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



March 4, 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 March 4, 2021

#### Welcome

Old Business	
Approval of December 2020 Meeting Minutes	page 5
Resource Utilization Review	
Enrollment Statistics	page 11
Pharmacy Utilization Statistics	page 11
Top 10 Drug Categories by Number of Claims	page 12
Top 10 Drug Categories by Amount Paid	page 13
Top 25 Drug Molecules by Number of Claims	page 14
Top 25 Drug Molecules by Dollars Paid	page 15
Top 25 Drug Molecules by Change in Number of Claims	page 16
Top 25 Drug Molecules by Change in Dollars Paid	page 17
Top 15 Solid Dosage Form High Volume Products By Percent Change In	
Amount Paid Per Unit	page 18
Follow-up and Discussion from the Board	
New Business	
MS-DUR Educational Interventions	page 21
Special Analysis Projects	
HIV Pre-Exposure Prophylaxis	page 22
Guest speaker: Dr. James Brock	
Epidiolex	page 33
Growth Hormones	page 45
FDA Drug Safety Updates	page 51
Pharmacy Program Update	Terri Kirby, RPh

#### **Next Meeting Information**

Remaining 2021 Meeting Dates: June 10, September 16, and December 9

**DUR Board Meeting Minutes** 

#### MISSISSIPPI DIVISION OF MEDICAID DRUG UTILIZATION REVIEW (DUR) BOARD MINUTES OF THE DECEMBER 3, 2020 MEETING

DUR Board Roster:	Mar	Jun	Sep	Dec
State Fiscal Year 2020*	2020	2020	2020	2020
(July 1, 2019- December 31,2020)				
Lauren Bloodworth, PharmD	<b>✓</b>	✓	<b>✓</b>	✓
(Chair)				
Rhonda Dunaway, RPh		✓	✓	<b>✓</b>
Tanya Fitts, MD	✓	✓	<b>✓</b>	<b>✓</b>
Ray Montalvo, MD	✓	✓	✓	<b>✓</b>
Holly Moore, PharmD	✓	<b>√</b>	<b>V</b>	
Janet Ricks, DO	✓	<b>✓</b>	<b>✓</b>	
Cheryl Sudduth, RPh		$\checkmark$		
			✓	✓_
James Taylor, PharmD	<b>√</b>	<b>√</b>	<b>V</b>	<b>√</b>
Alan Torrey, MD	<b>✓</b>	<b>√</b>		<b>✓</b>
TOTAL PRESENT**	9	11	9	7

<sup>\*</sup> DUR Board Member Terms extended through December 31, 2020

#### **Also Present:**

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

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

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

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

#### **Conduent Staff:**

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

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

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

#### **Alliant Health Staff:**

Catherine Brett, MD, Medical Director;

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

#### **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; David Condrick, BridgeBio; Brandon Cope, Otsuka; Bryan Dillon, Otsuka; Jill Gran, Otsuka; Julie Hardie, Novo Nordisk; Phil Hecht, Abbvie; Evelyn Johnson, Capital Resources; Bryan Leibowitz, Takeda; Nole Mangine, Allergen; Beau Pender, Otsuka; Mick Peoples, Eli Lilly; Kenneth Irvin Riddle, Braeburn; Michelle Shirley, Indivior; Justin Simmons, Abbvie; Mary Stoots, Artia Solutions; Jason Swartz, Otsuka; Bruce Wallace, Azurity; Gene Wingo, Biogen; Kim Wolak, Clark; Brent Yount, GBT.

#### Call to Order:

Dr. Pittman called the meeting to order at 1:02pm and welcomed everyone to the meeting via Zoom.

#### **OLD BUSINESS:**

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

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

Dr. Pittman presented the resource utilization report for July 2020 – September 2020. Enrollment numbers continued to climb since April 2020 with 6.4% more beneficiaries receiving pharmacy benefits compared to September 2019. While enrollment numbers increased, the number of prescription fills decreased compared to September 2019. The total dollars paid for prescriptions was approximately equal to that for the same period in 2019.

#### Feedback and Discussion from Board:

No follow-up discussion concerning previous DUR Board topics was held.

#### **NEW BUSINESS:**

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

Dr. Pittman provided an overview of all DUR mailings that occurred September 2020 – November 2020.

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

#### **Adult and Child Core Set Quality Measures**

Dr. Catherine Brett provided an overview to the Board describing quality measures and Medicaid's continued work to improve care provided to beneficiaries. Following Dr. Brett's presentation, Dr. Pittman reviewed the adult and child core set measures MS-DUR ran for CY 2019. For each measure, Dr. Pittman provided a brief description of the measure, performance reported, and comparative national data, when available.

No action was taken on items from this report.

#### Naloxone Use in High Risk Beneficiaries

Dr. Pittman provided a report describing the use of naloxone among beneficiaries at high risk of experiencing adverse opioid events or overdose. This report was the result of a request from the Board at the September 2020 DUR Board Meeting. The analysis revealed that among Medicaid beneficiaries identified as high risk, less than 2% had a naloxone claim. The board discussed various methods for increasing naloxone use among beneficiaries at high risk of overdose events. Following a robust discussion, the following recommendation was considered:

1. DOM should distribute educational reminders to prescribers and pharmacists regarding the FDA's recent recommendation for naloxone, the covered status of naloxone products on the Preferred Drug List, and the Mississippi State Department of Health's Naloxone Standing Order.

Dr. Torrey motioned to approve the recommendation, seconded by Dr. Bloodworth, and unanimously approved by the Board.

#### **Adult Vaccines**

Dr. Pittman reviewed a report on the administration of adult vaccines to Medicaid beneficiaries during calendar year 2019. DOM is seeking approval from CMS to expand adult vaccine services offered through pharmacies. The report detailed adult vaccination rates overall and highlighted opportunities for increasing vaccination rates through the pharmacy benefit. The following recommendation was considered:

1. Upon CMS approval of the Vaccine State Plan Amendment (SPA), DOM should begin an educational initiative targeting pharmacists. The education should highlight the expanded opportunities granted pharmacists through the updated SPA and serve as a call to action for pharmacists to actively engage in adult immunizations.

Dr. Fitts 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 September 2020 – November 2020.

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

Ms. Kirby provided the Board with the following Pharmacy Program Updates:

- 1. Dennis Smith was officially welcomed as the new DUR Coordinator in the Office of Pharmacy.
- 2. DOM is in the process of changing to a new fiscal agent, Gainwell (formerly known as DXC). This change will occur in 2022.

#### Miscellaneous:

#### 2021 Meeting Dates/Times

March 4, 2021
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 March 4, 2021 at 1pm.

Dr. Bloodworth motioned to adjourn the meeting at 2:19 pm, seconded by Ms. Dunaway, and unanimously approved by the Board.

Submitted,

Eric Pittman, PharmD Evidence-Based DUR Initiative, MS-DUR Meeting Location: Woolfolk Building, 501 North West Street, Virtual Meeting, Jackson, MS 39201

**Contact Information:** Office of Pharmacy:

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

Notice details:

**State Agency:** MS Division of Medicaid

Public Body: Drug Utilization Board (DUR) Meeting

**Subject:** Quarterly Meeting

Date and Time: March 19, 2020; June 11, 2020; September 17, 2020; and December 3, 2020 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.

#### December 3, 2020 DUR Board Meeting – Update

The December 3, 2020 Drug Utilization Review (DUR) Board Meeting will take place virtually beginning at 1pm. Link information will be posted the day before or day of the meeting at this page. <u>Participants are reminded to join the meeting at least 15 minutes prior</u> to meeting time. Registration will end once the meeting begins.

#### Meeting information:

https://zoom.us/j/96370462198?pwd=ZGY0UUIZN0FvTjlvZFpqUjVOOElpZz09

Meeting ID: 963 7046 2198 Passcode: 036569 Phone: 929-436-2866/301-715-8592

As a reminder, when joining the virtual meeting, <u>please register with your first and last name as well as the company/organization which you are representing.</u> When in Zoom meetings, this can be done using the "rename" function. If you are dialing in via phone and computer, please remember to mute your computer and microphone to limit feedback.

Meeting agenda and packet information is posted in the table below.

**Resource Utilizaton Review** 

	TABLE 04A: ENROLLMENT STATISTICS FOR LAST 6 MONTHS  July 1, 2020 through December 31, 2020									
	Jul-20 Aug-20 Sep-20 Oct-20 Nov-20 Dec-2									
To	otal enr	ollment	719,105	727,008	733,356	739,735	744,495	748,850		
Dı	ual-elig	ibles	165,716	165,287	164,903	164,801	164,668	164,390		
Pł	narmac	y benefits	606,067	613,808	619,975	626,087	630,676	634,877		
	LTC		15,952	15,640	15,410	15,268	15,086	14,868		
	6	FFS	25.4%	25.4%	25.5%	25.5%	25.2%	25.0%		
	% N	MSCAN-UHC	29.5%	29.5%	29.3%	29.1%	28.9%	28.8%		
	PLAN	MSCAN-Magnolia	32.4%	32.2%	31.9%	31.6%	31.4%	31.2%		
		MSCAN-Molina	12.7%	12.9%	13.3%	13.8%	14.5%	15.0%		

	TABLE	04B: PHARM	IACY UTILIZA	TION STATIST	TICS FOR LAST	r 6 MONTHS						
	July 1, 2020 through December 31, 2020											
		Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20					
	FFS	95,860	96,879	100,634	104,892	100,366	104,753					
#	MSCAN-UHC	132,284	132,080	135,751	139,984	131,214	133,739					
Rx Fills	MSCAN-Mag	162,021	161,023	165,246	169,811	159,575	160,871					
	MSCAN-Mol	39,167	40,621	43,662	46,822	46,149	49,393					
#	FFS	0.6	0.6	0.6	0.7	0.6	0.7					
Rx Fills	MSCAN-UHC	0.7	0.7	0.7	0.8	0.7	0.7					
/ Bene	MSCAN-Mag	0.8	0.8	0.8	0.9	0.8	0.8					
, belie	MSCAN-Mol	0.5	0.5	0.5	0.5	0.5	0.5					
	FFS	\$11,957,706	\$11,607,247	\$12,580,505	\$12,249,761	\$11,670,675	\$12,379,145					
\$	MSCAN-UHC	\$13,449,736	\$13,715,771	\$13,789,525	\$14,096,780	\$13,586,820	\$14,362,859					
Paid Rx	MSCAN-Mag	\$17,125,388	\$16,896,404	\$17,510,726	\$17,210,795	\$16,475,932	\$17,003,566					
	MSCAN-Mol	\$3,511,111	\$3,712,035	\$3,887,390	\$4,198,445	\$4,238,785	\$4,586,322					
	FFS	\$124.74	\$119.81	\$125.01	\$116.78	\$116.28	\$118.17					
\$	MSCAN-UHC	\$101.67	\$103.84	\$101.58	\$100.70	\$103.55	\$107.39					
/Rx Fill	MSCAN-Mag	\$105.70	\$104.93	\$105.97	\$101.35	\$103.25	\$105.70					
	MSCAN-Mol	\$89.64	\$91.38	\$89.03	\$89.67	\$91.85	\$92.85					
	FFS	\$77.68	\$74.45	\$79.58	\$76.73	\$73.43	\$77.99					
\$	MSCAN-UHC	\$75.23	\$75.75	\$75.91	\$77.37	\$74.54	\$78.55					
/Bene	MSCAN-Mag	\$87.21	\$85.49	\$88.54	\$86.99	\$83.20	\$85.84					
	MSCAN-Mol	\$45.62	\$46.88	\$47.14	\$48.59	\$46.35	\$48.16					

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 DEC 2020 (FFS AND CCOs)

Category	Month Year	Rank Volume	#RXs	\$ Paid	# Unique Benes
CNS stimulants	Dec 2020	1	24,163	\$4,349,818	20,474
	Nov 2020	1	23,610	\$4,303,959	20,457
	Oct 2020	1	24,868	\$4,537,672	21,465
atypical antipsychotics	Dec 2020	2	14,276	\$4,161,864	11,975
	Nov 2020	3	13,343	\$3,658,860	11,478
	Oct 2020	4	13,943	\$3,915,122	11,825
nonsteroidal anti-inflammatory agents	Dec 2020	3	13,378	\$194,421	12,674
	Nov 2020	4	13,337	\$197,060	12,741
	Oct 2020	2	14,396	\$213,609	13,734
SSRI antidepressants	Dec 2020	4	13,322	\$162,633	12,233
	Nov 2020	5	12,625	\$156,102	11,867
	Oct 2020	7	13,046	\$163,366	12,131
adrenergic bronchodilators	Dec 2020	5	13,288	\$629,625	11,391
	Nov 2020	2	13,372	\$644,457	11,488
	Oct 2020	3	14,345	\$726,097	12,212
narcotic analgesic combinations	Dec 2020	6	12,871	\$578,208	11,504
	Nov 2020	7	12,381	\$535,505	11,397
	Oct 2020	6	13,242	\$564,457	12,000
antihistamines	Dec 2020	7	12,103	\$178,196	11,526
	Nov 2020	6	12,396	\$182,029	11,932
	Oct 2020	5	13,682	\$198,243	13,105
proton pump inhibitors	Dec 2020	8	11,906	\$428,567	11,293
	Nov 2020	8	11,440	\$417,964	11,009
	Oct 2020	8	11,844	\$439,405	11,297
antiadrenergic agents, centrally acting	Dec 2020	9	10,876	\$229,829	9,750
	Nov 2020	10	10,209	\$214,754	9,387
	Oct 2020	10	10,741	\$219,694	9,835
macrolides	Dec 2020	10	10,291	\$222,226	10,010
	Nov 2020	11	9,501	\$202,900	9,279
	Oct 2020	14	8,967	\$208,991	8,744

TABLE D: TOP 10 DRUG CATEGORIES BY DOLLARS PAID IN DEC 2020 (FFS AND CCOs)

Category	Month Year	Rank Paid Amt	#RXs	\$ Paid	# Unique Benes
CNS stimulants	Dec 2020	1	24,163	\$4,349,818	20,474
	Nov 2020	1	23,610	\$4,303,959	20,457
	Oct 2020	1	24,868	\$4,537,672	21,465
atypical antipsychotics	Dec 2020	2	14,276	\$4,161,864	11,975
	Nov 2020	2	13,343	\$3,658,860	11,478
	Oct 2020	2	13,943	\$3,915,122	11,825
antirheumatics	Dec 2020	3	1,280	\$2,563,008	1,119
	Nov 2020	4	1,219	\$2,394,376	1,084
	Oct 2020	5	1,218	\$2,397,007	1,070
antiviral combinations	Dec 2020	4	834	\$2,446,875	746
	Nov 2020	3	775	\$2,455,563	719
	Oct 2020	3	817	\$2,601,481	740
insulin	Dec 2020	5	5,135	\$2,362,399	3,779
	Nov 2020	5	5,004	\$2,360,814	3,734
	Oct 2020	4	5,168	\$2,399,434	3,833
factor for bleeding disorders	Dec 2020	6	118	\$1,638,929	84
	Nov 2020	7	114	\$1,209,586	86
	Oct 2020	7	127	\$1,457,736	100
interleukin inhibitors	Dec 2020	7	282	\$1,576,897	255
	Nov 2020	6	279	\$1,462,404	254
	Oct 2020	6	256	\$1,472,861	234
CFTR combinations	Dec 2020	8	59	\$1,187,363	49
	Nov 2020	8	53	\$1,018,353	49
	Oct 2020	8	55	\$1,109,164	48
immune globulins	Dec 2020	9	296	\$1,118,628	205
	Nov 2020	10	263	\$943,578	194
	Oct 2020	10	225	\$912,239	172
bronchodilator combinations	Dec 2020	10	3,803	\$1,039,108	3,452
	Nov 2020	9	3,675	\$997,605	3,392
	Oct 2020	9	3,883	\$1,063,036	3,569

## TABLE E: TOP 25 DRUG MOLECULES BY NUMBER OF CLAIMS IN DEC 2020 (FFS and CCOs)

Drug Molecule Therapeutic Category	Nov 2020 # Claims	Dec 2020 # Claims	Dec 2020 \$ Paid	Dec 2020 # Unique Benes
albuterol / adrenergic bronchodilators	12,865	12,829	\$493,178	11,041
azithromycin / macrolides	9,190	9,990	\$159,610	9,740
amoxicillin / aminopenicillins	10,331	9,965	\$125,725	9,774
montelukast / leukotriene modifiers	9,020	8,836	\$135,255	8,536
gabapentin / gamma-aminobutyric acid analogs	7,827	8,207	\$126,533	7,587
acetaminophen-hydrocodone / narcotic analgesic combinations	7,808	8,016	\$106,642	7,375
cetirizine / antihistamines	8,166	7,606	\$100,882	7,394
lisdexamfetamine / CNS stimulants	7,040	7,149	\$2,230,444	6,859
clonidine / antiadrenergic agents, centrally acting	6,160	6,633	\$88,743	6,081
amphetamine-dextroamphetamine / CNS stimulants	5,999	6,280	\$203,866	5,316
methylphenidate / CNS stimulants	5,969	6,096	\$971,299	5,350
ibuprofen / nonsteroidal anti-inflammatory agents	5,860	6,060	\$73,742	5,861
fluticasone nasal / nasal steroids	6,326	5,899	\$89,314	5,787
amlodipine / calcium channel blocking agents	5,516	5,837	\$67,477	5,501
omeprazole / proton pump inhibitors	5,600	5,757	\$64,084	5,548
sertraline / SSRI antidepressants	4,605	4,941	\$60,348	4,564
ondansetron / 5HT3 receptor antagonists	4,673	4,938	\$70,982	4,729
atorvastatin / HMG-CoA reductase inhibitors (statins)	4,136	4,315	\$49,704	4,004
guanfacine / antiadrenergic agents, centrally acting	4,037	4,235	\$140,950	3,963
pantoprazole / proton pump inhibitors	3,545	3,755	\$46,338	3,537
aripiprazole / atypical antipsychotics	3,486	3,751	\$997,663	3,414
ethinyl estradiol-norgestimate / contraceptives	3,556	3,742	\$62,133	3,438
hydroxyzine / miscellaneous anxiolytics, sedatives and hypnotics	3,575	3,686	\$53,177	3,504
risperidone / atypical antipsychotics	3,382	3,620	\$180,329	3,201
trazodone / phenylpiperazine antidepressants	3,295	3,553	\$41,846	3,315

## TABLE F: TOP 25 DRUG MOLECULES BY DOLLARS PAID IN DEC 2020 (FFS and CCOs)

Drug Molecule Therapeutic Category	Nov 2020 \$ Paid	Dec 2020 \$ Paid	Dec 2020 # Claims	Dec 2020 # Unique Benes
adalimumab / antirheumatics	\$2,097,193	\$2,294,857	329	291
lisdexamfetamine / CNS stimulants	\$2,190,890	\$2,230,444	7,149	6,859
paliperidone / atypical antipsychotics	\$1,433,163	\$1,717,797	690	601
bictegravir/emtricitabine/tenofovir / antiviral combinations	\$1,090,717	\$1,102,588	355	334
aripiprazole / atypical antipsychotics	\$848,306	\$997,663	3,751	3,414
methylphenidate / CNS stimulants	\$959,677	\$971,299	6,096	5,350
insulin glargine / insulin	\$846,647	\$854,477	1,886	1,792
elexacaftor/ivacaftor/tezacaftor / CFTR combinations	\$647,604	\$791,121	37	32
palivizumab / immune globulins	\$605,953	\$667,883	250	170
dexmethylphenidate / CNS stimulants	\$648,969	\$646,956	3,027	2,473
dupilumab / interleukin inhibitors	\$604,723	\$592,430	194	173
etanercept / TNF alpha inhibitors	\$609,833	\$580,965	111	101
liraglutide / GLP-1 receptor agonists	\$522,594	\$539,094	680	647
lacosamide / miscellaneous anticonvulsants	\$498,998	\$531,120	576	506
somatropin / growth hormones	\$538,833	\$530,606	132	122
insulin aspart / insulin	\$516,706	\$523,831	1,372	1,285
budesonide-formoterol / bronchodilator combinations	\$493,927	\$510,942	1,619	1,562
albuterol / adrenergic bronchodilators	\$491,687	\$493,178	12,829	11,041
ustekinumab / interleukin inhibitors	\$346,521	\$479,908	24	24
emicizumab / factor for bleeding disorders	\$716,359	\$478,662	21	17
lurasidone / atypical antipsychotics	\$466,808	\$469,132	345	326
insulin detemir / insulin	\$438,276	\$432,549	791	738
buprenorphine-naloxone / narcotic analgesic combinations	\$383,126	\$421,113	1,512	1,188
cobicistat/elvitegravir/emtricitabine/tenofov / antiviral combinations	\$427,375	\$403,422	125	110
apixaban / factor Xa inhibitors	\$346,100	\$386,194	913	809

## TABLE G: TOP 25 DRUG MOLECULES BY CHANGE IN NUMBER OF CLAIMS FROM OCT 2020 TO DEC 2020 (FFS and CCOs)

Drug Molecule	Oct 2020 # Claims	Nov 2020 # Claims	Dec 2020 # Claims	Dec 2020 \$ Paid	Dec 2020 # Unique Benes
azithromycin / macrolides	8,660	9,190	9,990	\$159,610	9,740
famotidine / H2 antagonists	2,944	3,021	3,504	\$139,748	3,320
ondansetron / 5HT3 receptor antagonists	4,502	4,673	4,938	\$70,982	4,729
oseltamivir / neuraminidase inhibitors	162	297	451	\$22,169	450
dexamethasone / glucocorticoids	416	493	608	\$8,668	587
benzonatate / antitussives	753	826	943	\$11,377	908
amlodipine / calcium channel blocking agents	5,658	5,516	5,837	\$67,477	5,501
folic acid / vitamins	2,164	2,122	2,315	\$17,645	1,769
aripiprazole / atypical antipsychotics	3,612	3,486	3,751	\$997,663	3,414
clonidine / antiadrenergic agents, centrally acting	6,504	6,160	6,633	\$88,743	6,081
escitalopram / SSRI antidepressants	2,299	2,307	2,419	\$28,645	2,246
buprenorphine-naloxone / narcotic analgesic combinations	1,396	1,354	1,512	\$421,113	1,188
topiramate / carbonic anhydrase inhibitor anticonvulsants	1,643	1,653	1,751	\$104,587	1,629
ergocalciferol / vitamins	2,928	2,844	3,036	\$24,612	2,675
trazodone / phenylpiperazine antidepressants	3,446	3,295	3,553	\$41,846	3,315
doxycycline / tetracyclines	1,731	1,619	1,835	\$25,890	1,785
gabapentin / gamma-aminobutyric acid analogs	8,106	7,827	8,207	\$126,533	7,587
divalproex sodium / fatty acid derivative anticonvulsants	2,629	2,509	2,723	\$74,148	2,360
levothyroxine / thyroid hormones	3,135	2,997	3,228	\$67,675	2,987
sertraline / SSRI antidepressants	4,849	4,605	4,941	\$60,348	4,564
pantoprazole / proton pump inhibitors	3,675	3,545	3,755	\$46,338	3,537
dextromethorphan-promethazine / upper respiratory combinations	321	381	399	\$6,870	368
quetiapine / atypical antipsychotics	3,174	3,117	3,246	\$52,770	2,832
alprazolam / benzodiazepines	1,840	1,761	1,911	\$19,377	1,790
rosuvastatin / HMG-CoA reductase inhibitors (statins)	1,094	1,108	1,164	\$14,796	1,108

### TABLE H: TOP 25 DRUG MOLECULES BY CHANGE IN AMOUNT PAID FROM OCT 2020 TO DEC 2020 (FFS and CCOs)

Drug Molecule	Oct 2020 \$ Paid	Nov 2020 \$ Paid	Dec 2020 \$ Paid	Dec 2020 # Claims	Dec 2020 # Unique Benes
antihemophilic factor / factor for bleeding disorders	\$214,638	\$247,457	\$376,455	22	11
palivizumab / immune globulins	\$507,955	\$605,953	\$667,883	250	170
paliperidone / atypical antipsychotics	\$1,558,577	\$1,433,163	\$1,717,797	690	601
adalimumab / antirheumatics	\$2,135,640	\$2,097,193	\$2,294,857	329	291
cysteamine / miscellaneous uncategorized agents	\$60,853	\$188,636	\$188,636	3	3
coagulation factor ix / factor for bleeding disorders	\$106,752	\$84,226	\$225,796	7	5
asfotase alfa / miscellaneous metabolic agents	\$0	\$0	\$116,810	2	2
aripiprazole / atypical antipsychotics	\$885,824	\$848,306	\$997,663	3,751	3,414
ivacaftor-tezacaftor / CFTR combinations	\$179,955	\$202,416	\$269,869	15	11
corticotropin / corticotropin	\$239,417	\$239,358	\$319,092	3	3
elexacaftor/ivacaftor/tezacaftor / CFTR combinations	\$719,405	\$647,604	\$791,121	37	32
dupilumab / interleukin inhibitors	\$522,743	\$604,723	\$592,430	194	173
pancrelipase / digestive enzymes	\$262,005	\$269,985	\$318,212	157	142
dornase alfa / miscellaneous respiratory agents	\$207,812	\$234,568	\$262,526	66	61
ribociclib / CDK 4/6 inhibitors	\$23,954	\$23,954	\$77,160	6	5
c1 esterase inhibitor, human / factor for bleeding disorders	\$97,770	\$91,964	\$145,384	4	3
ustekinumab / interleukin inhibitors	\$435,910	\$346,521	\$479,908	24	24
cannabidiol / miscellaneous anticonvulsants	\$300,822	\$292,579	\$343,235	121	109
cariprazine / atypical antipsychotics	\$224,890	\$218,264	\$266,534	224	210
rufinamide / dibenzazepine anticonvulsants	\$148,725	\$173,645	\$188,676	62	55
valbenazine / VMAT2 inhibitors	\$219,400	\$283,581	\$257,628	38	35
pomalidomide / other immunosuppressants	\$18,297	\$36,594	\$54,892	3	3
glycerol phenylbutyrate / urea cycle disorder agents	\$136,020	\$146,082	\$171,299	4	3
riociguat / vasodilators	\$22,032	\$31,953	\$55,081	5	4
avapritinib / multikinase inhibitors	\$0	\$0	\$32,058	1	1

## TABLE I: TOP 15 DRUG SOLID DOSAGE FORM HIGH VOLUME (100+ RX FILLS LAST MONTH) PRODUCTS WITH UNIT COST > \$1 BY PERCENT CHANGE IN AMOUNT PAID PER UNIT OCT 2020 TO DEC 2020 (FFS and CCOs)

Drug Product Therapeutic Category	Dec 2020 # Claims	Dec 2020 \$ Paid	Dec 2020 Avr. Paid Per Rx	Dec 2020 Avr. Units Per Rx	Oct 2020 Paid Per Unit	Nov 2020 Paid Per Unit	Dec 2020 Paid Per Unit	Percent Change
atomoxetine 60 mg capsule / CNS stimulants (P)	119	\$8,199	\$68.90	30	\$1.73	\$1.86	\$1.92	10.6%
dexmethylphenidate 20 mg capsule, extended release / CNS stimulants (N)	134	\$14,743	\$110.02	30	\$3.03	\$3.44	\$3.32	9.6%
methylphenidate 18 mg/24 hr tablet, extended release / CNS stimulants (P)	439	\$24,518	\$55.85	30	\$1.40	\$1.54	\$1.50	7.4%
atomoxetine 25 mg capsule / CNS stimulants (P)	207	\$12,123	\$58.56	30	\$1.51	\$1.51	\$1.58	4.2%
methylphenidate 36 mg/24 hr tablet, extended release / CNS stimulants (P)	993	\$73,374	\$73.89	37	\$1.63	\$1.79	\$1.68	2.8%
methylphenidate 54 mg/24 hr tablet, extended release / CNS stimulants (P)	709	\$47,433	\$66.90	30	\$1.82	\$2.09	\$1.86	2.2%
Eliquis (apixaban) 2.5 mg tablet / factor Xa inhibitors (P)	104	\$45,404	\$436.57	55	\$7.20	\$7.18	\$7.34	1.9%
buprenorphine-naloxone 8 mg-2 mg film / narcotic analgesic combinations (N)	861	\$170,713	\$198.27	47	\$3.91	\$3.99	\$3.97	1.5%
Jardiance (empagliflozin) 10 mg tablet / SGLT-2 inhibitors (P)	211	\$145,818	\$691.08	42	\$16.37	\$16.48	\$16.57	1.2%
Focalin XR (dexmethylphenidate) 15 mg capsule, extended release / CNS stimulants (P)	309	\$118,708	\$384.17	30	\$12.38	\$12.53	\$12.52	1.2%
Vyvanse (lisdexamfetamine) 30 mg tablet, chewable / CNS stimulants (P)	242	\$74,646	\$308.46	30	\$9.91	\$9.91	\$10.01	1.0%
Tivicay (dolutegravir) 50 mg tablet / integrase strand transfer inhibitor (P)	128	\$228,882	\$1,788.14	35	\$53.78	\$54.12	\$54.30	1.0%
Jardiance (empagliflozin) 25 mg tablet / SGLT-2 inhibitors (P)	300	\$227,448	\$758.16	44	\$16.25	\$16.20	\$16.38	0.8%

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

## TABLE I: TOP 15 DRUG SOLID DOSAGE FORM HIGH VOLUME (100+ RX FILLS LAST MONTH) PRODUCTS WITH UNIT COST > \$1 BY PERCENT CHANGE IN AMOUNT PAID PER UNIT OCT 2020 TO DEC 2020 (FFS and CCOs)

Drug Product Therapeutic Category	Dec 2020 # Claims	Dec 2020 \$ Paid	Dec 2020 Avr. Paid Per Rx	Dec 2020 Avr. Units Per Rx	Oct 2020 Paid Per Unit	Nov 2020 Paid Per Unit	Dec 2020 Paid Per Unit	Percent Change
Dexilant (dexlansoprazole) 60 mg delayed release capsule / proton pump inhibitors (N)	102	\$36,875	\$361.52	36	\$9.16	\$9.12	\$9.23	0.8%
Saphris (asenapine) 5 mg tablet / atypical antipsychotics (P)	173	\$135,618	\$783.92	41	\$18.92	\$19.11	\$19.03	0.6%

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

**New Business** 

**Special Analysis Projects** 

#### MISSISSIPPI DIVISION OF MEDICAID

#### MS-DUR INTERVENTION / EDUCATIONAL INITIATIVE UPDATE

#### **DECEMBER 2020 – FEBRUARY 2021**

#### Ongoing Intervention(s):

PROVIDER SHOPPING FOR OPIOIDS ( <u>&gt;</u> 4 Prescribers AND <u>&gt;</u> 4 Pharmacies)							
Month	Prescribers	Pharms	Benes				
WOILLI	Mailed	Mailed	Addressed				
20-Mar	7	4	11				
20-Apr	4	3	7				
20-May	3	4	7				
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				

#### One-time Initiatives:

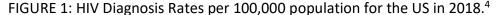
- An educational piece on PPI deprescribing will be part of DOM's upcoming Provider Bulletin.
- An educational piece on changes in adult vaccine coverage will be part of DOM's upcoming Provider Bulletin.
- A message was distributed to state pharmacy associations informing members of the new vaccine coverage and billing guidelines.

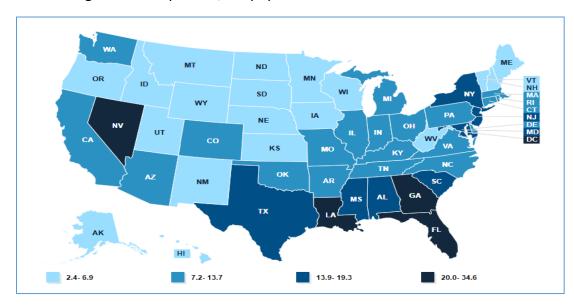
#### **HIV Pre-Exposure Prophylaxis**

#### **BACKGROUND**

At its peak in the mid-1990s, Acquired Immunodeficiency Syndrome (AIDS) was the leading cause of death for individuals aged 25 to 44 years in the United States.<sup>1</sup> Despite tremendous advances in care, data indicate Human Immunodeficiency Virus (HIV) infections continue to be a major public health problem in the United States and around the world. According to the Centers for Disease Control and Prevention (CDC), in 2018 over 1 million individuals in the United States and dependent areas had an HIV diagnosis with an estimated 38,000 new infections occurring that year.<sup>2</sup> While overall trends in new HIV infection rates have decreased in the US, progress has stalled in recent years.

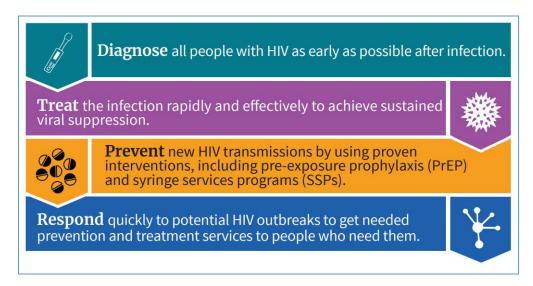
The disease burden of HIV is disproportionately distributed across the US. The overall rate of HIV diagnosis in the US in 2018 was 11.5 per 100,000 population. Individuals age 20 to 24 years and 25 to 29 years had the highest rates of HIV diagnoses per 100,000 population at 27.9 and 32.6, respectively. Incidence among Black/African Americans was more than twice the rate when compared to other racial/ethnic groups at 39.2.² Although Southern states make up 38% of the population, they accounted for 52% of new diagnoses in the US in 2018.² Drilling down even further, Mississippi was included among those states with high rates of HIV infections. According to the 2018 HIV Surveillance Report, there were over 9,000 people living with HIV in Mississippi.³ In 2018, Mississippi was tied with Maryland as having the 6th highest incidence of HIV infection among adolescents and adults in the US with a diagnosis rate of approximately 19.3 per 100,000 population, while the US average diagnosis rate was 13.6 per 100,000 population.⁴ (Figure 1) More specifically, Jackson, Mississippi had the 8th highest diagnosis rate of HIV infections (28.4) for all metropolitan statistical areas measured in the US.5





In 2019, the US Department of Health and Human Services (HHS) launched an initiative, *Ending the HIV Epidemic: A Plan for America*. This multi-year initiative's goal was to drastically reduce incident HIV infections in the US by 90% within 10 years. (Figure 2) The initiative was designed to rapidly increase utilization of these key components in 48 counties, plus Washington, D.C., and San Juan, Puerto Rico with the highest number of new HIV diagnoses in 2016 and 2017. Additionally seven states with a high proportion of HIV diagnoses in rural areas (Mississippi was included) were added to the focus areas.

FIGURE 2: Ending the HIV Epidemic: A Plan for America Key Components.<sup>6</sup>



One of the primary components of this initiative is prevention, which many consider the key to eliminating HIV.<sup>8</sup> Pre-exposure prophylaxis (PrEP) is one aspect of prevention that involves the use of antiretroviral medications on a routine basis by individuals that are HIV negative who are at high-risk of being exposed to HIV. Currently, there are two FDA products approved for use as PrEP. Both products are combination antiretroviral drug formulations consisting of emtricitabine and tenofovir. The first product approved by the FDA in 2012 to be used for PrEP was Truvada<sup>®</sup>.<sup>9</sup> A second product, Descovy<sup>®</sup>, was approved in October 2019.<sup>10</sup> Both products are approved for use in PrEP for adults and adolescents > 35kg to reduce the risk of HIV infection.<sup>9,10</sup> A key factor in the effectiveness of HIV PrEP therapy is adherence. Studies have shown that PrEP can reduce the risk of acquiring HIV from sex by up to 99% and from injection drug use by 74%, but effectiveness was highly associated with the degree of adherence.<sup>11</sup>

In 2019 the US Preventive Services Task Force (USPSTF) issued updated recommendations on PrEP for the prevention of HIV infection. After a systematic review of evidence, PrEP was found to be of substantial benefit in decreasing the risk of HIV infection among high-risk persons. Adherence to PrEP was highly associated with efficacy at preventing HIV infection, and PrEP use was associated

with minimal harms.<sup>12</sup> Categories of individuals identified by USPSTF as high-risk for acquiring HIV infection include:

- Men who have sex with men, are sexually active, and have 1 of the following characteristics:
  - A serodiscordant sex partner (i.e., in a sexual relationship with a partner living with HIV)
  - Inconsistent use of condoms during receptive or insertive anal sex
  - A sexually transmitted infection (STI) with syphilis, gonorrhea, or chlamydia within the past 6 months
- Heterosexually active women and men who have 1 of the following characteristics:
  - A serodiscordant sex partner (i.e., in a sexual relationship with a partner living with HIV)
  - Inconsistent use of condoms during sex with a partner whose HIV status is unknown and who is at high risk (e.g., a person who injects drugs or a man who has sex with men and women)
  - An STI with syphilis or gonorrhea within the past 6 months
- Persons who inject drugs and have 1 of the following characteristics
  - Shared use of drug injection equipment
  - Risk of sexual acquisition (see above)

For Mississippi Division of Medicaid beneficiaries, PrEP medications are covered under the Universal Preferred Drug List (UPDL). Both branded Truvada® and Descovy® are preferred agents available without prior authorization requirements. To further increase access to PrEP products, DOM's Family Planning Waiver is available to **women and men** to receive family planning related services, including many medications for the treatment of sexually transmitted infections/ sexually transmitted diseases (STIs/STDs). The two medications currently approved for PrEP use are included on the list of medications covered under the Waiver.

MS-DUR conducted an analysis assessing the utilization of PrEP products in Mississippi Medicaid between 2014 and 2020. A summary of those findings follows.

#### **METHODS**

A retrospective analysis was conducted using Mississippi Medicaid fee-for-service (FFS) and coordinated care organization [CCOs: United Healthcare (UHC), Magnolia (MAG), and Molina (MOL)] claims for the period of January 1, 2014 to November 30, 2020. The identification period for beneficiaries on HIV Pre-Exposure Prophylaxis (PrEP) was January 1, 2014 to October 31, 2020, which allowed for a 12 month look back period and a 30-day follow-up period for every beneficiary in the sample. MS-DUR has complete medical claims in its database beginning CY 2013. Beneficiaries on (PrEP) were identified according to the algorithm developed by Wu et.al. which is used by CDC. <sup>13,14</sup> Beneficiaries aged ≥ 16 years who were prescribed tenofovir and emtricitabine (TDF+FTC or TAF+FTC) for PrEP were included in the sample. The first claim was assigned as the index date. Dual eligible beneficiaries and those age > 64 years were excluded from the study sample. Additionally, beneficiaries with a diagnosis code for Hepatitis B (HBV) or an

HIV infection (assessed from medical claims) at any time before or within 30 days after the index date were excluded from analysis. All 25 ICD 10 diagnosis codes as well as the principal diagnosis code of each claim were checked from inpatient, outpatient and medical claim files to identify beneficiaries with HIV or HBV. Beneficiaries having a prescription intended to treat HIV or HBV (assessed from pharmacy claims), at any time before or within 30 days after the index date, were excluded from analysis. Finally, beneficiaries prescribed TDF+FTC or TAF+FTC for Post-Exposure Prophylaxis (PEP), identified as those with a prescription for ≤ 28 continuous days, were excluded from the analysis. Figure 3 provides a description of the attrition associated with the algorithm used.

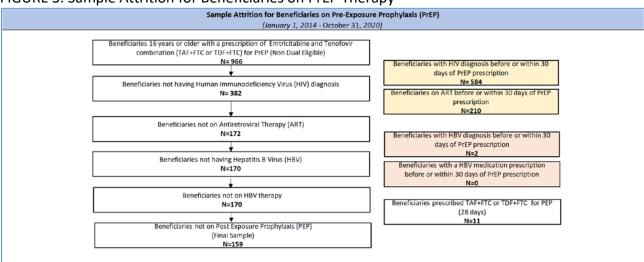


FIGURE 3: Sample Attrition for Beneficiaries on PrEP Therapy

Plan was determined as of index date (earliest prescription fill date for PrEP). Information on beneficiaries' race, gender, age, and plan (FFS/UHC/MAG/MOL) were summarized in the analysis (Table 1). Age and plan were assessed as of index date. Trends in number of people utilizing PrEP was reported according to the plan as of index date, for each year from 2014-2020 (Figure 4 & Figure 5). PrEP utilization patterns for beneficiaries on PrEP were reported according to plan at index date in terms of mean duration of continuous use and length of continuous use in the following categories 29-60 days, 61-90 days and 91 days or more (Table 2). Continuous use was defined as continuous PrEP use with a maximum allowable gap of up to 14 days between consecutive prescription fills after adjusting for early refills. Code of eligibility (COE) for each index PrEP fill was reported by plan in Table 3. County level distribution of number of unique providers that prescribed PrEP during the study period was reported in Figure 6.

#### **RESULTS**

In Table 1 demographic characteristics of beneficiaries initiated on pre-exposure prophylaxis (PrEP) between January 1, 2014 and October 31, 2020 are displayed.

- A total of 159 beneficiaries were initiated on PrEP therapy.
- 71.7% were between the ages of 18-35 years.
- 55.3% were male.
- 75.5% were African American.

TABLE 1: Demographic Characteristics of Beneficiaries Initiated on Pre-Exposure Prophylaxis (PrEP) (January 1, 2014 - October 31, 2020)									
		Plan At Index							
	Total	FFS UHC			MAG		MOL		
Characteristic	Beneficiaries (N=159)*	N	%	N	%	N	%	N	%
Age Category (years)									
16-18	20	4	5%	9	21%	6	17%	1	20%
18-35	114	63	84%	28	65%	22	61%	1	20%
36-50	18	7	9%	2	5%	6	17%	3	60%
51-64	7	1	1%	4	9%	2	6%	0	0%
Total	159	75		43		36		5	
Sex									
Female	71	22	29%	22	51%	23	64%	4	80%
Male	88	53	71%	21	49%	13	36%	1	20%
Total	159	<i>7</i> 5		43		36		5	
Race									
African American	120	61	81%	29	67%	27	75%	3	60%
Caucasian	28	10	13%	11	26%	7	19%	0	0%
Other	11	4	5%	3	7%	2	6%	2	40%
Total	159	75		43		36		5	

Note: FFS - Fee-for-Service; UHC - UnitedHealthcare; MAG - Magnolia; MOL - Molina

\*Beneficiaries on PrEP were identified according to the algorithm used by CDC/IQVIA developed by Wu et.al. which identifies persons aged ≥ 16 years who were prescribed Tenofovir and Emtricitabine for PrEP. The identification period for PrEP beneficiaries was Jan 1, 2014 to Oct 31, 2020. The first claim was the index date. Non dual eligible beneficiaries aged between 16 - 64 years were included in the study sample. Beneficiaries with a diagnosis of Hepatitis B (HBV) or an HIV infection or prescribed medications intended to treat HIV or HBV, at any time within one year prior or 30 days after the index date, were excluded from analysis. Finally, beneficiaries prescribed these agents for Post Exposure Prophylaxis (PEP), identified as those with a prescription for less than 28 continuous days, were excluded from analysis. Plan was determined as of index date (earliest date of prescription for PrEP).

Figure 4 displays yearly trends in beneficiaries initiating PrEP Therapy.

- The maximum number of annual initiates of PrEP therapy occurred in 2019 with 40 beneficiaries.
- 2020 saw a 30% drop compared to 2019.

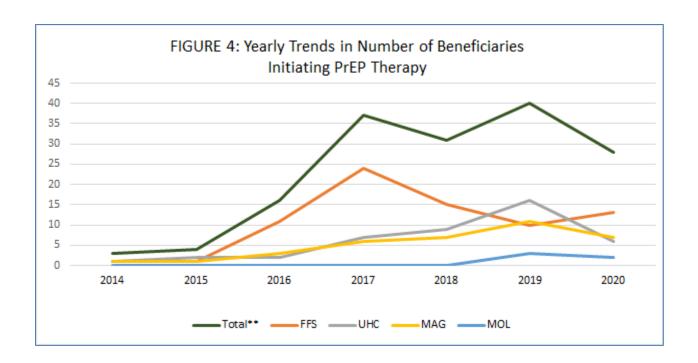
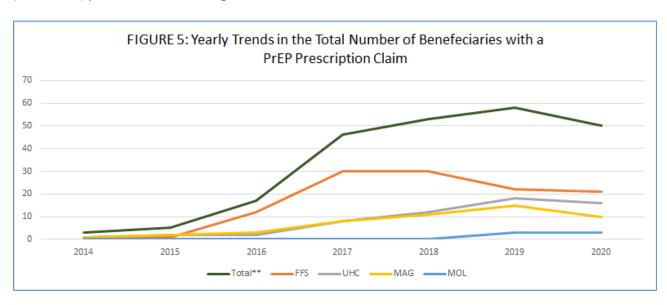


FIGURE 5 also shows a decrease in 2020 in the total number of beneficiaries having a PrEP prescription claim. These declines follow national trends associating the coronavirus disease 2019 (COVID-19) pandemic with changes in PrEP utilization. <sup>15</sup>



Length of therapy patterns for Medicaid beneficiaries prescribed PrEP products is detailed in Table 2.

- Mean length of therapy across all programs was 72.46 days.
- The majority of beneficiaries (104/159) appear to have taken PrEP ≤ 60 days.

TABLE 2: Description of PrEP Utilization Patterns Among Medicaid Beneficiaries (1st January 1, 2014 - October 31, 2020) Mean Length of Therapy (Days) \*\* Plan\* Length of Therapy\*\*\* (Days) 61-90 29-60 ≥ 91 Total FFS 75 76.51 48 20 UHC 50.53 33 4 6 43 MAG 4 12 36 93.64 20 MOL 48 3 1 5 Total 104 16 39 159

Notes: FFS - Fee-for-Service; UHC - UnitedHealthcare; MAG - Magnolia; MOL - Molina

\*Code of eligibility was calculated as of the index date

As mentioned earlier in the report, PrEP therapy is covered under Medicaid's Family Planning Waiver. Of the 159 beneficiaries started on PrEP therapy, 53 were covered under the Family Planning Waiver as of the index fill date. (Table 3)

TABLE 3: Description of Code Of Eligibility Types as of Index Fill (January 1, 2014 - October 31, 2020)							
Category	Plan						
Code Of Eligibility*	FFS	UHC	MAG	MOL	Total		
Family Planning	53	О	О	0	53		
Parents/Caretakers of children under the age 18							
(EFFECTIVE: 1/1/2014)	5	11	13	1	30		
Children 6-19 with income at or below 107% FPL							
(EFFECTIVE: 1/1/2014)	2	17	8	1	28		
SSI Individual via SDX	5	9	11	2	27		
Pregnant Women under 194%	2	2	1	1	6		
Quasi-CHIP – Children age 6 – 19 with income							
between 107% and 133% FPL who would have							
qualified for CHIP under per-ACA rules.							
(EFFECTIVE: 1/1/2014)	О	3	1	О	4		
Protected Foster Care	3	0	0	0	3		
Medical Assistance – Intact Family							
(END: 12/31/2013)	О	1	1	О	2		
Working Disabled	0	0	1	0	1		
Child Under Age 19, under 100%							
(END: 12/31/2013)	1	0	О	О	1		
Total	71	43	36	5	155		
Notes: Missing COE for 4 beneficiaries							

<sup>\*</sup>Plan calculated as of index date.

<sup>\*\*</sup>Length of Therapy was defined as continuous PrEP use with a maximum allowable gap of up to 14 days between prescriptions.

<sup>\*\*\*</sup>Mean duration of continuous PrEP Use

One of the key components to initiating PrEP therapy is beneficiary access to providers that will identify high-risk individuals and prescribe PrEP. Providers were identified across the state that had prescribed PrEP to Medicaid beneficiaries during the study period. (Figure 6)

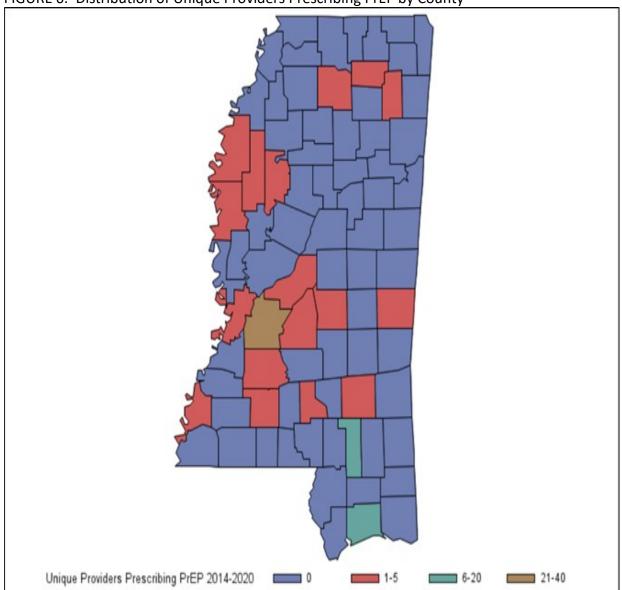


FIGURE 6: Distribution of Unique Providers Prescribing PrEP by County

A total of 76 Providers across 20 counties prescribed PrEP therapies to Medicaid beneficiaries between 2014–2020.

- Hinds county accounted for 48.7% (37) of the providers prescribing PrEP therapies.
- Only 24.4% (20) of the 82 counties in MS had a provider prescribe PrEP to a Medicaid beneficiary.
- 55% (11/20) of the counties where PrEP was prescribed only had 1 provider.

#### CONCLUSIONS

HIV infections continue to be a major public health issue in the United States, with Mississippi among the highest states in the nation in HIV incidence rates. One of the keys to ending the HIV epidemic is prevention through PrEP. PrEP therapy is covered under Medicaid's UPDL with no prior authorization criteria needed and is also included under the Family Planning Waiver. Even with no restrictions to access, there have been only 159 beneficiaries 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.

#### RECOMMENDATION

- 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.
- 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.).

#### REFERENCES:

- 1. Hariri S, McKenna MT. Epidemiology of Human Immunodeficiency Virus in the United States. *Clin Microbiol Rev.* 2007;20(3):478-488. doi:10.1128/CMR.00006-07
- 2. HIV Surveillance Report 2018 (updated). 31:119.
- 3. AIDSVu Mississippi|2018. AIDSVu. Accessed September 9, 2020. http://aidsvu.org/local-data/united-states/south/mississippi/
- 4. HIV Diagnoses, Adults and Adolescents. The Henry J. Kaiser Family Foundation. Published February 10, 2020. Accessed February 26, 2020. https://www.kff.org/hivaids/state-indicator/hiv-diagnoses-adults-and-adolescents/
- 5. HIV Surveillance Data Tables | Reports | Resource Library | HIV/AIDS | CDC. Published September 3, 2020. Accessed September 9, 2020. https://www.cdc.gov/hiv/library/reports/surveillance-data-tables/vol-1-no-3/index.html
- 6. Fauci AS, Redfield RR, Sigounas G, Weahkee MD, Giroir BP. Ending the HIV Epidemic: A Plan for the United States. *JAMA*. 2019;321(9):844. doi:10.1001/jama.2019.1343
- 7. Federal Response, Policy H, July 02 Hhsd last updated:, 2020. Federal-Response | Ending-the-HIV-Epidemic | Overview. HIV.gov. Published July 2, 2020. Accessed September 9, 2020. https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview
- 8. Poku NK. HIV Prevention: The Key to Ending AIDS by 2030. *Open AIDS J.* 2016;10:65-77. doi:10.2174/1874613601610010065
- 9. Truvada MICROMEDEX. Accessed February 23, 2020. https://www.micromedexsolutions.com/micromedex2/librarian/CS/51F374/ND\_PR/evidencexper t/ND\_P/evidencexpert/DUPLICATIONSHIELDSYNC/C72358/ND\_PG/evidencexpert/ND\_B/evidence xpert/ND\_AppProduct/evidencexpert/ND\_T/evidencexpert/PFActionId/evidencexpert.GoToDashb oard?docId=928216&contentSetId=100&title=Emtricitabine%2FTenofovir+Disoproxil+Fumarate&s ervicesTitle=Emtricitabine%2FTenofovir+Disoproxil+Fumarate&brandName=Truvada#
- 10. Descovy- MICROMEDEX. Accessed February 23, 2020. https://www.micromedexsolutions.com/micromedex2/librarian/CS/116FB3/ND\_PR/evidencexper t/ND\_P/evidencexpert/DUPLICATIONSHIELDSYNC/5C75F6/ND\_PG/evidencexpert/ND\_B/evidence xpert/ND\_AppProduct/evidencexpert/ND\_T/evidencexpert/PFActionId/evidencexpert.GoToDashb oard?docId=931813&contentSetId=100&title=Emtricitabine%2FTenofovir+Alafenamide&servicesT itle=Emtricitabine%2FTenofovir+Alafenamide&brandName=Descovy#

- 11. Riddell J, Amico KR, Mayer KH. HIV Preexposure Prophylaxis: A Review. *JAMA*. 2018;319(12):1261-1268. doi:10.1001/jama.2018.1917
- 12. US Preventive Services Task Force, Owens DK, Davidson KW, et al. Preexposure Prophylaxis for the Prevention of HIV Infection: US Preventive Services Task Force Recommendation Statement. *JAMA*. 2019;321(22):2203-2213. doi:10.1001/jama.2019.6390
- 13. Wu H, Mendoza MCB, Huang Y-LA, Hayes T, Smith DK, Hoover KW. Uptake of HIV Preexposure Prophylaxis Among Commercially Insured Persons-United States, 2010-2014. *Clin Infect Dis Off Publ Infect Dis Soc Am*. 2017;64(2):144-149. doi:10.1093/cid/ciw701
- 14. Furukawa NW, Smith DK, Gonzalez CJ, et al. Evaluation of Algorithms Used for PrEP Surveillance Using a Reference Population From New York City, July 2016-June 2018. *Public Health Rep Wash DC 1974*. 2020;135(2):202-210. doi:10.1177/0033354920904085
- 15. Pampati S, Emrick K, Siegler AJ, Jones J. Changes in sexual behavior, PrEP adherence, and access to sexual health services due to the COVID-19 pandemic among a cohort of PrEP-using MSM in the South. *JAIDS J Acquir Immune Defic Syndr*. 2021;Publish Ahead of Print. doi:10.1097/QAI.0000000000002640

#### **Epidiolex Utilization**

#### **BACKGROUND**

Epidiolex (cannabidiol) was approved by the US Food and Drug Administration (FDA) on June 25, 2018, making it the first and only plant-derived, purified, pharmaceutical-grade, cannabidiol (CBD) prescription medication. CBD is considered a phytocannabinoid, a chemical found within cannabis plants that interacts with cannabinoid receptors throughout the body, from neurons in the brain and peripheral nervous system to the thyroid, liver, gastrointestinal tract, and immune cells. While the exact mechanism of action is unknown, CBD has been found to be effective in treatment-resistant epilepsy. Unlike THC, another phytocannabinoid having antiepileptic effects, CBD has no known abuse potential and lacks detectable psychoactive properties, providing patients the benefit of reduction in seizure frequency while experiencing minimal psychoactive side effects.

Epidiolex is available as an oral solution and is indicated for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS), Dravet syndrome (DS), or tuberous sclerosis complex (TSC) in patients 1 year of age and older.<sup>4,5</sup> Several phase 3, randomized, placebo-controlled clinical trials have demonstrated that Epidiolex is effective and well tolerated when added to conventional antiepileptic regimens for these indications.<sup>6–9</sup> Dosing of Epidiolex should be initiated at 2.5 mg/kg by mouth twice daily, and titrated up in weekly increments of 2.5 mg/kg twice daily as necessary and tolerated to a maximum dose of 20 mg/kg/day for LGS and DS and 25 mg/kg/day for TSC.<sup>4,5</sup> Common adverse drug effects occurring in greater than 10% of trial participants included somnolence, fatigue, rash, decreased appetite, diarrhea, insomnia, infection, and elevated liver transaminases.<sup>6–9</sup>

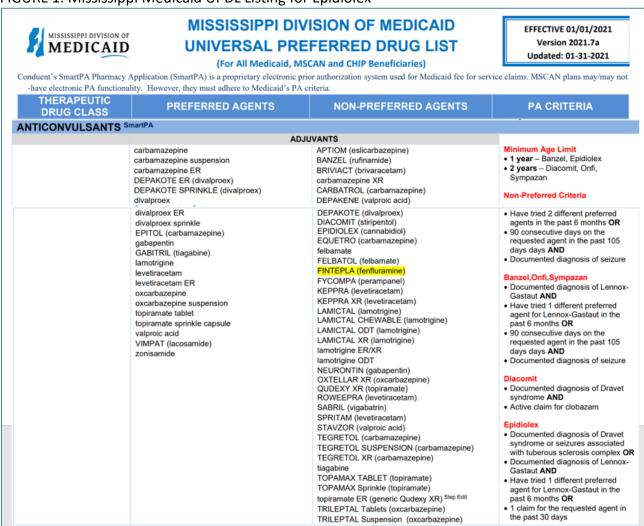
Epidiolex is considered an add-on therapy for treatment-resistant epilepsy, where patients are typically inadequately controlled on at least one antiepileptic drug (AED).<sup>4,5</sup> Valproate is commonly considered first-line treatment for LGS, with clonazepam, topiramate, lamotrigine, felbamate, clobazam, rufinamide, and Epidiolex considered adjunctive treatment options.<sup>10</sup> Clobazam and valproate are common first-line treatment options for DS, with stiripentol, topiramate, clonazepam, levetiracetam, zonisamide, ethosuximide, fenfluramine, and Epidiolex serving as second- and third-line treatment options.<sup>11</sup> There are many AEDs commonly used for the control of seizures associated with TSC and their use depends on several factors including seizure type, affected individual's age, other organ systems impacted, and symptom severity; however the only medications with FDA approved indications for the treatment of seizures associated with tuberous sclerosis are Epidiolex and Afinitor (everolimus).<sup>12,13</sup>

While Epidiolex is the only FDA-approved prescription CBD product, there are other cannabidiol containing products on the market, including hemp oil nationally and medical marijuana and CBD supplements in select states. In Mississippi, Initiative 65, a measure allowing qualified patients with debilitating medical conditions (including epilepsy and other seizures) to use medical marijuana, was passed by voters in November 2020. This amendment allows medical marijuana to

be provided only by licensed treatment centers.<sup>14</sup> Despite their availability, these other products are not federally regulated and either have mixed or are completely lacking efficacy and safety data in relation to seizures.<sup>15</sup>

Epidiolex is nonpreferred on the Universal Preferred Drug List (UPDL) with the following SmartPA requirements: minimum age limit of 1 year, diagnosis requirements, and prior anticonvulsant use requirements for those with a diagnosis of Lennox Gastaut. (Figure 1)

FIGURE 1: Mississippi Medicaid UPDL Listing for Epidiolex



Since its FDA approval in 2018, Epidiolex use has steadily risen in Mississippi Medicaid. MS-DUR conducted an analysis of Epidiolex utilization trends among Medicaid beneficiaries from June 2018 through December 2020.

#### **METHODS**

A retrospective analysis was conducted using Mississippi Medicaid fee-for-service (FFS) and coordinated care organization [CCOs: United Healthcare (UHC), Magnolia (MAG), and Molina (MOL)] claims for the period June 2018 to December 2020 to identify beneficiaries prescribed Epidiolex. Beneficiary age, race, sex, and health plan were identified according to the first claim of Epidiolex (index date) during the study period (Table 1). Target diagnoses were assessed in medical claims data during the period beginning January 2016 until the Epidiolex index date (Table 2). A beneficiary was considered to have a target diagnosis if medical claims data contained an ICD-code for any of the associated diagnoses during the measurement period. Quarterly trends in Epidiolex utilization by number of beneficiaries, pharmacy claims, and associated pharmacy costs were summarized (Tables 3-4, Figure 2). For each Epidiolex claim, characteristics of prescribing providers were also identified (Table 5). Quarterly dosing trends in Epidiolex utilization were evaluated and descriptive statistics were assessed during the study period (Figures 3a-e). Daily Epidiolex dose was calculated by taking the product of the submitted quantity on the claim (ml) and the strength of the product (100mg/ml) divided by the days supply submitted for that claim. Antiepileptic drug utilization in a 90-day period pre and post-Epidiolex utilization was assessed from pharmacy claims data (Tables 6-7). Trends in drug use were summarized by ranking utilization based on number of beneficiaries prescribed the drug and associated costs. Concurrent antiepileptic drug use was also summarized by number of distinct drugs and drug categories used in the pre and post-Epidiolex period.

#### **RESULTS**

In Table 1, beneficiary demographic characteristics are presented for those prescribed Epidiolex.

- 70.1% (115/164) of beneficiaries were < 18 years of age;
- 60.4% (99/164) were males;
- 52.4% (86/164) were Caucasian;
- 55% (91/164) were in FFS

Table 1. Demographic Characteristics of Beneficiaries Prescribed Epidiolex									
(June 2018* - December 2020)									
Variable	FFS UHC Magnolia Molin					lina	Total		
Age Category (yrs)									
0 - 6	15	16.5%	13	43.3%	9	23.7%	1	20.0%	38
7 - 12	24	26.4%	1	3.3%	13	34.2%	1	20.0%	39
13 - 17	28	30.8%	6	20.0%	4	10.5%	0	0.0%	38
18 and above	24	26.4%	10	33.3%	12	31.6%	3	60.0%	49
Total	91		30		38		5		164
Gender									
Female	33	36.3%	12	40.0%	17	44.7%	3	60.0%	65
Male	58	63.7%	18	60.0%	21	55.3%	2	40.0%	99
Total	91		30		38		5		164
Race									
Caucasian	56	61.5%	8	26.7%	21	55.3%	1	20.0%	86
African American	23	25.3%	8	26.7%	9	23.7%	2	40.0%	42
Hispanic	2	2.2%	1	3.3%	0	0.0%	0	0.0%	3
Other	10	11.0%	13	43.3%	8	21.1%	2	40.0%	33
Total	91		30		38		5		164

<sup>\*</sup>Although the study period started from June 2018 when Epidiolex was approved, pharmacy claims were not seen until November 2018.

Table 2 examines target diagnoses associated with beneficiaries prescribed Epidiolex. Medical claims data was evaluated from January 2016 (> 2 years prior to the first Epidiolex claim) to identify target diagnoses. A beneficiary could have more than one target diagnosis present in claims data. Each target diagnosis identified in claims data was noted in Table 2.

- 22.6% (37/164) of beneficiaries did not have a target diagnosis present in claims data.
  - Dravet syndrome did not have a specific ICD-10 diagnosis code assigned until late
     2020. Other ICD-10 codes commonly utilized for Dravet syndrome (G40.40, G40.41)
     were also used in identifying beneficiaries with that diagnosis.
- 18.3% (30/164) of beneficiaries had dual target diagnoses present in claims data.

Table 2: Summary of Target Diagnoses for Beneficiaries  Prescribed Epidiolex							
Torget Diagnoses*	Beneficiari	es (N=164)					
Target Diagnoses*	n	%					
Lennox-Gastaut Syndrome	57	34.8%					
Dravet Syndrome	92	56.1%					
Tuberous Sclerosis Complex	8	4.9%					
No Associated Diagnoses	37	22.6%					

<sup>\*</sup>Target diagnoses were evaluated from January 2016 until Epidiolex index date.

NOTE: Numbers are not unique across diagnoses, same beneficiary may have multiple diagnoses

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

#### Additional information for Table 2:

A beneficiary was considered to have target diagnoses if they had any claim with ICD-10 code for the said diagnoses during the evaluation period. ICD-10 codes assessed were as follows:

Epilepsy: G40\*

Lennox-Gastatut Syndrome: G40.81\*

Dravet Syndrome: G40.83\*, G40.40\*, G40.41\* [ICD-10 code specific for Dravet Syndrome (G40.83\*) was not approved until late

2020. 92 benes having a diagnosis of Dravet syndrome is based on ICD-10 codes G40.40\* and G40.41\*.]

Tuberous Sclerosis Complex: Q85.1

Of the 164 benes initiating Epidiolex, 37 beneficiaries did not have associated diagnoses. Among the remaining 127 beneficiaries, 30 beneficiaries had dual diagnoses (28 for LGS and DS, 1 for LGS and TSC, and 1 for DS and TSC); therefore, 97/164 (59.1%) unique beneficiaries had a single diagnosis.

Tables 3a/b detail quarterly trends in Epidiolex utilization by number of claims and number of beneficiaries.

- There have been a total of 2,061 claims for Epidiolex with 55.7% (1,148) in FFS.
- The total number of quarterly claims/beneficiaries treated rose consistently through Q2/2020 after which the numbers leveled off.

Table 3a: Trends in Epidiolex Utilization by Pharmacy Claims (November 2018 - December 2020)								
		Pl	an					
Quarter	FFS	FFS UHC Magnolia Molina						
Q4 2018	8	1	2	0	11			
Q1 2019	68	3	25	0	96			
Q2 2019	106	16	40	7	169			
Q3 2019	128	35	55	11	229			
Q4 2019	147	47	57	8	259			
Q1 2020	167	59	64	12	302			
Q2 2020	189	68	71	6	334			
Q3 2020	165	78	73	9	325			
Q4 2020	170	73	78	15	336			
Total	1,148	380	465	68	2,061			

Table 3b. Trends in Epidiolex Utilization by Beneficiaries (November 2018 - December 2020)									
	Plan								
Quarter	FFS	UHC	Magnolia	Molina	Total				
Q4 2018	8	1	2	0	11				
Q1 2019	65	3	24	0	92				
Q2 2019	99	14	38	7	158				
Q3 2019	119	35	53	9	216				
Q4 2019	137	46	54	8	245				
Q1 2020	159	53	59	10	281				
Q2 2020	178	60	63	6	307				
Q3 2020	153	74	67	8	302				
Q4 2020	158	63	68	14	303				
Total*	1,076	349	428	62	1,915				
*Does not represent unique beneficiaries.									

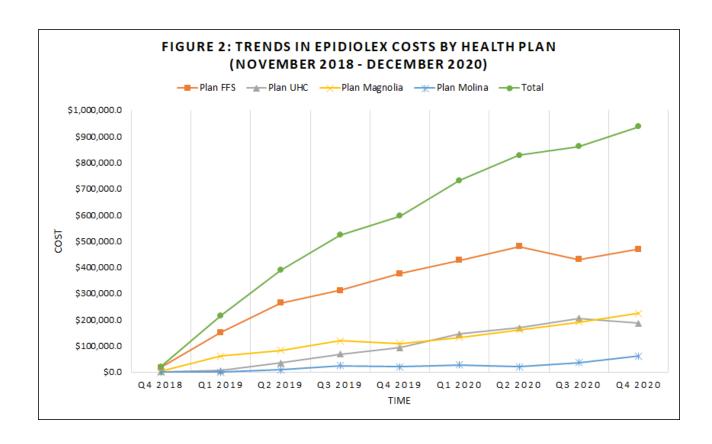
In Table 4/Figure 2, quarterly trends in costs associated with Epidiolex are shown.

- Total quarterly costs have consistently climbed every quarter although the number of beneficiaries treated quarterly leveled off in Q2/2020.
- The cost/beneficiary treated has risen from \$1,775/beneficiary in Q4/2018 to \$3,095/beneficiary Q4/2020.

Table 4. Trends in Epidiolex Costs by Beneficiaries (November 2018 - December 2020)										
	Total number		Pl	an			Costs per			
Quarter	of beneficiaries	FFS	UHC	Magnolia	Molina	Total	Beneficiary			
Q4 2018	11	\$16,213	\$1,320	\$1,986	\$0	\$19,520	\$1,775			
Q1 2019	92	\$150,528	\$5,181	\$60,115	\$0	\$215,824	\$2,346			
Q2 2019	158	\$263,917	\$34,277	\$82,346	\$8,159	\$388,699	\$2,460			
Q3 2019	216	\$311,547	\$67,862	\$118,869	\$24,778	\$523,056	\$2,422			
Q4 2019	245	\$376,104	\$92,716	\$108,226	\$19,045	\$596,091	\$2,433			
Q1 2020	281	\$426,605	\$145,841	\$132,347	\$26,440	\$731,232	\$2,602			
Q2 2020	307	\$478,606	\$169,087	\$161,386	\$19,083	\$828,162	\$2,698			
Q3 2020	302	\$429,005	\$205,261	\$191,057	\$36,020	\$861,343	\$2,852			
Q4 2020	303	\$468,530	\$185,986	\$223,353	\$60,036	\$937,904	\$3,095			
Total*	1,915	\$2,921,055	\$907,531	\$1,079,685	\$193,561	\$5,101,832				

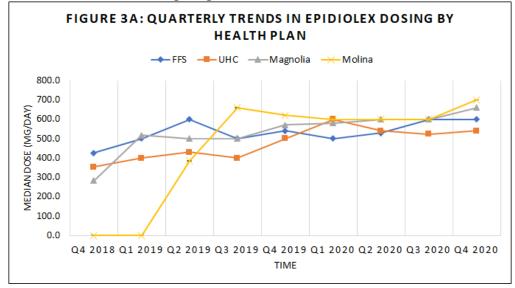
\*Does not represent unique beneficiaries.

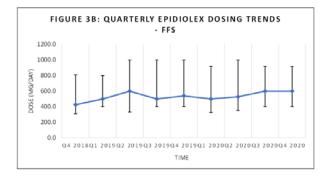
NOTE: This table is based on Table 3b in terms of Epidiolex utilization trends by beneficiaries.

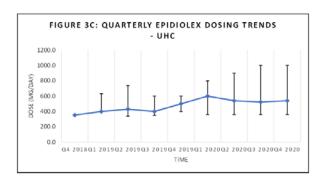


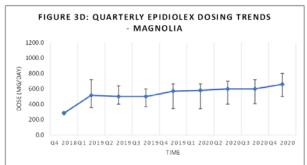
With the number of beneficiaries being treated leveling off in Q2/2020 yet the total costs and costs/beneficiary continuing to rise, MS-DUR assessed Epidiolex dosing trends. Figure 3a details quarterly dosing trends. Figures 3b-e show trends for each plan. Median daily dose point estimates and interquartile ranges are displayed for each quarter.

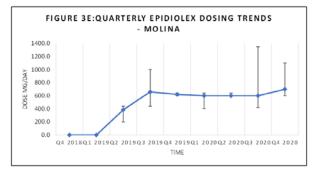
- Generally speaking, median daily dose has steadily risen across all plans with a few peaks occurring throughout the analysis period.
- When examining interquartile ranges, Magnolia and UHC appear to have had the largest consistent increases in dosing ranges.











Upon examining provider characteristics, neurologists and pediatricians made up the majority of prescribers associated with Epidiolex claims. (Table 5)

Table 5: Characteristics of Providers Prescribing Epidiolex (November 2018 - December 2020) (N=164)								
Provider type	Number of claims	Number of benes*						
MD-Neurology	876	77						
MD-Pediatrics	879	75						
NP-FM	78	15						
Prov-Other	83	9						
NP - Other	29	5						
MD-Sleep	5	1						
Missing	111	14						
Total								

<sup>\*</sup>Beneficiary numbers are not additive as one beneficiary can see multiple providers.

Tables 6a/b describe antiepileptic medication utilization during the 90-day period prior to and immediately following Epidiolex initiation.

- Spending on antiepileptic medications, excluding Epidiolex, in beneficiaries prescribed Epidiolex decreased from \$1,214,165 prior to initiating Epidiolex to \$1,061,593 after initiating Epidiolex. This is a decrease of \$152,572.
- The additional spending accounted for by Epidiolex was \$993,157

Table 6a: Pre-Epidiolex		tiepileptic Drugs Am nber 2018 - Decembe	•	escribed Epidio	lex between	Table 6b: Concur		nds of Antiepileptic E en November 2018 -		ciaries Prescribe	ed Epi
Drug name	Number of claims	Number of benes*	Total amount paid	Rank based on amount paid	Rank based on # of benes	Drug name	Number of claims	Number of benes*	Total amount paid	Rank based on amount paid	Ran #
/igabatrin	35	11	\$448,944	1	16	Cannabidiol	533	164	\$993,157	1	
lobazam	191	67	\$265,718	2	1	Vigabatrin	26	10	\$338,594	2	
ufinamide	83	30	\$203,345	3	7	Rufinamide	81	30	\$214,468	3	
acosamide	146	47	\$127,472	4	5	Clobazam	161	64	\$197,506	4	
erampanel	50	18	\$49,807	5	12	Lacosamide	149	48	\$139,782	5	
iazepam	112	48	\$28,760	6	4	Perampanel	47	19	\$52,508	6	
elbamate	25	9	\$20,142	7	17	Diazepam	98	40	\$28,014	7	
rivaracetam	15	7	\$17,235	8	18	Brivaracetam	19	8	\$23,593	8	
Slicarbazepine	10	4	\$10,245	9	19	Felbamate	25	9	\$16,210	9	
)xcarbazepine	41	14	\$6,779	10	14	Oxcarbazepine	38	13	\$7,466	10	
evetiracetam	132	51	\$5,818	11	2	Midazolam	7	4	\$5,931	11	
opiramate	49	21	\$4,957	12	10	Topiramate	49	19	\$5,681	12	
amotrigine	77	22	\$4,420	13	9	Eslicarbazepine	6	2	\$5,506	13	
Divalproex Sodium	67	24	\$3,869	14	8	Pregabalin	8	2	\$4,753	14	
onisamide	143	41	\$3,046	15	6	Lamotrigine	68	21	\$4,067	15	
Clonazepam	107	50	\$2,929	16	3	Levetiracetam	124	43	\$4,047	16	
henobarbital	54	20	\$2,875	17	11	Divalproex Sodium	62	24	\$3,404	17	
⁄Iidazolam	4	3	\$2,685	18	20	Phenobarbital	58	18	\$2,742	18	
regabalin	5	2	\$2,670	19	22	Clonazepam	83	39	\$2,361	19	
/alproic Acid	42	18	\$1,017	20	12	Zonisamide	113	35	\$2,293	20	
Lorazepam	30	14	\$434	21	14	Valproic Acid	54	20	\$1,416	21	
Gabapentin	9	3	\$382	22	20	Gabapentin	9	3	\$366	22	
cetazolamide	5	2	\$377	23	22	Lorazepam	31	10	\$334	23	
rimidone	5	2	\$128	24	22	Acetazolamide	4	2	\$278	24	
henytoin	4	2	\$109	25	22	Phenytoin	5	2	\$133	25	
nly 158/164 (96.3%) benefic	ciaries had information on	pre-Epidiolex pharmac	y utilization in the pri	or 90-day period.		Ethosuximide	1	1	\$93	26	
eneficiary numbers are not o	cumulative.					Primidone	2	1	\$47	27	
						*beneficiary numbers a	re not cumulative	<u> </u>			

NOTE for Tables 6a and 6ab: Drug utilization trends were assessed in a 90-day period prior to and following Epidiolev initiation. Benzodiazepines included in this evaluation are based on current MS-UPDL v2021.7a (diazepman, clobazam, and midazolam) or if they were classified under 'anticovulsants-benzodiazepine convulsants' in the main NDC file (lorazepam, diazepam, and clonazepam).

Normalian of division	Pre-Ep	oidiolex	Post-Epidiolex*		
Number of drugs	# of benes	%	# of benes	%	
1 - 2	41	25.9%	55	34.6%	
3 - 4	87	55.1%	85	53.5%	
5 or more	30	19.0%	19	11.9%	
Total	159		150		

Number of distinct drug	Pre-Ep	oidiolex	Post-Epidiolex*			
categories	# of benes	%	# of benes	%		
1 - 2	55	34.8%	65	40.9%		
3 - 4	86	54.4%	80	50.3%		
5 or more	17	10.8%	14	8.8%		
Total	158		159			

NOTE: Drug utilization trends were assessed in a 90-day period pre- and post-Epidiolex initiation. Only 158/164 (96.3%) beneficiaries had information on pre-Epidiolex pharmacy utilization.

\*For evaluation of concurrent medication usage following Epidiolex initiation, Epidiolex was excluded in the assessment of number of drugs. In post-Epidiolex column, 5/164 beneficiaries were only on Epidiolex, and thus, excluded giving a total of 159.

Table 7 shows a summary of the number of concurrent medications prescribed pre- and post-Epidiolex initiation.

• Compared to pre-Epidiolex figures, the number of beneficiaries receiving 1-2 additional medications increased while the number of beneficiaries taking 5 or more additional medications decreased during post-Epidiolex initiation.

#### CONCLUSIONS

Epidiolex is the first cannabidiol (CBD) prescription medication approved for use by the FDA as add-on therapy for certain types of treatment-resistant epilepsy. Since its introduction in 2018, utilization of Epidiolex in Mississippi Medicaid 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. Increased costs could be associated with an increase in dosage ranges prescribed for beneficiaries.

#### **RECOMMENDATION**

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.

#### REFERENCES

- 1. FDA Approves First Drug Comprised of an Active Ingredient Derived from Marijuana to Treat Rare, Severe Forms of Epilepsy. FDA. Published March 27, 2020. Accessed February 16, 2021. https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms
- 2. Sekar K, Pack A. Epidiolex as adjunct therapy for treatment of refractory epilepsy: a comprehensive review with a focus on adverse effects. *F1000Research*. 2019;8:234. doi:10.12688/f1000research.16515.1
- 3. O'Connell BK, Gloss D, Devinsky O. Cannabinoids in treatment-resistant epilepsy: A review. *Epilepsy Behav*. 2017;70:341-348. doi:10.1016/j.yebeh.2016.11.012
- 4. Epidiolex Drug Result Page MICROMEDEX. Accessed February 16, 2021. https://www.micromedexsolutions.com/micromedex2/librarian/CS/9FF940/ND\_PR/evidencexpert/ND\_P/evidencexpert/DUPLICATIONSHIELDSYNC/ED249C/ND\_PG/evidencexpert/ND\_B /evidencexpert/ND\_AppProduct/evidencexpert/ND\_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=932495&contentSetId=100&title=Cannabidiol&servicesTitle=Cannabidiol&brandName=Epidiolex#
- 5. Epidiolex Prescribing Information; Carlsbad, CA: Greenwich Biosciences Inc; October 2020. Accessed February 16, 2021. https://www.epidiolex.com/sites/default/files/pdfs/1120/EPX-03645-1120 EPIDIOLEX (cannabidiol) USPI.pdf
- 6. Thiele E, Marsh E, Mazurkiewicz-Beldzinska M, et al. Cannabidiol in patients with Lennox-Gastaut syndrome: Interim analysis of an open-label extension study. *Epilepsia*. 2019;60(3):419-428. doi:10.1111/epi.14670
- 7. Devinsky O, Patel AD, Cross JH, et al. Effect of Cannabidiol on Drop Seizures in the Lennox–Gastaut Syndrome. *N Engl J Med*. Published online May 16, 2018. doi:10.1056/NEJMoa1714631
- 8. Devinsky O, Cross JH, Laux L, et al. Trial of Cannabidiol for Drug-Resistant Seizures in the Dravet Syndrome. http://dx.doi.org/10.1056/NEJMoa1611618. doi:10.1056/NEJMoa1611618
- 9. Thiele EA, Bebin EM, Bhathal H, et al. Add-On Cannabidiol Treatment for Drug-Resistant Seizures in Tuberous Sclerosis Complex: A Placebo-Controlled Randomized Clinical Trial. *JAMA Neurol*. Published online December 21, 2020. doi:10.1001/jamaneurol.2020.4607
- 10. Lennox-Gastaut Syndrome Information Page | National Institute of Neurological Disorders and Stroke. Accessed February 16, 2021. https://www.ninds.nih.gov/Disorders/All-Disorders/Lennox-Gastaut-Syndrome-Information-Page

- 11. Wirrell EC, Laux L, Donner E, et al. Optimizing the Diagnosis and Management of Dravet Syndrome: Recommendations From a North American Consensus Panel. *Pediatr Neurol*. 2017;68:18-34.e3. doi:10.1016/j.pediatrneurol.2017.01.025
- 12. Tuberous sclerosis complex Highlights & Basics. Accessed February 16, 2021. https://online.epocrates.com/diseases/67311/Tuberous-sclerosis-complex/Key-Highlights
- 13. Tuberous sclerosis complex: Management and prognosis UpToDate. Accessed February 17, 2021. https://www.uptodate.com/contents/tuberous-sclerosis-complex-management-and-prognosis?search=tuberous%20sclerosis%20treatment&source=search\_result&selectedTitle= 1~109&usage\_type=default&display\_rank=1
- 14. Initiative Measure #65. Accessed February 19, 2021. https://www.sos.ms.gov/Elections-Voting/Pages/Initiative-Measure-65.aspx
- 15. Abu-Sawwa R, Stehling C. Epidiolex (Cannabidiol) Primer: Frequently Asked Questions for Patients and Caregivers. *J Pediatr Pharmacol Ther*. 2020;25(1):75-77. doi:10.5863/1551-6776-25.1.75

# **RECOMBINANT HUMAN GROWTH HORMONE UTILIZATION**

#### **BACKGROUND**

Recombinant human growth hormone (somatropin) is a protein designed to mimic naturally occurring growth hormone. Somatropin promotes tissue and linear growth along with stimulating the metabolism of carbohydrates, lipids, and minerals. Somatropin is a subcutaneous injection routinely administered daily. It is most commonly used to treat short stature due to growth hormone deficiency, Turner syndrome, Noonan syndrome, Prader-Willi syndrome, short stature homeobox-containing gene (SHOX) deficiency, chronic renal insufficiency, idiopathic short stature and children small for gestational age.<sup>1,2</sup>

The Division of Medicaid's Universal Preferred Drug List coverage for growth hormone is provided in Figure 1. Current Smart PA guidelines require diagnosis criteria for individuals  $\geq$  18 years.

Figure 1: Universal Preferred Drug List (01/01 2021)<sup>3</sup>

THERAPEUTIC DRUG CLASS	PREFERRED AGENTS	NON-PREFERRED AGENTS	PA CRITERIA
<b>GROWTH HORMONE</b>	SmartPA		
	NORDITROPIN (somatropin) NUTROPIN AQ (somatropin)	GENOTROPIN (somatropin) HUMATROPE (somatropin) OMNITROPE (somatropin) SAIZEN (somatropin) SEROSTIM (somatropin) ZOMACTON (somatropin) ZORBTIVE (somatropin)	All Agents for Age ≥ 18 years  • Documented diagnosis of craniopharyngioma, panhypopitultarism, Prader-Willi Syndrome, Turner Syndrome or an approvable indication OR  • Documented procedure of cranial irradiation  Non-Preferred Criteria  • Have tried 1 preferred agent in the past 6 months OR  • 84 consecutive days on the requested agent in the past 105 days

MS-DUR conducted a class review of growth hormone utilization within the Division of Medicaid to assess prescribing trends, associated diagnoses, and provider characteristics.

#### **METHODS**

A retrospective analysis of Medicaid point of sale (POS) pharmacy claims and medical claims data from fee-for-service (FFS) and the three coordinated care organizations (CCOs) was conducted for the measurement period January 1, 2018 − December 31, 2020. Beneficiaries were included in the analysis if they had at least one fill for any growth hormone agent during the study period. The date of the first prescription was identified as the index date. Medicaid's SmartPA criteria for growth hormones was used as a guide for this analysis. Beneficiaries were categorized by age as being either ≤ 17 years or 18+ years based on the SmartPA criteria. Beneficiaries were assigned to the respective age group and plan they were enrolled in as of the index date. The period from January 2017 - December 2020 was used to identify relevant diagnoses for beneficiaries. Current SmartPA guidelines do not require a diagnosis check for beneficiaries less than 18 years.

#### RESULTS

Table 1 provides demographic characteristics for beneficiaries prescribed growth hormone agents January 2018 - December 2020.

- 340 total beneficiaries were prescribed growth hormone agents during that period.
- 97.6% (332/340) were < 17 years.
- 62.4% (212/340) were male.
- 55.6% (189/340) were Caucasian.

Table 1: Demographics of Beneficiaries Prescribed Growth Hormone Agents in Mississippi Medicaid

January 2018 - December 2020

	,				
Characteristic	Number	Total			
Characteristic	FFS	UHC	Mag	Mol	Total
Age Group					
≤17 years	103	112	113	4	332
18+ years	4	2	2	0	8
Gender					
Female	38	39	49	2	128
Male	69	75	66	2	212
Race					
African American	24	37	35	0	96
Caucasian	62	62	61	4	189
Other	21	15	19	0	55
Total	107	114	115	4	340

Note: Beneficiaries were included in the analysis if they had at least one fill for any growth hormone agent in January 2018 - December 2020. The date of the first prescription was identified as the index date. Beneficiaries were assigned to the respective age group and plan they were enrolled in as of the index date.

Table 2 displays a monthly trend analysis of number of prescription claims and costs associated with growth hormone utilization.

- Average monthly costs and average monthly number of claims by Year:
  - 0 2018 \$651,385 / 154
  - o 2019 \$517,635 / 127
  - 0 2020 \$538,166 / 131
- Comparing 2018 figures to 2020:
  - o The average total monthly spend decreased by 17.4% in 2020.
  - o The average monthly number of claims decreased by 14.9% in 2020.

						January	2018 - Dece	mber 2	020						
		FFS			UHC			Mag		Mol				Total	
Month and Year	# Rx		Cost	# Rx		Cost	# Rx		Cost	# Rx		Cost	# Rx		Cost
Jan-18	53	\$	262,338.74	63	\$	295,836.99	60	\$	235,062.39	0	\$	-	176	\$	793,238.13
Feb-18	52	\$	235,923.50	61	\$	283,987.52	57	\$	228,305.14	0	\$	-	170	\$	748,216.1
Mar-18	58	\$	242,240.02	57	\$	283,003.61	63	\$	238,526.76	0	\$	-	178	\$	763,770.3
Apr-18	59	\$	280,879.96	62	\$	293,963.71	70	\$	271,991.20	0	\$	-	191	\$	846,834.8
May-18	55	\$	235,568.31	66	\$	308,484.66	69	\$	256,490.79	0	\$	-	190	\$	800,543.7
Jun-18	35	\$	144,967.03	33	\$	140,743.44	48	\$	169,706.93	0	\$	-	116	\$	455,417.4
Jul-18	55	\$	237,471.43	56	\$	227,905.94	58	\$	216,852.12	0	\$	-	169	\$	682,229.4
Aug-18	45	\$	209,063.02	49	\$	215,254.58	55	\$	194,723.81	0	\$	-	149	\$	619,041.4
Sep-18	41	\$	191,009.67	47	\$	207,118.16	53	\$	193,919.58	0	\$	-	141	\$	592,047.4
Oct-18	30	\$	116,945.42	51	\$	232,560.80	56	\$	180,974.04	0	\$	-	137	\$	530,480.2
Nov-18	33	\$	155,971.67	44	\$	187,176.10	46	\$	173,672.98	1	\$	3,422.57	124	\$	520,243.3
Dec-18	33	\$	175,045.90	32	\$	137,828.34	42	\$	151,677.44	0	\$	-	107	\$	464,551.6
Jan-19	44	\$	187,411.31	46	\$	199,221.59	43	\$	167,272.75	1	\$	3,753.19	134	\$	557,658.8
Feb-19	44	\$	177,495.78	33	\$	153,615.66	40	\$	149,495.91	1	\$	7,495.09	118	\$	488,102.4
Mar-19	45	\$	172,096.78	40	\$	171,065.33	40	\$	134,025.28	3	\$	15,001.47	128	\$	492,188.8
Apr-19	46	\$	174,472.20	33	\$	150,118.27	51	\$	198,618.19	3	\$	18,743.37	133	\$	541,952.0
May-19	41	\$	160,177.37	35	\$	172,794.69	45	\$	166,525.03	1	\$	3,753.19	122	\$	503,250.2
Jun-19	33	\$	127,504.67	35	\$	148,443.63	40	\$	140,487.43	2	\$	14,990.18	110	\$	431,425.9
Jul-19	42	\$	168,991.60	37	\$	160,919.32	61	\$	231,997.24	5	\$	28,794.60	145	\$	590,702.7
Aug-19	32	\$	129,224.64	44	\$	188,432.00	48	\$	181,511.58	5	\$	26,923.65	129	\$	526,091.8
Sep-19	34	\$	149,125.52	27	\$	117,817.95	46	\$	174,535.69	4	\$	25,041.41	111	\$	466,520.5
Oct-19	42	\$	171,251.07	38	\$	150,896.93	65	\$	230,055.37	6	\$	38,834.54	151	\$	591,037.9
Nov-19	35	\$	159,114.15	35	\$	148,575.22	46	\$	171,559.85	3	\$	18,743.37	119	\$	497,992.5
Dec-19	38	\$	183,809.45	34	\$	126,585.62	50	\$	191,175.58	4	\$	23,120.21	126	\$	524,690.8
Jan-20	43	\$	185,464.18	43	\$	173,188.05	53	\$	211,226.60	3	\$	21,647.52	142	\$	591,526.3
Feb-20	46	\$	181,766.96	29	\$	120,321.86	46	\$	180,360.88	3	\$	18,034.77	124	\$	500,484.4
Mar-20	51	\$	223,508.38	40	\$	161,276.09	46	\$	206,642.11	0	\$	-	137	\$	591,426.5
Apr-20	50	\$	197,052.35	40	\$	158,449.74	46	\$	178,683.75	3	\$	16,251.88	139	\$	550,437.7
May-20	42	\$	174,661.41	34	\$	143,224.23	39	\$	159,895.28	2	\$	8,240.19	117	\$	486,021.1
Jun-20	43	\$	183,587.58	43	\$	179,950.38	51	\$	205,412.29	5	\$	25,058.76	142	\$	594,009.0
Jul-20	45	\$	194,659.14	33	\$	143,058.31	43	\$	170,628.73	4	\$	24,380.77	125	\$	532,726.9
Aug-20	48	\$	190,820.46	30	\$	127,545.38	51	\$	204,092.99	2	\$	8,357.39	131	\$	530,816.2
Sep-20	43	\$	170,902.75	36	\$	154,520.63	50	\$	196,032.69	3	\$	16,369.08	132	\$	537,825.1
Oct-20	47	\$	201,724.14	43	\$	176,931.97	45	\$	189,895.71	1	\$	8,011.69	136	\$	576,563.5
Nov-20	43	\$	179,012.11	40	\$	157,590.71	42	\$	154,934.31	4	\$	17,047.07	129	\$	508,584.2
Dec-20	34	S	128,469.97	39	S	152,384.42	41	S	163,995.26	5	S	12,725.87	119	\$	457,575.5

Diagnoses associated with the use of growth hormone agents are detailed in Table 3:

- By far the most common associated diagnoses present in claims data were growth hormone deficiency and short stature.
- Of the 332 beneficiaries ≤ 17 years of age prescribed growth hormones, only 3.3% (11) did not have an associated diagnosis present in medical claims data.

Table 3: Diagnoses Associated with Growth Hormone Agent Use in Mississippi Medicaid January 2018 - December 2020										
Number of beneficiaries by Age group and Plan at index fill										
Diagnosis		≤17	years		18+ years					
	FFS	UHC	Mag	Mol	FFS	UHC	Mag	Mol		
Growth hormone deficiency	75	83	83	3	3	2	1	0		
latrogenic growth hormone deficiency	0	0	0	0	0	0	1	0		
Small for gestational age at birth	4	10	4	0	0	0	0	0		
Growth failure associated with renal insufficiency or	_	_	1	_	_	_	0	_		
chronic kidney disease	0	0	1	0	0	0	U	0		
Turner syndrome	8	9	13	1	0	0	0	0		
Prader-Willi syndrome	5	4	2	0	1	1	0	0		
Noonan syndrome	3	4	6	0	0	0	0	0		
Short-stature homeobox gene deficiency	13	16	14	0	0	1	0	0		
Blind loop syndrome	0	0	0	0	0	0	0	0		
Short bowel syndrome	4	1	2	0	0	0	0	0		
HIV-associated cachexia (or wasting)	1	0	1	0	0	0	0	0		
Short stature (child)	67	95	96	3	1	0	0	0		
No associated diagnoses	10	0	1	0	1	0	1	0		

Note: Beneficiaries were included in the analysis if they had at least one fill for any growth hormone agent in January 2018 - December 2020. The date of the first prescription was identified as the index date. Beneficiaries were assigned to the respective age group and plan they were enrolled in as of the index date. The period from January 2017 - December 2020 was used to identify relevant diagnoses for beneficiaries (please see below for list of ICD-10 codes included).

Beneficiaries may have had more than one diagnosis.

Growth hormone deficiency - E23.0

latrogenic growth hormone deficiency - E23.1, E89.3

Small for gestational age at birth - P05.1

Growth failure associated with renal insufficiency or chronic kidney disease - N25.0

Turner syndrome - Q96

Prader-Willi syndrome - Q87.11

Noonan syndrome - Q87.19

Short-stature homeobox gene deficiency - E34.3

Blind loop syndrome - K90.2

Short bowel syndrome - K91.2

HIV-associated cachexia (or wasting) - R64

Short stature (child) - R62.52

From Table 4 it can be determined that pediatric endocrinologists and pediatricians are responsible for the overwhelming majority of growth hormone prescriptions.

Table 4: Prescribers of Growth Hormone Agents in Mississippi Medicaid  January 2018 - December 2020																
	Prescriptions and beneficiaries by age group and plan at fill															
Smartaless	≤17 years 18+ years															
Specialty	FFS		UHC		Mag		Mol		FFS		UHC		Mag		Mol	
	Rx	Bene	Rx	Bene	Rx	Bene	Rx	Bene	Rx	Bene	Rx	Bene	Rx	Bene	Rx	Bene
Specialty not specified	54	8	83	9	11	4	14	2	0	0	0	0	0	0	0	0
Endocrinology, Diabetes & Metabolism	50	5	0	0	0	0	0	0	21	3	8	1	0	0	0	0
Pediatric Endocrinology	997	93	1223	98	1379	97	18	5	3	1	2	1	0	0	0	0
Family Medicine	23	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Internal Medicine	0	0	0	0	0	0	0	0	4	1	0	0	0	0	0	0
Pediatric Nephrology	3	2	9	2	49	4	0	0	0	0	0	0	0	0	0	0
Pediatrics - MD	396	37	171	26	312	31	42	6	0	0	4	1	0	0	0	0
Pediatrics - NP	1	1	4	1	1	1	0	0	0	0	0	0	0	0	0	0
Provider - Other	2	1	2	1	65	3	0	0	0	0	0	0	17	2	0	0
Total	1526	149	1492	137	1817	140	74	13	28	5	14	3	17	2	0	0
ote: All claims related to growth hormone agents and their respective prescribers were identified between January 2018 - December 2020. Plan at fill was identified for each prescription as of the fill date.																

#### **CONCLUSIONS**

Although a small number of beneficiaries receive treatment with growth hormone agents, this group of medications contributes to a significant amount of monthly spend. After conducting an analysis of utilization, 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.

#### RECOMMENDATIONS

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

#### REFERENCES

- 1. Research C for DE and. Somatropin Information. *FDA*. Published online November 3, 2018. Accessed January 21, 2021. https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/somatropin-information
- 2. Genotropin, Humatrope (somatropin) dosing, indications, interactions, adverse effects, and more. Accessed January 21, 2021. https://reference.medscape.com/drug/genotropin-somatropin-342860
- 3. Universal Preferred Drug List | Mississippi Division of Medicaid. Accessed January 21, 2021. https://medicaid.ms.gov/providers/pharmacy/preferred-drug-list/

# FDA DRUG SAFETY COMMUNICATIONS

# **December 2020 – February 2021**

• 2/4/2021 Initial safety trial results find increased risk of serious heart-related problems and cancer with arthritis and ulcerative colitis medicine Xeljanz, Xeljanz XR (tofacitinib)

# **APPENDIX**



# Division of Medicaid Drug Utilization Review Board By-Laws

# Article I. Purpose

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

# Article II. Membership

# Section 1 - Board Composition

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

# Section 2 - Appointment selection methodology

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

#### Section 3 - Term of Office

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

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

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

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

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

## **Section 6 - Removal**

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

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

DUR Bylaws V2= updated 12/06/2018

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

#### Section 7 - Board Officers

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

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

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

## **Section 8 - Reimbursement**

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

# Article III. Meetings

# Section 1 – Frequency

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

# **Section 2 - Regular Meetings**

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

## **Section 3 – Special Meetings**

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

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

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

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

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

DUR Bylaws V2= updated 12/06/2018

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

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

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

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

#### Section 6 - Quorum

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

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

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

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

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

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

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

#### Section 8 – Minutes

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

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

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

## Section 9 - Speakers & Special Topics

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

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

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

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

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

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

## **Section 11 - Conduct of Participants**

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

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

# Article IV. Public Participation

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

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

### Article V. Conflicts of Interest

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

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

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

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

# Article VI. Confidentiality

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

#### Article VII. Amendments

# **Proposed Amendments of By-Laws**

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

# MS-DUR BOARD COMMON ABBREVIATIONS

	1
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
СОВ	Coordination of Benefits
CPC	Complex Pharmaceutical Care
DME	Durable Medical Equipment
DOC	Department of Corrections
DOM	Division of Medicaid
DUR	Drug Utilization Review
EOB	Explanation of Benefits
EPSDT	Early and Periodic Screening,
	Diagnosis and Treatment
FA	Fiscal Agent
FFS	Fee For Service
FPW	Family Planning Waiver
FQHC	Federally Qualified Health Clinic
FY	Fiscal Year
НВ	House Bill
HCPCS/	Health Plan Employer Data and
HEIDIS	Information Set
HHS	Department of Health and Human
	Services
HIPAA	Health Insurance Portability and
	Accountability
IDD	Intellectual and Developmental
	Disabilities
LTC	Long Term Care
MAG	Magnolia Health
MEDD	Morphine Equivalent Daily Dose
MOL	Molina Healthcare
MPR	Medication Possession Ratio
MSCAN	Mississippi Coordinated Access
	Network
MSDH	Mississippi State Department of
	Health
NADAC	National Average Drug Acquisition
	Cost

NDC	National Drug Code
P&T	Pharmacy and Therapeutics
PA	Prior Authorization
PBM	Pharmacy Benefit Manager
PDC	Proportion of Days Covered
PDC	•
	Preferred Drug List
PI	Program Integrity
PIP	Performance Improvement
	Program
POS	Point of Sale, Place of Service,
	Point of Service
Pro-DUR	Prospective Drug Use Review
OTC	Over the Counter
QI	Quality Indicator
QIO	Quality Improvement Organization
QM	Quality Management
RA	Remittance Advise
REOMB	Recipient's Explanation of Medicaid
	Benefits
Retro-	Retrospective Drug Utilization
DUR	Review
RFI	Request for Information
RFP	Request for Proposal
RHC	Rural Health Clinic
SB	Senate Bill
SCHIP	State Child Health Insurance
	Program
SMART	Conduent's Pharmacy Application
PA	(SmartPA) is a proprietary
	electronic prior authorization
	system used for Medicaid fee for
	service claims
SPA	State Plan Amendment
UHC	United Healthcare
UM/QIO	Utilization Management and
	Quality Improvement Organization
UPDL	Universal Preferred Drug List
UR	Utilization Review
VFC	Vaccines for Children
WAC	Wholesale Acquisition Cost
WIC	Women, Infants, Children
340B	Federal Drug Discount Program
3400	I reactal blug biscoullt Plogram