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

MISSISSIPPI DIVISION OF
MEDICAID

May 31, 2018 at 2:00pm

Woolfolk Building, Room 145

Jackson, MS

Prepared by:

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

Drug Utilization Review Board

Rhonda Dunaway, RPh
Coastal Family Health Center
9113 Hwy 49 Suite 200
Gulfport 39503
Term Expires: June 30, 2020

Juanice Glaze, RPh
Wal-Mart Pharmacy
5901 U.S. Highway 49
Hattiesburg, MS 39402
Term Expires: June 30, 2019

Alice F. Messer, FNP-BC
Newsouth Neurospine
2470 Flowood Drive
Flowood, MS 39232
Term Expires: June 30, 2019

Ray Montalvo, MD
KDMC Specialty Clinic
940 Brookway Boulevard
Brookhaven, MS 39601
Term Expires: June 30, 2020

Holly R. Moore, PharmD
Anderson Regional Medical Center
2124 14th Street
Meridian, MS 39301
Term Expires: June 30, 2020

Janet Ricks, DO
UMMC, Family Medicine
2500 North State Street
Jackson, MS 39216
Term Expires: June 30, 2018

Sue H. Simmons, MD
Maben Medical Clinic
49 Turner St.
Maben, MS 39750
Term Expires: June 30, 2018

Dennis Smith, RPh
Polk's Discount Drugs
1031 Star Rd
Brandon, MS 39042
Term Expires: June 30, 2020

James Taylor, PharmD **(Chair)**
North MS Medical Center
830 S. Gloster Street
Tupelo, MS 38801
Term Expires: June 30, 2019

Pearl Wales, PharmD
Be Jay PE Pharmacy 1668
West Peace Street
Canton, MS 39047
Term Expires: June 30, 2018

2018 DUR Board Meeting Dates

March 1, 2018
May 31, 2018
September 13, 2018
December 6, 2018

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
May 31, 2018

Welcome — James Taylor, PharmD (Chair)

Old Business — James Taylor, PharmD
- Approval of March 2018 Meeting Minutes — page 5

Resource Utilization Review

Pharmacy Program Update — Terri Kirby, RPh; Sara (Cindy) Noble, PharmD, MPH

Feedback and Discussion from the Board

New Business

Next Meeting Information — James Taylor, PharmD

DUR Board Meeting Minutes

MISSISSIPPI DIVISION OF MEDICAID
DRUG UTILIZATION REVIEW (DUR) BOARD
MINUTES OF THE MARCH 1, 2018 MEETING

ATTENDANCE SFY2018

DUR Board Members:	July 2017	Nov 2017	Mar 2018
Allison Bell, PharmD	✓	✓	NA
Rhonda Dunaway, RPh		✓	✓
Craig Escudé, MD (Chair)	✓		✓
Juanice Glaze, RPh		✓	✓
Alice Messer, DNP, FNP-BC	✓	✓	✓
Ray Montalvo, MD	NA	✓	✓
Holly Moore, PharmD	NA		✓
Janet Ricks, DO		✓	✓
Sue Simmons, MD		✓	
Dennis Smith, RPh	NA		✓
James Taylor, PharmD (Co-Chair)		✓	✓
Pearl Wales, PharmD	✓	✓	
TOTAL PRESENT	**4***	**9**	**9****

**Only 8 members were active due to new appointments to DUR Board not being approved by Governor prior to meeting.*
*** Only 11 members were active due to resignation resulting from move and replacement not yet approved by Governor.*

Also Present:

Division of Medicaid (DOM) Staff:
Terri Kirby, RPh, CPM, Pharmacy Director; Cindy Noble, PharmD, MPH, DUR Coordinator; Gail McCorkle, RPh, Clinical Pharmacist; Chris Yount, MA, PMP, Staff Officer – Pharmacy; Dorthy Young, PhD, Deputy Director of Health Services; Tami Brooks, MD, Medical Director; Mark Leiker, MA, Office Director of Mental Health; Brenda Allred, RN, Clinical Support Services; Shereen Wilson, RN, Clinical Support Services; Elizabeth Hargrove, University of Mississippi Pharmacy Intern

University of Mississippi School of Pharmacy - MS-DUR Staff:
Ben Banahan, PhD, MS-DUR Project Director; Eric Pittman, PharmD, MS-DUR Clinical Director; Manasi Suryavanshi, MS, MS-DUR Analyst

Conduent Staff:
Leslie Leon, PharmD, Clinical Pharmacist, Mississippi Medicaid Project

Change Healthcare Staff:
Shannon Hardwick, RPh, CPC Pharmacist; Cheryl Rogers, PharmD, Mississippi PA Pharmacist

Coordinated Care Organizations:
Heather Odem, PharmD, United Healthcare Community & State, Director of Pharmacy- Mississippi; Conor Smith, MS, RPh, Director of Pharmacy, Magnolia Health; Mike Todaro, PharmD, Vice President, Pharmacy Operations, Magnolia Health

Visitors:
Phil Hecht, Abbvie; Wendy Phillabaum, Supernus; Tim Hambacher, Otsuka; Jason Swartz, Otsuka; Gene Wingo, Biogen; Bob Firnberg, Gilead

Call to Order:
Dr. Escudé, Chair, called the meeting to order at 2:00pm. Dr. Escudé informed the board that this would be his last meeting to attend since he is moving out of the state. His effective resignation as a DUR Board member is April 30th, 2018. Dr. Noble and the DUR Board members thanked Dr. Escudé for his service and wished him well in the future.

Old Business:
Mr. Smith moved to approve the minutes from the November 2017 DUR Board Meeting, seconded by Ms. Glaze and unanimously approved by the DUR Board.

Resource Utilization Review:
Dr. Pittman informed the board that encounter data for Magnolia was incomplete for November when the report was run. This should not impact any of the resource utilization ranks, but does impact dollar amounts paid, number of claims, and number of beneficiaries for the month of November. No utilization shifts for this time of year were noted in terms of top categories by volume or dollars.

Pharmacy Program Update:
Ms. Kirby informed the Board members of recent provider notices regarding Magnolia and United Healthcare pharmacy reimbursement issues that occurred with some claims related to the new NADAC methodology.

The most recent PDL changes approved in February 13th Pharmacy and Therapeutics meeting will go into effect April 1, 2018.

N**EW BUSINESS**

Feedback and Discussion from the Board
Dr. Noble pointed out that the topic regarding proton pump inhibitor prescribing and utilization previously brought up by Dr. Taylor was being addressed in today's meeting. Dr. Escude' expressed thanks to the Board for recently addressing the use of antipsychotics in beneficiaries with intellectual and developmental disabilities (IDD).

Update on MS-DUR Educational Interventions
Dr. Pittman reviewed a new report included in the DUR packet regarding educational intervention mailings conducted during the prior quarter. He noted that these interventions are related to previous board recommendations.

Research Reports:

Review of Pharmacy Quality Alliance (PQA) Recommendations for Diabetes Medication Dosing and Utilization in Mississippi Medicaid

Dr. Banahan provided an overview of the included report. MS-DUR recommended no changes at this time.

Review of Stimulants and Related Agents in Mississippi Medicaid

Dr. Banahan provided an overview of the stimulant/non-stimulant analysis conducted by MS-DUR. After a thorough discussion, the following recommendations were made by the DUR Board:

1. DOM should check for ADD/ADHD or other compendia recognized conditions for children, adolescents, and adults who are prescribed stimulants to assure appropriate use and assure adequate monitoring of beneficiaries taking stimulants.
    a. The electronic PA process will allow the system to check for the ICD-10 diagnosis code and automatically adjudicate the stimulant prescription claim upon finding that diagnosis.
    b. The prescribing physician should be encouraged to write on the face of the prescription the appropriate diagnosis which the pharmacist can enter as part of claim for the prescription to be processed.
    c. If possible, a new start on stimulants for children should be allowed to go through on the first fill without a diagnosis with notification to provider that a diagnosis will be required for future fills.

Mr. Smith moved to approve recommendation number 1. The motion was seconded by Dr. Montalvo and approved unanimously.

2. MS-DUR should conduct an educational intervention about diagnoses requirements and encourage prescribers to write ICD-10 codes on prescriptions.

Mr. Smith moved to approve recommendation number 2, seconded by Dr. Moore and approved unanimously.

Proton Pump Inhibitor Use and Potential Deprescribing Opportunities in Mississippi Medicaid

Dr. Pittman provided an overview of the issue of potential overuse of proton pump inhibitors and the analyses conducted by MS-DUR. After a robust discussion, the following recommendations were proposed by the DUR Board:

1. DOM should set an electronic PA edit to limit the maximum days supply for PPI therapy to 90 days in a 12-month period before a PA is required.

Mr. Smith made a motion to accept recommendation number 1, seconded by Dr. Taylor and unanimously approved by the Board.

2. For therapy exceeding the 90 day limit, DOM should implement electronic or manual PA requirements for the maximum number of days supply based on diagnoses listed in Table 5 with addition of the condition of refractory GERD.

Ms. Dunaway made a motion to accept recommendation number 2, seconded by Dr. Montalvo and unanimously approved by the Board.

3. MS-DUR should implement an educational initiative notifying providers of the new PPI prescribing criteria and guidance on deprescribing. MS-DUR should consider educational mailings to beneficiaries, if feasible.

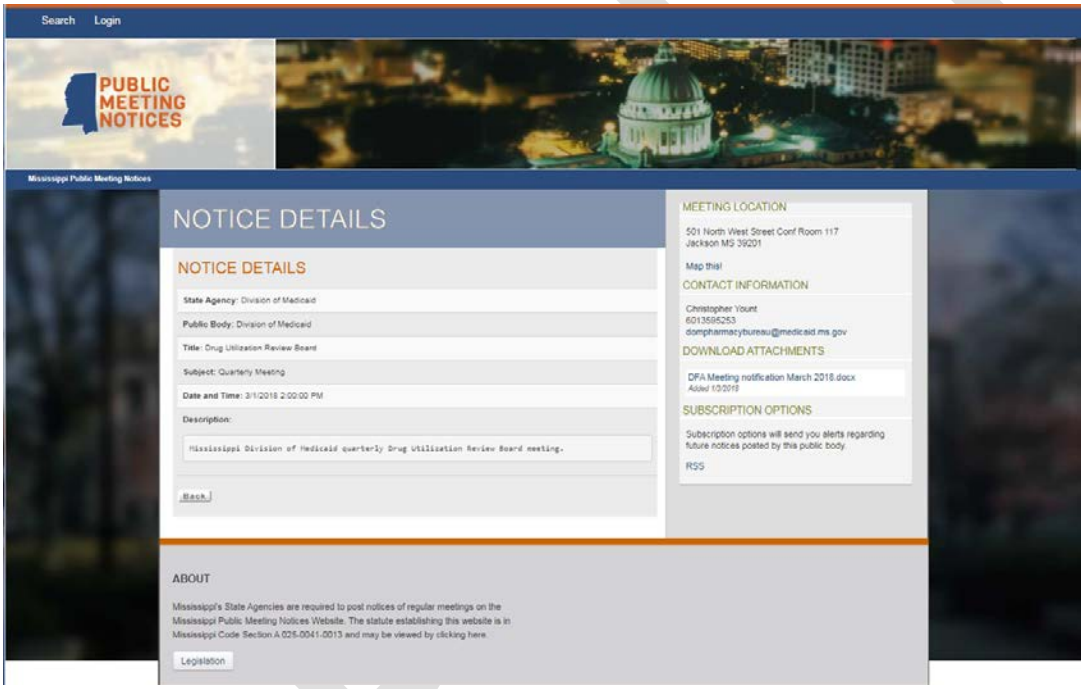
Dr. Messer made a motion to accept recommendation number 3, seconded by Mr. Smith and unanimously approved by the Board. Dr. Montalvo volunteered to help compile a list of alternative treatments and behavioral modifications.

FDA Drug Safety Updates
MS-DUR reviewed recent FDA drug safety communications with the Board.

Next Meeting Information:
Dr. Escudé announced that the next meeting of the DUR Board will take place on May 31, 2018 at 2:00 p.m. He thanked everyone for their attendance and participation at the March 1, 2018 DUR Board meeting.

The meeting adjourned at 3:43 pm.

Submitted,
Eric Pittman, PharmD, Evidence-Based DUR Initiative, MS-DUR
PUBLIC MEETING NOTICES



Meeting Location: Woolfolk Building, 501 North West Street, Conference Room 117 Jackson, MS 39201

Contact Information: Pharmacy Bureau:
Chris Yount, 601-359-5253: Christopher.yount@medicaid.ms.gov, or
Jessica Tyson, 601-359-5253; Jessica.Tyson@medicaid.ms.gov

Notice details:

State Agency: MS Division of Medicaid

Public Body: Drug Utilization Board (DUR) Meeting

Subject: Quarterly Meeting

Date and Time: March 1, 2018 at 2 PM

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.

Resource Utilizaton Review

TABLE 04A: ENROLLMENT STATISTICS FOR LAST 6 MONTHS
September 1, 2017 through February 28, 2018

			Sep-17	Oct-17	Nov-17	Dec-17	Jan-18	Feb-18
Total enrollment			738,793	737,218	735,654	728,707	724,595	718,850
Dual-eligibles			156,562	156,455	156,332	154,358	155,452	154,867
Pharmacy benefits			629,769	627,799	625,501	619,891	614,628	608,802
	LTC		17,271	17,269	17,244	17,112	17,078	16,816
	PLAN %	**FFS**	23.6%	23.5%	23.2%	23.3%	23.5%	23.8%
		MSCAN-UHC	37.0%	37.0%	37.1%	37.0%	36.5%	36.3%
		MSCAN-Magnolia	39.4%	39.5%	39.7%	39.7%	40.0%	39.9%

TABLE 04B: PHARMACY UTILIZATION STATISTICS FOR LAST 6 MONTHS
September 1, 2017 through February 28, 2018

		Sep-17	Oct-17	Nov-17	Dec-17	Jan-18	Feb-18
# Rx Fills	**FFS**	106,670	111,095	111,907	110,894	104,348	110,828
	MSCAN-UHC	188,225	197,946	202,665	197,297	201,300	193,574
	MSCAN-Mag	231,070	246,835	250,050	248,223	251,363	157,754
# Rx Fills / Bene	**FFS**	0.7	0.8	0.8	0.8	0.7	0.8
	MSCAN-UHC	0.8	0.9	0.9	0.9	0.9	0.9
	MSCAN-Mag	0.9	1.0	1.0	1.0	1.0	0.6
$ Paid Rx	**FFS**	$12,112,121	$12,473,500	$12,017,163	$12,131,722	$11,144,863	$12,133,937
	MSCAN-UHC	$14,440,161	$15,038,801	$15,621,211	$15,518,121	$16,590,353	$15,508,930
	MSCAN-Mag	$16,990,411	$18,020,869	$18,695,857	$18,645,433	$19,166,310	$12,521,002
$ /Rx Fill	**FFS**	$113.55	$112.28	$107.39	$109.40	$106.80	$109.48
	MSCAN-UHC	$76.72	$75.97	$77.08	$78.65	$82.42	$80.12
	MSCAN-Mag	$73.53	$73.01	$74.77	$75.12	$76.25	$79.37
$ /Bene	**FFS**	$81.49	$84.55	$82.81	$83.99	$77.16	$83.74
	MSCAN-UHC	$61.97	$64.74	$67.32	$67.66	$73.95	$70.18
	MSCAN-Mag	$68.47	$72.67	$75.29	$75.76	$77.96	$51.55

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 FEB 2018 (FFS AND CCOs)

Category	Month Year	Rank Volume	# RXs	$ Paid	# Unique Benes
CNS stimulants	Feb 2018	1	22,821	$4,912,870	20,053
	Jan 2018	1	26,750	$5,645,740	23,061
	Dec 2017	1	24,556	$5,408,912	21,359
aminopenicillins	Feb 2018	2	18,439	$233,406	18,161
	Jan 2018	3	19,386	$245,023	19,063
	Dec 2017	3	22,629	$291,281	22,198
neuraminidase inhibitors	Feb 2018	3	17,725	$2,466,531	17,639
	Jan 2018	2	24,477	$3,379,997	24,282
	Dec 2017	2	23,214	$3,413,293	23,085
narcotic analgesic combinations	Feb 2018	4	14,992	$532,505	13,881
	Jan 2018	4	19,171	$627,197	17,503
	Dec 2017	4	19,455	$644,092	17,853
macrolides	Feb 2018	5	14,976	$352,238	14,695
	Jan 2018	6	16,715	$378,947	16,316
	Dec 2017	5	18,500	$452,961	17,958
adrenergic bronchodilators	Feb 2018	6	13,986	$833,151	12,414
	Jan 2018	5	17,049	$1,001,325	15,038
	Dec 2017	6	18,183	$1,069,994	16,120
nonsteroidal anti-inflammatory agents	Feb 2018	7	13,291	$192,667	12,878
	Jan 2018	7	16,172	$230,773	15,457
	Dec 2017	8	16,204	$255,055	15,583
antihistamines	Feb 2018	8	13,022	$203,614	12,731
	Jan 2018	8	14,722	$231,945	14,220
	Dec 2017	9	15,112	$252,355	14,642
glucocorticoids	Feb 2018	9	13,020	$573,007	12,324
	Jan 2018	9	14,550	$703,916	13,719
	Dec 2017	7	16,336	$1,014,599	15,386
atypical antipsychotics	Feb 2018	10	9,647	$1,024,531	8,730
	Jan 2018	10	11,846	$1,221,880	10,467
	Dec 2017	10	11,668	$1,213,578	10,331

NOTE: Pharmacy encounter data for MMG is incomplete for the month of February. This should not affect ranks but may affect total amounts for paid, number of claims, and number of beneficiaries in February.

TABLE D: TOP 10 DRUG CATEGORIES BY DOLLARS PAID IN FEB 2018 (FFS AND CCOs)

Category	Month Year	Rank Paid Amt	# RXs	$ Paid	# Unique Benes
CNS stimulants	Feb 2018	1	22,821	$4,912,870	20,053
	Jan 2018	1	26,750	$5,645,740	23,061
	Dec 2017	1	24,556	$5,408,912	21,359
neuraminidase inhibitors	Feb 2018	2	17,725	$2,466,531	17,639
	Jan 2018	2	24,477	$3,379,997	24,282
	Dec 2017	2	23,214	$3,413,293	23,085
antiviral combinations	Feb 2018	3	658	$2,456,501	621
	Jan 2018	3	796	$2,796,295	727
	Dec 2017	4	760	$2,424,622	722
insulin	Feb 2018	4	3,805	$1,965,541	2,923
	Jan 2018	4	4,799	$2,485,576	3,589
	Dec 2017	3	4,760	$2,449,998	3,585
factor for bleeding disorders	Feb 2018	5	100	$1,875,447	83
	Jan 2018	5	92	$1,533,447	73
	Dec 2017	5	96	$2,273,824	77
antirheumatics	Feb 2018	6	716	$1,410,497	655
	Jan 2018	6	865	$1,509,519	775
	Dec 2017	6	886	$1,514,330	811
atypical antipsychotics	Feb 2018	7	9,647	$1,024,531	8,730
	Jan 2018	7	11,846	$1,221,880	10,467
	Dec 2017	7	11,668	$1,213,578	10,331
gamma-aminobutyric acid analogs	Feb 2018	8	7,032	$930,429	6,681
	Jan 2018	9	8,959	$1,064,799	8,355
	Dec 2017	11	8,840	$1,012,857	8,248
chelating agents	Feb 2018	9	80	$869,934	75
	Jan 2018	8	102	$1,160,687	88
	Dec 2017	9	98	$1,035,815	91
adrenergic bronchodilators	Feb 2018	10	13,986	$833,151	12,414
	Jan 2018	11	17,049	$1,001,325	15,038
	Dec 2017	8	18,183	$1,069,994	16,120

NOTE: Pharmacy encounter data for MAG is incomplete for the month of February. This should not affect ranks but may affect total amounts for paid, number of claims, and number of beneficiaries in February.

TABLE E: TOP 25 DRUG MOLECULES
BY NUMBER OF CLAIMS IN FEB 2018 (FFS and CCOs)

Drug Molecule Therapeutic Category	Jan 2018 # Claims	Feb 2018 # Claims	Feb 2018 $ Paid	Feb 2018 # Unique Benes
amoxicillin / aminopenicillins	19,291	18,359	$230,721	18,082
oseltamivir / neuraminidase inhibitors	24,477	17,725	$2,466,531	17,639
azithromycin / macrolides	15,915	14,339	$276,591	14,109
albuterol / adrenergic bronchodilators	16,523	13,521	$690,581	12,068
acetaminophen-hydrocodone / narcotic analgesic combinations	12,924	10,168	$143,565	9,604
montelukast / leukotriene modifiers	11,218	9,417	$170,412	9,308
cetirizine / antihistamines	9,188	8,421	$109,748	8,361
lisdexamfetamine / CNS stimulants	9,014	7,811	$2,281,542	7,680
ibuprofen / nonsteroidal anti-inflammatory agents	8,450	6,908	$89,762	6,802
ondansetron / 5HT3 receptor antagonists	7,845	6,881	$116,479	6,711
amoxicillin-clavulanate / penicillins/beta-lactamase inhibitors	7,270	6,455	$158,942	6,362
cefdinir / third generation cephalosporins	6,759	5,997	$164,146	5,937
prednisolone / glucocorticoids	6,619	5,984	$158,361	5,835
fluticasone nasal / nasal steroids	6,427	5,855	$83,225	5,832
gabapentin / gamma-aminobutyric acid analogs	7,500	5,794	$85,375	5,551
amlodipine / calcium channel blocking agents	6,980	5,372	$48,538	5,230
methylphenidate / CNS stimulants	5,984	5,172	$1,151,471	4,668
amphetamine-dextroamphetamine / CNS stimulants	6,065	5,069	$268,506	4,443
clonidine / antiadrenergic agents, centrally acting	6,079	5,029	$122,031	4,843
omeprazole / proton pump inhibitors	5,986	4,556	$51,238	4,481
guanfacine / antiadrenergic agents, centrally acting	4,496	3,853	$75,689	3,732
sulfamethoxazole-trimethoprim / sulfonamides	4,236	3,511	$74,637	3,465
ethinyl estradiol-norgestimate / contraceptives	4,344	3,451	$60,540	3,376
ranitidine / H2 antagonists	4,313	3,447	$45,161	3,366
lisinopril / angiotensin converting enzyme (ACE) inhibitors	4,182	3,333	$27,523	3,198

NOTE: Pharmacy encounter data for MAG is incomplete for the month of February. This should not affect ranks but may affect total amounts for paid, number of claims, and number of beneficiaries in February.

TABLE F: TOP 25 DRUG MOLECULES
BY DOLLARS PAID IN FEB 2018 (FFS and CCOs)

Drug Molecule Therapeutic Category	Jan 2018 $ Paid	Feb 2018 $ Paid	Feb 2018 # Claims	Feb 2018 # Unique Benes
oseltamivir / neuraminidase inhibitors	$3,379,997	$2,466,531	17,725	17,639
lisdexamfetamine / CNS stimulants	$2,555,343	$2,281,542	7,811	7,680
antihemophilic factor / factor for bleeding disorders	$709,368	$1,156,257	36	29
methylphenidate / CNS stimulants	$1,353,757	$1,151,471	5,172	4,668
adalimumab / antirheumatics	$1,001,795	$879,770	150	147
deferasirox / chelating agents	$1,160,687	$869,934	80	75
dexmethylphenidate / CNS stimulants	$868,378	$796,404	2,992	2,541
somatropin / growth hormones	$850,133	$728,559	156	148
albuterol / adrenergic bronchodilators	$824,917	$690,581	13,521	12,068
insulin aspart / insulin	$821,445	$632,209	1,096	1,059
insulin glargine / insulin	$775,960	$612,224	1,415	1,367
pregabalin / gamma-aminobutyric acid analogs	$668,935	$586,946	1,218	1,178
sofosbuvir-velpatasvir / antiviral combinations	$462,708	$560,120	23	22
palivizumab / immune globulins	$658,661	$555,796	233	174
lurasidone / atypical antipsychotics	$619,258	$476,056	374	364
anti-inhibitor coagulant complex / factor for bleeding disorders	$627,733	$471,557	5	3
ivacaftor-lumacaftor / CFTR combinations	$357,791	$461,818	23	20
cobicistat/elvitegravir/emtricitabine/tenofov / antiviral combinations	$587,581	$458,866	165	162
fluticasone-salmeterol / bronchodilator combinations	$474,234	$377,338	971	960
etanercept / antirheumatics	$354,109	$371,540	82	79
clobazam / benzodiazepine anticonvulsants	$359,993	$346,655	209	197
budesonide / inhaled corticosteroids	$430,811	$337,229	1,677	1,640
hydroxyprogesterone / progestins	$305,971	$337,112	105	98
lacosamide / miscellaneous anticonvulsants	$341,742	$319,609	392	368
glecaprevir-pibrentasvir / antiviral combinations	$105,669	$317,005	24	23

NOTE: Pharmacy encounter data for MAG is incomplete for the month of February. This should not affect ranks but may affect total amounts for paid, number of claims, and number of beneficiaries in February.

TABLE G: TOP 25 DRUG MOLECULES
BY CHANGE IN NUMBER OF CLAIMS FROM DEC 2017 TO FEB 2018 (FFS and CCOs)

Drug Molecule	Dec 2017 # Claims	Jan 2018 # Claims	Feb 2018 # Claims	Feb 2018 $ Paid	Feb 2018 # Unique Benes
ofloxacin otic / otic anti-infectives	7	134	125	$6,832	122
fluticasone / inhaled corticosteroids	20	90	121	$25,818	120
terconazole topical / vaginal anti-infectives	42	121	115	$4,349	114
fluoride / minerals and electrolytes	221	264	265	$3,254	262
hyoscyamine / anticholinergics/antispasmodics	500	573	538	$10,548	528
palivizumab / immune globulins	197	267	233	$555,796	174
asenapine / atypical antipsychotics	136	169	172	$151,171	167
linaclotide / guanylate cyclase-C agonists	65	100	97	$36,737	96
tretinoin topical / topical acne agents	296	403	328	$36,611	322
fesoterodine / urinary antispasmodics	8	30	37	$11,561	36
ivermectin topical / topical anti-infectives	62	96	89	$30,877	88
multivitamin with fluoride / vitamin and mineral combinations	156	194	181	$11,551	181
lvp solution / intravenous nutritional products	71	65	96	$3,243	38
glecaprevir-pibrentasvir / antiviral combinations	2	8	24	$317,005	23
dapagliflozin / SGLT-2 inhibitors	15	34	31	$14,033	31
glucagon / glucose elevating agents	66	109	82	$29,338	79
isotretinoin / miscellaneous uncategorized agents	69	92	85	$22,744	82
loperamide / antidiarrheals	68	112	84	$1,329	84
atropine ophthalmic / mydriatics	35	50	50	$2,741	48
prochlorperazine / phenothiazine antipsychotics	61	77	76	$965	75
rizatriptan / antimigraine agents	268	323	283	$5,589	278
timolol ophthalmic / ophthalmic glaucoma agents	88	121	102	$2,148	101
sofosbuvir-velpatasvir / antiviral combinations	10	19	23	$560,120	22
valbenazine / VMAT2 inhibitors	11	19	23	$153,769	21
perampanel / AMPA receptor antagonists	65	65	77	$63,986	69

NOTE: Pharmacy encounter data for MAG is incomplete for the month of February. This should not affect ranks but may affect total amounts for paid, number of claims, and number of beneficiaries in February.

TABLE H: TOP 25 DRUG MOLECULES
BY CHANGE IN AMOUNT PAID FROM DEC 2017 TO FEB 2018 (FFS and CCOs)

Drug Molecule	Dec 2017 $ Paid	Jan 2018 $ Paid	Feb 2018 $ Paid	Feb 2018 # Claims	Feb 2018 # Unique Benes
sofosbuvir-velpatasvir / antiviral combinations	$243,407	$462,708	$560,120	23	22
glecaprevir-pibrentasvir / antiviral combinations	$26,420	$105,669	$317,005	24	23
ustekinumab / interleukin inhibitors	$27,601	$46,221	$140,112	7	7
canakinumab / interleukin inhibitors	$200	$0	$96,836	6	6
palivizumab / immune globulins	$474,014	$658,661	$555,796	233	174
lisdexamfetamine / CNS stimulants	$2,201,197	$2,555,343	$2,281,542	7,811	7,680
oxcarbazepine / dibenzazepine anticonvulsants	$114,468	$174,578	$183,154	1,800	1,713
valbenazine / VMAT2 inhibitors	$86,659	$140,580	$153,769	23	21
cysteamine / miscellaneous uncategorized agents	$30,601	$33,544	$88,506	2	2
mifepristone / uterotonic agents	$0	$0	$55,018	1	1
glycerol phenylbutyrate / urea cycle disorder agents	$41,664	$96,134	$96,134	2	2
enzalutamide / antineoplastic hormones	$78,110	$97,174	$126,217	12	12
asenapine / atypical antipsychotics	$104,398	$135,190	$151,171	172	167
hydroxyprogesterone / progestins	$292,354	$305,971	$337,112	105	98
enasidenib / miscellaneous antineoplastics	$0	$0	$24,930	1	1
eteplirsen / miscellaneous uncategorized agents	$45,045	$45,045	$67,567	6	1
fluticasone / inhaled corticosteroids	$4,685	$18,741	$25,818	121	120
parathyroid hormone / parathyroid hormone and analogs	$0	$18,812	$18,812	2	2
leuprolide / antineoplastic hormones	$101,789	$197,939	$119,537	27	26
interferon beta-1a / interferons	$139,259	$168,372	$156,904	23	23
secukinumab / interleukin inhibitors	$55,510	$79,795	$72,789	12	12
ponatinib / multikinase inhibitors	$33,238	$33,238	$49,857	3	3
certolizumab / TNF alpha inhibitors	$7,448	$11,376	$23,926	4	3
midostaurin / multikinase inhibitors	$0	$0	$16,009	2	2
cabozantinib / multikinase inhibitors	$15,975	$31,951	$31,951	2	2

NOTE: Pharmacy encounter data for MAG is incomplete for the month of February. This should not affect ranks but may affect total amounts for paid, number of claims, and number of beneficiaries in February.

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 DEC 2017 TO FEB 2018 (FFS and CCOs)

Drug Product Therapeutic Category	Feb 2018 # Claims	Feb 2018 $ Paid	Feb 2018 Avr. Paid Per Rx	Feb 2018 Avr. Units Per Rx	Dec 2017 Paid Per Unit	Jan 2018 Paid Per Unit	Feb 2018 Paid Per Unit	Percent Change
atomoxetine 25 mg capsule / CNS stimulants ((N-P-)	162	$16,418	$101.35	30	$2.78	$3.10	$3.18	14.5%
atomoxetine 40 mg capsule / CNS stimulants ((N-P-)	189	$20,814	$110.13	30	$3.17	$3.42	$3.55	12.0%
fluconazole 200 mg tablet / azole antifungals (P)	268	$4,852	$18.10	9	$2.36	$2.40	$2.62	11.1%
Latuda (lurasidone) 80 mg tablet / atypical antipsychotics (N)	121	$155,577	$1,285.76	34	$35.57	$37.34	$39.15	10.1%
Latuda (lurasidone) 40 mg tablet / atypical antipsychotics (N)	112	$135,604	$1,210.75	31	$35.79	$37.47	$39.31	9.8%
Zetia (ezetimibe) 10 mg tablet / cholesterol absorption inhibitors (P)	112	$37,716	$336.75	30	$10.18	$10.42	$11.15	9.5%
Tivicay (dolutegravir) 50 mg tablet / integrase strand transfer inhibitor (P)	125	$217,886	$1,743.09	33	$48.72	$50.93	$53.32	9.4%
Tradjenta (linagliptin) 5 mg tablet / dipeptidyl peptidase 4 inhibitors (P)	184	$72,157	$392.16	29	$12.08	$12.41	$13.17	9.0%
Vyvanse (lisdexamfetamine) 20 mg capsule / CNS stimulants (P)	1,198	$350,153	$292.28	30	$8.87	$9.37	$9.65	8.8%
Vyvanse (lisdexamfetamine) 40 mg capsule / CNS stimulants (P)	1,673	$489,842	$292.79	30	$8.87	$9.33	$9.65	8.8%
Vyvanse (lisdexamfetamine) 30 mg capsule / CNS stimulants (P)	1,996	$585,132	$293.15	30	$8.90	$9.35	$9.68	8.8%
Vyvanse (lisdexamfetamine) 70 mg capsule / CNS stimulants (P)	580	$168,122	$289.86	30	$8.81	$9.33	$9.58	8.8%
Trintellix (vortioxetine) 10 mg tablet / miscellaneous antidepressants (P)	168	$61,064	$363.47	30	$11.20	$12.12	$12.18	8.8%
Trintellix (vortioxetine) 20 mg tablet / miscellaneous antidepressants (P)	124	$47,036	$379.32	30	$11.19	$12.11	$12.17	8.7%
Vyvanse (lisdexamfetamine) 10 mg capsule / CNS stimulants (P)	232	$66,628	$287.19	29	$8.88	$9.35	$9.65	8.6%

New Business

Special Analysis Projects

MISSISSIPPI DIVISION OF MEDICAID

MS-DUR INTERVENTION / EDUCATIONAL MAILING UPDATE

FEBRUARY 2017 – APRIL 2018

Ongoing Mailings:

HIGH MEDD (≥90 MEDD) MAILING Initiated Sept 2016			CONCOMITANT BENZODIAZEPINE / OPIOID USE Initiated Feb 2017		PROVIDER SHOPPING FOR OPIOIDS (≥4 Prescribers AND ≥4 Pharmacies) Initiated Nov 2017		
Month	Prescribers Mailed	Benes Addressed	Prescribers Mailed	Benes Addressed	Prescribers Mailed	Pharms Mailed	Benes Addressed
Nov-17	51	61	150	532	64	49	112
Dec-17	-	-	150	485	56	44	105
Jan-18	46	50	150	380	54	32	95
Feb-18	54	71	150	485	54	42	107
Mar-18	46	49	150	368	51	39	100
Apr-18	53	68	150	412	54	44	105

One-Time Mailings:

ANTIPSYCHOTIC USE IN IDD POPULATION	
	Prescribers Mailed
Dec-17	300
Jan-18	300
Feb-18	469
*Onetime mailing to 1069 prescribers spread over 3 months.	

TRAMADOL / CODEINE PROVIDER NOTICE	
	Prescribers Mailed
Feb-18	1,067

STIMULANTS AND ASSOCIATED DIAGNOSES FOR CLINICAL EDIT

BACKGROUND

The Drug Utilization Review (DUR) Board passed a recommendation during the March 1, 2018 Board Meeting that the Division of Medicaid (DOM) implement diagnosis edits for all stimulant use in both adults and children. MS-DUR was asked to evaluate stimulant prescriptions for the presence of medical claims with diagnoses that are FDA approved in labeling or classified as medically approved indications in compendia.

METHODS

A retrospective analysis was conducted using Mississippi Medicaid pharmacy and medical claims for calendar year 2017. All prescriptions for stimulants were extracted. Medical claims were examined for the beneficiaries receiving these prescriptions to determine which, if any, of the diagnosis of approved FDA indications or compendia supported diagnosis were found in the medical claims. It should be noted that the check for approved diagnoses was a search of medical claims for the entire year and not the customary 2-years back from time of prescription fill.

Under the current electronic prior authorization process (SmartPA®), the primary compendia resource for establishing medically accepted indications is Thompson Micromedex DrugDex® (Micromedex). This is one of the compendia approved by the Centers for Medicare and Medicaid Services. The criteria used for determining medically accepted indications are:

- “Strength of Recommendation” rating of at least IIB (Recommended, In Some Cases) **and**
- "Efficacy" rating of at least IIA (Evidence Favors Efficacy).*

**Indications with IIB rating in "Efficacy" are considered but would require manual prior authorization review*.

Table 1 displays the diagnoses that meet the DOM requirement for FDA approved or Thomson Micromedex DrugDex compendia supported diagnoses for each stimulant drug.

TABLE 1: MICROMEDEX Recommendations For CNS Stimulants				
Generic (Brand) Products	**FDA Indications**	**Compendia Approved Indications***	**Strength of Recommendation**	**Efficacy**
amphetamine salt combo (Adderall, Mydayis)	ADHD	None		
	Narcolepsy			
dexmethylphenidate (Focalin)	ADHD	None		
methylphenidate (Methylin, Aptensio, Quillichew, Quillivant, Ritalin, Concerta, Metadate, Cotempla, Daytrana)	ADHD	None		
	Narcolepsy			
dextroamphetamine (Procentra, Zenzedi, Dexedrine)	ADHD (P)	ADHD (A)	IIB	IIA
	Narcolepsy			
methamphetamine (Desoxyn)	ADHD	None		
	Simple Obesity			
amphetamine (Evekeo, Adzenys, Dyanavel)	ADHD	None		
	Narcolepsy			
	Simple Obesity; adjunct			
armodafinil (Nuvigil)	Narcolepsy (A)	Bipolar, depressed (A)	IIB	IIA
	Obstructive Sleep Apnea (A)			
	Shift Work Disorder (A)			
modafinil (Provigil)	Narcolepsy (A)	Narcolepsy (P)	IIB	IIA
	Obstructive Sleep Apnea (A)	ADHD	IIB	IIA
	Shift Work Disorder (A)	Depression (Unipolar /Bipolar) adjunct (A)	IIB	IIA
		Depression adjunct-fatigue (A)	IIB	IIA
		Sleep Deprivation (A)	IIA	IIA
		Steinert myotonic dystrophy syndrome (A)	IIB	IIA
lisdexamfetamine (Vyvanse)	ADHD	None		
	Binge Eating Disorder (A)			

Unless noted indication is for both pediatrics (P) and adult (A).

* *"Strength of Recommendation" rating of at least IIB and "Efficacy" rating of at least IIA are considered a "medically-accepted indication." Indications with IIB rating in "Efficacy" would require manual review.*

RESULTS

Although Medicaid uses the age of 21 years to be classified as an adult, Micromedex indications are classified as adult and/or children. Since the generally accepted age for the adult classification is 18 years of age, MS-DUR analyzed the presence of diagnoses using age 18 as the criteria for adult. Table 2 shows the number of unique beneficiaries prescribed each drug product and the number/percentage that did not have an approved diagnosis for the product in the medical claims.

TABLE 2: Presence of Approved Diagnoses by Drug Product
(FFS and CCOs - CY 2017)

	Age < 18				Age 18 +			
	Unique Beneficiaries	Approved Indication*			Unique Beneficiaries	Approved Indication*		
Drug Product		No	Yes			No	Yes	
Amphetamine-Dextroamphetamine	5,615	968	4,647	83%	1237	496	741	60%
Amphetamine-Dextroamphetamine ER	5,948	1,167	4,781	80%	610	199	411	67%
Adderall	47	7	40	85%	13	7	6	46%
Adderall XR	905	156	749	83%	103	40	63	61%
Mydayis	7	3	4	57%	0	0	0	0%
Dexmethylphenidate Hydrochloride	2,038	413	1,625	80%	45	11	34	76%
Dexmethylphenidate Hydrochloride ER	776	118	658	85%	25	6	19	76%
Focalin	74	16	58	78%	3	1	2	67%
Focalin XR	5,344	1,065	4,279	80%	151	54	97	64%
Methylphenidate Hydrochloride	2,337	442	1,895	81%	113	49	64	57%
Methylphenidate Hydrochloride CD	315	72	243	77%	9	3	6	67%
Methylphenidate Hydrochloride ER	6,863	1,512	5,351	78%	322	96	226	70%
Methylphenidate Hydrochloride SR	3	1	2	67%	0	0	0	0%
Aptensio XR	29	9	20	69%	0	0	0	0%
Concerta	96	22	74	77%	9	1	8	89%
Cotempla XR-ODT	10	1	9	90%	0	0	0	0%
Daytrana	210	48	162	77%	4	1	3	75%
Metadate CD	1,170	275	895	76%	36	10	26	72%
Metadate ER	15	4	11	73%	1	1	0	0%
Methylin	7	1	6	86%	0	0	0	0%
Ritalin	3	0	3	100%	1	0	1	100%
Ritalin LA	13	4	9	69%	0	0	0	0%
QuilliChew ER	1,950	391	1,559	80%	11	2	9	82%
Dextroamphetamine Sulfate	100	13	87	87%	8	6	2	25%
Zenzedi	6	1	5	83%	1	1	0	0%
Adzenys XR-ODT	1,723	265	1,458	85%	31	12	19	61%
Dyanavel XR	17	4	13	76%	0	0	0	0%
Evekeo	58	13	45	78%	4	3	1	25%
Armodafinil	1	1	0	0%	16	6	10	63%
Nuvigil	1	1	0	0%	6	2	4	67%
Modafinil	4	0	4	100%	46	14	32	70%
Provigil	11	5	6	55%	40	10	30	75%
Lisdexamfetamine	0	0	0	0%	0	0	0	0%
Vyvanse	18,419	3,852	14,567	79%	1154	462	692	60%
TOTAL	54,115	10,850	43,265	80%	3,999	1,493	2,506	63%

** Approved indications for each prodcut are listed in Table 1.*

It is not uncommon for providers to generalize indications across a therapeutic class or across similar products. Table 3 provides the number of cases where potential generalization of indications may have occurred for pediatric (age < 18 years) beneficiaries where a FDA approved or compendia supported diagnosis for each drug was not present in medical claims data. Since depression is a compendia accepted diagnosis for only Nuvigil and Provigil, it is reasonable to assume that this diagnosis is present due to an existing comorbidity rather than being the indication for use of the other stimulants. The results in Table 3 indicate that for children, the lack of an approved diagnosis is most likely the result of not currently requiring a diagnosis rather than class generalization of indications.

TABLE 3: Presence of Other Diagnoses by Drug
For Beneficiaries Not Having An Approved Diagnosis
Beneficiaries < 18 Years Old

	Unique Beneficiaries W/O Approved Indication	Number of Beneficiaries With Diagnoses that are FDA Indicated or Compendia Supported for Other Products *(shaded cells indicate diagnoses approved for the product itself)*								
		ADHD	NARC	OBES	DEP	INSOM	BIP-DEP	OSA	SHIFT	BINGE
Amphetamine-Dextroamphetamine	968			11	39	8	2	4	0	0
Amphetamine-Dextroamphetamine ER	1,167			9	46	10	2	1	0	1
Adderall	7			0	1	0	0	0	0	0
Adderall XR	156			0	5	3	0	1	0	0
Mydayis	3			0	0	0	0	0	0	0
Dexmethylphenidate Hydrochloride	413		0	4	28	2	2	0	0	0
Dexmethylphenidate Hydrochloride ER	118		0	0	1	0	0	0	0	0
Focalin	16		0	0	0	0	0	0	0	0
Focalin XR	1,065		0	7	49	3	5	3	0	0
Methylphenidate Hydrochloride	442			2	18	1	1	6	0	0
Methylphenidate Hydrochloride CD	72			0	2	0	0	0	0	0
Methylphenidate Hydrochloride ER	1,512			7	60	7	2	4	0	0
Methylphenidate Hydrochloride SR	1			0	0	0	0	0	0	0
Aptensio XR	9			0	0	0	0	0	0	0
Concerta	22			0	0	0	0	0	0	0
Cotempla XR-ODT	1			0	0	0	0	0	0	0
Daytrana	48			0	2	1	0	0	0	0
Metadate CD	275			3	14	0	0	1	0	0
Metadate ER	4			0	0	0	0	0	0	0
Methylin	1			0	0	0	0	0	0	0
Ritalin LA	4			0	0	0	0	0	0	0
QuilliChew ER	391			0	13	1	0	1	0	0
Dextroamphetamine Sulfate	13			0	0	0	0	0	0	0
Zenzedi	1			0	0	0	0	0	0	0
Adzenys XR-ODT	265				3	1	0	1	0	0
Dyanavel XR	4				0	0	0	0	0	0
Evekeo	13				0	1	0	0	0	0
Armodafinil	1	1	1	0	0	0	0	0	0	0
Nuvigil	1	0	1	0	1	0	0	0	0	0
Modafinil	0								0	0
Provigil	5			0	0	0	0	1	0	0
Lisdexamfetamine	0									
Vyvanse	3,852		5	33	196	20	19	12	0	3

ADHD - attention deficit/hyperactivity disorder
NARC - narcolepsy
OBES - simple obesity
DEP - depression (unipolar/bipolar) adjunct (A)
INSOM - sleep deprivation (A)
BIP-DEP - bipolar, depressed (A)
OSA - obstructive sleep apnea (A)
SHIFT - shift work disorder (A)
BINGE - binge eating disorder (A)

Table 4 provides the number of cases where potential generalization of indications may have occurred for adult (age ≥ 18 years) beneficiaries where a FDA approved or compendia supported diagnosis for each drug was not present in medical claims data. Since diagnoses are required for adults using some of the stimulants, it is not surprising that fewer adults had a lack of an approved indication. For the adults not having an approved indication, depression was again the most frequent diagnosis occurring in the medical records. As with children, the presence of depression as a comorbidity is more likely rather than the depression being the reason for prescribing the stimulant.

TABLE 4: Presence of Other Diagnoses by Drug
For Beneficiaries Not Having Approved Diagnsois
Beneficiaries 18 + Years Old

	Unique Beneficiaries W/O Approved Indication	Number of Beneficiaries With Diagnoses that are FDA Indicated or Compendia Supported for Other Products *(shaded cells indicate diagnoses approved for the product itself)*								
		ADHD	NARC	OBES	DEP	INSOM	BIP-DEP	OSA	SHIFT	BINGE
Amphetamine-Dextroamphetamine	496			15	104	8	21	10	0	0
Amphetamine-Dextroamphetamine ER	199			7	36	5	6	2	1	0
Adderall	7			1	0	0	0	0	0	0
Adderall XR	40			1	7	1	2	1	0	0
Dexmethylphenidate Hydrochloride	11		0	0	1	0	0	0	0	0
Dexmethylphenidate Hydrochloride ER	6		0	0	0	0	0	0	0	0
Focalin	1		0	0	0	0	0	0	0	0
Focalin XR	54		0	1	9	1	0	0	0	0
Methylphenidate Hydrochloride	49			1	11	0	3	2	0	0
Methylphenidate Hydrochloride CD	3			0	0	0	0	0	0	0
Methylphenidate Hydrochloride ER	96			1	6	1	2	1	0	0
Concerta	1			0	0	0	0	0	0	0
Daytrana	1			0	0	0	0	0	0	0
Metadate CD	10			0	1	0	0	0	0	0
Metadate ER	1			0	0	0	0	0	0	0
QuilliChew ER	2			0	1	0	0	0	0	0
Dextroamphetamine Sulfate	6			0	1	0	0	0	0	0
Zenzedi	1			0	0	0	0	0	0	0
Adzenys XR-ODT	12				3	0	2	0	0	0
Evekeo	3				1	0	0	0	0	0
Armodafinil	6	0		0	2	0				0
Nuvigil	2	0		0	0	0				0
Modafinil	14			0						0
Provigil	10			0						0
Lisdexamfetamine	0									
Vyvanse	462		3	15	93	14	26	10	0	

ADHD - attention deficit/hyperactivity disorder
NARC - narcolepsy
OBES - simple obesity
DEP - depression (unipolar/bipolar) adjunct (A)
INSOM - sleep deprivation (A)
BIP-DEP - bipolar, depressed (A)
OSA - obstructive sleep apnea (A)
SHIFT - shift work disorder (A)
BINGE - binge eating disorder (A)

CONCLUSIONS AND RECOMMENDATIONS

- Although children have not had a diagnosis required for use of stimulants, 20% were taking stimulants without an approved diagnosis present for the product.
- In spite of having diagnosis requirements for use of some stimulants by adults, 37% of adult beneficiaries taking stimulants did not have an approved diagnosis present for the product.
- A total of 1,499 prescribers wrote initial prescriptions for stimulants when an approved diagnosis was not available in the medical claims.

TABLE 5: Number of Beneficairies and Prescribers With Outlier Cases

BENEFICIARIES WITHOUT APPROVED DIAGNOSES				
age	Pharmacy Program			
	FFS	UHC	MAG	TOTAL
< 18	4,160	3,121	3,094	10,375
18 +	327	619	587	1,533
Total	4,487	3,740	3,681	11,908

PRESCRIBERS				
Number of Beneficiaries Without Approved Diagnoses				
1	2-4	5-9	10+	TOTAL
565	420	194	320	1,499

Recommendations:

1. DOM should implement an electronic prior authorization procedure requiring the presence of at least one of the listed FDA approved or compendia supported diagnoses for each stimulant product. This diagnosis can be present in the medical claims paid within 24 months of the prescription fill or written on the prescription by the provider and submitted by the pharmacist with the prescription claim. (NOTE: The DUR Board has already approved such an edit, this is a confirmation of the approved indications that will be listed for each product.)

Prior to Implementation of the Edit:

2. MS-DUR will initiate an educational mailing to inform providers about the diagnosis requirement and will work with the Mississippi Chapter of the American Academy of Pediatrics and other state professional medical, nursing and pharmacy associations to electronically disseminate information about the upcoming edit.

3. DOM will include a notice about the upcoming edit in the upcoming Provider Bulletin(s).

PHARMACOTHERAPEUTIC MANAGEMENT OF SICKLE CELL DISEASE

BACKGROUND

Sickle cell disease (SCD) is a term used to describe a group of genetic red blood cell disorders affecting hemoglobin. Hemoglobin is a protein in red blood cells that carries oxygen through the body. Red blood cells are normally disc shaped allowing them to be flexible and move freely through blood vessels delivering oxygen. In individuals with SCD, abnormal hemoglobin strands cause red blood cells to become an irregular, sickle shape. These sickle-shaped red blood cells are not flexible and can cause blockages slowing the flow of blood.

Sickle cell disease affects approximately 100,000 Americans.[1] It is primarily found in individuals of African, Mediterranean and Asian descents.[2] Although SCD is associated with high morbidity, currently 90 percent of children diagnosed with SCD survive into adulthood.[3] Pain and acute chest syndrome (ACS) are common complications associated with SCD. Pain, the most common symptom of SCD, can be characterized as acute or chronic.

As there is no cure for SCD, proactive management of SCD complications is a mainstay of therapy. For over 20 years, hydroxyurea has been the primary pharmacotherapeutic agent available for preventing SCD complications. Hydroxyurea increases fetal hemoglobin, reduces "sickling" of red blood cells, and improves blood flow.[4] In 2014 the Expert Panel Report on Evidenced-Based Management of Sickle Cell Disease recommended a treatment protocol for the utilization of hydroxyurea.[5] With each recommendation, the panel listed strength of recommendation and quality of evidence based on:

- protocols used in published clinical trials and observational studies,
- indirect evidence derived from basic science and pharmacokinetics of hydroxyurea, and
- a consensus process

The Expert Panel's recommended treatment protocol is summarized in Figure 1.

[1] Minniti CP, Lu K, Groninger H. Pain in sickle cell disease. *J Palliat Med* 2013; 16:697-9.
[2] Kanter J, Kruse-James R. Management of sickle cell disease from childhood through adulthood. *Blood Rev* 2013: 27: 279-87.
[3] US Department of Health and Human Services, National Institutes of Health. Evidence-based management of sickle cell disease. Expert panel report, 2014: 1. http://www.nhlbi.nih.gov/health-pro/guidelines/sickle-cell-disease-guidelines/. (Accessed April 2018).
[4] Green NS, Barral S. Emerging science of hydroxyurea therapy for pediatric sickle cell disease. *Pediatr Res* 2014; 75: 196-204.
[5] US Department of Health and Human Services, National Institutes of Health. Evidence-based management of sickle cell disease. Expert panel report, 2014:77 . http://www.nhlbi.nih.gov/health-pro/guidelines/sickle-cell-disease-guidelines/. (Accessed April 2018).

Figure 1: Evidence-Based Hydroxyurea Treatment Recommendations

Hydroxyurea Treatment Recommendations

Recommendations
1. Educate all patients with SCA and their family members about hydroxyurea therapy. (See consensus treatment protocol on page 145). **(*Consensus–Panel Expertise*)**
2. In adults with SCA who have three or more sickle cell-associated moderate to severe pain crises in a 12-month period, treat with hydroxyurea. ***(Strong Recommendation, High-Quality Evidence)***
3. In adults with SCA who have sickle cell-associated pain that interferes with daily activities and quality of life, treat with hydroxyurea. ***(Strong Recommendation, Moderate-Quality Evidence)***
4. In adults with SCA who have a history of severe and/or recurrent ACS, treat with hydroxyurea.* ***(Strong Recommendation, Moderate-Quality Evidence)***
5. In adults with SCA who have severe symptomatic chronic anemia that interferes with daily activities or quality of life, treat with hydroxyurea. ***(Strong Recommendation, Moderate-Quality Evidence)***
6. In infants 9 months of age and older, children, and adolescents with SCA, offer treatment with hydroxyurea regardless of clinical severity to reduce SCD-related complications (e.g., pain, dactylitis, ACS, anemia). ***(Strong Recommendation, High-Quality Evidence* for ages 9–42 months;** ***Moderate Recommendation, Moderate-Quality Evidence* for children >42 months and adolescents).** Note: The panel intentionally used the term "offer" realizing that patients' values and preferences may differ particularly considering treatment burden (e.g., laboratory monitoring, office visits), availability of drug in a liquid form, and cost. Therefore, the panel strongly encourages shared decisionmaking and discussion of hydroxyurea therapy with all patients.
7. In adults and children with SCD who have chronic kidney disease and are taking erythropoietin, hydroxyurea therapy can be added to improve anemia. ***(Weak Recommendation, Low-Quality Evidence)***
8. In females who are pregnant or breastfeeding, discontinue hydroxyurea therapy. ***(Moderate Recommendation, Very Low-Quality Evidence)***
9. To ensure proper use of hydroxyurea and maximize benefits and safety, use an established prescribing and monitoring protocol. ***(Strong Recommendation, High-Quality Evidence)***
10. In people with HbSβ⁺-thalassemia or HbSC who have recurrent sickle cell-associated pain that interferes with daily activities or quality of life, consult a sickle cell expert for consideration of hydroxyurea therapy. *(Moderate Recommendation, Low-Quality Evidence)*
11. In people not demonstrating a clinical response to appropriate doses and duration of hydroxyurea therapy, consult a sickle cell expert. ***(Moderate Recommendation, Very Low-Quality Evidence)***
* For more information, see the ACS section of the "Managing Acute Complications of Sickle Cell Disease" chapter.

In July 2017, the U.S. Food and Drug Administration (FDA) approved L-glutamine (Endari®), the first new therapeutic agent for treating SCD in over two decades.[6] Endari is approved for use in patients ≥ 5 years to reduce acute complications of sickle cell disease. Preliminary data suggests Endari can reduce painful events, acute chest syndrome events, and hospitalizations. [7] In the clinical trials, most patients studied

[6] FDA. FDA approves new treatment of sickle cell disease. July 2017. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm566084.htm. (Accessed April 2018).

[7] FDA. Oncologic drugs advisory committee: advisory committee briefing materials. May 24, 2017. https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/OncologicDrugsAdvisoryCommittee/UCM559736.pdf. (Accessed April 2018)

were also receiving hydroxyurea. Endari was approved through the orphan drug designation and is distributed through specialty pharmacies.

MS-DUR conducted an analysis of the treatment of Mississippi Medicaid beneficiaries with SCD. The primary objectives were to examine hydroxyurea utilization and any Endari claim approvals through March 2018. This analysis, along with clinical trial data and expert panel recommendations, will serve as references in the development of recommendations in the treatment of SCD in Mississippi Medicaid beneficiaries.

METHODS

MS-DUR identified all Mississippi Medicaid beneficiaries with a diagnosis of SCD (ICD-10 D57 – excluding D57.4 sickle cell trait) present on a medical claim paid anytime between July 2016 and March 2018. Pharmacy claims for hydroxyurea or Endari paid between January 2017 and March 2018 were extracted for these beneficiaries.

RESULTS

Table 1 shows the characteristics of beneficiaries identified with SCD through medical claims. Almost half (54%) of the SCD patients were adults (ages 21 and above) and over a fourth (28%) were children ages ≤ 6 years.

Hydroxyurea, Endari and narcotics can be used for treatment of pain associated with SCD. Only one (1) prescription claim for Endari had been paid at the time of this analysis. Over half of the beneficiaries with SCD had not received a prescription for hydroxyurea or narcotics during the last year. Of those that had received prescriptions that could have been for pain, most were being treated with narcotics only. Although the ages of beneficiaries with SCD varied amongst the fee-for-service (FFS) and the coordinated care plans (CCOs), the treatment patterns for SCD did not meaningfully vary across pharmacy programs.

TABLE 1: Characteristics of Medicaid Beneficiaries With Sickle Cell Disease*
(January 2017 - March 2018)

		Pharmacy Program							
		FFS		UHC		MAG		TOTAL	
TOTAL		1,312		1,725		1,936		4,973	
Age	0 - 6	128	10%	595	34%	649	34%	1,372	28%
	7-13	131	10%	260	15%	285	15%	676	14%
	14 - 18	109	8%	166	10%	188	10%	463	9%
	19 - 20	88	7%	74	4%	60	3%	222	4%
	21 +	855	65%	630	37%	754	39%	2,239	45%
Products Prescribed for Pain	No Rx	793	60%	991	57%	1,084	56%	2,868	58%
	Hydroxyurea only	25	2%	36	2%	32	2%	93	2%
	Hydroxyurea and narcotics	85	6%	160	9%	212	11%	457	9%
	Narcotics only	409	31%	538	31%	608	31%	1,555	31%

** At least one medical claim had a diagnosis code of D57 Sickle Cell Disases -- excluding D57.4 Sickle Cell Trait.*

Table 2 illustrates use of hydroxyurea by beneficiary age for those beneficiaries continuously enrolled in the last four months included in the analysis. There are just over 4,000 beneficiaries currently enrolled that have SCD. The currently enrolled beneficiaries represent 82% of all beneficiaries with SCD that have been enrolled in Medicaid for any length of time during the last year. This indicates that the SCD population in Medicaid is fairly stable and many of these patients will remain enrolled; thus managing progression of the disease is critical.

Although younger children were somewhat less likely to be treated with hydroxyurea, use of the product was very low for all ages. Overall, 88% of beneficiaries with SCD were not treated with hydroxyurea between January 2017 and March 2018.

TABLE 2: Number of Claims for Hydorxyurea Paid Between January 2017 and March 2018 by Age
(ONLY includes beneficiaries continously enrolled December 2017 - March 2018; FFS and CCOs)

Age (years)	Number of Claims for Hydroxyurea *(Percentages are of each age group)*										Total
	0		1 - 2		3 - 5		6 - 10		11 +		
0 - 6	1,101	93%	27	2%	31	3%	14	1%	7	1%	1,180
7 - 13	471	78%	31	5%	33	5%	39	6%	32	5%	606
14 - 18	322	81%	21	5%	24	6%	22	6%	11	3%	400
19 - 20	122	84%	6	4%	7	5%	6	4%	5	3%	146
21 +	1,539	89%	70	4%	56	3%	47	3%	14	1%	1,726
Total	3,555	88%	155	4%	151	4%	128	3%	69	2%	4,058

Table 3 shows the number claims for hydroxyurea and narcotics for beneficiaries with SCD who were continuously enrolled during the last four months of the analysis. Overall, 37% of SCD patients were treated with narcotics while receiving no prescriptions for hydroxyurea. It should be noted that 13% of all beneficiaries receiving narcotics received 6 or more prescriptions for narcotics in this timeframe. Thus these beneficiaries can be classified as being chronically treated with narcotics.

TABLE 3: Number of Claims for Hydorxyurea and Narcotics Paid Between January 2017 and March 2018
(ONLY includes beneficiaries continously enrolled December 2017 - March 2018; FFS and CCOs)

Percentages are of total		Number of Claims for Narcotics										TOTAL	
		0		1 - 2		3 - 5		6 - 10		11 +			
Number of Claims for Hydroxyurea	0	2,242	55%	832	21%	216	5%	108	3%	157	4%	3,555	88%
	1 - 2	19	0%	40	1%	30	1%	25	1%	41	1%	155	4%
	3 - 5	21	1%	36	1%	17	0%	23	1%	54	1%	151	4%
	6 - 10	20	0%	26	1%	27	1%	17	0%	38	1%	128	3%
	11 +	14	0%	16	0%	13	0%	11	0%	15	0%	69	2%
	TOTAL	2,316	57%	950	23%	303	7%	184	5%	305	8%	4,058	100%

CONCLUSIONS AND RECOMMENDATIONS

Endari should provide a new treatment alternative for pain associated with SCD. However, Endari is recommended as (a) adjunctive therapy with hydroxyurea when treatment with hydroxyurea alone is not adequate or (b) as monotherapy when a patient cannot tolerate hydroxyurea. Two major conclusions from this analysis are:

- Hydroxyurea appears to have limited utilization in the SCD population.
- Narcotics are being over-utilized to treat pain associated with SCD and appear to be used instead of hydroxyurea rather than in conjunction with hydroxyurea.

***Recommendations*:**

1. MS-DUR should implement an educational initiative encouraging the utilization of hydroxyurea, as referenced in **Figure 1**, for the proactive management of sickle cell complications such as pain and ACS while discouraging the inappropriate use of narcotics. The educational initiative should also address the role of Endari in the management of SCD.

2. Endari should be prescribed for use in addition to hydroxyurea unless intolerance or contraindication of hydroxyurea has been documented.

3. DOM Office of Pharmacy should implement manual PA criteria for Endari use.

MAKENA UTILIZATION IN MISSISSIPPI MEDICAID

BACKGROUND

Makena® (hydroxyprogesterone caproate) is a progestin indicated to reduce the risk of preterm birth in women with a history of single child spontaneous preterm birth.[1] Makena was approved by the U.S. Food and Drug Administration (FDA) in February 2011.[2] Prior to its approval, a compounded version of the active ingredient, 17-hydroxyprogesterone caproate (17P), was available to Medicaid beneficiaries whose physician requested the drug through compounding pharmacies. In June 2012, following the release of Makena, the FDA released an updated statement on the compounding of 17P.[3] The FDA recommended using an FDA-approved drug product, such as Makena, instead of a compounded drug except when there is a specific medical need (e.g., an allergy) that cannot be met by the approved drug. FDA is not aware of any scientifically reliable evidence demonstrating that compounding 17P without a preservative or in an oil base different than the one used in Makena produces a significant difference for an identifiable group of patients (aside from the rare patient who is known to be allergic to either the preservative or the oil base). Currently, the MS Division of Medicaid (DOM) does not cover for compounded prescriptions except for hyperalimentation, as defined in DOM's Administrative Code.[4]

Many obstetricians believe that utilization of Makena is critical in reducing preterm birth rates in at-risk pregnant beneficiaries. Ensuring access to Makena for women with a singleton pregnancy who have a history of singleton spontaneous preterm birth is important for assuring appropriate care and maximizing outcomes. Concerns regarding Makena access and lengthy delays in obtaining the product have been expressed to the Division of Medicaid (DOM). As noted in Senate Bill (SB) 2836, signed by the Governor after the Mississippi Legislature 2018 Regular Session, "It is the intent of the Legislature that the division and any managed care entity described in subsection (H) of this section encourage the use of Alpha-Hydroxyprogesterone Caproate (17P) to prevent recurrent preterm birth."

METHODS

MS-DUR conducted a retrospective analysis of Makena utilization among Mississippi Medicaid beneficiaries using Mississippi Medicaid FFS and CCO pharmacy and medical claims from January 1, 2017 through January 31, 2018. A concern expressed from providers was not being able to start treatment as soon as desired due to delays in obtaining Makena after placing an order with the pharmacy. Claims data cannot be used to determine the actual time interval between a provider ordering and receiving Makena. However, this time lag can be estimated by examining the number of days between the first pharmacy claim for each beneficiary and the first medical claim for administration of the product. MS-DUR examined medical claims with either a J-code for administering Makena or a CPT code for therapeutic administration of an injectable product MS-DUR also identified the major specialty pharmacies involved in distribution of Makena to Medicaid providers. Phone interviews were conducted with, AMAG Pharmaceuticals, the

[1] Makena [package insert]. AMAG Pharmaceuticals, Waltham, MA; Accessed March 2018.
[2] U.S. Food and Drug Administration. FDA Statement on Makena. March 2011. Accessed March 2018
[3] U.S. Food and Drug Administration. Updated FDA Statement on Compounded Version of Hydroxyprogesterone Caproate (the Active Ingredient in Makena). https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm402614.htm June 2012. Accessed March 2018
[4] MS-DOM Administrative Code Part 214. https://medicaid.ms.gov/wp-content/uploads/2014/01/Admin-Code-Part-214.pdf. Accessed May 2018

manufacturer and with selected specialty pharmacies in order to explore the ordering/distribution process and to determine what problems, if any, existed in the timely acquisition of Makena.

RESULTS

Table 1 shows the number of paid pharmacy claims per month for Makena by pharmacy program. No paid claims for the compounded product, 17P, were present in the data analyzed. Although Makena has been covered by Medicaid since it was FDA approved, it was not listed in the Universal Preferred Drug List (UPDL) until April 2017. At that time it was added as a preferred product in the Miscellaneous Brand/Generic category in order to encourage use. As shown in Table 1, there were no pharmacy claims for Makena prior to April 2017 in the fee-for-service (FFS) or United Healthcare (UHC) programs. There were pharmacy claims before this time in Magnolia (MAG). Utilization in all three programs increased significantly after April 2017.

TABLE 1: Makena Pharmacy Prescriptions by Month and Pharmacy Program

	Pharmacy Program			
Month	FFS	UHC	MAG	Total
Jan-17	0	0	26	26
Feb-17	0	0	24	24
Mar-17	0	0	26	26
Apr-17	1	16	24	41
May-17	5	34	47	86
Jun-17	10	41	39	90
Jul-17	12	37	40	89
Aug-17	20	49	47	116
Sep-17	12	54	39	105
Oct-17	16	54	46	116
Nov-17	17	46	39	102
Dec-17	16	42	40	98
Jan-18	12	33	49	94

NOTE: Makena was added to the UPDL effective 4/1/2017 as a preferred product in the Miscellaneous Brand/Generic category. It's coverage status was made retroactively effective as of 1/1/2017.

Table 2 provides utilization information for all beneficiaries beginning treatment with Makena between January 1, 2017 and September 1, 2017. If treatment was started at the earliest time indicated in the Makena labeling (16 weeks gestation) and given for the recommended period of time (37 weeks gestation), beneficiaries could receive up to 21 doses. As shown in Table 2, women treated with Makena averaged 12 doses (12 weeks of treatment).

TABLE 2: Utilization Summary for Beneficiaries Initiating Treatment With Makena Before September 1, 2017

(January 1, 2017 - January 31, 2018)

		Pharmacy Program			
		FFS	UHC	MAG	Total
TOTAL number of beneficiaries		12	85	129	226
Number of Prescription Fills	1	7	12	36	55
	2	3	16	25	44
	3	0	19	15	34
	4	0	18	32	50
	5	2	15	20	37
	6+	0	5	1	6
	Mean	1.9	3.3	2.9	3.0
Number of Doses Dispensed	3 - 5	7	12	36	55
	6 - 10	3	17	26	46
	11 - 15	0	19	14	33
	16 - 21	2	32	52	86
	22 or more	0	5	1	6
	Mean	7.7	13.3	11.8	12.1
Age At Initiation of Makena Therapy	16 - 20 years old	2	4	9	15
	21 - 25 years old	4	31	46	81
	26 - 30 years old	4	33	39	76
	31 - 35 years old	2	13	25	40
	36 - 40 years old	0	3	10	13
	41 or more years old	0	1	0	1
	Mean	25.7	26.9	27.3	27.1

Table 3 shows the number of Makena prescriptions filled by each pharmacy. Almost half of the prescriptions were filled by Transcript Pharmacy in Jackson, MS. Transcript is the only specialty pharmacy in Mississippi designated for distribution of Makena by the manufacturer. The manufacturer directs orders to designated pharmacies when orders are initiated using their 800 number. Although the manufacturer tries to limit distribution to designated specialty pharmacies in order to assure appropriate patient management, they will ship Makena to other pharmacies when requested by payers or prescribers. Table 3 illustrates that almost half of Makena prescriptions were filled by Transcript Pharmacy. The remainder of prescriptions were primarily split between Briovarx in Columbus, MS (UHC's preferred specialty pharmacy) and Acariahealth Pharmacy in Slidell, LA (Magnolia's preferred specialty pharmacy).

TABLE 3: Number of Makena Claims Filled by Pharmacies

(January 1, 2017 - January 31, 2018)

Pharmacy	Pharmacy Program			
	FFS	UHC	MAG	Total
Transcript Pharmacy Inc - Jackson, Ms	95	165	204	464
Briovarx Llc - Columbus, Ms	3	208	12	223
Acariahealth Pharmacy Inc - Slidell, La	3	0	205	208
Caremark Inc - Bartlett, Tn	5	2	18	25
Accredo Health Group Inc - Memphis, Tn	4	0	14	18
Freds Westside Pharmacy Inc - Picayune, Ms	4	2	7	13
Picayune Drug Co Inc - Picayune, Ms	1	8	0	9
Walgreens # 11599 - Columbus, Ms	0	3	6	9
Walgreens Specialty Pharmacy L - Pitsburgh, Pa	1	0	5	6
Medicaid Provider Number 1370783	5	0	0	5
Freds Stores Of Tennessee Inc - Poplarville, Ms	0	0	5	5
Reeves Sain Drug Store Inc - Columbus, Ms	0	5	0	5
Proxsys Rx-Rush, Llc - Ocean Springs, Ms	0	4	0	4
Save Rite Pharmacy - Ocean Springs, Ms	0	4	0	4
Polks Crossgates Discounts Dru - Biloxi, Ms	0	3	0	3
Wal Mart Pharmacy 10-1346 - Ocean Springs, Ms	0	0	2	2
Wal-Mart Stores East Lp - Picayune, Ms	0	0	2	2
Bioscrip Pharmacy Inc - Memphis, Tn	0	1	0	1
Sartin Discount Drug's Inc - Gulfport, Ms	0	1	0	1
Pharmacy ID missing on claim	0	0	6	6

NOTE: Transcript Pharmacy is the specialty pharmacy designated by the manufacturer of Makena for distribution in Mississi

Table 4 shows the number of unique beneficiaries treated by prescribers initiating Makena therapy. Providers are grouped by clinic when possible. A total of 403 women were treated with Makena during the study period. Over half (216) were treated by providers in 11 practices. Using the clinic groupings that were identified, there were no more than 73 different practice locations involved in treatment of Medicaid beneficiaries with Makena.

TABLE 4: Number of Unique Beneficiaries Started on Makena

(January 1, 2017 - January 31, 2018)

Practice / Physician		Pharmacy Program			
		FFS	UHC	MAG	Total
P & S Clinic Ob-Gyn - Amory, Ms	TOTAL	1	0	7	8
	Stephen Otey	0	0	1	1
	Duke Wood	1	0	1	2
	James Chaney	0	0	1	1
	Meredith Griffin	0	0	1	1
	Pamela Lacy	0	0	3	3
Kenyetta Brummitt - Batesville, Ms		0	0	1	1
Dimitri Yanez - Bay St Louis, Ms		0	1	0	1
Biloxi Regional Medical Center - Biloxi, Ms	TOTAL	3	2	2	7
	Courtney Meredith	2	1	1	4
	John Mallett	0	1	0	1
	Stephen Jones	1	0	1	2
Hebe Diaz - Biloxi, Ms		0	1	1	2
Brookhaven Ob-Gyn Assoc - Brookhaven, Ms	TOTAL	0	0	3	3
	Joey Sessums	0	0	1	1
	Leigh Gray	0	0	1	1
	William Rushing	0	0	1	1
Jennifer Hicks - Canton, Ms		0	1	0	1
The Woman's Clinic - Clarksdale, Ms	TOTAL	6	12	10	28
	Kimberly Fava	1	4	3	8
	Carie Cesare	0	2	1	3
	Charles Cesare	0	0	1	1
	Kushna Damallie	5	6	5	16
Linda Wright - Clarksdale, Ms		0	0	2	2
Bradley Baugh - Cleveland, Ms		2	2	4	8
Clay Hudson - Columbus, Ms		0	0	1	1
James Holzhauer - Columbus, Ms		1	0	2	3
Magnolia Physician Services - Corinth, Ms	TOTAL	3	2	2	7
	Jason Cesario	1	0	0	1
	Tiffany General	2	2	1	5
	Quinisha Logan	0	0	1	1
Valarie Alder - Corinth, Ms		0	1	0	1
Patrick Hsu - Corinth, Ms		0	1	0	1
Bridget Cahill - Ellisville, Ms		0	0	1	1
William Hood - Flowood, Ms		0	4	2	6
Womens Health Associates - Flowood, Ms	TOTAL	4	2	2	8
	Gregory Vance	1	1	1	3
	Kay Midler	3	0	0	3
	Shane Sims	0	0	1	1
John Cook - Flowood, Ms		0	0	1	1
Vanessa Givens - Germantown, Tn		1	0	0	1
James Beckham - Greenville, Ms		1	0	0	1
Delta Medical Group - Greenville, Ms	TOTAL	0	5	6	11
	Janice Adams	0	2	2	4
	Lakeisha Richardson	0	3	4	7
Greenwood Obstetrics & Gynecology Associates - Greenwood, MS	TOTAL	4	3	1	8
	Nneka Okezie-Okeh	1	0	1	2
	Tracey Mullins	3	2	0	5

TABLE 4: Number of Unique Beneficiaries Started on Makena (Continued)

(January 1, 2017 - January 31, 2018)

Practice / Physician		Pharmacy Program			
		FFS	UHC	MAG	Total
Woman's Health Clinic of Grenada - Grenada, Ms	TOTAL	1	1	3	5
	Woman's Health Clinic of Grenada	0	1	0	1
	Gale Moore	1	0	3	4
Aimee Robinson - Grenada, Ms		1	0	0	1
Wendy Shaw - Gulfport, Ms		0	1	2	3
Gulfport Obstetrical & Gynecol - Gulfport, Ms	TOTAL	1	4	5	10
	Ashley Dean-Reaves	0	0	1	1
	Jacob Lassiter	0	0	2	2
	David Taylor	1	3	2	6
	Kathrine Hicks	0	1	0	1
Woman's Clinic - Gulfport, MS	TOTAL	2	4	2	8
	Keith Goodfellow	1	0	0	1
	John Pappas	0	2	0	2
	Thomas Lehman	1	0	1	2
	Shahira Hanna	0	2	1	3
Hattiesburg Clinic ObGyn - Hattiesburg, Ms	TOTAL	5	3	5	13
	Amanda Sellers	0	0	1	1
	Benjamin Moore	1	0	2	3
	Deanna Stewart	0	0	1	1
	Hilton Gillespie	1	1	0	2
	Jeffrey Hudson	0	1	1	2
	Libby Kot	0	1	0	1
	Louis Benton	3	0	0	3
Shantele Hinton - Hattiesburg, Ms		1	0	0	1
Traci Suber - Hattiesburg, Ms		1	0	0	1
Womens Pavilion Of South Mississippi - Hattiesburg, Ms	TOTAL	5	7	8	20
	Eldred Wiser	1	0	1	2
	Joseph Mcintire	0	1	1	2
	Joseph Washburne	0	2	2	4
	Samuel Cole	2	3	1	6
	Eugene Shannon	2	0	1	3
	Jana Keith	0	1	2	3
East Lakeland Ob-Gyn Assoc - Jackson, Ms	TOTAL	2	1	1	4
	Shani Meck	1	0	0	1
	William Bush	1	0	0	1
	Ashley Canizaro	0	1	0	1
	Natasha Hardeman	0	0	1	1
University Medical Center - Jackson, Ms	TOTAL	11	20	28	59
	George Ball	0	0	1	1
	Sarah Novotny	4	10	11	25
	Charlotte Peavie	0	0	2	2
	Amber Shiflett	1	1	0	2
	Elizabeth Lutz	1	0	0	1
	Jermaine Gray	0	1	3	4
	Lindsey Turner	1	0	1	2
	Michelle Owens	3	5	8	16
	Rachael Morris	1	1	1	3
	Rebecca Bates	0	1	1	2
	Sheila Bouldin	0	1	0	1
River Oaks Hospital - Jackson, Ms	TOTAL	4	3	7	14
	Robert Naef	4	1	2	7
	Walter Wolfe	0	2	0	2
	Michael Livingston	0	0	5	5

TABLE 4: Number of Unique Beneficiaries Started on Makena (Continued)

(January 1, 2017 - January 31, 2018)

Practice / Physician		Pharmacy Program			
		FFS	UHC	MAG	Total
South Central Regional Medical - Laurel, Ms	TOTAL	0	0	4	4
	Jennifer Roberts	0	0	3	3
	Sonja Johnson	0	0	1	1
Robert Desantis - Laurel, Ms		0	0	2	2
Stephanie Gong - Madison, Ms		0	0	1	1
Cynthia Bean - Madison, Ms		1	0	3	4
The Womens Health Center - McComb, MS	TOTAL	4	3	4	11
	Kevin Richardson	1	0	1	2
	Anh Vu	1	0	1	2
	Louise Gombako-Amos	2	3	2	7
Roy Bors-Koefoed - Memphis, Tn		3	5	12	20
Jacques Samson - Memphis, Tn		0	0	1	1
Meridian ObGyn - Meridian, Ms	TOTAL	0	1	2	3
	Elizabeth Trest	0	1	1	2
	Melissa Bryan	0	0	1	1
Womans Group of Meridian Meridian, Ms	TOTAL	9	2	4	15
	Heather Patchin	0	1	0	1
	Nicole Powe	0	1	3	4
	William Hamilton	0	0	1	1
Virginia Nelson - Meridian, Ms		0	1	1	2
Leslie Bender - Meridian, Ms		0	1	0	1
Urelaine Simon - Hart - Meridian, Ms		1	0	0	1
Greater Meridian Health Clinic - Meridian, Ms	TOTAL	1	1	0	2
	Candace Pringle	0	1	0	1
	Ericka Vaughn	1	0	0	1
Central MS Family Health Center - Meridian, MS	TOTAL	0	1	2	3
	Michelle Roark	0	0	1	1
	Linda Mclendon	0	1	1	2
Susan Baker - Mobile, Al		0	0	1	1
Delta Health Center, Inc. - Mound Bayou, Ms	TOTAL	2	0	1	3
	Michael Morris	0	0	1	1
	Jalarna Grant	2	0	0	2
Natchez Women's Center - Natchez, Ms	TOTAL	0	2	3	5
	Duncan Guedon	0	1	1	2
	Melissa Jones	0	1	1	2
	Kappi Rushing	0	0	1	1
Kofi Kumi - Natchez, Ms		3	1	2	6
Chi Dola - New Orleans, La		1	0	0	1
Mississippi Coast OB/Gyn - Ocean Springs, MS	TOTAL	0	2	2	4
	Gregory Horn	0	0	1	1
	William Moore	0	2	1	3
Michael Christie		0	7	2	9
Primary Care Group - Olive Branch, Ms	TOTAL	2	2	2	6
	Robin Taylor	1	1	1	3
	Laxmisilpa Hansen	0	1	1	2
	Sarah Ziebarth	1	0	0	1
Charles Ryan - Olive Branch, Ms		1	0	0	1
Oxford Ob/Gyn Associates - Oxford, Ms	TOTAL	0	3	1	4
	Marion Hunt	0	1	0	1
	Elizabeth Mize	0	1	1	2
Oxford Clinic For Women - Oxford, Ms	TOTAL	0	4	1	5
	Ronald Smith	0	1	0	1
	William Henderson	0	3	1	4

TABLE 4: Number of Unique Beneficiaries Started on Makena (Continued)

(January 1, 2017 - January 31, 2018)

Practice / Physician		Pharmacy Program			
		FFS	UHC	MAG	Total
Gulf Coast Ob/Gyn - Pascagoula, Ms	TOTAL	0	3	1	4
	Marshall White	0	1	0	1
	Nestor Delgado	0	1	0	1
	Holly Summerlin	0	1	1	2
Highland Center for Womens Health - Picayune, Ms	TOTAL	3	1	3	7
	James Blount	0	0	3	3
	Cynthia Jean-Pierre	3	1	0	4
John Jones - Richton, Ms		0	0	2	2
Melissa Smith - Slidell, La		1	0	0	1
Gregory Berault - Slidell, La		0	1	0	1
Memphis Obstetrics & Gynecology - Southaven, Ms	TOTAL	1	1	6	8
	Jane Mcadory	0	0	2	2
	Elaine Thompson	0	1	0	1
	Fazal Manejwala	0	0	1	1
	Alok Kumar	1	0	1	2
	Daniel Lee	0	0	2	2
Starkville Clinic For Women Pa - Starkville, Ms	TOTAL	4	6	5	15
	Jacob Brown	2	2	0	4
	Allison Bennett	0	1	3	4
	Chester Lott	1	1	0	2
	Kristen Fyke	1	2	1	4
	William Locke	0	0	1	1
Miguel Luna Russo - Tupelo, Ms		1	0	0	1
Street Clinic - Vicksburg, Ms	TOTAL	0	3	2	5
	Thomas Weeks	0	1	0	1
	Sarah Williams	0	2	2	4
Timothy Whittle - West Point, Ms		0	2	0	2
Dian Kinch - West Point, Ms		0	1	0	1
John Shields - West Point, Ms		0	1	0	1
Barbrette Baldwin - West Point, Ms		0	0	2	2

In order to estimate delays in obtaining Makena, MS-DUR examined the number of days between the first pharmacy claim and the first medical claim for administration following the pharmacy claim. It should be noted that this is the time between dispensing and administration and NOT the time delay in being able to obtain the medication.

- In Table 5, the time between dispensing and administering Makena varied from the same day to up to 4 weeks; with an average of 9.6 days.

TABLE 5: Association of First Pharmacy Claims for Makena With Medical Claims For Injection of Product[a]

(January 1, 2017 - January 31, 2018)

		Pharmacy Program			
		FFS	UHC	MAG	Total
TOTAL number of beneficiaries		89	133	181	403
Number with Associated Medical Claim		42	71	102	215
Number of Days Between First Pharmacy Claim and First Medical Claim	0 days	4	4	8	16
	1 - 3 days	5	11	15	31
	4 - 7 days	15	23	27	65
	8 - 10 days	2	11	9	22
	11 - 14 days	3	11	15	29
	15 - 17 days	7	3	8	18
	18 - 21 days	2	3	12	17
	22 - 28 days	4	5	8	17
	Mean	9.3	9.0	10.1	9.6
J-code Claim With Drug Charge for		2	1	1	4
CPT Code for Injection		35	57	70	162

[a] *First prescription fill for Makena was associated with first medical claim within 28 days having J-code for Makena and.or CPT code for injection.*

[b] *J-code charge for Makena associated with prescription fill could indicate double-billing error or administration of first dose in office using buy-and-bill.*

MS-DUR contacted AMAG Pharmaceuticals and two of the top dispensing specialty pharmacies for Makena in Mississippi, Transcript Pharmacy and Briovarx, to discuss the ordering and delivery process and to identify any problems with timely delivery of the product. Representatives involved in the dispensing of Makena from all three companies provided MS-DUR with information. A summary of the information from each company is provided below:

AMAG Pharmaceuticals – Makena is a limited-distribution specialty pharmaceutical product. The manufacturer prefers to ship the product to select specialty pharmacies, which were designated based on additional patient support provided. When a provider prescribes Makena, the manufacturer is contacted. AMAG Pharmaceuticals' program, Makena Care Connect, has a care manager assigned for each state. Once notified by the provider, the care manager contacts the patient, conducts a benefits investigation, and arranges copay assistance when needed. Once the benefits investigation is complete, the care manager sends the information to the approved specialty pharmacy, Transcript Pharmacy. Other pharmacies may be utilized at the request of the pharmacy benefits manager (PBM). After the specialty pharmacy receives a prescription from AMAG Pharmaceuticals, they contact the patient to confirm they want the prescription filled and after talking with the patient, the pharmacy routinely ships the medication to the prescriber ("white bagging"). According to the care manager for Mississippi, the process from the time the physician writes the prescription until the time the medication is delivered to the practice site is typically 2-4 days. To help educate physicians on the appropriate procedure for prescribing Makena, AMAG Pharmaceuticals has representatives calling on physician practices. The Mississippi Care Manager indicated that the major delay in shipping the medication in a timely manner to the provider is the difficulty of contacting Medicaid beneficiaries by phone. The care manager reported that Mississippi Medicaid is the easiest payer in the

state for getting Makena approved for a beneficiary. There are no prior authorization requirements with Medicaid that delay the dispensing.

Transcript Pharmacy – Transcript Pharmacy is the specialty pharmacy preferred by AMAG Pharmaceuticals for distribution of Makena in the state of Mississippi. Transcript Pharmacy has Makena stocked and available in their pharmacy and can typically dispense the product either the same or next day upon receiving information about the prescription from the manufacturer. Makena is shipped overnight to the prescriber's practice. Transcript also echoed the comments from AMAG Pharmaceuticals that Makena coverage is not an issue for Mississippi Medicaid beneficiaries. Transcript Pharmacy employs a representative who provides education to providers regarding the ordering process for Makena.

Briovarx – Briovarx, the preferred specialty pharmacy for United Healthcare, stocks Makena in their pharmacy and can quickly ship the product. They stated that it is easy to get Makena approved for Mississippi Medicaid beneficiaries. No prior authorization is required. Briovarx also identified that the only delay noted occurs when there is difficulty contacting the beneficiary by phone to confirm the prescription.

CONCLUSIONS AND RECOMMENDATIONS

Results from this project indicate that any delays experienced by prescribing providers in obtaining the product are most likely caused by the manufacturer and/or specialty pharmacy having difficulty contacting the beneficiary before shipment can be approved. Another potential problem that may be limiting utilization could inexperience with Makena's appropriate process for contacting the manufacturer when prescribing.

The manufacturer requires certain paperwork be filed by physicians before they approve shipping of the product for a patient. The manufacturer provides an '800' number and a care manager for providing assistance in approvals. Transcript Pharmacy, the designated specialty pharmacy distributor in Mississippi, also provides support for physicians. Both the manufacturer and Transcript Pharmacy indicated they had resources committed to physician education in order to help improve the timely dispensing of Makena.

Recommendations:

1. MS-DUR should share results with other health service office directors within Mississippi Medicaid who are examining access to Makena.

2. MS-DUR should assist in coordinating educational initiatives for providers and beneficiaries. Provider education should highlight benefits of prescribing Makena, outline the ordering process and stress the need for patient education regarding the confirmation phone call from the manufacturer that must be completed prior to initiation of treatment.

3. MS-DUR should work with AMAG Pharmaceuticals, Transcript Pharmacy and other specialty pharmacies to coordinate additional education. The benefits of Makena and the ordering process for prescribers, especially those prescribers who may not be as familiar with the process, should also be addressed.

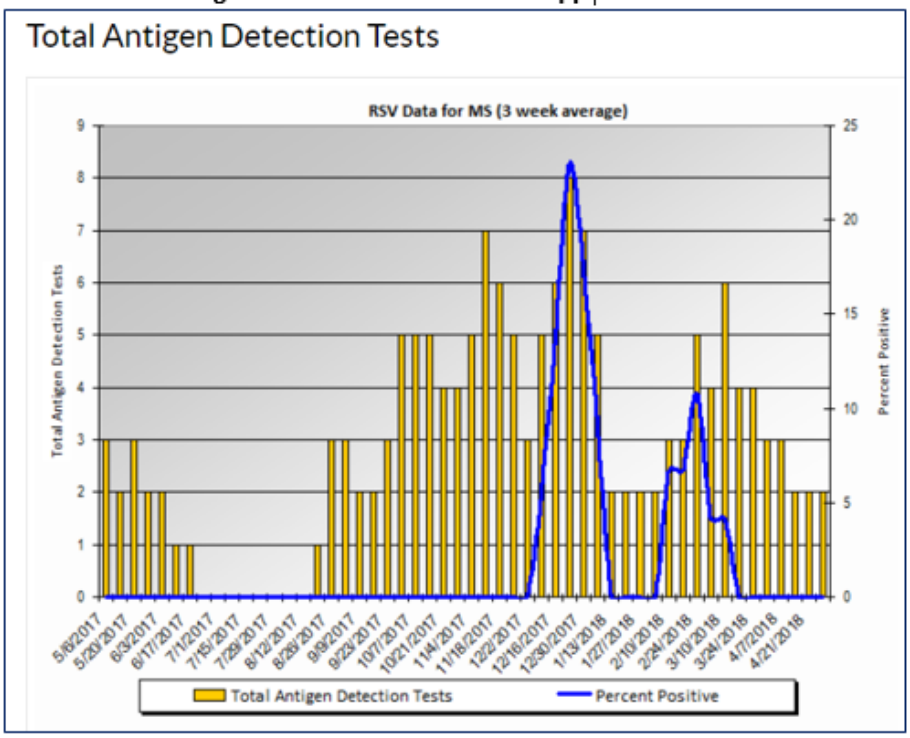
PALIVIZUMAB UTILIZATION UPDATE: 2015-16 THROUGH 2017-18 SEASONS

BACKGROUND

Palivizumab (Synagis®) was licensed in June 1998 by the Food and Drug Administration for the reduction of serious lower respiratory tract infection caused by respiratory syncytial virus (RSV) in children at increased risk of severe disease. The Mississippi Division of Medicaid (DOM) supports the administration of Synagis® for children meeting the American Academy of Pediatrics (AAP) criteria for RSV immunoprophylaxis. On July 28, 2014, the AAP published their latest policy statement, "Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection" on-line in *Pediatrics*[1]. At the August 2014 DUR Board Meeting the board voted to adopt the new guidelines as the criteria to be used by DOM for the 2014-15 Season.

In the United States, RSV infections typically occur at the time of annual community outbreaks, during late fall, winter, and early spring. There may be variation in the timing of outbreaks between regions and between communities in the same region. The recommended beginning and ending dates for the RSV season in Mississippi is determined by monitoring the antigen detection test and when applicable, the PCR (polymerase chain reaction) results reported by the Centers for Disease Control (CDC) National Respiratory and Enteric Surveillance System (NREVSS). Participating laboratories report weekly to CDC the total number of RSV tests performed that week, and the number of those tests that were positive. For example, the antigen detection test results for Mississippi are shown in Figure 1.[2] Each point on the trend graph displays the average number of RSV tests that were performed, and the average percent of those that were positive from three adjacent weeks: the specified week, and the weeks preceding and following it. This is also known as a centered 3-

FIGURE 1: RSV Antigen Detection Data for Mississippi



[1] American Academy of Pediatric Committee on Infectious Diseases and Bronchiolitis Guidelines Committee. Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection. *Pediatrics.* Available at http://pediatrics.aappublicaions.org/content/early/2014/07/23/peds.2014-1665.

[2] https://www.cdc.gov/surveillance/nrevss/rsv/index.html. (accessed 5/3/2018).

week moving average. There was insufficient data reported for MS during the 2017-2018 season to utilize PCR data. DOM also considers regional trend data, specifically the South region. In addition, DOM uses data from HHS Regional Trends. Mississippi is included in the Atlanta HHS 4 region. The DOM Office of Pharmacy consults with an infectious disease physician to determine the appropriate timeframe using the aforementioned CDC NREVSS data for determining the RSV season timeframe for Mississippi.

PALIVIZUMAB UTILIZATION

Table 1 shows a summary of palavizumab utilization for the last three seasons. The total number of beneficiaries treated has dropped slowly over the last 3 years. The average number of pharmacy claims per beneficiary rose slightly between the 2015-16 season and the 2016-17 season, but decreased to 3.3 for 2017-18 season. The average paid amount per beneficiary treated has fluctuated slightly and was $8,014 this last season. This lower amount is due to the slight decrease in the average number of claims per beneficiary during the last season.

TABLE 1: Palivizumab Utilization Summary by Season and Pharmacy Program

	Pharmacy Program			
	FFS	UHC	MAG	TOTAL
Season	Number of Unique Beneficiaries			
2015-16	70	144	157	371
2016-17	24	152	153	329
2017-18	18	142	154	314
	Mean Number of Claims/Beneficiary			
2015-16	2.8	3.5	3.6	3.4
2016-17	3.5	3.5	4.0	3.7
2017-18	3.3	3.1	3.4	3.3
	Total Dollars Paid			
2015-16	$419,724	$1,321,154	$1,409,679	$3,150,557
2016-17	$203,037	$1,401,091	$1,606,513	$3,210,641
2017-18	$94,015	$1,095,534	$1,326,848	$2,516,397
	Dollars Paid / Beneficiary			
2015-16	$5,996	$9,175	$8,979	$8,492
2016-17	$8,460	$9,218	$10,500	$9,759
2017-18	$5,223	$7,715	$8,616	$8,014

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

FDA DRUG SAFETY COMMUNICATIONS

FEBRUARY 2018 – April 2018

- FDA Drug Safety Communication: FDA review finds additional data supports the potential for increased long-term risks with antibiotic clarithromycin (Biaxin) in patients with heart disease. 2/22/2018
- FDA Drug Safety Communication: FDA warns of serious immune system reaction with seizure and mental health medicine lamotrigine (Lamictal). 4/25/2018

APPENDIX

MS-DUR BOARD COMMON ABBREVIATIONS

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