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

MISSISSIPPI DIVISION OF
MEDICAID

June 11, 2020 at 1:00pm

ZOOM Meeting

Jackson, MS

Prepared by:

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

Drug Utilization Review Board

Lauren Bloodworth, PharmD (Co-Chair)
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, 2022

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

2020 DUR Board Meeting Dates

March 19, 2020
June 11, 2020
September 17, 2020
December 3, 2020

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

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

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

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

MISSISSIPPI DIVISION OF MEDICAID
OFFICE OF THE GOVERNOR
DRUG UTILIZATION REVIEW BOARD
AGENDA
June 11, 2020

Welcome

Old Business

Resource Utilization Review

Follow-up and Discussion from the Board

New Business

Pharmacy Program Update Terri Kirby, RPh

Next Meeting Information
Remaining 2020 Dates: September 17, December 3

DUR Board Meeting Minutes

MISSISSIPPI DIVISION OF MEDICAID
DRUG UTILIZATION REVIEW (DUR) BOARD
MINUTES OF THE MARCH 19, 2020 MEETING

DUR Board Roster: State Fiscal Year 2020 (July 1, 2019- June 30, 2020)	May 2019	Sep 2019	Dec 2019	Mar 2020
Lauren Bloodworth, PharmD	✓	✓	✓	✓
Beverly Bryant, MD		✓	✓	✓
Rhonda Dunaway, RPh	✓	✓	✓	
Tanya Fitts, MD	✓		✓	✓
Ray Montalvo, MD (Chair)		✓	✓	✓
Holly Moore, PharmD	✓	✓	✓	✓
Janet Ricks, DO	✓			✓
Dennis Smith, RPh	✓	✓	✓	✓
Cheryl Sudduth, RPh	NA	✓	✓	
James Taylor, PharmD	✓	✓		✓
Alan Torrey, MD	NA	✓		✓
Veda Vedanarayanan, MD	✓	✓		
TOTAL PRESENT	**8***	**10**	**8**	**9**

** Total Present may not be reflected by individual members marked as present above due to members whose terms expired being removed from the list.*

Also Present:

Division of Medicaid (DOM) Staff:
Terri Kirby, RPh, CPM, Pharmacy Director; Cindy Noble, PharmD, MPH, DUR Coordinator; Gail McCorkle, RPh, Clinical Pharmacist; Chris Yount, MA, PMP, Staff Officer – Pharmacy; Carlos Latorre, MD, Medical Director;

University of Mississippi School of Pharmacy - MS-DUR Staff:
Eric Pittman, PharmD, MS-DUR Project Director; Kaustuv Bhattacharya, PhD, Research Assistant Professor - CPMM; Sujith Ramachandran, PhD, Assistant Director – CPMM; Yiran Rong, MS, Research Analyst – MS-DUR;

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

Change Healthcare Staff:
Paige Clayton, PharmD, On-Site Clinical Pharmacist; Shannon Hardwick, RPh, CPC Pharmacist; Sarah Boydstun, PharmD, PA Pharmacist;

Alliant Health Staff:
Buddy Ogletree, PharmD, Clinical Pharmacist;

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; Joseph Vazhappilly, PharmD, MBA, Associate Vice President, Pharmacy Services, Molina Healthcare;

Visitors:
Kevin Aholt, Neurelis Pharmaceuticals; Brian Berhow, Sunovion; Kimberly Clark, ViiV; Scott Farris, Amgen; Phil Hecht, Abbvie; Hope Ladner, The Clay Firm; Chris Lauhoff, Genentech; Nole Mangine, Allergan; Mike Peoples, Lilly; Maria Porter, Actelion Pharmaceuticals; Sonya Powell, Janssen; Michelle Shirley, Indivior; Tracy Smalley, Amgen; Cindy Snyder, Viiv; Joseph Sturgeon, Azurity; Bruce Wallace, Azurity; Doug Welch, Merck; Wendy Williams, Supernaus; Brent Young, Global Blood Therapeutics;

Call to Order:
Dr. Pittman called the meeting to order at 1:05pm and welcomed everyone to the meeting via Zoom.

COVID-19 Update:
Dr. Latorre, Medicaid Medical Director, provided the Board with an update on the status of COVID-19 in MS and Medicaid's response.

OLD BUSINESS:

Dr. Bloodworth moved to approve the minutes from the December 2019 DUR Board Meeting, seconded by Dr. Bryant, and unanimously approved by the DUR Board.

Resource Utilization Review:
Dr. Pittman presented the resource utilization report for October 2019 – December 2019. No abnormal shifts in drug categories were noted.

Feedback and Discussion from Board:
Dr. Pittman shared with the Board a manuscript that the resulted from collaborative work between Medicaid and the University of Mississippi that was recently published in Vaccine entitled, "Factors Influencing Human Papillomavirus (HPV) Vaccination Series Completion in Mississippi Medicaid." Dr. Pittman recognized MS-DUR analyst, Sushmitha Inguva, for her work as first author on this project.

NEW BUSINESS:

Update on MS-DUR Educational Interventions:
Dr. Pittman provided an overview of all DUR mailings that occurred December 2019 – February 2020. He pointed out the downward trend in the number of beneficiaries classified as provider shopping. He also provided the Board with copies of the metformin provider education that was released in December 2019 based on recommendations from the DUR Board. The March Medicaid Provider Bulletin will include an article detailing HPV vaccination recommendations based on recommendations by the DUR Board.

Dr. Pittman also presented the Board with a draft version of a tricyclic antidepressant (TCA) provider education letter that will be distributed. This letter will be mailed prior to Medicaid implementing a minimum age edit for the prescribing of TCAs. The Board recommended a minor addition to the letter. This recommendation will be incorporated into the final version, and letters will be mailed beginning April 2020 with the anticipated minimum age edit becoming effective July 1, 2020.

Special Analysis Projects:
Antiretroviral Adherence in the Treatment of HIV
Dr. Pittman presented a report on the adherence to antiretroviral therapies for the treatment of HIV. Adherence to antiretroviral therapy (ART) has been found to be critical to achieving viral load suppression and preventing progression to AIDS. A minimum adherence goal of 90% is recommended by the World Health Organization. Analysis using Pharmacy Quality Alliance's Proportion of Days Covered: Antiretroviral Medications Measure (PDC-ARV-2019) revealed only 42.1% of Medicaid beneficiaries achieved PDC $\geq$ 90% during the study period of calendar year 2019. The PQA measure included patients 18 years and older. The Board recommended MS-DUR expand the analysis to include those younger than 18 years taking ART. Following discussion by the Board, the subsequent recommendations were presented:

1. DOM to collaborate with MSDH, UMMC Infectious Disease Department, and state medical/pharmacy/nursing associations on ART adherence issues.

2. DOM to conduct targeted outreach to providers:
    a. Commend providers having patients with PDCs $\geq$ 90 and seek guidance on best practices;
    b. Educate providers with patients having PDCs < 90.

3. Expand analysis to include beneficiaries less than 18 years. Educational mailings will include providers treating patients less than 18 years.

Dr. Montalvo motioned to approve the recommendations, seconded by Dr. Fitts, and unanimously approved by the Board.

Atrial Fibrillation and Potential Gaps in Care

Dr. Pittman presented a report detailing potential gaps in care for patients diagnosed with atrial fibrillation (Afib). Afib-affected individuals are at increased risk of stroke, and the use of oral anticoagulants serves as a major modifiable protective factor against stroke in patients living with Afib. In the selection of appropriate candidates for thromboembolic prophylaxis, emphasis is placed on balancing risks and benefits. Using the CHA_2DS_2VASC risk assessment criteria, MS-DUR identified Medicaid beneficiaries with Afib diagnosis, high CHA_2DS_2VASC score ($\geq$ 3 females; $\geq$2 males), and no prior bleeding events as potential candidates for anticoagulant drug therapy. Among those beneficiaries, anticoagulant drug utilization during the study period was determined. Following a robust discussion, the subsequent recommendation was presented:

1. DOM should implement an educational intervention notifying prescribers of those beneficiaries diagnosed with Afib that are potential candidates for anticoagulant therapy.

Dr. Montalvo motioned to approve the recommendations, seconded by Dr. Bryant, and unanimously approved by the Board.

An Update to DUR Recommendations for Proton Pump Inhibitor Deprescribing in Mississippi Medicaid

During the March 2018 DUR Board meeting the use of proton pump inhibitors (PPIs) in the Medicaid population was reviewed examining the potential of deprescribing these products. The Board recommended the implementation of a maximum days supply edit of 90 days in a 12-month period for the use of PPIs based on diagnosis. Due to the prioritized implementation of opioid criteria, the implementation of the PPI maximum days supply edit was postponed. At this time the Division of Medicaid requested the DUR Board reevaluate the previous DUR recommendations based on a review of current literature regarding PPI chronic therapy and evaluation of current prescribing trends in Medicaid. Following presentation of an updated DUR analysis and robust discussion, the DUR Board was asked to reaffirm the recommendations from the March 2018 DUR Board meeting or alter those recommendations. The recommendations were as follows:

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

2. For therapy exceeding the 90 day limit, DOM should implement electronic or manual PA requirements for the maximum number of days supply based on diagnoses.

3. MS-DUR should implement an educational initiative notifying providers of the new PPI prescribing criteria and guidance on deprescribing.

Dr. Montalvo motioned to approve the recommendations, seconded by Dr. Fitts, and unanimously approved by the Board.

FDA Drug Safety Updates:
Dr. Pittman presented FDA drug safety communications for December 2019 – March 2020.

Pharmacy Program Update:
At this time, the upcoming Pharmacy and Therapeutics Committee is still scheduled for May 12, 2020. Ms. Kirby informed the DUR Board that the state plan amendment (SPA) in response to the SUPPORT Act was approved by CMS. Ms. Kirby also informed the Board that DOM is holding discussions regarding lifting early prescription refill edits during COVID-19. She encouraged pharmacists to monitor DOM social media accounts for notification of changes that may occur.

Miscellaneous:
2020 Meeting Dates/Times
June 11, 2020
September 17, 2020
December 3, 2020
**Meeting times will remain at 1 pm for the next year.*

Next Meeting Information:
Dr. Pittman announced that the next meeting of the DUR Board will take place on June 11, 2020 at 1pm.

Dr. Montalvo motioned to adjourn the meeting at 2:40 pm, seconded by Dr. Bloodworth, and unanimously approved by the Board.

Submitted,

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

Announcement concerning the March 19, 2020 Drug Utilization Review (DUR) Board Meeting:

In response to the coronavirus outbreak, the Mississippi Division of Medicaid has changed the March 19, 2020 DUR meeting format.

This meeting will be held as a **virtual meeting for DUR Board members, DOM staff and the public**. It will not take place in Room 145 of the Woolfolk Building.

Participants wishing to attend the virtual meeting can attend by visiting the following link: https://zoom.us/j/749765662?pwd=YVBjdldSK0Jrb0duQW9taWxXVEtOdz09 .

Meeting ID: 749 765 662
Password: 307489

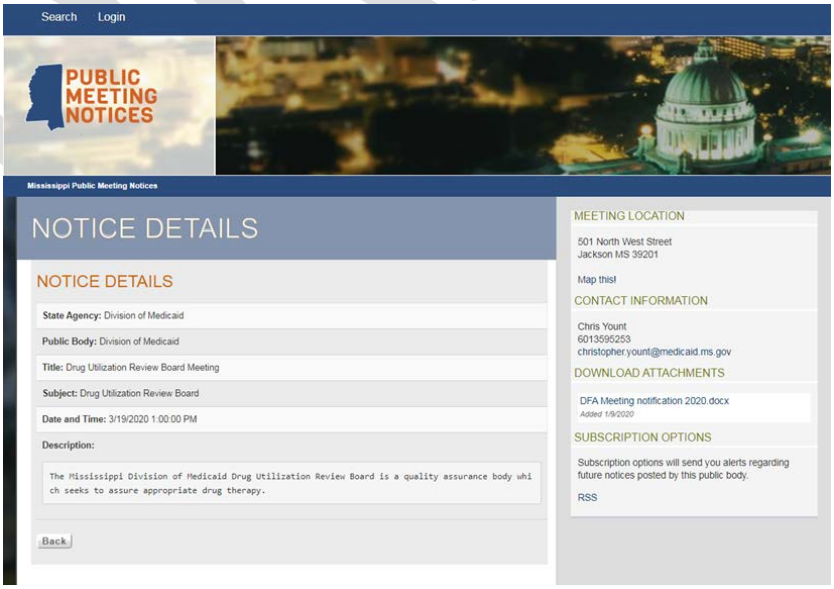
Dial by your location

1-312-626-6799 US (Chicago)

1-929-436-2866 US (New York)

General public attending is asked to please mute audio and disable video connections. When logging into the Zoom meeting, participants must enter their name and company, e.g. John Smith - Company.

Pursuant to DUR bylaws, comments and questions from both industry and the general public will not be allowed during the meeting.



Resource Utilizaton Review

TABLE 04A: ENROLLMENT STATISTICS FOR LAST 6 MONTHS
October 1, 2019 through March 31, 2020

			Oct-19	Nov-19	Dec-19	Jan-20	Feb-20	Mar-20
Total enrollment			694,416	692,688	690,350	691,279	688,260	683,339
Dual-eligibles			157,582	157,456	155,631	156,860	156,874	156,406
Pharmacy benefits			583,934	581,965	580,378	579,713	576,200	570,731
	LTC		17,209	17,164	16,982	17,057	16,954	16,778
	PLAN %	FFS	25.7%	25.3%	24.7%	24.8%	24.8%	24.4%
		MSCAN-UHC	28.8%	29.1%	29.4%	29.3%	29.4%	29.7%
		MSCAN-Magnolia	33.6%	33.7%	33.8%	33.9%	33.7%	33.7%
		MSCAN-Molina	11.9%	11.9%	12.1%	12.0%	12.1%	12.2%

TABLE 04B: PHARMACY UTILIZATION STATISTICS FOR LAST 6 MONTHS
October 1, 2019 through March 31, 2020

		Oct-19	Nov-19	Dec-19	Jan-20	Feb-20	Mar-20
# Rx Fills	FFS	111,925	105,872	105,483	110,165	106,108	104,529
	MSCAN-UHC	161,688	160,551	160,643	164,969	159,444	161,918
	MSCAN-Mag	210,988	209,567	207,595	211,634	201,301	192,003
	MSCAN-Mol	43,950	45,010	45,879	47,469	46,392	43,978
# Rx Fills / Bene	FFS	0.7	0.7	0.7	0.8	0.7	0.8
	MSCAN-UHC	1.0	0.9	0.9	1.0	0.9	1.0
	MSCAN-Mag	1.1	1.1	1.1	1.1	1.0	1.0
	MSCAN-Mol	0.6	0.6	0.7	0.7	0.7	0.6
$ Paid Rx	FFS	$12,492,726	$11,648,894	$11,895,606	$12,627,410	$11,368,451	$12,347,679
	MSCAN-UHC	$14,890,528	$13,867,141	$14,158,122	$14,560,474	$13,933,471	$15,617,485
	MSCAN-Mag	$19,372,924	$18,443,182	$18,464,572	$19,518,551	$18,225,188	$19,140,481
	MSCAN-Mol	$3,275,207	$3,254,891	$3,208,985	$3,458,606	$3,451,447	$3,731,024
$ /Rx Fill	FFS	$111.62	$110.03	$112.77	$114.62	$107.14	$118.13
	MSCAN-UHC	$92.09	$86.37	$88.13	$88.26	$87.39	$96.45
	MSCAN-Mag	$91.82	$88.01	$88.95	$92.23	$90.54	$99.69
	MSCAN-Mol	$74.52	$72.31	$69.94	$72.86	$74.40	$84.84
$ /Bene	FFS	$83.25	$79.12	$82.98	$87.83	$79.56	$88.67
	MSCAN-UHC	$88.54	$81.88	$82.98	$85.72	$82.25	$92.13
	MSCAN-Mag	$98.74	$94.04	$94.13	$99.32	$93.86	$99.52
	MSCAN-Mol	$47.13	$47.00	$45.70	$49.72	$49.50	$53.58

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

TABLE C: TOP 10 DRUG CATEGORIES BY NUMBER OF CLAIMS IN MAR 2020 (FFS AND CCOs)

Category	Month Year	Rank Volume	# RXs	$ Paid	# Unique Benes
CNS stimulants	Mar 2020	1	25,254	$5,053,096	21,653
	Feb 2020	1	26,921	$5,445,571	23,514
	Jan 2020	1	28,373	$5,734,654	24,444
antihistamines	Mar 2020	2	20,150	$293,100	18,770
	Feb 2020	3	17,518	$253,923	16,772
	Jan 2020	3	18,032	$262,876	17,107
adrenergic bronchodilators	Mar 2020	3	18,539	$848,565	15,678
	Feb 2020	6	15,385	$713,197	13,444
	Jan 2020	5	16,001	$754,181	13,886
atypical antipsychotics	Mar 2020	4	14,188	$3,863,500	11,783
	Feb 2020	8	13,134	$3,396,133	11,380
	Jan 2020	7	13,991	$3,618,797	11,832
nonsteroidal anti-inflammatory agents	Mar 2020	5	14,155	$204,465	13,396
	Feb 2020	4	16,470	$239,507	15,801
	Jan 2020	4	17,789	$259,083	16,977
aminopenicillins	Mar 2020	6	14,043	$184,070	13,777
	Feb 2020	2	19,392	$255,824	19,076
	Jan 2020	2	19,030	$249,397	18,664
leukotriene modifiers	Mar 2020	7	13,378	$221,915	12,834
	Feb 2020	12	11,414	$188,086	11,244
	Jan 2020	12	11,708	$189,111	11,403
SSRI antidepressants	Mar 2020	8	12,572	$159,335	11,403
	Feb 2020	11	11,848	$145,786	11,188
	Jan 2020	10	12,501	$152,359	11,596
proton pump inhibitors	Mar 2020	9	11,781	$442,108	11,088
	Feb 2020	13	11,045	$397,093	10,661
	Jan 2020	13	11,496	$427,517	10,978
narcotic analgesic combinations	Mar 2020	10	11,670	$589,479	10,636
	Feb 2020	10	12,110	$563,082	11,241
	Jan 2020	8	13,234	$617,333	12,035

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

Category	Month Year	Rank Paid Amt	# RXs	$ Paid	# Unique Benes
CNS stimulants	Mar 2020	1	25,254	$5,053,096	21,653
	Feb 2020	1	26,921	$5,445,571	23,514
	Jan 2020	1	28,373	$5,734,654	24,444
atypical antipsychotics	Mar 2020	2	14,188	$3,863,500	11,783
	Feb 2020	2	13,134	$3,396,133	11,380
	Jan 2020	2	13,991	$3,618,797	11,832
antiviral combinations	Mar 2020	3	867	$2,863,933	769
	Feb 2020	3	749	$2,499,359	716
	Jan 2020	3	838	$2,659,916	744
TNF alpha inhibitors	Mar 2020	4	425	$2,665,292	375
	Feb 2020	5	364	$2,246,583	337
	Jan 2020	5	385	$2,381,963	338
insulin	Mar 2020	5	5,435	$2,653,092	3,934
	Feb 2020	4	4,641	$2,303,492	3,557
	Jan 2020	4	4,869	$2,568,811	3,651
factor for bleeding disorders	Mar 2020	6	107	$1,436,463	77
	Feb 2020	6	104	$1,415,530	76
	Jan 2020	6	99	$1,586,660	76
interleukin inhibitors	Mar 2020	7	188	$1,205,793	163
	Feb 2020	8	163	$1,025,543	154
	Jan 2020	11	163	$888,831	140
CFTR combinations	Mar 2020	8	59	$1,155,710	49
	Feb 2020	9	53	$989,734	51
	Jan 2020	10	47	$984,897	42
bronchodilator combinations	Mar 2020	9	4,251	$1,148,734	3,810
	Feb 2020	10	3,539	$974,395	3,256
	Jan 2020	9	3,785	$1,033,690	3,447
immune globulins	Mar 2020	10	287	$919,271	213
	Feb 2020	11	325	$972,911	236
	Jan 2020	8	358	$1,064,456	249

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

Drug Molecule Therapeutic Category	Feb 2020 # Claims	Mar 2020 # Claims	Mar 2020 $ Paid	Mar 2020 # Unique Benes
albuterol / adrenergic bronchodilators	14,882	17,977	$680,765	15,278
amoxicillin / aminopenicillins	19,348	14,014	$183,359	13,748
montelukast / leukotriene modifiers	11,413	13,377	$221,839	12,833
cetirizine / antihistamines	9,496	12,045	$158,708	11,562
azithromycin / macrolides	13,466	9,741	$172,034	9,487
fluticasone nasal / nasal steroids	7,885	8,619	$135,755	8,465
gabapentin / gamma-aminobutyric acid analogs	7,548	8,049	$131,705	7,342
lisdexamfetamine / CNS stimulants	8,496	7,785	$2,438,949	7,544
acetaminophen-hydrocodone / narcotic analgesic combinations	7,816	7,481	$106,881	6,984
ibuprofen / nonsteroidal anti-inflammatory agents	9,129	7,113	$95,446	6,896
clonidine / antiadrenergic agents, centrally acting	6,222	6,655	$117,118	6,057
methylphenidate / CNS stimulants	7,007	6,576	$1,254,369	5,829
amlodipine / calcium channel blocking agents	5,445	6,036	$70,939	5,608
amphetamine-dextroamphetamine / CNS stimulants	6,087	5,877	$261,221	5,055
omeprazole / proton pump inhibitors	5,516	5,843	$68,425	5,580
oseltamivir / neuraminidase inhibitors	15,618	5,755	$378,283	5,724
ondansetron / 5HT3 receptor antagonists	7,437	5,528	$85,069	5,314
cefdinir / third generation cephalosporins	7,219	5,272	$119,066	5,188
amoxicillin-clavulanate / penicillins/beta-lactamase inhibitors	6,771	5,173	$125,781	5,053
prednisolone / glucocorticoids	6,088	4,975	$79,587	4,835
sertraline / SSRI antidepressants	4,334	4,638	$56,285	4,205
guanfacine / antiadrenergic agents, centrally acting	4,367	4,577	$148,186	4,225
atorvastatin / HMG-CoA reductase inhibitors (statins)	3,999	4,440	$56,399	4,079
triamcinolone topical / topical steroids	3,592	4,182	$78,640	4,040
risperidone / atypical antipsychotics	3,558	3,784	$186,410	3,326

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

Drug Molecule Therapeutic Category	Feb 2020 $ Paid	Mar 2020 $ Paid	Mar 2020 # Claims	Mar 2020 # Unique Benes
lisdexamfetamine / CNS stimulants	$2,656,201	$2,438,949	7,785	7,544
adalimumab / TNF alpha inhibitors	$1,660,118	$1,878,500	282	244
paliperidone / atypical antipsychotics	$1,269,804	$1,500,313	629	545
methylphenidate / CNS stimulants	$1,350,132	$1,254,369	6,576	5,829
bictegravir/emtricitabine/tenofovir / antiviral combinations	$906,682	$1,125,268	333	302
insulin glargine / insulin	$795,559	$877,016	1,977	1,838
aripiprazole / atypical antipsychotics	$780,051	$876,785	3,629	3,277
dexmethylphenidate / CNS stimulants	$799,862	$740,488	3,258	2,693
elexacaftor/ivacaftor/tezacaftor / CFTR combinations	$555,351	$719,847	36	29
albuterol / adrenergic bronchodilators	$564,920	$680,765	17,977	15,278
insulin aspart / insulin	$560,927	$673,342	1,427	1,313
etanercept / TNF alpha inhibitors	$525,270	$659,550	125	114
somatropin / growth hormones	$504,268	$602,983	139	118
palivizumab / immune globulins	$692,771	$600,821	255	186
deferasirox / chelating agents	$411,940	$599,641	59	50
lurasidone / atypical antipsychotics	$500,137	$549,981	397	367
emicizumab / factor for bleeding disorders	$387,410	$525,850	23	18
budesonide-formoterol / bronchodilator combinations	$467,642	$525,424	1,614	1,563
cobicistat/elvitegravir/emtricitabine/tenofov / antiviral combinations	$487,874	$511,929	154	143
lacosamide / miscellaneous anticonvulsants	$451,774	$509,051	548	500
insulin detemir / insulin	$428,731	$481,334	879	828
corticotropin / corticotropin	$438,920	$478,851	8	5
liraglutide / GLP-1 receptor agonists	$429,557	$462,990	592	575
buprenorphine-naloxone / narcotic analgesic combinations	$406,630	$430,145	1,224	1,030
vigabatrin / gamma-aminobutyric acid analogs	$288,328	$410,878	40	34

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

Drug Molecule	Jan 2020 # Claims	Feb 2020 # Claims	Mar 2020 # Claims	Mar 2020 $ Paid	Mar 2020 # Unique Benes
cetirizine / antihistamines	9,489	9,496	12,045	$158,708	11,562
albuterol / adrenergic bronchodilators	15,446	14,882	17,977	$680,765	15,278
montelukast / leukotriene modifiers	11,708	11,413	13,377	$221,839	12,833
fluticasone nasal / nasal steroids	7,091	7,885	8,619	$135,755	8,465
olopatadine ophthalmic / ophthalmic antihistamines and decongestants	668	667	1,155	$30,037	1,125
budesonide / inhaled corticosteroids	1,918	1,749	2,273	$261,109	2,191
triamcinolone topical / topical steroids	3,849	3,592	4,182	$78,640	4,040
furosemide / loop diuretics	2,375	2,210	2,643	$24,933	2,376
atorvastatin / HMG-CoA reductase inhibitors (statins)	4,197	3,999	4,440	$56,399	4,079
ergocalciferol / vitamins	2,580	2,510	2,817	$24,333	2,469
trazodone / phenylpiperazine antidepressants	3,251	3,009	3,476	$42,459	3,160
metoprolol / beta blockers, cardioselective	3,394	3,248	3,595	$47,231	3,349
insulin glargine / insulin	1,788	1,781	1,977	$877,016	1,838
insulin lispro / insulin	403	449	583	$207,878	523
fluticasone-salmeterol / bronchodilator combinations	1,078	985	1,243	$323,702	1,184
hydrochlorothiazide-losartan / angiotensin II inhibitors with thiazides	520	517	682	$11,804	658
pantoprazole / proton pump inhibitors	3,302	3,198	3,463	$47,784	3,229
budesonide-formoterol / bronchodilator combinations	1,463	1,384	1,614	$525,424	1,563
levetiracetam / pyrrolidine anticonvulsants	2,909	2,700	3,054	$80,959	2,676
esomeprazole / proton pump inhibitors	2,134	2,147	2,279	$271,444	2,170
amlodipine / calcium channel blocking agents	5,892	5,445	6,036	$70,939	5,608
oxcarbazepine / dibenzazepine anticonvulsants	2,210	2,109	2,340	$131,103	2,081
insulin aspart / insulin	1,300	1,124	1,427	$673,342	1,313
buspirone / miscellaneous anxiolytics, sedatives and hypnotics	2,158	2,106	2,282	$33,476	2,116
beclomethasone / inhaled corticosteroids	556	552	676	$147,782	652

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

Drug Molecule	Jan 2020 $ Paid	Feb 2020 $ Paid	Mar 2020 $ Paid	Mar 2020 # Claims	Mar 2020 # Unique Benes
paliperidone / atypical antipsychotics	$1,271,995	$1,269,804	$1,500,313	629	545
emicizumab / factor for bleeding disorders	$350,718	$387,410	$525,850	23	18
elexacaftor/ivacaftor/tezacaftor / CFTR combinations	$551,045	$555,351	$719,847	36	29
adalimumab / TNF alpha inhibitors	$1,735,753	$1,660,118	$1,878,500	282	244
glecaprevir-pibrentasvir / antiviral combinations	$167,135	$231,636	$309,466	24	19
ustekinumab / interleukin inhibitors	$188,971	$303,812	$329,149	17	15
bictegravir/emtricitabine/tenofovir / antiviral combinations	$990,693	$906,682	$1,125,268	333	302
corticotropin / corticotropin	$359,128	$438,920	$478,851	8	5
etanercept / TNF alpha inhibitors	$556,293	$525,270	$659,550	125	114
canakinumab / interleukin inhibitors	$130,756	$147,661	$229,387	11	8
eteplirsen / miscellaneous uncategorized agents	$6,461	$102,522	$102,522	2	1
insulin glargine / insulin	$781,819	$795,559	$877,016	1,977	1,838
albuterol / adrenergic bronchodilators	$589,881	$564,920	$680,765	17,977	15,278
glycerol phenylbutyrate / urea cycle disorder agents	$105,634	$120,927	$176,391	5	4
cannabidiol / miscellaneous anticonvulsants	$222,313	$217,208	$291,663	115	99
secukinumab / interleukin inhibitors	$149,656	$190,748	$213,127	40	34
empagliflozin / SGLT-2 inhibitors	$268,609	$283,309	$329,695	501	463
idursulfase / lysosomal enzymes	$26,348	$49,343	$86,984	3	2
pancrelipase / digestive enzymes	$249,490	$261,694	$306,051	153	143
nintedanib / multikinase inhibitors	$0	$52,713	$52,713	5	5
deferasirox / chelating agents	$552,062	$411,940	$599,641	59	50
lacosamide / miscellaneous anticonvulsants	$461,957	$451,774	$509,051	548	500
insulin lispro / insulin	$161,337	$164,113	$207,878	583	523
emtricitabine/rilpivirine/tenofovir / antiviral combinations	$140,881	$160,570	$185,785	61	55
deflazacort / glucocorticoids	$16,856	$27,853	$61,675	10	6

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

Drug Product Therapeutic Category	Mar 2020 # Claims	Mar 2020 $ Paid	Mar 2020 Avr. Paid Per Rx	Mar 2020 Avr. Units Per Rx	Jan 2020 Paid Per Unit	Feb 2020 Paid Per Unit	Mar 2020 Paid Per Unit	Percent Change
dexmethylphenidate 10 mg capsule, extended release / CNS stimulants (N)	167	$21,916	$131.23	30	$1.92	$3.12	$4.03	110.0%
dexmethylphenidate 20 mg capsule, extended release / CNS stimulants (N)	168	$21,073	$125.43	30	$3.41	$3.49	$3.76	10.3%
cefprozil 500 mg tablet / second generation cephalosporins (P)	111	$3,917	$35.29	19	$1.18	$1.21	$1.28	8.5%
amphetamine-dextroamphetamine 30 mg capsule, extended release / CNS stimulants (P)	691	$41,616	$60.23	30	$1.51	$1.31	$1.62	7.4%
Tradjenta (linagliptin) 5 mg tablet / dipeptidyl peptidase 4 inhibitors (P)	229	$131,189	$572.88	39	$13.75	$14.25	$14.42	4.9%
Trintellix (vortioxetine) 20 mg tablet / miscellaneous antidepressants (P)	228	$97,305	$426.78	33	$12.26	$12.73	$12.80	4.4%
Biktarvy (bictegravir/emtricitabine/tenofovir) 50 mg-200 mg-25 mg tablet / antiviral combinations (P)	333	$1,125,268	$3,379.18	35	$94.40	$97.58	$98.51	4.4%
Xarelto (rivaroxaban) 20 mg tablet / factor Xa inhibitors (P)	378	$168,485	$445.73	30	$14.00	$14.45	$14.58	4.1%
Trintellix (vortioxetine) 10 mg tablet / miscellaneous antidepressants (P)	189	$79,624	$421.29	32	$12.28	$12.75	$12.77	4.0%
Entresto (sacubitril-valsartan) 97 mg-103 mg tablet / angiotensin receptor blockers and neprilysin inhibitors (P)	149	$80,769	$542.08	64	$8.29	$8.54	$8.61	3.8%
atomoxetine 25 mg capsule / CNS stimulants (P)	222	$16,989	$76.53	31	$2.03	$2.18	$2.10	3.7%
oseltamivir 75 mg capsule / neuraminidase inhibitors (P)	1,832	$72,903	$39.79	10	$2.76	$2.86	$2.86	3.6%
Entresto (sacubitril-valsartan) 24 mg-26 mg tablet / angiotensin receptor blockers and neprilysin inhibitors (P)	167	$88,140	$527.78	60	$8.33	$8.60	$8.62	3.4%

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

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

Drug Product Therapeutic Category	Mar 2020 # Claims	Mar 2020 $ Paid	Mar 2020 Avr. Paid Per Rx	Mar 2020 Avr. Units Per Rx	Jan 2020 Paid Per Unit	Feb 2020 Paid Per Unit	Mar 2020 Paid Per Unit	Percent Change
Entresto (sacubitril-valsartan) 49 mg-51 mg tablet / angiotensin receptor blockers and neprilysin inhibitors (P)	143	$78,336	$547.80	60	$8.38	$8.63	$8.63	2.9%
Janumet (metformin-sitagliptin) 1000 mg-50 mg tablet / antidiabetic combinations (P)	144	$88,671	$615.77	77	$7.28	$7.41	$7.49	2.8%

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

New Business

Special Analysis Projects

MISSISSIPPI DIVISION OF MEDICAID

MS-DUR INTERVENTION / EDUCATIONAL INITIATIVE UPDATE

MARCH 2020 – MAY 2020

Ongoing Intervention(s):

HIGH MEDD (≥90 MEDD) MAILING Initiated Sept 2016 Completed July 2019			CONCOMITANT BENZODIAZEPINE / OPIOID USE Initiated Feb 2017 Completed July 2019		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**
19-Jun	***30	***46	ǂ388	ǂ645	27	20	47
19-Jul	23	31	ǂ234	ǂ373	17	13	30
19-Aug					16	13	30
19-Sep					18	14	32
19-Oct					18	14	32
19-Nov					13	12	27
19-Dec					14	9	23
20-Jan					15	12	27
20-Feb					8	6	14
20-Mar					7	4	11
20-Apr					4	3	7
20-May					3	4	7

Notes

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

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

One-Time Intervention(s):

TRICYCLIC ANTIDEPRESSANT AGE EDIT LETTER		
	Prescribers Mailed	Benes Addressed
20-May	507	1,220

SICKLE CELL DISEASE AND NEW PHARMACOLOGIC AGENTS

BACKGROUND

Sickle cell disease (SCD) is a broad term that describes a group of genetic disorders that impact hemoglobin (Hb) causing red blood cells to become an irregular, sickle shape. These sickle-shaped red blood cells are rigid and can cause blockages slowing the flow of blood. Blood vessel occlusion is the primary pathophysiology associated with SCD resulting in painful vaso-occlusive crises (VOC).[1,2]

In the United States (US), it is estimated approximately 100,000 people are living with SCD.[3] SCD is primarily present in individuals of African, Mediterranean, Central/South American, and Asian descent.[4,5] According to the Centers for Disease Control and Prevention (CDC), SCD impacts an estimated 1 out of every 365 African-American births and 1 out of every 16,300 Hispanic-American births in the US.[4]

VOCs impact nearly all individuals with SCD and can occur as early as 6 months of age. Patients with sickle cell disease-related pain events have been shown to have low health-related quality of life.[6] These SCD-related pain events can be managed with analgesics, however it has been shown that the use of analgesics may be underutilized due to stigma and provider bias.[6]

Prevention of VOCs is key in treating patients living with SCD. For over 20 years, hydroxyurea has been the primary pharmacotherapeutic agent available for preventing SCD complications. Hydroxyurea increases fetal hemoglobin, reduces "sickling" of red blood cells, and improves blood flow.[7] In 2014, the National Heart, Lung and Blood Institute (NHLBI) updated guidelines for the management of SCD.[8] The evidence-based guidelines provided recommendations for the use of hydroxyurea therapy.

Figure 1: Evidence-Based Recommendations for Use of Hydroxyurea Therapy[8]

Evidence-Based Recommendations for Use of Hydroxyurea Therapy	Strength of Recommendation	Quality of Evidence
In adults with sickle cell anemia (SCA) who have ≥3 moderate to severe pain crises associated with sickle cell disease (SCD) during a 12-mo period, initiate treatment with hydroxyurea	Strong	High
In adults with SCA who have sickle cell-associated pain that interferes with daily activities and quality of life, initiate treatment with hydroxyurea	Strong	Moderate
In adults with SCA who have a history of severe or recurrent acute chest syndrome (ACS), initiate treatment with hydroxyurea[a]	Strong	Moderate
In adults with SCA who have severe symptomatic chronic anemia that interferes with daily activities or quality of life, initiate treatment with hydroxyurea	Strong	Moderate
In infants 9 mo of age or older, in children, and in adolescents with SCA, offer treatment with hydroxyurea regardless of clinical severity to reduce complications (eg, pain, dactylitis, ACS, anemia) related to SCD	Strong[b] and moderate[c]	High[b] and moderate[c]
In adults and children with SCD who have chronic kidney disease and are taking erythropoietin, add hydroxyurea therapy to improve anemia	Weak	Low
Discontinue hydroxyurea therapy in women who are pregnant or breastfeeding	Moderate	Low
Use an established prescribing and monitoring protocol to ensure proper use of hydroxyurea and maximize benefits and safety	Strong	High
In persons with HbSβ⁺-thalassemia or HbSC who have recurrent SCD-associated pain that interferes with daily activities or quality of life, consult an SCD expert for consideration of hydroxyurea therapy	Moderate	Low
In persons not demonstrating a clinical response to appropriate doses and duration of hydroxyurea therapy, consult an SCD expert	Moderate	Very low

[a] More information appears in the chapter entitled "Managing Acute Complications of Sickle Cell Disease" in the full guideline.

[b] Strong recommendation and high quality of evidence for persons aged 9 to 42 months.

[c] Moderate recommendation and moderate quality of evidence for children older than 42 months and adolescents.

In 2017 the FDA approved L-glutamine (Endari®) as the first new therapeutic agent for the treatment of SCD in over two decades.[9] Endari® is indicated to reduce the acute complications of sickle cell disease in adult and pediatric patients 5 years of age and older. In 2019 two new agents were approved for the treatment of SCD, crizanlizumab (Adakveo®) and voxelotor (Oxbryta®). Adakveo® is a selectin blocker indicated to reduce the frequency of vaso-occlusive crises in adults and pediatric patients aged 16 years and older with sickle cell disease.[10] Oxbryta® is a hemoglobin S polymerization inhibitor indicated for the treatment of sickle cell disease in adults and pediatric patients 12 years of age and older.[11] Each of these agents has a unique mechanism of action in treating SCD. Although these four agents are the current medications indicated for treatment of SCD, other potential therapies in this disease state are on the horizon. One of the first gene therapy agents for sickle cell treatment received approval from the European Medicines Agency (EMA) in 2019 with an estimated price of €1.575 million ($1.8 million). It is currently under review by the FDA in the US. [12–14]

Determining the place in therapy for each agent is crucial in the treatment of SCD. The Institute for Clinical and Economic Review (ICER) released their Draft Evidence Report for sickle cell disease in February 2020.[15] Their review included data on clinical and cost effectiveness for each of the newer agents approved for use in the United States. Figure 2 is a table describing recently approved therapies for SCD.

Figure 2: Recently Approved Therapies for SCD.[15]

	Date of FDA Approval	FDA Indication	FDA Dosage	How Supplied	WAC*	Cost per Year**
Crizanlizumab (Adakveo®)	11/15/2019	Indicated to reduce the frequency of vaso-occlusive crises in adults and pediatric patients age ≥16 years with SCD	Administer 5 mg/kg (IV) over a period of 30 minutes on week 0, week 2, and every 4 weeks thereafter	100mg/10ml (10mg/ml) single-dose vial	$2,357.14 per 10ml vial	$107,700
Voxelotor (Oxbryta®)	11/25/2019	Indicated for the treatment of SCD in adults and pediatric patients age ≥ 12 years	1,500 mg orally once daily with or without food	500 mg tablets; 90 count bottle	$10,417.00 per 90 count bottle. ($115.74 per tablet)	$104,357
L-Glutamine (Endari®)	7/7/2017	Indicated to reduce the acute complications of SCD in adult and pediatric patients ≥ 5 years	5-15 grams orally, twice daily based on body weight	5 gram packets; carton of 60	$1,154.00 per 60 count carton; $19.23 per 5 gram packet	$26,082

Notes: IV - intravenous; SCD - sickle cell disease; WAC - wholesale acquisition cost.
*WAC accessed June 1, 2020
** Cost per Year estimates based on ICER figures[15]

The Mississippi Division of Medicaid requested MS-DUR conduct an analysis of Medicaid beneficiaries diagnosed with SCD. Utilization of therapies for the treatment of SCD was analyzed. Applying key inclusion/exclusion criteria used in clinical trials for both Adakveo® and Oxbryta®, MS-DUR examined claims data to forecast beneficiaries that may be potential candidates for these newly approved therapies.

METHODS

A retrospective analysis was conducted using Mississippi Medicaid fee-for-service (FFS) and coordinated care organization [CCOs: Magnolia (MAG), Molina Health (MOL), and UnitedHealthcare (UHC)] claims for the period of January 1, 2018 to December 31, 2019. Medicaid beneficiaries with SCD were identified using the ICD-10 codes from CMS Chronic Conditions Warehouse (CCW) algorithm.[16] All 25 ICD-10 diagnosis codes as well as the principal diagnosis code of each claim were checked from inpatient, outpatient and medical claim files to identify beneficiaries with SCD. Information on the beneficiaries' race, gender, age, and plan (FFS/UHC/MAG/MOL) were summarized in the analysis. Age and plan were assessed as of the date for first SCD diagnosis claim in the analysis period, referred to as the index SCD diagnosis date hereafter.

RESULTS

A total of 2,331 beneficiaries were identified through claims data as being diagnosed with SCD during the study period.

- 0.33% of the average Medicaid enrollment during the study period (702,956) were diagnosed with SCD.
- 1,914 (82.1%) were 35 years of age or below.
- Females made up 60.9% of those diagnosed with SCD.
- 86.8% were African American.

TABLE 1a: Proportion of Medicaid Beneficiaries with Sickle Cell Disease Diagnosis
(January 2018 - December 2019)

Plan	Average Enrollment	Beneficiaries with SCD	Percent
FFS	181,187	668	0.37%
UHC	226,557	724	0.32%
MAG	257,634	847	0.33%
MOL	37,578	92	0.24%
Total	**702,956**	**2,331**	**0.33%**

Note: SCD - Sickle Cell Diagnosis
Average enrollment calculated over the study period.

TABLE 1b: Demographic Characteristics of Beneficiaries Diagnosed with Sickle Cell Disease
(January 2018 - December 2019)

Characteristic	Total Beneficiaries	Plan							
		FFS		UHC		MAG		MOL	
		N	%	N	%	N	%	N	%
Age Category									
0-17	**1,088**	213	32%	385	53%	451	53%	39	42%
18-35	**826**	251	38%	245	34%	283	33%	47	51%
36-50	**274**	127	19%	67	9%	74	9%	6	7%
51-64	**143**	77	12%	27	4%	39	5%	0	0%
Total	**2,331**	**668**	**100%**	**724**	**100%**	**847**	**100%**	**92**	**100%**
Sex									
Female	**1,420**	392	59%	446	62%	511	60%	71	77%
Male	**911**	276	41%	278	38%	336	40%	21	23%
Total	**2,331**	**668**	**100%**	**724**	**100%**	**847**	100%	**92**	**100%**
Race									
Caucasian	**30**	10	1%	12	2%	8	1%	0	0%
Other	**278**	64	10%	91	13%	111	13%	12	13%
African Amer	**2,023**	594	89%	621	86%	728	86%	80	87%
Total	**2,331**	**668**	**100%**	**724**	**100%**	**847**	**100%**	**92**	**100%**

Note: FFS - Fee-for-Service; UHC - UnitedHealthcare; MAG - Magnolia; MOL - Molina
Patients with Sickle Cell Disease were identified using CCW Chronic Conditions algorithm, and all 25 ICD-10 diagnosis codes, as well as the principal diagnosis code of patients, were checked using claims from inpatient, outpatient and medical claim files. Plan was determined as of the date of index diagnosis date of SCD.

For all beneficiaries with SCD, beneficiaries on Endari®, hydroxyurea, or opioid pain medications were identified during the 24-month study period. Methadone, buprenorphine and buprenorphine-naloxone were excluded from the list of opioid medications as these medications are often used in opioid abuse treatment and have been excluded from opioid pain dosing guidelines.[17] For all the beneficiaries on opioid pain medication, opioid doses were converted into MEDDs (morphine equivalent daily doses) and number of beneficiaries with average and max daily doses were stratified into the following categories: less than 50 MEDD, 50 to 89 MEDD and 90 MEDD or above. Average MEDD is defined as a beneficiary's mean opioid dose level across the duration of their opioid treatment while max MEDD is defined as the maximum opioid dose level at any point during the treatment continuum.

Table 2 displays the utilization of medications among beneficiaries diagnosed with SCD.

- 60.8% (1,417) of beneficiaries diagnosed with SCD had a prescription claim for Endari®, hydroxyurea, opioid medication, or any combination of these medications during the study period.
- Only 2.4% (56) of beneficiaries had a claim for Endari®.
- 27% (629) of beneficiaries diagnosed with SCD had at least one claim for hydroxyurea during the study period.
- 56.5% (1,317) of beneficiaries had claims for opioid pain medication:
    - 83.1% (1,094) of those beneficiaries had an average MEDD of < 50 and
    - 63.1% (831) had a max MEDD of < 50.

TABLE 2: Drug Utilization Stratified by Plan

(January 2018 - December 2019)

Plan*	#Benes on Endari	#Benes on Hydroxyurea	#Benes on Opioid Pain Medication	Opioid Pain Medication											
				Average MEDD ǂ						Max MEDD ǂ					
				< 50 MED		50 -89 MED		90 MED or Higher		< 50 MED		50 -89 MED		90 MED or Higher	
N = 2,331	N = 1,417**			N	%	N	%	N	%	N	%	N	%	N	%
FFS	16	133	275	226	82%	36	13%	13	5%	185	67%	63	23%	27	10%
UHC	11	220	471	396	84%	49	10%	26	6%	293	62%	111	24%	67	14%
MAG	29	273	536	445	83%	66	12%	25	5%	330	62%	125	23%	81	15%
MOL	0	3	35	27	77%	8	23%	0	0%	23	66%	12	34%	0	0%
Total	**56**	**629**	**1,317**	**1,094**		**159**		**64**		**831**		**311**		**175**	

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

*Patients with Sickle Cell Disease were identified using CCW Chronic Conditions algorithm, and all 25 ICD-10 diagnosis codes as well as the principal diagnosis code of patients were checked using claims from inpatient, outpatient and medical claim files. Plan was determined as of the date of index diagnosis date of SCD.

**1,417 unique beneficiaries were on one or more of the 3 therapies.

ǂ MEDD - Morphine Equivalent Daily Dose

Inpatient sickle cell related hospitalizations on or after index SCD diagnosis date were identified. Each hospitalization's length of stay was calculated. Hospitalizations within 3 days of a previous hospitalization were considered as the same hospitalization event. Average number of hospitalizations per beneficiary, average length of stay per beneficiary and average length of stay per hospitalization event (stay) were reported stratified by plan. For each plan, the average length of stay per hospitalization event was calculated by dividing the total days of hospitalization across all beneficiaries enrolled in that plan by the total number of hospitalization events across all beneficiaries in that plan. Sickle cell-related hospitalization events were identified from inpatient claims with a primary diagnosis for one of the sickle cell-related events, consistent with literature.[18] For sickle cell-related hospitalizations, average cost per beneficiary and average cost per stay were reported, stratified by plan for the entire study period. In calculating sickle cell-related hospitalizations in each plan, the average cost per stay was calculated by dividing the total cost across all beneficiaries enrolled in that plan by the total number of hospitalization events across all beneficiaries in that plan.

TABLE 3.1: Cost and Length of Stay of Sickle Cell-related Hospitalization Stratified by Plan
(January 2018 - December 2019)

Plan at Index Sickle Cell Diagnosis	#Benes	Hospitalization Cost		Length of Stay (LOS) in days		No. of Hospitalizations
		Average Cost/Bene	Average Cost/Stay	Average LOS/Bene	Average LOS/Stay	Average Hospitalizations /Bene
FFS	**153**	$22,840.1	$5,424.9	27.6	9.8	4.3
UHC	**246**	$20,271.7	$5,479.2	4.9	1.5	3.7
MAG	**272**	$22,768.3	$5,531.1	24.3	5.1	4.3
MOL	**6**	$6,395.7	$3,999.4	5.8	3.4	1.5

Note: FFS - Fee For Service, UHC - UnitedHealthcare, MAG - Magnolia, MOL - Molina
Plan was determined as of the index Sickle Cell Diagnosis. Patients with Sickle Cell Disease were identified using CCW Chronic Conditions algorithm, and all 25 ICD-10 diagnosis codes as well as the principal diagnosis code of patients were checked using claims from inpatient, outpatient and medical claim files. SCD-related hospitalizations were calculated using inpatient claims that had a primary diagnosis code for a sickle cell related event [Kauf, Teresa L., et al. "The cost of health care for children and adults with sickle cell disease." American Journal of Hematology 84.6 (2009): 323-327.]

- 28.8% (671) of beneficiaries diagnosed with SCD had a sickle cell-related hospitalization during the study period.
- The average cost per sickle cell-related hospitalization across all plans was $5,356.51.
- Over $14.5 million was spent on sickle cell-related hospitalizations during the study period.

Moreover, for beneficiaries with a diagnosis for SCD in the study period, all-cause and SCD-related costs post index SCD diagnosis were determined. Costs included amount paid by Medicaid for hospitalizations, non-hospitalization medical events, and prescription drug use. Months of Medicaid eligibility post index diagnosis were assessed to standardize costs to per member per year (PMPY) metrics while reporting the plan stratified results. (Table 3.2)

TABLE 3.2: All-Cause and Sickle Cell Disease (SCD)-related costs for Beneficiaries with a SCD Diagnosis
(January 2018 - December 2019)

Plan at Index Sickle Cell Diagnosis	#Benes	All-cause Cost (PMPY*)		SCD-related Cost** (PMPY*)	
		Average Cost/Bene	Total (annualized)	Average Cost/Bene	Total (annualized)
FFS	**638**	$24,534.1	$15,652,755.8	$11,508.4	$7,342,359.2
UHC	**724**	$19,351.5	$14,010,486.0	$11,059.5	$8,007,078.0
MAG	**847**	$26,696.8	$22,612,189.6	$15,052.5	$12,749,467.5
MOL	**92**	$12,922.5	$1,188,870.0	$1,124.4	$103,444.8

Note: PMPY - Per Member Per Year
FFS - Fee For Service, UHC - UnitedHealthcare, MAG - Magnolia, MOL - Molina
Plan was determined as of the index Sickle Cell Diagnosis. Patients with Sickle Cell Disease were identified using CCW Chronic Conditions algorithm, and all 25 ICD-10 diagnosis codes as well as the principal diagnosis code of patients were checked using claims from inpatient, outpatient and medical claim files.
Number of beneficiaries in each plan may differ from the number of beneficiaries in the descriptive table due to loss of Medicaid eligiblility in the follow-up period.
*PMPY costs assessed by taking into account number of months of Medicaid eligibility in the follow-up period.
**SCD-related costs were calculated using medical claims that had a primary diagnosis code for a sickle cell related event and pharmacy claims for hydroxyurea, endari, or iron chelation agents [Kauf, Teresa L., et al. "The cost of health care for children and adults with sickle cell disease." American Journal of Hematology 84.6 (2009): 323-327.]

- DOM spent over $53 million annually to care for beneficiaries diagnosed with SCD, with approximately $28 million annually being spent directly on sickle cell-related costs.

When forecasting to identify potential candidates for therapy with either Adakveo® or Oxbryta®, MS-DUR looked to clinical trial data utilized in gaining FDA approval for both of these products. In the clinical trials cited in the ICER Report, there were some common criteria across both the SUSTAIN (Adakveo®) and HOPE (Oxbryta®) noted.[15,19,20]

- **Age ≥ 12 years** - The minimum age approved for Adakveo® is 16 years and for Oxbryta® is 12 years. Anyone below the age of 12 years was excluded as a potential candidate for either Adakveo® or Oxbryta®.
- **Stable Hydroxyurea use** - In trials for both medications, the majority of participants had been maintained on a stable hydroxyurea dose for 3 months prior to enrollment and continued on hydroxyurea therapy during the trials. For this analysis, beneficiaries were considered as being on stable hydroxyurea dosing if they had been on the same dose of hydroxyurea for 90 days or more, allowing for compliance gaps of up to 60 days. Number of beneficiaries on stable hydroxyurea dose enrolled in each plan (as of their index SCD diagnosis date) were reported.
- **Receipt of chronic transfusion** – Both the SUSTAIN and HOPE trials excluded participants that had received chronic red-cell blood transfusions. MS-DUR ran 2 analyses, with and without chronic transfusion as an exclusion criteria. For all the beneficiaries on stable hydroxyurea dosing, beneficiaries undergoing blood transfusion were identified according to CPT codes for blood transfusion.[21] Beneficiaries were classified as having "chronic transfusion" if they had transfusions every 6 weeks or less.
- **Number of pain crises experienced**– The SUSTAIN trial included participants with 2-10 acute pain crises during the previous 12 months, while the HOPE trial included participants with 1-10 acute pain crises in the previous 12 months. Pain crisis events were identified during the study period using ICD-10 codes for pain crisis events as described by Stettler et.al. [22] Number of beneficiaries having 1, 2, 3 or more pain crisis events during the study period were reported, stratified by plan.

MS-DUR used these criteria to forecast the number of possible beneficiaries that may be prescribed therapy with one of the two new agents.

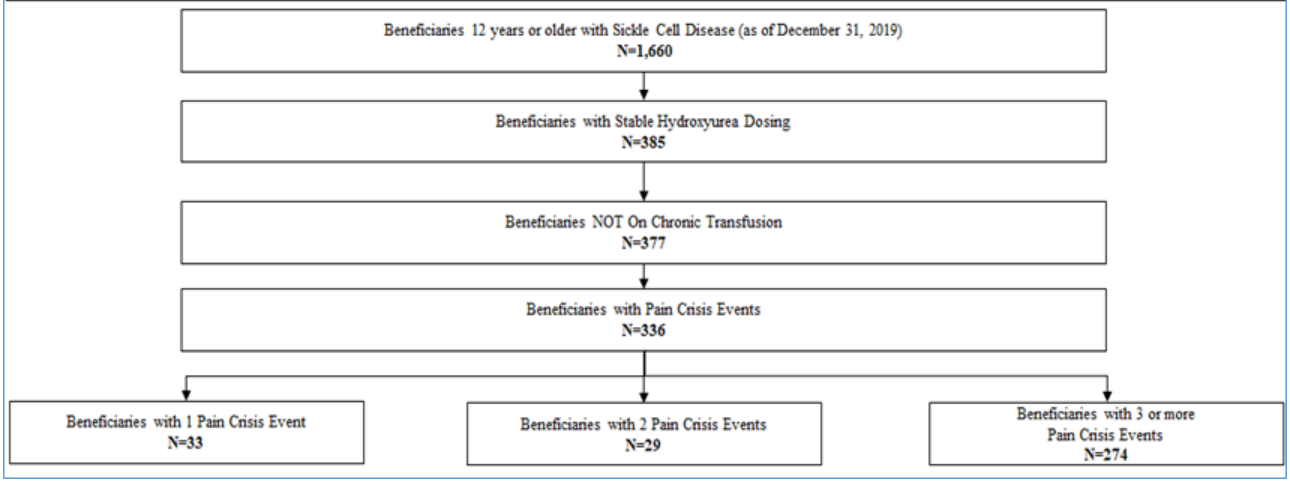
Table 4/Figure 3 describe potential beneficiaries **excluding** those receiving chronic transfusions.

TABLE 4: Description of Pain Crisis Events in Beneficiaries ≥ 12 Years on Stable Hydroxyurea Doses and NOT on Chronic Blood Tranfusion
(January 2018 - December 2019)

Plan	Beneficiaries on Hydroxyurea N= 446	Beneficiaries on Stable Hydroxyurea Dose* N = 385	Beneficiaries NOT on Chronic Blood Transfusion** N= 377	Beneficiaries with Pain Crisis by Number of Pain Crises in During Study Period*** N= 336			
				1	2	3	Total
FFS	105	91	90	10	11	56	**77**
UHC	143	123	121	9	8	90	**107**
MAG	197	170	165	14	10	127	**151**
MOL	1	1	1	0	0	1	**1**
Total	**446**	**385**	**377**	**33**	**29**	**274**	**336**

Notes: FFS - Fee-for-Service; UHC - UnitedHealthcare; MAG - Magnolia; MOL - Molina
*Stable Hydroxyurea dosing was identified as beneficiaries on the same dose of hydroxyurea for 90 days or more, allowing for compliance gaps of up to 60 days
**Blood Transfusion was identified according to CPT codes for blood transfusion and were classified as a "Chronic Transfusion" if the beneficiary had tranfusions every 6 weeks or less; CPT Codes for blood transfusion were referenced from CPT Codes for Transfusion Service Testing retrieved from https://abo20.lstream.org/images/HS_Manual/CPT_Codes.pdf and Kalman, R., Mack, J.P. (2018). Blood products and coagulation. Critical Care Secrets E-Book, 373
***Pain crisis identified using ICD-10 codes as used in Stettler, N., McKiernan, C. M., Melin, C. Q., Adejoro, O. O., & Walczak, N. B. (2015). Proportion of adults with sickle cell anemia and pain crises receiving hydroxyurea. JAMA - Journal of the American Medical Association, 313(16), 1671–1672. https://doi.org/10.1001/jama.2015.3075

FIGURE 3: Sample Attrition for Beneficiaries ≥ 12 Years with Stable Hydroxyurea Dosing and NOT on Chronic Transfusion Having Pain Crisis Events
(January 2018 - December 2019)



- Excluding beneficiaries that were considered as receiving chronic transfusions, a total of 336 beneficiaries across all pharmacy programs could be considered as potential candidates for either Adakveo® or Oxbryta®.

Table 5/Figure 4 describe potential beneficiaries **including** those receiving chronic transfusions.

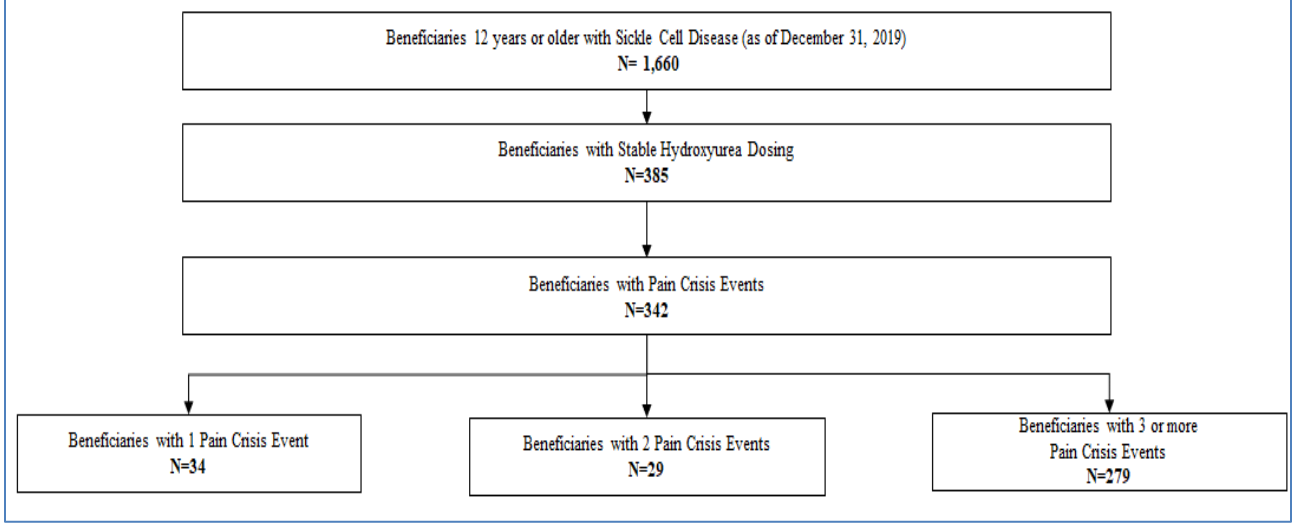
- Only 6 additional potential beneficiaries were added when those receiving chronic transfusions were included in the forecasting.

TABLE 5: Description of Pain Crisis Events in Beneficiaries ≥ 12 Years on Stable Hydroxyurea Doses
(January 2018 - December 2019)

Plan	Beneficiaries on Hydroxyurea N= 446	Beneficiaries on Stable Hydroxyurea Dose* N = 385	Beneficiaries with Pain Crisis by Number of Pain Crises in Previous Year*** (N= 342) 1	2	3	Total
FFS	105	91	10	11	56	77
UHC	143	123	10	8	91	109
MAG	197	170	14	10	131	155
MOL	1	1	0	0	1	1
Total	446	385	34	29	279	342

Notes: FFS - Fee-for-Service; UHC - UnitedHealthcare; MAG - Magnolia; MOL - Molina
*Stable Hydroxyurea dosing was identified as beneficiaries on the same dose of hydroxyurea for 90 days or more, allowing for compliance gaps of up to 60 days.
***Pain crisis identified using ICD-10 codes as used in Stettler, N., McKiernan, C. M., Melin, C. Q., Adejoro, O. O., & Walczak, N. B. (2015). Proportion of adults with sickle cell anemia and pain crises receiving hydroxyurea. JAMA - Journal of the American Medical Association, 313(16), 1671–1672. https://doi.org/10.1001/jama.2015.3075

FIGURE 4: Sample Attrition for Beneficiaries ≥ 12 years with Stable Hydroxyurea Doses Having Pain Crisis Events
(January 2018 - December 2019)



CONCLUSIONS

Although sickle cell disease affects a relatively small proportion of the population, the impact on the health-related quality of life for those living with sickle cell disease can be substantial. Historically, treatment options have been limited. Two new agents recently received FDA approval and more are expected to be approved in the near future. Balancing clinical and cost effectiveness in determining the most appropriate place in therapy for these new agents is essential. Modeling prior authorization requirements after the criteria utilized in clinical trials used to gain FDA approval is a logical place to begin.

RECOMMENDATIONS

1. MS-DUR recommends that DOM create manual prior authorization criteria for Oxbryta® and Adakveo® for review/approval of appropriate use of these products.

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CYTOKINE AND CAM ANTAGONIST UTILIZATION IN MISSISSIPPI MEDICAID

BACKGROUND

Cytokine and cell-adhesion molecule (CAM) antagonists have a major role in the treatment of a group of diseases that are linked to an overactive immune system response such as rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, plaque psoriasis and inflammatory bowel disease. Utilization of this class of medications continues to increase. Medicaid and other pharmacy payers across the United States are tasked with the responsibility of ensuring these medications are appropriately prescribed.

Mississippi Division of Medicaid's (DOM) current Universal Preferred Drug List (UPDL) for this class of medications is shown below. Presently, Cosentyx®, Enbrel®, Humira® and generic methotrexate are preferred products

DOM Universal Preferred Drug List – Effective 1-1-2020

CYTOKINE & CAM ANTAGONISTS			
	COSENTYX (secukinumab) SmartPA ENBREL (etanercept) HUMIRA (adalimumab) methotrexate	ACTEMRA (tocilizumab) CIMZIA (certolizumab) ENTYVIO (vedolizumab) ILARIS (canakinumab) ILUMYA (tildrakizumab) INFLECTRA (infliximab) KEVZARA (sarilumab) KINERET (anakinra) OLUMIANT (baricitinib) ORENCIA (abatacept) OTEZLA (apremilast) OTREXUP (methotrexate) RASUVO (methotrexate) REMICADE (infliximab) RENFLEXIS (infliximab-abda) RHEUMATREX (methotrexate) RINVOQ (upadacitinib) SILIQ (brodalumab) SIMPONI (golimumab) SKYRIZI (risankizumab) STELARA (ustekinumab) TALTZ (ixekizumab) TREMFYA (guselkumab) TREXALL (methotrexate) XELJANZ (tofacitinib) XELJANZ XR (tofacitinib)	Orencia IV Infusion, Remicade IV Infusion, Renflexis and Stelara (first dose) are for administration in hospital or clinic setting. PA will not be issued at Point of Sale without justification. Cosentyx • ≥ **18 years** = Minimum Age • Documented diagnosis of plaque psoriasis, psoriatic arthritis or ankylosing spondylitis in the past 2 years **AND** • 90 consecutive days of Humira in the past year

Due to increasing utilization within Medicaid for agents within this category, MS-DUR examined cytokine and CAM antagonist utilization trends to determine if additional criteria might be needed to appropriately manage this class of medications.

METHODS

A retrospective analysis was conducted using Mississippi Medicaid medical and pharmacy claims for the period January 2018 – December 2019. The analysis included data from the Fee-for-Service (FFS) program and the coordinated care organizations (CCOs) which include Magnolia Health (MAG), Molina Healthcare (MOL), and UnitedHealthcare (UHC). Pharmacy and office-

administered medical claims for all drugs listed in the Cytokine & CAM Antagonists category in the UPDL were extracted. Utilization of each agent and dose form for selected agents were examined monthly. Since there is not a current diagnosis check, beneficiaries with paid claims for the two most commonly utilized preferred agents, Humira® and Enbrel®, were evaluated for the presence of an approved diagnosis in the medical claims prior to new starts of therapy. A first prescription claim was considered to be a new start of therapy if the beneficiary was continuously enrolled for the prior 3 months without a claim for the product.

RESULTS

Number and Type of Claims

Table 1 provides the number of claims from this class with the majority accounted for in the pharmacy point-of-sale (POS) system. Humira®, Enbrel® and Cosentyx® are almost always paid through POS. However, methotrexate injection and several other agents in this category are often billed through medical encounter claims.

TABLE 1: Number of Claims by Type and Drug
(January 2018 - December 2019)

Drug	TOTAL Claims	Type of Claim		Drug Class				
		Medical	Pharmacy	TNF	INTER	JAK	METH	OTHER
TOTAL for UPDL Category	22,215	2,909	19,306					
abatacept (Orencia)	568	206	362					X
adalimumab (Humira)	5,444	32	5,412	X				
anakinra (Kineret)	51	0	51		X			
apremilast (Otezla)	315	0	315					X
baricitinib (Olumiant)	2	0	2			X		
brodalumab (Siliq)	9	0	9		X			
canakinumab (Ilaris)	166	0	166		X			
certolizumab (Cimzia)	157	30	127	X				
etanercept (Enbrel)	2,528	6	2,522	X				
golimumab (Simponi)	177	92	85	X				
guselkumab (Tremfya)	14	0	14		X			
infliximab (Remicade)	1,080	1,061	19	X				
ixekizumab (Taltz)	111	1	110		X			
methotrexate (Otrexup/Rrasuvo/Trexall/ Rheumatrex, etc)	9,933	1,102	8,831				X	
risankizumab (Skyrizi)	6	0	6		X			
sarilumab (Kevzara)	41	0	41		X			
secukinumab (Cosentyx)	472	10	462		X			
tildrakizumab (Ilumya)	0	0	0		X			
tocilizumab (Actemra)	256	151	105		X			
tofacitinib (Xeljanz/Xeljanz XR)	510	0	510			X		
upadacitinib (Rinvoq)	3	0	3			X		
ustekinumab (Stelara)	173	25	148		X			
vedolizumab (Entyvio)	199	193	6					X

TNF = tumor necrosis factor inhibitor, INTER = interleukin inhibitor or antagonist, JAK = janus kinase inhibitor, METH = methotrexate, OTHER = all other drugs in PDL category.

Preferred drugs on UPDL

Utilization Trends for Cytokine and CAM Antagonists

Table 2 shows the total number of monthly claims for each drug. From January 2018 to December 2019 there has been a 20.7% increase in total claims for this category primarily driven by a 33% increase in claims for Humira®.

TABLE 2: Number of Prescriptons and Office-Administered Claims by Drug and Month
(Includes FFS and CCOs)

	Month Filled / Administered																							
Drug	Jan 2018	Feb 2018	Mar 2018	Apr 2018	May 2018	Jun 2018	Jul 2018	Aug 2018	Sep 2018	Oct 2018	Nov 2018	Dec 2018	Jan 2019	Feb 2019	Mar 2019	Apr 2019	May 2019	Jun 2019	Jul 2019	Aug 2019	Sep 2019	Oct 2019	Nov 2019	Dec 2019
TOTAL for UPDL Category	841	813	878	903	880	837	865	883	823	897	886	855	974	859	960	958	983	952	1,050	1,034	1,008	1,110	951	1,015
abatacept (Orencia)	23	21	25	27	25	19	22	24	20	27	22	18	30	21	30	22	25	24	23	25	21	25	23	26
adalimumab (Humira)	197	202	206	203	208	202	203	215	200	211	207	201	216	214	234	249	250	229	261	276	252	290	256	262
anakinra (Kineret)	2	1	1	3	2	0	1	1	2	2	3	2	2	3	1	2	3	2	2	4	4	3	2	3
apremilast (Otezla)	13	11	17	13	9	15	11	11	12	14	10	12	15	10	10	12	11	12	13	15	16	18	16	19
baricitinib (Olumiant)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1
brodalumab (Siliq)	0	0	0	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1	1	1	0	0	0	0
canakinumab (Ilaris)	0	8	7	6	6	7	4	7	5	8	9	6	7	10	5	11	7	7	6	10	6	8	7	9
certolizumab (Cimzia)	4	5	4	1	5	2	5	5	5	3	5	6	6	6	8	9	9	11	11	12	9	9	8	9
etanercept (Enbrel)	95	100	97	104	106	107	109	97	85	109	103	95	110	99	96	109	111	115	123	108	107	111	116	116
golimumab (Simponi)	6	5	4	9	6	7	9	8	6	8	5	11	9	6	7	7	6	9	6	11	5	10	8	9
guselkumab (Tremfya)	0	0	0	0	1	1	0	1	0	2	1	0	1	0	0	0	0	0	0	2	0	2	3	0
infliximab (Remicade)	57	42	47	46	57	38	41	46	42	46	35	41	48	36	44	45	48	41	55	39	49	55	33	49
ixekizumab (Taltz)	4	3	3	4	2	4	4	6	5	3	5	5	4	5	7	7	8	8	5	4	3	4	4	4
methotrexate (Otrexup/Rrasuvo/Trexall/ Rheumatrex, etc)	396	366	417	430	399	380	401	395	392	403	420	402	456	390	443	413	430	410	449	443	440	470	373	415
risankizumab (Skyrizi)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	2	1
sarilumab (Kevzara)	1	1	1	1	0	2	1	1	0	1	1	0	0	0	2	2	4	1	4	3	4	4	4	3
secukinumab (Cosentyx)	15	14	16	15	16	15	12	14	11	21	20	16	19	18	15	18	26	22	25	25	25	33	31	30
tildrakizumab (Ilumya)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
tocilizumab (Actemra)	10	8	8	11	7	7	10	11	13	7	9	9	15	11	15	17	7	14	13	12	11	13	9	9
tofacitinib (Xeljanz/ Xeljanz XR)	8	14	16	19	16	19	15	25	16	19	17	19	21	19	28	24	21	31	30	27	28	28	28	22
upadacitinib (Rinvoq)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	1
ustekinumab (Stelara)	4	8	4	5	10	5	11	9	6	6	6	4	5	5	6	2	7	4	12	6	11	12	10	15
vedolizumab (Entyvio)	6	4	5	6	5	7	6	7	3	7	8	7	9	5	8	8	9	11	11	11	17	12	15	12

As demonstrated in Table 3 and Figure 1, when examining number of claims by drug class, tumor necrosis factor (TNF) inhibitors and methotrexate make up the majority of claims for this UPDL category.

TABLE 3: Number of Prescriptons and Office-Administered Claims by Drug Class and Month
(Includes FFS and CCOs)

Drug Class	Month Filled / Administered																							
	Jan 2018	Feb 2018	Mar 2018	Apr 2018	May 2018	Jun 2018	Jul 2018	Aug 2018	Sep 2018	Oct 2018	Nov 2018	Dec 2018	Jan 2019	Feb 2019	Mar 2019	Apr 2019	May 2019	Jun 2019	Jul 2019	Aug 2019	Sep 2019	Oct 2019	Nov 2019	Dec 2019
TOTAL for UPDL Category	841	813	878	903	880	837	865	883	823	897	886	855	974	859	960	958	983	952	1,050	1,034	1,008	1,110	951	1,015
TNF inhibitors	359	354	358	363	382	356	367	371	338	377	355	354	389	361	389	419	424	405	456	446	422	475	421	445
Interleukin inhibitors	35	42	39	44	44	39	42	49	42	49	53	43	54	53	50	58	59	58	64	64	60	78	68	71
JAK inhibitors	8	14	16	19	16	19	15	25	16	19	17	19	21	19	28	24	21	31	30	27	28	28	31	24
Methotrexate	396	366	417	430	399	380	401	395	392	403	420	402	456	390	443	413	430	410	449	443	440	470	373	415
Other	43	37	48	47	39	43	40	43	35	49	41	37	54	36	50	44	49	48	51	54	58	59	58	60

FIGURE 1: Number of Prescriptions and Medical Claims by Drug Class and Month

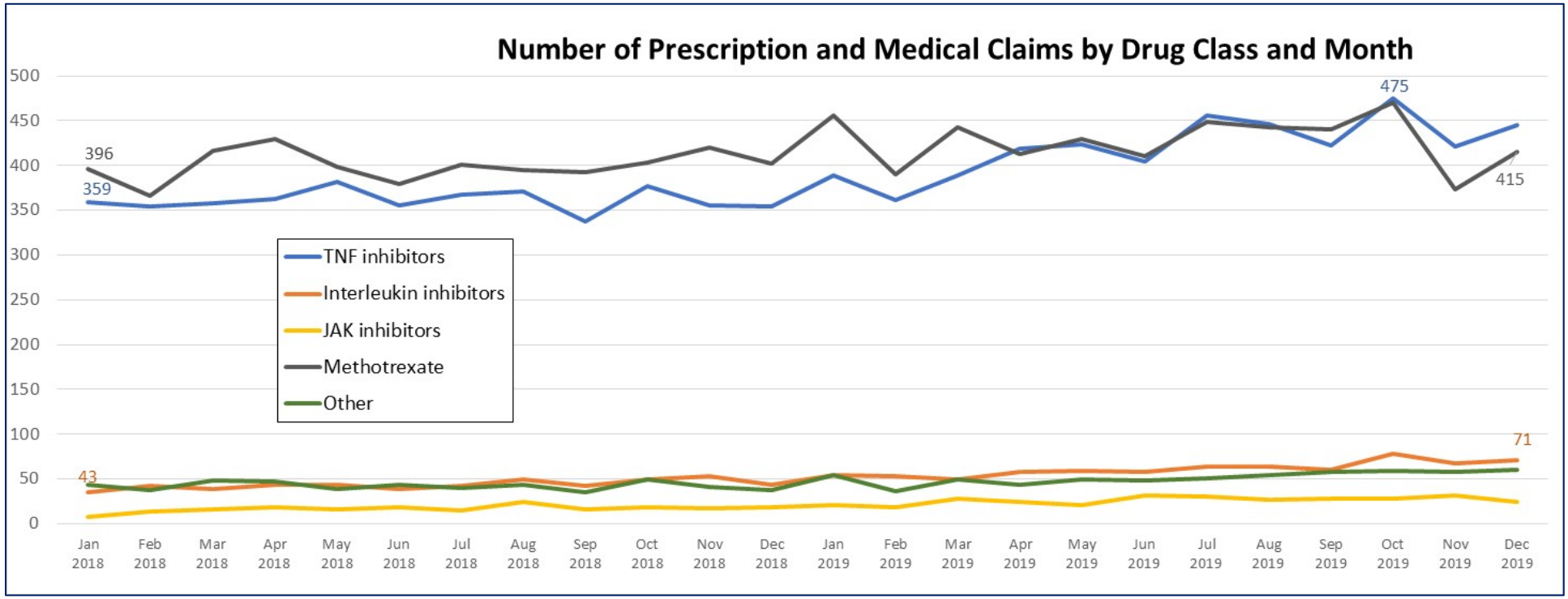


Figure 2 depicts the number of claims for the preferred-branded agents in this UPDL category. Of the preferred agents, Humira® and Enbrel®, received the majority of utilization among the TNF inhibitors.

FIGURE 2: Utilization Trend for Humira®, Enbrel® and Cosentyx®

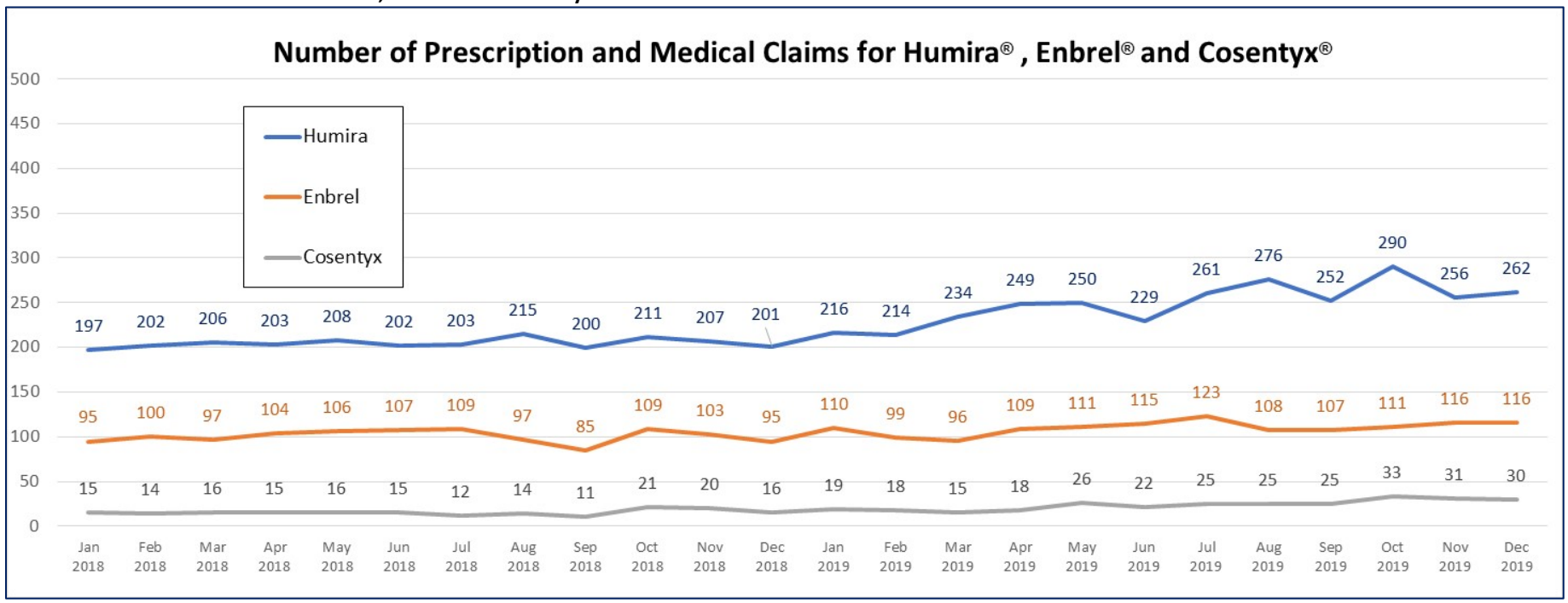


Table 4/Figures 3&4 display the number of claims for both Humira® and Enbrel® by pharmacy program and month. From January 2018 to December 2019:

- Humira® claims increased overall 33% with the most significant increase in **FFS by 84.6% and MAG by 36.3%**.*
- Enbrel® claims increased overall 22%, but did not show a significant increase within individual plans during the study period.*

** Change in Molina claims was not considered in the calculation of percent increase in utilization among individual plans as Molina was not providing service during the entire study period.*

TABLE 4: Number of Prescriptons and Office-Administered Claims For Humira® and Enbrel® by Pharmacy Program and Month

	Month Filled / Administered																							
Pharmacy Program	Jan 2018	Feb 2018	Mar 2018	Apr 2018	May 2018	Jun 2018	Jul 2018	Aug 2018	Sep 2018	Oct 2018	Nov 2018	Dec 2018	Jan 2019	Feb 2019	Mar 2019	Apr 2019	May 2019	Jun 2019	Jul 2019	Aug 2019	Sep 2019	Oct 2019	Nov 2019	Dec 2019
	Humira®																							
Fee-For-Service	26	33	29	33	42	39	34	31	40	42	37	27	25	36	35	34	34	32	48	49	43	43	40	48
United Healthcare	78	73	76	69	59	60	70	79	69	66	69	68	82	68	79	83	88	80	89	86	71	87	66	75
Magnolia	91	94	99	98	105	102	96	103	90	101	97	101	103	104	112	118	113	103	109	122	117	137	127	124
Molina	0	0	0	0	0	0	0	0	0	1	3	4	4	5	7	12	13	13	14	18	20	22	21	15
	Enbrel®																							
Fee-For-Service	19	19	18	20	17	19	24	11	17	17	10	17	12	14	14	16	16	14	13	13	16	23	19	20
United Healthcare	31	41	37	43	44	36	40	35	33	44	45	34	41	35	32	39	40	41	51	34	34	37	38	36
Magnolia	45	40	42	41	45	52	45	51	35	48	47	43	56	48	48	51	50	54	51	53	51	48	50	50
Molina	0	0	0	0	0	0	0	0	0	0	1	1	1	2	2	3	5	6	8	8	6	3	9	10

FIGURE 3: Utilization Trend for Humira® by Pharmacy Program and Month

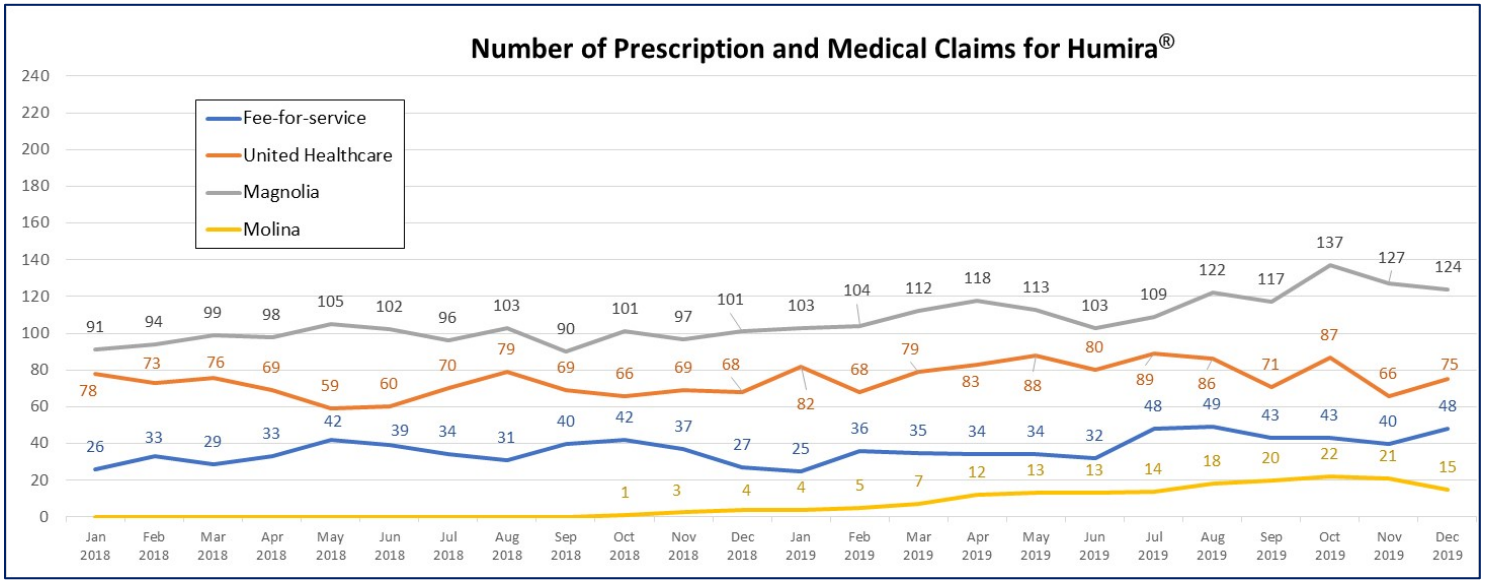


FIGURE 4: Utilization Trend for Enbrel® by Pharmacy Program and Month

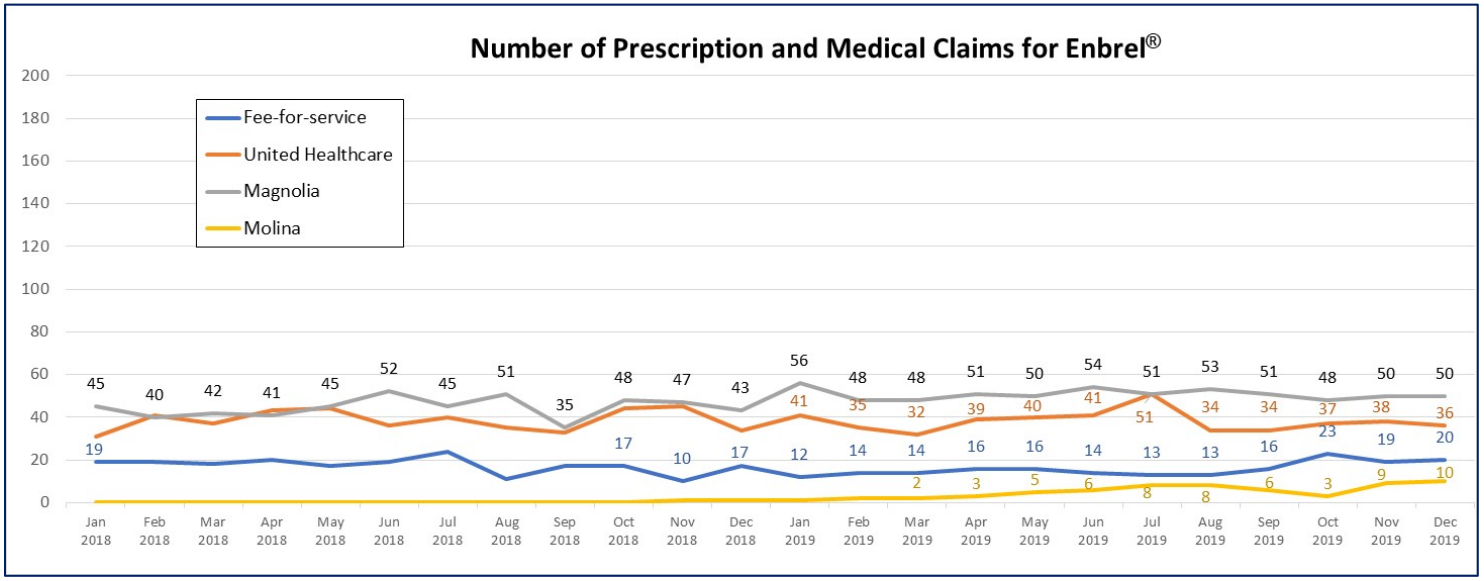


Table 5 examines the number of vials dispensed per claim for Humira®. The recommended dosing for the majority of indications for Humira® is every other week or 2 vials monthly.[1] It has been noted that the number of claims for ≥ 3 vials monthly has been increasing. **The data reveals that although the total number of claims for ≥ 3 vials monthly has increased over the study period, the proportion of claims for ≥ 3 doses monthly has remained relatively consistent between 20-25% of the monthly Humira claims.**

TABLE 5: Number of Vials for Humira® Prescriptions by Month
(Includes FFS and CCOs)

		Month Filled / Administered																							
		Jan 2018	Feb 2018	Mar 2018	Apr 2018	May 2018	Jun 2018	Jul 2018	Aug 2018	Sep 2018	Oct 2018	Nov 2018	Dec 2018	Jan 2019	Feb 2019	Mar 2019	Apr 2019	May 2019	Jun 2019	Jul 2019	Aug 2019	Sep 2019	Oct 2019	Nov 2019	Dec 2019
TOTAL Humira claims		193	198	202	203	207	202	203	215	200	210	205	199	215	214	233	249	250	229	261	276	250	287	254	257
Number of Vials/Claim	2 vials	148	151	157	155	164	158	165	172	166	168	158	154	163	171	187	196	198	176	199	206	191	218	199	203
	3 vials	0	1	0	0	0	0	0	0	3	5	8	6	11	7	5	6	6	7	9	15	7	12	13	8
	4 vials	39	41	40	41	39	38	37	41	30	35	36	37	41	35	41	45	46	45	53	55	52	57	42	46
	6 vials	6	5	5	7	4	6	1	2	1	2	3	2	0	1	0	2	0	1	0	0	0	0	0	0
% of claims with 3+ vials		23.3%	23.7%	22.3%	23.6%	20.8%	21.8%	18.7%	20.0%	17.0%	20.0%	22.9%	22.6%	24.2%	20.1%	19.7%	21.3%	20.8%	23.1%	23.8%	25.4%	23.6%	24.0%	21.7%	21.0%
% of claims with 4+ vials		23.3%	23.2%	22.3%	23.6%	20.8%	21.8%	18.7%	20.0%	15.5%	17.6%	19.0%	19.6%	19.1%	16.8%	17.6%	18.9%	18.4%	20.1%	20.3%	19.9%	20.8%	19.9%	16.5%	17.9%

According to the manufacturer, Humira® dosing greater than every other week is supported only in hidradenitis suppurativa and certain circumstances of rheumatoid arthritis.[2] Table 6 examines diagnosis information for beneficiaries receiving ≥ 3 vials monthly. The following observations were:

- Of the 395 beneficiaries with Humira® claims, 318 (80.5%) had 0 or 1 claims for ≥ 3 vials. Those with 1 claim for ≥ 3 vials most likely reflect the use of starter kits. Starter kits are packaged with 3-6 dosage units per kit.
- Of the 77 beneficiaries that had 2 or more claims for ≥ 3 vials, at least 48 (62.3%) had a diagnosis of either hidradenitis suppurativa or rheumatoid arthritis.
    - *The number of beneficiaries with a diagnosis of either hidradenitis suppurativa or rheumatoid arthritis could be as many as 55 (71.4%) assuming no beneficiary had both diagnoses.*
- **At the most, 29 (7.3%) beneficiaries had more than one claim for > 2 vials of Humira® and did not have a supporting diagnosis in claims data.**
    - *A beneficiary could have both hidradenitis suppurativa and rheumatoid arthritis. Assuming all beneficiaries that had a diagnosis of rheumatoid arthritis also had a diagnosis of hidradenitis suppurativa, the total would be 29 beneficiaries. If no beneficiary had both diagnoses, then the total of beneficiaries that had more than one claim for > 2 vials of Humira and did not have a supporting diagnosis in claims data would be 22 (5.6%).*

TABLE 6: Number of Beneficiaries With Claims for 3-Plus and 4-Plus Vials of Humira®
by Diagnoses Detected in Medical Claims
(January 2018 - December 2019, Includes FFS and CCOs)

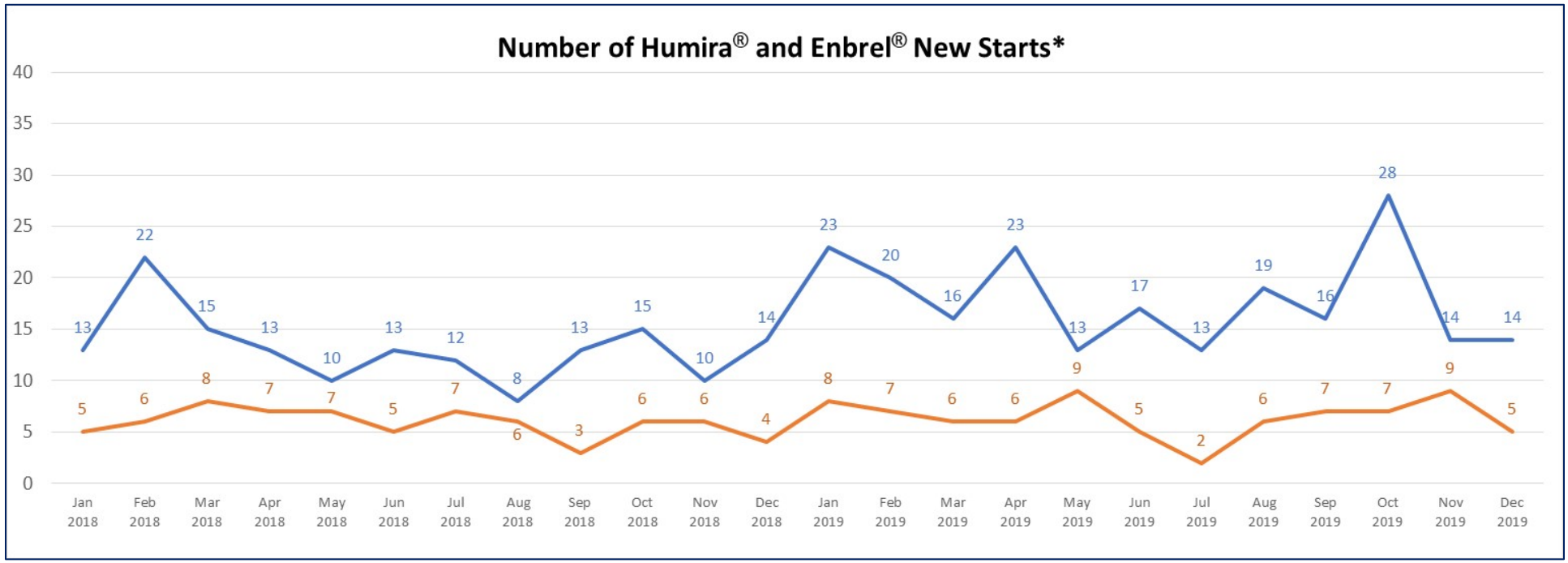
	Number of Beneficiaries With Diagnosis	Number of Claims With 3-Plus Vials					Number of Claims With 4-Plus Vials				
		0	1	2	3 - 5	6+	0	1	2	3 - 5	6+
All Humira Users*	**395**	**187**	**131**	**16**	**23**	**38**	**269**	**59**	**11**	**19**	**37**
Ankylosing spondylitis	18	16	1	0	0	1	17	0	0	0	1
Crohn's disease	60	13	37	3	2	5	40	10	4	1	5
Hidradenitis suppurativa	63	1	14	6	15	27	11	10	4	12	26
Psoriatic arthropathic	46	20	23	1	1	1	36	8	0	1	1
Plaque psoriasis	0	-	-	-	-	-	0	-	-	-	-
Polyarticular Juvenile idiopathic arthritis	31	26	2	0	2	1	28	0	0	2	1
Rheumatoid arthritis	96	88	1	2	2	3	88	1	2	2	3
Ulcerative colitis	35	6	23	1	2	3	21	9	0	2	3
Uveitis	24	19	2	0	2	1	21	0	0	2	1

*The numbers in the "All Humira Users" row represents unique beneficiaries. A beneficiary could be listed under more than one diagnosis or not represented at all by the listed diagnoses.

To further examine the increase in utilization of TNF inhibitors, MS-DUR looked at new starts for Humira® and Enbrel®. Figure 6 shows the number of new starts each month.

- Humira® new starts increased 36%, from 158 in 2018 to 216 in 2019.
- Enbrel® new starts increased 10%, from 70 in 2018 to 77 in 2019.

FIGURE 6: Number of Humira® and Enbrel® New Starts by Month



Using provider affiliations, provider type associated with new starts for both Humira® and Enbrel® were analyzed. Data was stratified by year to detect any potential shifts in provider type initiating TNF therapy. Little shifting in provider type occurred during the study period. Rheumatologists were the most frequent specialty identified as initiating therapy.

TABLE 7: Humira® and Enbrel® New Starts by Type of Provider Writing Prescription

	Humira®		Enbrel®	
	2018	2019	2018	2019
TOTAL	**158**	**216**	**70**	**77**
HOSP	0 0.0%	1 0.5%	0 0.0%	0 0.0%
MD-Allergy	1 0.6%	0 0.0%	0 0.0%	0 0.0%
MD-Derm	17 10.8%	19 8.8%	4 5.7%	1 1.3%
MD-EM	1 0.6%	0 0.0%	0 0.0%	0 0.0%
MD-FP	1 0.6%	0 0.0%	0 0.0%	0 0.0%
MD-GP	0 0.0%	3 1.4%	1 1.4%	1 1.3%
MD-Gastro	24 15.2%	24 11.1%	0 0.0%	0 0.0%
MD-IM	20 12.7%	25 11.6%	9 12.9%	10 13.0%
MD-Ophthal	0 0.0%	1 0.5%	0 0.0%	0 0.0%
MD-Ped	3 1.9%	2 0.9%	1 1.4%	2 2.6%
MD-Rheum	26 16.5%	49 22.7%	32 45.7%	28 36.4%
NP	3 1.9%	10 4.6%	3 4.3%	6 7.8%
NP-FM	20 12.7%	21 9.7%	7 10.0%	6 7.8%
PA	7 4.4%	10 4.6%	0 0.0%	2 2.6%
Prov-Other	29 18.4%	38 17.6%	12 17.1%	16 20.8%
UNKNOWN	6 3.8%	13 6.0%	1 1.4%	5 6.5%

NOTE: Provider specialty area was determined by matching the NPI number for the prescriber to specialty information provided in the National Provider Identifier data base.

Table 8 shows the number and percentage of Humira® starter kit prescriptions that were first Humira® claims and new starts of Humira® therapy.

- **The percentage of starter kit claims that were not new starts of Humira® therapy ranged from 11% to 14% for the three pharmacy programs with the greatest use.** Molina had zero claims for starter kits that were not new starts of Humira®.

TABLE 8: Use of Humira® Starter Kits by Pharmacy Program
(January 2018 - December 2019)

		Number / Percent of Starter Kit Prescriptions			
		FFS	UHC	MAG	MOL
New Start of Humira Therapy	Yes	32 88.9%	55 85.9%	75 87.2%	9 100.0%
	No	4 11.1%	9 14.1%	11 12.8%	0 0.0%

NOTE: First Humira claim is the initial claim during the observation period. A NEW START of Humira therapy is a first fill where the beneficiary was enrolled for at least 3 prior months.

Presence of Diagnoses to Support Use for Humira® and Enbrel®

Table 9 summarizes the various FDA approved indications for Enbrel® and Humira®.[1,2] Medical claims for beneficiaries taking these two products were examined to determine whether diagnoses were present that supported use for an approved indication.

TABLE 9: ICD-10 Codes Used to Identify Approved Diagnoses

ICD - 10	Descriptor	Aproved Indications	
		Humira	Enbrel
M45xxx	Ankylosing spondylitis	X	X
K50xxx	Crohn's disease	X	
L73.2	Hidradenitis suppurativa	X	
L40.5x	Psoriatic arthropathic	X	X
L40xxx excluding L40.5x	Plaque psoriasis	X	X
M08xxx	Polyarticular Juvenile idiopathic arthritis	X	X
M05xxx, M06.0x, M06.8x	Rheumatoid arthritis	X	X
K51xxx	Ulcerative colitis	X	
H20xxx	Uveitis	X	

TABLE 10: Diagnoses Found In Medical Claims Prior to New Start of Humira® or Enbrel® Therapy
(January 2018 - December 2019)

		HUMIRA®		ENBREL®	
		Diagnosis Found Within		Diagnosis Found Within	
		4 Years of Start	2 Years of Start	4 Years of Start	2 Years of Start
Total Number of New Starts		374		147	
Number of Diagnoses Found	0	66 17.6%	68 18.2%	30 20.4%	30 20.4%
	1	259 69.3%	260 69.5%	98 66.7%	98 66.7%
	2	44 11.8%	41 11.0%	17 11.6%	18 12.2%
	3	5 1.3%	5 1.3%	2 1.4%	1 0.7%
Ankylosing spondylitis		18 4.8%	18 4.8%	7 4.8%	7 4.8%
Crohn's disease		56 15.0%	56 15.0%	0 0.0%	0 0.0%
Hidradenitis suppurativa		60 16.0%	58 15.5%	2 1.4%	2 1.4%
Psoriatic arthropathic		46 12.3%	46 12.3%	23 15.6%	23 15.6%
Plaque psoriasis		0 0.0%	0 0.0%	0 0.0%	0 0.0%
Polyarticular Juvenile idiopathic arthritis		30 8.0%	30 8.0%	34 23.1%	34 23.1%
Rheumatoid arthritis		96 25.7%	94 25.1%	68 46.3%	68 46.3%
Ulcerative colitis		32 8.6%	32 8.6%	0 0.0%	0 0.0%
Uveitis		24 6.4%	23 6.1%	4 2.7%	3 2.0%

Table 10 displays diagnoses found in medical claims prior to new starts of Humira® and Enbrel®.

- **Approximately 18-20% of new starts did not have a diagnosis present to support use.**
- Rheumatoid Arthritis was the most common diagnosis documented in claims data.

Table 11 shows length of therapy for new starts of both Humira® and Enbrel®. The majority of beneficiaries started on these agents remained on those therapies for 94 days or more.

TABLE 11: Length of Therapy for Humira® and Enbrel® New Starts by Diagnoses Found in Medical Claims Within 48 Months of New Start

(January 2018 - December 2019; includes FFS and CCOs)

	HUMIRA® Length of Therapy (days)					ENBREL® Length of Therapy (days)				
Diagnosis	N	31 or less	32 - 62	63 - 93	94 or more	N	31 or less	32 - 62	63 - 93	94 or more
TOTAL NEW STARTS	**374**	**12.8%**	**9.6%**	**9.1%**	**68.4%**	**147**	**9.5%**	**16.3%**	**16.3%**	**57.8%**
Ankylosing spondylitis	18	16.7%	11.1%	11.1%	61.1%	7	0.0%	28.6%	28.6%	42.9%
Crohn's disease	56	12.5%	14.3%	1.8%	71.4%	0	-	-	-	-
Hidradenitis suppurativa	60	16.7%	6.7%	10.0%	66.7%	2	0.0%	50.0%	50.0%	0.0%
Psoriatic arthropathic	46	17.4%	15.2%	8.7%	58.7%	23	34.8%	13.0%	4.3%	56.5%
Plaque psoriasis	0	-	-	-	-	0	-	-	-	-
Polyarticular Juvenile idiopathic arthritis	30	13.3%	10.0%	3.3%	73.3%	34	8.8%	14.7%	26.5%	50.0%
Rheumatoid arthritis	96	9.4%	5.2%	11.5%	74.0%	68	8.8%	14.7%	13.2%	25.0%
Ulcerative colitis	32	9.4%	12.5%	3.1%	75.0%	0	-	-	-	-
Uveitis	24	4.2%	12.5%	4.2%	79.2%	4	0.0%	25.0%	0.0%	75.0%

NOTE: Length of therapy reported is based on claims paid. A Short length of therapy for some beneficiaries may result from loss of eligibility shortly after initiating therapy and the new start period beginning near end of observation period.

Documentation of prior DMARD use for Humira® and Enbrel® new starts

Many guidelines or disease state recommendations in which TNF inhibitors are indicated for use recommend trials of other pharmacologic agents prior to initiating a TNF inhibitor.[3–15] Non-biologic disease-modifying anti-rheumatic drugs (DMARDs) are recommended as initial treatment in some of these disease states. Tables 12 and 13 display the prior use of DMARDs by diagnoses present for new starts of Humira® and Enbrel®. *(Note: This list of DMARDs is not exhaustive but includes all the agents listed in the cytokine/CAM antagonist category of the UPDL {see Table 1}).*

- In rheumatoid arthritis (RA), a trial of a non-biologic DMARD is often recommended.[3] During the study period, for those new starts with a diagnosis of rheumatoid arthritis, 76% of Humira® users and 67.6% of Enbrel users had a history of prior methotrexate use within the 24 months.

TABLE 12: Prior DMARD Use by Diagnoses Found In Medical Claims For Humira® New Starts within 24 Months of New Start

(January 2018 - December 2019)

Diagnosis	N	Any DMARD	DMARD Drug Class				
			TNF Inhibitor	Interleukin	JAK Inhibitor	Methotrexate	Other
No Dx Found	66	28 42.4%	6 9.1%	2 3.0%	0 0.0%	22 33.3%	1 1.5%
Ankylosing spondylitis	18	9 50.0%	0 0.0%	0 0.0%	0 0.0%	9 50.0%	0 0.0%
Crohn's disease	56	9 16.1%	5 8.9%	0 0.0%	0 0.0%	5 8.9%	0 0.0%
Hidradenitis suppurativa	60	7 11.7%	0 0.0%	0 0.0%	0 0.0%	7 11.7%	1 1.7%
Psoriatic arthropathic	46	28 60.9%	6 13.0%	1 2.2%	0 0.0%	22 47.8%	2 4.3%
Plaque psoriasis	0	-	-	-	-	-	-
Polyarticular Juvenile idiopathic arthritis	30	26 86.7%	8 26.7%	0 0.0%	1 3.3%	24 80.0%	2 6.7%
Rheumatoid arthritis	96	76 79.2%	11 11.5%	1 1.0%	3 3.1%	73 76.0%	3 3.1%
Ulcerative colitis	32	2 6.3%	2 6.3%	0 0.0%	0 0.0%	0 0.0%	0 0.0%
Uveitis	24	13 54.2%	2 8.3%	0 0.0%	0 0.0%	12 50.0%	0 0.0%

TABLE 13: Prior DMARD Use by Diagnoses Found In Medical Claims For Enbrel® New Starts within 24 Months of New Start (January 2018 - December 2019)+B19:O31

Diagnosis	N	Any DMARD	DMARD Drug Class				
			TNF Inhibitor	Interleukin	JAK Inhibitor	Methotrexate	Other
No Dx Found	30	12 40.0%	7 23.3%	0 0.0%	0 0.0%	11 36.7%	0 0.0%
Ankylosing spondylitis	7	6 85.7%	2 28.6%	0 0.0%	0 0.0%	6 85.7%	0 0.0%
Crohn's disease	0	-	-	-	-	-	-
Hidradenitis suppurativa	2	2 100%	0 0.0%	0 0.0%	0 0.0%	2 100%	0 0.0%
Psoriatic arthropathic	23	16 69.6%	8 34.8%	0 0.0%	0 0.0%	12 52.2%	0 0.0%
Plaque psoriasis	0	-	-	-	-	-	-
Polyarticular Juvenile idiopathic arthritis	34	28 82.4%	4 11.8%	0 0.0%	0 0.0%	26 76.5%	0 0.0%
Rheumatoid arthritis	68	50 73.5%	19 27.9%	0 0.0%	1 1.5%	46 67.6%	0 0.0%
Ulcerative colitis	0	-	-	-	-	-	-
Uveitis	4	4 100%	3 75.0%	0 0.0%	0 0.0%	3 75.0%	0 0.0%

Some treatment recommendations include the concomitant use of methotrexate with a TNF inhibitor. Table 14 shows the prevalence of concomitant use of methotrexate with Humira® or Enbrel® by pharmacy program. Concomitant use of methotrexate was determined as at least one methotrexate claim occurring after initiating treatment with Humira® or Enbrel® and before the last day or treatment with the other product. Overall only 11.9% of Humira® users and 21.2% of Enbrel® users had concomitant claims for methotrexate.

TABLE 14: Concomitant Use of Methotrexate With Humira® or Enbrel® (January 2018 - December 2019)										
Cocomitant Use of Methotrexate	Humira® Users*									
	Total		FFS		UHC		MAG		MOL	
Yes	47	11.9%	12	12.6%	9	7.8%	23	14.6%	3	11.5%
No	348	88.1%	83	87.4%	107	92.2%	135	85.4%	23	88.5%
	Enbrel® Users*									
Yes	35	21.2%	5	14.3%	9	16.4%	17	26.6%	4	36.4%
No	130	78.8%	30	85.7%	46	83.6%	47	73.4%	7	63.6%

** Pharmacy Program beneficiary was enrolled in at time of first Humira® or Enbrel® prescription fill.*

CONCLUSIONS

The cytokine & CAM class experienced a 20.7% increase in utilization from January 2018 until December 2019. This increase was largely due to a 33% increase in claims for Humira®. Although TNF inhibitors can be used to treat a broad array of disease states, appropriate diagnosis was absent in claims data for approximately 18-20% of new starts of Humira® and Enbrel® during the study period. MS-DUR suggests the following recommendations to the DUR Board.

RECOMMENDATIONS

1. DOM should implement an electronic PA edit to add a diagnosis check for utilization of TNF inhibitors in the Cytokine & CAM antagonists' category.

2. MS-DUR should continue to monitor this category of drugs to determine whether future step-therapy requirements would be appropriate, especially with the advent of biosimilar alternatives in this therapeutic category.

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HEPATITIS C TREATMENT OVERVIEW

BACKGROUND

According to the Centers for Disease Control and Prevention (CDC), Hepatitis C (Hep C) is a blood-borne viral infection of the liver that is most commonly transmitted by the sharing of needles or other percutaneous exposure to infected blood.[1,2] Hep C infection can be an acute illness, but for over half of individuals infected, it develops into a chronic infection. Chronic Hep C infection can lead to long-term health problems and even death.[1] Hep C infection is also a major cause of liver transplants.[3] Between 2013-2016, it was estimated that 2.4 million people were living with Hep C in the United States.[4] There are 6 main genotypes of the hepatitis C virus (HCV) along with subtypes that are based on the virus' genetic makeup.[5] The specific genotype an individual carries determines treatment.

For many years, interferon (IFN)-based therapies combined with ribavirin (RBV) were the mainstay of treatment for chronic hepatitis C (CHC), however, treatment response was suboptimal. In 2013 with the release of the direct-acting antiviral (DAA) sofosbuvir, a new era in HCV treatment began.[6] These second generation DAA agents have been shown to produce high levels of sustained virologic response (SVR) and are now the standard treatment for CHC.[7]

Medicaid's current Universal Preferred Drug List (UPDL) category for Hep C treatments is below (Figure 1). The current preferred DAA agents are branded Mavyret® and sofosbuvir/velpatasvir (generic Epclusa®).

FIGURE 1: MS Medicaid's UPDL for Hepatitis C Treatments.

THERAPEUTIC DRUG CLASS	PREFERRED AGENTS	NON-PREFERRED AGENTS	PA CRITERIA
HEPATITIS C TREATMENTS			
	MAVYRET (glecaprevir/pibrentasvir)∞ PEGASYS (peginterferon alfa-2a) PEG-INTRON (peginterferon alfa-2b) ribavirin tablets sofosbuvir/velpatasvir∞	COPEGUS (ribavirin) DAKLINZA (daclatasvir) ∞ EPCLUSA (sofosbuvir/velpatasvir) ∞ HARVONI (ledipasvir/sofosbuvir)∞ ledipasvir/sofosbuvir∞ MODERIBA (ribavirin) OLYSIO (simeprevir) REBETOL (ribavirin) RIBASPHERE (ribavirin) RIBASPHERE RIBAPAK DOSEPACK (ribavirin) ribavirin capsules	∞ **Daklinza, Epclusa, Harvoni, Mavyret, Sovaldi, Vosevi, Zepatier – MANUAL PA** Note: Harvoni and Sovaldi have FDA pediatric indications
		SOVALDI (sofosbuvir)∞ TECHNIVIE (ombitasvir/paritaprevir/ritonavir) VIEKIRA (ombitasvir/paritaprevir/ritonavir) VIEKIRA XR (ombitasvir/paritaprevir/ritonavir) VOSEVI (sofosbuvir/velpatasvir/voxilaprevir)∞ ZEPATIER (elbasvir/grazoprevir)∞	

MS-DUR was asked to provide a treatment overview of hepatitis C among Medicaid beneficiaries since the introduction of the second generation DAAs in 2013.

METHODS

A retrospective database analysis was conducted using Mississippi Medicaid fee-for-service (FFS) and coordinated care organization [CCOs: Magnolia Health (MAG), Molina Healthcare (MOL), and UnitedHealthcare (UHC)] claims. Beneficiaries prescribed direct-acting antivirals (DAAs) were identified between January 1, 2013 and December 31, 2019.

RESULTS

Descriptive characteristics of beneficiaries who were treated by the DAAs are presented in Table 1. Age and health plan were assessed as of the date for the first DAA claim in the analysis period.

TABLE 1: Demographic Characteristics of Beneficiaries Prescribed Direct-Acting Anti-retroviral (DAA) Therapy (January 2013 - December 2019)

Variable	FFS		UHC		Magnolia		Molina		Total
Age Category (yrs)									
0-17	0	0.0%	5	1.1%	2	0.3%	0	0.0%	**7**
18-25	5	2.1%	8	1.7%	8	1.3%	3	17.6%	**24**
26-44	32	13.7%	114	24.7%	148	23.3%	6	35.3%	**300**
45-64	194	83.3%	334	72.5%	475	74.9%	8	47.1%	**1,011**
65+	2	0.9%	0	0.0%	1	0.2%	0	0.0%	**3**
Total	*233*		*461*		*634*		*17*		***1,345***
Gender									
Female	105	45.1%	258	56.0%	342	53.9%	7	41.2%	**712**
Male	128	54.9%	203	44.0%	292	46.1%	10	58.8%	**633**
Total	*233*		*461*		*634*		*17*		***1,345***
Race									
Caucasian	136	58.4%	281	61.0%	375	59.1%	11	64.7%	**803**
African American	82	35.2%	103	22.3%	160	25.2%	2	11.8%	**347**
Other	15	6.4%	77	16.7%	99	15.6%	4	23.5%	**195**
Total	*233*		*461*		*634*		*17*		***1,345***

Note: Insurance plan at the first DAA treatment.

- A total of 1,345 beneficiaries have been treated with DAAs since January 2013.
- 75.4% (1,014) were 45 years or older.
- 52.9% (712) were female.
- 59.7% (803) were Caucasian.

The overall utilization of DAAs was analyzed using pharmacy point-of-sale (POS) claims data to identify the number of DAA prescription fills as well as the number of treated beneficiaries in each quarter stratified by pharmacy program (Tables 2a/2b). A red line in the tables represents the point in time when the Complex Pharmacy Care (CPC) was initiated in FFS. The CPC program was designed to help ensure that complex and high-cost pharmaceuticals are only used in the correct patient and that they are taken as intended. The agents used in the treatment of Hep C fall under the CPC program management in FFS.

TABLE 2a: Hep C DAA Claims by Quarter and Pharmacy Program *(January 2013 - December 2019)*

Quarter	Pharmacy Program				
	FFS	UHC	MAG	MOL	Total
Q1 2013	0	0	0	0	0
Q2 2013	0	0	0	0	0
Q3 2013	0	0	0	0	0
Q4 2013	0	1	0	0	1
Q1 2014	5	19	7	0	31
Q2 2014	30	31	38	0	99
Q3 2014	18	27	44	0	89
Q4 2014	35	17	41	0	93
Q1 2015	32	27	51	0	110
Q2 2015	26	56	140	0	222
Q3 2015	29	93	142	0	264
Q4 2015	42	74	86	0	202
Q1 2016	29	57	88	0	174
Q2 2016	44	48	122	0	214
Q3 2016	41	52	76	0	169
Q4 2016	31	55	91	0	177
Q1 2017	23	49	70	0	142
Q2 2017	25	51	114	0	190
Q3 2017	20	51	62	0	133
Q4 2017	14	48	56	0	118
Q1 2018	30	92	67	0	189
Q2 2018	39	64	71	0	174
Q3 2018	32	65	86	0	183
Q4 2018	34	67	95	1	197
Q1 2019	26	66	80	12	184
Q2 2019	30	42	73	13	158
Q3 2019	22	46	78	20	166
Q4 2019	22	41	36	7	106
Total	*679*	*1,239*	*1,814*	*53*	*3,785*

Note: Count Rx claims only for DAA.
Red line denotes when CPC was initiated in FFS .

TABLE 2b: Beneficiaries Treated by Hep C DAA Medications by Quarter and Pharmacy Program *(January 2013 - December 2019)*

Quarter	Pharmacy Program				
	FFS	UHC	MAG	MOL	Total
Q1 2013	0	0	0	0	0
Q2 2013	0	0	0	0	0
Q3 2013	0	0	0	0	0
Q4 2013	0	1	0	0	1
Q1 2014	4	17	7	0	28
Q2 2014	20	25	33	0	78
Q3 2014	15	21	41	0	77
Q4 2014	27	11	35	0	73
Q1 2015	32	21	48	0	101
Q2 2015	25	51	133	0	209
Q3 2015	26	89	126	0	241
Q4 2015	39	65	79	0	183
Q1 2016	28	54	71	0	153
Q2 2016	36	48	102	0	186
Q3 2016	28	51	67	0	146
Q4 2016	27	50	83	0	160
Q1 2017	22	47	63	0	132
Q2 2017	21	48	106	0	175
Q3 2017	17	48	56	0	121
Q4 2017	13	47	52	0	112
Q1 2018	28	87	62	0	177
Q2 2018	39	63	64	0	166
Q3 2018	31	63	76	0	170
Q4 2018	32	65	87	1	185
Q1 2019	25	61	77	10	173
Q2 2019	29	37	67	8	141
Q3 2019	19	42	73	16	150
Q4 2019	22	38	35	7	102
Total	*605*	*1,150*	*1,643*	*42*	*3,440*

Note: Count beneficiaries with DAA claims
Red line denotes when CPC was initiated in FFS.

- Although the first breakthrough DAA agent received FDA approval in late 2013, it appears that utilization of DAA therapies for the treatment Hep C in Medicaid substantially increased around Q2 2015.
- On average, 151 beneficiaries have been treated with DAAs each quarter since Q4 2016.

In order to determine the total dollars paid on Hep C treatment, quarterly cost of DAA regimens (DAA plus supplementary drug, e.g. ribavirin and/or interferon) was measured and stratified by pharmacy plans (Table 3). (*Paid amounts represent the amount reported on claims as paid to the pharmacy. These amounts do not reflect final actual costs after rebates, etc.)*

TABLE 3: Total Paid for Hep C Rx Claims by Quarter and Pharmacy Program
(January 2013 - December 2019)

	Pharmacy Program				
Quarter	FFS	UHC	MAG	MOL	Total
Q1 2013	-	-	-	-	-
Q2 2013	-	-	-	-	-
Q3 2013	-	-	-	-	-
Q4 2013	-	$ 30,613.32	-	-	$ 30,613.32
Q1 2014	$ 152,313.20	$ 583,419.78	$ 213,621.33	-	$ 949,354.31
Q2 2014	$ 853,186.08	$ 922,107.55	$ 1,216,935.15	-	$ 2,992,228.78
Q3 2014	$ 552,301.88	$ 776,064.87	$ 1,225,183.56	-	$ 2,553,550.31
Q4 2014	$ 1,044,872.91	$ 442,761.01	$ 1,252,419.35	-	$ 2,740,053.27
Q1 2015	$ 1,029,952.74	$ 881,014.62	$ 1,629,124.85	-	$ 3,540,092.21
Q2 2015	$ 849,230.14	$ 1,839,944.97	$ 4,574,774.19	-	$ 7,263,949.30
Q3 2015	$ 950,815.93	$ 2,994,787.07	$ 4,602,629.95	-	$ 8,548,232.95
Q4 2015	$ 1,382,503.27	$ 2,406,338.90	$ 2,769,166.38	-	$ 6,558,008.55
Q1 2016	$ 943,913.41	$ 1,875,157.19	$ 2,751,787.68	-	$ 5,570,858.28
Q2 2016	$ 1,375,067.69	$ 1,576,193.50	$ 3,765,475.48	-	$ 6,716,736.67
Q3 2016	$ 1,203,145.95	$ 1,700,663.12	$ 2,379,040.07	-	$ 5,282,849.14
Q4 2016	$ 972,026.98	$ 1,625,549.78	$ 2,791,303.15	-	$ 5,388,879.91
Q1 2017	$ 708,870.69	$ 1,480,623.46	$ 2,173,957.87	-	$ 4,363,452.02
Q2 2017	$ 734,202.38	$ 1,468,251.12	$ 3,273,298.43	-	$ 5,475,751.93
Q3 2017	$ 528,108.10	$ 1,421,546.29	$ 1,687,775.15	-	$ 3,637,429.54
Q4 2017	$ 268,393.21	$ 1,334,112.38	$ 1,518,145.00	-	$ 3,120,650.59
Q1 2018	$ 598,363.79	$ 1,877,609.03	$ 1,629,244.63	-	$ 4,105,217.45
Q2 2018	$ 737,588.08	$ 1,253,768.44	$ 1,281,978.32	-	$ 3,273,334.84
Q3 2018	$ 594,435.23	$ 1,159,546.03	$ 1,687,628.06	-	$ 3,441,609.32
Q4 2018	$ 664,260.22	$ 1,288,682.77	$ 2,070,271.26	$ 12,888.85	$ 4,036,103.10
Q1 2019	$ 529,863.63	$ 1,066,486.79	$ 1,297,273.06	$ 171,139.24	$ 3,064,762.72
Q2 2019	$ 656,339.05	$ 517,860.46	$ 1,156,771.79	$ 166,185.53	$ 2,497,156.83
Q3 2019	$ 435,297.68	$ 493,847.22	$ 1,131,714.94	$ 333,151.46	$ 2,394,011.30
Q4 2019	$ 324,625.00	$ 456,153.95	$ 402,571.44	$ 114,645.03	$ 1,297,995.42
Total	*$ 18,089,677.24*	*$ 31,473,103.62*	*$ 48,482,091.09*	*$ 798,010.11*	*$ 100,134,611.00*

Note: Includes overall paid amounts on DAA regimens (DAAs + supplement drugs).
Manufacturer rebates are not reflected in cost reports.
Red line denotes when CPC was initiated in FFS

- There has been a marked decrease in total spend on Hep C treatments across all programs since Q4 2016. This could be the result of patient management programs across pharmacy plans.

The provider types associated with DAA prescription claims are summarized in Table 4. Adjustments were made for some nurse practitioners according to the records of physician-type or practice-type they were affiliated.

- 43.8% (1,658) of DAA claims were associated with gastroenterology.

TABLE 4: Summary of DAA Prescriptions by Provider Type
(January 2013 - December 2019)

Provider Type	Number of Prescriptions	Percent
MD-Gastro - Gastroenterology	1,658	43.8%
NP-FM - Family Medicine	526	13.9%
MD-Nephr - Nephrology	240	6.3%
MD-IM - Internal Medicine	192	5.1%
Prov-Other - Specialist	162	4.3%
MD-Hospit - Hospitalist	160	4.2%
Prov-Other - Student in an Organized Health Care Education/Training Progr	103	2.7%
MD-ID - Infectious Disease	93	2.5%
MD-EM - Emergency Medicine	86	2.3%
PA - Physician Assistant	85	2.2%
PA - Medical	65	1.7%
NP - Acute Care	52	1.4%
NP-Ped - Pediatrics	52	1.4%
MD-Transpl - Transplant Hepatology	47	1.2%
NP - Nurse Practitioner	33	0.9%
MD-Gastro - Pediatric Gastroenterology	30	0.8%
MD-OB/GYN - Obstetrics & Gynecology	27	0.7%
MD-Other - Hepatology	10	0.3%
NP - Adult Health	10	0.3%
MD-FP - Family Medicine	9	0.2%
MD-Card - Cardiovascular Disease	4	0.1%
NP-FM - Dental	3	0.1%
NP-FM - Student Health	2	0.1%
No provider type available	139	3.7%

Note: There were 139 claims without information available for provider type.
Some nurse practitioners were adjusted based on their provider affliation ID.

For individuals receiving DAA therapy, it is recommended they receive quantitative HCV RNA level testing to determine treatment response.[8,9] HCV RNA level testing results cannot be obtained through claims data. As an alternative, MS-DUR examined the number of DAA treatments beneficiaries received (Table 5). It could be assumed that beneficiaries receiving 1 treatment with DAA therapy were more likely to have experienced a positive treatment response.

- 96.1% of beneficiaries received 1 treatment with DAA therapy.

TABLE 5: Number of Treatments for Beneficiaries Prescribed DAA Therapy
(January 2013 - December 2019)

Total number of treatments	Beneficiaries	Percent
1	1,292	96.1%
2	51	3.8%
3	2	0.1%
Total	**1,345**	100.0%

Table 6 displays the overall distribution of beneficiaries across various DAA treatment regimens stratified by program.

TABLE 6: Overall Distribution of Beneficiaries by DAA Therapy and Plan including Retreatments
(January 2013 - December 2019)

Regimen	Plan				Total
	FFS	UHC	MAG	MOL	
Harvoni	101	202	296	0	**599**
Mavyret	47	101	98	3	**249**
Epclusa	48	81	105	10	**244**
Sovaldi	26	42	89	0	**157**
Sofosbuvir-Velpatasvir (Generic for Epclusa)	4	30	34	5	**73**
Zepatier	3	7	13	0	**23**
Viekira Pak	3	4	8	0	**15**
Olysio / Sovaldi	7	5	0	0	**12**
Daklinza / Sovaldi	3	0	8	0	**11**
Vosevi	1	1	5	0	**7**
Epclusa / Sofosbuvir-Velpatasvir	2	2	2	0	**6**
Harvoni / Viekira Pak	0	0	1	0	**1**
Ledipasvir-Sofosbuvir (Generic for Harvoni)	0	1	0	0	**1**
Sovaldi / Daklinza	1	0	0	0	**1**
Viekira XR	0	0	1	0	**1**
Total	**246**	**476**	**660**	**18**	**1400***

*Does not represent unique beneficiaries. Beneficiaires with retreatments are counted multiple times.

Tables 7 and 8 examine completion rates for DAA therapies since 2013. Completion of therapy was based on the number of days supply equal to or exceeding the days supply for the shortest approved regimen for a product. Beneficiaries were excluded if their initiation date did not allow them to complete therapy before the study period ended. Treatment was considered complete if days' supply were at least equal to the minimum days of therapy approved for that product. A 30-day treatment gap was allowed in determining completion. Pharmacy program was flagged at the start and end of each treatment episode. A beneficiary was flagged as plan switching if they were enrolled in different pharmacy programs at the start and end of each treatment episode. Continuous Medicaid eligibility was assessed during each treatment episode.

TABLE 7: Treatment Completion By Regimen for First Hep C Treatment

(January 2013 - December 2019, Includes FFS and CCOs)

Regimen	TOTAL	Minimum Regimen Duration (in days)	Completed		Not Completed	Not Completed Associated With	
						Lost Enrollment	Switched Plans
Epclusa	282	84	251	89.0%	31	6	11
Harvoni	579	56	541	93.4%	38	5	11
Harvoni / Viekira	1	84	0	0.0%	1	0	0
Mavyret	227	56	210	92.5%	17	0	0
Olysio / Sovaldi	12	84	11	91.7%	1	0	0
Sovaldi	150	84	110	73.3%	40	5	11
Sovaldi / Daklinza	11	84	11	100.0%	0	0	0
Viekira	13	84	10	76.9%	3	0	0
Zepatier	22	84	20	90.9%	2	0	0
Total	**1297**		**1164**	**89.7%**	**133**	**16**	**33**

NOTE: Completion of therapy is based on number of days supply equal to or exceeding the days supply for the shortest approved regimen for the product combination.

- Overall, 89.7% of beneficiaries that started DAA during the entire study period completed therapy.
- Of those that did not complete therapy:
  - 16 lost enrollment
  - 33 switched pharmacy plans

In Table 8 completion rates were further analyzed by pharmacy program and time period excluding beneficiaries that lost eligibility during treatment.

TABLE 8: Treatment Completion by Pharmacy Program and Start Time Period

-- Only Includes Beneficiaries With Continuous Enrollment During Expected Treatment Period --

Pharmacy Program	Jan 2013 - Sep 2016					Oct 2016 - Dec 2019				
During Treatment*	Completed		Not completed		Total	Completed		Not completed		Total
FFS	65	86.7%	10	13.3%	75	107	89.9%	12	10.1%	119
MAG	210	86.8%	32	13.2%	242	326	93.9%	21	6.1%	347
UHC	145	92.9%	11	7.1%	156	257	93.8%	17	6.2%	274
MOL	0	0.0%	0	0.0%	0	10	71.4%	4	28.6%	14
FFS-MAG	6	85.7%	1	14.3%	7	3	100.0%	0	0.0%	3
FFS-MOL	0	0.0%	0	0.0%	0	2	100.0%	0	0.0%	2
FFS-UHC	4	44.4%	5	55.6%	9	5	62.5%	3	37.5%	8
MAG-FFS	7	70.0%	3	30.0%	10	6	66.7%	3	33.3%	9
MAG-UHC	0	0.0%	0	0.0%	0	1	100.0%	0	0.0%	1
UHC-FFS	4	80.0%	1	20.0%	5	3	60.0%	2	40.0%	5
UHC-MAG	1	100.0%	0	0.0%	1	0	0.0%	1	100.0%	1
Total	**442**	**87.5%**	**63**	**12.5%**	**505**	**720**	**92.0%**	**63**	**8.0%**	**783**

** Pharmacy program during treatment equals pharmacy program at time of first prescription fill for therapy and pharmacy program at time treatment regimen should be completed.*

NOTE: Completion of therapy is based on number of days supply equal to or exceeding the days supply for the shortest approved regimen for the product combination.

- Overall completion rates improved across all programs from 87.5% to 92% when comparing the 2 time periods. This improvement could be related to patient management programs.
- **Beneficiaries that switched programs during their treatment period had a higher likelihood of not completing therapy.**

A major complication associated with chronic HCV infection is liver transplantation. In the past HCV infection has been cited as the most common indication for liver transplantation.[10] With the introduction of DAA therapy into the treatment landscape for HCV, the leading indications for liver transplantation are shifting toward alcoholic liver disease and nonalcoholic fatty liver disease.[11] By utilizing DAA therapy among chronic HCV patients, it is expected that the need for liver transplantation would be reduced.

Table 9 shows the proportion of beneficiaries diagnosed with Hep C that experienced liver transplant. The proportion of patients diagnosed with Hep C that were not prescribed a DAA and received a liver transplant during the study period was 1.44%, whereas the proportion of patients prescribed DAA therapy that received a liver transplant was 0.74%.

TABLE 9: Proportion of Hep C Patients Experiencing Liver Transplant (Jan 2013- Dec 2019)			
Prescribed DAA therapy	Total number of beneficiaries	Liver transplant	Percentage
No	5,607	81	1.44%
Yes	1,345	10*	0.74%
Note: *Beneficiaries who had liver transplant after the initiation of DAA			

CONCLUSIONS

Chronic HCV infection can be a debilitating and deadly disease. With the introduction of DAA therapy for the treatment of HCV infection, outcomes have changed dramatically. MS Medicaid has treated 1345 beneficiaries with DAA therapy since 2013. Overall completion rates for DAA therapy across all pharmacy programs since 2013 was at 89.7% with overall completion rates since Q4 2016 increasing to 92% across all pharmacy programs. One area with frequent suboptimal completion rates is among those beneficiaries that switch pharmacy programs during DAA therapy. From data analysis, it appears that treatment with DAA therapy reduced the proportion of Hep C positive beneficiaries that received liver transplant during the study period**.**

RECOMMENDATIONS

1. MS-DUR recommends DOM restrict the switching of pharmacy programs by beneficiaries while undergoing DAA therapy.

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FDA DRUG SAFETY COMMUNICATIONS

April 2020 – June 2020

- 4/24/2020 FDA cautions against use of hydroxychloroquine or chloroquine for COVID-19 outside of the hospital setting or a clinical trial due to risk of heart rhythm problems

APPENDIX

Division of Medicaid
Drug Utilization Review Board
By-Laws

Article I. Purpose

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

Article II. Membership

Section 1 – Board Composition

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

Section 2 – Appointment selection methodology

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

Section 3 - Term of Office

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

Section 4 - Attendance

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

Section 5 - Resignation

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

Section 6 - Removal

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

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

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

Section 7 - Board Officers

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

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

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

Section 8 – Reimbursement

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

Article III. Meetings

Section 1 – Frequency

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

Section 2 – Regular Meetings

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

Section 3 – Special Meetings

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

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

Section 4 – Meeting Notice

DUR Board members will be notified of the location for the meeting a minimum of ten (10) days in advance. Notification may include one or a combination of the following methods: e-mail, fax, or other written communication. DUR Board members are required to keep on file with
DOM Office of Pharmacy his or her address, primary phone number, alternate phone number (i.e., cell), fax number, and email address to which notices and DUR related communications may be submitted.

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

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

Section 5 – Meeting Sign-In

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

Section 6 – Quorum

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

Section 7 – Voting

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

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

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

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

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

Section 8 – Minutes

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

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

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

Section 9 – Speakers & Special Topics

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

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

Section 10 – Executive Session

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

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

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

Section 11 – Conduct of Participants

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

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

Article IV. Public Participation

Section 1 - Disclosure of Persons Appearing Before DUR Board

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

Article V. Conflicts of Interest

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

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

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

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

Article VI. Confidentiality

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

Article VII. Amendments

Proposed Amendments of By-Laws

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

MS-DUR BOARD
COMMON ABBREVIATIONS

AWP	Any Willing Provider, Average Wholesale Price
BENE	Beneficiary
CAH	Critical Access Hospital
CCO	Coordinated Care Organization
CDC	Centers for Disease Control
CHIP	Children's Health Insurance Program
CMS	Center for Medicare and Medicaid Services
COB	Coordination of Benefits
CPC	Complex Pharmaceutical Care
DME	Durable Medical Equipment
DOC	Department of Corrections
DOM	Division of Medicaid
DUR	Drug Utilization Review
EOB	Explanation of Benefits
EPSDT	Early and Periodic Screening, Diagnosis and Treatment
FA	Fiscal Agent
FFS	Fee For Service
FPW	Family Planning Waiver
FQHC	Federally Qualified Health Clinic
FY	Fiscal Year
HB	House Bill
HCPCS/ HEIDIS	Health Plan Employer Data and Information Set
HHS	Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability
IDD	Intellectual and Developmental Disabilities
LTC	Long Term Care
MAG	Magnolia Health
MEDD	Morphine Equivalent Daily Dose
MOL	Molina Healthcare
MPR	Medication Possession Ratio
MSCAN	Mississippi Coordinated Access Network
MSDH	Mississippi State Department of Health
NADAC	National Average Drug Acquisition Cost
NDC	National Drug Code
P&T	Pharmacy and Therapeutics
PA	Prior Authorization
PBM	Pharmacy Benefit Manager
PDC	Proportion of Days Covered
PDL	Preferred Drug List
PI	Program Integrity
PIP	Performance Improvement Program
POS	Point of Sale, Place of Service, Point of Service
Pro-DUR	Prospective Drug Use Review
OTC	Over the Counter
QI	Quality Indicator
QIO	Quality Improvement Organization
QM	Quality Management
RA	Remittance Advise
REOMB	Recipient's Explanation of Medicaid Benefits
Retro-DUR	Retrospective Drug Utilization Review
RFI	Request for Information
RFP	Request for Proposal
RHC	Rural Health Clinic
SB	Senate Bill
SCHIP	State Child Health Insurance Program
SMART PA	Conduent's Pharmacy Application (SmartPA) is a proprietary electronic prior authorization system used for Medicaid fee for service claims
SPA	State Plan Amendment
UHC	United Healthcare
UM/QIO	Utilization Management and Quality Improvement Organization
UPDL	Universal Preferred Drug List
UR	Utilization Review
VFC	Vaccines for Children
WAC	Wholesale Acquisition Cost
WIC	Women, Infants, Children
340B	Federal Drug Discount Program