be effective in reducing incident HIV infections in Mississippi, more high-risk individuals need to be identified and initiated on PrEP therapy. The following recommendations were discussed:

- 1. The Division of Medicaid should conduct provider education on PrEP therapy to include:
 - Incidence rates for HIV infections in Mississippi;
 - Categories of individuals identified as being high-risk for acquiring HIV infection;
 - Preferred status of PrEP products on UPDL;
 - Inclusion of PrEP products as covered medications under the Family Planning Waiver for both males and females;
 - Need for more providers around the state to identify high-risk beneficiaries and prescribe PrEP.
 - Strategies to improve provider comfort and eliminate potential provider bias in prescribing PrEP.
- 2. MS-DUR to conduct future research related to PrEP utilization in the Medicaid population to include:
 - Compare sociodemographic, clinical, and social determinant of health characteristics between PrEP utilizers and those newly diagnosed with HIV infections;
 - Assess PrEP persistence patterns and predictors of PrEP persistence;
 - Assess geographical disparities in PrEP uptake and persistence;
 - Assess potential barriers to PrEP therapy (social stigma, provider stigma, adherence, lab monitoring, etc.).

The Board encouraged DOM to partner with state medical associations to disseminate education on PrEP. Following discussion, Ms. Dunaway made a motion, seconded by Dr. Bloodworth, and unanimously approved by the Board to accept the recommendations presented.

Epidiolex

Dr. Pittman provided a report describing the use of Epidiolex among Medicaid beneficiaries. Since its approval in 2018, utilization has steadily increased. Analyses indicated that while the number of beneficiaries being treated with Epidiolex appeared to stabilize beginning Q2/2020, costs associated with its use continued to climb. These increased costs could be associated with increased dosage ranges prescribed for beneficiaries. The following recommendation was presented:

1. In light of the apparent increase in the dosage ranges being prescribed, DOM should establish dosing limits based on the labeled maximum dose recommendations. Such limits would allow for clinical review through prior authorization for doses exceeding these limits.

Following a robust discussion, Dr. Taylor motioned to take no action at this time regarding dosing limits for Epidiolex. The motion was seconded by Dr. Bloodworth and unanimously approved by the Board.

Growth Hormone

Dr. Pittman reviewed a report on the utilization of growth hormone among Medicaid beneficiaries between 2018 and 2020. The vast majority of growth hormones are being prescribed for beneficiaries under the age of 18 years (97.6%). Although SmartPA criteria does not require a diagnosis edit for beneficiaries under 18 years, analysis showed that only 3.3% of beneficiaries under 18 years did not have an associated diagnosis present in medical claims data. Most beneficiaries receiving these agents had an associated diagnosis of growth hormone deficiency or short stature present in claims data. There does not appear to be any significant inconsistencies in the prescribing of growth hormone agents with regards to appropriate diagnoses. MS-DUR presented the following recommendation:

1. MS-DUR recommends extending Smart PA diagnosis requirements to all beneficiaries prescribed growth hormone agents.

Following discussion, Dr. Taylor motioned to approve the recommendation, seconded by Ms. Dunaway, and unanimously approved by the board.

FDA Drug Safety Updates:

Dr. Pittman presented FDA drug safety communications for October 2020 – December 2020.

Pharmacy Program Update:

Mr. Smith provided the Board with the following Pharmacy Program Updates:

- The PPI deprescribing edit will be delayed possibly until summer 2021 due to the limited availability of alternative agents.
- Omnipod insulin pumps will be available through POS beginning April 1, 2021.
- Medicaid will be transitioning to a new fiscal agent, Gainwell, in 2022 and has begun testing.
- CMS approved the State Plan Amendment #20-0013 in December 2020. Beginning March 1, 2021, pharmacists will be reimbursed an administration fee equal to that paid to primary care providers for administering vaccines. Additionally all vaccines recommended on CDC Immunization Schedules can be administered by pharmacy providers and billed on pharmacy claims. There will be no copay associated with these vaccines and they will not count toward monthly prescription limits.
- Covid Vaccine Administration Fee Schedules for pharmacist were implemented in December 2020.

Miscellaneous:

Remaining 2021 Meeting Dates/Times

June 10, 2021 September 16, 2021 December 9, 2021 *Meeting time will remain at 1 pm.

Next Meeting Information:

Dr. Pittman announced that the next meeting of the DUR Board will take place on June 10, 2021 at 1pm.

Dr. Taylor motioned to adjourn the meeting at 2:38 pm, seconded by Dr. Bloodworth, and unanimously approved by the Board.

Submitted,

Eric Pittman, PharmD Evidence-Based DUR Initiative, MS-DUR **Meeting Location**: Meetings will be held virtually until further notice. Please visit Medicaid.ms.gov and click on the Pharmacy Information link for further information.

Contact Information: Office of Pharmacy:

Chris Yount, 601-359-5253: <u>Christopher.yount@medicaid.ms.gov</u>, or Jessica Tyson, 601-359-5253; <u>Jessica.Tyson@medicaid.ms.gov</u>

Notice details:

State Agency: MS Division of Medicaid

Public Body: Drug Utilization Board (DUR) Meeting

Subject: Quarterly Meeting

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

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

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

The Drug Utilization Review (DUR) Board meets quarterly.



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March 4, 2021 DUR Board Meeting Information

The Drug Utilization Review (DUR) Board meets quarterly. Meetings are normally scheduled for room 145 at 1 p.m. in the Woolfolk Building, 501 North West Street, Jackson, MS. Due to the current pandemic, meetings will be held virtually.

March 4 DUR Zoom Meeting Link Information (link will be taken down 20 minutes after meeting start time to minimize disruptions to proceedings):

https://zoom.us/j/93257967440?pwd=aXJ4VGpseFFLTXJtNG9vTDFxbnluQT09

Meeting ID: 932 5796 7440

Passcode: 264082

- 1. Participants are required to join the meeting no less than 15 minutes prior to meeting start time
- 2. All lines will be muted upon joining
- 3. Participants are expected to conduct themselves professionally.
- 4. Please join the meeting by entering your NAME & COMPANY NAME. You may enter this information after joining by selecting the RENAME option.

DUR Meeting Dates & Registration Information

2021 dates: March 4, 2021; June 10, 2021; September 16, 2021; and December 9, 2021.

Important Update: beginning July 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. Registrants will be emailed attendance link information the day before the meeting

- Pharmacy Home
- Drug Utilization Review Board
- Mississippi Preferred Drug List
- Prior Authorization
- Pharmacy and Therapeutics Committee •
- Pharmacy Resources
- Pharmacy Reimbursement

Resource Utilizaton Review

	October 1, 2020 through March 31, 2021										
			Oct-20	Nov-20	Dec-20	Jan-21	Feb-21	Mar-21			
Тс	otal enr	ollment	740,936	746,566	752,185	757,262	760,818	764,658			
Dı	ual-elig	ibles	165,051	164,992	164,837	164,433	163,899	163,667			
Pł	Pharmacy benefits		627,322	632,796	638,334	643,542	647,096	650,974			
	LTC		15,303	15,160	15,092	14,849	14,576	14,512			
	6	FFS	25.6%	25.4%	25.4%	25.4%	25.4%	25.4%			
	% N	MSCAN-UHC	29.1%	28.9%	28.7%	28.5%	28.5%	28.5%			
	PLAN	MSCAN-Magnolia	31.5%	31.3%	31.0%	30.9%	30.8%	30.7%			
	-	MSCAN-Molina	13.8%	14.4%	14.9%	15.2%	15.3%	15.4%			

TABLE 04A: ENROLLMENT STATISTICS FOR LAST 6 MONTHS

TABLE 04B: PHARMACY UTILIZATION STATISTICS FOR LAST 6 MONTHS

.

	October 1, 2020 through March 31, 2021										
		Oct-20	Nov-20	Dec-20	Jan-21	Feb-21	Mar-21				
	FFS	105,081	100,623	105,116	104,384	94,676	113,328				
#	MSCAN-UHC	140,029	131,239	133,735	137,307	119,409	142,127				
Rx Fills	MSCAN-Mag	169,972	159,701	160,970	157,122	143,212	168,572				
	MSCAN-Mol	46,845	46,189	49,414	48,822	44,963	54,276				
#	FFS	0.7	0.6	0.6	0.6	0.6	0.7				
Rx Fills	MSCAN-UHC	0.8	0.7	0.7	0.7	0.6	0.8				
/ Bene	MSCAN-Mag	0.9	0.8	0.8	0.8	0.7	0.8				
, bene	MSCAN-Mol	0.5	0.5	0.5	0.5	0.5	0.5				
	FFS	\$12,271,806	\$11,688,834	\$12,415,581	\$12,859,934	\$11,406,359	\$13,989,629				
\$	MSCAN-UHC	\$14,097,753	\$13,577,066	\$14,373,773	\$15,193,469	\$13,086,448	\$15,386,363				
Paid Rx	MSCAN-Mag	\$17,217,996	\$16,485,632	\$17,023,568	\$16,794,168	\$15,818,330	\$18,108,045				
	MSCAN-Mol	\$4,198,656	\$4,237,952	\$4,565,960	\$4,621,196	\$4,266,525	\$4,922,669				
	FFS	\$116.78	\$116.16	\$118.11	\$123.20	\$120.48	\$123.44				
\$	MSCAN-UHC	\$100.68	\$103.45	\$107.48	\$110.65	\$109.59	\$108.26				
/Rx Fill	MSCAN-Mag	\$101.30	\$103.23	\$105.76	\$106.89	\$110.45	\$107.42				
	MSCAN-Mol	\$89.63	\$91.75	\$92.40	\$94.65	\$94.89	\$90.70				
	FFS	\$76.41	\$72.72	\$76.57	\$78.67	\$69.40	\$84.61				
\$	MSCAN-UHC	\$77.23	\$74.24	\$78.46	\$82.84	\$70.96	\$82.93				
/Bene	MSCAN-Mag	\$87.13	\$83.23	\$86.03	\$84.45	\$79.37	\$90.61				
	MSCAN-Mol	\$48.50	\$46.51	\$48.01	\$47.24	\$43.09	\$49.10				

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

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

Category	Month Year	Rank Volume	#RXs	\$ Paid	# Unique Benes
CNS stimulants	Mar 2021	1	26,744	\$4,922,875	22,774
	Feb 2021	1	22,453	\$4,102,214	19,699
	Jan 2021	1	24,736	\$4,542,496	21,408
antihistamines	Mar 2021	2	14,770	\$215,230	14,113
	Feb 2021	8	10,687	\$157,280	10,362
	Jan 2021	7	12,156	\$180,880	11,628
atypical antipsychotics	Mar 2021	3	14,526	\$4,169,089	12,115
	Feb 2021	2	12,838	\$3,634,853	11,231
	Jan 2021	2	13,962	\$3,762,357	11,920
nonsteroidal anti-inflammatory agents	Mar 2021	4	14,466	\$204,463	13,762
	Feb 2021	4	11,897	\$170,226	11,432
	Jan 2021	3	13,517	\$197,432	12,877
SSRI antidepressants	Mar 2021	5	14,149	\$174,845	12,968
	Feb 2021	3	12,244	\$148,910	11,615
	Jan 2021	4	13,423	\$164,177	12,529
narcotic analgesic combinations	Mar 2021	6	13,359	\$558,548	12,089
	Feb 2021	5	11,403	\$494,456	10,643
	Jan 2021	8	12,116	\$509,752	11,124
adrenergic bronchodilators	Mar 2021	7	13,304	\$835,037	11,363
	Feb 2021	7	10,794	\$642,146	9,428
	Jan 2021	5	12,166	\$744,684	10,448
proton pump inhibitors	Mar 2021	8	12,625	\$441,942	11,971
	Feb 2021	6	10,927	\$366,449	10,589
	Jan 2021	6	12,164	\$442,279	11,618
antiadrenergic agents, centrally acting	Mar 2021	9	11,406	\$217,989	10,170
	Feb 2021	9	9,983	\$199,231	9,291
	Jan 2021	9	10,920	\$225,747	9,996
aminopenicillins	Mar 2021	10	11,115	\$140,498	10,887
	Feb 2021	10	9,337	\$118,467	9,218
	Jan 2021	10	10,056	\$126,041	9,841

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

Category	Month Year	Rank Paid Amt	#RXs	\$ Paid	# Unique Benes
CNS stimulants	Mar 2021	1	26,744	\$4,922,875	22,774
	Feb 2021	1	22,453	\$4,102,214	19,699
	Jan 2021	1	24,736	\$4,542,496	21,408
atypical antipsychotics	Mar 2021	2	14,526	\$4,169,089	12,115
	Feb 2021	2	12,838	\$3,634,853	11,231
	Jan 2021	2	13,962	\$3,762,357	11,920
TNF alpha inhibitors	Mar 2021	3	396	\$2,863,329	346
	Feb 2021	3	353	\$2,490,169	336
	Jan 2021	3	386	\$2,632,262	345
antiviral combinations	Mar 2021	4	881	\$2,823,005	791
	Feb 2021	4	741	\$2,427,832	711
	Jan 2021	4	830	\$2,611,157	769
insulin	Mar 2021	5	5,486	\$2,515,299	4,021
	Feb 2021	5	4,748	\$2,200,932	3,620
	Jan 2021	5	5,241	\$2,445,520	3,919
interleukin inhibitors	Mar 2021	6	324	\$1,797,074	289
	Feb 2021	6	280	\$1,593,969	266
	Jan 2021	6	296	\$1,622,382	259
factor for bleeding disorders	Mar 2021	7	135	\$1,410,442	98
	Feb 2021	7	110	\$1,285,519	88
	Jan 2021	7	123	\$1,483,350	86
CFTR combinations	Mar 2021	8	68	\$1,375,941	59
	Feb 2021	9	54	\$1,077,199	52
	Jan 2021	10	57	\$1,180,866	49
bronchodilator combinations	Mar 2021	9	3,969	\$1,218,503	3,617
	Feb 2021	10	3,432	\$1,047,047	3,197
	Jan 2021	9	3,951	\$1,218,023	3,590
immune globulins	Mar 2021	10	291	\$1,135,103	212
	Feb 2021	8	320	\$1,132,790	221
	Jan 2021	8	338	\$1,219,339	232

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

Drug Molecule Therapeutic Category	Feb 2021 # Claims	Mar 2021 # Claims	Mar 2021 \$ Paid	Mar 2021 # Unique Benes
albuterol / adrenergic bronchodilators	10,337	12,581	\$613,718	10,818
amoxicillin / aminopenicillins	9,313	11,085	\$139,947	10,858
cetirizine / antihistamines	6,661	9,982	\$134,671	9,716
montelukast / leukotriene modifiers	7,461	9,792	\$152,077	9,514
gabapentin / gamma-aminobutyric acid analogs	7,478	8,412	\$129,530	7,777
acetaminophen-hydrocodone / narcotic analgesic combinations	7,085	8,374	\$109,532	7,775
lisdexamfetamine / CNS stimulants	6,527	7,946	\$2,591,319	7,600
fluticasone nasal / nasal steroids	5,679	7,752	\$118,465	7,635
azithromycin / macrolides	7,537	7,487	\$124,257	7,338
clonidine / antiadrenergic agents, centrally acting	6,164	6,964	\$92,522	6,415
methylphenidate / CNS stimulants	5,690	6,802	\$1,061,720	6,023
amphetamine-dextroamphetamine / CNS stimulants	5,856	6,802	\$207,238	5,819
ondansetron / 5HT3 receptor antagonists	5,276	6,579	\$96,368	6,343
amlodipine / calcium channel blocking agents	5,669	6,441	\$70,045	6,101
ibuprofen / nonsteroidal anti-inflammatory agents	5,225	6,423	\$76,979	6,250
omeprazole / proton pump inhibitors	5,367	6,027	\$67,628	5,821
sertraline / SSRI antidepressants	4,456	5,235	\$65,300	4,791
atorvastatin / HMG-CoA reductase inhibitors (statins)	4,042	4,501	\$52,061	4,212
guanfacine / antiadrenergic agents, centrally acting	3,816	4,436	\$125,387	4,112
triamcinolone topical / topical steroids	3,050	4,320	\$80,706	4,195
pantoprazole / proton pump inhibitors	3,438	4,089	\$49,711	3,872
hydroxyzine / miscellaneous anxiolytics, sedatives and hypnotics	3,310	3,913	\$56,545	3,726
aripiprazole / atypical antipsychotics	3,441	3,901	\$968,287	3,540
cefdinir / third generation cephalosporins	3,312	3,849	\$86,910	3,812
ethinyl estradiol-norgestimate / contraceptives	3,187	3,840	\$62,967	3,522

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

Drug Molecule Therapeutic Category	Feb 2021 \$ Paid	Mar 2021 \$ Paid	Mar 2021 # Claims	Mar 2021 # Unique Benes
lisdexamfetamine / CNS stimulants	\$2,130,121	\$2,591,319	7,946	7,600
adalimumab / TNF alpha inhibitors	\$2,238,132	\$2,563,696	340	297
paliperidone / atypical antipsychotics	\$1,496,951	\$1,683,685	660	575
bictegravir/emtricitabine/tenofovir / antiviral combinations	\$1,081,132	\$1,332,686	392	367
methylphenidate / CNS stimulants	\$881,090	\$1,061,720	6,802	6,023
aripiprazole / atypical antipsychotics	\$827,215	\$968,287	3,901	3,540
elexacaftor/ivacaftor/tezacaftor / CFTR combinations	\$748,811	\$959,542	46	40
insulin glargine / insulin	\$807,975	\$924,773	2,027	1,921
etanercept / antirheumatics	\$577,023	\$719,011	138	117
dexmethylphenidate / CNS stimulants	\$614,284	\$707,642	3,379	2,802
liraglutide / GLP-1 receptor agonists	\$614,771	\$703,105	850	810
dupilumab / interleukin inhibitors	\$594,537	\$694,489	220	198
palivizumab / immune globulins	\$762,916	\$676,867	239	173
emicizumab / factor for bleeding disorders	\$508,944	\$674,502	32	23
somatropin / growth hormones	\$538,265	\$616,114	159	141
albuterol / adrenergic bronchodilators	\$501,881	\$613,718	12,581	10,818
lacosamide / miscellaneous anticonvulsants	\$496,108	\$570,687	604	528
insulin aspart / insulin	\$472,265	\$544,350	1,437	1,343
budesonide-formoterol / bronchodilator combinations	\$468,041	\$527,136	1,676	1,627
lurasidone / atypical antipsychotics	\$431,661	\$486,708	339	317
deferasirox / chelating agents	\$344,939	\$466,702	88	71
insulin detemir / insulin	\$414,314	\$464,230	865	815
empagliflozin / SGLT-2 inhibitors	\$336,244	\$426,053	572	547
cobicistat/elvitegravir/emtricitabine/tenofov / antiviral combinations	\$452,326	\$424,229	120	111
antihemophilic factor / factor for bleeding disorders	\$293,360	\$413,699	31	15

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

Drug Molecule	Jan 2021 # Claims	Feb 2021 # Claims	Mar 2021 # Claims	Mar 2021 \$ Paid	Mar 2021 # Unique Benes
cetirizine / antihistamines	7,564	6,661	9,982	\$134,671	9,716
fluticasone nasal / nasal steroids	6,132	5,679	7,752	\$118,465	7,635
sars-cov-2 (covid-19) mrna-1273 vaccine / viral vaccines	8	240	1,482	\$32,746	1,406
montelukast / leukotriene modifiers	8,597	7,461	9,792	\$152,077	9,514
amoxicillin / aminopenicillins	10,024	9,313	11,085	\$139,947	10,858
albuterol / adrenergic bronchodilators	11,635	10,337	12,581	\$613,718	10,818
prednisolone / glucocorticoids	2,697	2,692	3,463	\$55,766	3,366
acetaminophen-hydrocodone / narcotic analgesic combinations	7,646	7,085	8,374	\$109,532	7,775
methylphenidate / CNS stimulants	6,186	5,690	6,802	\$1,061,720	6,023
triamcinolone topical / topical steroids	3,728	3,050	4,320	\$80,706	4,195
lisdexamfetamine / CNS stimulants	7,358	6,527	7,946	\$2,591,319	7,600
sars-cov-2 (covid-19) mrna bnt-162b2 vaccine / viral vaccines	1,088	1,317	1,632	\$36,242	1,486
ondansetron / 5HT3 receptor antagonists	6,076	5,276	6,579	\$96,368	6,343
mupirocin topical / topical antibiotics	2,508	2,125	3,010	\$44,931	2,951
amphetamine-dextroamphetamine / CNS stimulants	6,315	5,856	6,802	\$207,238	5,819
ibuprofen / nonsteroidal anti-inflammatory agents	5,948	5,225	6,423	\$76,979	6,250
amoxicillin-clavulanate / penicillins/beta-lactamase inhibitors	3,273	3,090	3,706	\$76,825	3,645
olopatadine ophthalmic / ophthalmic antihistamines and decongestants	531	415	889	\$20,825	874
pantoprazole / proton pump inhibitors	3,735	3,438	4,089	\$49,711	3,872
metronidazole / miscellaneous antibiotics	2,480	2,190	2,818	\$32,375	2,732
gabapentin / gamma-aminobutyric acid analogs	8,115	7,478	8,412	\$129,530	7,777
clindamycin / lincomycin derivatives	1,856	1,722	2,150	\$52,577	2,089
escitalopram / SSRI antidepressants	2,428	2,278	2,711	\$32,830	2,505
sulfamethoxazole-trimethoprim / sulfonamides	3,058	2,607	3,337	\$51,954	3,255
sars-cov-2 (covid-19) ad26 vaccine, recombinant / viral vaccines	0	0	251	\$5,897	251

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

Drug Molecule	Jan 2021 \$ Paid	Feb 2021 \$ Paid	Mar 2021 \$ Paid	Mar 2021 # Claims	Mar 2021 # Unique Benes
adalimumab / TNF alpha inhibitors	\$2,336,864	\$2,238,132	\$2,563,696	340	297
caplacizumab / platelet aggregation inhibitors	\$0	\$0	\$219,058	1	1
elexacaftor/ivacaftor/tezacaftor / CFTR combinations	\$743,906	\$748,811	\$959,542	46	40
lisdexamfetamine / CNS stimulants	\$2,380,060	\$2,130,121	\$2,591,319	7,946	7,600
conestat alfa / hereditary angioedema agents	\$0	\$0	\$209,341	1	1
paliperidone / atypical antipsychotics	\$1,485,301	\$1,496,951	\$1,683,685	660	575
palbociclib / CDK 4/6 inhibitors	\$156,315	\$183,820	\$341,379	26	19
etanercept / antirheumatics	\$570,974	\$577,023	\$719,011	138	117
methylphenidate / CNS stimulants	\$952,812	\$881,090	\$1,061,720	6,802	6,023
ixekizumab / interleukin inhibitors	\$50,861	\$129,449	\$152,867	16	14
ledipasvir-sofosbuvir / antiviral combinations	\$0	\$63,023	\$94,534	3	2
liraglutide / GLP-1 receptor agonists	\$614,370	\$614,771	\$703,105	850	810
aripiprazole / atypical antipsychotics	\$880,693	\$827,215	\$968,287	3,901	3,540
somatropin / growth hormones	\$528,917	\$538,265	\$616,114	159	141
bictegravir/emtricitabine/tenofovir / antiviral combinations	\$1,248,734	\$1,081,132	\$1,332,686	392	367
antihemophilic factor / factor for bleeding disorders	\$347,223	\$293,360	\$413,699	31	15
gilteritinib / multikinase inhibitors	\$0	\$28,238	\$64,265	4	3
sofosbuvir-velpatasvir / antiviral combinations	\$115,625	\$109,994	\$178,606	19	17
lenalidomide / other immunosuppressants	\$283,179	\$274,419	\$341,629	20	17
selumetinib / multikinase inhibitors	\$98,695	\$81,189	\$155,386	9	9
immune globulin intravenous and subcutaneous / immune globulins	\$214,399	\$200,054	\$268,481	27	19
epinephrine / adrenergic bronchodilators	\$133,917	\$113,530	\$186,989	643	638
hydroxyprogesterone / progestins	\$324,848	\$230,190	\$376,845	117	104
ivacaftor / CFTR modulators	\$23,957	\$47,915	\$71,872	3	3
lurasidone / atypical antipsychotics	\$440,905	\$431,661	\$486,708	339	317

TABLE I: TOP 15 DRUG SOLID DOSAGE FORM HIGH VOLUME (100+ RX FILLS LAST MONTH) PRODUCTS WITH UNIT COST > \$1 BY PERCENT CHANGE IN AMOUNT PAID PER UNIT JAN 2021 TO MAR 2021 (FFS and CCOs)

Drug Product Therapeutic Category	Mar 2021 # Claims	Mar 2021 \$ Paid	Mar 2021 Avr. Paid Per Rx	Mar 2021 Avr. Units Per Rx	Jan 2021 Paid Per Unit	Feb 2021 Paid Per Unit	Mar 2021 Paid Per Unit	Percent Change
atomoxetine 40 mg capsule / CNS stimulants (P)	245	\$11,621	\$47.43	30	\$1.07	\$1.18	\$1.19	11.5%
Balcoltra (ethinyl estradiol-levonorgestrel) with iron 20 mcg-100 mcg tablet / contraceptives (P)	258	\$71,140	\$275.74	34	\$7.09	\$7.49	\$7.71	8.7%
Xarelto (rivaroxaban) 20 mg tablet / factor Xa inhibitors (P)	407	\$196,746	\$483.40	31	\$14.65	\$15.08	\$15.31	4.5%
colchicine 0.6 mg capsule / antigout agents (P)	153	\$26,203	\$171.26	37	\$4.14	\$4.18	\$4.32	4.3%
Linzess (linaclotide) 145 mcg capsule / guanylate cyclase-C agonists (P)	162	\$78,687	\$485.72	32	\$14.19	\$14.67	\$14.78	4.2%
Januvia (sitagliptin) 100 mg tablet / dipeptidyl peptidase 4 inhibitors (P)	380	\$256,077	\$673.89	42	\$15.07	\$15.47	\$15.62	3.7%
Entresto (sacubitril-valsartan) 97 mg-103 mg tablet / angiotensin receptor blockers and neprilysin inhibitors (P)	156	\$96,129	\$616.21	63	\$8.95	\$9.27	\$9.27	3.5%
Trintellix (vortioxetine) 10 mg tablet / miscellaneous antidepressants (P)	171	\$71,318	\$417.07	31	\$13.00	\$13.40	\$13.40	3.1%
Entresto (sacubitril-valsartan) 24 mg-26 mg tablet / angiotensin receptor blockers and neprilysin inhibitors (P)	222	\$126,778	\$571.07	63	\$8.95	\$9.22	\$9.20	2.7%
Eliquis (apixaban) 5 mg tablet / factor Xa inhibitors (P)	827	\$365,631	\$442.12	56	\$7.54	\$7.71	\$7.73	2.6%
Vimpat (lacosamide) 200 mg tablet / miscellaneous anticonvulsants (P)	187	\$173,086	\$925.59	61	\$14.82	\$15.25	\$15.20	2.6%
Trintellix (vortioxetine) 20 mg tablet / miscellaneous antidepressants (P)	197	\$97,325	\$494.04	35	\$13.13	\$13.25	\$13.36	1.7%
Focalin XR (dexmethylphenidate) 40 mg capsule, extended release / CNS stimulants (P)	108	\$46,453	\$430.12	30	\$13.73	\$13.96	\$13.96	1.7%

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

TABLE I: TOP 15 DRUG SOLID DOSAGE FORM HIGH VOLUME (100+ RX FILLS LAST MONTH) PRODUCTS WITH UNIT COST > \$1 BY PERCENT CHANGE IN AMOUNT PAID PER UNIT JAN 2021 TO MAR 2021 (FFS and CCOs)

Drug Product Therapeutic Category	Mar 2021 # Claims	Mar 2021 \$ Paid	Mar 2021 Avr. Paid Per Rx	Mar 2021 Avr. Units Per Rx	Jan 2021 Paid Per Unit	Feb 2021 Paid Per Unit	Mar 2021 Paid Per Unit	Percent Change
Taytulla (ethinyl estradiol-norethindrone) with iron 20 mcg-1 mg capsule / contraceptives (P)	231	\$52,987	\$229.38	30	\$6.95	\$7.05	\$7.05	1.5%
Vimpat (lacosamide) 100 mg tablet / miscellaneous anticonvulsants (P)	152	\$156,645	\$1,030.56	70	\$14.20	\$14.09	\$14.41	1.5%

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

MARCH 2021 – MAY 2021

Ongoing Intervention(s):

PROVIDER SHOPPING FOR OPIOIDS (≥4 Prescribers AND ≥4 Pharmacies)						
Month	Prescribers	Pharms	Benes			
WOILI	Mailed	Mailed	Addressed			
20-Jun	9	5	14			
20-Jul	6	5	11			
20-Aug	9	4	13			
20-Sep	10	8	18			
20-Oct	8	6	14			
20-Nov	6	4	10			
20-Dec	5	4	9			
21-Jan	3	3	6			
21-Feb	5	4	9			
21-Mar	6	5	11			
21-Apr	6	6	12			
21-May	3	3	6			

CONCOMITANT USE OF OPIOIDS AND ANTIPSYCHOTICS

Month	Prescribers	Benes	
	Mailed	Addressed	
21-May	74	94	





{Date}

IMPORTANT INFORMATION REGARDING CONCURRENT PRESCRIBING OF OPIOIDS AND ANTIPSYCHOTICS

Dear Dr. {Prescriber Name},

In accordance with recent updates in the Centers for Medicare & Medicaid Services' (CMS) Minimum Standards in Medicaid State Drug Utilization Review (DUR), the Mississippi Division of Medicaid's DUR program has initiated a program monitoring the concurrent prescribing of opioids and antipsychotics to Medicaid beneficiaries. The intention of this review is to encourage coordination of care for beneficiaries taking antipsychotic and opioid medications concurrently.

This monitoring program is supported by the FDA's boxed warning of increased risk of respiratory and central nervous system (CNS) depression with concurrent use of opioids and CNS depressants such as antipsychotics or sedatives.¹ According to CMS, *"Patients concurrently prescribed opioid and antipsychotic drugs can benefit from increased coordination of care. Additionally, improving treatment of comorbid mental disorders is an important consideration when trying to reduce the overall negative impacts of pain. Evidence indicates that optimizing mental health and pain treatment can improve outcomes in both areas for patients seen in primary and specialty care settings. Untreated psychiatric conditions may increase the risk of both unintentional and intentional medication mismanagement, opioid use disorder, and overdose.² Given the intersection between psychiatric/psychological symptoms and chronic pain, it is important that the behavioral health needs of patients with pain are appropriately and carefully evaluated and treated with the concurrent physical pain problem. As such, beneficiaries who are concurrently prescribed both opioids and antipsychotics should be considered from a health system or policy perspective when addressing their treatment.³ A patient's unique presentation and circumstances should be considered when prescribing opioids and antipsychotics."*

WHY YOU ARE RECEIVING THIS LETTER

Our analysis of prescription claims data identified the following beneficiary(ies) who filled a prescription written by you that resulted in the concurrent use of antipsychotic and opioid therapy for \geq 14 days.

		Opioid		Antipsychotic			
			Date			Date	
Beneficiary Name	DOB	Drug Name	Filled	Prescriber	Drug Name	Filled	Prescriber

¹ Office of the Commissioner. "Drug Safety Communications—FDA warns about serious risks and death when combining opioid pain or cough medicines with benzodiazepines; requires its strongest warning." *U.S. Food and Drug Administration Home Page*, Office of the Commissioner. https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-warns-aboutserious-risks-and-death-when-combining-opioid-pain-or

³ Davis, Matthew A., et al. "Prescription Opioid Use among Adults with Mental Health Disorders in the United States." The Journal of the American Board of Family Medicine, vol. 30, no. 4, 2017, pp. 407–417, doi:10.3122/jabfm.2017.04.170112.



² Pain Management Best Practices Inter-Agency Task Force. "Pain Management Best Practices."

https://www.hhs.gov/sites/default/files/ pmtf-final-report-2019-05-23.

Evidence-Based DUR Initiative

WHAT WE ASK OF YOU?

When prescribing antipsychotics and opioids, ensure the coordination of care for both pain management and mental health conditions is occurring and both conditions are being appropriately treated. Optimizing both mental health and pain treatment can improve patient outcomes in both areas and minimize the risks of adverse events.

We want to thank you for the care you provide to Medicaid beneficiaries. If we can be of any assistance, please do not hesitate to contact us.

Sincerely,

Teni R. Kney

Terri R. Kirby, RPh, CPM Director, Office of Pharmacy Mississippi Division of Medicaid

Eic Pettman, PharmD

Eric Pittman, PharmD Project Director MS-DUR

A REVIEW OF THE CURRENT STATE OF MIGRAINE TREATMENT AMONG MEDICAID BENEFICIARIES

BACKGROUND

Migraine is a common condition with a 12% one-year prevalence in the US population overall, affecting 17% of women and 6% of men.^{1–3} As represented in data, migraine is two to three times more common in women than in men and has a large impact in women from 15-49 years, during life years of high productivity.^{1–4} Though the effects of migraines are not easily measured, migraine has been identified as a disease condition.¹ Migraine impairs participation in multiple facets of life, including academic, occupational, personal and social aspects. The impact of migraine is significant. In 2016, migraine resulted in 45.1 million years lived with disability (YLD) and in women 15 to 49 years old, 20.3 million years lived with disability (YLD).¹

Aside from female gender, other sociodemographic and lifestyle factors are associated with migraine including low household income, obesity and daily caffeine intake.^{1,3} Common comorbid diseases and conditions associated with migraine include depression, asthma, head and neck injuries, and insomnia.¹ Both depression and anxiety disorders are strongly associated with migraine with depression being associated with the progression of episodic migraine to chronic migraine.³

Medication treatment for migraine can be divided into acute and preventive therapy. According to the American Headache Society, triptans, dihydroergotamine, acetaminophen, nonsteroidal antiinflammatory drugs (NSAIDs), opioids, sumatriptan/naproxen and acetaminophen/aspirin/caffeine all have level A evidence for acute migraine treatment.⁵ In clinical practice, first line therapies for mild to moderate migraine attacks are acetaminophen and NSAIDs (aspirin, diclofenac, ibuprofen, and naproxen).⁶ For moderate to severe migraine attacks, the triptans (almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, and zolmitriptan) are recommended. Even though intranasal dihydroergotamine and opioids, butorphanol, codeine, tramadol, meperidine, were found to have level A evidence, they are second-line therapies for acute migraine treatment due to severe nausea, leg cramps, and their high abuse potential.⁶ Antiemetics chlorpromazine, droperidol, metoclopramide, and prochlorperazine are second line therapies with moderate evidence for treating acute migraine.⁶ These are useful parenteral options for acute migraine treatment when oral administration is not possible due to nausea symptoms.⁶ In recent years new classes of medications have been approved for the acute treatment of migraines. Lasmiditan, approved October 2019, binds to the (5-HT)1F serotonin receptor.^{7,8} Gepants, small molecule CGRP antagonists, were first approved in December 2019.⁸

The progression of migraine involves episodic migraines increasing in frequency to a chronic migraine diagnosis. Those who suffer from migraine attacks at least 10 to 14 times a month are more likely to develop chronic migraine over time, at which point preventive treatment has utility.⁵ Patients may be indicated for preventive treatment of migraines if they have more than four migraine headache days per month, if attacks significantly interfere with daily functioning in

spite of acute treatment, if patients use ten or more days of acute non-NSAID treatment monthly, or if patients use 15 or more days of NSAID treatment monthly.⁹ Additionally, patient preference is a factor in the decision to treat migraine headaches preventively.⁹ A major goal of migraine preventive treatment is to reduce the frequency, severity, duration, and disability of migraines and to improve patients' health-related quality of life.⁹ There are few medication classes with FDA indications for migraine prevention or prophylaxis. Rather, many medications that are utilized have compendia-supported use. Medications with FDA indications for migraine prevention include antiepileptics topiramate and divalproex sodium/valproic acid; the beta blocker propranolol; onabotulinumtoxin A; and, most recently, calcitonin gene-related peptide (CGRP) inhibitors. A list of FDA-approved and compendia-supported migraine therapies can be found in Appendix A. Since the introduction of the first CGRP inhibitor in 2018, the landscape for migraine treatment has continued to evolve.

The following reports focus on migraine treatment among Medicaid beneficiaries. There are three reports centered on the following areas:

- Overall trends in the utilization of medications for the treatment of migraine;
- Calcitonin gene-related peptide inhibitor utilization trends and outcomes assessment;
- Utilization of preventive therapy for migraine among Medicaid beneficiaries.

REPORT 1: TRENDS IN OVERALL MEDICATION TREATMENT IN MIGRAINE

OBJECTIVE

The objective of this analysis was to assess utilization trends in migraine-related medications among Medicaid beneficiaries since the approval of the CGRP inhibitor medication class.

METHODS

A retrospective analysis was conducted using Mississippi Medicaid pharmacy and medical claims data to assess the utilization of agents used in the treatment of migraine during the study period March 2018 – February 2021. The analysis included data from the Fee-for-Service (FFS) program and the coordinated care organizations (CCOs) [Magnolia Health (MAG), Molina Healthcare (MOL), and UnitedHealthcare (UHC)].

Agents utilized in migraine treatment were identified through literature review. ^{6,9–11} These drugs were classified into prophylactic and acute migraine treatment (Appendix A). Pharmacy claims for these drugs during the study period were extracted. Pharmacy claims for inclusion in the trend analysis were assessed as follows:

- 1. **Migraine specific drugs:** Pharmacy claims for migraine specific drugs (calcitonin generelated peptide (CGRP) inhibitors, triptans, and 5-HTF receptor agonists) were included in the trend analysis regardless of a beneficiary's prior migraine diagnosis.
- 2. **Drugs with indications in addition to migraine-specific treatment:** For pharmacy claims of these drugs, medical claims of beneficiaries prescribed these drugs were extracted for the

period September 2017 – February 2021. The first date of migraine diagnosis for each beneficiary was identified by checking for any medical claim with a diagnosis code (ICD 10 code: G43) for migraine in any position. If the pharmacy claim date was on or after the first date of migraine diagnosis, the claim was included in trend analysis.

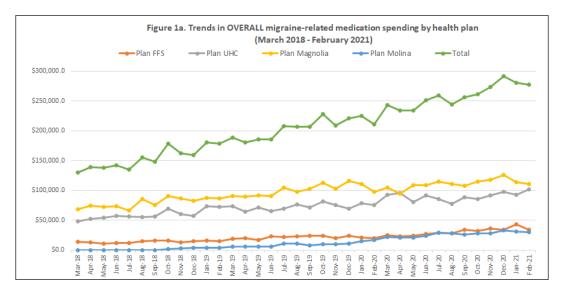
For all eligible pharmacy claims, monthly plan variables were extracted. Monthly pharmacy costs were evaluated with focus on the following specific trends: overall migraine-related pharmacy spending, spending on migraine-related preventive medications; spending on migraine-related acute medications; and spending on CGRP inhibitors. All analyses were stratified by health plan.

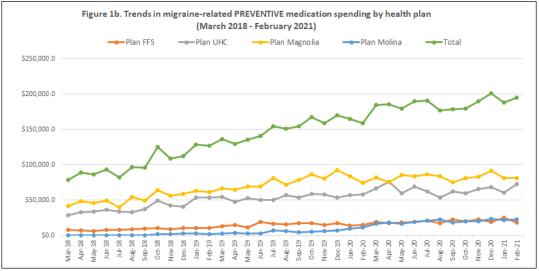
RESULTS

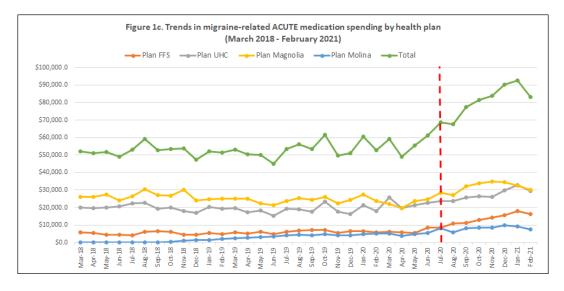
A total of 217,734 pharmacy claims met the eligibility criteria. Of these, 105 claims (49 beneficiaries) were excluded due to missing health plan information. The remaining 217,629 pharmacy claims, representing 24,858 beneficiaries, were included in the analyses.

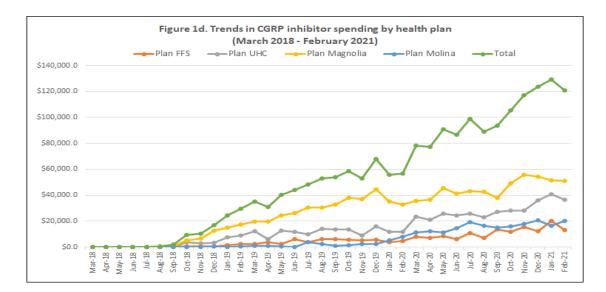
Figures 1a-1d display trends in migraine-related spending by health plan. Tables 1a-1h detail migraine trends associated with each figure and can be found in Appendix B. The following observations can be drawn from the figures/tables:

- There has been a consistent increase in the **overall** spending associated with migrainerelated medications, specifically CGRP inhibitors. (Figures 1a & 1d) Overall monthly spending has more than doubled from \$130,335 in March 2018 to \$287,077 in February 2021.
- Migraine-related spending on preventive medications began climbing in October 2018. Although the first injectable CGRP inhibitors were approved in spring 2018, the first paid pharmacy claims for injectable CGRP inhibitors occurred in September 2018 and corresponds with the upward trend. (Figure 1b) Spending on preventive therapies increased 149% over the analysis period.
- Migraine-related spending on **acute** medications showed minimal change until July 2020. (Figure 1c) The upward trend noted at that point can be correlated with the addition of the first oral CGRP inhibitor for acute treatment as a preferred agent on the preferred drug list.









CONCLUSIONS

Total spending on migraine-related medications has shown a consistent increase since 2018. This increase can be primarily attributed to the utilization of CGRP inhibitor products. Further examination of the utilization of CGRP inhibitor products is warranted.

RECOMMENDATIONS

There are no formal recommendations as a result of this report.

REPORT 2: CGRP INHIBITOR UTILIZATION AND OUTCOMES ASSESSMENT

CGRP is a vasoactive peptide involved in the pathophysiology of migraines and is a potent vasodilator that has been noted to exist in high concentrations in smooth muscle tissues.¹⁰ CGRP inhibitors were developed specifically for the treatment of migraine. There are two types of CGRP inhibitors approved for use in the US by the Federal Drug Administration (FDA) – monoclonal antibodies and CGRP receptor antagonists (gepants). Monoclonal antibodies are large molecules delivered subcutaneously or intravenously that work by either blocking the binding of the CGRP peptide to its receptor or by binding CGRP itself.¹² These agents have a slow onset and long half-lives. There are currently four monoclonal antibody agents approved in the US, Aimovig (erenumab-aooe), Ajovy (fremanezumab-vfrm), Emgality (galcanezumab-gnlm) and Vyepti (eptinezumab-jjmr). In contrast, gepants are smaller molecules that block the CGRP receptor, are orally bioavailable, and tend to have short half-lives. Nurtec (rimegepant) and Ubrelvy (ubrogepant) are the gepants approved at this time. At this time the injectable monoclonal antibodies are indicated for migraine prophylaxis and Ubrelvy (ubrogepant) is indicated for acute therapy.^{6,11} The FDA recently added an indication for preventive treatment in those experiencing episodic migraines to Nurtec (rimegepant), making it the first product indicated for both the

prevention and treatment of migraines.¹³ A copy of Mississippi Medicaid's Universal Preferred Drug List (UPDL) and Manual PA for CGRP inhibitors is available in Appendix C.

This report aims to assess the utilization of CGRP inhibitor medications, establish if CGRP inhibitor medications are being utilized by Mississippi Division of Medicaid health plans in a cost-effective manner, and to determine if current utilization strategies, including prior authorization, are effective in encouraging appropriate CGRP inhibitor utilization among this population.

OBJECTIVE 1

Objective 1 of this analysis was to assess the utilization of CGRP inhibitors among Medicaid beneficiaries.

METHODS

A retrospective analysis was conducted using Mississippi Medicaid Fee-for-Service (FFS) and coordinated care organization [CCOs: Magnolia Health (MAG), Molina Healthcare (MOL), and UnitedHealthcare (UHC)] pharmacy and medical claims for the period of January 1, 2018 to February 28, 2021 (observation period) to assess utilization of CGRP inhibitors among Medicaid beneficiaries with migraine. Beneficiaries with migraine diagnosis were identified during the observational period using the ICD 10 code of 'G43' from any diagnosis field in medical claims (inpatient, outpatient and medical files). Additionally, to identify beneficiaries with migraine from pharmacy claims, the criteria used by Bonafede et.al. of beneficiaries having at least two pharmacy claims for a triptan and/or ergotamine/dihydroergotamine, 7 to 180 days apart was utilized.¹ Among the identified beneficiaries with migraine, CGRP inhibitor use was identified from pharmacy claims using NDC codes for CGRP inhibitors and from outpatient claims using the procedure codes of 'J3031', 'J3032' and 'J3590'. Assessed medications included oral gepants Nurtec (rimegepant) and Ubrelvy (ubrogepant) along with injectable monoclonal antibodies Aimovig (erenumab-aooe), Ajovy (fremanezumab-vfrm), Emgality (galcanezumab-gnlm) and Vyepti (eptinezumab-jjmr).

Information on beneficiaries' race, gender, age, and plan (FFS/UHC/MAG/MOL) were summarized in the analysis (Table 2a). Age was determined as of January 1, 2019, the start of the study period. Plan was determined as the plan corresponding to the last month of enrollment for the beneficiaries during the analysis period. CGRP inhibitor utilization for the included beneficiaries was stratified by plan for the study period January 1, 2019 to February 28, 2021 (Tables 2b & 2c). The number of unique beneficiaries that used CGRP inhibitors within the study period was reported under the 'Any CGRP Use' column (Table 2b). The number of beneficiaries with any oral CGRP inhibitor use during the study period, regardless of concomitant use with injectables, was reported under 'Oral CGRP' column (Table 2b). The number of beneficiaries with any injectable CGRP inhibitor use during the study period, regardless of concomitant use of oral CGRP inhibitors, was reported under the 'Injectable CGRP' column (Table 2b). Among these beneficiaries, those that had any concomitant use of oral and injectable CGRP inhibitors during the observation period were reported under the 'Concomitant Use' column. Concomitant use was defined as one or more days of overlap between the use of oral and injectable CGRP inhibitors. The number of beneficiaries with cumulative length of concomitant use in the following categories (0-14 days, 15-29 days and 30 days or more) was described in Table 2c.

RESULTS

During the period from January 1, 2019 to February 28, 2021, a total of 524 beneficiaries with a migraine diagnosis had paid claims for CGRP inhibitors in Mississippi Medicaid. Of those 524 beneficiaries:

- 95% were female;
- 81.7% were between ages 18-50 years;
- 51.1% were Caucasian.

					Plan	1			
Chavestavistics	Total	FFS		UHC		MAG		MOL	
Characteristics	Beneficiaries	N	%	N	%	N	%	N	%
Age Category									
0-17	22	12	9.60%	7	5.51%	2	0.93%	1	1.72%
18-35	221	54	43.20%	44	34.65%	91	42.52%	32	55.17%
36-50	207	37	29.60%	58	45.67%	93	43.46%	19	32.76%
51-64	74	22	17.60%	18	14.17%	28	13.08%	6	10.34%
Total	524	125		127		214		58	
Sex									
Female	498	118	94.40%	119	93.70%	205	95.79%	56	96.55%
Male	26	7	5.60%	8	6.30%	9	4.21%	2	3.45%
Total	524	125		127		214		58	
Race							I		
Caucasian	268	58	46.40%	76	59.84%	104	48.60%	30	51.72%
Other	36	11	8.80%	7	5.51%	15	7.01%	3	5.17%
African American	220	56	44.80%	44	34.65%	95	44.39%	25	43.10%
Total	524	125		127		214		58	

Note: FFS - Fee-for-Service; UHC - UnitedHealthcare; MAG - Magnolia; MOL - Molina; CGRP - Calcitonin Gene-Related Peptide *Beneficiaries diagnosed with Migraine were identified from medical claims using the ICD 10 code of "G43" and from pharmacy claims using the algorithm of beneficiaries having a prescription of at least two outpatient pharmacy claims for triptan and/or ergotamine/dihydroergotamine (7–180 days apart) as used by Bonafede et.al. (2020). The identification period for beneficiaries with Migraine was January 1, 2018 to February 28, 2021. CGRP use was identified between January 1, 2019 to February 28, 2021. Age was determined as of January 1, 2019 which was the start of the observation period. Plan was determined as of the plan of the last month of enrollment during the study period.

Table 2b describes the types of CGRP inhibitor use among beneficiaries during the study period. Of the 524 beneficiaries with CGRP inhibitor use, 83.6% had claims for injectable CGRP inhibitors and 20.4% had claims for oral CGRP inhibitors. **Approximately 5% had claims for concomitant injectable and oral CGRP inhibitor use.**

TABLE 2b. CGRP Utilization Stratified by Plan(January 1, 2019 - February 28, 2021)						
Beneficiaries with Plan* Migraine Beneficiaries using CGRP**						
		Any CGRP Use	Oral CGRP	Injectable CGRP	Concomitant Use*** (Oral+Injectable)	
FFS	9304	125	19	107	3	
UHC	6624	127	33	99	3	
MAG	7104	214	44	179	15	
MOL	2364	58	11	53	5	
Total	25,396	524	107	438	26	

Note: FFS - Fee-for-Service; UHC - United Healthcare; MAG - Magnolia; MOL- Molina; CGRP - Calcitonin Gene-Related Peptide CGRP use was identified between January 1, 2019 to February 28, 2021 from pharmacy claims using NDC codes for CGRPs and from outpatient claims using the J Codes of 'J3031', 'J3032' and 'J3590'.* Plan was determined as of the last month of enrollment within the observation period. CGRPs that were assessed were Nurtec (rimegepant), Ubrelvy (ubrogepant), Aimovig (erenumab-aooe), Ajvoy (fremanezumab-vrfm), Emgality (galcenezumab-gnlm), and Vyepti (eptinezumab-jjmr). **'Any CGRP Use' column describes the number of unique benefeciaries that used CGRPs within the study period. 'Oral CGRP' column describes the number of beneficiaries with oral CGRP use during the study period regardless of concomitant use with injectables. 'Injectable CGRP' column describes the number of benefeciaries with injectable CGRP use during the study period regardless of concomitant use. 'Concomitant Use' column describes those that had overlapping use of oral and injectable CGRPs during the study period. ***Concomitant use was defined as one or more days of overlap between oral and injectable CGRP use.

At the time of the analysis, injectable monoclonal antibody CGRP inhibitors were indicated for migraine prophylaxis and oral gepants were indicated for acute migraine treatment. Despite different indications, both oral and injectable CGRP inhibitors work by blocking the binding of calcitonin gene-related peptide to its receptor thereby preventing the inflammatory cascade leading to migraine. Among patients taking injectable CGRP inhibitors for preventive migraine therapy, there is debate as to whether the concomitant use of oral CGRP inhibitors for acute migraine treatment may be effective and safe.

Limited studies exist that assess the concomitant use of injectable and oral CGRP inhibitors, but those that do exist appear to indicate little risk of harm and a potential for therapeutic benefit. A phase 1b drug interaction study found that when Ubrelvy (ubrogepant) was administered with either Aimovig (erenumab-aooe) or Emgality (galcanezumab-gnlm) over fifteen days, the pharmacokinetic profile of Ubrelvy (ubrogepant) remained largely unchanged.¹⁴ Additionally, combination therapy with these agents appeared safe, with the most common adverse events including constipation, nausea, and upper abdominal pain.¹⁴ Case reports representing two individuals indicated effective and safe use of combination therapy with Aimovig (erenumab-aooe) and Nurtec ODT (rimegepant).¹⁵ These two individuals, who were both adult white females, reported no adverse effects over the study period.¹⁵ Effectiveness of oral CGRP inhibitors among these patients led to discontinuation of other therapies for acute migraine treatment, including NSAIDs ibuprofen, aspirin/caffeine, and ketorolac.¹⁵ A separate twelve-week longitudinal study of thirteen patients examined the safety of combination therapy with Nurtec ODT (rimegepant) with either Aimovig (erenumab-aooe), Emgality (galcanezumab-gnlm), or Ajovy (fremanezumabvfrm).¹⁶ Over the study period, no patient-reported serious adverse effects related to dual use of CGRP inhibitors were reported, and the most commonly-reported adverse event among the study

population was nasopharyngitis.¹⁶ Of note, one patient receiving Nurtec ODT (rimegepant) and Aimovig (erenumab-aooe) experienced atrioventricular block that investigators concluded may possibly be related to treatment, but this adverse event resolved without dose changes of either CGRP inhibitor therapy.¹⁶

Table 2c details the concomitant use of oral and injectable CGRP inhibitors among Medicaid beneficiaries. Of the 26 beneficiaries with concomitant use, 14 had \geq 30 days of concomitant use. Ten unique provider practices were affiliated with the claims for the 26 beneficiaries that experienced concomitant use.

TABLE 2c. Concomitant Use of Oral and Injectable CGRPs Stratified by Plan (January 1, 2019 - February 28, 2021)							
Plan	Plan Concomitant Use*						
	<15 Days 15-29 Days 30 Days or More Total						
FFS	2	1	0	3			
UHC	1	0	2	3			
MAG	4	3	8	15			
MOL	1	0	4	5			
Total	8	4	14	26			

Note: FFS - Fee-for-Service; UHC - United Healthcare; MAG - Magnolia; MOL- Molina; CGRP - Calcitonin Gene-Related Peptide

*Concomitant use was defined as one or more days of overlap between Oral and Injectable CGRP use.

OBJECTIVE 2

Migraine outcomes reported in clinical trials often include monthly migraine days, achievement of 50% reduction in monthly migraine days, and number of days using acute medications. However, the structure of medical claims data prevents the examination of outcomes similar to those reported in clinical trials. While total costs and trends for CGRP inhibitor utilization can be gleaned from claims data, patients' migraine logs and accurate measurements of acute migraine medication use are not available within data sets. In order to assess migraine outcomes through claims data, surrogate outcome measures may be assessed.

Objective 2 of this analysis was to assess healthcare resource utilization and opioid use pre- and post- CGRP inhibitor initiation.

METHODS

Using the observational period of January 1, 2018 to February 28, 2021, the analysis for objective 2 included beneficiaries that initiated therapy with any CGRP inhibitor agent between January 1, 2019 to August 31, 2020. The date of the first prescription was identified as the index date. A three-month look-back period was used to guarantee all CGRP inhibitor users were newly initiated with CGRP inhibitor agents.

All-cause total costs (inpatient, outpatient, office visit and pharmacy claims), all-cause medical costs (inpatient, outpatient and office visit claims), and migraine-specific costs (inpatient, outpatient and office visit claims) with a primary diagnosis code of migraine (ICD-10-code G43) were captured in the 6-month period pre- and post-index date. All cost values were reported in terms of per-beneficiary-per-month (PMPM) cost. Opioid use was captured in the 3-month period pre- and post-index date through pharmacy claims. Each prescription for any opioid agent was transformed to morphine equivalent daily dose (MEDD) based on dose and days supply on the claim using the conversion factor of the opioid agent. The average and maximum MEDD in both the pre- and post-index periods were calculated for each beneficiary.

Beneficiaries were further categorized by the time from CGRP inhibitor initiation to treatment discontinuation as either early discontinuers or continuers. CGRP inhibitor discontinuation was defined as a gap of at least 60 days in treatment after the daily supply of the last prescription was exhausted. Early discontinuers were identified if a beneficiary's last effective date of their last CGRP inhibitor prescription before treatment discontinuation was \leq 90 days from the CGRP inhibitor initiation date. Continuers were identified if a beneficiary's last effective date of their last CGRP inhibitor prescription before treatment discontinuation was \geq 90 days from the CGRP inhibitor prescription before treatment discontinuation was \geq 90 days from the CGRP inhibitor initiation date. Beneficiaries were assigned to the plan they were enrolled in as of the January 1, 2019.

RESULTS

Tables 3a-3d display healthcare resource utilization pre- and post- CGRP inhibitor initiation among Medicaid beneficiaries. When examining Table 3a, mean PMPM medical and migraine-specific costs were lower in the post-initiation period compared to the pre-initiation period. In contrast, Total PMPM costs, which included pharmacy claims, were higher in the post-initiation period compared to the pre-initiation period.

		TABLE 3a. He		Utilization Pre & Post Try 1, 2019 - August 31		tified by Plan		
				Total PMPN	l Cost **			
[Pre-ini	tiation			Post-ini	tiation	
Plan*	Mean	Median	25th percentile	75th percentile	Mean	Median	25th percentile	75th percentile
FFS	\$1,405.3	\$718.1	\$273.3	\$2,053.9	\$1,702.0	\$981.2	\$466.0	\$1,742.9
UHC	\$1,651.0	\$750.5	\$433.8	\$1,317.4	\$1,605.0	\$1,047.7	\$680.6	\$2,000.
MAG	\$1,808.7	\$983.5	\$395.3	\$2,124.6	\$2,290.2	\$1,223.4	\$701.1	\$2,579.3
MOL	\$1,157.2	\$572.7	\$225.1	\$1,193.0	\$1,528.1	\$1,135.2	\$820.3	\$1,601.
Total	\$1,589.1	\$797.0	\$323.4	\$1,777.3	\$1,886.2	\$1,079.3	\$662.7	\$2,020.
Plan*	Mean	Pre-ini Median	tiation 25th percentile	Medical PMP 75th percentile	M Cost ** Mean	Post-ini Median	tiation 25th percentile	75th percentile
FFS	\$1,175.2	\$449.0	\$197.0	\$1,593.2	\$1,205.9	\$470.5	\$116.0	\$1,093.4
UHC	\$1,391.5	\$534.3	\$235.3	\$1,049.7	\$892.3	\$450.6	\$181.6	\$1,098.
MAG	\$1,361.6	\$614.3	\$228.7	\$1,357.5	\$1,457.2	\$533.7	\$216.7	\$1,299.
MOL	\$1,056.3	\$347.1	\$156.1	\$1.032.0	\$619.9	\$421.4	\$140.7	\$827.
Total	\$1,283.3	\$528.8	\$208.2	\$1,309.2	\$1,165.6	\$474.3	\$185.6	\$1,094.
			\$208.2	\$1,309.2 Migriane-specific		\$474.3	\$185.6	\$1,094.:
						\$474.3 Post-ini		\$1,094.:
		\$528.8						\$1,094. 75th percentile
Total	\$1,283.3	\$528.8 Pre-ini	tiation	Migriane-specific	PMPM Cost **	Post-ini	tiation	75th percentile
Total Plan*	\$1,283.3 Mean	\$528.8 Pre-ini Median	tiation 25th percentile	Migriane-specific 75th percentile	PMPM Cost ** Mean	Post-ini Median	tiation 25th percentile	\$1,094.8 75th percentile \$19.5 \$33.8
Plan* FFS	\$1,283.3 Mean \$89.1	\$528.8 Pre-ini Median \$21.1	tiation 25th percentile \$0.0	Migriane-specific 75th percentile \$57.7	PMPM Cost ** Mean \$24.7	Post-ini Median \$0.0	tiation 25th percentile \$0.0	75th percentile \$19.

\$20.9 Note: CGRP initiators are defined as beneficiaries who had CGRP use in Jan 2019 - Aug 2020 and didn't have any CGRP claims in 3 months proir to the first CGRP claims of the observation peroid. A total of 344 initiators are finally included. Values of cost are calculated based on HCRU in 6 months pre-CGRP initiation and 6 months post-CGRP initiation. * Plan was determined as of date of January 1, 2019. ** Total PMPM costs involve all-cause medical cost and pharmacy cost; medical PMPM costs involve all-cause medical cost; migriane-specific costs involve cost of medical claims with migraine (ICD-10-Code G43) as the principle diagnosis.

\$62.8

\$67.5

\$60.9

\$51.8

\$11.3

\$11.3

\$0.0

\$0.0

\$25.0

\$34.7

\$0.0

\$0.0

MOL

Total

\$40.3

\$76.2

\$17.1

Tables 3b-3d display healthcare resource utilization by early discontinuers and continuers. An early discontinuer was defined as a beneficiary with < 90 days of CGRP inhibitor therapy. When CGRP inhibitors are initially approved through the prior authorization process, approval is granted for 12 weeks or approximately 90 days. Beneficiaries in which CGRP inhibitor therapy is clinically effective at reducing migraine symptoms and improving function during the initial approval period can obtain reauthorization for an additional 12 months. In an attempt to determine if there was a difference in healthcare resource utilization between early discontinuers and continuers, costs for these two groups were compared separately.

- In both discontinuers and continuers, similar to the trends noted overall, mean PMPM medical and migraine-specific costs were lower in the post-initiation period compared to the pre-initiation period while total PMPM costs were higher in the post-initiation period. (Tables 3b & 3c)
- CGRP inhibitor continuers had slightly higher costs for all categories in the post-initiation period when compared to CGRP inhibitor early discontinuers. (Table 3d)

	TABLE	3b. Healthcare R		Pre & Post CGRP Init ary 1, 2019 - August 3		Plan - Early Discont	inuers	
	Total PMPM Cost **							
		Pre-ini	tiation			Post-ini	tiation	
Plan*	Mean	Median	25th percentile	75th percentile	Mean	Median	25th percentile	75th percentile
FFS	\$1,307.9	\$1,307.9 \$505.3 \$201.4 \$1,238.0 \$1,564.9 \$919.0 \$305.2 \$1,53						
UHC	\$1,371.1	\$616.9	\$300.9	\$1,126.3	\$1,455.7	\$880.9	\$484.0	\$1,919.2
MAG	\$1,658.4	\$869.5	\$425.9	\$2,079.2	\$1,755.4	\$920.3	\$585.6	\$2,033.2
MOL	\$1,822.7	\$374.1	\$167.8	\$2,036.1	\$1,431.0	\$1,112.3	\$263.2	\$1,326.5
Total	\$1,483.6	\$609.6	\$273.5	\$1,840.9	\$1,593.9	\$929.5	\$468.4	\$1,692.1
				Medical PM	PM Cost **			
		Pre-ini	tiation			Post-ini	tiation	
Plan*	Mean	Median	25th percentile	75th percentile	Mean	Median	25th percentile	75th percentile
FFS	\$1,093.7	\$375.7	\$161.7	\$1,049.2	\$1,234.4	\$560.6	\$100.8	\$1,021.4
UHC	\$1,102.5	\$517.4	\$211.3	\$884.6	\$912.9	\$446.4	\$181.6	\$827.3
MAG	\$1,128.9	\$578.6	\$233.1	\$1,348.8	\$975.6	\$523.9	\$287.9	\$1,115.0
MOL	\$1,725.0	\$254.9	\$144.3	\$1,997.4	\$544.9	\$436.1	\$58.2	\$986.8

				Migriane-specific	: PMPM Cost **			
		Pre-ini	tiation			Post-ini	tiation	
Plan*	Mean	Median	25th percentile	75th percentile	Mean	Median	25th percentile	75th percentile
FFS	\$69.9	\$24.2	\$0.0	\$57.7	\$25.7	\$0.0	\$0.0	\$20.2
UHC	\$65.0	\$15.5	\$0.0	\$73.1	\$36.9	\$14.6	\$0.0	\$33.4
MAG	\$71.4	\$18.4	\$0.0	\$91.6	\$60.8	\$14.9	\$0.0	\$61.0
MOL	\$61.9	\$37.9	\$11.0	\$93.8	\$67.5	\$10.9	\$0.0	\$100.4
Total	\$68.6	\$22.4	\$0.0	\$78.7	\$43.9	\$10.7	\$0.0	\$34.6

\$1,325.8

\$1,010.6

\$169.0

Total

\$1,152.1

\$487.8

\$505.3

\$181.6

\$1,017.0

Note: CGRP initiators are defined as beneficiaries who had CGRP use in Jan 2019 - Aug 2020 and didn't have any CGRP claims in 3 months proir to the first CGRP claims of the observation peroid. CGRP discontinuation is defined as a gap of at least 60 days in treatment after the daily supply of the last prescription was exhausted. Early discontinuers are classified as beneficiaries where the last effective date of their last prescription before CGRP discontinuation is less equal to 90 days from their initiation date. A total of 159 early discontinuers are finally included. Values of cost are calculated based on HCRU in 6 months pre-CGRP initiation and 6 months post-CGRP initiation. * Plan was determined as of date of January 1, 2019. ** Total PMPM costs involve all-cause medical cost and pharmacy cost; medical PMPM costs involve all-cause medical costs involve cost of medical claims with migraine (ICD-10-Code G43) as the principle diagnosis.

TABLE 3c. Healthcare Resource Utilization Pre & Post CGRP Initiation Stratified by Plan - Continuers (January 1, 2019 - August 31, 2020)

	Total PMPM Cost **									
[Pre-ini	tiation			Post-ini	tiation			
Plan*	Mean	Median	25th percentile	75th percentile	Mean	Median	25th percentile	75th percentile		
FFS	\$1,513.5	\$860.4	\$444.4	\$2,116.2	\$1,854.2	\$1,104.1	\$715.5	\$2,141.6		
UHC	\$1,968.9	\$913.7	\$590.1	\$1,317.4	\$1,774.4	\$1,272.6	\$923.0	\$2,000.7		
MAG	\$1,919.4	\$1,143.8	\$363.4	\$2,134.6	\$2,684.2	\$1,461.9	\$833.4	\$2,675.1		
MOL	\$886.1	\$629.3	\$227.7	\$1,185.2	\$1,567.6	\$1,283.8	\$820.3	\$1,640.0		
Total	\$1,679.8	\$930.0	\$372.8	\$1,766.4	\$2,137.4	\$1,305.5	\$817.7	\$2,104.6		

	Medical PMPM Cost **									
		Pre-ini	tiation		Post-initiation					
Plan*	Mean	Median	25th percentile	75th percentile	Mean	Median	25th percentile	75th percentile		
FFS	\$1,265.8	\$659.8	\$256.1	\$2,049.4	\$1,174.2	\$451.2	\$187.8	\$1,093.4		
UHC	\$1,719.5	\$605.0	\$378.8	\$1,124.1	\$869.0	\$450.6	\$184.3	\$1,098.0		
MAG	\$1,533.0	\$641.6	\$228.7	\$1,449.4	\$1,812.1	\$614.0	\$178.7	\$1,547.9		
MOL	\$783.8	\$361.6	\$199.6	\$1,026.0	\$650.4	\$415.5	\$182.3	\$827.7		
Total	\$1,396.0	\$610.3	\$244.6	\$1,298.8	\$452.4	\$186.9	\$1,098.0			

	Migriane-specific PMPM Cost **									
		Pre-ini	tiation			Post-ini	tiation	75th percentile \$17.6 \$33.8 \$53.2		
Plan*	Mean	Median	25th percentile	75th percentile	Mean	Median	25th percentile	75th percentile		
FFS	\$110.4	\$14.7	\$8.8	\$31.6	\$23.5	\$6.1	\$0.0	\$17.6		
UHC	\$93.9	\$20.8	\$9.7	\$183.6	\$110.3	\$14.7	\$5.1	\$33.8		
MAG	\$79.0	\$29.0	\$8.6	\$64.4	\$54.1	\$12.5	\$0.0	\$53.3		
MOL	\$31.4	\$8.8	\$0.0	\$28.4	\$58.3	\$11.4	\$0.0	\$25.0		
Total	\$82.7	\$20.8	\$6.9	\$63.0	\$58.5	\$12.3	\$0.0	\$34.9		

Note: CGRP initiators are defined as beneficiaries who had CGRP use in Jan 2019 - Aug 2020 and didn't have any CGRP claims in 3 months proir to the first CGRP claims of the observation peroid. CGRP discontinuation is defined as a gap of at least 60 days in treatment after the daily supply of the last prescription was exhausted. Continuers are classified as beneficiaries where the last effective date of their last prescription before CGRP discontinuation is greater than 90 days from their initiation date. A total of 185 continuers are finally included. Values of cost are calculated based on HCRU in 6 months pre-CGRP initiation and 6 months post-CGRP initiation. * Plan was determined as of date of January 1, 2019. ** Total PMPM costs involve all-cause medical cost; migriane-specific cost involve cost of medical claims with migraine (ICD-10-Code G43) as the principle diagnosis.

	TABLE 3d.	Healthcare Resou	rce Utilization Post	t CGRP Initiation Stra	tified by Plan - Early	Discontinuers vs C	Continuers	
			(Janua	ry 1, 2019 - August 3	1, 2020)			
				Total PMP	A Cost **			
		Early Disc	ontinuers			Contir	nuers	
Plan*	Mean	Median	25th percentile	75th percentile	Mean	Median	25th percentile	75th percentile
FFS	\$1,564.9	\$919.0	\$305.2	\$1,536.1	\$1,854.2	\$1,104.1	\$715.5	\$2,141.6
UHC	\$1,455.7	\$880.9	\$484.0	\$1,919.2	\$1,774.4	\$1,272.6	\$923.0	\$2,000.7
MAG	\$1,755.4	\$920.3	\$585.6	\$2,033.2	\$2,684.2	\$1,461.9	\$833.4	\$2,675.1
MOL	\$1,431.0	\$1,112.3	\$263.2	\$1,326.5	\$1,567.6	\$1,283.8	\$820.3	\$1,640.0
Total	\$1,593.9	\$929.5	\$468.4	\$1,692.1	\$2,137.4	\$1,305.5	\$817.7	\$2,104.6
				Medical PMI	PM Cost **			
		Early Disc	ontinuers			Contir	nuers	
Plan*	Mean	Median	25th percentile	75th percentile	Mean	Median	25th percentile	75th percentile
FFS	\$1,234.4	\$560.6	\$100.8	\$1,021.4	\$1,174.2	\$451.2	\$187.8	\$1,093.4
UHC	\$912.9	\$446.4	\$181.6	\$827.3	\$869.0	\$450.6	\$184.3	\$1,098.0

	Migriane-specific PMPM Cost **									
	Early Discontinuers Continuers									
Plan*	Mean	Median	25th percentile	75th percentile	Mean	Median	25th percentile	75th percentile		
FFS	\$25.7	\$0.0	\$0.0	\$20.2	\$23.5	\$6.1	\$0.0	\$17.6		
UHC	\$36.9	\$14.6	\$0.0	\$33.4	\$110.3	\$14.7	\$5.1	\$33.8		
MAG	\$60.8	\$14.9	\$0.0	\$61.0	\$54.1	\$12.5	\$0.0	\$53.3		
MOL	\$67.5	\$10.9	\$0.0	\$100.4	\$58.3	\$11.4	\$0.0	\$25.0		
Total	\$43.9	\$10.7	\$0.0	\$34.6	\$58.5	\$12.3	\$0.0	\$34.9		

\$1.115.0

\$986.8

\$1,017.0

\$1.812.1

\$650.4

\$1,298.8

\$614.0

\$415.5

\$452.4

\$178.7

\$182.3

\$186.9

\$1.547.9

\$1,098.0

\$827.7

MAG

MOL

Total

\$975.6

\$544.9

\$1,010.6

\$523.9

\$436.1

\$505.3

\$287.9

\$58.2

\$181.6

Note: CGRP initiators are defined as beneficiaries who had CGRP use in Jan 2019 - Aug 2020 and didn't have any CGRP claims in 3 months proir to the first CGRP claims of the observation peroid. CGRP discontinuation is defined as a gap of at least 60 days in treatment after the daily supply of the last prescription was exhausted. Early discontinuers are classified as beneficiaries where the last effective date of their last prescription before CGRP discontinuation is less than or equal to 90 days from their initiation date. Continuers are classified as beneficiaries where the last effective date of their last prescription before CGRP discontinuation is greater than 90 days from their initiation date. Continuers are classified as beneficiaries where the last effective date of their last prescription before CGRP discontinuation is greater than 90 days from their initiation date. A total of 159 early discontinuers and 185 continuers are finally included. Values of cost are calculated based on HCRU in 6 months post-CGRP initiation. * Plan was determined as of date of January 1, 2019. ** Total PMPM costs involve all-cause medical cost and pharmacy cost; medical PMPM costs involve all-cause medical cost; migriane specific costs involve cost of medical claims with migraine (ICD-10-Code G43) as the principle diagnosis.

Another method used to evaluate outcomes through claims data was examining opioid use in a 3month period pre- and post- CGRP inhibitor initiation. Average and maximum MEDD was calculated for each beneficiary during the pre- and post- CGRP inhibitor initiation period and compared. (Tables 4a-4d)

- Overall mean Average and mean Maximum MEDD values were higher in the post-initiation period compared to the pre-initiation period. (Table 4a)
- When separating out early discontinuers and continuers, some differences were noted:
 * For early discontinuers, the mean Average and mean Maximum MEDD values were higher in the post-initiation period. (Table 4b)

* For continuers, however, the mean Average and mean Maximum MEDD values were lower in the post-initiation period. (Table 4c)

• Comparing post-initiation MEDD levels between early discontinuers and continuers, mean Average and mean Maximum MEDD values were lower for continuers. (Table 4d)

	TABLE 4a. Opioid Use Pre & Post CGRP Initiation Stratified by Plan (January 1, 2019 - August 31, 2020)										
		Pre-i	nitiation			Post-i	nitiation				
	Mean Average	Median Average	Mean Maximun	Median Maximum	Mean Average	Median Average	Mean Maximum	Median Maximum			
	MEDD	MEDD	MEDD	MEDD	MEDD	MEDD	MEDD	MEDD			
FFS	6.0	0.0	6.7	0.0	5.1	0.0	5.2	0.0			
UHC	8.4	0.0	9.1	0.0	18.7	0.0	29.8	0.0			
MAG	10.6	0.0	12.7	0.0	10.1	0.0	11.7	0.0			
MOL	4.8 0.0 5.2 0.0 5.2 0.0 5.4 0.0										
Total	8.2 0.0 9.4 0.0 10.1 0.0 13.4 0.0										

Note: CGRP Initiators are defined as beneficiaries who had CGRP use in Jan 2019 - Aug 2020 and didn't have any CGRP claims in 3 months proir to the first CGRP claims of the observation peroid. A total of 344 initiators are included. Opioid use is calculated based on pharmacy claims for 3 months pre-CGRP initiation and 3 months post-CGRP initiation. Among the CGRP initiators, 134 beneficiaries had at least one pharmacy claim of opioid in either pre or post peroid. * Plan was determined as of date of January 1, 2019.

TABLE 4b. Opioid Use Pre & Post CGRP Initiation Stratified by Plan - Early Discontinuers (January 1, 2019 - August 31, 2020)

		Pre-i	nitiation			Post-i	nitiation			
	Mean Average	Median Average	Mean Maximun	Median Maximum	n Mean Average Median Average Mean Maximum		Mean Maximum	Median Maximum		
	MEDD	MEDD	MEDD	MEDD	MEDD	MEDD	MEDD	MEDD		
FFS	5.3	0.0	6.3	0.0	6.0	0.0	6.2	0.0		
UHC	6.0	0.0	6.4	0.0	26.5	0.0	46.4	0.0		
MAG	8.3	0.0	9.2	0.0	7.3	0.0	8.8	0.0		
MOL	5.9	0.0	6.4	0.0	6.8	0.0	6.8	0.0		
Total	6.6	0.0	7.4	0.0	11.9	0.0	17.8	0.0		

Note: CGRP initiators are defined as beneficiaries who had CGRP use in Jan 2019 - Aug 2020 and didn't have any CGRP claims in 3 months proir to the first CGRP claims of the observation peroid. A total of 344 initiators are included. Opioid use is calculated based on pharmacy claims for 3 months pre-CGRP initiation and 3 months post-CGRP initiation. Among the CGRP initiators, 134 beneficiaries had at least one pharmacy claim of opioid in either pre or post peroid. CGRP discontinuation is defined as a gap of at least 60 days in treatment after the daily supply of the last prescription was exhausted. Early discontinuers are classified as beneficiaries who had the last effective date of their last prescription before CGRP discontinuation is less equal to 90 days from their initiation date. A total of 159 early discontinuers are finally included. * Plan was determined as of date of January 1, 2019.

	TABLE 4c. Opioid Use Pre & Post CGRP Initiation Stratified by Plan - Continuers (January 1, 2019 - August 31, 2020)										
		Pre-i	nitiation			Post-i	nitiation				
	Mean Average	Median Average	Mean Maximun	Median Maximum	Mean Average	Median Average	Mean Maximum	Median Maximum			
	MEDD	MEDD	MEDD	MEDD	MEDD	MEDD	MEDD	MEDD			
FFS	6.7	0.0	7.1	0.0	4.1	0.0	4.1	0.0			
UHC	11.2	0.0	12.2	0.0	9.8	0.0	10.9	0.0			
MAG	12.3	0.0	15.2	0.0	12.1	0.0	13.9	0.0			
MOL	ML 4.3 0.0 4.7 0.0 4.5 0.0 4.8 0.										
Total	9.6	0.0	11.1	0.0	8.6	0.0	9.6	0.0			

Note: CGRP initiators are defined as beneficiaries who had CGRP use in Jan 2019 - Aug 2020 and didn't have any CGRP claims in 3 months proir to the first CGRP claims of the observation peroid. A total of 344 initiators are included. Opioid use is calculated based on pharmacy claims for 3 months pre-CGRP initiation and 3 months post-CGRP initiation. Among the CGRP initiators, 134 beneficiaries had at least one pharmacy claim of opioid in either pre or post peroid. CGRP discontinuation is defined as a gap of at least 60 days in treatment after the daily supply of the last prescription was exhausted. Early discontinuers are classified as beneficiaries who had the last effective date of their last prescription before CGRP discontinuation is less equal to 90 days from their initiation date. A total of 185 continuers are finally included. * Plan was determined as of date of January 1, 2019.

	TABLE 4d. Opioid Use Post CGRP Initiation Stratified by Plan - Early Discontinuers vs Continuers (January 1, 2019 - August 31, 2020)										
	Early Discontinuers Continuers										
	Mean Average Median Average Mean Maximum Median Maximum Mean Average Median Average Mean Maximum Median Maximum										
	MEDD	MEDD	MEDD	MEDD	MEDD	MEDD	MEDD	MEDD			
FFS	6.0	0.0	6.2	0.0	4.1	0.0	4.1	0.0			
UHC	26.5	0.0	46.4	0.0	9.8	0.0	10.9	0.0			
MAG	7.3	0.0	8.8	0.0	12.1	0.0	13.9	0.0			
MOL	6.8 0.0 6.8 0.0 4.5 0.0 4.8 0.0										
Total	11.9	0.0	17.8	0.0	8.6	0.0	9.6	0.0			

Note: Note: CGRP initiators are defined as beneficiaries who had CGRP use in Jan 2019 - Aug 2020 and didn't have any CGRP claims in 3 months proir to the first CGRP claims of the observation peroid. A total of 344 initiators are included. Opioid use is calculated based on pharmacy claims for 3 months pre-CGRP initiation and 3 months post-CGRP initiation. Among the CGRP initiators, 134 beneficiaries had at least one pharmacy claim of opioid in either pre or post peroid. CGRP discontinuation is defined as a gap of at least 60 days in treatment after the daily supply of the last prescription was exhausted. Early discontinuers are classified as beneficiaries who had the last effective date of their last prescription before CGRP discontinuation is less equal to 90 days from their initiation date. A total of 159 early discontinuers and 185 continuers are finally included. * Plan was determined as of date of January 1, 2019.

When assessing the impact of CGRP inhibitors on healthcare resource utilization and opioid use, outcomes appear to be mixed. However, caution should be used when basing clinical effectiveness primarily on healthcare resource utilization or opioid prescribing trends. Although treatment with CGRP inhibitors may represent an increase or no change to healthcare resource utilization or opioid use in some instances, the full benefit of CGRP inhibitor therapies may not be captured through claims data. Treatment with CGRP inhibitors may lead to indirect benefit and cost savings through improvement of patient functional status, quality of life, and workplace presenteeism. Across the United States, indirect costs attributable to reduced productivity and missed work days due to migraine were responsible for a loss of over \$13 billion not accounting for under- or unemployment due to migraine.² Additionally, a 2007 analysis found that annual indirect expenditures were roughly \$2,800 higher for patients suffering from migraine as compared to peers without migraine.¹⁷ Aside from broad economic consequences, migraine has personal implications for patients as well. A 2020 study published in The Journal of Headache and Pain found that patients with insufficient response to triptan medications had significantly poorer quality of life and greater activity impairment, including lost work productivity and increased absenteeism.18

Although cost savings associated with CGRP inhibitor therapy may not be tangible through secondary data analysis, these therapies may still present significant utility for patients. Notably, a 2018 report by the Institute for Clinical and Economic Review (ICER) found CGRP inhibitors to be a cost-effective treatment for patients for whom one to three previous preventive migraine therapies have failed.¹⁹ Previous studies have measured initial CGRP inhibitor efficacy at 12 weeks, which aligns with current prior authorization requirements under Mississippi Medicaid.

CONCLUSIONS

With the introduction of CGRP inhibitors, treatment options for those suffering from migraines have changed tremendously. Given the high cost of CGRP inhibitor therapy^{19,20}, appropriate utilization of these treatments and ensured effectiveness during treatment is imperative. This report aimed to establish if CGRP inhibitor medications are being utilized within the Mississippi Division of Medicaid in a cost-effective manner and to determine if current utilization strategies, including prior authorization, are being optimized to encourage appropriate CGRP inhibitor utilization among this population. Although assessing outcomes through claims data does not provide a complete picture of clinical effectiveness, the results presented in this study point to a need for improved identification of appropriate beneficiaries for continued CGRP inhibitor therapy.

RECOMMENDATIONS

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

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

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

• Manual PA requirements for reauthorization.

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

REPORT 3: MIGRAINE PREVENTIVE THERAPY UTILIZATION AND FACTORS IMPACTING USE AMONG ELIGIBLE MEDICAID BENEFICIARIES

Both underdiagnosis and undertreatment remain significant barriers to effective migraine care and best possible patient outcomes.²¹ Although migraine is a common condition affecting approximately 11-13% of all United States adults, it remains underdiagnosed.²² Migraine underdiagnosis and undertreatment have been linked to various causes such as patients' low expectations of effective treatment, poor experiences with older drugs, interpersonal barriers between physician and patient, variable clinical presentation, and misdiagnosis of migraine.^{21,23–25} Although it is estimated that half of migraine sufferers in the United States remain undiagnosed²⁵, these estimations of underdiagnosis vary based on setting. In 2012, it was estimated that 56% of patients suffering from migraine lacked a formal diagnosis.²⁶ A 2012 study assessing migraine resource utilization found that 26% of patients utilizing migraine medications lacked a diagnosis.²⁶ Along with high percentages of underdiagnosis, undertreatment is also a problem. A 2014 report noted that more than two-thirds of eligible migraine headache patients have never or do not currently seek treatment.²³ This problem not only impacts abortive migraine treatment, but affects patients with chronic migraine as well. Of all patients with migraine headaches eligible for preventive treatment, only 12% receive it.²⁶

Because migraine inhibits functionality and productivity, the underdiagnosis and undertreatment of migraine lead to diminished quality of life and financial burdens on the healthcare system.² Direct costs of emergency room visits, hospitalizations and physician visits were found to be significantly higher in those with migraine compared to those without.² Indirect costs of migraine based on missed work days and impaired work performance in the US is conservatively estimated

at \$13.3 billion dollars. Indirect costs are responsible for approximately 93% of the total economic impact of migraine burden.² Additional costs of unemployment and underemployment due to migraine, inability to manage home responsibilities, and loss of time caring for family members are a few of many indirect costs not captured in data analysis.^{2,3}

Migraine is now understood as being a progressive disease in which episodic migraines evolve into a chronic condition.²⁷ Migraine preventive therapy is effective at reducing health system utilization by decreasing the frequency of emergency room and physician visits along with the use of other migraine medications.² Targeting preventive therapy to reduce migraine frequency and severity may reduce the progression of migraine to a more severe and debilitating condition.² However, current practices are not reflective of the research.

In a retrospective observation study of a commercially insured migraine population, patients used both acute and preventive treatment with most, 67.9%, discontinuing their preventive therapy in a median time of 5 months.²⁸ Approximately 77.6% of those who discontinued their preventive therapy used acute treatment to manage their migraines with 1.6% of patients excessively using triptans and 7.1% using non-migraine specific acute treatment.²⁸ Those who managed their migraines with acute medications were found to commonly receive opioids and barbiturates as first-line therapy (34%) and to be at risk for opioid dependence (12%).²⁸ Due to both the progressive and evolving nature of migraine, as well as the risks associated with sole use of acute migraine treatment, it is necessary to re-evaluate migraine treatment as a chronic illness and specifically examine migraine preventive therapy utilization.^{2,28}

OBJECTIVE 1

Objective 1 of this analysis was to determine the number of Medicaid beneficiaries that were eligible to receive migraine preventive therapy and to determine the proportion of those eligible beneficiaries that actually received migraine preventive therapy.

METHODS

A retrospective analysis was conducted using Mississippi Medicaid Fee-for-Service (FFS) and coordinated care organization [CCOs: Magnolia Health (MAG), Molina Healthcare (MOL), and UnitedHealthcare (UHC)] pharmacy and medical claims for the period of March 1, 2020 to February 28, 2021 to assess utilization of preventive migraine therapy in those beneficiaries aged 18 years and older determined to be eligible to receive preventive therapy. Beneficiaries were identified as eligible for receiving preventive medications if they filled at least one prescription for any acute migraine medication between March 1, 2020 and November 30, 2020 and had at least 12 migraine headaches within the 120 days following the date of service for an acute migraine treatment medication. The number of headaches for each prescription was calculated by utilizing a methodology that involved multiplying the quantity of acute medication dispensed by a conversion factor. Beneficiaries who were not continuously enrolled in Medicaid from March 2020 to February 2021 or those who were dual-eligible for Medicare & Medicaid at any time during the

study period were excluded. Of the beneficiaries who were eligible for preventive migraine treatment, individuals were identified as receiving preventive migraine treatment if they had at least one claim for migraine preventive therapy between March 1, 2020 and February 28, 2021.

RESULTS

Table 5a displays demographic characteristics of Medicaid beneficiaries eligible to receive migraine preventive therapy during the study period.

- A total of 1786 beneficiaries were determined eligible to receive migraine preventive therapy.
- 49.9% were <<u><</u> 35 years
- 90.5% were female
- 51.2% were Caucasian
- Only 52% of beneficiaries determined as eligible to receive migraine preventive therapy had a migraine diagnosis.

TABLE 5a. Baseline Descriptive St	atistics of Medicaid B	eneficiaries Eligi	ble for Migrair	ne Preventive Tr	reatment
	(March 1, 2020 - F	ebruary 28, 202	1)		
Characteristic	FFS	UHC	Mag	Mol	Total
Overall	431	522	600	233	1786
	Baseline De	mographics			
Age Group					
18 - 35 years	303	221	229	138	891
36 - 50 years	66	205	232	76	579
51 - 64 years	62	96	139	19	316
Gender	·		·	·	
Female	396	460	542	218	1616
Male	35	62	58	15	170
Race					
Caucasian	229	268	307	112	916
African American	177	216	243	108	744
Other	25	38	50	13	126
Migraine diagnosis	·				
Yes	142	308	356	123	929
No	289	214	244	110	857

Table 5b displays the rates of preventive migraine treatment among eligible Medicaid beneficiaries.

- Overall, 52.4% of those eligible to receive migraine preventive treatment actually had claims for preventive treatment during the study period.
- There were differences in the rates of preventive migraine treatment across pharmacy programs:
 - MAG 61.7%; UHC 56.9%; MOL 48.9%; FFS 35.7%.
- For beneficiaries in the largest eligible age group (18-35 years), rates were lowest compared to other age groups across all pharmacy programs. This was most pronounced in the FFS program.
- FFS had varying rates among all subgroups based on age, gender, and race.

				TA	ABLE 5B. Rates of	Preventive M	Vigraine Treat	ment Among Me	edicaid Bene	ficiaries						
						(March 1	L, 2020 - Febru	iary 28, 2021)								
Characteristic		FFS		UHC				Mag			Mol			Total		
Characteristic	Numerator	Denominator	Rate	Numerator	Denominator	Rate	Numerator	Denominator	Rate	Numerator	Denominator	Rate	Numerator	Denominator	Rate	
Overall	154	431	35.7%	297	522	56.9%	370	600	61.7%	114	233	48.9%	935	1786	52.4%	
Age Group																
18 - 35 years	83	303	27.4%	110	221	49.8%	124	229	54.1%	61	138	44.2%	378	891	42.4%	
36 - 50 years	35	66	53.0%	125	205	61.0%	156	232	67.2%	42	76	55.3%	358	579	61.8%	
51 - 64 years	36	62	58.1%	62	96	64.6%	90	139	64.7%	11	19	57.9%	199	316	63.0%	
Gender																
Female	135	396	34.1%	262	460	57.0%	332	542	61.3%	106	218	48.6%	835	1616	51.7%	
Male	19	35	54.3%	35	62	56.5%	38	58	65.5%	8	15	53.3%	100	170	58.8%	
Race																
Caucasian	68	229	29.7%	156	268	58.2%	189	307	61.6%	60	112	53.6%	473	916	51.6%	
African American	71	177	40.1%	126	216	58.3%	150	243	61.7%	48	108	44.4%	395	744	53.1%	
Other	15	25	60.0%	15	38	39.5%	31	50	62.0%	6	13	46.2%	67	126	53.2%	
Note: Numerator refers to t	he number of	beneficiaries elig	ible for and re	eceiving preve	ntive treatment;	denominator	refers to the n	umber of benefic	iaries eligible	e for preventiv	e treatment					

OBJECTIVE 2

Objective 2 of this analysis was to assess sociodemographic and social determinants of health (SDOH) correlates to preventive medication use among Medicaid beneficiaries.

METHODS

For beneficiaries determined to be eligible for preventive treatment, multiple sociodemographic and SDOH factors were assessed to determine potential impacts on preventive migraine medication use. Comorbidity of beneficiaries was evaluated by Charlson Comorbidity Index (CCIs) score, which was identified during the study period from March 1, 2020 to Feb 28, 2021 using ICD-

10 codes. The Charlson Comorbidity Index (CCI) is a measure of comorbidity that was originally utilized to predict mortality risk for patients with specific comorbid conditions within one year of hospitalization.^{29,30} The CCI assigns weight to patient age and comorbid conditions based on those factors' influence on estimated one-year mortality^{29,30}, and category scores are summed to determine overall CCI score.³¹ For some conditions, such as liver disease, diabetes, or cancers, severity determines the assigned CCI weight.³¹ A list of conditions that are accounted for within the CCI, along with their respective weights, can be found in Figure 2.

FIGURE 2. Charlson Comorbidity Index Scoring

Condition	Response	Weight
	< 50 years	+ 0
	50-59 years	+ 1
Age	60-69 years	+ 2
	70-79 years	+ 3
	≥ 80 years	+ 4
Myocardial Infarction*	Yes	+ 1
Congestive Heart Failure*	Yes	+ 1
Peripheral Vascular Disease*	Yes	+ 1
Cerebrovascular Accident* or	Yes	+ 1
Transient Ischemic Attack*		
Dementia*	Yes	+1
Chronic Obstructive	Yes	+ 1
Pulmonary Disease*		
Connective Tissue Disease*	Yes	+ 1
Peptic Ulcer Disease*	Yes	+ 1
Liver Disease*	Mild	+ 1
	Moderate to Severe	+ 3
	Well-Controlled	+ 0
Diabetes Mellitus*	Uncomplicated	+1
	End-organ Damage	+ 2
Solid Tumor*	Localized	+ 2
	Metastatic	+ 6
Leukemia*	Yes	+ 2
Lymphoma*	Yes	+ 2
AIDS*	Yes	+ 6

*If not present, then + 0 points

Access to care was evaluated by the number of claims for which patients had to travel more than the zip code average to visit the provider or pharmacy. To identify SDOH factors, each eligible beneficiary's county Federal Information Processing Standards (FIPS) code was used to determine the county of residence and linked to data from the 2020 County Health Rankings & Roadmaps (CHRR) databases.³² For each SDOH factor, counties were grouped into quartiles where the higher the quartile, the higher the rate for the factor. A brief description for each included SDOH factor (as provided by County Health Rankings) is provided below:

- Median household income: The income where half of households in a county earn more and half of households earn less.
- Unemployment: Percentage of population ages 16 and older unemployed but seeking work.
- Uninsured adults: Percentage of adults under age 65 without health insurance.
- Limited access to healthy foods: Percentage of population who are low-income and do not live close to a grocery store.
- Some college: Percentage of adults ages 25-44 with some post-secondary education.
- Physical inactivity: Percentage of adults age 20 and over reporting no leisure-time physical activity.
- Primary care physicians: Ratio of population to primary care physicians.
- Preventable hospital stays: Rate of hospital stays for ambulatory-care sensitive conditions per 100,000 Medicare enrollees.

Descriptive statistics were computed for all study variables. Frequencies were reported for categorical variables and means and standard deviations were reported for continuous variables. A multivariate logistic regression model was developed to assess sociodemographic and SDOH correlates of preventive medication use. The rate of preventive medication use in each county was classified as follows: ≤ 25%; 26%-50%; 51%-75%; and >75%. The rate of preventive medication use across each county was demonstrated by county level mapping.

RESULTS

Table 6a displays the results from the regression analysis assessing the impact of sociodemographic and SDOH factors on the use of migraine preventive therapy. (**It should be noted that SDOH factors are not beneficiary specific, but rather represent county-level rankings where the beneficiary resides.*)

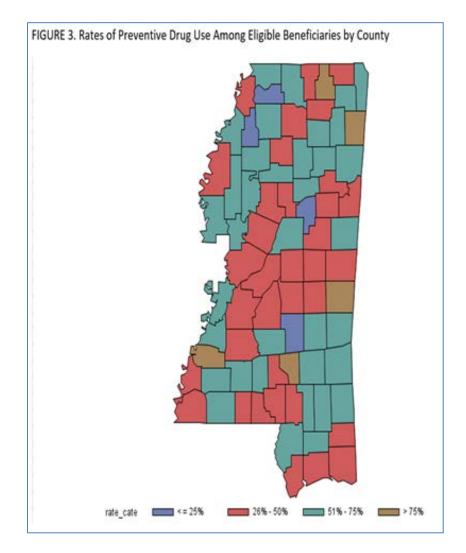
- Age For every year older in age for a beneficiary, the odds of receiving migraine preventive treatment increased.
- Plan When compared to FFS, the odds of receiving preventive treatment increased across all CCOs.
- CCI For those beneficiaries with a CCI index score greater than zero (presence of comorbid conditions), the odds of receiving preventive treatment were greater when compared to beneficiaries with no comorbid conditions.
- Traveling further distances to providers Beneficiaries that traveled greater distances to see providers compared to the average distance other beneficiaries in their same zip code traveled had an increased odds of receiving preventive treatment.
- SDOH Overall there were no major impacts of SDOH factors on the odds of beneficiaries receiving preventive treatment therefore the county-level data included did not show any inherent differences. Only one subgroup under median household income showed a statistically significant difference from the reference group. However, this difference was not found across all subgroups and did not appear to be clinically significant.

Characteristics	Point Estimate	95% LCL	95% UCL
Age	1.026	1.016	1.035
Gender			
Female	0.896	0.626	1.281
Male		Reference	
Race			
African American	1.206	0.961	1.513
Other	0.903	0.596	1.367
Caucasian		Reference	
Plan			
UHC	1.871	1.411	2.482
Mag	2.19	1.656	2.895
Mol	1.698	1.207	2.39
FFS		Reference	
Charlson comorbidity index (CCI)	1 101	1.097	4 707
1 2 or more	<u>1.401</u> 2.08	1.097	<u>1.787</u> 2.924
2 or more	2.08	1.48 Reference	2.924
Iumber of claims of traveling more than the			
verage to visit the provider	1.266	1.043	1.536
Number of claims of traveling more than the			
verage to visit the pharmacy	1.047	0.845	1.297
	al Determinants of Health	Factors	
Iedian Household Income			
1st Quartile	0.984	0.495	1.957
2nd Quartile	1.125	0.726	1.743
3rd Quartile	1.659	1.084	2.538
4th Quartile		Reference	
imited access to healthy foods			
1st Quartile	1.011	0.646	1.584
2nd Quartile	1.259	0.874	1.814
3rd Quartile	0.785	0.529	1.167
4th Quartile		Reference	
nemployment rate			
1st Quartile	0.837	0.445	1.575
2nd Quartile	0.82	0.467	1.437
3rd Quartile	0.69	0.403	1.184
4th Quartile		Reference	
Physical Inactivity			
1st Quartile	0.768	0.474	1.244
2nd Quartile	0.67	0.438	1.027
3rd Quartile	0.801	0.55	1.165
4th Quartile		Reference	
Porcentage of adults <65 who are write out - 1		<u>├</u>	
Percentage of adults <65 who are uninsured 1st Quartile	0.756	0.468	1.223
2nd Quartile	1.132	0.468	1.223
3rd Quartile	0.629	0.388	1.022
4th Quartile	0.029	Reference	1.022
reventable Hospital Stays		Kererence	
1st Quartile	0.856	0.568	1.289
2nd Quartile	1.248	0.854	1.825
3rd Quartile	1.112	0.752	1.644
4th Quartile		Reference	
rimary care physicians			
1st Quartile	0.898	0.531	1.517
2nd Quartile	0.887	0.554	1.42
3rd Quartile	0.732	0.484	1.107
4th Quartile		Reference	
College graduation			
1st Quartile	0.53	0.274	1.025
2nd Quartile	0.839	0.496	1.418
3rd Quartile	0.883	0.481	1.619

th Quartile
 the significant impact on the use of migraine preventive treatment when adjusting for other variables in the model

County-level rates of migraine preventive treatment among Medicaid beneficiaries (Figure 3 and Table 6b) corresponded with the findings from the regression analysis for county level SDOH factors in Table 6a. A map of Mississippi identifying each county can be found in Appendix D.

Of the 82 counties in Mississippi, rates for 71 counties were in middle ranges of rates (26% - 75%) for eligible beneficiaries receiving preventive treatment. Only 6 counties had rates < 25% and 5 counties had rates > 75%, indicating the county of residence did not have a substantial impact on the rate of preventive migraine treatment for the majority of eligible beneficiaries in the state.



County Code	County	Rate	County Code	County	Rate
1	Adams	28.57	42	Leflore	69.5
2	Alcorn	40.00	43	Lincoln	53.3
3	Amite	60.00	44	Lowndes	48.6
4	Attala	54.55	45	Madison	31.2
5	Benton	33.33	46	Marion	46.8
6	Bolivar	50.00	47	Marshall	61.2
7	Calhoun	66.67	48	Monroe	75.0
8	Carroll	33.33	49	Montgomery	44.4
9	Chickasaw	62.50	50	Neshoba	40.0
10	Choctaw	0.00	51	Newton	50.0
11	Claiborne	62.07	52	Noxubee	63.6
12	Clarke	58.33	53	Oktibbeha	42.8
13	Clay	40.00	54	Panola	63.6
14	Coahoma	66.67	55	Pearl River	57.4
15	Copiah	36.00	56	Perry	72.7
16	Covington	81.82	57	Pike	47.3
17	DeSoto	51.72	58	Pontotoc	60.0
18	Forrest	56.52	59	Prentiss	66.6
19	Franklin	60.00	60	Quitman	20.0
20	George	33.33	61	Rankin	42.3
21	Greene	69.23	62	Scott	50.0
22	Grenada	63.64	63	Sharkey	0.0
23	Hancock	34.38	64	Simpson	62.5
24	Harrison	45.16	65	Smith	22.2
25	Hinds	47.50	66	Stone	53.8
26	Holmes	50.00	67	Sunflower	57.1
27	Humphreys	57.14	68	Tallahatchie	66.6
28	Issaquena	0.00	69	Tate	20.0
29	Itawamba	90.00	70	Tippah	86.6
30	Jackson	39.82	71	Tishomingo	55.5
31	Jasper	75.00	72	Tunica	50.0
32	Jefferson	87.50	73	Union	37.5
33	Jefferson Davis	50.00	74	Walthall	42.8
34	Jones	73.91	75	Warren	51.5
35	Kemper	50.00	76	Washington	63.9
	Lafayette	50.00	77	Wayne	61.9
	Lamar	45.71		Webster	57.1
	Lauderdale	82.35		Wilkinson	33.3
39	Lawrence	64.29		Winston	50.0
	Leake	33.33		Yalobusha	40.0
	Lee	57.14		Yazoo	27.2

CONCLUSIONS

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

RECOMMENDATIONS

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

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Appendix A

		Migraine Treatments		Compandia Supported	
Chemical Entity	Drug Class	Formulations	FDA Migraine Indication	Compendia-Supported Indication	Reference
Lasmiditan	5-HT Receptor Agonist	Oral Tablet	Migraine, Acute		3
Acetaminophen/Codeine	Analgesic/Opioid Combination	Oral Elixir Oral Solution		Migraine, Acute	1
Acetaminophen/Tramadol	Analgesic/Opioid Combination	Oral Tablet		Migraine, Acute	1
Magnesium Sulfate	Anticonvulsant	IV			1, 3
Valproate Sodium	Anticonvulsant	IV			1, 3
Butalbital/Aspirin/Caffeine	Barbiturate Combination	Oral Capsule Oral Tablet			1
Butalbital/Acetaminophen/Caffeine	Barbiturate Combination	Oral Capsule Oral Tablet		Migraine, Acute	1
Butalbital/Acetaminophen/Caffeine/Codeine	Barbiturate/Opioid Combination	Oral Capsule		Migraine, Acute	1
Rimegepant	CGRP Inhibitor	Oral Disentigrating Tablet	Migraine, Acute		3
Ubrogepant	CGRP Inhibitor	Oral Tablet	Migraine, Acute		3
Droperidol	Dopamine Antagonist	IM		Migraine	1, 3
Ergotamine	Ergot Alkaloid	Sublingual Tablet	Migraine		1
Dihydroergotamine	Ergot Alkaloid	Injection Solution Nasal Spray	Migraine		1, 2, 3
Diclofenac	NSAID	Oral Capsule Oral Powder for Solution	Migraine		1, 2, 3
Ibuprofen	NSAID	Oral Capsule, Liquid Filled Oral Suspension	Migraine		1, 2, 3
Naproxen	NSAID	Oral Suspension Oral Tablet			1, 2, 3
Ketorolac	NSAID	Nasal Spray Injection Solution		Migraine	3
Flurbiprofen	NSAID	Oral Tablet		Migraine	1
Butorphanol	Opioid	Nasal Spray			1
Butorphanol	Opioid	Nasal Spray IV			1, 3
Meperidine	Opioid	IM IV			1, 3
Methadone	Opioid	IM IV			1
Tramadol	Opioid	Oral ER Capsule Oral Tablet			1, 3
Codeine	Opioid	Oral Tablet			1, 3
Dexamethasone sodium phosphate	Steroid	IV			1, 3
Almotriptan	Triptan	Oral Tablet	Migraine, Acute		1, 2, 3
Eletriptan	Triptan	Oral Tablet	Migraine, Acute		1, 2, 3
Frovatriptan	Triptan	Oral Tablet	Migraine, Acute		1, 2, 3
Naratriptan	Triptan	Oral Tablet	Migraine, Acute		1, 2, 3
Rizatriptan	Triptan	Oral Tablet Oral Disentigrating Tablet	Migraine, Acute		1, 2, 3
Sumatriptan	Triptan	Nasal Spray	Migraine, Acute		1, 2, 3
Sumatriptan Succinate	Triptan	Oral Tablet SubQ Solution	Migraine, Acute		1, 2, 3
Zolmitriptan	Triptan	Nasal Spray Oral Tablet	Migraine, Acute		1, 2, 3
Sumatriptan/Naproxen	Triptan/NSAID Combination	Oral Tablet	Migraine, Acute		1, 3

	Chemical Entity	Drug Class	Formulations	FDA Migraine Indication	Compendia-Supported Indication	Reference
	Cyproheptadine	5-HT and Histamine Antagonist	Oral Solution Oral Syrup			1, 2, 4
	Lisinopril	ACE Inhibitor	Oral Tablet Oral Solution		Migraine, Prophylaxis	1, 2, 4
	Clonidine	Alpha-2 Agonist	Oral Tablet Oral ER Tablet			1, 2
	Guanfacine	Alpha-2 Agonist	Oral Tablet Oral ER Tablet			1, 2
	Topiramate	Antiepileptic	Oral Capsule Oral ER Capsule	Migraine, Prophylaxis		1, 2, 4
	Divalproex Sodium/Valproic Acid	Antiepileptic	Oral DR Capsule Oral DR Tablet	Migraine, Prophylaxis		1, 2, 4
	Carbamazepine	Antiepileptic	Oral ER Capsule Oral Suspension			1, 2, 4
	Candesartan	ARB	Oral Tablet		Migraine, Prophylaxis	1, 2, 4
	Metoprolol Tartrate	Beta Blocker	Oral Tablet		Migraine, Prophylaxis	1, 2, 4
	Propranolol	Beta Blocker	Oral ER Capsule Oral Solution	Migraine, Prophylaxis		1, 2, 4
	Timolol	Beta Blocker	Oral Tablet			1, 2, 4
	Atenolol	Beta Blocker	Oral Tablet		Migraine, Prophylaxis	1
	Nadolol	Beta Blocker	Oral Tablet		Migraine, Prophylaxis	1
	Metoprolol Succinate	Beta Blocker	Oral ER TabletOral ER Capsule			1, 2, 4
	Nebivolol	Beta Blocker	Oral Tablet	-	Migraine, Prophylaxis	1, 4
'	Pindolol	Beta Blocker	Oral Tablet			1, 4
	Verapamil	Calcium Channel Blocker	Oral ER CapsuleOral TabletOral ER Tablet		Migraine, Prophylaxis	4
·	Nifedipine	Calcium Channel Blocker	Oral Capsule, Liquid-filledOral ER Tablet			4
	Nimodipine	Calcium Channel Blocker	Oral Capsule, Liquid-filledOral Solution			4
	Nicardipene	Calcium Channel Blocker	Oral Capsule		Migraine	4
	Galcanezumab-gnlm	CGRP Inhibitor	SubQ Solution	Migraine, Prophylaxis		2
	Fremanezumab-vfrm	CGRP Inhibitor	SubQ Solution	Migraine, Prophylaxis		2
	Eptinezumab-jjmr	CGRP Inhibitor	IV	Migraine, Prophylaxis		2
	Erenumab-aooe	CGRP Inhibitor	SubQ Solution	Migraine, Prophylaxis		2
	Onabotulinumtoxin A	Neuromuscular Blocker	Injection Powder for Solution	Prophylaxis		2, 4
	Amitriptyline	SNRI	Oral Tablet		Headache, Treatment and Prophylaxis	1, 2, 4
	Venlafaxine	SNRI	Oral ER Capsule Oral Tablet			1, 2, 4
	Frovatriptan	Triptan	Oral Tablet			1, 2, 4
	Zolmitriptan	Triptan	Nasal Spray Oral Tablet			1, 4
	Naratriptan	Triptan	Oral Tablet			1, 4

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Appendix B

ι	itilization b	y health p	lan and be	neficiaries	
	(Mar	ch 2018 - F	ebruary 20	21)	
Month		Pl	an		Total
WOITT	FFS	UHC	Magnolia	Molina	TOLAI
Mar-18	369	1,268	1,447	0	3,084
Apr-18	393	1,316	1,570	0	3,279
May-18	399	1,330	1,600	0	3,329
Jun-18	408	1,385	1,621	0	3,414
Jul-18	412	1,378	1,675	0	3,465
Aug-18	466	1,549	1,842	0	3,857
Sep-18	461	1,464	1,900	0	3,825
Oct-18	503	1,533	2,001	54	4,091
Nov-18	443	1,456	1,882	70	3,851
Dec-18	426	1,448	1,849	96	3,819
Jan-19	431	1,584	2,108	139	4,262
Feb-19	452	1,489	1,942	161	4,044
Mar-19	479	1,583	2,037	199	4,298
Apr-19	519	1,582	2,026	207	4,334
May-19	518	1,591	1,998	233	4,340
Jun-19	507	1,443	1,939	258	4,147
Jul-19	511	1,575	2,096	302	4,484
Aug-19	575	1,666	2,159	331	4,731
Sep-19	561	1,623	2,071	321	4,576
Oct-19	611	1,700	2,134	352	4,797
Nov-19	563	1,573	2,083	353	4,572
Dec-19	552	1,556	2,090	348	4,546
Jan-20	550	1,780	2,302	407	5,039
Feb-20	571	1,718	2,149	394	4,832
Mar-20	562	1,871	2,136	380	4,949
Apr-20	497	1,703	1,937	366	4,503
May-20	557	1,659	1,954	423	4,593
Jun-20	577	1,752	2,012	447	4,788
Jul-20	622	1,791	2,079	477	4,969
Aug-20	653	1,736	2,085	496	4,970
Sep-20	717	1,785	2,103	513	5,118
Oct-20	733	1,738	2,080	558	5,109
Nov-20	748	1,756	2,034	531	5,069
Dec-20	787	1,790	2,036	576	5,189
Jan-21	846	1,851	2,128	543	5,368
Feb-21	813	1,736	1,954	538	5,041
Total*	19,792	57,758	71,059	10,073	158,682

	# of	# of Rx		PI	an		
Month	benes*	claims	FFS	UHC	Magnolia	Molina	Total
Mar-18	3,084	4,213	\$13,592.3	\$48,740.7	\$68,002.3	\$0.0	\$130,335
Apr-18	3,279	4,564	\$12,782.6	\$52,533.6	\$74,378.0	\$0.0	\$139,694
May-18	3,329	4,604	\$10,796.9	\$54,086.1	\$72,951.9	\$0.0	\$137,83
Jun-18	3,414	4,697	\$11,692.6	\$56,958.4	\$73,510.8	\$0.0	\$142,16
Jul-18	3,465	4,768	\$11,870.5	\$56,461.7	\$66,370.9	\$0.0	\$134,70
Aug-18	3,857	5,354	\$14,653.6	\$55,755.3	\$85,247.0	\$0.0	\$155,65
Sep-18	3,825	5,196	\$16,190.8	\$56,520.2	\$75,789.6	\$0.0	\$148,50
Oct-18	4,091	5,703	\$16,221.3	\$69,328.0	\$90,829.2	\$2,289.0	\$178,66
Nov-18	3,851	5,263	\$13,418.9	\$60,151.0	\$86,246.3	\$2,947.4	\$162,76
Dec-18	3,819	5,081	\$14,919.3	\$57,832.2	\$82,937.6	\$4,011.2	\$159,70
Jan-19	4,262	5,843	\$16,110.2	\$73,356.2	\$87,508.5	\$3,931.0	\$180,90
Feb-19	4,044	5,504	\$15,207.3	\$72,567.4	\$86,507.0	\$4,166.2	\$178,44
Mar-19	4,298	5,875	\$18,563.0	\$73,813.5	\$91,177.6	\$5,400.4	\$188,95
Apr-19	4,334	5,935	\$20,072.1	\$64,453.2	\$89,880.4	\$5,902.4	\$180,30
May-19	4,340	6,023	\$17,298.4	\$71,312.0	\$91,356.7	\$5,794.0	\$185,76
Jun-19	4,147	5,698	\$23,396.4	\$65,227.6	\$90,623.7	\$6,023.1	\$185,27
Jul-19	4,484	6,281	\$22,463.0	\$69,339.4	\$104,800.1	\$11,033.5	\$207,63
Aug-19	4,731	6,549	\$22,669.8	\$76,499.8	\$97,390.1	\$10,448.1	\$207,00
Sep-19	4,576	6,280	\$24,511.1	\$71,437.0	\$103,117.5	\$8,287.0	\$207,35
Oct-19	4,797	6,680	\$24,214.5	\$81,895.1	\$112,455.1	\$9,997.9	\$228,56
Nov-19	4,572	6,287	\$20,481.3	\$75,554.3	\$102,597.1	\$10,324.5	\$208,95
Dec-19	4,546	6,317	\$24,051.9	\$69,580.1	\$116,438.6	\$10,854.5	\$220,92
Jan-20	5,039	7,004	\$20,875.7	\$78,746.5	\$111,197.1	\$14,449.0	\$225,26
Feb-20	4,832	6,463	\$20,314.4	\$75,933.6	\$98,196.8	\$16,743.7	\$211,18
Mar-20	4,949	6,963	\$24,818.0	\$92,488.5	\$104,592.9	\$21,619.5	\$243,51
Apr-20	4,503	6,235	\$23,239.8	\$95,382.6	\$94,604.7	\$21,426.1	\$234,65
May-20	4,593	6,355	\$23,975.1	\$80,451.7	\$108,965.3	\$21,241.0	\$234,63
Jun-20	4,788	6,763	\$27,298.3	\$91,747.8	\$108,443.6	\$24,062.8	\$251,55
Jul-20	4,969	6,866	\$29,250.3	\$86,144.2	\$115,021.7	\$29,207.0	\$259,62
Aug-20	4,970	6,715	\$27,802.7	\$77,324.1	\$111,250.2	\$27,966.4	\$244,34
Sep-20	5,118	6,936	\$33,774.2	\$88,398.2	\$107,591.2	\$26,322.5	\$256,08
Oct-20	5,109	6,921	\$32,383.5	\$85,882.2	\$114,926.9	\$28,310.7	\$261,50
Nov-20	5,069	6,815	\$36,577.2	\$91,343.3	\$117,505.4	\$28,151.3	\$273,57
Dec-20	5,189	7,009	\$34,619.4	\$97,662.1	\$126,067.7	\$33,008.6	\$291,35
Jan-21	5,368	7,211	\$42,866.8	\$93,233.7	\$113,780.0	\$30,878.5	\$280,75
Feb-21	5,041	6,658	\$34,596.5	\$101,849.8	\$111,410.1	\$30,220.7	\$278,07
Total	158,682	217,629	\$797,569.4	\$2,669,991.1	\$3,493,669.7	\$455,017.8	\$7,416,24

-		h 2018 - F	lan and ber ebruary 20				I		(March	2018 - February	•		T
Month			lan		Total	Month	# of	# of Rx			an		Total
	FFS	UHC	Magnolia	Molina			benes*	claims	FFS	UHC	Magnolia	Molina	
Mar-18	214	733	855	0	1,802	Mar-18	1,802	2,140	\$7,695.0	\$28,881.7	\$41,789.5	\$0.0	\$78,366.2
Apr-18	226	773	955	0	1,954	Apr-18	1,954	2,345	\$7,330.8	\$32,954.1	\$48,166.6	\$0.0	\$88,451.4
May-18	240	803	961	0	2,004	May-18	2,004	2,416	\$6,293.0	\$34,070.9	\$45,593.5	\$0.0	\$85,957.4
Jun-18	250	799	996	0	2,045	Jun-18	2,045	2,482	\$7,365.6	\$36,330.8	\$49,405.3	\$0.0	\$93,101.7
Jul-18	259	805	1,009	0	2,073	Jul-18	2,073	2,503	\$7,710.6	\$34,025.8	\$39,979.7	\$0.0	\$81,716.1
Aug-18	271	887	1,081	0	2,239	Aug-18	2,239	2,734	\$8,656.2	\$33,097.1	\$54,645.9	\$0.0	\$96,399.1
Sep-18	272	826	1,138	0	2,236	Sep-18	2,236	2,716	\$9,633.2	\$37,363.3	\$48,791.8	\$0.0	\$95,788.3
Oct-18	320	876	1,247	34	2,477	Oct-18	2,477	2,997	\$9,992.2	\$49,420.2	\$63,978.9	\$1,738.9	\$125,130.1
Nov-18	270	843	1,157	35	2,305	Nov-18	2,305	2,805	\$8,855.8	\$42,296.8	\$56,097.2	\$1,736.7	\$108,986.5
Dec-18	258	852	1,179	48	2,337	Dec-18	2,337	2,798	\$10,323.5	\$40,758.0	\$58,907.4	\$2,425.0	\$112,414.0
Jan-19	255	943	1,283	70	2,551	Jan-19	2,551	3,120	\$10,603.2	\$53,088.6	\$62,663.7	\$2,429.3	\$128,784.8
Feb-19	262	854	1,196	63	2,375	Feb-19	2,375	2,896	\$10,561.9	\$53,122.6	\$61,291.5	\$2,035.2	\$127,011.2
Mar-19	294	955	1,302	85	2,636	Mar-19	2,636	3,244	\$12,914.7	\$54,020.7	\$66,202.1	\$2,823.4	\$135,960.9
Apr-19	321	956	1,283	91	2,651	Apr-19	2,651	3,232	\$14,809.5	\$47,192.7	\$64,651.3	\$3,094.8	\$129,748.3
May-19	326	940	1,286	102	2,654	May-19	2,654	3,291	\$11,066.3	\$53,073.9	\$68,905.1	\$2,585.9	\$135,631.1
Jun-19	316	884	1,224	105	2,529	Jun-19	2,529	3,124	\$18,626.1	\$49,846.5	\$69,370.0	\$2,462.3	\$140,304.9
Jul-19	323	945	1,307	117	2,692	Jul-19	2,692	3,401	\$16,169.0	\$50,086.9	\$81,088.2	\$6,739.9	\$154,084.1
Aug-19	366	983	1,351	153	2,853	Aug-19	2,853	3,518	\$15,888.3	\$57,363.2	\$71,822.9	\$5,862.8	\$150,937.2
Sep-19	341	993	1,282	153	2,769	Sep-19	2,769	3,365	\$17,270.2	\$53,813.5	\$78,732.7	\$4,233.4	\$154,049.7
Oct-19	385	1,017	1,325	165	2,892	Oct-19	2,892	3,638	\$16,982.9	\$58,637.1	\$86,250.1	\$5,255.1	\$167,125.3
Nov-19	364	976	1,307	183	2,830	Nov-19	2,830	3,465	\$14,914.0	\$57,990.1	\$80,128.9	\$6,100.3	\$159,133.2
Dec-19	360	922	1,307	186	2,775	Dec-19	2,775	3,488	\$17,630.9	\$53,389.5	\$92,190.9	\$6 <i>,</i> 587.4	\$169,798.6
Jan-20	352	1,007	1,419	208	2,986	Jan-20	2,986	3,715	\$14,241.1	\$57,368.1	\$83,622.2	\$9,666.9	\$164,898.3
Feb-20	374	1,010	1,333	226	2,943	Feb-20	2,943	3,536	\$14,568.6	\$57,996.7	\$74,343.5	\$11,654.8	\$158,563.6
Mar-20	376	1,114	1,378	227	3,095	Mar-20	3,095	3,897	\$18,682.2	\$66,761.9	\$82,398.6	\$16,467.9	\$184,310.6
Apr-20	329	1,107	1,293	217	2,946	Apr-20	2,946	3,658	\$17,403.4	\$75,650.1	\$74,912.3	\$17,805.6	\$185,771.5
May-20	381	1,052	1,326	261	3,020	May-20	3,020	3,743	\$18,411.3	\$59,259.9	\$85,241.9	\$16,299.9	\$179,213.1
Jun-20	376	1,112	1,336	266	3,090	Jun-20	3,090	3,869	\$18,910.8	\$69,026.5	\$83,675.9	\$18,623.3	\$190,236.5
Jul-20	414	1,093	1,365	262	3,134	Jul-20	3,134	3,894	\$20,786.2	\$62,550.5	\$86,561.8	\$21,029.3	\$190,927.8
Aug-20	406	1,057	1,368	268	3,099	Aug-20	3,099	3,805	\$16,867.5	\$53,518.9	\$84,032.6	\$22,176.8	\$176,595.7
Sep-20	428	1,036	1,332	276	3,072	Sep-20	3,072	3,770	\$22,682.6	\$62,539.9	\$75,309.9	\$17,992.9	\$178,525.3
Oct-20	426	1,020	1,324	299	3,069	Oct-20	3,069	3,755	\$19,564.4	\$59,499.4	\$81,077.9	\$19,744.1	\$179,885.8
Nov-20	478	1,075	1,321	304	3,178	Nov-20	3,178	3,852	\$22,234.2	\$65,353.0	\$82,550.0	\$19,550.0	\$189,687.1
Dec-20	487	1,129	1,322	326	3,264	Dec-20	3,264	4,004	\$18,848.1	\$67,806.7	\$91,399.8	\$23,049.8	\$201,104.5
Jan-21	524	1,131	1,378	288	3,321	Jan-21	3,321	4,005	\$24,969.7	\$60,485.4	\$81,150.8	\$21,607.9	\$188,213.8
Feb-21	489	1,064	1,287	313	3,153	Feb-21	3,153	3,764	\$18,472.1	\$72,524.0	\$81,145.8	\$22,611.0	\$194,753.0
Total*	12,333	34,572	44,813	5,331	97,049	Total	97.049	118,985	\$527,934.8	\$1,901,164.9	\$2,538,076.3	\$314,390.7	\$5,281,566.6

u		••••	lan and be ebruary 20	neficiaries 121)					(March 2	018 - February	2021)		
	•	P	an			Month	# of	# of Rx		PI	an		Total
Month	FFS	UHC	Magnolia	Molina	Total	wonth	benes*	claims	FFS	UHC	Magnolia	Molina	Total
Mar-18	201	716	841	0	1,758	Mar-18	1,758	2,073	\$5,897.4	\$19,859.0	\$26,212.8	\$0.0	\$51,969.
Apr-18	220	742	889	0	1,851	Apr-18	1,851	2,219	\$5,451.8	\$19,579.5	\$26,211.3	\$0.0	\$51,242.
May-18	202	710	904	0	1,816	May-18	1,816	2,188	\$4,503.9	\$20,015.2	\$27,358.5	\$0.0	\$51,877
Jun-18	204	771	887	0	1,862	Jun-18	1,862	2,215	\$4,327.0	\$20,627.6	\$24,105.5	\$0.0	\$49,060
Jul-18	195	759	958	0	1,912	Jul-18	1,912	2,265	\$4,159.9	\$22,435.9	\$26,391.3	\$0.0	\$52,987
Aug-18	243	873	1,080	0	2,196	Aug-18	2,196	2,620	\$5,997.4	\$22,658.2	\$30,601.2	\$0.0	\$59,256
Sep-18	237	812	1,047	0	2,096	Sep-18	2,096	2,480	\$6,557.6	\$19,156.9	\$26,997.7	\$0.0	\$52,712
Oct-18	252	862	1,094	27	2,235	Oct-18	2,235	2,706	\$6,229.1	\$19,907.8	\$26,850.2	\$550.1	\$53,537.
Nov-18	214	787	1,042	44	2,087	Nov-18	2,087	2,458	\$4,563.1	\$17,854.2	\$30,149.1	\$1,210.7	\$53,777.
Dec-18	206	762	933	56	1,957	Dec-18	1,957	2,283	\$4,595.8	\$17,074.2	\$24,030.1	\$1,586.1	\$47,286
Jan-19	223	852	1,155	88	2,318	Jan-19	2,318	2,723	\$5,507.0	\$20,267.6	\$24,844.7	\$1,501.7	\$52,121
Feb-19	230	848	1,041	111	2,230	Feb-19	2,230	2,608	\$4,645.4	\$19,444.8	\$25,215.6	\$2,131.0	\$51,436
Mar-19	232	834	1,034	139	2,239	Mar-19	2,239	2,631	\$5,648.2	\$19,792.8	\$24,975.6	\$2,577.0	\$52,993
Apr-19	255	832	1,054	148	2,289	Apr-19	2,289	2,703	\$5,262.6	\$17,260.5	\$25,229.1	\$2,807.6	\$50,559
May-19	251	862	1,033	165	2,311	May-19	2,311	2,732	\$6,232.1	\$18,238.1	\$22,451.7	\$3,208.2	\$50,130
Jun-19	244	750	1,008	185	2,187	Jun-19	2,187	2,574	\$4,770.3	\$15,381.1	\$21,253.8	\$3,560.8	\$44,965
Jul-19	253	855	1,093	218	2,419	Jul-19	2,419	2,880	\$6,294.0	\$19,252.5	\$23,711.8	\$4,293.6	\$53,551
Aug-19	288	913	1,141	219	2,561	Aug-19	2,561	3,031	\$6,781.5	\$19,136.6	\$25,567.2	\$4,585.3	\$56,070
Sep-19	286	860	1,099	204	2,449	Sep-19	2,449	2,915	\$7,240.9	\$17,623.5	\$24,384.9	\$4,053.6	\$53,302
Oct-19	304	892	1,111	228	2,535	Oct-19	2,535	3,042	\$7,231.6	\$23,258.0	\$26,205.0	\$4,742.7	\$61,437
Nov-19	260	808	1,087	209	2,364	Nov-19	2,364	2,822	\$5,567.3	\$17,564.2	\$22,468.2	\$4,224.2	\$49,823
Dec-19	257	842	1,078	198	2,375	Dec-19	2,375	2,829	\$6,421.0	\$16,190.6	\$24,247.7	\$4,267.1	\$51,126
Jan-20	264	1,002	1,220	252	2,738	Jan-20	2,738	3,289	\$6,634.6	\$21,378.5	\$27,574.8	\$4,782.1	\$60,369
Feb-20	263	911	1,122	217	2,513	Feb-20	2,513	2,927	\$5,745.8	\$17,936.9	\$23 <i>,</i> 853.3	\$5 <i>,</i> 088.9	\$52,625
Mar-20	252	1,007	1,045	203	2,507	Mar-20	2,507	3,066	\$6,135.7	\$25,726.6	\$22,194.3	\$5,151.7	\$59,208
Apr-20	213	846	872	194	2,125	Apr-20	2,125	2,577	\$5 <i>,</i> 836.4	\$19,732.5	\$19,692.4	\$3,620.5	\$48,881
May-20	240	831	869	218	2,158	May-20	2,158	2,612	\$5 <i>,</i> 563.8	\$21,191.8	\$23,723.4	\$4,941.0	\$55,420
Jun-20	268	905	955	244	2,372	Jun-20	2,372	2,894	\$8,387.5	\$22,721.4	\$24,767.7	\$5,439.4	\$61,316
Jul-20	287	938	1,016	281	2,522	Jul-20	2,522	2,972	\$8,464.2	\$23,593.7	\$28,459.8	\$8,177.7	\$68,695
Aug-20	309	883	986	298	2,476	Aug-20	2,476	2,910	\$10,935.3	\$23,805.2	\$27,217.6	\$5,789.6	\$67,747
Sep-20	364	964	1,045	306	2,679	Sep-20	2,679	3,166	\$11,091.6	\$25,858.3	\$32,281.3	\$8,329.5	\$77,560
Oct-20	391	929	1,047	324	2,691	Oct-20	2,691	3,166	\$12,819.1	\$26,382.7	\$33,849.0	\$8,566.6	\$81,617
Nov-20	362	895	996	294	2,547	Nov-20	2,547	2,963	\$14,343.0	\$25,990.3	\$34,955.4	\$8,601.4	\$83,890
Dec-20	372	894	976	315	2,557	Dec-20	2,557	3,005	\$15,771.3	\$29,855.4	\$34,667.8	\$9,958.9	\$90,253
Jan-21	417	950	1,027	319	2,713	Jan-21	2,713	3,206	\$17,897.1	\$32,748.3	\$32,629.2	\$9,270.6	\$92,545
Feb-21	409	888	925	292	2,514	Feb-21	2,514	2,894	\$16,124.3	\$29,325.8	\$30,264.3	\$7,609.7	\$83,324
Total*	9,668	30,785	36,710	5,996	83,159	Total	83,159	98.644	\$269,634.6	\$768,826.2	\$955,593.4	\$140,627.1	\$2,134,681.

			ebruary 20	21)			1			medication ut 018 - February	2021)	Jenuing by nea	
Month	FFS	P UHC	lan Magnolia	Molina	Total	Month	# of benes*	# of Rx claims	FFS	UHC	an Magnolia	Molina	Total
Mar-18	0	0	0	0	0	Mar-18	0	0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Apr-18	0	0	0	0	0	Apr-18	0	0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
May-18	0	0	0	0	0	May-18	0	0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Jun-18	0	0	0	0	0	Jun-18	0	0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Jul-18	0	0	0	0	0	Jul-18	0	0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Aug-18	0	0	1	0	1	Aug-18	1	1	\$0.0	\$0.0	\$583.3	\$0.0	\$583.3
Sep-18	1	0	2	0	3	Sep-18	3	3	\$583.3	\$0.0	\$1,166.6	\$0.0	\$1,749.9
Oct-18	1	5	9	0	15	Oct-18	15	15	\$583.3	\$3,960.0	\$5,089.4	\$0.0	\$9,632.7
Nov-18	1	4	12	0	13	Nov-18	17	17	\$565.0	\$2,837.2	\$6,822.1	\$0.0	\$10,224.3
Dec-18	1	5	20	1	27	Dec-18	27	28	\$565.6	\$3,437.7	\$12,483.6	\$565.6	\$17,052.4
Jan-19	3	12	25	0	40	Jan-19	40	41	\$1,696.1	\$7,348.5	\$15,265.1	\$0.0	\$24,309.7
Feb-19	4	14	30	1	49	Feb-19	49	49	\$2,259.3	\$9,011.2	\$17,550.3	\$563.1	\$29,383.9
Mar-19	4	19	33	2	58	Mar-19	58	60	\$2,261.7	\$12,408.5	\$19,562.4	\$1,131.1	\$35,363.
Apr-19	6	10	32	2	50	Apr-19	50	52	\$3,951.7	\$6,222.2	\$19,761.8	\$1,128.7	\$31,064.
May-19	4	18	42	1	65	May-19	65	71	\$2,255.6	\$12,881.5	\$24,549.6	\$563.1	\$40,249.8
Jun-19	10	20	43	0	73	Jun-19	73	74	\$6,245.8	\$11,915.0	\$26,125.6	\$0.0	\$44,286.4
Jul-19	7	15	51	6	79	Jul-19	79	81	\$3,947.2	\$10,117.3	\$30,420.9	\$3,939.4	\$48,424.6
Aug-19	11	23	50	4	88	Aug-19	88	88	\$6,197.2	\$14,064.9	\$30,377.4	\$2,248.8	\$52,888.3
Sep-19	10	22	56	2	90	Sep-19	90	92	\$6,189.7	\$13,497.1	\$32,959.3	\$1,123.8	\$53,769.9
Oct-19	10	20	62	3	95	Oct-19	95	100	\$5,629.4	\$13,468.1	\$37,756.8	\$1,685.7	\$58,540.0
Nov-19	9	16	60	4	89	Nov-19	89	92	\$5,067.5	\$9,001.1	\$36,823.4	\$2,247.6	\$53,139.
Dec-19	10	22	70	4	106	Dec-19	106	115	\$5,629.6	\$15,748.2	\$44,476.7	\$2,254.3	\$68,108.
Jan-20	7	20	58	8	93	Jan-20	93	96	\$3,941.2	\$11,903.0	\$34,944.1	\$5,099.1	\$55,887.
Feb-20	8	20	53	13	94	Feb-20	94	95	\$4,667.0	\$11,755.0	\$32,663.4	\$7,812.0	\$56,897.3
Mar-20	13	33	56	19	121	Mar-20	121	130	\$8,190.8	\$23,443.5	\$35,512.9	\$11,271.1	\$78,418.3
Apr-20	12	34	58	18	122	Apr-20	122	128	\$7,188.9	\$20,950.1	\$36,596.3	\$12,420.5	\$77,155.
May-20	14	40	68	18	140	May-20	140	147	\$8,336.5	\$25,807.9	\$45,312.1	\$11,213.4	\$90,669.
Jun-20	11	38	66	23	138	Jun-20	138	143	\$6,331.8	\$24,354.3	\$41,342.4	\$14,409.1	\$86,437.0
Jul-20	18	36	64	30	148	Jul-20	148	161	\$10,942.2	\$25,644.0	\$43,323.3	\$19,039.3	\$98,948.
Aug-20	12	35	63	26	136	Aug-20	136	146	\$7,157.1	\$22,952.8	\$42,448.8	\$16,548.9	\$89,107.0
Sep-20	21	38	54	21	134	Sep-20	134	148	\$13,814.6	\$27,138.1	\$37,830.7	\$14,894.9	\$93,678.
Oct-20	18	42	70	23	153	Oct-20	153	166	\$11,964.8	\$27,963.4	\$49,269.2	\$16,077.6	\$105,275.0
Nov-20	22	40	80	23	165	Nov-20	165	182	\$15,350.2	\$28,373.7	\$55,593.5	\$17,722.0	\$117,039.5
Dec-20	17	53	79	29	178	Dec-20	178	194	\$12,269.9	\$36,142.9	\$54,585.2	\$20,454.3	\$123,452.2
Jan-21	29	53	77	26	185	Jan-21	185	201	\$20,323.3	\$40,599.4	\$51,651.5	\$16,592.3	\$129,166.5
Feb-21	19	47	72	29	167	Feb-21	167	179	\$13,156.6	\$36,392.2	\$51,291.7	\$20,073.0	\$120,913.5
Total*	313	754	1,516	336	2,919	Total	2,919	3,095	\$197,262.7	\$509,338.6	\$974,139.3	\$221,078.6	\$1,901,819.2

Appendix C



MISSISSIPPI DIVISION OF MEDICAID UNIVERSAL PREFERRED DRUG LIST (For All Medicaid, MSCAN and CHIP Beneficiaries)

EFFECTIVE 01/01/2021 Version 2021.10 Updated: 4-30-2021

Conduent's SmartPA Pharmacy Application (SmartPA) is a proprietary electronic prior authorization system used for Medicaid fee for service claims. MSCAN plans may/may not -have electronic PA functionality. However, they must adhere to Medicaid's PA criteria.

THERAPEUTIC DRUG CLASS	PREFERRED AGENTS	NON-PREFERRED AGENTS	PA CRITERIA
ACNE AGENTS			
ANTIMIGRAINE AGEN	ITS, CALCITONIN GENE RELATED PE	PTIDE INHIBITOR	
		RAL	
	NURTEC ODT (rimegepant)	UBRELVY (ubrogepant)	Minimum Age Limit • 18 years – Nurtec ODT, Ubrelvy Quantity Limit • 8 tablets/31 day – Nurtec ODT • 16 tablets/31 day – Ubrelvy Nurtec ODT • Documented diagnosis of migrain AND • Have tried 2 different triptans in th past 6 months AND • No concurrent therapy with anoth CGRP agent Ubrelvy • Documented diagnosis of migrain AND • Have tried 2 different triptans in th past 6 months AND • Have tried 2 different triptans in th past 6 months AND • Have tried 2 different triptans in th past 6 months AND • Have tried preferred Nurtec ODT the past 6 months AND • No concurrent therapy with anoth CGRP agent AND • No concurrent therapy with a stro CYP3A4 inhibitor
		CTIBLES	
	AIMOVIG AUTOINJECTOR (erenumab-acoe) AJOVY AUTOINJECTOR (fremanezumab-vfrm) AJOVY SYRINGE (fremanezumab-vfrm)	EMGALITY PEN (galcanezumab-gnlm) EMGALITY SYRINGE (galcanezumab-gnlm) VYEPTI (eptinezumab-jjmr)	Aimovig - <u>MANUAL PA</u> Ajovy - <u>MANUAL PA</u> Emgality - <u>MANUAL PA</u> Vyepti - <u>MANUAL PA</u>

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Prior Authorization Criteria



Injectable Calcitonin Gene Related Peptides (CGRP) inhibitors PA Criteria

- AIMOVIG[™](erenumab-aooe)
- AJOVY[™] (fremanezumab-vfrm)
- EMGALITY[™] (galcanezumab-gnlm)

AIMOVIG, AJOVY and EMGALITY impact calcitonin gene-related peptides, which have been observed to increase during a migraine. These drugs are indicated for the *preventive* treatment of migraine.

Emgality 300mg is indicated for the treatment of episodic cluster headache in adults.

VYEPTITM (eptinezumab-jjmr) – Please see separate criteria at https://medicaid.ms.gov /manual-prior-authorization -criteria/

Denial Criteria for any of the CGRP inhibitors: Medication will not be used in combination with another (CGRP) inhibitor

- Medication will not be used within 12 weeks of date of last Botox® administration
- History of myocardial infarction, stroke, unstable angina, and coronary bypass surgery or other revascularization procedures within the past 12 months, vascular ischemia, deep vein thrombosis, pulmonary embolism or thrombotic events
- Currently pregnant or nursing
- Medication Overuse Headache, Hemiplegic Migraine or Tension-Type Headache

Required Medical Information:

- Diagnosis of Episodic or Chronic Migraine
- Chart notes (documentation required upon request)
- Previous therapies tried/failed

Initial Authorization-Episodic or Chronic migraine: select product requested

Preferred Agents

□ Aimovig 70mg/1ml subcutaneous once monthly

□ Aimovig 140mg/2ml subcutaneously once monthly (2 consecutive 70 mg-SC injections)

□ Ajovy 225mg/1.5ml subcutaneously once monthly

□ Ajovy 675mg/4.5ml subcutaneously once quarterly (*3 consecutive 225mg-SC injections*)

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Non-preferred Agents (must try and fail 2 preferred agents or provide evidence as to why that is unreasonable)



Emgality 240 mg/1ml subcutaneously once as loading dose* (2 consecutive 120-mg injections) followed by Emgality 120 mg subcutaneously once monthly

* Please document date of first administered dose in prescriber's office of requested medication. _____

A. Episodic Migraine

Initial Authorization: 12 weeks

Patient must be within the age range as recommended by the FDA label AND

 \square Documentation of at least 4 to 14 migraine days per month, but no more than 14 headaches per month

AND

□ Documented failure to a consecutive 8-week trial as evidenced by paid pharmacy claims, *OR* intolerance *OR* contraindication, of at least ONE therapy, from any TWO of the following different therapeutic classes:

- (a) Antidepressants: amitriptyline or venlafaxine
- (b) Antiepileptics: divalproex sodium, sodium valproate, or topiramate
- (c) Beta-blockers: metoprolol, propranolol, timolol, atenolol, nadolol

B. Chronic Migraine

Initial Authorization: 12 weeks

□ Patient must be within the age range as recommended by the FDA label *AND*

□ Documentation of greater than or equal to 15 headache days per month, of which at least 8 must be migraine days for at least 3 months. *AND*

□ Documented failure to a consecutive 8-week trial as evidenced by paid pharmacy claims for drugs "*a-d*" below, or a 12-week trial for "e", onabotulinumtoxinA, as documented by physician attestation and/ or paid medical claims *OR* intolerance *OR* contraindication of at least ONE therapy , from any TWO of the following different therapeutic classes:

(a) Antidepressants: amitriptyline or venlafaxine

(b) Antiepileptics: divalproex sodium, valproate sodium, or topiramate

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(c) Beta-blockers: metoprolol, propranolol, timolol, atenolol, nadolol,

(d) Botulinum Toxin serotype A: specifically onabotulinumtoxinA (Botox[®])



Reauthorization for Episodic or Chronic Migraine: 12 months

Select product requested:

Aimovig 70mg subcutaneous once monthly

□ Aimovig 140mg subcutaneously once monthly (2 consecutive injections of 70mg)

Ajovy 225mg subcutaneously once monthly

□ Ajovy 675mg subcutaneously once quarterly (3 consecutive injections of 225 mg)

□ Emgality 120 mg subcutaneously once monthly

Reauthorization will be based on the following criteria:

□ Positive response to therapy demonstrated by a reduction in frequency or severity of migraines [documentation required]; *AND*

Patient has an overall improvement in function with therapy; AND

□ Verified pharmacy prescription claims history of Aimovig, Ajovy or Emgality and demonstrated adherence to monthly or quarterly fills per FDA approved dosing.

C. Episodic Cluster Headache

Select product requested:

□ Emgality 300 mg subcutaneously once quarterly (3 consecutive injections of 100 mg)

Required Medical Information:

- Diagnosis of Episodic Cluster Headache
- Chart notes (documentation required upon request)
- Previous therapies tried/failed

Initial Authorization: Episodic Cluster Headache

Emgality 300 mg* (*3 consecutive injections of 100 mg*) at the onset of the cluster period, and then monthly until the end of the cluster period

* Please document date of first administered dose in prescriber's office of

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requested medication. _



Episodic Cluster Headaches - Initial Therapy (Emgality only: 12 weeks)

□ Yes □ No Patient must be within the age range as recommended by the FDA label; AND □ Yes □ No Diagnosis of episodic cluster headaches; AND \Box Yes \Box No At least 2 cluster periods lasting from 7 days to \leq 1 year each and separated by pain-free remission periods of \geq 3 months; AND □ Yes □ No Prescribed by or in consultation with a neurologist or headache specialist; AND □ Yes □ No Failure of verapamil at a dose of 360 mg per day, unless contraindicated

or clinically significant adverse effects are experienced; AND

□ Yes □ No Emgality is not prescribed concurrently with other injectable CGRP antagonists or inhibitors;

AND

□ Yes □ No Dose does not exceed 300 mg once monthly.

Episodic Cluster Headaches Reauthorization (Emgality only: up to a total of 12 months supply per cluster period)

□ Yes □ No Positive response to therapy demonstrated by a reduction in cluster headache attack frequency;

AND

□ Yes □ No Must meet <u>one</u> of the following:

- a. Patient has not received more than 12 months of consecutive treatment; OR
- b. It has been at least 3 months since the patient last received Emgality;

AND

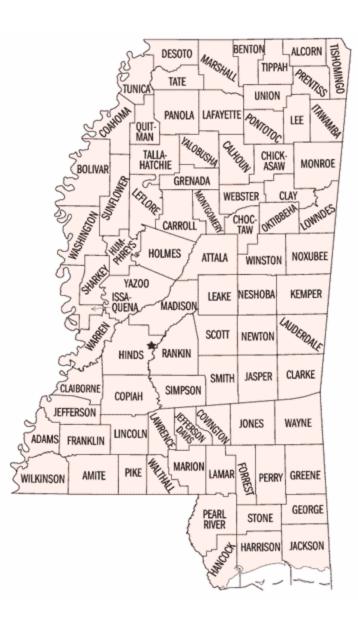
□ Yes □ No Emgality is not prescribed concurrently with other injectable CGRP antagonist antagonists or inhibitors;

AND

□ Yes □ No Dose does not exceed 300 mg once monthly.

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Appendix D



FDA DRUG SAFETY COMMUNICATIONS

March 2021 – May 2021

- 5/26/2021 Due to risk of serious liver injury, FDA restricts use of Ocaliva (obeticholic acid) in primary biliary cholangitis (PBC) patients with advanced cirrhosis
- 3/31/2021 Studies show increased risk of heart rhythm problems with seizure and mental health medicine lamotrigine (Lamictal) in patients with heart disease
- 3/25/2021 FDA warns that abuse and misuse of the nasal decongestant propylhexedrine causes serious harm

APPENDIX



Division of Medicaid Drug Utilization Review Board By-Laws

Article I. Purpose

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

Article II. Membership

Section 1 - Board Composition

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

Section 2 - Appointment selection methodology

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

Section 3 - Term of Office

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

Section 4 - Attendance

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

Section 5 - Resignation

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

Section 6 - Removal

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

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

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.

Conflicts of Interest Article V.

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/	Health Plan Employer Data and	
HEIDIS	Information Set	
HHS	Department of Health and Human	
	Services	
HIPAA	Health Insurance Portability and	
	Accountability	
IDD	Intellectual and Developmental	
	Disabilities	
LTC	Long Term Care	
MAG	Magnolia Health	
MEDD	Morphine Equivalent Daily Dose	
MOL	Molina Healthcare	
MPR	Medication Possession Ratio	
MSCAN	Mississippi Coordinated Access	
	Network	
MSDH	Mississippi State Department of	
	Health	
NADAC	National Average Drug Acquisition	
	Cost	
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NDCNational Drug CodeP&TPharmacy and TherapeutiPAPrior AuthorizationPBMPharmacy Benefit ManagePDCProportion of Days CoveraPDLPreferred Drug ListPIProgram IntegrityPIPPerformance ImprovementProgramPOSPoint of Sale, Place of SerPoint of ServicePro-DURProspective Drug Use RevOTCOver the CounterQIQuality IndicatorQIOQuality Improvement OrgQMQuality ManagementRARecipient's Explanation of BenefitsRetro-Retrospective Drug UtilizaDURReviewRFIRequest for Information	er ed nt vice, iew	
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PEI Poquest for Information		
RFI Request for Information		
RFP Request for Proposal		
RHC Rural Health Clinic		
SB Senate Bill		
SCHIP State Child Health Insurar	ice	
Program		
SMART Conduent's Pharmacy Ap	plication	
PA (SmartPA) is a proprietary	/	
electronic prior authoriza	tion	
system used for Medicaid	fee for	
service claims		
SPA State Plan Amendment		
UHC United Healthcare		
UM/QIO Utilization Management a	and	
Quality Improvement Org		
UPDL Universal Preferred Drug	List	
UR Utilization Review		
VFC Vaccines for Children		
WAC Wholesale Acquisition Co	Wholesale Acquisition Cost	
WIC Women, Infants, Children	Women, Infants, Children	
340B Federal Drug Discount Pro		

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