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

MISSISSIPPI DIVISION OF
MEDICAID

September 19, 2019 at 1:00pm

Woolfolk Building, Room 145

Jackson, MS

Prepared by:

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

Drug Utilization Review Board

Lauren Bloodworth, PharmD
University of MS School of Pharmacy
201D Faser Hall
University, MS 38677
Term Expires: June 30, 2021

Beverly Bryant, MD
UMMC, School of Medicine
2500 North State Street
Jackson, MS 39216
Term Expires: June 30, 2021

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

Tanya Fitts, MD
Lafayette Pediatric Clinic
1300 Access Road, Suite 400
Oxford, MS 38655
Term Expires: June 30, 2021

Ray Montalvo, MD (Chair)
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, 2021

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

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

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

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

Veda Vedanarayanan, MD
Mississippi Center for Advanced Medicine
7731 Old Canton Road, Suite B
Madison, MS 39110
Term Expires: June 30, 2021

2019 DUR Board Meeting Dates

March 7, 2019
May 23, 2019
September 19, 2019
December 5, 2019

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

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

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

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

MISSISSIPPI DIVISION OF MEDICAID
OFFICE OF THE GOVERNOR
DRUG UTILIZATION REVIEW BOARD
AGENDA
September 19, 2019

DUR Board Meeting Minutes

MISSISSIPPI DIVISION OF MEDICAID
DRUG UTILIZATION REVIEW (DUR) BOARD
MINUTES OF THE MAY 23, 2019 MEETING

DUR Board Members:	Sep 2018	Dec 2018	Mar 2019	May 2019
Lauren Bloodworth, PharmD	✓	✓		✓
Beverly Bryant, MD	✓	✓	✓	
Rhonda Dunaway, RPh	✓	✓	✓	✓
Tanya Fitts, MD	✓	✓	✓	✓
Juanice Glaze, RPh	✓	✓	✓	
Alice Messer, DNP, FNP-BC			✓	
Ray Montalvo, MD		✓	✓	
Holly Moore, PharmD	✓	✓		✓
Janet Ricks, DO	✓	✓	✓	✓
Dennis Smith, RPh	✓	✓	✓	✓
James Taylor, PharmD (Chair)	✓	✓	✓	✓
Veda Vedanarayanan, MD		✓	✓	✓
TOTAL PRESENT	**9**	**11**	**10**	**8**

Also Present:

Division of Medicaid (DOM) Staff:
Cindy Noble, PharmD, MPH, DUR Coordinator; Gail McCorkle, RPh, Clinical Pharmacist; Sue Reno, RN, Program Integrity; Vanessa Banks, RN, Program Integrity

University of Mississippi School of Pharmacy - MS-DUR Staff:
Eric Pittman, PharmD, MS-DUR Project Director

Conduent Staff:
Lew Anne Snow, RN, BSN, Pharmacy Services Sr. Analyst, Mississippi Medicaid Project

Change Healthcare Staff:
Paige Clayton, PharmD, On-Site Clinical Pharmacist; Cheryl Rogers, PharmD, Mississippi PA Pharmacist

IBM Watson Health:
Mary Sawardecker, MHA, RHIA, Analytic Consultant Sr., Mississippi Medicaid Project

Coordinated Care Organization (CCO) Staff:
Heather Odem, PharmD, Director of Pharmacy - Mississippi, UnitedHealthcare Community & State; Jenni Grantham, PharmD, Director of Pharmacy, Magnolia Health; Mike Todaro; PharmD, Vice President Pharmacy Operations, Magnolia Health; Trina Stewart, PharmD, Pharmacy Manager, Molina Healthcare

Visitors:
Jason Swartz, Otsuka; Eric Marchant, Amgen; Susan Abbott, AMAG; Brynna Clark, MPhA; Judy Clark, Consultant; Evelyn Johnson, Capital Resources; Allison Balducci, BMS; Meg Pearson, MS State Department of Health; Chris Shannon, MS Department of Finance and Administration; Wengora Thompson, March of Dimes; Mariah Cole, Pharmacy Student; Anna Crider, Pharmacy Student.

Call to Order:
Dr. Taylor, Chair, called the meeting to order at 1:05pm and welcomed everyone.

OLD BUSINESS:
Dr. Bloodworth moved to approve the minutes from the March 2018 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 January – March 2019. No significant trends or shifts were noted for this period.

NEW Business

Update on MS-DUR Educational Interventions:
Dr. Pittman provided an overview of all DUR mailings that occurred February – April 2019.

Special Analysis Projects:
Update on Makena Utilization in Mississippi Medicaid
Dr. Meg Pearson with the MS State Department of Health gave a historical presentation to the Board on the Department of Health's efforts to improve access to Makena in Mississippi. Dr. Pittman followed up Dr. Pearson by providing a report on an updated DUR analysis project on Makena. The DUR project highlighted the impact of the Clinician Administered Drugs and Implantable Drug System Devices (CADD) List on Makena prescribing for Medicaid beneficiaries. A robust discussion occurred regarding additional efforts that could increase the utilization of Makena in beneficiaries with at risk pregnancies. Dr. Fitts asked if there was a "fast-track" approval process in Medicaid for mothers identified by providers as high risk of preterm birth to prevent delays in receiving Makena. Dr. Bloodworth suggested DOM/MS-DUR target providers and beneficiaries in those counties with preterm birth rates higher than the state average for education. The Board also encouraged DOM to explore the potential to partner with primary care physicians, local pharmacies, and home health agencies to administer Makena to beneficiaries in rural areas where access to providers may be limited.

MS-DUR presented the following recommendations:

1. Results should be shared with other health service office directors within Mississippi Medicaid who are currently working to improve access to Makena and an active task force should be developed to address barriers. The results of this analysis should be presented to the MS State Department of Health's Infant Mortality Committee, external agencies, professional associations and healthcare organizations by DOM / MS-DUR.

2. MS-DUR should continue assisting in educating providers and beneficiaries about

Makena. The ordering process can be confusing, particularly for those providers who may not routinely prescribe this medication. Provider education should highlight the ordering process and stress the need for patient education.

3. Providing data issues can be correlated, MS-DUR will work with DOM to assess health outcomes associated with beneficiaries who have received Makena. Specifically, beneficiary gestational weeks at delivery will be compared for pregnancy(s) prior to and after Makena use. Healthcare costs associated with each pregnancy will also be compared.

4. CCOs were invited to present at the next DUR meeting their case management services for Mississippi Medicaid beneficiaries identified as high risk for preterm birth.

Dr. Bloodworth made a motion, seconded by Mr. Smith, to accept the MS-DUR recommendations. The motion was unanimously approved by the Board.

Update on CGRP Inhibitor Prescribing in Mississippi Medicaid

Dr. Pittman presented an analysis on the utilization of CGRP inhibitors in Medicaid since their introduction in May 2018. The majority of claims in Medicaid have occurred since December 2018. The board engaged in healthy discussion of CGRP inhibitor utilization.

MS-DUR presented the following recommendation:

1. MS-DUR will work with the DOM to assess outcomes associated with CGRP inhibitors. MS-DUR will specifically compare change in hospitalizations, ED visits, and utilization of rescue agents for beneficiaries diagnosed with both episodic and chronic migraine receiving CGRP inhibitors.

Ms. Dunaway made a motion, seconded by Dr. Bloodworth, to accept the MS-DUR recommendations. The motion was unanimously approved by the Board.

Concurrent Prescribing of Opioids and Antipsychotics

Dr. Pittman presented the Board with a report on the concurrent prescribing of opioids and antipsychotics. Part of the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act contains Medicaid provisions that pertain to drug review and utilization. One requirement within the Medicaid provisions is for state Medicaid programs to have an automated claims review process to monitor concurrent prescribing of opioids and antipsychotics. The Board held a vigorous discussion regarding options for reviewing concurrent use of opioid and antipsychotics. The consensus from the Board was for DOM to implement a retrospective DUR intervention initially targeting chronic concurrent users of opioids and antipsychotics.

MS-DUR presented the following recommendations:

1. MS-DUR should work with the DOM to develop an automatic claims review process to monitor concomitant use of opioids and antipsychotics and implement the process prior to October 1, 2019.

2. MS-DUR should implement an educational initiative to notify providers and/or pharmacists, depending on the review process being initiated.

Dr. Bloodworth made a motion, seconded by Dr. Fitts, to accept the MS-DUR recommendations. The motion was unanimously approved by the Board.

FDA Drug Safety Updates:
Dr. Pittman presented FDA drug safety communications for March 2019 – April 2019. The Board discussed the safety update related to the sudden discontinuation of opioid pain medicines and the required label changes to guide prescribers on gradual, individualized tapering. The Board expressed a need for providers to have access to tools to calculate morphine equivalent daily doses and conversion factors between formulations. Dr. Taylor referred to a tapering tool that he helped to develop with the Atom Alliance. The Board recommended DOM provide education through a link or reference to a tapering tool for prescribers.

Pharmacy Program Update:
Dr. Noble took this opportunity to update the Board on the opioid edits that will be implemented August 2019. She provided a brief description of the edits that are based on recommendations made by the DUR Board.

Dr. Noble discussed the FDA indication of Vyvanse for binge eating disorder in adults. Presently the only stimulant with FDA approval for binge eating disorder is Vyvanse. No other stimulants have compendia support for binge eating disorder at this time. The recommendation was to add the ICD-10 codes for binge eating disorder to the list of approved diagnoses for stimulants when there is FDA approved indication or compendia support. The Board expressed no objections to the recommendation to add binge eating disorder as one of the approved diagnoses for stimulants.

Dr. Noble also informed the Board that on July 1, 2019, the prescription drug limit for Medicaid beneficiaries will be expanded to 6 prescriptions monthly. She noted that some of the CCOs have already been allowing beneficiaries to receive 6 prescriptions monthly.

Dr. Noble took this opportunity to recognize the Board members whose terms of service on the Board have been completed. She thanked Juanice Glaze, Alice Messer, and James Taylor for their service and dedication to the DUR Board. James Taylor has agreed to serve another term on the DUR Board.

Next Meeting Information:
Dr. Taylor announced that the next meeting of the DUR Board will take place on September 19, 2019 at 1pm.

The meeting adjourned at 2:59 pm.

Submitted,

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

Meeting Location: Woolfolk Building, 501 North West Street, Conference Room 145, 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: May 23, 2019 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.

Resource Utilizaton Review

TABLE 04A: ENROLLMENT STATISTICS FOR LAST 6 MONTHS January 1, 2019 through June 30, 2019							
			Jan-19	Feb-19	Mar-19	Apr-19	May-19	Jun-19
Total enrollment			696,335	695,664	694,715	692,421	689,313	684,668
Dual-eligibles			157,060	156,968	156,513	156,275	155,791	155,350
Pharmacy benefits			587,215	586,232	585,258	583,185	580,381	575,403
	LTC		17,216	17,204	17,210	17,111	17,043	16,718
	PLAN %	FFS	25.4%	25.5%	25.6%	25.3%	24.7%	23.9%
		MSCAN-UHC	32.1%	31.5%	30.9%	30.5%	30.3%	30.2%
		MSCAN-Magnolia	36.9%	36.3%	35.8%	35.3%	35.2%	35.2%
		MSCAN-Molina	5.6%	6.7%	7.7%	8.9%	9.8%	10.7%

TABLE 04B: PHARMACY UTILIZATION STATISTICS FOR LAST 6 MONTHS January 1, 2019 through June 30, 2019							
		Jan-19	Feb-19	Mar-19	Apr-19	May-19	Jun-19
# Rx Fills	FFS	112,013	112,721	106,530	108,488	101,610	90,234
	MSCAN-UHC	182,790	181,859	161,133	162,497	149,042	128,569
	MSCAN-Mag	236,702	236,206	213,733	214,564	199,058	175,546
	MSCAN-Mol	14,254	18,011	20,602	30,894	30,465	29,348
# Rx Fills / Bene	FFS	0.8	0.8	0.7	0.7	0.7	0.7
	MSCAN-UHC	1.0	1.0	0.9	0.9	0.8	0.7
	MSCAN-Mag	1.1	1.1	1.0	1.0	1.0	0.9
	MSCAN-Mol	0.4	0.5	0.5	0.6	0.5	0.5
$ Paid Rx	FFS	$12,588,513	$12,552,029	$12,096,669	$12,664,778	$11,613,231	$10,786,795
	MSCAN-UHC	$16,077,500	$15,406,814	$14,656,567	$14,589,940	$14,059,528	$12,860,199
	MSCAN-Mag	$20,346,900	$20,417,845	$19,782,775	$20,052,602	$18,910,480	$17,253,438
	MSCAN-Mol	$1,015,019	$1,260,039	$1,285,875	$1,964,406	$2,092,930	$2,138,799
$ /Rx Fill	FFS	$112.38	$111.35	$113.55	$116.74	$114.29	$119.54
	MSCAN-UHC	$87.96	$84.72	$90.96	$89.79	$94.33	$100.03
	MSCAN-Mag	$85.96	$86.44	$92.56	$93.46	$95.00	$98.28
	MSCAN-Mol	$71.21	$69.96	$62.42	$63.59	$68.70	$72.88
$ /Bene	FFS	$84.40	$83.97	$80.74	$85.84	$81.01	$78.44
	MSCAN-UHC	$85.29	$83.43	$81.05	$82.03	$79.95	$74.01
	MSCAN-Mag	$93.90	$95.95	$94.42	$97.41	$92.56	$85.18
	MSCAN-Mol	$30.87	$32.08	$28.53	$37.85	$36.80	$34.74

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 JUN 2019 (FFS AND CCOs)

Category	Month Year	Rank Volume	# RXs	$ Paid	# Unique Benes
CNS stimulants	Jun 2019	1	19,368	$3,964,079	17,031
	May 2019	1	24,556	$5,157,948	21,192
	Apr 2019	1	27,928	$5,959,178	24,241
narcotic analgesic combinations	Jun 2019	2	14,640	$640,267	13,530
	May 2019	2	15,686	$689,020	14,063
	Apr 2019	5	15,609	$659,720	14,214
nonsteroidal anti-inflammatory agents	Jun 2019	3	13,537	$182,125	12,969
	May 2019	3	14,559	$197,152	13,869
	Apr 2019	6	14,968	$200,349	14,309
atypical antipsychotics	Jun 2019	4	12,587	$3,171,566	10,961
	May 2019	7	13,408	$3,370,033	11,429
	Apr 2019	8	13,605	$3,242,705	11,729
adrenergic bronchodilators	Jun 2019	5	11,091	$683,841	9,677
	May 2019	6	13,576	$781,656	11,820
	Apr 2019	4	15,946	$942,819	13,895
SSRI antidepressants	Jun 2019	6	11,068	$132,787	10,429
	May 2019	9	11,818	$137,667	10,970
	Apr 2019	10	11,929	$140,567	11,115
antihistamines	Jun 2019	7	10,805	$159,443	10,473
	May 2019	5	13,835	$203,411	13,352
	Apr 2019	3	16,395	$241,409	15,801
aminopenicillins	Jun 2019	8	10,402	$130,735	10,239
	May 2019	4	14,315	$182,747	14,045
	Apr 2019	2	17,418	$227,748	17,094
leukotriene modifiers	Jun 2019	9	9,886	$165,191	9,730
	May 2019	8	12,060	$201,206	11,775
	Apr 2019	7	13,874	$233,628	13,560
proton pump inhibitors	Jun 2019	10	9,871	$327,730	9,560
	May 2019	11	10,559	$356,972	10,092
	Apr 2019	13	10,598	$354,988	10,165

TABLE D: TOP 10 DRUG CATEGORIES BY DOLLARS PAID IN JUN 2019 (FFS AND CCOs)

Category	Month Year	Rank Paid Amt	# RXs	$ Paid	# Unique Benes
CNS stimulants	Jun 2019	1	19,368	$3,964,079	17,031
	May 2019	1	24,556	$5,157,948	21,192
	Apr 2019	1	27,928	$5,959,178	24,241
atypical antipsychotics	Jun 2019	2	12,587	$3,171,566	10,961
	May 2019	2	13,408	$3,370,033	11,429
	Apr 2019	2	13,605	$3,242,705	11,729
insulin	Jun 2019	3	4,834	$2,667,594	3,678
	May 2019	4	5,059	$2,819,499	3,775
	Apr 2019	4	5,037	$2,746,664	3,784
antiviral combinations	Jun 2019	4	796	$2,523,358	739
	May 2019	3	884	$2,849,221	808
	Apr 2019	3	891	$2,870,873	809
TNF alpha inhibitors	Jun 2019	5	358	$2,044,763	340
	May 2019	5	374	$2,133,756	345
	Apr 2019	5	370	$2,137,678	339
factor for bleeding disorders	Jun 2019	6	85	$1,198,505	63
	May 2019	6	87	$1,363,104	77
	Apr 2019	6	99	$1,470,667	75
gamma-aminobutyric acid analogs	Jun 2019	7	8,925	$1,108,157	8,391
	May 2019	7	9,320	$1,232,620	8,572
	Apr 2019	7	9,178	$1,248,111	8,516
bronchodilator combinations	Jun 2019	8	3,473	$1,047,217	3,196
	May 2019	8	3,699	$1,137,935	3,380
	Apr 2019	8	3,743	$1,162,977	3,462
CFTR combinations	Jun 2019	9	38	$731,165	35
	May 2019	11	38	$735,435	36
	Apr 2019	11	38	$732,365	36
selective immunosuppressants	Jun 2019	10	303	$703,847	278
	May 2019	12	315	$698,500	295
	Apr 2019	13	299	$609,803	278

TABLE E: TOP 25 DRUG MOLECULES
BY NUMBER OF CLAIMS IN JUN 2019 (FFS and CCOs)

Drug Molecule Therapeutic Category	May 2019 # Claims	Jun 2019 # Claims	Jun 2019 $ Paid	Jun 2019 # Unique Benes
albuterol / adrenergic bronchodilators	13,027	10,494	$504,545	9,205
amoxicillin / aminopenicillins	14,271	10,354	$129,890	10,194
montelukast / leukotriene modifiers	12,060	9,886	$165,191	9,730
acetaminophen-hydrocodone / narcotic analgesic combinations	10,372	9,650	$131,031	9,147
gabapentin / gamma-aminobutyric acid analogs	7,818	7,503	$114,348	7,087
cetirizine / antihistamines	9,218	6,761	$87,449	6,673
ibuprofen / nonsteroidal anti-inflammatory agents	7,047	6,279	$74,652	6,144
lisdexamfetamine / CNS stimulants	8,091	6,066	$1,813,777	5,992
clonidine / antiadrenergic agents, centrally acting	6,195	5,668	$110,288	5,389
amlodipine / calcium channel blocking agents	6,321	5,662	$49,877	5,481
azithromycin / macrolides	8,214	5,230	$95,067	5,111
omeprazole / proton pump inhibitors	5,528	5,168	$53,639	5,063
fluticasone nasal / nasal steroids	6,836	5,123	$86,222	5,080
amphetamine-dextroamphetamine / CNS stimulants	5,835	4,792	$228,515	4,178
methylphenidate / CNS stimulants	5,881	4,644	$995,402	4,249
ondansetron / 5HT3 receptor antagonists	5,499	4,594	$75,637	4,453
triamcinolone topical / topical steroids	4,644	4,565	$80,218	4,428
mupirocin topical / topical antibiotics	4,045	4,246	$75,811	4,168
sulfamethoxazole-trimethoprim / sulfonamides	4,299	4,048	$81,603	3,967
sertraline / SSRI antidepressants	4,120	3,921	$45,725	3,672
ranitidine / H2 antagonists	4,302	3,847	$56,179	3,722
atorvastatin / HMG-CoA reductase inhibitors (statins)	3,898	3,815	$46,152	3,613
guanfacine / antiadrenergic agents, centrally acting	4,217	3,723	$118,387	3,558
amoxicillin-clavulanate / penicillins/beta-lactamase inhibitors	5,205	3,673	$84,191	3,625
metformin / biguanides	3,750	3,666	$39,963	3,502

TABLE F: TOP 25 DRUG MOLECULES
BY DOLLARS PAID IN JUN 2019 (FFS and CCOs)

Drug Molecule Therapeutic Category	May 2019 $ Paid	Jun 2019 $ Paid	Jun 2019 # Claims	Jun 2019 # Unique Benes
lisdexamfetamine / CNS stimulants	$2,411,814	$1,813,777	6,066	5,992
adalimumab / TNF alpha inhibitors	$1,547,438	$1,438,318	230	217
paliperidone / atypical antipsychotics	$1,284,874	$1,207,962	556	509
methylphenidate / CNS stimulants	$1,294,222	$995,402	4,644	4,249
insulin aspart / insulin	$876,228	$825,330	1,332	1,266
insulin glargine / insulin	$853,809	$785,689	1,720	1,663
aripiprazole / atypical antipsychotics	$744,793	$719,264	3,176	2,981
pregabalin / gamma-aminobutyric acid analogs	$743,219	$709,999	1,397	1,368
deferasirox / chelating agents	$736,998	$681,084	63	52
bictegravir/emtricitabine/tenofovir / antiviral combinations	$641,847	$638,493	212	205
dexmethylphenidate / CNS stimulants	$846,926	$630,938	2,511	2,133
etanercept / TNF alpha inhibitors	$526,444	$544,696	115	111
cobicistat/elvitegravir/emtricitabine/tenofov / antiviral combinations	$634,568	$511,836	168	162
albuterol / adrenergic bronchodilators	$619,445	$504,545	10,494	9,205
lurasidone / atypical antipsychotics	$528,441	$501,719	375	364
sofosbuvir-velpatasvir / antiviral combinations	$653,723	$499,454	31	29
ivacaftor-lumacaftor / CFTR combinations	$420,797	$484,111	27	25
hydroxyprogesterone / progestins	$483,473	$483,529	149	140
ciprofloxacin-dexamethasone otic / otic steroids with anti-infectives	$375,020	$477,190	2,040	2,022
somatropin / growth hormones	$514,289	$442,285	111	100
budesonide-formoterol / bronchodilator combinations	$448,095	$428,396	1,301	1,278
insulin detemir / insulin	$447,957	$425,457	801	777
anti-inhibitor coagulant complex / factor for bleeding disorders	$580,475	$418,507	5	3
fluticasone-salmeterol / bronchodilator combinations	$466,484	$413,089	1,151	1,117
lacosamide / miscellaneous anticonvulsants	$454,490	$407,854	468	429

TABLE G: TOP 25 DRUG MOLECULES
BY CHANGE IN NUMBER OF CLAIMS FROM APR 2019 TO JUN 2019 (FFS and CCOs)

Drug Molecule	Apr 2019 # Claims	May 2019 # Claims	Jun 2019 # Claims	Jun 2019 $ Paid	Jun 2019 # Unique Benes
ciprofloxacin-dexamethasone otic / otic steroids with anti-infectives	1,369	1,600	2,040	$477,190	2,022
mupirocin topical / topical antibiotics	3,584	4,045	4,246	$75,811	4,168
hydrocortisone/neomycin/polymyxin b otic / otic steroids with anti-infectives	58	60	319	$19,433	315
triamcinolone topical / topical steroids	4,417	4,644	4,565	$80,218	4,428
hydroxyzine / miscellaneous anxiolytics, sedatives and hypnotics	2,553	2,655	2,695	$40,344	2,605
ofloxacin otic / otic anti-infectives	392	429	471	$16,028	460
hydrocortisone topical / topical steroids	2,024	2,186	2,083	$45,880	2,040
buspirone / miscellaneous anxiolytics, sedatives and hypnotics	1,845	1,905	1,889	$26,589	1,824
silver sulfadiazine topical / topical antibiotics	117	160	149	$3,120	147
pimecrolimus topical / miscellaneous topical agents	320	319	348	$139,924	344
ofloxacin ophthalmic / ophthalmic anti-infectives	184	223	212	$4,818	209
diclofenac topical / topical non-steroidal anti-inflammatories	487	535	514	$45,130	495
azelastine nasal / nasal antihistamines and decongestants	6	7	32	$798	31
hydrochlorothiazide-valsartan / angiotensin II inhibitors with thiazides	175	193	199	$3,994	195
diclofenac / nonsteroidal anti-inflammatory agents	1,052	1,079	1,076	$18,597	1,059
nifedipine / calcium channel blocking agents	974	982	996	$23,810	947
methotrexate / antimetabolites	351	386	373	$11,123	361
mometasone nasal / nasal steroids	18	6	39	$2,200	38
megestrol / progestins	149	162	170	$6,277	164
formoterol-glycopyrrolate / bronchodilator combinations	52	67	72	$25,746	71
acyclovir topical / topical antivirals	39	46	58	$36,067	54
fluvoxamine / SSRI antidepressants	157	166	175	$6,920	156
diltiazem / group IV antiarrhythmics	410	407	427	$11,686	416
glycopyrrolate / anticholinergics/antispasmodics	141	148	158	$11,966	149
adapalene-benzoyl peroxide topical / topical acne agents	348	353	365	$135,391	364

TABLE H: TOP 25 DRUG MOLECULES
BY CHANGE IN AMOUNT PAID FROM APR 2019 TO JUN 2019 (FFS and CCOs)

Drug Molecule	Apr 2019 $ Paid	May 2019 $ Paid	Jun 2019 $ Paid	Jun 2019 # Claims	Jun 2019 # Unique Benes
ciprofloxacin-dexamethasone otic / otic steroids with anti-infectives	$321,090	$375,020	$477,190	2,040	2,022
anti-inhibitor coagulant complex / factor for bleeding disorders	$338,970	$580,475	$418,507	5	3
coagulation factor ix / factor for bleeding disorders	$29,784	$0	$106,352	4	3
sorafenib / VEGF/VEGFR inhibitors	$53,789	$67,030	$114,834	8	8
bictegravir/emtricitabine/tenofovir / antiviral combinations	$587,735	$641,847	$638,493	212	205
lomitapide / miscellaneous antihyperlipidemic agents	$0	$43,634	$43,634	1	1
fingolimod / selective immunosuppressants	$39,799	$39,842	$80,025	10	8
valbenazine / VMAT2 inhibitors	$99,773	$117,634	$139,177	22	20
selexipag / agents for pulmonary hypertension	$17,557	$52,670	$52,670	3	3
ponatinib / multikinase inhibitors	$0	$0	$33,183	1	1
etanercept / TNF alpha inhibitors	$511,992	$526,444	$544,696	115	111
eltrombopag / platelet-stimulating agents	$0	$0	$32,319	3	3
dimethyl fumarate / selective immunosuppressants	$117,239	$156,318	$148,502	19	19
tofacitinib / antirheumatics	$104,797	$91,722	$135,394	31	29
sitagliptin / dipeptidyl peptidase 4 inhibitors	$251,749	$273,100	$281,971	544	532
cannabidiol / miscellaneous anticonvulsants	$105,944	$141,024	$136,092	59	57
empagliflozin / SGLT-2 inhibitors	$195,965	$218,932	$223,441	403	393
ibrutinib / multikinase inhibitors	$48,523	$48,523	$74,510	6	6
immune globulin intravenous / immune globulins	$46,293	$57,101	$69,492	9	6
dupilumab / interleukin inhibitors	$119,793	$136,943	$142,909	47	45
deflazacort / glucocorticoids	$41,503	$46,923	$63,144	10	7
ivacaftor-lumacaftor / CFTR combinations	$462,646	$420,797	$484,111	27	25
mifepristone / progesterone receptor modulators	$0	$0	$21,126	1	1
ethinyl estradiol-norethindrone / sex hormone combinations	$149,658	$157,479	$170,733	1,909	1,787
mupirocin topical / topical antibiotics	$55,239	$64,764	$75,811	4,246	4,168

TABLE I: TOP 15 DRUG SOLID DOSAGE FORM HIGH VOLUME (100+ RX FILLS LAST MONTH) PRODUCTS WITH UNIT COST > $1
BY PERCENT CHANGE IN AMOUNT PAID PER UNIT APR 2019 TO JUN 2019 (FFS and CCOs)

Drug Product Therapeutic Category	Jun 2019 # Claims	Jun 2019 $ Paid	Jun 2019 Avr. Paid Per Rx	Jun 2019 Avr. Units Per Rx	Apr 2019 Paid Per Unit	May 2019 Paid Per Unit	Jun 2019 Paid Per Unit	Percent Change
amphetamine-dextroamphetamine 20 mg capsule, extended release / CNS stimulants (P)	601	$40,372	$67.17	31	$1.53	$1.50	$1.81	18.2%
atomoxetine 60 mg capsule / CNS stimulants (P)	114	$10,647	$93.39	30	$2.34	$2.44	$2.74	17.1%
amphetamine-dextroamphetamine 15 mg capsule, extended release / CNS stimulants (P)	377	$23,166	$61.45	30	$1.44	$1.32	$1.68	16.8%
amphetamine-dextroamphetamine 30 mg capsule, extended release / CNS stimulants (P)	610	$40,274	$66.02	30	$1.58	$1.59	$1.81	14.7%
amphetamine-dextroamphetamine 10 mg capsule, extended release / CNS stimulants (P)	305	$18,842	$61.78	30	$1.58	$1.60	$1.70	7.3%
clonidine 0.1 mg/12 hr tablet, extended release / antiadrenergic agents, centrally acting (N)	176	$28,706	$163.10	74	$1.93	$1.91	$2.05	6.3%
atomoxetine 25 mg capsule / CNS stimulants (P)	159	$14,526	$91.36	31	$2.45	$2.44	$2.53	3.4%
Genvoya (cobicistat/elvitegravir/emtricitabine/tenofov) 150 mg-150 mg-200 mg-10 mg tablet / antiviral combinations (P)	168	$511,836	$3,046.64	31	$95.40	$96.61	$98.01	2.7%
Lyrica (pregabalin) 300 mg capsule / gamma-aminobutyric acid analogs (P)	123	$54,036	$439.31	59	$7.21	$7.35	$7.35	2.0%
atomoxetine 40 mg capsule / CNS stimulants (P)	223	$19,484	$87.37	30	$2.46	$2.29	$2.50	1.8%
colchicine 0.6 mg capsule / antigout agents (P)	140	$22,242	$158.87	35	$4.00	$4.03	$4.06	1.5%
Vyvanse (lisdexamfetamine) 10 mg capsule / CNS stimulants (P)	140	$41,679	$297.71	30	$9.50	$9.56	$9.63	1.5%
Jardiance (empagliflozin) 10 mg tablet / SGLT-2 inhibitors (P)	178	$99,358	$558.19	32	$15.26	$15.26	$15.46	1.3%

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

TABLE I: TOP 15 DRUG SOLID DOSAGE FORM HIGH VOLUME (100+ RX FILLS LAST MONTH) PRODUCTS WITH UNIT COST > $1
BY PERCENT CHANGE IN AMOUNT PAID PER UNIT APR 2019 TO JUN 2019 (FFS and CCOs)

Drug Product Therapeutic Category	Jun 2019 # Claims	Jun 2019 $ Paid	Jun 2019 Avr. Paid Per Rx	Jun 2019 Avr. Units Per Rx	Apr 2019 Paid Per Unit	May 2019 Paid Per Unit	Jun 2019 Paid Per Unit	Percent Change
Tivicay (dolutegravir) 50 mg tablet / integrase strand transfer inhibitor (P)	129	$234,865	$1,820.66	34	$52.72	$52.81	$53.39	1.3%
Spiriva HandiHaler (tiotropium) 18 mcg capsule / anticholinergic bronchodilators (P)	411	$169,500	$412.41	30	$13.28	$13.43	$13.38	0.8%

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

New Business

Special Analysis Projects

MISSISSIPPI DIVISION OF MEDICAID

MS-DUR INTERVENTION / EDUCATIONAL MAILING UPDATE

MAY 2019 – AUGUST 2019

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**
18-Sep	41	50	150	292	36	31	67
18-Oct	33	45	150	321	39	30	74
18-Nov	*19	*25	150	*232	43	31	77
18-Dec	-	-	150	338	*21	*17	38
19-Jan	37	48	150	276	28	22	50
19-Feb	21	29	150	267	29	25	56
19-Mar	**68	**89	150	249	27	22	49
19-Apr	45	72	150	252	20	16	36
19-May	41	54	150	229	24	21	47
19-Jun	***30	***46	ł 388	ł 645	27	20	47
19-Jul	23	31	ł 234	ł 373	17	13	30
19-Aug	-	-	-		16	13	30

Notes:

Began excluding sickle cell diagnosis in Oct 2018.

* Data for CCOs was incomplete at the time the mailing was run.

** Revised and updated MEDD calculation method incorporated into analysis.

*** Criteria for high MEDD threshold value changed from value of 50 or more to 90 or more.

ł Letter changed to incorporate information about opioid PA edits. Did not limit to 150 providers.

One-time Mailing:

OPIOID PA EDIT NOTIFICATION LETTER (Targeting Providers with Beneficiaries whose Care may be Impacted by Edit)		
Month	**Prescribers Mailed**	**Benes Addressed**
19-Jun	95	176
19-Jul	93	166

OFFICE OF THE GOVERNOR
Walter Sillers Building | 550 High Street, Suite 1000 | Jackson, Mississippi
39201

MISSISSIPPI DIVISION OF MEDICAID

June 7, 2019

IMPORTANT NOTICE REGARDING OPIOID PRESCRIBING AND PHARMACY CLAIMS PROCESSING CHANGES EFFECTIVE AUGUST 1, 2019

Dear [PRESCRIBER'S NAME],

On August 1, 2019, the Division of Medicaid (DOM) will implement several new pharmacy claims system edits as recommended by the Drug Utilization Review (DUR) Board in response to the Centers for Disease Control and Prevention (CDC) Guidelines for Prescribing Opioids for Chronic Pain and per the Centers for Medicare and Medicaid Services(CMS) requirements[1]. These changes will be applicable for beneficiaries in the fee for service (FFS) and Coordinated Access Network (CAN) plans.

The intent of DOM is to improve the safety and effectiveness of pain treatment and reduce the risks of long-term opioid therapy by taking a two-pronged approach:

(1) appropriate treatment of opiate-naive patients or 'new starts' (preventing new users from becoming addicted)
(2) to allow prescribers to continue treating beneficiaries with chronic pain and to not abruptly stop these medications which could lead to adverse unintended consequences. At this time, chronic users of short-acting opioids, long-acting opioids, benzodiazepines or any combination thereof will be not be impacted in that prior authorization (PA) will not be required, unless they are taking ≥ 90 MEDD.

The four (4) opioid initiatives to be implemented on August 1, 2019 are:

1. **New opioid prescriptions** (first opioid fill within 90 days) **for opiate-naïve patients must be for short-acting (SA) opioid.***
2. **For new starts** (first opioid fill within 90 days) **a SA opioid can be filled for a maximum of two 7-day supplies in a 30 day period.** Use of SA opioids for longer periods will require a manual PA.*
3. **Any prescriptions (whether individual and/or cumulative daily sum of all prescriptions for the patient) with a Morphine Equivalent Daily Dose (MEDD) of ≥ 90 will require a manual PA** with documentation that the benefits outweigh the risks and that the patient has been counseled about the risks of overdose and death.*

   *** Patients with a diagnosis of cancer or sickle-cell disease are exempt from the 3 edits above. To ensure that prescriptions process for these patients, please denote the patient's diagnosis code on the prescription.**

[1] The Centers for Medicare and Medicaid Services (CMS) requires that state Medicaid programs have drug utilization review safety edits for opioid refills and an automated claims review process to identify refills in excess of state limits, monitor concurrent prescribing of opioids and benzodiazepines, on or prior to October 1, 2019. This is one of the many Medicaid–related provisions specified in Section 1004 of the SUPPORT Act (H.R. 6, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, the bipartisan bill aimed at addressing the nation's opioid overdose epidemic).

4. **Concomitant use of opioids and benzodiazepines should require a manual PA.**
   To allow for the short-term treatment of pre-procedure anxiety or other short-term anxiety, a prescription for up to 2 units of a solid oral dosage form of a benzodiazepine can be overridden at the point-of-sale by the dispensing pharmacist based upon his/her clinical judgment and consultation with the prescriber. A maximum of two, 2-unit prescriptions may be overridden in a 60 day period. Prospective DUR billing directions can be found on DOM's website.

Your patient(s) listed below was identified as being a chronic user of a short-acting or long-acting opioid with an individual prescription or cumulative prescriptions totaling a MEDD ≥ 90. On August 1, 2019, these users will require a PA to continue chronic use of this dosage. The PA form and opioid related material can be found at https://medicaid.ms.gov/providers/pharmacy/pharmacy-prior-authorization/ .

Beneficiary Name	Beneficiary Plan
BENEFICIARY 1	BENE 1 PLAN
BENEFICIARY 2	BENE 2 PLAN
BENEFICIARY 3	BENE 3 PLAN
BENEFICIARY 4	BENE 4 PLAN
BENEFICIARY 5	BENE 5 PLAN

You are being informed of this change to allow you adequate time to prepare prior to August 1, 2019. You are encouraged to query the Prescription Monitoring Program (PMP) for the most up-to-date opioid information for your patient(s).

If you have questions please do not hesitate to call the pharmacy director of the plan in which your patient is enrolled:

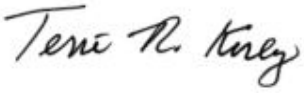
Fee For Service-601-359-5253, extension # 4 and ask for a pharmacist,

Magnolia- Jenni Grantham (601-863-3409),

Molina- Trina Stewart (844-826-4335),

UnitedHealthcare - Heather Odem (1-877-743-8734 or 601-718-6579).

Sincerely,



Carlos A. Latorre, MD, FAAFP
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UTILIZATION OF AGENTS ON THE CLINICIAN ADMINISTERED DRUGS AND IMPLANTABLE DRUG SYSTEM DEVICES (CADD) LIST

BACKGROUND

In 2018 the Division of Medicaid (DOM) initiated "The Enhancing Access to Services and Engagement (EASE)" Initiative, a multi-faceted approach to increase Medicaid beneficiaries' access to needed services. Prior to the development of the EASE Initiative, DOM began taking steps toward improving beneficiary access to care. One such step was the implementation of the Clinician Administered Drugs and Implantable Drug System Devices (CADD) List. DOM sought and gained approval from the Centers for Medicare and Medicaid Services (CMS) to allow certain injectable drugs to be billed and reimbursed as either a medical or point-of-sale (POS) claim to improve access to these drugs. The CADD List became effective July 1, 2018. CADDs do not count toward the monthly prescription drug limit.

The current CADD List contains injectable drugs and drug system devices in the following categories:

- Chemical dependency treatment agents
- Typical antipsychotic long-acting injectable agents
- Atypical antipsychotic long-acting injectable agents
- Long acting reversible contraceptive (LARCs) agents
- Pregnancy maintaining agents (Makena)

MS-DUR analyzed utilization data for each of the categories reviewing utilization trends before and after implementation of the CADD List. For this report, pregnancy maintaining agents were omitted as MS-DUR presented a detailed report on this category at May's 2019 DUR Board meeting.

METHODS

In order to evaluate trends in billing type for pharmaceuticals included in the CADD list, a retrospective database analysis of Mississippi Medicaid beneficiaries was conducted. Medical and pharmacy (POS) claims from July 2017 to May 2019 having NDCs related to the products included in the CADD list were reviewed.

In examining specifically the initiation of atypical long-acting injectable (LAI) antipsychotics, one consideration in determining appropriate use was to examine adherence rates to oral antipsychotic (AP) medications prior to atypical LAI APs. For this review, inclusion criteria were:

- The beneficiary had to have an initial claim for the LAI AP (index date) between July 2016 - May 2019; *AND*
- The beneficiary had to be continuously enrolled in Medicaid for the 6 months prior to the index date.

All pharmacy claims for oral APs were extracted for the six-month period prior to the index date. Adherence was calculated as the proportion of days covered (PDC) a measure of refill record-based adherence.

RESULTS

Note: Red horizontal line in Tables 2, 4, 6 and 8 reflects the implementation date of the CADD list.

Chemical Dependency Treatment Agents

FIGURE 1: Chemical Dependency Treatment Agents on CADD List

Chemical Dependency Treatment Agents		
Drug Name	NDC	Effective Date
Probuphine 74.2 mg Implant	52440010014	2/2/2019
Probuphine 74.2 mg Implant	58284010014	7/1/2018
Sublocade 100mg/0.5ml	12496010001	7/1/2018
Sublocade 300mg/1.5ml	12496030001	7/1/2018
Vivitrol 380mg	65757030001	7/1/2018

Table 1 shows the demographic characteristics of the beneficiaries receiving chemical dependency treatment with agents listed on the CADD list. This population was predominately female and younger adults (ages 26 to 44 years old).

TABLE 1: Demographic Characteristics of Beneficiaries Using Chemical Dependency Treatment Agents on CADD List
(July 2016 - May 2019; FFS and CCOs)

Characteristic		Number	Percent
TOTAL		19	100%
Age	<18	0	0.0%
	18-25	3	15.8%
	26-44	12	63.2%
	45-64	4	21.1%
	65+	0	0.0%
Gender	Male	5	26.3%
	Female	14	73.7%
Race	Caucasians	16	84.2%
	African American	1	5.3%
	Other	2	10.5%
Medicaid Program	FFS	2	10.5%
	UHC	10	52.6%
	MAG	7	36.8%
	MOL	0	0.0%

Note: Probuphines were not included because of the potential for misuse of the J-code in medical claims and there were no pharmacy claims during the time peroid.

Table 2 shows the billing type for the claims for chemical dependency treatment agents before and after the CADD list implementation. Although the total number of claims remains low, a significant increase in claims occurred after the CADD list, due almost exclusively to an increase in POS claims.

TABLE 2: Number of Paid Claims for Chemical Dependency Treatment Agents on CADD List by Billing Type

Claim Quarter	TOTAL			Medicaid Program							
				FFS		UHC		MAG		MOL	
	Total	Medical	POS	Medical	POS	Medical	POS	Medical	POS	Medical	POS
Q3 2017	1	1	0	0	0	1	0	0	0	0	0
Q4 2017	1	1	0	0	0	1	0	0	0	0	0
Q1 2018	2	2	0	0	0	2	0	0	0	0	0
Q2 2018	1	1	0	1	0	0	0	0	0	0	0
Q3 2018	2	0	2	0	0	0	0	0	2	0	0
Q4 2018	10	0	10	0	1	0	2	0	7	0	0
Q1 2019	11	1	10	0	0	1	1	0	9	0	0
Q2 2019	12	1	11	0	1	1	4	0	6	0	0

Notes: (a) Since there were very few claims for this class of drug, the number of claims were reported by quarter. (b) Probuphines were not included because of the potential for misuse of the J-code in medical claims and there were no pharmacy claims during the time peroid.

Long-Acting Reversible Contraceptives

FIGURE 2: Long Acting Reversible Contraceptives on CADD List

Long Acting Reversible Contraceptive		
Drug Name	NDC	Effective Date
Kyleena 19.5mg	50419042401	7/1/2018
Liletta 52 mg System	00023585801	7/1/2018
	52544003554	7/1/2018
Mirena	50419042101	7/1/2018
	50419042301	7/1/2018
Nexplanon 68 mg Implant	00052433001	7/1/2018
Paragard T 380-A IUD	51285020401	7/1/2018
Paragard T 380-A IUD	59365512801	9/1/2018
Skyla 1 kit 14mcg/24hr	50419042201	7/1/2018

Table 3 shows the demographic characteristics of beneficiaries using long-acting reversible contraceptives. As would be expected, this population is predominantly female and young.

TABLE 3: Demographic Characteristics of Beneficiaries Using Long-Acting Reversible Contraceptives on CADD List
(July 2016 - May 2019; FFS and CCOs)

Characteristic		Number	Percent
TOTAL		13,110	100%
Age	<18	2,057	15.7%
	18-25	6,450	49.2%
	26-44	4,531	34.6%
	45-64	71	0.5%
	65+	1	0.0%
Gender	Male	0	0.0%
	Female	13,110	100.0%
Race	Caucasians	5,623	42.9%
	African American	6,926	52.8%
	Other	561	4.3%
Medicaid Program	FFS	2,800	21.4%
	UHC	4,767	36.4%
	MAG	5,295	40.4%
	MOL	248	1.9%

Notes: (a) FDA Approval Date for Kyleena was Sep 19, 2016. (b) J-code for Nexplanon not used to extract medical claims since it is not exclusive to Nexplanon and may apply to other medical items or services.

As shown in Table 4, overall utilization of long-acting reversible contraceptives did not increase with the introduction of the CADD list. However, there was a slight shift to greater use of POS for filing claims. Conversations with providers in practice settings where LARCs are likely to be used have indicated there are multiple factors other than billing type that have limited the use of these products.

TABLE 4: Number of Paid Claims for Long-Acting Reversible Contraceptive Agents on CADD List by Billing Type

Claim Month	TOTAL			Medicaid Program							
				FFS		UHC		MAG		MOL	
	Total	Medical	POS	Medical	POS	Medical	POS	Medical	POS	Medical	POS
Jul 17	340	339	1	56	0	143	0	139	1	0	0
Aug 17	452	449	3	93	0	164	0	192	3	0	0
Sep 17	383	381	2	74	0	150	0	157	2	0	0
Oct 17	434	428	6	90	0	171	5	166	1	0	0
Nov 17	388	386	2	84	1	134	1	168	0	0	0
Dec 17	330	323	7	82	0	119	6	122	1	0	0
Jan 18	411	406	5	95	0	157	4	154	1	0	0
Feb 18	434	424	10	109	0	152	8	163	2	0	0
Mar 18	477	472	5	118	0	179	3	175	2	0	0
Apr 18	431	425	6	96	0	152	6	177	0	0	0
May 18	383	377	6	88	0	123	3	166	3	0	0
Jun 18	380	375	5	89	0	128	1	157	4	0	0
Jul 18	415	405	10	70	0	161	6	174	4	0	0
Aug 18	439	425	14	110	4	156	4	158	6	0	0
Sep 18	355	344	11	86	1	132	4	126	6	0	0
Oct 18	426	417	9	93	1	156	4	164	4	4	0
Nov 18	328	323	5	72	1	113	1	134	3	4	0
Dec 18	305	300	5	68	0	102	3	112	1	16	1
Jan 19	409	398	11	83	0	143	4	152	7	19	0
Feb 19	376	358	18	95	1	108	6	115	11	40	0
Mar 19	320	305	15	61	2	94	4	108	9	42	0
Apr 19	362	346	16	87	2	122	7	93	7	43	0
May 19	361	347	14	62	1	89	6	112	6	83	1

Notes: (a) FDA Approval Date for Kyleena was Sep 19, 2016. (b) J-code for Nexplanon not used to extract medical claims since it is not exclusive to Nexplanon and may apply to other medical items or services.

Typical Long-Acting Injectable (LAI) Antipsychotics (APs)

FIGURE 3: Typical LAI AP Agents on CADD List

Antipsychotic Long-Acting Agents		
Drug Name	NDC	Effective Date
Fluphenazine Decanoate 125mg/5ml	00143952901	11/1/2018
	42023012901	11/1/2018
	42023012989	11/1/2018
	55150026705	11/1/2018
	63323027205	11/1/2018
	67457035959	11/1/2018
Haloperidol Decanoate 50mg/ml ampule	10147092103	11/1/2018
	70069003003	11/1/2018
Haloperidol Decanoate 100mg/ml ampule	10147092205	11/1/2018
	63323047141	3/2/2019
	70069003105	11/1/2018
Haloperidol Decanoate 50mg/ml vial	00703701103	11/1/2018
	00703701301	11/1/2018
	25021083101	11/1/2018
	63323046901	11/1/2018
	63323046905	11/1/2018
	67457041013	11/1/2018
	70069038110	8/27/2019
Haloperidol Decanoate 100mg/ml vial	00703702103	11/1/2018
	00703702301	11/1/2018
	00703713101	8/14/2019
	00703713103	8/14/2019
	25021083301	11/1/2018
	25021083405	11/1/2018
	63323047101	11/1/2018
	63323047105	11/1/2018
	67457038158	11/1/2018
	67457040913	11/1/2018
	70069038310	8/27/2019

Table 5 provides the demographic characteristics of beneficiaries using typical LAI APs included on the CADD list. The characteristics of this population are similar to those receiving other types of antipsychotic medications in Medicaid.

TABLE 5: Demographic Characteristics of Beneficiaries Using Typical Long-Acting Injectable Antipsychotic Agents on CADD List
(July 2016 - May 2019; FFS and CCOs)

Characteristic		Number	Percent
TOTAL		1,111	100%
Age	<18	14	1.3%
	18-25	136	12.2%
	26-44	509	45.8%
	45-64	438	39.4%
	65+	14	1.3%
Gender	Male	709	63.8%
	Female	402	36.2%
Race	Caucasians	194	17.5%
	African American	798	71.8%
	Other	119	10.7%
Medicaid Program	FFS	287	25.8%
	UHC	394	35.5%
	MAG	424	38.2%
	MOL	6	0.5%

Notes: The listed CADD effective date for both Fluphenazine Decanoate and Haloperidol Decanoate was November 1st 2018, but the data showed POS claims were paid starting July 2018.

As shown in Table 6, overall utilization of typical LAI APs has remained fairly stable for the last few years.

- Prior to Introduction of the CADD list, almost all claims were medical. After introduction of the CADD list, almost all claims were paid through POS.
- It should be noted that these products were not officially added to the CADD list until November 2018.
- Paid POS claims began increasing after the CADD list was initially implemented in July 2018.

TABLE 6: Number of Paid Claims Per Month for Typical Long-Acting Injectable Antipsychotic Agents on CADD List											
Claim Month	TOTAL			Medicaid Program							
				FFS		UHC		MAG		MOL	
	Total	Medical	POS	Medical	POS	Medical	POS	Medical	POS	Medical	POS
Jul 17	470	435	35	77	35	159	0	199	0	0	0
Aug 17	464	428	36	59	36	176	0	193	0	0	0
Sep 17	453	416	37	57	37	175	0	184	0	0	0
Oct 17	488	453	35	57	35	186	0	210	0	0	0
Nov 17	508	468	40	60	40	181	0	227	0	0	0
Dec 17	458	425	33	57	33	175	0	193	0	0	0
Jan 18	515	479	36	68	36	182	0	229	0	0	0
Feb 18	448	419	29	57	29	158	0	204	0	0	0
Mar 18	508	474	34	63	34	183	0	228	0	0	0
Apr 18	470	436	34	59	34	173	0	204	0	0	0
May 18	493	463	30	69	30	193	0	201	0	0	0
Jun 18	432	396	36	57	36	164	0	175	0	0	0
Jul 18	518	332	186	47	55	130	75	155	56	0	0
Aug 18	527	319	208	51	53	124	83	144	72	0	0
Sep 18	484	204	280	22	62	86	103	96	115	0	0
Oct 18	478	100	378	8	71	36	128	53	177	3	2
Nov 18	500	84	416	10	76	32	146	41	193	1	1
Dec 18	502	51	451	4	90	21	143	23	217	3	1
Jan 19	504	43	461	1	80	16	157	23	220	3	4
Feb 19	449	28	421	6	83	3	140	18	191	1	7
Mar 19	486	13	473	3	96	4	155	5	213	1	9
Apr 19	481	5	476	2	87	2	163	1	216	0	10
May 19	461	9	452	3	84	4	143	2	213	0	12

Notes: The listed CADD effective date for both Fluphenazine Decanoate and Haloperidol Decanoate was November 1st 2018, but the data showed POS claims were paid starting July 2018.

Atypical Long-Acting Injectable (LAI) Antipsychotics (APs)

FIGURE 4: Atypical LAI AP Agents on CADD List

Atypical Antipsychotic Long-Acting Agents - Injectable		
Drug Name	NDC	Effective Date
Abilify Maintena ER 300 mg	59148001870	7/1/2018
	59148001871	7/1/2018
	59148004580	7/1/2018
Abilify Maintena ER 400 mg	59148001970	7/1/2018
	59148001971	7/1/2018
	59148007280	7/1/2018
Aristada ER 441 mg/1.6 ml	65757040101	7/1/2018
	65757040103	7/1/2018
Aristada ER 662 mg/2.4 ml	65757040201	7/1/2018
	65757040203	7/1/2018
Aristada ER 882 mg/3.2 ml	65757040301	7/1/2018
	65757040303	7/1/2018
Aristada ER 1064 mg/3.9 ml	65757040401	7/1/2018
	65757040403	7/1/2018
Aristada Initio ER 675mg/2ml	65757050003	11/1/2018
Invega Sustenna 39 mg/0.25ml	50458056001	7/1/2018
Invega Sustenna 78 mg/0.5 ml	50458056101	7/1/2018

Table 7 provides the demographic characteristics of beneficiaries using atypical long-acting injectable antipsychotics (LAI APs) included on the CADD list. The characteristics of this population are similar to those receiving other types of antipsychotic medications in Medicaid.

TABLE 7: Demographic Characteristics of Beneficiaries Using Atypical Long-Acting Injectable Antipsychotic Agents on CADD List

(July 2016 - May 2019; FFS and CCOs)

Characteristic		Number	Percent
TOTAL		1,869	100%
Age	<18	29	1.6%
	18-25	364	19.5%
	26-44	942	50.4%
	45-64	516	27.6%
	65+	18	1.0%
Gender	Male	1,040	55.6%
	Female	829	44.4%
Race	Caucasians	413	22.1%
	African American	1,227	65.7%
	Other	229	12.3%
Medicaid Program	FFS	430	23.0%
	UHC	706	37.8%
	MAG	711	38.0%
	MOL	22	1.2%

Table 8 depicts that overall utilization of atypical LAI APs has increased significantly since introduction of the CADD list with most of the claims moving to POS.

TABLE 8: Number of Paid Claims Per Month for Atypical Long-Acting Injectable Antipsychotic Agents on CADD List											
Claim Month	TOTAL			Medicaid Program							
				FFS		UHC		MAG		MOL	
	Total	Medical	POS	Medical	POS	Medical	POS	Medical	POS	Medical	POS
Jul 17	701	688	13	80	13	312	0	296	0	0	0
Aug 17	745	731	14	88	14	347	0	295	0	0	0
Sep 17	657	643	14	65	14	322	0	256	0	0	0
Oct 17	740	726	14	78	14	333	0	315	0	0	0
Nov 17	753	739	14	72	14	342	0	325	0	0	0
Dec 17	680	672	8	72	8	319	0	281	0	0	0
Jan 18	736	727	9	78	9	348	0	301	0	0	0
Feb 18	667	655	12	64	12	302	0	289	0	0	0
Mar 18	735	722	13	68	13	328	0	326	0	0	0
Apr 18	708	695	13	69	13	332	0	294	0	0	0
May 18	724	709	15	80	15	344	0	285	0	0	0
Jun 18	659	646	13	72	13	327	0	245	0	0	0
Jul 18	855	518	337	59	43	226	163	233	131	0	0
Aug 18	887	481	406	65	52	202	173	214	181	0	0
Sep 18	803	280	523	43	64	115	238	122	221	0	0
Oct 18	842	162	680	26	79	66	268	69	331	1	2
Nov 18	781	111	670	24	75	41	273	44	316	2	6
Dec 18	817	39	778	12	76	9	327	15	369	3	6
Jan 19	810	37	773	14	98	5	344	13	323	5	8
Feb 19	783	27	756	16	75	1	306	7	368	3	7
Mar 19	791	16	775	7	93	2	300	4	373	3	9
Apr 19	871	8	863	0	101	4	331	3	406	1	25
May 19	861	2	859	0	87	0	338	1	401	1	33

Adding the atypical LAI AP medications to the CADD list has greatly increased their access. On a monthly basis, atypical LAI APs generally cost much more than oral formulations of the same products. Due to the substantial cost difference, atypical LAI AP medications were initially reserved for patients who could not be adherent on oral products.

To determine whether adherence was still a major factor in provider decisions in the use of LAI APs, MS-DUR examined medication adherence rates for oral APs during the six-month period prior to patients initiating therapy with an atypical LAI AP medication.

Table 9 illustrates the adherence rates for beneficiaries initiating treatment with atypical LAI APs. The date of initial injectable AP use was categorized as before and after the July 1, 2018 effective date for the CADD list.

As illustrated in Table 9:

- Approximately one-fourth of beneficiaries starting treatment with an atypical LAI AP had no prior use of an oral AP.
- Over half of the beneficiaries starting treatment with an atypical LAI AP were adherent (PDC ≥ 80%) with oral APs prior to the switch.
- Percentages for the above findings are about the same pre- and post-CADD list.

These results indicate that providers are **NOT** using adherence related issues to oral APs as a major factor in deciding to initiate therapy with atypical LAI APs.

TABLE 9. Adherence To Oral Antipsychotics In the 12-month Period Prior to First Use of AtypIcal Long-Acting Injectable Antipsychotic on CADD List

Date of Initial Injectable AP Use	Pharmacy Program When Initiating Injectable AP Use	Number of Beneficiaries							
		Adherence (PDC) Level							
		No Oral AP Use		< 50%	50% - 69%	70% - 79%	≥ 80%		Total
Before CADD effective date (July 1, 2018)	Fee for Service	97	54%	0	9	11	63	35%	180
	United Health Care	47	16%	0	34	35	176	60%	292
	Magnolia	56	20%	1	28	33	160	58%	278
	All Plans	200	27%	1	71	79	399	53%	750
After CADD effective date (≥ July 1, 2018)	Fee for Service	31	39%	0	4	3	42	53%	80
	United Health Care	27	20%	2	11	14	84	61%	138
	Magnolia	28	16%	0	25	24	100	56%	177
	Molina	5	31%	0	1	4	6	38%	16
	All Plans	91	22%	2	41	45	232	56%	411

CONCLUSIONS

Introduction of the CADD List was intended to increase beneficiary access to certain drugs and drug devices.

- Medications across **ALL** categories of the CADD List have seen shifts in claims from medical to POS claims since the introduction of the list.
- Atypical long-acting injectable antipsychotics, in particular, have seen a significant increase in utilization since addition to the CADD List, indicating improved access.
- Utilization of other agents, such as LARCs, has not increased as significantly. This can point to factors, outside of access, that impact utilization of some of the LARCs.

RECOMMENDATIONS

MS-DUR has no formal recommendations at this time regarding the CADD List. DUR Board input regarding the CADD List is welcome.

TYPE 2 DIABETES TREATMENT PATTERNS AND THE UTILIZATION OF METFORMIN IN MISSISSIPPI MEDICAID

BACKGROUND

Type 2 diabetes mellitus (T2DM) is the most common form of diabetes accounting for 90-95% of all diabetes cases[1]. According to the CDC, in 2015 over 30 million Americans (9.4% of the US population) had diabetes. The prevalence of type 2 diabetes (T2DM) in the United States (U.S.) is approximately 11.3% in individuals 20 years or older and continues to rise[2,3]. Prevalence of T2DM varies among racial and ethnic populations. African Americans, American Indians, Hispanic/Latinos, and Asian Americans experience increased rates[1]. Although the prevalence of T2DM increases with age, adolescents and young adults are increasingly being diagnosed with T2DM. This rise in prevalence in adolescents and young adults can be partially attributed to increases in obesity and sedentary lifestyles in combination with other risk factors such as genetic predisposition, female sex, and low socioeconomic status[4].

Diabetes' substantial burden on society is in the form of higher medical costs, lost productivity, premature mortality, and intangible costs in the form of reduced quality of life.

- The national annual cost associated with elevated blood glucose in 2017 reached nearly $404 billion[5].
    - $327.2 billion for diagnosed diabetes
    - $31.7 billion for undiagnosed diabetes
    - $43.4 billion for prediabetes
    - $1.56 billion for gestational diabetes
- Of $4 in total economic burden associated with diabetes and prediabetes, $3 was associated with medical costs and $1 was associated with nonmedical costs[5].
- In 2017, Mississippi tied for second in the nation for overall prevalence of diabetes at 12.2% and an estimated prevalence of prediabetes at 35.6%[5].
- Diabetes and prediabetes cost an estimated $4.1 billion each year in Mississippi[5].
- People with diagnosed diabetes incur average medical expenditures of ~$16,750 per year, of which ~$9,600 is attributed to diabetes[6].

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[1] American Diabetes Association Diabetes Care 2019 Jan; 42(Supplement 1): S13-S28. https://doi.org/10.2337/dc19-S002

[2] Triplitt CL, Repas T, Alvarez C. Diabetes Mellitus. In: DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L. eds. Pharmacotherapy: A Pathophysiologic Approach, 10e New York, NY: McGraw-Hill; . http://accesspharmacy.mhmedical.com/content.aspx?bookid=1861&sectionid=146065891. Accessed August 12, 2019.

[3] CDC – Diabetes Quick Facts. https://www.cdc.gov/diabetes/basics/quick-facts.html.

[4] Copeland KC, Zeitler P, Geffner M, et al.; TODAY Study Group. Characteristics of adolescents and youth with recent-onset type 2 diabetes: the TODAY cohort at baseline. J Clin Endocrinol Metab 2011;96:159–167

[5] The Economic Burden of Elevated Blood Glucose Levels in 2017: Diagnosed and Undiagnosed, Gestational Diabetes Mellitus, and Prediabetes; Diabetes Care 2019 Sep; 42(9): 1661-1668 https://doi.org/10.2337/dc18-1226

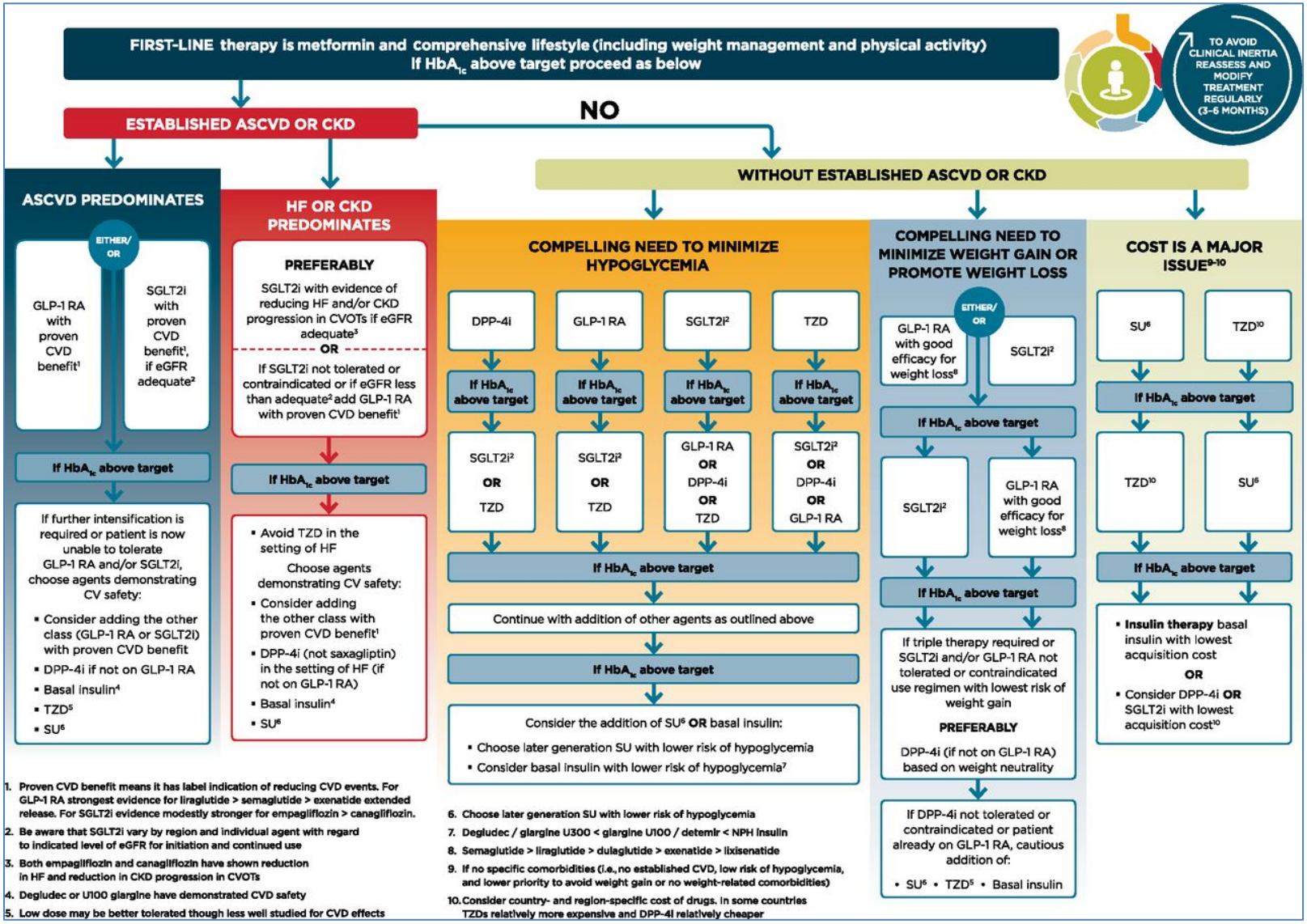
[6] Economic Costs of Diabetes in the U.S. in 2017 Diabetes Care 2018; 41:917–928 | https://doi.org/10.2337/dci18-0007

With the extensive burden imposed by diabetes, effective treatment is crucial. Therapeutic agents that manage hyperglycemia can be broadly characterized as belonging to one of five groups: (i) insulin sensitizers (metformin and pioglitazone); (ii) insulin providers (insulin, sulfonylureas, and meglitinides); (iii) incretin-based therapies (GLP1-RAs and DPP4 inhibitors); (iv) gastrointestinal glucose absorption inhibitor (acarbose); and (v) renal glucose reuptake inhibitors (SGLT2 inhibitors).

The ADA's annual "Standards of Medical Care in Diabetes," (referred to as the "Standards of Care") provides the components of diabetes care, general treatment goals, and tools to evaluate quality of care. The Standards of Care recommendations are not intended to preclude clinical judgement and must be applied in the context of excellent clinical care, with adjustments for individual preferences, comorbidities, and other patient factors. The "Standards of Care" 2019 publication provides the following recommendations regarding glucose-lowering pharmacologic therapy for T2DM[7]:

[7] American Diabetes Association Diabetes Care 2019 Jan; 42(Supplement 1): S90-S102. https://doi.org/10.2337/dc19-S009

FIGURE 1: ADA Glucose-Lowering Medication in T2DM[7].

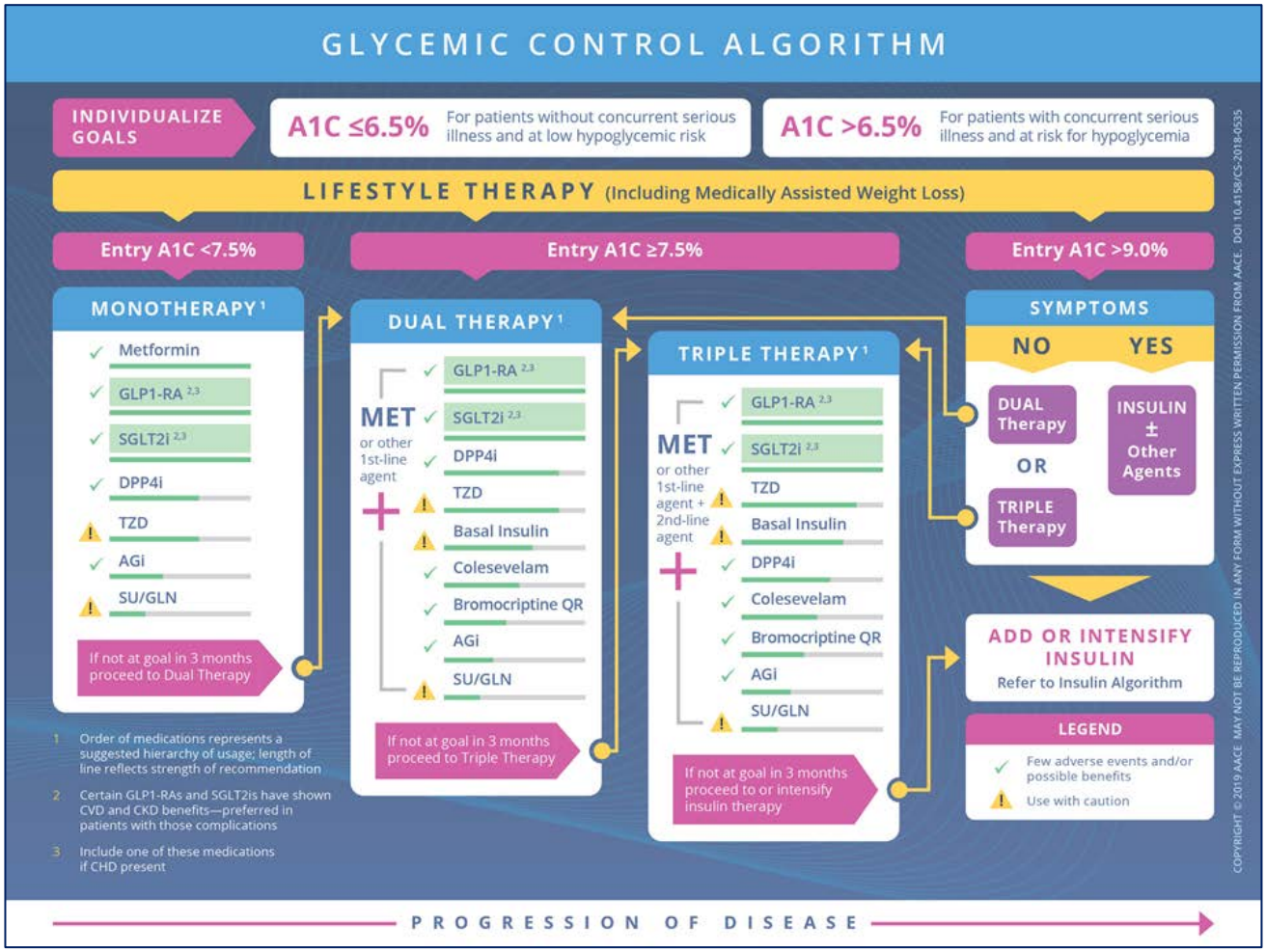


The ADA's "Standards of Medical Care in Diabetes" summary of glucose-lowering recommendations for T2DM is as follows:

- Metformin is the preferred initial agent for the treatment of T2DM.
- Once initiated, metformin should be continued as long as it is tolerated and not contraindicated. Other agents should be added to metformin.
- Long-term use of metformin may be associated with biochemical vitamin B12 deficiency, and periodic measurement of vitamin B12 levels should be considered in metformin-treated patients, especially in those with anemia or peripheral neuropathy.
- The early introduction of insulin should be considered if there is evidence of ongoing catabolism (weight loss), if symptoms of hyperglycemia are present, or when A1C levels (>10% [86 mmol/mol]) or blood glucose levels ($\geq$300 mg/dL [16.7 mmol/L]) are very high.
- Consider initiating dual therapy in patients with newly diagnosed type 2 diabetes who have A1C $\geq$1.5% (12.5 mmol/ mol) above their glycemic target.
- A patient-centered approach should be used to guide the choice of pharmacologic agents. Considerations include comorbidities (atherosclerotic cardiovascular disease, heart failure, and chronic kidney disease), hypoglycemia risk, impact on weight, cost, risk for side effects, and patient preferences.
- Among patients with T2DM who have established atherosclerotic cardiovascular disease (ASCVD), sodium–glucose cotransporter 2 (SGLT2) inhibitors, or glucagon-like peptide 1 receptor agonists (GLP-1 RA) with demonstrated cardiovascular disease benefit are recommended as part of the anti-hyperglycemic regimen.
- Among patients with ASCVD at high risk of heart failure or in whom heart failure coexists, SGLT2 inhibitors are preferred.
- For patients with T2DM and chronic kidney disease (CKD), consider use of a SGLT2 inhibitor or GLP-1 RA shown to reduce risk of chronic kidney disease progression, cardiovascular events, or both.
- In most patients who need the greater glucose-lowering effect of an injectable medication, GLP-1 RAs are preferred to insulin.
- Intensification of treatment for patients with T2DM not meeting treatment goals should not be delayed.
- The medication regimen should be reevaluated at regular intervals (every 3–6 months) and adjusted as needed to incorporate new patient factors.

The American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE) Consensus Statement on the Comprehensive Type 2 Diabetes Management provides similar recommendations to the ADA "Standards of Care" stratifying therapies relative to initial hemoglobin A1C levels and comorbidities. AACE/ACE current 2019 recommendations are displayed in Figure 2[8].

FIGURE 2: AACE/ACE Glycemic Control Algorithm – 2019[8]



[8] Alan J. Garber, Martin J. Abrahamson, Joshua I. Barzilay, Lawrence Blonde, Zachary T. Bloomgarden, Michael A. Bush, Samuel Dagogo-Jack, Ralph A. DeFronzo, Daniel Einhorn, Vivian A. Fonseca, Jeffrey R. Garber, W. Timothy Garvey, George Grunberger, Yehuda Handelsman, Irl B. Hirsch, Paul S. Jellinger, Janet B. McGill, Jeffrey I. Mechanick, Paul D. Rosenblit, and Guillermo E. Umpierrez (2019) CONSENSUS STATEMENT BY THE AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGISTS AND AMERICAN COLLEGE OF ENDOCRINOLOGY ON THE COMPREHENSIVE TYPE 2 DIABETES MANAGEMENT ALGORITHM – 2019 EXECUTIVE SUMMARY. Endocrine Practice: January 2019, Vol. 25, No. 1, pp. 69-100. https://doi.org/10.4158/CS-2018-0535

Both guidelines recommend the utilization of metformin as first-line therapy in the treatment of T2DM unless contraindications are present.

Metformin has proven efficacy, safety, and is a low-cost treatment option for most T2DM patients[9]. Although metformin safety has been established, there are some common obstacles to using metformin. (Figure 3[9]) Recent FDA label changes allow for metformin use in chronic kidney disease (CKD) patients and with a stable estimated glomerular filtration rate (eGFR) >30 ml/min/1.73m^2.

Figure 3:

Common obstacles to using metformin

Condition	Suggested approach
GI intolerance	• Reduce dose until adverse effects resolve • Consider use of extended-release form
Impaired kidney function	• Use freely if eGFR ≥45 mL/min • Use with caution if eGFR 30-45 mL/min • Do not use if eGFR <30 mL/min
Heart failure	• Acceptable to use with stable, chronic heart failure • Do not use with acute heart failure and evidence of end-organ hypoperfusion
Liver disease	• Acceptable to use with chronic liver disease (including mildly elevated liver enzymes, but intact liver function) • Do not use with functional hepatic failure or acute liver injury

In patients who do not reach their glycemic target on metformin monotherapy, the ADA Standards of Care and the AACE/ACE Consensus Statement both recommend that metformin be continued in combination with other agents. Both also recommend initiating dual therapy with metformin plus another agent in patients with initial A1C values above certain levels.

- ADA's Standards of Care recommend initiating dual therapy in patients with an initial A1C $\geq$1.5% their target,
- AACE/ACE guidelines recommend dual therapy with initial A1C $\geq$7.5%.

In individuals with diabetes and ASCVD or CKD, several controlled trials have demonstrated benefits associated with the use of certain SGLT2 inhibitors and GLP-1 RAs. A summary of the evidence and the place in therapy for these agents in patients with ASCVD or CKD was discussed in the ADA Standards of Care 2019 in the following quote:

> *"There are now multiple large randomized controlled trials reporting statistically significant reductions in cardiovascular events in patients with type 2 diabetes treated with an SGLT2 inhibitor (empagliflozin, canagliflozin) or GLP-1 receptor agonist (liraglutide, semaglutide). In people with diabetes with established ASCVD, empagliflozin decreased a composite three-point major cardiovascular event (MACE) outcome and mortality compared with placebo. Similarly, canagliflozin reduced the occurrence of MACE in a group of subjects with, or at high risk for, ASCVD. Dapagliflozin, in contrast, did not reach statistical significance for MACE, but did show a significant lowering of cardiovascular death or hospitalization for heart failure (HF), which reflected a lower rate of hospitalization for heart failure. In all three of these trials, SGLT2 inhibitors reduced hospitalization for HF; this was a secondary outcome of these studies. In people with type 2 diabetes with ACVD or increased risk for ASCVD, the*

[9] Flory J, Lipska K. Metformin in 2019. JAMA. 2019;321(19): 1926. doi:10.1001/jama.2019.3805.

addition of liraglutide decreased MACE and mortality, and the closely related GLP-1 receptor agonist semaglutide also had favorable effects on cardiovascular end points in high-risk subjects. In these cardiovascular outcomes trials, empagliflozin, canagliflozin, dapagliflozin, liraglutide, and semaglutide all had beneficial effects on composite indices of CKD. Additional large randomized trials of other agents in these classes are ongoing.

The subjects enrolled in the cardiovascular outcomes trials using empagliflozin, canagliflozin, liraglutide and semaglutide had A1C ≥7%, and more than 70% were taking metformin at baseline. The cardiovascular outcome trial with dapagliflozin, in contrast, enrolled subjects with an A1C ≥6.5% with more than 80% taking metformin at baseline. Moreover, the benefit of treatment was less evident in subjects with lower risk for ASCVD. ***Thus, extension of these results to practice is most appropriate for people with type 2 diabetes and established ASCVD who require additional glucose-lowering treatment beyond metformin and lifestyle management.*** *For these patients, incorporating one of the SGLT2 inhibitors or GLP-1 receptor agonists that have been demonstrated to reduce cardiovascular events is recommended."*[10]

The European Society of Cardiology (ESC) and the European Association for the Study of Diabetes (EASD) published its third set of collaborative guidelines on the management and prevention of cardiovascular disease in individuals with, and at risk of developing, diabetes mellitus on August 2019[11]. This was the first update of these guidelines since 2013. Incorporating evidence from clinical trials of glucose-lowering products for the treatment of diabetes, the 2019 ESC Guideline recommendations provided guidance based on risk categorization of patients.

Cardiovascular Risk Categories in Patients with Diabetes:

- Very High Risk: Patients with DM *and* established CVD or other target organ damage(a), *or* ≥ 3 or more major risk factors(b), *or* early onset T1DM of long duration (>20 years)
- High Risk: Patients with DM duration ≥ 10 years without target organ damage plus any other additional risk factors
- Moderate Risk: Young patients (T1DM < 35 years or T2DM aged <50 years) with DM duration ≤10 years, without other risk factors

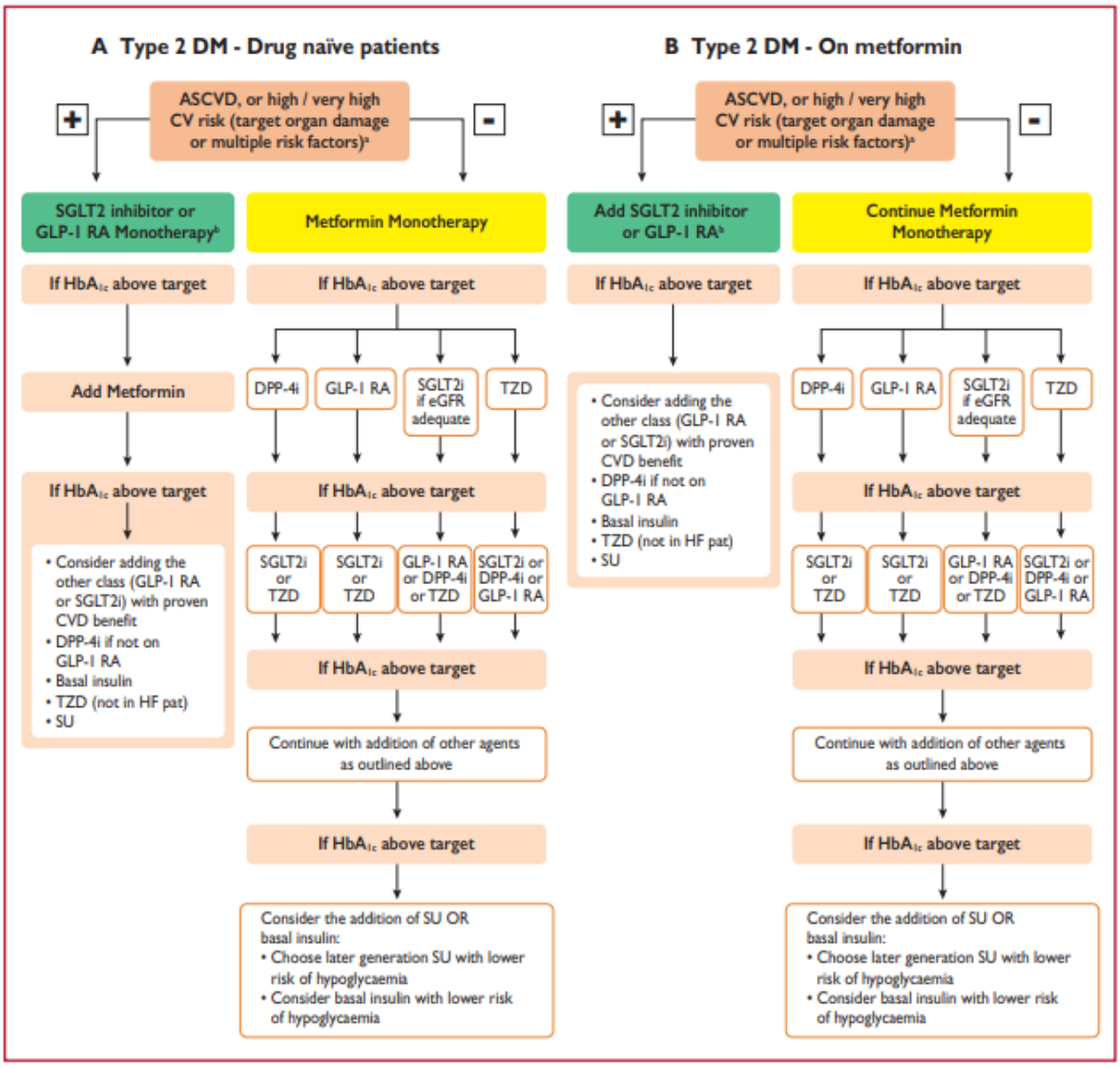
* CV = cardiovascular; CVD = cardiovascular disease; DM = diabetes mellitus; T1DM = type 1 diabetes mellitus; T2DM = type 2 diabetes mellitus.
a =Proteinuria, renal impairment defined as eGFR ≥30 mL/min/1.73 m2, left ventricular hypertrophy, or retinopathy.
b =Age, hypertension, dyslipidemia, smoking, obesity.

[10] American Diabetes Association. 9. Pharmacologic approaches to glycemic treatment: Standards of Medical Care in Diabetes—2019 [web annotation]. Diabetes Care 2019;42(Suppl. 1):S90–S102. Retrieved from https://hyp.is/jsTAhlCsEembh5N0A0d5Bw/care.diabetesjournals.org/content/42/Supplement_1/S90.

[11] Cosentio F, Grant P, Aboyans V, et al. 2019 ESC Guidelines on diabetes, pre-diabetes, and cardiovascular diseases developed in collaboration with the EASD: The Task Force for diabetes, pre-diabetes, and cardiovascular diseases of the European Society of Cardiology (ESC) and the European Association for the Study of Diabetes (EASD). European Heart Journal, Aug 31, 2019 ehz486, https://doi.org/10.1093/eurheartj/ehz486

The treatment algorithm based on the ESC guidelines is displayed in Figure 4[11].

Figure 4: 2019 ESC Guidelines T2DM Treatment Algorithm[11]



Treatment algorithm in patients with type 2 diabetes mellitus and atherosclerotic cardiovascular disease, or high/very high CV risk Treatment algorithms for (*A*) drug-naïve and (*B*) metformin-treated patients with diabetes mellitus. ASCVD = atherosclerotic cardiovascular disease: CV = cardiovascular; CVD = cardiovascular disease; DM = diabetes mellitus; DPP4i = dipeptidyl peptidase-4 inhibitor; eGFR = estimated glomerular filtration rate; GLP1-RA = glucagon-like peptide-1 receptor agonist; HbA1c = haemoglobin A1c; HF = heart failure; SGLT2i = sodium-glucose co-transporter 2 inhibitor; SU = sulphonylureas; T2DM = type 2 diabetes mellitus; TZD = thiazolidinedione. [a]See *Table 7*. [b]Use drugs with proven CVD benefit.

- **Glucose-lowering Treatment Recommendations (class of recommendation):**
    - SGLT-2 inhibitors empagliflozin, canagliflozin, and dapagliflozin are recommended in patients with T2DM and CVD, or at very high/high CV risk, to reduce CV events (Ia)
    - Empagliflozin is recommended in patients with T2DM and CVD to reduce the risk of death (Ia)
    - GLP-1 RA's liraglutide, semaglutide and dulaglutide are recommended in patients with T2DM and CVD, or very high/high CV risk, to reduce CV events (Ia)
    - Liraglutide is recommended in patients with T2DM and CVD, or at very high/high CV risk, to reduce the risk of death (Ia)
    - Treatment with an SGLT2 inhibitor (emplagliflozin, canagliflozin, or dapagliflozin) is associated with a lower risk of renal endpoints and is recommended if eGFR is 30 to <90 mL/min/1.73m^2 (I)
    - Treatment with the GLP-1 RAs liraglutide and semaglutide is associated with a lower risk of renal endpoints, and should be considered for DM treatment if eGFR is >30 mL/min/1.73m^2(IIa)

- **DM Treatment to Reduce HF Risk (class of recommendation):**
    - SGLT2 inhibitors (empagliflozin, canagliflozin, and dapagliflozin) are recommended to lower the risk of hospitalization (Ia)
    - Metformin should be considered in patients with DM and HF if eGFR >30mg/min/1.73m2 (IIa)
    - GLP-1 RAs and the DPP4 inhibitors sitagliptin and linagliptin have a neutral effect on risk of HF and may be considered (IIb)
    - Insulin treatment may be considered (IIb)
    - DPP4 inhibitor saxagliptin in HF is not recommended (III)
    - Thiazolidinediones (pioglitazone and rosiglitazone) in HF are not recommended (III)

    Class of Recommendation:
        - *Class I – is recommended or is indicated*
        - *Class IIa – should be considered*
        - *Class IIb – may be considered*
        - *Class III – is not recommended*

- Glycemic status should be systematically evaluated in all patients with CAD.
- Intensive glycemic control may have more favorable CV effects when initiated early in the course of DM.

With numerous therapeutic options available in the treatment of T2DM, cost is an important consideration. Monthly costs associated with the different glucose-lowering agents vary across the classes.

The Mississippi Division of Medicaid uses the National Average Drug Acquisition Cost (NADAC) for pharmacy reimbursement for medications. Figure 5 displays typical monthly reimbursed prices to pharmacies associated with each noninsulin agent.

FIGURE 5 – Monthly prices of noninsulin glucose-lowering agents in the U.S as of September 2018[7].

Class	Compound(s)	Dosage strength/product (if applicable)	Median AWP (min, max)†	Median NADAC (min, max)†	Maximum approved daily dose*
Biguanides	• Metformin	500 mg (IR)	$84 ($4, $93)	$2	2,000 mg
		850 mg (IR)	$108 ($6, $109)	$3	2,550 mg
		1,000 mg (IR)	$87 ($4, $88)	$2	2,000 mg
		500 mg (ER)	$89 ($82, $6,671)	$4 ($4, $1,267)	2,000 mg
		750 mg (ER)	$72 ($65, $92)	$4	1,500 mg
		1,000 mg (ER)	$1,028 ($1,028, $7,214)	$311 ($311, $1,321)	2,000 mg
Sulfonylureas (2nd generation)	• Glimepiride	4 mg	$71 ($71, $198)	$4	8 mg
	• Glipizide	10 mg (IR)	$75 ($67, $97)	$5	40 mg (IR)
		10 mg (XL)	$48	$15	20 mg (XL)
	• Glyburide	6 mg (micronized)	$50 ($48, $71)	$10	12 mg (micronized)
		5 mg	$93 ($63, $103)	$13	20 mg
Thiazolidinediones	• Pioglitazone	45 mg	$348 ($283, $349)	$4	45 mg
	• Rosiglitazone	4 mg	$407	$329	8 mg
α-Glucosidase inhibitors	• Acarbose	100 mg	$106 ($104, $106)	$23	300 mg
	• Miglitol	100 mg	$241	$311	300 mg
Meglitinides (glinides)	• Nateglinide	120 mg	$155	$46	360 mg
	• Repaglinide	2 mg	$878 ($162, $898)	$48	16 mg
DPP-4 inhibitors	• Alogliptin	25 mg	$234	$170	25 mg
	• Saxagliptin	5 mg	$490 ($462, $490)	$392	5 mg
	• Linagliptin	5 mg	$494	$395	5 mg
	• Sitagliptin	100 mg	$516	$413	100 mg
SGLT2 inhibitors	• Ertugliflozin	15 mg	$322	$257	15 mg
	• Dapagliflozin	10 mg	$557	$446	10 mg
	• Canagliflozin	300 mg	$558	$446	300 mg
	• Empagliflozin	25 mg	$558	$448	25 mg
GLP-1 receptor agonists	• Exenatide (extended release)	2 mg powder for suspension or pen	$792	$634	2 mg**
	• Exenatide	10 µg pen	$850	$680	20 µg
	• Dulaglutide	1.5/0.5 mL pen	$876	$702	1.5 mg**
	• Semaglutide	1 mg pen	$875	$704	1 mg**
	• Liraglutide	18 mg/3 mL pen	$1,044	$835	1.8 mg
Bile acid sequestrants	• Colesevelam	625 mg tabs	$712 ($674, $712)	$354	3.75 g
		3.75 g suspension	$674	$598	3.75 g
Dopamine-2 agonists	• Bromocriptine	0.8 mg	$855	$685	4.8 mg
Amylin mimetics	• Pramlintide	120 µg pen	$2,547	$2,036	120 µg/injection†††

AWP, average wholesale price; DPP-4, dipeptidyl peptidase 4; ER and XL, extended release; GLP-1, glucagon-like peptide 1; IR, immediate release; NADAC, National Average Drug Acquisition Cost; SGLT2, sodium–glucose cotransporter 2. †Calculated for 30-day supply (AWP [44] or NADAC [45] unit price × number of doses required to provide maximum approved daily dose × 30 days); median AWP or NADAC listed alone when only one product and/or price. *Utilized to calculate median AWP and NADAC (min, max); generic prices used, if available commercially. **Administered once weekly. †††AWP and NADAC calculated based on 120 µg three times daily.

The following is a summary of these monthly prices:

- The median NADAC cost for all strengths of immediate release (IR) metformin products and for the 500mg and 750mg strength extended release (ER) products is less than $5.
- Only the 1,000mg strength ER metformin products had a median NADAC cost of $311.
- SGLT2 inhibitor product NADAC costs range from$257 to $448 for different SGLT2 products.
- GLP-1 RA products had NADAC costs from $634 to $835.

The Mississippi Division of Medicaid's Universal Preferred Drug List (UPDL) contains preferred and non-preferred agents from each glucose-lowering drug class on the PDL. *(See **Appendix A** for detailed list of brand/generic drug names for agents in each noninsulin glucose-lowering drug class.)* In 2018 DOM implemented the following clinical criteria, recommended by the DUR Board, related to noninsulin glucose-lowering agents.

- Manual prior authorization (PA) for concomitant use of GLP-1 RA and DDP4.
- Manual prior authorization (PA) for the addition of a fourth concurrent oral anti-hyperglycemic agent.

Beyond these two clinical criteria, other criteria in the PDL for noninsulin glucose-lowering agents relate to requirements for obtaining non-preferred agents.

For this report, MS-DUR examined noninsulin glucose-lowering regimens used in the treatment of beneficiaries with T2DM from ***January 2016 through March 2019*** to determine treatment patterns in reference to metformin utilization as recommended in the 2019 ADA Standards of Care and the AACE/ACE Consensus Statement.

METHODS

A retrospective database analysis of Mississippi Medicaid beneficiaries was conducted using claims from January 1, 2014 to March 31, 2019 as the study period. In order to evaluate whether a trial of metformin was attempted prior to prescribing another hypoglycemic agent, MS-DUR identified all new starts of therapy with GLP-1 RA, SGLT2 inhibitor, dipeptidyl peptidase 4 (DPP4) inhibitor, sulfonylurea, and thiazolidinedione (TZD) products during the time frame between January 2016 and March 2019. Beneficiaries with a new start of any noninsulin glucose-lowering agent were identified.

- New starts were defined as initial prescriptions for a class of product preceded by at least 90 days without a prescription fill for that class of product (medication free period). Beneficiaries had to be continuously enrolled in Medicaid during the medication free period.

For the new start cohort, prescription claims were examined to determine if metformin had been used during the two years prior to the new start. A two-year lookback in medical claims was also conducted to identify diagnoses indicating the presence of diabetes, chronic kidney disease (CKD) and atherosclerotic cardiovascular disease (ASCVD) prior to the new start.

- CKD included diagnoses of medication induced or idiopathic kidney damage, disorder or disease.
- ASCVD included diagnoses of coronary artery disease, cerebrovascular disease, or peripheral artery disease.

Trends over time were analyzed for claim volume and cost of the drug therapy selected.

RESULTS

To determine concordance with the ADA and AACE/ACE treatment guideline recommendations for metformin as first-line therapy unless contraindications exist, the following results are presented.

Figure 6 shows the trend in new starts for the various noninsulin glucose-lowering classes. Detailed information about the number of new starts each quarter includes:

- Sulfonylurea new starts dropped significantly during 2016; however there are still a relatively large number of beneficiaries being initiated on sulfonylureas (approximate 200-250 new sulfonyl new starts per quarter).
- TZD new starts each quarter have been fairly low from 2016 through first quarter of 2019.
- DPP4 inhibitor new starts have decreased slowly over the entire period.
- GLP-1 RA new starts increased during 2017 and have remained somewhat stable since then. GLP-1 RA products were well established in the market by the beginning of 2016.
- SGLT2 inhibitor new starts increased to approximately the same level as GLP-1 RAs following the change in January 2017 of Jardiance (empagliflozin) to a preferred product. Following this change, SGLT2 inhibitor new starts increased to about the same level as GLP-1 RA new starts. During 2016, all SGLT2 inhibitors were non-preferred.

FIGURE 6 - Trend in New Starts

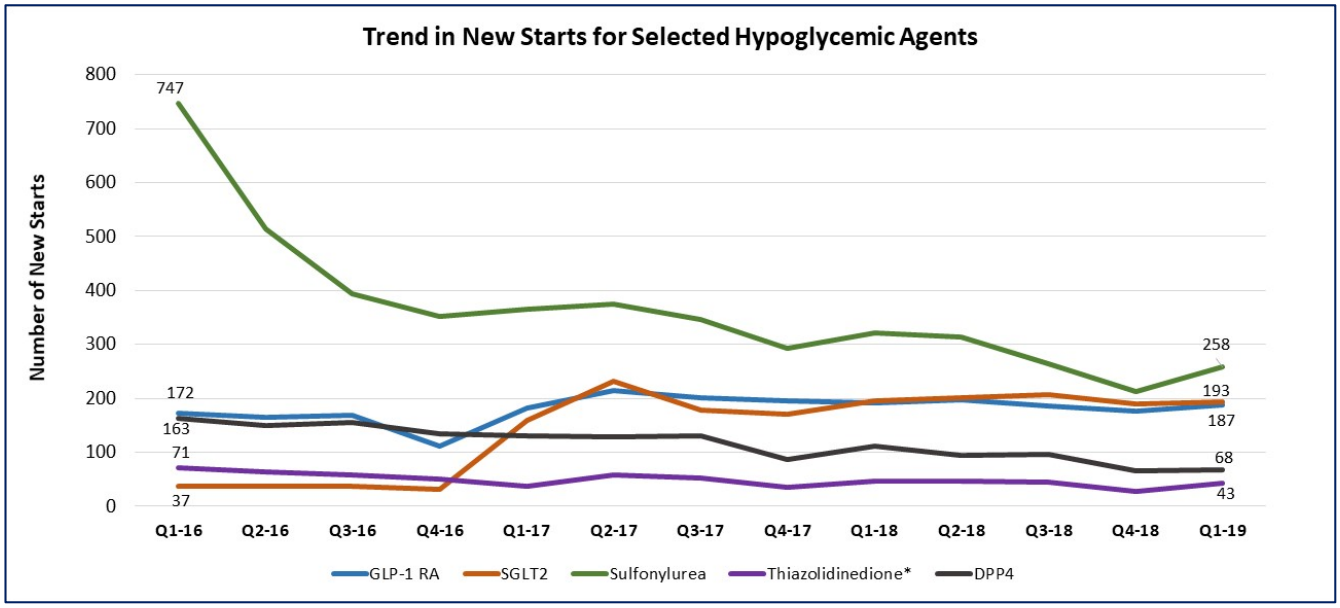


TABLE 1: Trend in New Starts for Selected Hypoglycemic Agents													
Pharmacy Program	Quarter												
	Q1-16	Q2-16	Q3-16	Q4-16	Q1-17	Q2-17	Q3-17	Q4-17	Q1-18	Q2-18	Q3-18	Q4-18	Q1-19
New Starts on GLP-1 RA Products													
FFS	20	20	18	13	30	29	37	23	25	31	26	19	37
UHC	58	47	59	33	54	74	72	79	66	76	59	63	46
MAG	94	96	92	65	96	111	92	94	100	90	101	88	93
MOL	0	1	0	0	2	0	0	0	1	0	0	6	11
All Programs	172	164	169	111	182	214	201	196	192	197	186	176	187
New Starts on SGLT2 Inhibitor Products													
FFS	3	4	3	3	20	29	27	24	26	35	31	33	42
UHC	12	9	21	12	49	73	57	48	51	71	84	74	70
MAG	22	25	13	16	90	128	94	99	118	96	88	76	78
MOL	0	0	0	0	1	1	1	0	1	0	4	6	3
All Programs	37	38	37	31	160	231	179	171	196	202	207	189	193
New Starts on Sulfonylurea Products													
FFS	142	89	71	73	73	80	75	70	76	84	60	59	70
UHC	243	183	147	119	126	121	116	100	95	106	92	66	72
MAG	362	240	176	159	166	171	155	122	148	122	104	73	102
MOL	0	2	0	0	1	3	1	1	2	1	9	14	14
All Programs	747	514	394	351	366	375	347	293	321	313	265	212	258
New Starts on Thiazolidinedione Products													
FFS	12	12	13	7	8	13	8	4	10	9	11	4	9
UHC	21	18	25	18	11	22	14	11	13	13	17	9	15
MAG	38	34	20	26	19	23	31	19	24	24	17	11	19
MOL	0	0	0	0	0	0	0	1	0	0	0	4	0
All Programs	71	64	58	51	38	58	53	35	47	46	45	28	43
New Starts on DPP4													
FFS	28	17	21	15	21	13	31	22	16	21	21	12	14
UHC	51	44	55	48	48	36	32	26	42	30	30	19	19
MAG	83	88	79	72	61	76	68	38	53	43	44	33	33
MOL	1	1	0	0	0	4	0	0	0	0	1	2	2
All Programs	163	150	155	135	130	129	131	86	111	94	96	66	68

The electronic prior authorization (SMART PA) process maintains access to a rolling two-year period of prescription and medical claims data. For all new starts, the initial fill for the product was set as the index date for initiating therapy. The two-year period prior to each index date was examined for the presence of any claim for metformin.

Table 2 illustrates:

- The percentage of new starts having a documented metformin trial varied among pharmacy programs with the percentage being slightly lower in the FFS program.
- The percentage of new starts of other glucose lowering products with a documented metformin trial was:
    - 61.0% for Sulfonylurea products
    - 65.6% for GLP-1 RA products
    - 68.0% for DPP4 products
    - 69.2% for TZD products
    - 76.7% for SGLT2 inhibitor products.

TABLE 2: Percent of New Starts with Documented Metformin Trial During Prior Two Years

Pharmacy Program	Sulfonylurea New Starts		TZD New Starts		GLP-1 RA New Starts		SGLT2 Inhibitor New Starts		DPP4 New Starts	
	Total	% With Metformin Trial*	Total	% With Metformin Trial*	Total	% With Metformin Trial*	Total	% With Metformin Trial*	Total	% With Metformin Trial*
FFS	1,022	54.8%	120	55.0%	328	54.0%	280	66.1%	252	58.3%
UHC	1,586	59.5%	207	70.0%	786	63.0%	631	79.1%	480	69.0%
MAG	2,100	64.6%	305	74.1%	1,212	70.6%	943	78.5%	771	70.6%
MOL	48	58.3%	5	80.0%	21	52.4%	17	64.7%	11	63.6%
All Programs	4,756	61.0%	637	69.2%	2,347	65.6%	1,871	76.7%	1,514	68.0%

** Any paid metformin claim found in two years prior to new start of each product.*

One reason often noted for metformin discontinuation is intolerance. Metformin extended release (ER) is associated with better tolerability than metformin immediate release (IR). Since both ADA and AACE/ACE treatment guidelines strongly recommend all T2DM patients take metformin, the ER formulation may provide a higher level of tolerability.

As shown in Table 3:

- Majority of beneficiaries with documented prior metformin trials used metformin IR only.

TABLE 3: Type of Metformin Trial Prior to New Start

Metformin Trial*	Sulfonylurea New Starts *(Total = 4,756)*	TZD New Starts *(Total = 637)*	DPP4 New Starts *(Total = 1,514)*	GLP-1 RA New Starts *(Total = 2,347)*	SGLT2 Inhibitor New Starts *(Total = 1,871)*
None	39.3%	30.8%	32.0%	34.4%	23.3%
Metformin IR only	49.6%	52.6%	51.3%	44.7%	53.4%
Metformin ER only	6.1%	7.1%	8.5%	12.1%	11.3%
Metforming IR and ER	5.0%	9.6%	8.1%	8.8%	12.0%

** Any paid metformin claim found in two years prior to new start of GLP-1 RA or SGLT2.*

Several controlled trials have demonstrated potential benefits associated with use of certain SGLT2 inhibitors and GLP-1 RAs for individuals with diabetes and ASCVD or CKD. The ADA, AACE/ACE, and ESC guidelines recognize the potential additional benefits in these populations. This may be viewed as justification for bypassing a metformin trial before prescribing these products. In order to determine if the presence of these conditions is associated with the absence of a documented metformin trial, MS-DUR examined all medical claims for the two-year period before the index date for the presence of diagnostic codes for CKD, ASCVD, hypertension and heart failure.

Table 4 shows the number of new starts for each product class with documentation of each condition and the percentage of these beneficiaries with a documented prior metformin trial.

- Beneficiaries with special conditions were significantly less likely to have a prior metformin trial than were beneficiaries without these conditions in only heart failure.

TABLE 4: Number of GLP-1 RA and SGLT2 Inhibitor New Starts Having Documented Special Conditions Which May Warrant Early Use and Percentage With Condition Having Metformin Trial

Special Conditions Which May Justify Early Metformin Use	GLP-1 RA New Starts *(Total = 2,045)*		SGLT2 Inhibitor New Starts *(Total = 1,730)*	
	# With Condition	% With Condition Having Metformin Trial*	# With Condition	% With Condition Having Metformin Trial*
CKD	1,554	70.0%	1,381	77.0%
ASCVD	585	63.3%	563	75.8%
Hypertension	979	66.9%	653	77.2%
Heart Failure	344	57.6%**	247	68.8%**
Any of The Conditions	1,885	68.6%	1,546	77.0%

** Any paid metformin claim found in two years prior to new start of GLP-1 RA or SGLT2.*

*** Significantly lower for beneficiaries with condition ($p < 0.01$).*

Since the use of certain glucose-lowering products can result in weight loss, another concern is the potential prescribing of these products for weight loss in beneficiaries without diabetes. As patients with diabetes should receive routine medical care for managing and monitoring their condition, MS-DUR checked for medical claims with diagnostic codes for diabetes during the two-year period prior to each index date for new starts.

Table 5 depicts:

- 270 (11.5%) beneficiaries initiating GLP-1 RAs did not have claims documenting a diabetes diagnosis prior to being prescribed these products.
    - It is worth noting that Saxenda® (liraglutide) is indicated only for treatment of obesity. Currently DOM does not cover weight loss products.
- The percentage of beneficiaries prescribed a SGLT2 inhibitor without a diabetes diagnosis present is low (n= 52, 2.8%).

TABLE 5: Percent of GLP-1 RA and SGLT2 Inhibitor New Starts Having Documented Diabetes During Two Years Prior to Start of Therapy

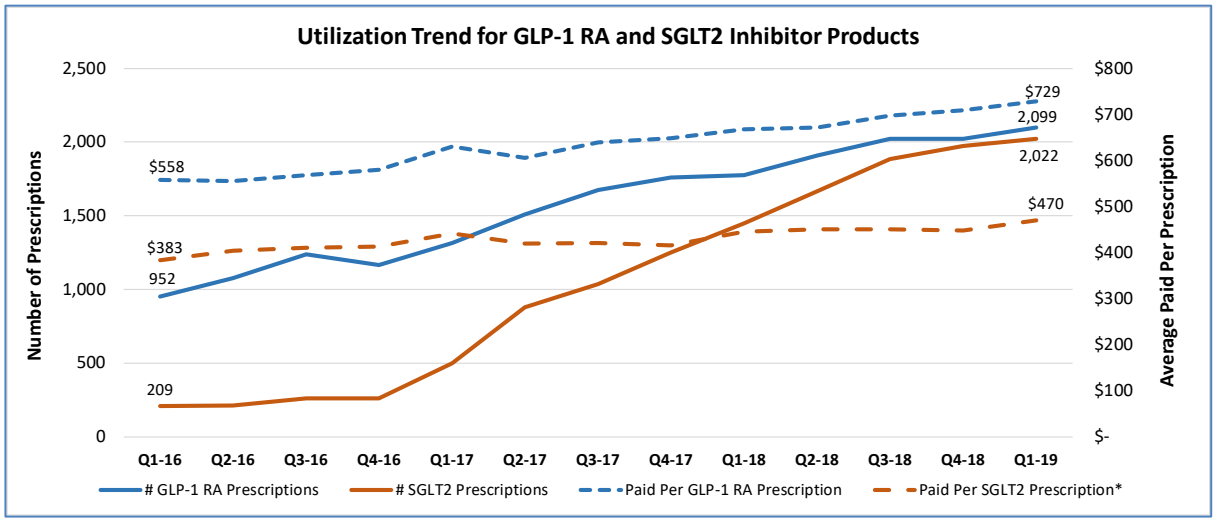
Pharmacy Program	GLP-1 RA New Starts Documented Diabetes Diagnosis			SGLT2 Inhibitor New Starts Documented Diabetes Diagnosis		
	Yes	No		Yes	No	
FFS	300	28	8.5%	263	17	6.1%
UHC	671	115	14.6%	612	19	3.0%
MAG	1,092	120	9.9%	927	16	1.7%
MOL	14	7	33.3%	17	0	0.0%
All Programs	2,077	270	11.5%	1819	52	2.8%

GLP-1 RA and SGLT2 inhibitor products play a prominent role in diabetes treatment guidelines, thus an increased utilization of these products in the Mississippi Medicaid population was anticipated. Figure 7 affirms utilization of both SLGT2 inhibitors and GLP-1 RAs has increased steadily over the last three years. During this time period,

- The average amount paid per prescription has increased slightly for SGLT2 inhibitor single agent products ($383 to $470, 23% increase) and
- The average amount paid per prescription for GLP-1 RA products is a somewhat more substantial increase ($558 to $729, 31% increase).

Detailed tables for each pharmacy program are provided in Tables 6 and 7.

FIGURE 7: Utilization Trend for GLP-1 RA and SGLT2 Inhibitor Products



** Paid per prescription is for single agent products only.*

TABLE 6: Utilization Trend for GLP-1 RA Products													
Pharmacy Program	Quarter												
	Q1 2016	Q2 2016	Q3 2016	Q4 2016	Q1 2017	Q2 2017	Q3 2017	Q4 2017	Q1 2018	Q2 2018	Q3 2018	Q4 2018	Q1 2019
Number of Paid Prescription Claims													
FFS	132	151	170	153	184	213	258	243	231	261	273	278	292
UHC	363	385	447	388	416	481	519	597	610	683	697	668	680
MAG	457	542	620	626	714	814	897	921	935	963	1,050	1,066	1,095
MOL	0	0	0	0	0	0	0	0	0	0	0	9	32
All Programs	952	1,078	1,237	1,167	1,314	1,508	1,674	1,761	1,776	1,907	2,020	2,021	2,099
Total Dollars Paid for Claims													
All Programs	$ 530,877	$ 598,570	$ 702,677	$ 677,876	$ 830,221	$ 913,651	$ 1,072,235	$ 1,141,912	$ 1,184,847	$ 1,279,917	$ 1,407,852	$ 1,432,821	$ 1,530,237
Average Paid Per Prescription													
All Programs	$ 558	$ 555	$ 568	$ 579	$ 630	$ 605	$ 639	$ 648	$ 667	$ 671	$ 697	$ 709	$ 729

TABLE 7: Utilization Trend for SGLT2 Inhibitor Products													
Pharmacy Program	Quarter												
	Q1 2016	Q2 2016	Q3 2016	Q4 2016	Q1 2017	Q2 2017	Q3 2017	Q4 2017	Q1 2018	Q2 2018	Q3 2018	Q4 2018	Q1 2019
Number of Paid Prescription Claims													
FFS	34	28	32	31	72	129	151	213	234	283	331	314	372
UHC	66	66	86	73	144	266	321	371	417	507	627	660	688
MAG	109	120	144	158	284	482	565	666	798	876	928	984	946
MOL	0	0	0	0	0	0	0	0	0	0	0	15	16
All Programs	209	214	262	262	500	877	1,037	1,250	1,449	1,666	1,886	1,973	2,022
Single Agent Product Claims*													
Total # Paid Claims	179	173	211	215	416	708	831	1,004	1,191	1,377	1,570	1,610	1,667
Total Paid	$ 68,546	$ 69,825	$ 86,480	$ 88,708	$ 183,818	$ 297,050	$ 349,381	$ 417,070	$ 531,172	$ 619,608	$ 707,603	$ 721,798	$ 782,937
Average Paid Per Prescription	$ 383	$ 404	$ 410	$ 413	$ 442	$ 420	$ 420	$ 415	$ 446	$ 450	$ 451	$ 448	$ 470

** Total amount paid and average paid per prescription are only reported for single agent products since combination products have higher costs due to multiple active ingredients and the cost of SGLT2 cannot be determined.*

CONCLUSIONS

Diabetes imparts a tremendous burden on hundreds of thousands of Mississippians annually. Treatment is important and established guidelines provide evidence-based recommendations for effectively treating beneficiaries. Both the ADA and AACE/ACE guidelines recommend the utilization of metformin as first-line therapy in the treatment of T2DM unless contraindications are present. MS-DUR analysis indicates that approximately 31.4% of beneficiaries initiated on noninsulin glucose-lowering agents other than metformin from Q1 2016 – Q1 2019 did not have a documented trial of metformin within the prior two years. Of those who did have a documented trial of metformin, most were tried on metformin IR formulations only. With Mississippi having one of the highest rates of diabetes in the US, evidence-based treatment for beneficiaries is imperative.

RECOMMENDATIONS

MS-DUR seeks input from the DUR Board for clinically appropriate recommendations related to the treatment of T2DM in Medicaid beneficiaries.

APPENDIX A

Diabetes Medications

Generic Name	Brand Name
Biguanides	
Metformin	Glucophage, Fortamet, Glumetza, Riomet
Meglitinides	
Repaglinide	Prandin
Nateglinide	Starlix
Thiazolidinediones	
Pioglitazone	Actos
Rosiglitazone	Avandia
Sodium Glucose Co-Transporter 2 Inhibitors	
Canagliflozin	Invokana
Dapagliflozin	Farxiga
Empagliflozin	Jardiance
Ertugliflozin	Seglatro
Glucagon-Like Peptide 1 Agonists	
Exenatide	Byetta
Exenatide ER	Bydureon
Liraglutide	Victoza
Dulaglutide	Trulicity
Albiglutide	Tanzeum
Lixisenatide	Adlyxin
Semaglutide	Ozempic

Generic Name	Brand Name
Sulfonylureas	
Glipizide	Glucotrol, Glipizide
Glimepiride	Amaryl
Glyburide	Glynase
Chlorpropamide	Diabinese
Tolbutamide	N/A
Tolazamide	N/A
Dipeptidyl Peptidase 4 Inhibitors	
Sitagliptin	Januvia
Saxagliptin	Onglyza
Linagliptin	Tradjenta
Alogliptin	Nesina
Alpha-Glucosidase Inhibitors	
Miglitol	Glyset
Acarbose	Precose
Amylin Analog	
Pramlintide	SymlinPen 60,120
Dopamine Agonist	
Bromocriptine	Cycloset
Bile Acid Binding Resin	
Colesevelam	Welchol

Combination Products			
Pioglitazone/Metformin	ActoPlus Met	Canagliflozin/Metformin	Invokamet
Rosiglitazone/Metformin	Avandamet	Sitagliptin/Metformin	Janumet
Rosiglitazone/Glimepiride	Avandaryl	Linagliptin/Metformin	Jentadueto
Pioglitazone/Glimepiride	Duetact	Alogliptin/Metformin	Kazano
Glyburide/Metformin	Glucovance	Saxagliptin/Metformin	Kombiglyze
Glipizide/Metformin	Metaglip	Alogliptin/Pioglitazone	Oseni
Repaglinide/Metformin	PrandiMet	Dapagliflozin/Metformin	Xigduo
Insulin glargine/lixisenatide	Soliqua	Insulin deludec/Liraglutide	Xultophy
Empagliflozin/Metformin	Synjardy	Empagliflozin/Linagliptin	Glyxambi
Dapagliflozin/Saxagliptin	Qtern	Ertugliflozin/Metformin	Segluromet
Ertugliflozin/Sitagliptin	Steglujan		

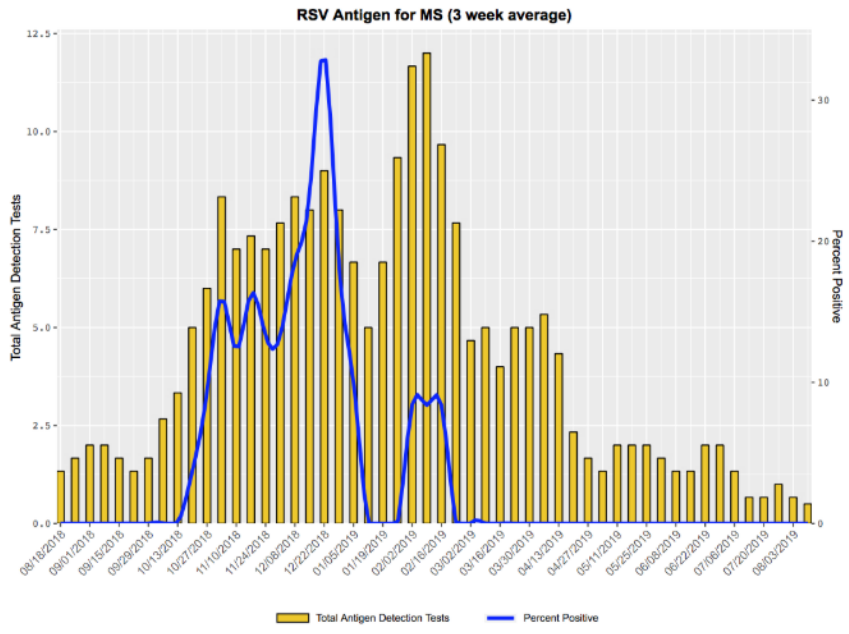
PALIVIZUMAB UTILIZATION UPDATE: 2015-16 THROUGH 2018-2019 SEASONS

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. The AAP Committee on Infectious Diseases and the Subcommittee on Bronchiolitis regularly review and evaluate all data as they become available. In September 2017, all available data regarding palivizumab (Synagis®) were considered, and both groups reaffirmed the recommendations in the RSV policy statement and technical report.[2]

In the United States, RSV infections typically occur at the time of annual community outbreaks, during late fall, winter, and early spring. Annually RSV leads to an average of 2.1 million outpatient visits and over 57,000 hospitalizations among children under 5 years of age.[3] 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 are 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

Figure 1 for 2018-2019 season



[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] American Academy of Pediatrics News. October 19, 2017. https://www.aappublications.org/news/2017/10/19/RSV101917

[3] Hall CB, Weinberg GA, Iwane MK, Blumkin AK, Edwards KM, et al. The burden of respiratory syncytial virus infection in young childrenExternal. New Engl J Med. 2009;360(6):588-98.

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.[4] 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-week moving average. 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 palivizumab utilization for the last four seasons. The total number of beneficiaries treated rose slightly last year almost returning to the same number of beneficiaries treated in the 2015-2016 season. The average paid amount per beneficiary treated was the highest it has been at $10,136 last season. This increase in average paid amount per beneficiary can be attributed to an increase in the mean number of claims/beneficiary to 4.4. The maximum recommended doses in a season is 5. The total dollars paid for 2018-2019 season was the highest of the past four seasons at $3,740,227.

Table 1: Palivizumab Utilization Summary by Season and Pharmacy Program

Season	Pharmacy Program				
	FFS	UHC	MAG	MOL	Total
	Number of Unique Beneficiaries				
2015-16	70	148	157	0	375
2016-17	24	158	153	0	335
2017-18	18	164	165	0	347
2018-19	34	155	175	5	369
	Total Dollars Paid				
2015-16	$419,724	$1,322,920	$1,409,679	$ -	$3,152,323
2016-17	$203,037	$1,406,196	$1,606,513	$ -	$3,215,746
2017-18	$93,812	$1,283,588	$1,725,471	$ -	$3,102,871
2018-19	$270,004	$1,384,210	$2,078,395	$7,619	$3,740,227
	Mean Number of Claims/Beneficiary				
2015-16	2.8	3.5	3.6	0	3.4
2016-17	3.5	3.5	4.0	0	3.7
2017-18	3.3	3.6	4.2	0	3.8
2018-19	4.1	4.0	4.9	1	4.4
	Dollars Paid / Beneficiary				
2015-16	$5,996	$8,939	$8,979	$ -	$8,406
2016-17	$8,460	$8,900	$10,500	$ -	$9,599
2017-18	$5,212	$7,827	$10,457	$ -	$8,942
2018-19	$7,941	$8,930	$11,877	$1,524	$10,136

Note: Previous year numbers in this report vary slightly from the numbers reported in the May 2018 DUR Update due to lag time in the reporting of medical claims.

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

[4] https://www.cdc.gov/surveillance/nrevss/rsv/index.html. (accessed 8/19/2019).

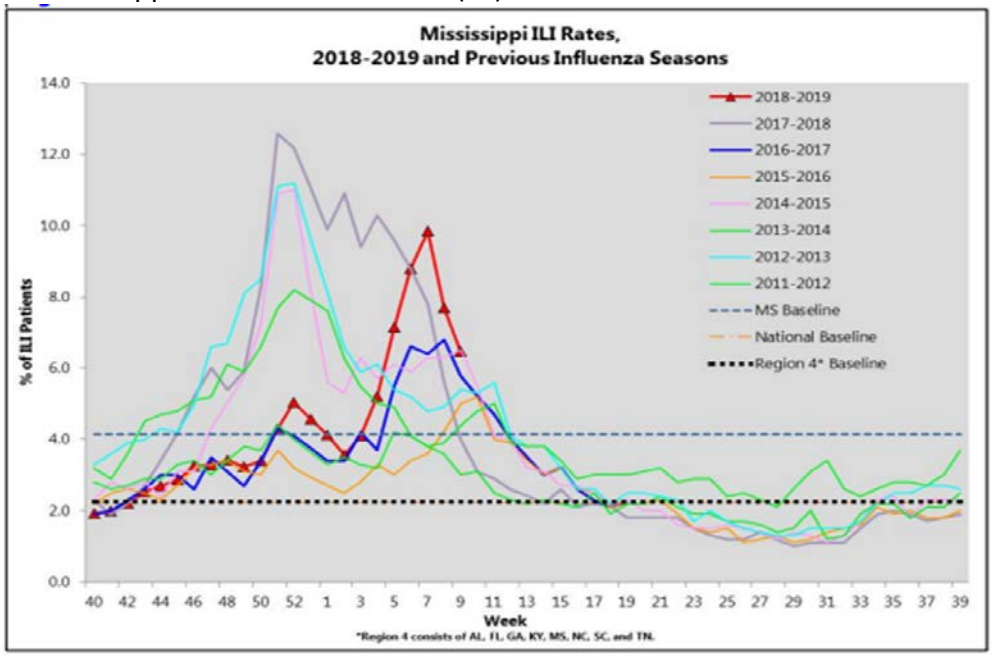
INFLUENZA AND TREATMENT UPDATE
2018-2019 SEASON

BACKGROUND

Influenza (Flu) is a contagious respiratory illness that can cause mild to severe illness, and can even lead to death. While infection from the influenza virus can occur at any time, influenza viruses typically circulate in the United States from late fall through early spring.[1]
For the 2018-2019 flu season[2]:

- In contrast to the United States 2017-2018 severe influenza season, the 2018-2019 flu season was moderately severe. Activity began to increase in November, peaked mid-February, and returned to below baseline in mid-April. This 21-week season was the longest in 10 years, according to CDC's recent Morbidity and Mortality Weekly Report.
- Compared to 2017-2018's flu season, rates of hospitalization were lower for adults but similar for children.
- Influenza-like-illness (ILI) peaked in February 2019, significantly lower than 2017-2018's peak. (Figure 1)

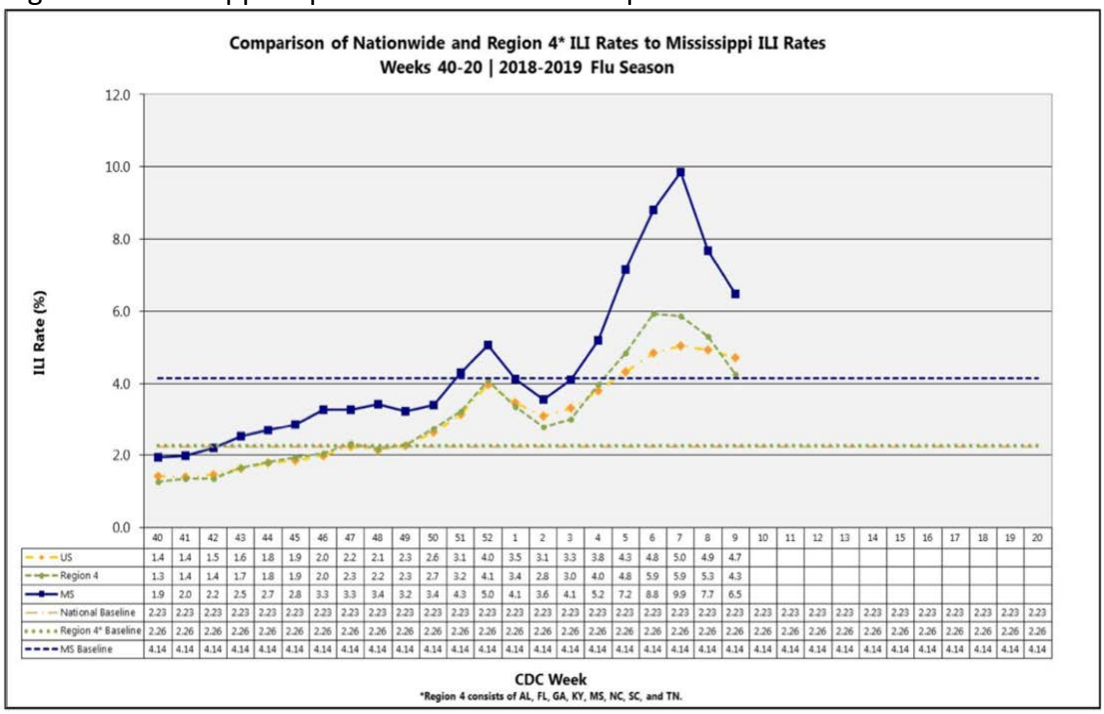
Figure 1: Mississippi Influenza Like Illness (ILI) Rates 2011-2019[3]



[1] Season. MMWR Recomm Rep 2019;68(No. RR-3):1–21. DOI: http://dx.doi.org/10.15585/mmwr.rr6803a1
[2] Centers for Disease Control and Prevention: Estimated Influenza Illnesses, Medical visits, Hospitalizations, and Deaths in the United States — 2018–2019 influenza season. https://www.cdc.gov/flu/about/burden/preliminary-in-season-estimates.htm
[3] Mississippi State Department of Health: 2018-2019 Influenza Surveillance Report. Week 9; February 24-March2, 2019; https://msdh.ms.gov/msdhsite/_static/resources/8038.pdf.

- Comparing the rates of ILI in Mississippi for the 2018-2019 flu season to nationwide and regional rates, Mississippi consistently had higher rates. (Figure 2)

Figure 2: Mississippi Department of Health Comparison of ILI Rates[3]



	40	41	42	43	44	45	46	47	48	49	50	51	52	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
US	1.4	1.4	1.5	1.6	1.8	1.9	2.0	2.2	2.1	2.3	2.6	3.1	4.0	3.5	3.1	3.3	3.8	4.3	4.8	5.0	4.9	4.7											
Region 4	1.3	1.4	1.4	1.7	1.8	1.9	2.0	2.3	2.2	2.3	2.7	3.2	4.1	3.4	2.8	3.0	4.0	4.8	5.9	5.9	5.3	4.3											
MS	1.9	2.0	2.2	2.5	2.7	2.8	3.3	3.3	3.4	3.2	3.4	4.3	5.0	4.1	3.6	4.1	5.2	7.2	8.8	9.9	7.7	6.5											
National Baseline	2.23	2.23	2.23	2.23	2.23	2.23	2.23	2.23	2.23	2.23	2.23	2.23	2.23	2.23	2.23	2.23	2.23	2.23	2.23	2.23	2.23	2.23	2.23	2.23	2.23	2.23	2.23	2.23	2.23	2.23	2.23	2.23	2.23
Region 4* Baseline	2.26	2.26	2.26	2.26	2.26	2.26	2.26	2.26	2.26	2.26	2.26	2.26	2.26	2.26	2.26	2.26	2.26	2.26	2.26	2.26	2.26	2.26	2.26	2.26	2.26	2.26	2.26	2.26	2.26	2.26	2.26	2.26	2.26
MS Baseline	4.14	4.14	4.14	4.14	4.14	4.14	4.14	4.14	4.14	4.14	4.14	4.14	4.14	4.14	4.14	4.14	4.14	4.14	4.14	4.14	4.14	4.14	4.14	4.14	4.14	4.14	4.14	4.14	4.14	4.14	4.14	4.14	4.14

- During the 2018-2019 season the vaccine was approximately 30% effective in reducing influenza illness and hospitalizations.[4] The effectiveness of influenza vaccines varies depending on several factors, such as the age and health of the recipient, the types and subtypes of circulating influenza viruses, and the degree of similarity between circulating viruses and those included in the vaccine.
- There were an estimated 37.4-42.9 million flu illnesses, 531-647,000 hospitalizations and 36,400-61,200 deaths from the flu.[5]

[4] Centers for Disease Control and Prevention: Advisory Committee on Immunization Practices (ACIP); June 2019 Meeting; Preliminary Estimates of 2019-19 Seasonal Influenza Vaccine Effectiveness against Medically Attended Influenza from three U.S. Networks. https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2019-06/flu-3-flannery-508.pdf

[5]Centers for Disease Control and Prevention: Estimated Influenza Illnesses, Medical visits, Hospitalizations, and Deaths in the United States — 2018–2019 influenza season. https://www.cdc.gov/flu/about/burden/preliminary-in-season-estimates.htm

Preventing infection is vital with flu vaccination serving as the primary source of flu prevention. Vaccination has been shown to reduce the morbidity and mortality associated with influenza. The flu vaccine causes antibodies to develop in the body approximately 2 weeks after vaccination. Protection from the flu vaccine is thought to persist for approximately 6 months and declines over time due to waning antibodies and changes in the circulating influenza virus from year to year. [6,7]

RECOMMENDATIONS FOR THE USE OF INFLUENZA VACCINES, 2019–20[8]

Groups Recommended for Vaccination

Routine annual influenza vaccination for all persons aged ≥6 months who do not have contraindications has been recommended by CDC and CDC's Advisory Committee on Immunization Practices (ACIP) since 2010. ACIP's most recent recommendations for seasonal influenza vaccines for the 2019-2020 season, published August 23, 2019, updates the 2018-2019 recommendations. All persons aged ≥6 months who do not have contraindications should be vaccinated annually. However, vaccination to prevent influenza is particularly important for persons who are at increased risk for severe illness and complications from influenza and for influenza-related outpatient, emergency department, or hospital visits. When vaccine supply is limited, vaccination efforts should focus on delivering vaccination to persons at higher risk for medical complications attributable to severe influenza who do not have contraindications. These persons include (no hierarchy is implied by order of listing):

- *All children aged 6 through 59 months;*
- *All persons aged ≥50 years;*
- *Adults and children who have chronic pulmonary (including asthma), cardiovascular (excluding isolated hypertension), renal, hepatic, neurologic, hematologic, or metabolic disorders (including diabetes mellitus);*
- *Persons who are immunocompromised due to any cause (including but not limited to immunosuppression caused by medications or HIV infection);*
- *Women who are or will be pregnant during the influenza season;*
- *Children and adolescents (aged 6 months through 18 years) who are receiving aspirin- or salicylate-containing medications and who might be at risk for experiencing Reye syndrome after influenza virus infection;*
- *Residents of nursing homes and other long-term care facilities;*
- *American Indians/Alaska Natives; and*

[6] Immunization Action Coalition. http://www.immunize.org/askexperts/experts_inf.asp

[7] Centers for Disease Control and Prevention: Children & Influenza. https://www.cdc.gov/flu/protect/children.htm

[8] Grohskopf LA, Alyanak E, Broder KR, Walter EB, Fry AM, Jernigan DB. Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2019–20 Influenza Season. MMWR Recomm Rep 2019;68(No. RR-3):1–21. DOI: http://dx.doi.org/10.15585/mmwr.rr6803a1

- *Persons who are extremely obese (body mass index ≥40 for adults)*

Vaccination of persons who live with or care for those who are at increased risk is also emphasized. When vaccine supply is limited, vaccination efforts should focus on delivering vaccination to persons at higher risk for influenza-related complications, as well as persons who live with or care for such persons, including the following:

- *Health care personnel working in health-care settings who have the potential for exposure to patients and/or to infectious materials. ACIP guidance for immunization of health care personnel has been published previously;*
- *Household contacts (including children) and caregivers of children aged ≤59 months (i.e., aged <5 years) and adults aged ≥50 years, particularly contacts of children aged <6 months; and*
- *Household contacts (including children) and caregivers of persons with medical conditions that put them at higher risk for severe complications from influenza.*

Timing of Vaccination:

Optimally, vaccination should occur before onset of influenza activity in the community. However, because timing of the onset, peak, and decline of influenza activity varies, the ideal time to start vaccinating cannot be predicted each season. Vaccination efforts should continue throughout the season because the duration of the influenza season varies, and influenza activity might not occur in certain communities until February or March.

- *Balancing considerations regarding the unpredictability of timing of onset of the influenza season and concerns that vaccine-induced immunity might wane over the course of a season, it is recommended that vaccination should be offered by the end of October.*
- *Children aged 6 months through 8 years who require 2 doses should receive their first dose as soon as possible after the vaccine becomes available to allow the second dose (which must be administered ≥4 weeks later) to be received by the end of October.*
- *For those requiring only 1 dose for the season, early vaccination (i.e., in July and August) is likely to be associated with suboptimal immunity before the end of the influenza season, particularly among older adults. No recommendation is made for revaccination later in the season of persons who have already been fully vaccinated (i.e., providing a booster dose).*
- *Vaccination should continue to be offered as long as influenza viruses are circulating and unexpired vaccine is available. To avoid missed opportunities for vaccination, providers should offer vaccination during routine health care visits and hospitalizations.*

Primary Changes and Updates in the Recommendations:

- *Routine annual influenza vaccination of all persons aged ≥6 months who do not have contraindications continues to be recommended. No preferential recommendation is made for one influenza vaccine product over another for persons for whom more than one licensed, recommended, and appropriate product is available.*

TREATMENT

When patients with the flu are treated within 48 hours of becoming sick, antiviral drugs can reduce symptoms and duration of the illness. Antivirals have been shown to lessen symptoms and shorten illness duration by 1 to 2 days and can prevent serious flu complications such as pneumonia. Antiviral medications can be grouped into the following classes:

- adamantanes - *amantadine (Symmetrel) and rimantadine (Flumadine)*;
- neuraminidase inhibitors - *oseltamivir (Tamiflu), peramivir (Rapivab), and zanamivir (Relenza)*;
- endonuclease inhibitors – *baloxavir marboxil (Xofluza)*.

Adamantanes are active against influenza A viruses only. Additionally, high levels of resistance to adamantanes have been noted in past flu seasons; and thus, adamantanes are not recommended for antiviral treatment or chemoprophylaxis of currently circulating influenza viruses.[9]

At this time, antiviral resistance to neuraminidase inhibitors is currently low. The only oral neuraminidase inhibitor, oseltamivir (Tamiflu®), is FDA indicated for the treatment of acute, uncomplicated influenza in patients 2 weeks of age and older who have been symptomatic for no more than 2 days.[10] Although it is also FDA indicated for prophylaxis of influenza in patients 1 year and older, the CDC and American Academy of Pediatrics (AAP) recommend prophylactic therapy in children as young as 3 months of age.[11] Treatment dosing is typically twice daily for 5 days, while prophylactic dosing is typically once daily for 10 days.

On October 24, 2018 the FDA approved the first new antiviral for flu in nearly 20 years. Xofluza® (baloxavir marboxil) is indicated for the treatment of acute, uncomplicated influenza in patients 12 years and older who have been symptomatic for no more than 48 hours. Xofluza, taken as a single oral dose, should be administered within 48 hours of symptom onset and may be taken with or without food.

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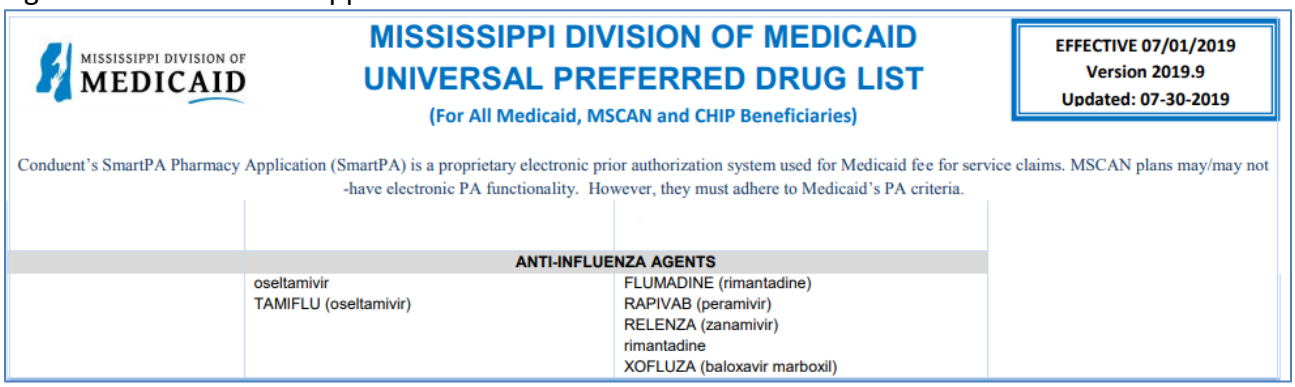
[9] Centers for Disease Control and Prevention: Influenza Antiviral Medications: Summary for Clinicians. https://www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm

[10] Tamiflu®{package insert}. California: Genentech, Inc. 2012; https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021087s062lbl.pdf (Accessed November 2018).

[11] American Academy of Pediatrics Committee on Infectious Diseases. Recommendations for prevention and control of influenza in children, 2011-2012. Pediatrics 2011; 128:813-25; PMID:21890834; http://dx.doi.org.umiss.idm.oclc.org/10.1542/peds.2011-2295

Currently Mississippi's Universal Preferred Drug List (UPDL) lists branded Tamiflu and its generic, oseltamivir, as preferred agents. Other neuraminidase inhibitors, adamantanes, and Xofluza are categorized as non-preferred agents. (Figure 3)

Figure 3: Current Mississippi Medicaid UPDL[12]



MISSISSIPPI DIVISION OF MEDICAID

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

EFFECTIVE 07/01/2019
Version 2019.9
Updated: 07-30-2019

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

ANTI-INFLUENZA AGENTS	
oseltamivir TAMIFLU (oseltamivir)	FLUMADINE (rimantadine) RAPIVAB (peramivir) RELENZA (zanamivir) rimantadine XOFLUZA (baloxavir marboxil)

At the December 2018 DUR Board meeting, MS-DUR was asked to present an annual influenza update to the Board at the conclusion of each flu season. Specifically, MS-DUR was asked to assess the utilization of anti-influenza therapies among Medicaid beneficiaries.

METHODS

Pharmacy and medical claims for anti-influenza agents were extracted for state fiscal years (SFY) 2018 (July 1, 2017 to June 30, 2018) and 2019 (July 1, 2018 to June 30, 2019), respectively. As of June 30, 2019 there were 673,247 beneficiaries enrolled in the DOM.[13] The analysis included prescriptions for all anti-influenza agents listed on MS DOM PDL (Tamiflu®, oseltamivir, Flumadine®, rimantadine, Rapivab®, Relenza®, Xofluza®) from all pharmacy programs -- fee-for-service and all three Coordinated Care Organizations (UHC, Mag, Mol). The number of beneficiaries taking these agents, the number of prescriptions filled and the amounts paid for these prescriptions were determined for state fiscal years 2018 and 2019, respectively.

[12]Mississippi Division of Medicaid Universal Preferred Drug List; https://medicaid.ms.gov/wp-content/uploads/2019/04/MSPDLeffective07012019.pdf

[13] Mississippi Division of Medicaid Enrollment Report CY 2019. https://medicaid.ms.gov/wp-content/uploads/2019/02/2019-Enrollment-Report.pdf

RESULTS

In Table 1 the number of Medicaid beneficiaries with documented influenza vaccination for SFY 2019 is displayed.

- 73,223 beneficiaries had documentation of receiving flu vaccination during SFY 2019.
- It should be noted that vaccinations provided through the Vaccines for Children (VFC) Program do not appear in Medicaid claims data.

Table 1: Influenza Vaccination Utilization in Mississippi Medicaid for Fiscal Year 2019 (July 2018 - June 2019)

Plan at time of flu vaccination	Number of beneficiaries who received flu vaccines	Amount paid
FFS	9,919	$1,450,632.00
UHC	27,909	$3,880,669.00
Mag	33,750	$4,682,897.00
Mol	1,645	$214,326.00
Total	73,223	$10,228,524.00

Note: FFS = Fee-for-service, UHC = United Health Care, Mag = Magnolia, Mol = Molina
* Beneficiaries with medical or pharmacy claims were identified.
CPT codes for influenza vaccines included: 90630, 90685-90688, 90654-90658, 90660-90662, 90653, 90666, 90668, 90664, 90672-90674, 90756, 90682, 90686, 90682, Q2035.
References:
1. www.immunize.org/catg.d/p4072.pdf
2. https://www.aapc.com/blog/44189-code-the-shots-for-flu-vaccine/

Table 2 displays number of anti-influenza prescriptions filled, beneficiaries treated and the amounts paid for each antiviral agent during SFY 2018 and SFY 2019.

- The 2018-2019 influenza season was not as severe as the prior season as evidenced by a decrease in number of prescriptions filled, beneficiaries treated, and amounts paid for anti-influenza treatments in SFY 2019.
- Utilization of branded Tamiflu® decreased substantially in SFY 2019 attributed to a shortage of generic oseltamivir in SFY 2018 which led to increased utilization of the branded product that year.

Table 2: Number of Prescriptions Filled, Benes and Paid Amounts for Anti-Influenza Agents by State Fiscal Years 2018 and 2019 in Mississippi Medicaid							
Drug	Plan	SFY 2018 (Jul-17 to Jun-18)			SFY 2019 (Jul-18 to Jun-19)		
		Prescriptions Filled	Benes	Paid Amount	Prescriptions Filled	Benes	Paid Amount
Tamiflu	FFS	838	828	$210,337.04	23	23	$6,189.42
	UHC	2610	2584	$637,671.79	127	127	$32,265.40
	Mag	1618	1611	$385,542.74	61	61	$13,158.91
	Mol	0	0	$0.00	55	54	$14,270.60
	Total	5066	5023	$1,233,551.57	266	265	$65,884.33
Oseltamivir Phosphate	FFS	13859	13035	$1,923,570.85	11798	11339	$1,257,210.29
	UHC	31318	29532	$4,345,165.38	25043	23868	$2,700,883.56
	Mag	32289	31651	$4,465,566.72	28190	26760	$3,001,291.58
	Mol	0	0	$0.00	2823	2753	$296,874.60
	Total	77466	74218	$10,734,302.95	67854	64720	$7,256,260.03
Relenza	FFS	12	6	$828.78	0	0	$0.00
	UHC	2	1	$140.58	2	1	$135.34
	Mag	10	5	$696.90	10	5	$670.70
	Mol	0	0	$0.00	0	0	$0.00
	Total	24	12	$1,666.26	12	6	$806.04
Xofluza	FFS	0	0	$0.00	40	39	$6,148.12
	UHC	0	0	$0.00	89	89	$13,743.24
	Mag	0	0	$0.00	4	4	$570.61
	Mol	0	0	$0.00	0	0	$0.00
	Total	0	0	$0.00	133	132	$20,461.97
Grand total (across plans and drugs)		**82,556**	**79,253**	**$11,969,520.78**	**68,265**	**65,123**	**$7,343,412.37**

Note:
Other anti-influenza agents, namely Rapivab (peramivir) and Flumadine (rimantadine), did not have any pharmacy or medical claims in the study period.
Total represents sum of number of prescriptions filled/number of benes/paid amounts across all plans for a drug.
Grand total represents sum of number of prescriptions filled/number of benes/paid amounts across all plans and all drugs within each fiscal year.
Paid amounts represent amount reported on claims as paid to the pharmacy. These amounts do not reflect final actual costs after rebates, etc.
Beneficiaries may be represented under multiple drugs if they had multiple drug utilizations.

Table 3 displays anti-influenza drug utilization in Mississippi Medicaid for SFY 2019. The total number of unique beneficiaries receiving drugs is shown by health plan and number of prescription fills.

- Majority of beneficiaries receiving anti-influenza drugs received one prescription fill (n=61,842, 95.2%).
- Very few beneficiaries (n=189, 0.3%) received ≥3 prescription fills.
- 8,606 beneficiaries had documentation of receiving flu vaccination prior to filling a prescription for an antiviral.

Table 3: Anti-influenza Drug Utilization in Mississippi Medicaid for State Fiscal Year 2019 (July 2018 - June 2019)					
Plan	Total number of beneficiaries with antiviral RX fills	Number of beneficiaries by the number of fills received			Number of beneficiaries who received flu vaccine prior to antiviral RX fill*
		1	2	3 or more	
FFS	11,341	10,835	474	32	617
UHC	24,034	22,891	1,069	74	3,525
Mag	26,794	25,427	1,286	81	4,192
Mol	2,762	2,689	71	2	272
Total	64,931	61,842	2,900	189	8,606

Note: FFS = Fee-for-service, UHC = United Health Care, Mag = Magnolia, Mol = Molina
Numbers represent beneficiaries who had pharmacy claims only. No beneficiaries with anti-influenza drug related medical claims were identified in the study period.
* Beneficiaries with medical or pharmacy claims were identified. Beneficiaries receiving vaccines under the VFC Program are not included
CPT codes for influenza vaccines included: 90630, 90685-90688, 90654-90658, 90660-90662, 90653, 90666, 90668, 90664, 90672-90674, 90756, 90682, 90686, 90682, Q2035.
References:
1. www.immunize.org/catg.d/p4072.pdf

Table 4 shows the number of beneficiaries who had a hospitalization after receiving anti-influenza drug treatment.

- Only 62 beneficiaries had a respiratory-related hospitalization within 14 days of receiving anti-influenza drugs.

Table 4: Hospitalizations Among Beneficiaries with Anti-infleunza Drug Utilization in Mississippi Medicaid for State Fiscal Year 2019 (July 2018 - June 2019)						
Plan at initial fill date	Number of benes					
	Benes with antiviral fills	Benes with at least one hospitalization	Benes with at least one respiratory-related hospitalization within 14 days of antiviral fill date (A)	Benes by days between antiviral drug fill and hospitalization (B)		
				0 to 3	4 to 7	8 or more
FFS	11,341	51	15	6	7	9
UHC	24,034	61	20	12	7	1
Mag	26,794	100	26	13	5	8
Mol	2,762	4	1	0	1	0
Total	64,931	216	62	31	20	18

Note: Benes = Beneficiaries, FFS = Fee-for-service, UHC = United Health Care, Mag = Magnolia, Mol = Molina
Sum of numbers across cells under (B) may not add up to numbers in (A) as some benes might have had more than one hospitalization within 14 days from drug fill date.
Hospitalizations - only hospitalizations with ICD-10 primary diagnosis codes for diseases of the respiratory system (J00-J99) were included.

CONCLUSIONS AND RECOMMENDATIONS

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

MISSISSIPPI MEDICAID PERFORMANCE IN CY 2018 ON CHILD CORE SET: USE OF MULTIPLE CONCURRENT ANTIPSYCHOTICS IN CHILDREN AND ADOLESCENTS

Prepared by University of Mississippi MS-DUR
Version 08/11/2019

The "Use of Multiple Concurrent Antipsychotics in Children and Adolescents" (APC-CH) was added to the Medicaid Child Core Set in 2016. The APC-CH assesses the potentially inappropriate prescribing and use of antipsychotic medications among children and adolescents. The APC-CH measure is defined as the percentage of children and adolescents 1 – 17 years of age who were treated with antipsychotic medications and who were on two or more concurrent antipsychotics medications for at least 90 consecutive days during the measurement year. This measure was developed by the National Collaborative for Innovation in Quality Measurement, and is included in HEDIS® 2019.

This report provides information for DOM to use in evaluating performance across pharmacy programs and for reporting overall performance to the Centers for Medicare and Medicaid Services for the FFY 2019 reporting. The measurement specifications are listed in Table 1.

TABLE 1: APC-CH Measurement Specifications

Measurement Year	January 1, 2018 - December 31, 2018
Denominator	Medicaid enrollees 1 - 17 years of age with 90 days or more of continuous antipsychotic medication treatment during the measurement year. For each different medication used, a gap in possession of 32 days or less is considered to be continuous treatment.
Numerator	Medicaid enrollees on two or more concurrent antipsychotic medications for at least 90 consecutive days during the measurement year. Up to 14 day gap in concurrent use considered to be continuous concurrent use.
Continuous Enrollment	Beneficiary must be enrolled for entire measurement year. No more than one gap in continuous enrollment of up to 45 days is allowed.
Anchor Date	The enrollee must be enrolled on December 31st of the measurement year. This is the anchor date for determining age.

Table 2 shows the population meeting the age and continuous enrollment criteria for the measure. This is the total population enrolled and meeting the inclusion criteria, not just the beneficiaries taking antipsychotics.

TABLE 2: Characteristics of Eligible Population*

Mississippi Medicaid January 1, 2018 - December 31, 2018

Benericiary Characteristics		TOTAL		Medicaid Program							
				FFS		United Healthcare		Magnolia		Molina	
TOTAL		294,992		25,052		122,944		139,682		7,314	
Age	1 - 5	89,933	30.5%	6,917	27.6%	37,105	30.2%	43,087	30.8%	2,824	38.6%
	6 - 11	106,860	36.2%	8,947	35.7%	44,673	36.3%	50,755	36.3%	2,485	34.0%
	12 - 17	98,199	33.3%	9,188	36.7%	41,166	33.5%	45,840	32.8%	2,005	27.4%
Gender	Female	144,808	49.1%	11,641	46.5%	60,635	49.3%	69,236	49.6%	3,566	48.8%
	Male	150,182	50.9%	13,409	53.5%	62,579	50.9%	70,446	50.4%	3,748	51.2%
	Unknown	2	0.0%	2	0.0%	0	0.0%	0	0.0%	0	0.0%
Race	Caucasian	85,474	29.0%	7,421	29.6%	37,676	30.6%	38,609	27.6%	1,768	24.2%
	Afr. Amer.	165,179	56.0%	12,900	51.5%	66,160	53.8%	81,607	58.4%	4,512	61.7%
	Amer. Indian	1,642	0.6%	1,284	5.1%	125	0.1%	204	0.1%	29	0.4%
	Hispanic	9,473	3.2%	530	2.1%	4,612	3.8%	4,161	3.0%	170	2.3%
	Other	33,224	11.3%	2,917	11.6%	14,371	11.7%	15,101	10.8%	835	11.4%
CHIP	Yes	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
	No	294,992	100.0%	25,052	100.0%	122,944	100.0%	139,682	100.0%	7,314	100.0%

** Eligible population includes all beneficiaries meeting continous enrollment and age criteria for the measurement year.*

Table 3 shows the measure rates for CY 2018 for all Mississippi Medicaid beneficiaries meeting the inclusion criteria for the denominator of the measure. The overall rate within Mississippi Medicaid was 0.8% which is a slight drop from the prior year. The rates for the two of the Coordinated Care Organizations (CCOs) were the same (0.6% for United Healthcare and Magnolia) while higher for Molina (1.4%). The rate for Fee-For-Service (FFS) was the highest (1.8%) but was a significant drop from the prior year of 2.2%. The higher rate for FFS is at least partially due to the fact that more institutional care patients are in FFS than in the CCOs and institutional patients are not excluded from the measure.

TABLE 3: Multiple Concurrent Antipsychotic Use by Beneficiary Characteristic

Mississippi Medicaid January 1, 2018 - December 31, 2018

Benericiary Characteristics		Denominator	Numerator	Rate
TOTAL		7,982	67	0.8%
Age	1 - 5	157	1	0.6%
	6 - 11	3,121	21	0.7%
	12 - 17	4,704	45	1.0%
Gender	Female	2,729	18	0.7%
	Male	5,252	49	0.9%
	Unknown	1	0	0.0%
Race	Caucasian	3,391	37	1.1%
	Afr. Amer.	4,219	26	0.6%
	Amer. Indian	10	0	0.0%
	Hispanic	91	1	1.1%
	Other	271	3	1.1%
Pharmacy Program	FFS	1,442	26	1.8%
	United Healthcare	2,824	16	0.6%
	Magnolia	3,438	21	0.6%
	Molina	278	4	1.4%

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Center for Medicaid and CHIP Services

CMCS Informational Bulletin

DATE: August 5, 2019

FROM: Calder Lynch, Acting Deputy Administrator and
Director Center for Medicaid and CHIP Services

SUBJECT: **State Guidance for Implementation of Medicaid Drug Utilization Review (DUR) provisions included in Section 1004 of the *Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act* (P.L. 115-271)**

This guidance provides information to the states concerning implementation of the new Medicaid Drug Utilization Review (DUR) provisions that were included in Section 1004 of the *Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act*, also referred to as the *SUPPORT for Patients and Communities Act* or the SUPPORT Act,[1] that are designed to reduce opioid related fraud, misuse and abuse. This document addresses the required implementation of these provisions, including requirements regarding opioid prescription claim reviews at the point of sale (POS) and retrospective reviews; the monitoring and management of antipsychotic medication in children; identification of processes to detect fraud and abuse; and mandatory DUR report updates, as well as requirements for Medicaid Managed Care Organizations (MCOs).[2] This guidance also describes the components of the State Plan Amendment (SPA) that each state must submit by December 31, 2019, in order to comply with these new requirements.

BACKGROUND

Section 1927(g) of the Social Security Act (the Act) requires each state to develop a DUR program targeted, in part, at reducing clinical abuse and misuse of prescription drugs covered under the

[1] https://www.congress.gov/115/bills/hr6/BILLS-115hr6enr.pdf

[2] Although the text of the provisions added by the SUPPORT for Patients and Communities Act (and therefore, this guidance) addresses only MCOs in the managed care context, CMS encourages states to act consistently in imposing the new requirements on all managed care plans with regards to the new responsibilities added by the SUPPORT Act. States may include Prepaid Ambulatory Health Plans (PAHP) and Prepaid Inpatient Health Plans (PIHP) when implementing SUPPORT for Patients and Communities Act updates. CMS intends to consider future rulemaking to implement the requirements of the SUPPORT for Patients and Communities Act discussed in this Bulletin uniformly for all Medicaid managed care plans.

State's Medicaid Program. In implementing these requirements, CMS regulations at 42 CFR 456.703(e)[3,4] require that the state assess drug use information against predetermined standards. Pursuant to 42 CFR 456.703(e), these predetermined standards may be developed directly by the state or its contractor, obtained by the state through commercial vendors of DUR services, obtained by the state from independent organizations, or any combination of these means. Thus, in administering their DUR programs, states have had the flexibility to use standards that may best fit their Medicaid programs and patient populations.

Consistent with section 1927(g)(3)(D) of the Act, CMS requires each State Medicaid Program to submit to CMS an annual report on the operation of its Medicaid DUR fee-for-service (FFS) program, including information on prescribing patterns, cost savings generated by the state's DUR program, and the state's DUR program's overall operations, including any new or innovative practices. Additionally, § 438.3(s)(4) and (5) require any MCO, PIHP or PAHP that covers covered outpatient drugs to operate a DUR program that complies with section 1927(g) and 42 CFR 456, subpart K and to submit detailed information about its DUR program activities to the state. CMS has compiled state Medicaid DUR annual reports since 1995 and has published them on Medicaid.gov since 2010. As part of its 2019 DUR report for Federal Fiscal Year (FFY) 2018 data, CMS is collecting from states using managed care plans the same DUR data that states report on FFS plans. See 42 C.F.R. § 438.3(s).

The recently-enacted SUPPORT for Patients and Communities Act includes measures to combat the opioid crisis in part by reducing opioid abuse and misuse by advancing treatment and recovery initiatives, improving prevention, protecting communities, and bolstering efforts to fight deadly illicit synthetic drugs. There are several Medicaid-related DUR provisions contained within Section 1004 of the SUPPORT for Patients and Communities Act with respect to FFS and MCO pharmacy programs. These provisions establish drug review and utilization standards to supplement existing requirements under Section 1927(g) of the Act, in an effort to reduce opioid-related fraud, abuse and misuse. State implementation of these strategies is required by October 1, 2019, and the Secretary is required to report to Congress starting with information from states' fiscal year 2020 DUR reports.

DISCUSSION

Section 1004 of the SUPPORT for Patients and Communities Act requires states to implement minimum opioid standards within their FFS and managed care programs. Through amendments to Section 1902 of the Act, Section 1004 of the SUPPORT for Patients and Communities Act requires States to implement "safety edits" and "claims review automated process[es]." CMS interprets "safety edits" to refer to a prospective drug review, of the sort defined in section 1927(g)(2)(A) of the Act. These safety edits provide for a prospective DUR review for each prescription identifying potential problems at point of sale (POS) to engage both patients and prescribers about possible opioid abuse and overdose risk at the time of dispensing. The POS

[3] With respect to a managed care organization, prepaid inpatient health plan, or prepaid ambulatory health plan that provides covered outpatient drugs, see 42 CFR 438.3(s)(4) and (5).
[4] 42 CFR 456.703(e). GovInfo, October, 2018. www.govinfo.gov/content/pkg/CFR-2018-title42-vol4/pdf/CFR-2018-title42-vol4-sec456-703.pdf

prospective safety edits provide real-time information prior to the prescription being dispensed to the patients. When a safety edit is triggered, the pharmacist receives an alert and may be required to take further action to resolve the alert before the prescription can be dispensed.[5] A "claims review automated process", which we interpret to refer to a retrospective drug use review of the sort defined in section 1927(g)(2)(B) of the Act, provides for additional examination of claims data to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care. These retrospective claims reviews give healthcare providers access to information relevant to the items and services they furnish to beneficiaries, and better enable and encourage prescribers and dispensers to minimize opioid risk in their patients, such as avoiding duplicate prescriptions.

CMS encourages states to develop prospective and retrospective DUR reviews that are consistent with medical practice patterns in the state to help meet the health care needs of the Medicaid patient population. In doing so, CMS encourages states to utilize, for example, the 2016 Centers for Disease Control and Prevention (CDC) Guideline for primary care practitioners on prescribing opioids in outpatient settings for chronic pain. Translation and support materials related to the CDC Guideline are also available.

The SUPPORT for Patients and Communities Act requires State Medicaid Programs to have in place the following:

I. Claims Review Requirements

1. **Safety Edits Including Early, Duplicate, and Quantity Limits**: The SUPPORT for Patients and Communities Act requires states to have in place prospective safety edits (as specified by the state) for subsequent fills for opioids and a claims review automated process (as designed and implemented by the state) that indicates when an individual enrolled under the State plan (or under a waiver of the State plan) is prescribed a subsequent fill of opioids in excess of any limitation that may be identified by the state.[6] State-identified limitations should include restrictions on duplicate fills, early fills, and drug quantity limitations.

   The use of multiple opioids is associated with a higher risk of mortality, with mortality risk increasing in direct relation to the number of opioids prescribed concurrently. [7,8] Beneficiaries who receive multiple opioids may lack coordinated care and be at higher risk for opioid overdose.[9]

[5] Prada, Sergio. (2019). Comparing the Medicaid Prospective Drug Utilization Review Program Cost-Savings Methods Used by State Agencies in 2015 and 2016. American Health and Drug Benefits. 12. 7-12.
[6] Section 1902(oo)(1)(A)(i)(I) of the Act, as added by section 1004 of the SUPPORT for Patients and Communities Act.
[7] Ray WA, Chung CP, Murray KT, Hall K, Stein CM. Prescription of Long-Acting Opioids and Mortality in Patients with Chronic Noncancer Pain. JAMA. 2016 Jun 14; 315(22):2415-23.
[8] Baumblatt JA, Wiedeman C, Dunn JR, Schaffner W, et al. High-risk use by patients prescribed opioids for pain and its role in overdose deaths. JAMA Intern Med. 2014 May; 174(5):796-801.
[9] Bonnie, Richard J., et al. Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use. The National Academies Press, 2017.

2. **Maximum Daily Morphine Milligram Equivalents (MME) Safety Edits:** The SUPPORT for Patients and Communities Act requires prospective safety edits (as specified by the state) on maximum MMEs that can be prescribed to an individual enrolled under the State plan (or under a waiver of the State plan) for treatment of chronic pain and a claims review automated process (as designed and implemented by the state) that indicates when an individual enrolled under the plan (or waiver) is prescribed the morphine equivalent for such treatment in excess of the maximum MME dose limitation identified by the state.[10]

   This safety edit must include a MME threshold amount to meet the statutory requirement, which may assist in identifying patients at potentially high clinical risk who may benefit from closer monitoring and care coordination.[11]

3. **Concurrent Utilization Alerts**: The SUPPORT for Patients and Communities Act requires states to have an automated process for claims review (as designed and implemented by the state) that monitors when an individual enrolled under the State plan (or under a waiver of the State plan) is concurrently prescribed opioids and benzodiazepines or opioids and antipsychotics.[12]

   Clinically, through the use of retrospective automated claim reviews, concurrent use of opioids and benzodiazepines and/or opioids and antipsychotics, as well as potential complications resulting from other medications concurrently being prescribed with opioids, can be reduced. States are reminded that the requirement for a retrospective automated claims review added by section 1004 of the SUPPORT for Patients and Communities Act does not preclude the State from also establishing a prospective safety edit system to provide additional information to patients and providers at the POS about concurrent utilization alerts.[13]

   - Opioid and Benzodiazepines Concurrent Fill Reviews: In 2016, the Food and Drug Administration (FDA) added a boxed warning to prescription opioid analgesics, opioid-containing cough products, and benzodiazepines with information about the serious risks associated with using these medications concurrently.[14] This review will alert providers when these drugs have been prescribed concurrently to assist in avoiding and mitigating these associated risks.

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[10] Section 1902(oo)(1)(A)(i)(II) of the Act, as added by section 1004 of the SUPPORT for Patients and Communities Act.
[11] Staff, News. "CDC Clarifies Opioid Guideline Dosage Thresholds." AAFP Home, 12 Jan. 2018, www.aafp.org/news/health-of-the-public/20180112cdcopioidclarify.html
[12] Section 1902(oo)(1)(A)(i)(III) of the Act, as added by section 1004 of the SUPPORT for Patients and Communities Act.
[13] *See* Section 1902(oo)(1)(A)(iii) of the Act, as added by section 1004 of the SUPPORT for Patients and Communities Act.
[14] Office of the Commissioner. "Press Announcements - FDA Requires Strong Warnings for Opioid Analgesics, Prescription Opioid Cough Products, and Benzodiazepine Labeling Related to Serious Risks and Death from Combined Use." *U S Food and Drug Administration Home Page*, Office of the Commissioner, www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm518697.htm

- Opioid and Antipsychotic Concurrent Fill Reviews: This alert is supported by the FDA's warning of increased risk of respiratory and Central Nervous System (CNS) depression with concurrent use of opioid and CNS depressants such as antipsychotics or sedatives, including extreme sleepiness, slowed or difficult breathing, unresponsiveness or the possibility that death can occur.[15] Patients concurrently prescribed opioid and antipsychotic drugs benefit from increased coordination of care. Additionally, improving treatment of comorbid mental health disorders is an important consideration when trying to reduce the overall negative impacts of opioid use disorders, and the treatment of pain. This review will encourage coordination of care for patients taking antipsychotic and opioid medication concurrently.

Permitted Exclusions: The above described safety edits and claims review requirements added by section 1004 of the SUPPORT for Patients And Communities Act to subsection 1902(oo) of the Act do not apply with respect to individuals who are receiving hospice or palliative care; receiving treatment for cancer; residents of a long-term care facility, a facility described in section 1905(d) of the Act, or of another facility for which frequently abused drugs are dispensed for residents through a contact with a single pharmacy; or other individuals the state elects to treat as exempted from such requirements.[16] States are expected to develop specifications that will exclude these beneficiaries from all of the opioid review activities outlined above.

When implementing these requirements, CMS encourages states to offer education and training and to provide consistent messaging across all healthcare providers. Education and training of all providers on new opioid provisions will help minimize workflow disruption and ensure beneficiaries have access to their medications in a timely manner. In order to avoid abrupt opioid withdrawal, prior authorization may be necessary for patients who will need clinical intervention to taper off high doses of opioids to minimize potential symptoms of withdrawal and manage their treatment regimen, while encouraging pain treatment using non-pharmacologic therapies and non-opioid medications, where appropriate. CMS recognizes that patients who are on opioid-based MAT drugs should continue their therapy without disruption. In this regard, states may at their discretion include these drugs in their DUR programs when clinically appropriate.

II. Program to Monitor Antipsychotic Medications by Children

The state must have in place a program (as designed and implemented by the state), to monitor and manage the appropriate use of antipsychotic medications by children enrolled under the State plan (or under a waiver of the State plan).[17] Additionally the state must submit, annually as part of the DUR report under section 1927(g)(3)(D) of the Act, information on activities carried out under this program for individuals not more than the age of 18 years old generally, and children in foster care specifically.

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[15] Center for Drug Evaluation and Research. "Drug Safety and Availability - FDA Drug Safety Communication: FDA Warns about Serious Risks and Death When Combining Opioid Pain or Cough Medicines with Benzodiazepines; Requires Its Strongest Warning." *U S Food and Drug Administration Home Page*, Center for Drug Evaluation and Research, https://www.fda.gov/downloads/Drugs/DrugSafety/UCM518672.pdf

[16] Section 1902(oo)(3) of the Act, as added by section 1004 of the SUPPORT for Patients and Communities Act.

[17] Section 1902(oo)(1)(B) of the Act, as added by section 1004 of the SUPPORT for Patients and Communities Act.

III. Fraud and Abuse Identification Requirements

The state must have in place a process (as designed and implemented by the state) that identifies potential fraud or abuse of controlled substances by individuals enrolled under the State plan (or under a waiver of the State plan), health care providers prescribing drugs to individuals so enrolled, and pharmacies dispensing drugs to individuals so enrolled.[18] Lock in programs[19] and prescription drug monitoring programs[20] play an important role in detecting and preventing opioid-related fraud and abuse. Data analytics can help to determine the extent to which beneficiaries are prescribed high amounts of opioids, identify beneficiaries who may be at serious risk of opioid misuse or overdose, and identify prescribers with questionable opioid prescribing patterns with respect to these beneficiaries.[21]

IV. Managed Care Organization Requirements

Each Medicaid MCO within a state must operate a DUR program that complies with the above specified requirements.[22] Furthermore, states must include these DUR provisions in managed care contracts with MCOs by October 1, 2019**.** CMS encourages states to consider including similar requirements in PIHP and PAHP contracts.

Consistent with section 1902(oo)(1)(A)(ii) of the Act, as added by the SUPPORT for Patients and Communities Act, states also must ensure that their contract with an MCO requires that the contracted entity has in place, for individuals eligible for medical assistance under the State plan (or waiver of the State plan) who are enrolled with the entity, subject to the exemptions for individuals described above, safety edits, claims review automated processes, a program to monitor antipsychotic medications in children, and fraud and abuse identification requirements, as described above.

STATE PLAN AMENDMENT (SPA) REQUIREMENTS

Section. 1004 of the SUPPORT for Patients and Communities Act amends section 1902(a) of the Social Security Act to include a new paragraph (85), requiring the State plan to provide that the state is in compliance with the new drug review and utilization requirements set forth in section 1902(oo) of the Act. States are required to submit an amendment to their State plan for CMS review and approval for implementation of these DUR requirements.

Section 1004 of the SUPPORT for Patients and Communities Act also requires all states to implement these requirements by October 1, 2019, and to submit an amendment to their State plan no later than December 31, 2019 in order to describe how the state addresses these provisions in

[18] Section 1902(oo)(1)(C) of the Act, as added by section 1004 of the SUPPORT for Patients and Communities Act.
[19] "Pharmacy Lock-In Programs Slated For Expanded Use." OPEN MINDS, www.openminds.com/market-intelligence/executive-briefings/pharmacy-lock-programs-slated-expanded-use/
[20] Office of National Drug Control Policy. Prescription Drug Monitoring Program. Prescription Drug Monitoring Program, April, 2011. https://www.ncjrs.gov/pdffiles1/ondcp/pdmp.pdf
[21] Beaton, Thomas. "Preventing Provider Fraud through Health IT, Data Analytics." *HealthPayerIntelligence*, 5 Oct. 2018, https://healthpayerintelligence.com/news/preventing-provider-fraud-through-health-it-data-analytics
[22] H.R. 6. 24 Oct. 2018, www.congress.gov/115/bills/hr6/BILLS-115hr6enr.pdf . Page 17.

the State plan. States are also expected to give appropriate tribal notification, as required, if applicable.

CMS understands it may take time for states to implement these new strategies. The October 1, 2019 date should give states sufficient time to update systems if not already implemented and to document processes, policies and procedures in order to address these new requirements.

Required Provisions to include in State Plans:

In its State plan submission, each state should provide a description of how it currently supports or is implementing and providing oversight for the new requirements added by Section 1004 of the SUPPORT for Patients and Communities Act in the pharmacy coverage pages (3.1 A (Categorically Needy) and, if applicable, 3.1 B (Medically Needy)). States do not have to list specific numbers or quantities in the SPA for the safety edits (e.g. "100 MME quantity limitation", "do not refill until 75% used", etc.), as these could change from time to time based on considerations including updated clinical guidelines. However, CMS will review each state's safety edits annually upon submission of the state's report required under section 1927(g)(3)(D) of the Act to assess the consistency of the state's safety edits with current medical best practices, for example, as informed by the current CDC opioid guideline. Therefore, CMS requests that each state address the provisions below in the state's SPA submission, in the following order:

1. **Claims Review Limitations:** Describe the opioid related prospective POS safety edits and retrospective reviews the state has in place to address: duplicate fill and early fill alerts, quantity limits, dosage limits, and MME limitations. Additionally, describe concurrent utilization reviews for opioids and benzodiazepines or opioids and antipsychotics. Describe all actions for these reviews that will occur.

2. **Program to Monitor Antipsychotic Medications by Children:** Describe the program the state uses to monitor and manage utilization of antipsychotic medications in children and foster children. Describe the actions that the state will take based on the monitoring undertaken in the program.

3. **Fraud and Abuse Identification:** Describe the state program in place to identify and address fraud and abuse. Describe the actions that the state will take based on the program's findings.

4. **Medicaid Managed Care Organizations Requirements:** Specifications regarding MCOs do not have to appear on the State plan's pharmacy pages, as these pages apply to FFS populations only. However, states should confirm that they have updated their contracts with MCOs to comply with the requirements applicable to MCOs as added by section 1004 of the SUPPORT for Patients and Communities Act. (*Beginning in October 2019, the SUPPORT for Patients and Communities Act requires each MCO also be compliant with utilizing safety edits relating to subsequent fills of opioids, MME limitations, and concurrent prescribing of opioids and benzodiazepines and opioids and antipsychotics. Additionally, as a reminder, the state is required to modify the MCO's contracts regarding these new DUR requirements in order to be in compliance by October 1, 2019.)*

Availability of Enhanced Federal Matching Funds

Under 42 CFR §433.112(a), CMS provides 90 percent enhanced federal financial participation (FFP) for Medicaid technology investments for design, development, installation, or enhancement of mechanized claims processing and information retrieval systems, provided they meet specified requirements. Such expenditures to meet the new requirements of section 1004 of the SUPPORT for Patients and Communities Act may qualify for this enhanced matching rate. States should also review SMD # 18-006, "Leveraging Medicaid Technology to Address the Opioid Crisis," to consider if there are complementary efforts around technology that could assist with states' efforts. Also, states should review section 5042 of the SUPPORT for Patients and Communities Act and consider if there are opportunities to acquire technologies which complement these efforts or further promote interoperability and data sharing. These can all be funded through an approved Advanced Planning Document (APD) provided the requirements of 42 CFR part 433, subpart C and all other applicable requirements are met.[23]

CMS looks forward to continuing to work together with the states to implement DUR provisions within Section 1004 of the SUPPORT for Patients and Communities Act. Questions can be submitted through the CMS DUR resource mailbox at CMSDUR@cms.hhs.gov.

[23] Medicaid.gov. https://www.medicaid.gov/federal-policy-guidance/downloads/smd18005.pdf

FDA DRUG SAFETY COMMUNICATIONS

May - August 2019

- 8/28/2019 FDA warns about rare occurrence of serious liver injury with use of hepatitis C medicines Mavyret, Zepatier, and Vosevi in some patients with advanced liver disease
- 8/13/2019 FDA review finds no increased risk of prostate cancer with Parkinson's disease medicines containing entacapone (Comtan, Stalevo)
- 7/26/2019 FDA approves Boxed Warning about increased risk of blood clots and death with higher dose of arthritis and ulcerative colitis medicine tofacitinib (Xeljanz, Xeljanz XR)

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