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

MISSISSIPPI DIVISION OF
MEDICAID

June 11, 2026 at 1:00pm

Walter Sillers Building, Cobb Conference Room

Jackson, MS

Prepared by:

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

Drug Utilization Review Board

Amy Catherine Baggett, PharmD
Love's Pharmacy of Diamondhead
45000 E Aloha Dr., Suite B
Diamondhead, MS 39525
Term Expires: June 30, 2027

Terrence Brown, PharmD
BioScrip Infusion Services
187 Country Place Pkwy, Suite C
Pearl, MS 39208
Term Expires: June 30, 2026

Greg Browning, MD
Premier Medical Group
332 MS-12
Kosciusko, MS 39090
Term Expires: June 30, 2028

Rachel Burt, PharmD
Walmart Pharmacy
2530 Jackson Avenue West
Oxford, MS 38655
Term Expires: June 30, 2026

Steven Clark, MD
Cleveland Medical Clinic
810 East Sunflower Road
Cleveland, MS 38732
Term Expires: June 30, 2028

Chrysanthia Davis, PharmD
Omnicare Pharmacy
100 Business Park Dr, Suite D
Ridgeland, MS 39157
Term Expires: June 30, 2028

Dena Jackson, MD
King's Daughters Specialty Clinic
940 Brookway Blvd
Brookhaven, MS 39601
Term Expires: June 30, 2026

Jessica Lavender, MD (Chair-Elect)
UMMC
2500 N. State Street
Jackson, MS 39216
Term Expires: June 30, 2028

Holly R. Moore, PharmD
Anderson Regional Medical Center
2124 14th Street
Meridian, MS 39301
Term Expires: June 30, 2026

Joshua Pierce, PharmD (Chair)
McGuffee Drugs
102 Main Street
Magee, MS 39111
Term Expires: June 30, 2027

Gaylen Sanders, MD
The Pediatric Clinic
415 South 28th Avenue
Hattiesburg, MS 39401
Term Expires: June 30, 2027

Joshua Trull, DO
UMMC Dept of Psychiatry
2500 N. State Street
Jackson, MS 39216
Term Expires: June 30, 2027

2026 DUR Board Meeting Dates

March 19, 2026
June 11, 2026
September 10, 2026
December 10, 2026

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 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, 2026

Welcome

Old Business

Resource Utilization Review

Follow-up and Discussion from the Board

New Business

Pharmacy Program Update

Next Meeting Information
September 10, 2026

DUR Board Meeting Minutes

MISSISSIPPI DIVISION OF MEDICAID
DRUG UTILIZATION REVIEW (DUR) BOARD
MINUTES OF THE MARCH 19, 2026 MEETING
COBB CONFERENCE CENTER, SILLERS BUILDING, JACKSON, MS

DUR Board Roster: State Fiscal Year 2025 (July 1, 2025 – June 30, 2026)	**Jun 2025**	**Sep 2025**	**Dec 2025**	**Mar 2026**
Amy Catherine Baggett, PharmD		✓		✓
Terrence Brown, PharmD	✓	✓	✓	✓
Greg Browning, MD	NA	✓	✓	✓
Rachel Burt, PharmD	NA	✓	✓	✓
Steven Clark, MD	NA	✓	✓	✓
Chrysanthia Davis, PharmD	✓	✓	✓	✓
Dena Jackson, MD	✓		✓	✓
Jessica Lavender, MD	✓	✓		✓
Holly Moore, PharmD		✓		✓
Joshua Pierce, PharmD	✓	✓	✓	
Gaylen Sanders, MD	✓	✓	✓	✓
Joshua Trull, DO		✓	✓	✓
TOTAL PRESENT**	**7**	**11**	**9**	**11**

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

Also Present:

Division of Medicaid (DOM) Staff:
Dennis Smith, RPH, DUR Coordinator; Amy Ly-Ha, PharmD, Pharmacist II;

University of Mississippi School of Pharmacy - MS-DUR Staff:
Eric Pittman, PharmD, PhD, MS-DUR Project Director; Kaustuv Bhattacharya, PhD, Research Assistant Professor; John Bentley, PhD, CPMM Director; Jyotirmoy Sarker, PhD, Research Assistant Professor;

Coordinated Care Organization (CCO) Staff:
Jenni Grantham, PharmD, Director of Pharmacy, Magnolia Health; Jessica Lawson, PharmD, TrueCare;

Gainwell Staff:
Lew Ann Snow, RN, Advisor Business Analyst; Jeremy Campbell, PharmD, PA Pharmacist;

Visitors: Paula Whatley, Novo Nordisk; David Large, Chiesi GRD; Laurie Schneiderhan, Abbvie; Shawn Headley, Gilead; Amanda Ellis, Boehringer Ingelheim; Scott McConnell, Sanofi; Nancy Borden, Sanofi; Jay Milton, Bayer.

Call to Order/Welcome:
The meeting was called to order at 1:02 PM by Dr. Lavender, Co-chair.

OLD BUSINESS:
Dr. Davis moved to approve the minutes from the December 2025 DUR Board Meeting, seconded by Dr. Moore, and unanimously approved by the DUR Board.

Resource Utilization Review
Dr. Pittman presented the resource utilization report for December 2025. Data presented was across all pharmacy programs.

Follow-up from Previous Board Projects
Dr. Ly-Ha presented the Board with an updated version of the calcitonin gene-related peptide prior authorization criteria. Changes were made to the criteria as a result of discussions at the December 2025 DUR Board meeting. Dr. Ly-Ha also shared with the Board about efforts between DOM and MS State Department of Health (MSDH) to improve the uptake of human immunodeficiency virus (HIV) pre-exposure prophylaxis. Dr. Pittman provided updated data on changes in healthcare utilization 12 months pre- and post-initiation of glucagon-like peptide (GLP-1) receptor agonists (RAs) for obesity management.

NEW BUSINESS:

Update on MS-DUR Educational Interventions
Dr. Pittman provided an overview of all DUR mailings and educational notices that occurred between December 2025 and February 2026.

HIV Antiretroviral Therapy (ART) Adherence Trajectory Modeling
Adherence to HIV antiretroviral therapy is key to attaining viral suppression and the long-term goal of eliminating HIV in the U.S. Although group-based trajectory modeling revealed four distinct adherence groups, few factors were identified that predicted members with being in the consistent adherence trajectory group compared to other groups. These findings point to the need for DOM to engage in broad efforts in increase HIV ART adherence among Medicaid members.

The Board suggested DOM examine prescribers and pharmacies associated with members who are consistently adherent to determine if that may impact adherence. The Board affirmed the recommendations made at the December 2025 DUR Board meeting.

1. DOM should collaborate with Mississippi State Department of Health, infectious disease practice groups, and state medical/pharmacy/nursing associations on strategies to improve ART adherence among Medicaid members.

2. DOM should conduct targeted outreach to providers with members who have low ART adherence.

Appropriate Prescribing of Antipsychotics for Medicaid Members in Long-term Care (LTC)
While antipsychotic medications are vital for the treatment of several conditions, the use of these medications should be monitored to reduce side effects and ensure appropriateness of care, particularly among individuals residing in long-term care facilities. This project demonstrated that most Medicaid members taking antipsychotics while enrolled in long-term care were not concurrently prescribed multiple antipsychotics, had an appropriate diagnosis in claims data supporting the use of these medications, and had timely metabolic monitoring. In compliance with CMS's new requirements for reporting, monitoring of antipsychotic medication use in the long-term care population will continue.

Dr. Burt made a motion to approve the following recommendations:

1. *MS-DUR will begin quarterly monitoring of the appropriateness of antipsychotic medication use among adults in LTC facilities.*
2. *DOM should conduct quarterly provider education targeting these three measures utilizing a report card-type mailing.*

The motion was seconded by Dr. Brown and unanimously approved by the Board.

Updated Compliance Measurements for Initiators of GLP-1 RA Anti-obesity Medications (AOMs)

This real-world analysis of Mississippi Medicaid members initiating GLP-1 RA AOMs demonstrated that adherence and persistence improved substantially among individuals who began therapy in 2025 compared with those who initiated treatment in 2023. Despite these improvements, adherence and persistence rates among MS Medicaid members remain lower than those reported in recently published literature. Although national product shortages during 2023 and 2024 likely contributed to treatment interruptions, they do not fully explain the relatively low adherence and persistence rates observed. Additional factors may include medication-related adverse events, barriers to consistent medication access, and gaps in care coordination or ongoing clinical management. Further research is needed to better understand these barriers and to identify strategies that may improve sustained use of GLP-1 RA AOMs among Medicaid members.

The Board held extensive discussions around potential reasons for low adherence and persistence. Several providers on the Boad voiced the need for more flexible dose escalation requirements due tolerability issues.

Following the discussion, Dr. Clark made a motion to approve the following recommendation:

1. *Mississippi Medicaid should explore opportunities to identify barriers to adherence and persistence with GLP-1 RA anti-obesity medications and develop strategies to support sustained use among Medicaid members.*

The motion was seconded by Dr. Jackson and unanimously approved by the Board.

FDA Drug Safety Updates:
The FDA issued one drug safety update between December 2025 and February 2026.

Pharmacy Program Update:
Mr. Smith expressed appreciation to the Board for their commitment to the meetings and their engagement.

Next Meeting Information:
June 11, 2026

Dr. Lavender adjourned the meeting at 2:42 pm.

Submitted,

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

DUR Board Meeting Resources

Members

The DUR Board is composed of twelve participating Medicaid providers who are in good standing with their representative organizations.

- DUR Board Member List

Meetings

Meetings will be held on the following dates at 1:00 p.m. in the Cobb Conference Room at 550 High St, Jackson, MS (**see map**).

- March 19, 2026
- June 11, 2026
- September 10, 2026
- December 10, 2026

The March 19 meeting may be viewed virtually by clicking on the following link: Click Here for MS Medicaid DUR Live Broadcast on March 19, 2026, at 1:00 p.m.

Please note: This link will only be live during the meeting and will not be archived for future viewing.

Resource Utilizaton Review

TABLE 04A: ENROLLMENT STATISTICS FOR LAST 6 MONTHS October 1, 2025 through March 31, 2026							
			Oct-25	Nov-25	Dec-25	Jan-26	Feb-26	Mar-26
Total enrollment			713,052	711,542	709,513	710,315	708,142	705,310
Dual-eligibles			163,947	164,223	162,659	164,021	164,058	163,836
Pharmacy benefits			552,484	550,722	549,740	549,470	547,225	544,191
	LTC		15,908	15,834	15,687	15,725	15,735	15,613
	PLAN %	FFS	19.4%	17.8%	17.7%	18.0%	17.9%	17.9%
		MSCAN-UHC	0.1%	0.1%	0.1%	0.0%	0.0%	0.0%
		MSCAN-Magnolia	38.9%	39.6%	39.7%	39.8%	39.8%	39.8%
		MSCAN-Molina	24.9%	25.6%	25.7%	25.6%	25.7%	25.7%
		MSCAN-TruCare	16.7%	16.9%	16.8%	16.6%	16.6%	16.6%

TABLE 04B: PHARMACY UTILIZATION STATISTICS FOR LAST 6 MONTHS October 1, 2025 through March 31, 2026							
		Oct-25	Nov-25	Dec-25	Jan-26	Feb-26	Mar-26
# Rx Fills	FFS	96,290	84,605	92,151	91,048	89,841	93,580
	MSCAN-UHC	274	253	281	176	162	145
	MSCAN-Mag	179,736	170,763	183,055	179,172	181,149	186,199
	MSCAN-Mol	95,455	91,211	98,898	96,170	98,085	100,670
	MSCAN-Tru	71,562	67,941	73,475	69,709	70,757	72,865
# Rx Fills / Bene	FFS	0.9	0.9	0.9	0.9	0.9	1.0
	MSCAN-UHC	0.5	0.5	0.5	1.1	1.0	0.9
	MSCAN-Mag	0.8	0.8	0.8	0.8	0.8	0.9
	MSCAN-Mol	0.7	0.6	0.7	0.7	0.7	0.7
	MSCAN-Tru	0.8	0.7	0.8	0.8	0.8	0.8
$ Paid Rx	FFS	$15,132,091	$12,715,482	$14,168,474	$13,156,182	$13,235,269	$14,517,972
	MSCAN-UHC	$99,903	$93,407	$100,351	$35,664	$34,180	$33,670
	MSCAN-Mag	$27,893,958	$24,650,711	$28,309,051	$25,372,957	$25,717,563	$27,761,999
	MSCAN-Mol	$13,695,896	$12,184,229	$13,856,581	$13,105,073	$12,851,283	$15,002,317
	MSCAN-Tru	$10,641,973	$9,727,859	$10,901,238	$9,861,875	$10,148,133	$10,661,148
$ /Rx Fill	FFS	$157.15	$150.29	$153.75	$144.50	$147.32	$155.14
	MSCAN-UHC	$364.61	$369.20	$357.12	$202.64	$210.99	$232.21
	MSCAN-Mag	$155.19	$144.36	$154.65	$141.61	$141.97	$149.10
	MSCAN-Mol	$143.48	$133.58	$140.11	$136.27	$131.02	$149.02
	MSCAN-Tru	$148.71	$143.18	$148.37	$141.47	$143.42	$146.31
$ /Bene	FFS	$141.18	$129.71	$145.61	$133.02	$135.12	$149.04
	MSCAN-UHC	$180.83	$169.61	$182.54	$216.35	$208.20	$206.24
	MSCAN-Mag	$129.79	$113.03	$129.71	$116.02	$118.08	$128.18
	MSCAN-Mol	$99.56	$86.42	$98.08	$93.17	$91.38	$107.27
	MSCAN-Tru	$115.34	$104.52	$118.03	$108.32	$111.92	$118.23

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 2026 (FFS AND CCOs)

subcategory_top_drug	Month Year	Rank Volume	# RXs	$ Paid	# Unique Benes
CNS stimulants (e.g.,Amphetamine-Dextroamphetamine)	Mar 2026	1	25,195	$3,099,108	21,755
	Feb 2026	1	22,950	$2,885,433	20,297
	Jan 2026	1	23,835	$3,000,958	20,848
atypical antipsychotics (e.g.,Risperidone)	Mar 2026	2	14,599	$5,681,918	11,982
	Feb 2026	4	13,586	$5,072,261	11,472
	Jan 2026	2	14,086	$5,144,566	11,656
SSRI antidepressants (e.g.,Sertraline Hydrochloride)	Mar 2026	3	13,513	$176,864	12,314
	Feb 2026	6	12,424	$159,554	11,544
	Jan 2026	3	13,177	$169,882	12,009
adrenergic bronchodilators (e.g.,Albuterol Sulfate)	Mar 2026	4	13,488	$561,169	11,631
	Feb 2026	5	12,905	$514,215	11,388
	Jan 2026	4	13,061	$529,820	11,392
aminopenicillins (e.g.,Amoxicillin)	Mar 2026	5	13,102	$189,822	12,853
	Feb 2026	2	14,907	$219,784	14,673
	Jan 2026	5	12,963	$191,635	12,756
antihistamines (e.g.,Cetirizine Hydrochloride)	Mar 2026	6	12,813	$228,108	12,277
	Feb 2026	11	10,647	$178,638	10,359
	Jan 2026	9	10,210	$170,577	9,829
antiadrenergic agents, centrally acting (e.g.,Clonidine Hydrochloride)	Mar 2026	7	12,519	$201,436	11,121
	Feb 2026	10	11,351	$184,869	10,381
	Jan 2026	7	11,927	$200,702	10,732
nonsteroidal anti-inflammatory agents (e.g.,Ibuprofen)	Mar 2026	8	12,097	$160,759	11,549
	Feb 2026	8	12,061	$159,669	11,613
	Jan 2026	6	11,962	$158,996	11,476
glucocorticoids (e.g.,Prednisolone Sodium Phosphate)	Mar 2026	9	11,254	$515,323	10,889
	Feb 2026	7	12,262	$479,122	11,850
	Jan 2026	8	11,100	$488,810	10,731
proton pump inhibitors (e.g.,Pantoprazole)	Mar 2026	10	10,076	$292,901	9,512
	Feb 2026	12	9,534	$268,450	9,165
	Jan 2026	10	9,943	$282,040	9,399

TABLE D: TOP 10 DRUG CATEGORIES BY DOLLARS PAID IN MAR 2026 (FFS AND CCOs)

subcategory_top_drug	Month Year	Rank Paid Amt	# RXs	$ Paid	# Unique Benes
interleukin inhibitors (e.g.,Dupixent Pre-Filled Pen)	Mar 2026	1	1,164	$6,563,617	1,024
	Feb 2026	1	979	$6,050,446	932
	Jan 2026	1	998	$5,831,686	931
atypical antipsychotics (e.g.,Invega Sustenna)	Mar 2026	2	14,599	$5,681,918	11,982
	Feb 2026	2	13,586	$5,072,261	11,472
	Jan 2026	2	14,086	$5,144,566	11,656
GLP-1 receptor agonists for obesity (e.g.,Wegovy Pen)	Mar 2026	3	4,136	$5,335,514	3,842
	Feb 2026	3	3,503	$4,494,208	3,344
	Jan 2026	3	3,559	$4,585,543	3,347
TNF alpha inhibitors (e.g.,Humira Pen)	Mar 2026	4	432	$3,752,186	374
	Feb 2026	4	371	$3,211,368	345
	Jan 2026	4	386	$3,324,799	357
CNS stimulants (e.g.,Quillichew Er)	Mar 2026	5	25,195	$3,099,108	21,755
	Feb 2026	5	22,950	$2,885,433	20,297
	Jan 2026	5	23,835	$3,000,958	20,848
CFTR combinations (e.g.,Trikafta)	Mar 2026	6	104	$2,806,538	83
	Feb 2026	6	94	$2,496,790	82
	Jan 2026	8	86	$2,239,489	77
antiviral combinations (e.g.,Biktarvy)	Mar 2026	7	632	$2,646,946	593
	Feb 2026	7	609	$2,488,679	589
	Jan 2026	6	642	$2,494,925	608
GLP-1 receptor agonists for non-obesity indications (e.g.,Trulicity Pen)	Mar 2026	8	2,660	$2,567,969	2,494
	Feb 2026	8	2,532	$2,436,561	2,446
	Jan 2026	7	2,568	$2,435,961	2,423
factor for bleeding disorders (e.g.,Hemlibra)	Mar 2026	9	152	$2,091,304	130
	Feb 2026	9	139	$1,852,889	119
	Jan 2026	9	125	$1,673,824	105
miscellaneous uncategorized agents (e.g.,Evrysdi)	Mar 2026	10	34	$1,471,835	28
	Feb 2026	10	33	$1,473,408	25
	Jan 2026	11	27	$1,204,705	22

TABLE E: TOP 25 DRUG MOLECULES
BY NUMBER OF CLAIMS IN MAR 2026 (FFS and CCOs)

Drug Molecule Therapeutic Category	Feb 2026 # Claims	Mar 2026 # Claims	Mar 2026 $ Paid	Mar 2026 # Unique Benes
Amoxicillin / aminopenicillins	14,880	13,077	$188,423	12,831
Ventolin Hfa / adrenergic bronchodilators	12,348	12,808	$371,278	11,111
Cetirizine Hydrochloride / antihistamines	7,204	9,162	$166,668	8,995
Quillivant Xr / CNS stimulants	8,248	9,019	$1,702,430	8,012
Ondansetron Hydrochloride / 5HT3 receptor antagonists	9,412	8,519	$130,540	8,187
Azithromycin 5 Day Dose Pack / macrolides	11,195	8,077	$123,625	7,920
Mydayis / CNS stimulants	7,019	7,799	$221,352	6,723
Onyda Xr / antiadrenergic agents, centrally acting	7,043	7,699	$114,690	7,132
Xhance / nasal steroids	6,368	7,609	$135,576	7,542
Montelukast Sodium / leukotriene modifiers	5,181	6,520	$94,349	6,324
Ibuprofen / nonsteroidal anti-inflammatory agents	6,781	6,464	$81,666	6,319
Gabapentin / gamma-aminobutyric acid analogs	5,656	6,072	$93,379	5,651
Oseltamivir Phosphate / neuraminidase inhibitors	14,186	5,670	$140,676	5,651
Prednisolone Sodium Phosphate Odt / glucocorticoids	6,203	5,566	$117,238	5,412
Sertraline Hydrochloride / SSRI antidepressants	4,984	5,436	$68,737	4,954
Amoxicillin-Clavulanate / penicillins/beta-lactamase inhibitors	5,872	5,392	$105,291	5,305
Vitamin D2 / vitamins	4,687	5,254	$49,059	4,354
Cefdinir / third generation cephalosporins	5,993	5,082	$103,826	5,037
Acetaminophen-Hydrocodone Bitartrate / narcotic analgesic combinations	4,353	4,903	$88,656	4,644
Intuniv / antiadrenergic agents, centrally acting	4,306	4,817	$86,149	4,543
Triamcinolone Acetonide Topical / topical steroids	3,983	4,738	$84,955	4,626
Norvasc / calcium channel blocking agents	4,293	4,497	$84,091	4,225
Hydroxyzine Pamoate / miscellaneous anxiolytics, sedatives and hypnotics	4,048	4,473	$74,908	4,266
Protonix / proton pump inhibitors	4,168	4,392	$54,722	4,117
Uzedy / atypical antipsychotics	3,794	4,155	$588,052	3,690

TABLE F: TOP 25 DRUG MOLECULES
BY DOLLARS PAID IN MAR 2026 (FFS and CCOs)

Drug Molecule Therapeutic Category	Feb 2026 $ Paid	Mar 2026 $ Paid	Mar 2026 # Claims	Mar 2026 # Unique Benes
Wegovy Pen / GLP-1 receptor agonists for obesity	$4,393,456	$5,209,371	4,020	3,738
Dupixent Pre-Filled Syringe / interleukin inhibitors	$2,900,661	$3,427,041	827	727
Humira Pre-Filled Syringe / TNF alpha inhibitors	$2,502,941	$2,948,422	317	272
Trikafta / CFTR combinations	$2,326,297	$2,579,214	96	76
Paliperidone Er / atypical antipsychotics	$2,125,876	$2,340,072	714	629
Trulicity Pen / GLP-1 receptor agonists for non-obesity indications	$1,852,809	$1,945,111	1,999	1,887
Quillivant Xr / CNS stimulants	$1,571,109	$1,702,430	9,019	8,012
Biktarvy / antiviral combinations	$1,482,122	$1,649,495	358	343
Aristada Initio / atypical antipsychotics	$1,440,868	$1,625,313	3,875	3,559
Hemlibra / factor for bleeding disorders	$1,083,118	$1,236,294	39	30
Taltz Prefilled Syringe / interleukin inhibitors	$1,014,337	$1,029,742	124	105
Vraylar / atypical antipsychotics	$641,922	$708,789	466	440
Enbrel Sureclick / TNF alpha inhibitors	$609,089	$671,879	96	84
Uzedy / atypical antipsychotics	$491,598	$588,052	4,155	3,690
Epidiolex / miscellaneous anticonvulsants	$521,941	$585,445	166	142
Farxiga / SGLT-2 inhibitors	$546,836	$570,889	1,164	1,100
Rinvoq Lq / antirheumatics	$413,398	$555,546	83	76
Jardiance / SGLT-2 inhibitors	$533,952	$543,356	1,107	1,058
Privigen / immune globulins	$584,495	$538,253	27	25
Omnitrope Pen 5 Cartridge / growth hormones	$496,162	$518,122	113	101
Symbicort / bronchodilator combinations	$467,404	$512,447	2,198	2,142
Nuwiq / factor for bleeding disorders	$348,186	$480,405	10	8
Cosentyx Unoready Pen / interleukin inhibitors	$361,764	$469,626	41	36
Vyvanse / CNS stimulants	$421,945	$438,772	3,646	3,537
Zenpep / digestive enzymes	$394,909	$423,924	161	150

TABLE G: TOP 25 DRUG MOLECULES
BY CHANGE IN NUMBER OF CLAIMS FROM JAN 2026 TO MAR 2026 (FFS and CCOs)

Drug Molecule	Jan 2026 # Claims	Feb 2026 # Claims	Mar 2026 # Claims	Mar 2026 $ Paid	Mar 2026 # Unique Benes
Cetirizine Hydrochloride / antihistamines	6,686	7,204	9,162	$166,668	8,995
Xhance / nasal steroids	5,942	6,368	7,609	$135,576	7,542
Montelukast Sodium / leukotriene modifiers	5,353	5,181	6,520	$94,349	6,324
Triamcinolone Acetonide Topical / topical steroids	3,873	3,983	4,738	$84,955	4,626
Wegovy Pen / GLP-1 receptor agonists for obesity	3,463	3,409	4,020	$5,209,371	3,738
Lyumjev Kwikpen / insulin	849	960	1,405	$184,945	1,265
Quillivant Xr / CNS stimulants	8,541	8,248	9,019	$1,702,430	8,012
Mydayis / CNS stimulants	7,368	7,019	7,799	$221,352	6,723
Mupirocin / topical antibiotics	2,670	2,600	3,082	$45,030	3,031
Vitamin D2 / vitamins	4,871	4,687	5,254	$49,059	4,354
Ventolin Hfa / adrenergic bronchodilators	12,466	12,348	12,808	$371,278	11,111
Onyda Xr / antiadrenergic agents, centrally acting	7,370	7,043	7,699	$114,690	7,132
Acetaminophen-Hydrocodone Bitartrate / narcotic analgesic combinations	4,589	4,353	4,903	$88,656	4,644
Hydroxyzine Pamoate / miscellaneous anxiolytics, sedatives and hypnotics	4,183	4,048	4,473	$74,908	4,266
Intuniv / antiadrenergic agents, centrally acting	4,555	4,306	4,817	$86,149	4,543
Ondansetron Hydrochloride / 5HT3 receptor antagonists	8,258	9,412	8,519	$130,540	8,187
Proctozone-Hc / topical steroids	1,478	1,389	1,728	$28,791	1,681
Celecoxib / cox-2 inhibitors	33	35	274	$3,938	272
Aristada Initio / atypical antipsychotics	3,656	3,620	3,875	$1,625,313	3,559
Vyvanse / CNS stimulants	3,432	3,326	3,646	$438,772	3,537
Focalin Xr / CNS stimulants	2,981	2,865	3,189	$152,645	2,692
Clindamycin Phosphate / lincomycin derivatives	1,308	1,272	1,502	$31,988	1,462
Escitalopram Oxalate / SSRI antidepressants	2,715	2,518	2,900	$37,648	2,713
Chlorhexidine Gluconate / mouth and throat products	747	765	928	$12,321	919
Polymyxin B-Trimethoprim / ophthalmic anti-infectives	386	442	566	$8,328	564

TABLE H: TOP 25 DRUG MOLECULES
BY CHANGE IN AMOUNT PAID FROM JAN 2026 TO MAR 2026 (FFS and CCOs)

Drug Molecule	Jan 2026 $ Paid	Feb 2026 $ Paid	Mar 2026 $ Paid	Mar 2026 # Claims	Mar 2026 # Unique Benes
Wegovy Pen / GLP-1 receptor agonists for obesity	$4,481,797	$4,393,456	$5,209,371	4,020	3,738
Trikafta / CFTR combinations	$2,040,581	$2,326,297	$2,579,214	96	76
Dupixent Pre-Filled Syringe / interleukin inhibitors	$2,939,829	$2,900,661	$3,427,041	827	727
Hemlibra / factor for bleeding disorders	$899,685	$1,083,118	$1,236,294	39	30
Humira Pre-Filled Syringe / TNF alpha inhibitors	$2,621,825	$2,502,941	$2,948,422	317	272
Zycubo / minerals and electrolytes	$0	$0	$280,095	4	2
Aristada Initio / atypical antipsychotics	$1,437,446	$1,440,868	$1,625,313	3,875	3,559
Amondys 45 / miscellaneous uncategorized agents	$0	$128,034	$185,634	3	2
Biktarvy / antiviral combinations	$1,468,945	$1,482,122	$1,649,495	358	343
Cosentyx Unoready Pen / interleukin inhibitors	$297,361	$361,764	$469,626	41	36
Epidiolex / miscellaneous anticonvulsants	$457,937	$521,941	$585,445	166	142
Uzedy / atypical antipsychotics	$467,192	$491,598	$588,052	4,155	3,690
Andembry Prefilled Autoinjector / hereditary angioedema agents	$0	$114,211	$114,223	2	1
Paliperidone Er / atypical antipsychotics	$2,243,735	$2,125,876	$2,340,072	714	629
Bimzelx Prefilled Syringe / interleukin inhibitors	$297,912	$377,735	$388,112	22	19
Tremfya Prefilled Syringe / interleukin inhibitors	$240,941	$289,882	$328,824	18	18
Taltz Prefilled Syringe / interleukin inhibitors	$945,488	$1,014,337	$1,029,742	124	105
Trulicity Pen / GLP-1 receptor agonists for non-obesity indications	$1,861,314	$1,852,809	$1,945,111	1,999	1,887
Revlimid / other immunosuppressants	$106,174	$118,655	$187,338	10	9
Enbrel Sureclick / TNF alpha inhibitors	$591,735	$609,089	$671,879	96	84
Winrevair / agents for pulmonary hypertension	$165,251	$183,680	$244,884	10	6
Rinvoq Lq / antirheumatics	$477,584	$413,398	$555,546	83	76
Caplyta / atypical antipsychotics	$97,714	$133,316	$173,140	100	89
Sevenfact / factor for bleeding disorders	$0	$80,250	$74,850	1	1
Jakafi / antineoplastic Janus kinase (JAK) inhibitors	$107,449	$104,672	$182,002	9	8

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 2026 TO MAR 2026 (FFS and CCOs)

Drug Product Therapeutic Category	Mar 2026 # Claims	Mar 2026 $ Paid	Mar 2026 Avr. Paid Per Rx	Mar 2026 Avr. Units Per Rx	Jan 2026 Paid Per Unit	Feb 2026 Paid Per Unit	Mar 2026 Paid Per Unit	Percent Change
dexmethylphenidate 25 mg capsule, extended release / CNS stimulants (Y)	231	$16,017	$69.34	30	$1.80	$1.85	$1.97	9.1%
dexmethylphenidate 5 mg capsule, extended release / CNS stimulants (Y)	246	$11,404	$46.36	30	$1.13	$1.20	$1.19	4.6%
Vraylar (cariprazine) 1.5 mg capsule / atypical antipsychotics (N)	162	$243,661	$1,504.08	30	$48.42	$50.10	$50.12	3.5%
Trintellix (vortioxetine) 20 mg tablet / miscellaneous antidepressants (Y)	126	$64,905	$515.12	29	$16.64	$17.05	$17.19	3.3%
Xarelto (rivaroxaban) 20 mg tablet / factor Xa inhibitors (Y)	334	$186,903	$559.59	29	$18.26	$18.42	$18.86	3.3%
Vraylar (cariprazine) 3 mg capsule / atypical antipsychotics (N)	195	$297,160	$1,523.90	30	$49.31	$50.50	$50.81	3.0%
Qelbree (viloxazine) 150 mg capsule, extended release / noradrenergic uptake inhibitors for ADHD (Y)	139	$85,284	$613.55	48	$12.34	$12.66	$12.70	2.9%
dexmethylphenidate 20 mg capsule, extended release / CNS stimulants (Y)	406	$27,834	$68.56	30	$1.86	$1.91	$1.91	2.8%
Qelbree (viloxazine) 200 mg capsule, extended release / noradrenergic uptake inhibitors for ADHD (Y)	419	$207,358	$494.89	39	$12.39	$12.57	$12.63	1.9%
Qelbree (viloxazine) 100 mg capsule, extended release / noradrenergic uptake inhibitors for ADHD (Y)	154	$60,456	$392.57	30	$12.49	$12.71	$12.63	1.1%
Spiriva HandiHaler (tiotropium) 18 mcg capsule / anticholinergic bronchodilators (Y)	144	$46,626	$323.79	30	$10.36	$10.55	$10.47	1.1%
dexmethylphenidate 10 mg capsule, extended release / CNS stimulants (Y)	610	$36,649	$60.08	30	$1.62	$1.68	$1.63	0.9%
Xulane (ethinyl estradiol-norelgestromin) 35 mcg-150 mcg/24 hr film, extended release / contraceptives (Y)	1,366	$146,134	$106.98	3	$31.58	$31.46	$31.86	0.9%

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 2026 TO MAR 2026 (FFS and CCOs)

Drug Product Therapeutic Category	Mar 2026 # Claims	Mar 2026 $ Paid	Mar 2026 Avr. Paid Per Rx	Mar 2026 Avr. Units Per Rx	Jan 2026 Paid Per Unit	Feb 2026 Paid Per Unit	Mar 2026 Paid Per Unit	Percent Change
Slynd (drospirenone) 4 mg tablet / progestins (Y)	289	$73,633	$254.79	37	$6.54	$6.60	$6.57	0.5%
Biktarvy (bictegravir/emtricitabine/tenofovir) 50 mg-200 mg-25 mg tablet / antiviral combinations (Y)	358	$1,649,495	$4,607.53	37	$122.00	$122.93	$122.58	0.5%

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

New Business

Special Analysis Projects

MISSISSIPPI DIVISION OF MEDICAID

MS-DUR INTERVENTION / EDUCATIONAL INITIATIVE UPDATE

MARCH – MAY 2026

Ongoing Mailings:

PROVIDER SHOPPING FOR OPIOIDS (≥4 Prescribers AND ≥4 Pharmacies)				CONCOMITANT USE OF OPIOIDS AND ANTIPSYCHOTICS			SABA MONOTHERAPY		
Month	Prescribers Mailed	Pharms Mailed	Members Addressed	Month	Prescribers Mailed	Members Addressed	Month	Prescribers Mailed	Members Addressed
Jun-25	2	3	5	Jun-25	38	46	Jun-25	150	186
Jul-25	3	3	6	Jul-25	36	36	Jul-25	150	195
Aug-25	3	3	6	Aug-25	41	43	Aug-25	150	179
Sep-25	1	1	2	Sep-25	41	42	Sep-25	150	183
Oct-25	1	1	2	Oct-25	48	51	Oct-25	150	182
Nov-25	2	2	4	Nov-25	36	40	Nov-25	150	183
Dec-25	1	1	2	Dec-25	33	35	Dec-25	150	184
Jan-26	1	1	2	Jan-26	44	47	Jan-26	150	187
Feb-26	2	2	4	Feb-26	40	44	Feb-26	150	193
Mar-26	0	0	0	Mar-25	37	43	Mar-25	150	193
Apr-26	0	0	0	Apr-25	36	39	Apr-25	150	179
May-26	2	2	4	May-25	30	32	May-25	148	188

MISSISSIPPI DIVISION OF MEDICAID

MISSISSIPPI MEDICAID OPIOID OVERUTILIZATION ASSESSMENT PROGRAM

[DATE]

[PRESCRIBER'S NAME]

The Mississippi Division of Medicaid (DOM) Office of Pharmacy is committed to improving the quality of care provided to Mississippi Medicaid beneficiaries. DOM's Drug Utilization Review (DUR) Board has recommended several quality improvement initiatives addressing the use of opioids for the treatment of pain. The Centers for Medicare and Medicaid Services have included the use of opioids from multiple providers as one of the quality measures for adults in Medicaid programs. This measure identifies **beneficiaries without cancer who received prescriptions for opioid medications from four (4) or more prescribers and four (4) or more pharmacies.**

WHY YOU ARE RECEVING THIS LETTER

Our analysis of data from Medicaid and the Mississippi Prescription Monitoring Program for period [REPORT_START_DATE] to [REPORT_END_DATE] identified that the following beneficiary(ies) listed in the included table filled an opioid prescription written by you and met the above criteria of potential provider shopping.

WHAT WE ASK OF YOU?

Multimodal and multidisciplinary therapies can help reduce pain and improve function more effectively than single modalities. Several non-opioid pharmacologic therapies (including acetaminophen, NSAIDs, and selected antidepressants and anticonvulsants) are recommended first-line for chronic pain, and we encourage you to consider these options first. When you do think an opioid is appropriate, please use the Mississippi Prescription Monitoring Program to be sure the patient is not provider shopping and/or receiving too high a dose or too many opioids.

Sincerely,

Eric Pittman, PharmD
Clinical Director
MS-DUR

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

OPIOID UTILIZATION FOR: [BENEFICIARY NAME]			
Name of Prescriber	**Last drug prescribed**	**Date of last prescription**	**Name of Pharmacy**
[PRESCRIBER_1]	[DRUG_1]	[DATE_1]	[{JHARMACY_1]
[PRESCRIBER_2]	[DRUG_2]	[DATE_2]	[{JHARMACY_2]
[PRESCRIBER_3]	[DRUG_3]	[DATE_3]	[{JHARMACY_3]
[PRESCRIBER_4]	[DRUG_4]	[DATE_4]	[{JHARMACY_4]

{Date}

IMPORTANT INFORMATION REGARDING CONCURRENT PRESCRIBING OF OPIOIDS AND ANTIPSYCHOTICS

Dear Dr. {Prescriber Name},

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

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

WHY YOU ARE RECEIVING THIS LETTER

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

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

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

[2] Pain Management Best Practices Inter-Agency Task Force. ''Pain Management Best Practices.'' https://www.hhs.gov/sites/default/files/ pmtf-final-report-2019-05-23.

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

Evidence-Based DUR Initiative

WHAT WE ASK OF YOU?

When prescribing antipsychotics and opioids, ensure the coordination of care for both pain management and mental health conditions is occurring and both conditions are being appropriately treated. Optimizing both mental health and pain treatment can improve patient outcomes in both areas and minimize the risks of adverse events. Although not pain therapies, buprenorphine/naloxone products are included on the list of opioids that trigger this letter. In such cases, we are encouraging optimization of mental health treatment to support the successful management of opioid use disorder (OUD).

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

Sincerely,

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

Eric Pittman, PharmD
Project Director
MS-DUR

{Date}

IMPORTANT INFORMATION REGARDING THE TREATMENT OF ASTHMA

Dear Dr. {Prescriber Name},

The 2024 Global Initiative for Asthma (GINA) report provides recommendations for the management of asthma across various age groups.[1] In recent years, asthma treatment guidelines have been updated to reflect a shift away from the use of short-acting beta-agonists (SABA) as monotherapy in asthma patients due to increased risks of adverse events. The use of 3 or more SABA inhalers per year is associated with a higher risk of severe exacerbations, while the use of 12 or more SABA inhalers per year is associated with a higher risk of asthma-related death.[1] Conversely, the use of inhaled corticosteroids (ICS) has been shown to significantly reduce the risks of adverse events such as emergency department visits, hospitalizations, and death.[2] In general, maintenance and reliever therapy (MART) or single-inhaler maintenance and reliever therapy (SMART) with an ICS-containing product is recommended as initial therapy for most individuals with asthma ages 6 years and above. Specifically, guidelines recommend the use of a single combination agent containing a low-dose ICS and the long-acting beta-agonist formoterol.[1]

Recently, Medicaid's Drug Utilization Review Board affirmed their support for the use of ICS/formoterol products as both maintenance and reliever therapy for the treatment of asthma. To make it easier to prescribe SMART for Medicaid beneficiaries, we have included a table listing products that are preferred and available without prior authorization for both maintenance and reliever use.

Drug	Strength	PDL Status
Symbicort (budesonide/formoterol)	80mcg/4.5mcg 160mcg/4.5mcg	Preferred
Dulera (mometasone/formoterol)	50mcg/5mcg 100mcg/5mcg 200mcg/5mcg	Preferred

We examined the use of ICS-containing products among members 6 years and older with an asthma diagnosis and a history of 3 or more SABA fills in the previous six months. Our analysis of Medicaid claims data revealed that **56.9%** of members received only SABA inhalers for the treatment of their asthma. This indicates SABA monotherapy in a majority of members being treated for asthma for whom guidelines recommend the use of an ICS-containing product.

WHY YOU ARE RECEIVING THIS LETTER?

You have been identified as an outlier in our analysis. During our most recent analysis, we identified Medicaid members under your care who were 6 years and older with an asthma diagnosis who received 3 or more SABA inhalers in the previous 6 months with no pharmacy claims for ICS-containing medications. In this six-month period, you are in the lowest quartile of providers examined estimated based on the proportion of members you have prescribed SABA to who also received ICS. See figure below:

Your performance compared to your peers

$$\text{Rate of ICS therapy in conjunction with SABA use} = \frac{\text{Members with SABA \& ICS use}}{\text{Members prescribed SABA inhalers}}$$

[1] Global Initiative for Asthma, 2024. Global Initiative for Asthma - GINA. Accessed June 3, 2024. https://ginasthma.org/

[2] Crossingham I, Turner S, Ramakrishnan S, et al. Combination fixed-dose beta agonist and steroid inhaler as required for adults or children with mild asthma. *Cochrane Database Syst Rev*. 2021;5(5):CD013518. doi:10.1002/14651858.CD013518.pub2

The following Medicaid member(s) under your care were identified as receiving 3 or more SABA inhalers in the previous 6 months and did not have any pharmacy claims for ICS-containing medications.

INSERT TABLE IDENTIFYING MEMBER(S)

OUR GOAL FOR ASTHMA PATIENTS

Medicaid is looking to improve the health of individuals experiencing asthma. We support the use of ICS-containing products, specifically ICS/formoterol products, in the treatment of asthma and encourage providers to engage in shared clinical decision-making discussions with eligible members. We want to thank you for the care you provide to Medicaid members. If we can be of any assistance, please do not hesitate to contact us.

Sincerely,

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

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

HEPATITIS C VIRUS TREATMENT OVERVIEW

BACKGROUND

Hepatitis C is a blood-borne infection of the liver caused by the hepatitis C virus (HCV). It is most commonly transmitted by the sharing of needles or other percutaneous exposure to infected blood.[1] The first six months after someone is exposed to HCV is classified as acute hepatitis-C infection. Most individuals infected with HCV do not experience symptoms, and therefore, do not seek treatment from a healthcare provider. As a result, only a small portion of acute hepatitis C infections are reported. However, over half of people infected with HCV develop chronic hepatitis C. Chronic hepatitis C infection can lead to long-term health problems, including liver transplants and even death.[2,3]

Because of the high number of undiagnosed cases of hepatitis C, precise surveillance reporting is difficult. Between 2017-2020, it was estimated that between 2.4-4 million people were living with hepatitis C in the United States.[4] While 4,966 new cases of acute hepatitis C were reported in 2023, the CDC estimates 69,000 acute HCV infections occurred after adjusting for underreporting.[5]

In 2013, a new era in HCV treatment began with the introduction of direct-acting antiviral (DAA) medications.[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 HCV.[7]

In recent years, Medicaid was the payer that accounted for the largest share of DAA prescription claims in the U.S., surpassing Medicare and commercial insurance.[8] When DAAs were initially approved, many public and private payers imposed restrictions on their use around disease severity, sobriety status, and prescriber specialty.[9] Following guideline recommendations[10], payers, including MS Medicaid, removed these restrictions on use.

In 2020, MS-DUR presented a treatment overview of DAA therapy among Medicaid members with HCV between 2013 – 2019.[11] The objective of this project is to provide an extension of previous work.

METHODS

Data Source and Setting

A retrospective database analysis was conducted using Mississippi Medicaid administrative claims between January 1, 2020 through December 31, 2025 for Medicaid members enrolled in fee-for-service (FFS) and coordinated care organizations [CCOs: Magnolia Health (MAG), Molina Healthcare (MOL), UnitedHealthcare (UHC), and TrueCare (TRU)]. This work comprised three related analyses of HCV infection and treatment among Mississippi Medicaid members.

Identification of Direct-Acting Antiviral Medications

In all three studies, DAA medications were identified from the Multum drug reference using a combination of generic names, brand names, and proprietary drug identifiers. Agents included sofosbuvir, ledipasvir-sofosbuvir (Harvoni®), sofosbuvir-velpatasvir (Epclusa®), sofosbuvir-velpatasvir-voxilaprevir (Vosevi®), glecaprevir-pibrentasvir (Mavyret®), elbasvir-grazoprevir (Zepatier®), daclatasvir (Daklinza®), simeprevir (Olysio®), and the ombitasvir-paritaprevir-ritonavir and dasabuvir products (Technivie®, Viekira Pak®, and Viekira XR®).

Race and Ethnicity Classification

Race and ethnicity were derived directly from the beneficiary master file using a single, consistent algorithm applied to each study cohort. For each member, up to five race values and five ethnicity values were examined. Each non-missing race value was mapped to one of the following groups: White, Black, Asian, American Indian or Alaska Native, Native Hawaiian or Other Pacific Islander, Hispanic, or Other. Ethnicity values were mapped to Hispanic, non-Hispanic, other, or missing. A member was classified as Hispanic if any race or ethnicity field indicated Hispanic origin, and as multiracial if two or more distinct race values were recorded. For reporting, categories were collapsed into White, Black, Hispanic, Other, and Missing.

Study 1: Overview of DAA Treatment, Utilization, Cost, and Completion

Design and population. This study described the use, cost, and completion of DAA therapy among all Mississippi Medicaid members who filled at least one DAA prescription between January 1, 2020 and December 31, 2025. Each member entered the cohort on the date of their first DAA pharmacy claim, defined as the index date. Age, sex, race, and health plan recorded at the index date were used for descriptive characterization.

Utilization and cost. DAA pharmacy claims were aggregated to the member-month level to count prescription fills and the number of treated members by calendar quarter and plan. Cost was summarized as the total pre-rebate amount paid per quarter and plan. For the cost analysis, all HCV-related pharmacy claims occurring on or after the index date were included so that complete regimens were captured.

Prescriber specialty. Each DAA claim was linked to the prescribing provider through the National Provider Identifier. For claims written by nurse practitioners, the specialty of the affiliated supervising physician was used when available, so that prescribing patterns reflected the responsible clinical specialty.

Treatment episodes and completion. Sequential DAA fills for each member were grouped into treatment episodes. A new episode was defined whenever more than 30 days elapsed between the end of the days supply of one fill and the start of the next fill. Each episode was named according to the medication dispensed. Treatment completion was assessed against the minimum expected duration of therapy for each regimen. Episodes that began too close to the end of the data period to permit a full course of therapy were classified as not evaluable and were excluded from completion analyses. Continuous Medicaid eligibility and any change in health plan during an episode were also captured. To examine whether completion changed over time, episodes were grouped into two periods defined by the end of the Complex Pharmacy Care (CPC) program for hepatitis C on September 30, 2022. The CPC program was designed to manage complex and high-cost pharmaceuticals products, such as DAAs, in the FFS program. Period 1 covered the first quarter of 2020 (Q1 2020) through the third quarter of 2022 (Q3 2022), and Period 2 covered the fourth quarter of 2022 (Q4 2022) through the end of 2025 (Q4 2025).
Statistical analysis. Member characteristics, utilization, regimen distribution, and completion were summarized using frequencies and percentages for categorical variables and means or medians for continuous variables. Costs were reported as total dollars paid.

Study 2: Liver Transplant Among Members with HCV

Design and population. This study examined the occurrence of liver transplant among all Mississippi Medicaid members with diagnosed HCV between January 2020 and December 2025, comparing transplant rates between members who received DAA therapy and those who did not. To capture the broadest population of members with recognized HCV, this analysis included both incident and prevalent cases, did not require a ribonucleic acid (RNA) test, and did not impose a continuous enrollment requirement.

Case identification. HCV was identified from acute and chronic HCV diagnosis codes recorded in any diagnosis field across outpatient, inpatient, and medical claims. Each member entered the cohort on the date of their first observed HCV diagnosis, defined as the index date.

DAA exposure. Members were classified as DAA-treated if they filled any DAA prescription on or after the index date.

Liver transplant. Liver transplant was identified using two methods. The first used International Classification of Diseases, Tenth Revision (ICD-10), Procedure Coding System codes for liver transplantation (0FY00Z0, 0FY00Z1, and 0FY00Z2) on inpatient claims. The second used the diagnosis code for liver transplant status (Z94.4) in any diagnosis field on outpatient, inpatient, or medical claims. Only transplants occurring on or after the HCV index date were counted.

Temporal ordering. Because the analysis evaluated transplant occurrence following treatment, DAA exposure was required to precede the transplant. Members whose first DAA fill occurred on or after the transplant date were reclassified as not DAA-treated for this comparison.

Statistical analysis. Liver transplant rates were compared between DAA-treated and untreated members using the chi-square test, and transplant rates were also examined across race and ethnicity, age category, sex, and health plan.

Study 3: DAA Initiation Among Newly Diagnosed Members

Design and population. This study identified members with newly diagnosed HCV and evaluated the proportion who initiated DAA therapy within one year of diagnosis. New infection was defined using an algorithm adapted from Zhang and colleagues (2024), which requires a qualifying HCV RNA test followed by an HCV diagnosis.[12]

Case identification. HCV RNA testing was identified from outpatient, inpatient, and medical claims using Current Procedural Terminology (CPT) codes 87520, 87521, and 87522. HCV diagnosis was identified from ICD codes for acute and chronic HCV recorded in any diagnosis field. A member qualified when an HCV diagnosis code occurred between 0 and 180 days after an RNA test, and the earliest qualifying diagnosis date served as the index date. To allow adequate look-back and follow-up, the index date was required to fall between January 1, 2021 and December 31, 2024.

Enrollment and exclusions. Members were required to have 12 months of continuous Medicaid eligibility before and 12 months after the index date. Members with any DAA fill before the index date were excluded, because their true initial diagnosis could not be established within the observation window.

Outcome and subgroups. The primary outcome was initiation of any DAA within 365 days after the index date. Time to initiation was measured in days from the index date to the first DAA fill. DAA initiation was compared across race and ethnicity, age category, sex, health plan, and year of diagnosis.

Statistical analysis. DAA initiation was summarized as frequencies and percentages, and differences across subgroups were assessed using the chi-square test. Time to initiation was described using means, medians, and ranges.

RESULTS

Descriptive characteristics of members treated with 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: Descriptive Characteristics of DAA-Treated Members (2020–2025)							
Age Group	**FFS**	**UHC**	**MAG**	**MOL**	**TRU**	**Total**	**% of Total**
0 – 17	6	10	6	2	0	24	2.6%
18 – 25	8	6	3	3	0	20	2.2%
26 – 44	62	81	103	82	4	332	36.2%
45 – 64	113	173	172	76	2	536	58.5%
65 +	4	1	0	0	0	5	0.5%
Total	**193**	**271**	**284**	**163**	**6**	**917**	**100.0%**
Sex	**FFS**	**UHC**	**MAG**	**MOL**	**TRU**	**Total**	**% of Total**
Female	94	149	159	107	4	513	55.9%
Male	99	122	125	56	2	404	44.1%
Total	**193**	**271**	**284**	**163**	**6**	**917**	**100.0%**
Race/Ethnicity	**FFS**	**UHC**	**MAG**	**MOL**	**TRU**	**Total**	**% of Total**
White	133	131	156	90	5	515	56.2%
Black	36	38	46	12	0	132	14.4%
Hispanic	1	3	3	1	0	8	0.9%
Other	8	6	4	3	0	21	2.3%
Missing	15	93	75	57	1	241	26.3%
Total	**193**	**271**	**284**	**163**	**6**	**917**	**100.0%**

Note: DAA = Direct-acting antiviral; FFS = Fee-for-service; UHC = UnitedHealthcare; MAG = Magnolia Health; MOL = Molina Healthcare; TRU = TrueCare

A total of 917 members were treated with DAAs between 2020-2025. Among those treated, 60.0% (541) were 45 years or older. This is down from 75.4% among those treated between 2013-2019. The largest growing population of individuals treated with DAAs are those between 26-44 years. This trend in younger individuals being treated for HCV with DAAs aligns with recently reported national DAA prescribing trends.[8]

The 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 members 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 ended in FFS.

TABLE 2a: DAA Prescription Claims by Quarter and Program (2020–2025)

Quarter	Pharmacy Program					
	FFS	UHC	MAG	MOL	TRU	Total
Q1 2020	25	34	50	17	0	126
Q2 2020	12	26	36	10	0	84
Q3 2020	18	42	34	17	0	111
Q4 2020	16	27	35	16	0	94
Q1 2021	13	18	41	9	0	81
Q2 2021	14	72	26	19	0	131
Q3 2021	14	55	30	10	0	109
Q4 2021	32	54	21	13	0	120
Q1 2022	29	38	13	12	0	92
Q2 2022	17	63	26	25	0	131
Q3 2022	21	25	24	11	0	81
Q4 2022	27	26	22	16	0	91
Q1 2023	30	33	25	27	0	115
Q2 2023	28	37	37	24	0	126
Q3 2023	40	27	19	20	0	106
Q4 2023	27	22	30	27	0	106
Q1 2024	20	34	33	18	0	105
Q2 2024	20	45	34	30	0	129
Q3 2024	14	18	23	21	0	76
Q4 2024	18	32	26	14	0	90
Q1 2025	16	20	21	13	0	70
Q2 2025	13	29	27	16	0	85
Q3 2025	10	0	34	14	19	77
Q4 2025	8	0	25	21	1	55
Total	**482**	**777**	**692**	**420**	**20**	**2391**

Note: DAA = Direct-acting antiviral; FFS = Fee-for-service; UHC = UnitedHealthcare; MAG = Magnolia Health; MOL = Molina Healthcare; TRU = TrueCare
Each row = Count of pharmacy point of sale (POS) DAA claims for each calendar quarter.
Red line denotes when Complex Pharmacy Care program ended in FFS.

TABLE 2b: Members with DAA Claims by Quarter and Program (2020–2025)

Quarter	Pharmacy Program					
	FFS	UHC	MAG	MOL	TRU	Total
Q1 2020	23	29	48	16	0	116
Q2 2020	11	25	33	10	0	79
Q3 2020	17	39	32	16	0	104
Q4 2020	12	23	33	14	0	82
Q1 2021	11	13	38	9	0	71
Q2 2021	13	48	23	14	0	98
Q3 2021	11	37	28	9	0	85
Q4 2021	30	35	20	11	0	96
Q1 2022	26	24	13	12	0	75
Q2 2022	17	44	23	23	0	107
Q3 2022	19	19	24	8	0	70
Q4 2022	25	20	21	16	0	82
Q1 2023	27	32	24	24	0	107
Q2 2023	25	33	34	23	0	115
Q3 2023	37	26	19	20	0	102
Q4 2023	24	18	28	23	0	93
Q1 2024	18	24	31	18	0	91
Q2 2024	17	41	33	28	0	119
Q3 2024	12	18	22	20	0	72
Q4 2024	15	26	22	13	0	76
Q1 2025	15	19	20	12	0	66
Q2 2025	13	25	25	16	0	79
Q3 2025	10	0	30	13	17	70
Q4 2025	8	0	24	20	1	53
Total	**436**	**618**	**648**	**388**	**18**	**2108**

Note: DAA = Direct-acting antiviral; FFS = Fee-for-service; UHC = UnitedHealthcare; MAG = Magnolia Health; MOL = Molina Healthcare; TRU = TrueCare
Each row = Count of unique members with DAA claims for each calendar quarter.
Red line denotes when Complex Pharmacy Care program ended in FFS.

The number of Medicaid members treated with DAA therapy quarterly reached its peak between Q2 2015 and Q2 2016 (see September 2020 DUR Board Report).[11] On average, 194 members quarterly were treated with DAAs during that period. Across the current study period (Q1 2020 – Q4 2025), approximately 88 members per quarter were treated. However, beginning Q4 2024, there was a notable decrease in the number of members treated. Between Q3 2024 and Q4 2025, the mean number of members treated quarterly fell to 69.

This decrease in the number of individuals treated with DAAs follows national trends. DAA prescribing peaked in the U.S. in 2015 with approximately 185,677 courses dispensed that year. Prescribing declined substantially in the following years with an estimated 68,523 courses

dispensed in 2025.[8] When DAAs were initially approved, older adults with Medicare and commercial insurance accounted for the majority of DAA claims. As Medicaid programs across the country loosened coverage restrictions for DAAs over the years, Medicaid coverage grew, peaking in 2019. Medicaid remains the largest payer of DAA therapy in the U.S.[8]

Table 3 displays the total dollars paid each quarter for DAA treatment, stratified by pharmacy plans. As previously noted, paid amounts represent the amount reported on claims as paid to the pharmacy. These amounts do not reflect final actual costs after rebates. Paid amounts for DAAs peaked in Q3 2015 at $8,548,233 (see September 2020 DUR report).[11] In line with the downward trend in the number of members treated, the total paid for DAA therapy has decreased during this current study period. The mean quarterly paid amount over the entire study period was $978,592, however, the mean quarterly paid amount decreased to $670,696 between Q3 2024 and Q4 2025.

Table 3: Quarterly Paid Amount for DAA Regimens by Pharmacy Program (2020–2025)

Quarter	Pharmacy Program					
	FFS	UHC	MAG	MOL	TRU	Total
Q1 2020	$286,058	$369,734	$578,043	$266,347	$0	$1,500,183
Q2 2020	$135,217	$308,041	$395,425	$132,220	$0	$970,903
Q3 2020	$173,514	$431,095	$306,469	$186,658	$0	$1,097,737
Q4 2020	$157,102	$264,371	$333,141	$152,279	$0	$906,893
Q1 2021	$134,369	$147,650	$504,465	$126,281	$0	$912,765
Q2 2021	$118,132	$671,289	$302,705	$272,737	$0	$1,364,863
Q3 2021	$194,352	$569,923	$284,285	$100,146	$0	$1,148,705
Q4 2021	$295,264	$508,789	$167,449	$98,214	$0	$1,069,717
Q1 2022	$254,535	$339,170	$108,995	$136,702	$0	$839,402
Q2 2022	$140,141	$553,232	$247,184	$371,721	$0	$1,312,278
Q3 2022	$200,848	$223,838	$242,550	$99,654	$0	$766,891
Q4 2022	$335,843	$304,286	$216,562	$134,105	$0	$990,796
Q1 2023	$337,309	$298,394	$226,312	$249,902	$0	$1,111,918
Q2 2023	$320,339	$349,822	$404,540	$248,944	$0	$1,323,645
Q3 2023	$353,893	$254,836	$169,524	$192,375	$0	$970,628
Q4 2023	$271,643	$204,605	$277,159	$221,697	$0	$975,104
Q1 2024	$248,737	$329,878	$291,976	$160,695	$0	$1,031,287
Q2 2024	$163,079	$389,836	$337,566	$277,839	$0	$1,168,320
Q3 2024	$162,718	$142,541	$201,268	$216,765	$0	$723,293
Q4 2024	$139,337	$256,193	$241,506	$163,405	$0	$800,441
Q1 2025	$125,872	$152,605	$186,398	$126,346	$0	$591,221
Q2 2025	$113,754	$254,216	$244,024	$127,315	$0	$739,310
Q3 2025	$93,104	$0	$287,633	$126,066	$168,482	$675,285
Q4 2025	$59,475	$0	$222,127	$200,174	$12,854	$494,629
Total	**$4,814,634**	**$7,324,346**	**$6,777,307**	**$4,388,589**	**$181,336**	**$23,486,212**

Note: DAA = Direct-acting antiviral; FFS = Fee-for-service; UHC = UnitedHealthcare; MAG = Magnolia Health; MOL = Molina Healthcare; TRU = TrueCare

Red line denotes when Complex Pharmacy Care program ended in FFS.

Paid amounts represent the amount paid to the pharmacy. Rebated costs are not reflected in cost reports.

The provider-types associated with DAA prescription claims are summarized in Table 4. *(For this analysis, nurse practitioners (NPs) affiliated with a specific physician-type were included under that specialty.)* One of the changes MS Medicaid made to the prior authorization process to improve access to DAAs was to remove the specialist requirement for prescribing these agents. Approximately 45.1% of DAA claims were associated with gastroenterologists. Nurse practitioners accounted for second highest provider-type at 31.6% of DAA claims, up from 13.9% in our previous analysis covering 2013-2019.

TABLE 4: DAA Claims by Prescriber Specialty (2020–2025)

Prescriber Specialty	Number of Claims	% of Claims
MD - Gastroenterology	3952	45.1%
FNP - Family Nurse Practitioner	2770	31.6%
MD - Infectious Disease	532	6.1%
NP - Nurse Practitioner	215	2.5%
MD - Hepatology (Internal Medicine)	186	2.1%
MD - Internal Medicine	166	1.9%
MD - Pediatric Gastroenterology	151	1.7%
PROV-OTHER - Specialist	126	1.4%
MD - Family Medicine	104	1.2%
MD - Hospitalist	98	1.1%
PROV-OTHER - Adult Health NP	77	0.9%
MD - Transplant Hepatology	65	0.7%
PA - Physician Assistant	50	0.6%
ACNP - Acute Care NP	48	0.6%
MD - Pediatric Infectious Diseases	42	0.5%
PROV-OTHER - Gerontology NP	42	0.5%
MD - Emergency Medicine (Pediatric)	35	0.4%
MD - Pediatric Hematology/Oncology	22	0.3%
MD-OTHER - Public Health/Preventive	18	0.2%
MD - Transplant Surgery	15	0.2%
PA - Medical Physician Assistant	14	0.2%
PROV-OTHER - Primary Care NP	11	0.1%
MD - Cardiovascular Disease	6	0.1%
MD - Psychiatry	6	0.1%
MD - Pediatrics	3	0.0%
PROV-OTHER - Student/Trainee	2	0.0%
Total	**8756**	**100.0%**

NP records adjusted to reflect affiliated physician specialty where applicable.
N = 8,786 claims (30 missing prescriber info).

For individuals receiving DAA therapy, it is recommended they receive quantitative HCV RNA level testing to determine treatment response.[10,13] HCV RNA level testing results cannot be obtained through claims data. As an alternative, MS-DUR examined the number of DAA treatment courses members received (Table 5). It could be estimated that members receiving one course of DAA therapy were more likely to have experienced a positive treatment response. Approximately 96% of members received one course of DAA therapy.

TABLE 5: Number of DAA Treatment Courses per Member (2020–2025)

Number of Treatments	Members	Percent
1	880	96.0%
2	35	3.8%
3	2	0.2%
Total	**917**	**100.0%**

Note: DAA = direct-acting antiviral

Table 6 displays the overall distribution of members across various DAA treatment regimens stratified by program. The two most prescribed products were generic sofosbuvir/velpatasvir and Mavyret®. Both products were preferred on the Mississippi Universal Preferred Drug List (PDL) during this period. (Figure 1)

TABLE 6: DAA Regimen Distribution by Pharmacy Program (2020–2025)

Regimen	FFS	MAG	MOL	UHC	TRU	Total	% of Total
Epclusa® (sofosbuvir/velpatasvir)	11	3	6	3	0	23	2.4%
sofosbuvir/velpatasvir - generic	110	164	84	164	2	524	54.8%
Mavyret® (glecaprevir/pibrentasvir)	78	125	75	108	3	389	40.7%
Harvoni® (ledipasvir/sofosbuvir)	1	3	2	2	0	8	0.8%
ledipasvir/sofosbuvir - generic	0	0	2	1	1	4	0.4%
Vosevi® (sofosbuvir/velpatasvir/voxilaprevir)	1	2	1	3	0	7	0.7%
Mavyret® / Epclusa® (combination)	0	1	0	0	0	1	0.1%
Total	**201**	**298**	**170**	**281**	**6**	**956**	**100.0%**

Note: DAA = direct-acting antiviral; FFS = Fee-for-service; UHC = UnitedHealthcare; MAG = Magnolia Health; MOL = Molina Healthcare; TRU = TrueCare
Includes all courses of DAA therapy prescribed to members (1st, 2nd, and 3rd, when applicable)

Figure 1: Medicaid PDL for Hepatitis C Treatments[14]

HEPATITIS C TREATMENTS		
PREFERRED AGENTS	**NON-PREFERRED AGENTS**	**PA CRITERIA**
MAVYRET (glecaprevir/pibrentasvir)	EPCLUSA (sofosbuvir/velpatasvir)	EPCLUSA, HARVONI, MAVYRET, SOVALDI, VOSEVI, ZEPATIER • Require MANUAL PA Note: • **EPCLUSA, HARVONI, MAVYRET and SOVALDI have FDA-approved pediatric indications**
PEGASYS (peginterferon alfa-2a)	HARVONI (ledipasvir/sofosbuvir)	
ribavirin tablet	ledipasvir/sofosbuvir	
sofosbuvir/velpatasvir	ribavirin capsule	
	SOVALDI (sofosbuvir)	
	VIEKIRA PAK (ombitasvir/paritaprevir/ritonavir)	
	VOSEVI (sofosbuvir/velpatasvir/voxilaprevir)	
	ZEPATIER (elbasvir/grazoprevir)	

Tables 7 and 8 examine completion rates for DAA therapies between 2020-2025. Completion of therapy was based on the number of days supply equal to or exceeding the days supply for the shortest approved regimen for each product. Members were excluded if their initiation date did not allow them to complete therapy before the study period ended. Treatment was considered complete if the days supply was 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 member 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: DAA Therapy Completion Rates (2020–2025)

Regimen	Total	Complete	Completion Rate	Incomplete	Factors Associated with Incompletion	
					Lost Enrollment	Switched Plan
Epclusa® | sofosbuvir/velpatasvir*	530	415	78.3%	115	9	21
Harvoni® |ledipasvir/sofosbuvir*	12	12	100.0%	0	NA	NA
Mavyret®	377	333	88.3%	44	5	12
Vosevi®	7	6	85.7%	1	0	0
Total (All Evaluable Episodes)	**926**	**766**	**82.7%**	**160**	**14**	**33**

Notes: DAA = direct-acting antiviral;
Completion was based on the days' supply ≥ the minimum approved treatment regimen duration, allowing for a 30-day treatment gap. Episodes that started too late to be completed before the study ended were excluded.
** Includes both brand and generic products*

Table 7 displays completion rates by product. Overall, 82.7% of members who started DAA treatment during the entire study period completed therapy. Of those that did not complete therapy, 8.8% (14/160) lost enrollment and 20.6% (33/160) switched pharmacy plans.

In Table 8, completion rates were further analyzed by pharmacy program and time period. This table includes only first treatment courses and excludes members who lost eligibility during treatment. Two time periods were examined, the time during the CPC program era and the period after the CPC program ended. The completion rates across both time periods were nearly identical. However, some changes occurred across pharmacy programs during the two periods. The completion rate for FFS fell from 87% to 81.7% comparing the two time periods, correlating with the ending of the CPC program in FFS. However, completion rates in MAG and MOL increased substantially when comparing the two periods. These increases could be related to care management programs the CCOs have in place for members diagnosed with hepatitis C. Compared to those who remained in the same pharmacy program during DAA therapy, members who switched programs during treatment were less likely to complete therapy.

TABLE 8: Completion Rates by Pharmacy Program and Time Period (2020–2025)
(Only Includes First Treatment Episodes and Members with Continuous Enrollment During the Expected Treatment Period)

Pharmacy Program During Treatment*	Q1 2020 – Q3 2022 (CPC Era)					Q4 2022 – Q4 2025 (Post-CPC)				
	Completed	(%)	Not Completed	(%)	Total	Completed	(%)	Not Completed	(%)	Total
FFS	67	87.0%	10	13.0%	77	67	81.7%	15	18.3%	82
UHC	122	91.0%	12	9.0%	134	89	88.1%	12	11.9%	101
MAG	107	81.1%	25	18.9%	132	104	87.4%	15	12.6%	119
MOL	49	84.5%	9	15.5%	58	73	90.1%	8	9.9%	81
FFS-MAG	1	100.0%	0	0.0%	1	5	100.0%	0	0.0%	5
FFS-MOL	3	60.0%	2	40.0%	5	6	100.0%	0	0.0%	6
FFS-UHC	3	60.0%	2	40.0%	5	1	33.3%	2	66.7%	3
MAG-FFS	6	66.7%	3	33.3%	9	5	50.0%	5	50.0%	10
MOL-FFS	3	60.0%	2	40.0%	5	5	71.4%	2	28.6%	7
MOL-UHC	0	0.0%	0	0.0%	0	2	100.0%	0	0.0%	2
UHC-FFS	7	87.5%	1	12.5%	8	7	58.3%	5	41.7%	12
UHC-MAG	1	100.0%	0	0.0%	1	2	66.7%	1	33.3%	3
UHC-MOL	0	NA	0	NA	0	3	60.0%	2	40.0%	5
TRU-FFS	0	NA	0	NA	0	1	100.0%	0	0.0%	1
UHC-TRU	0	NA	0	NA	0	6	85.7%	1	14.3%	7
Total	**369**	**84.8%**	**66**	**15.2%**	**435**	**376**	**84.7%**	**68**	**15.3%**	**444**

Note: DAA = Direct-acting antiviral; FFS = Fee-for-service; UHC = UnitedHealthcare; MAG = Magnolia Health; MOL = Molina Healthcare; TRU = TrueCare; CPC = Complex Pharmacy Care
Completion is based on total days supply ≥ minimum approved regimen duration, with a 30-day gap allowance.
CPC program ended September 30, 2022. Period split aligns with CPC program termination.
* Pharmacy program during treatment. For those with multiple plans, plan at first prescription fill and plan at the time the treatment regimen should be completed were included.

A major complication associated with chronic HCV infection is liver transplantation. Historically, HCV infection has been cited as major reason for liver transplantation.[15] 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 metabolic dysfunction-associated steatohepatitis (MASH).[16]

Table 9 shows the proportion of members diagnosed with HCV that experienced liver transplant. The proportion of members with an HCV diagnosis that were not prescribed a DAA and received a liver transplant during the study period was 1.13%, whereas the proportion of patients prescribed DAA therapy who received a liver transplant was 0.34%. Those who received DAA therapy were significantly less likely to receive a liver transplant.

TABLE 9: Liver Transplant by DAA Treatment Status

DAA Status	No Transplant	Transplant	Total	Transplant Rate
No DAA	7783	89	7872	1.13%
DAA Treated	868	3	871	0.34%
Total	**8651**	**92**	**8743**	**1.05%**

Statistical Test	Value	p-value
Pearson Chi-Square (df=1)	4.6551	0.0310
Fisher's Exact (two-sided)	—	0.0332

Note: DAA - Direct-acting antiviral.
DAA treatment counted only if the first DAA fill occurred BEFORE the transplant date.

Despite the availability of accurate testing and short-course, effective treatment, a large proportion of people diagnosed with HCV do not receive timely treatment. Data from a national sample of individuals diagnosed with HCV in 2019-2020 revealed that 23% Medicaid of members received DAA treatment initiation within 360 days of receiving a positive HCV RNA test.[17]

An analysis of Mississippi Medicaid members showed similar results. Utilizing an algorithm adapted from Zhang et al., 1290 members newly diagnosed with HCV between 2021-2024 were identified. [12] (Table 10a) Among those 1290 members, 22.5% initiated DAA therapy within one year of their HCV diagnosis. (Table 10b) Subgroup analysis revealed that members enrolled in FFS were less likely to initiate DAA therapy within one year of an HCV diagnosis than those in CCOs.

Table 10a: Newly Diagnosed HCV Cohort - Attrition Flow Chart

Selection Step	N Patients
1. Patients with ≥1 HCV RNA test (2020–2025)	5981
2. Qualifying HCV ICD diagnosis within 180 days (2021–2024)	1918
3. 12-month continuous enrollment before and after diagnosis	1334
4. Excluded: DAA fill before index diagnosis date	44
5. Final analytic cohort	**1290**
Notes: HCV = Hepatitis C Virus; RNA = Ribonucleic Acid; DAA - Direct-acting Antiviral	

TABLE 10b: Overall DAA Initiation Within 1 Year of Diagnosis

DAA Status	N	Percent
Did Not Initiate DAA	1000	77.5%
Initiated DAA	290	22.5%
Total	**1290**	**100.0%**
Notes: DAA - Direct-acting Antiviral		

CONCLUSIONS

DAA therapy has proven to be highly effective in curing individuals diagnosed with HCV. This report analyzed the use and effectiveness of DAA therapy for hepatitis C among Mississippi Medicaid members. It examined provider types, treatment regimens, therapy completion rates, and the impact of DAA therapy on liver transplant rates. While improved access due to policy changes, high completion rates for DAA therapy, and significant reductions in liver transplants for those treated were noted, gaps remain in timely treatment initiation and therapy completion.

RECOMMENDATIONS

1. MS-DUR recommends DOM work with the pharmacy programs to:
    a. Improve the proportion of members initiating DAA therapy within one year of an HCV diagnosis.
    b. Increase the therapy completion rate of individuals prescribed DAA regimens.

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SICKLE CELL DISEASE GENE THERAPY MODELING

BACKGROUND

Gene therapy represents a transformative therapeutic approach that seeks to modify, replace, repair, or regulate genetic material to treat or potentially cure disease. The U.S. Food and Drug Administration (FDA) defines human gene therapy as interventions that modify or manipulate the expression of a gene or alter the biological properties of living cells for therapeutic use. Gene therapy may be accomplished through several mechanisms, including replacement of defective genes, inactivation of disease-causing genes, introduction of functional genetic material, or direct gene editing of cellular deoxyribonucleic acid (DNA). Gene therapy products may utilize viral vectors, plasmid DNA, bacterial vectors, gene-editing technologies such as clustered regularly interspaced short palindromic repeats (CRISPR), or genetically modified autologous cellular products.[1]

In the United States, gene therapy products are regulated as biologic products by the FDA's Center for Biologics Evaluation and Research (CBER). Prior to clinical investigation, sponsors must submit an Investigational New Drug (IND) application, and commercialization requires approval through a Biologics License Application (BLA).[1,2] Given the unique manufacturing, safety, and long-term follow-up considerations associated with gene therapies, FDA oversight includes extensive requirements for product characterization, manufacturing consistency, post-marketing surveillance, and long-term safety monitoring.[1,2]

The gene therapy market has expanded rapidly over the past decade and is expected to continue growing. A 2023 analysis estimated U.S. spending on gene therapy could rise to over $25 billion in 2026.[3,4] The increasing number of approved products, coupled with one-time treatment costs frequently exceeding $1 million per patient, has raised concerns regarding affordability, payer budget impact, and equitable access to treatment.

Sickle cell disease (SCD) has emerged as a major target for gene therapy development. SCD is an inherited hemoglobinopathy caused by a mutation in the β-globin gene (HBB), resulting in production of abnormal hemoglobin S and subsequent red blood cell sickling, hemolytic anemia, vaso-occlusive crises, end-organ damage, and premature mortality. Historically, treatment options have focused on supportive care, hydroxyurea, chronic transfusion therapy, and, for a limited subset of patients, allogeneic hematopoietic stem cell transplantation.[5]

On December 8, 2023, the FDA approved the first two gene therapies for the treatment of sickle cell disease: exagamglogene autotemcel (Casgevy®) and lovotibeglogene autotemcel (Lyfgenia®).[6,7] Casgevy®, developed jointly by Vertex Pharmaceuticals and CRISPR Therapeutics, is an autologous CRISPR/Cas9 gene-edited hematopoietic stem cell therapy indicated for patients aged 12 years and older with recurrent vaso-occlusive crises. It was introduced at an wholesale acquisition cost of approximately $2.2 million per treatment.[8]

Lyfgenia®, developed by Genetix Biotherapeutics, is an autologous lentiviral vector-mediated gene addition therapy also approved for patients aged 12 years and older with recurrent vaso-occlusive events. Lyfgenia® was introduced at an estimated wholesale acquisition cost of approximately $3.1 million per treatment.[9]

Although both therapies offer the potential for long-term disease modification or cure, their implementation presents substantial challenges. The complex treatment process, which includes stem cell collection, myeloablative conditioning chemotherapy, prolonged hospitalization, and specialized transplant-center infrastructure, can only be administered through qualified treatment centers. Additionally, the unprecedented acquisition costs associated with these therapies have generated significant concerns regarding payer coverage, patient access, and long-term healthcare system sustainability.

Initially focused on sickle cell disease therapies, the Cell and Gene Therapy (CGT) Access Model is a multi-year initiative that tests whether a Centers for Medicare and Medicaid Services (CMS)-led approach to developing and administering outcomes-based agreements for CGTs can expand Medicaid members' access to innovative treatments, improve health outcomes, and reduce health care costs and burden to state Medicaid programs. The Mississippi Division of Medicaid (MS DOM) began participation in the CGT Access Model on January 1, 2026.

As the gene therapy journey is complex, states also had the opportunity to seek funding to improve access-supporting services. The MS DOM was one of eight applicants awarded Cooperative Agreement funding through this Model. From 2026 to 2030, the MS DOM will use these funds to create dedicated patient support roles, partner with a community-based organization to enhance transportation, travel-related support, and subsidized childcare for eligible members, and develop educational efforts for members, providers, and communities about sickle cell disease, CGTs, and available supportive services.

This report aims to identify a population of Medicaid members who are eligible to receive sickle cell disease gene therapy products.

METHODS

A retrospective claims analysis was conducted using Mississippi Medicaid medical and point of sale (POS) pharmacy claims for fee-for-service (FFS) and coordinated care organizations [CCOs: UnitedHealthcare (UHC), Magnolia Health (MAG), Molina Healthcare (MOL), and TrueCare (TRU)] to identify Medicaid members with sickle cell disease.

Individuals were identified with sickle cell disease (SCD) between January 2025 and December 2025 based on the International Classification of Diseases, Tenth Revision (ICD-10) diagnosis codes D57.0x, D57.1x, D57.2x, D57.8x in any position during the identification period. Continuous enrollment was not required during this period, and the index date was the last occurrence of a diagnosis during the identification period. Eligibility modeling for the gene therapy of interest

(Casgevy® and Lyfgenia®) was guided by the Mississippi Medicaid prior authorization criteria.[10] For this study, all individuals meeting SCD diagnosis criteria were included, regardless of age. Members with a SCD diagnosis were evaluated for hydroxyurea treatment failure or intolerance, vaso-occlusive crises (VOCs), and chronic transfusions due to recurrent VOCs. Members were evaluated for hydroxyurea (HU) treatment failure or intolerance between January 2024 and December 2025. Hydroxyurea treatment failure was operationalized as ≥ 2 VOCs during the period an individual was persistent to HU therapy. Persistence to HU therapy was defined as having no more than 15 days gap between fills for HU, with a total days' supply of 84 days or more. VOC events were identified based on ICD-10 diagnosis codes used by MS Medicaid and considered unique events if they occurred at least 7 days apart. In addition to VOCs, chronic transfusion was identified using Current Procedural Terminology (CPT), Healthcare Common Procedure Coding System (HCPCS), and ICD-10 codes. Chronic transfusion was stratified as those with (1) 6 or more transfusions, and (2) 8 or more transfusions in the one-year period prior to the index date.

RESULTS

Baseline descriptive characteristics are provided in Table 1. Between January 1, 2025 and December 31, 2025, 1,663 Medicaid members had a diagnosis for SCD. Most Medicaid members with SCD were 35 years and younger, with 31% (515) of members between 18-35 years. A majority of members were female (57.3%). In terms of race, 72.5% were Black, with members identifying as Other accounting for 26.5% and Whites making up 1%. The distribution of members with SCD by plan type were as follows: 603 (36.3%) in FFS, 55 (3.3%) in UHC, 524 (31.5%) in MAG, 289 (17.4%) in MOL, and 192 (11.5%) in TRU.

TABLE 1: Demographic Characteristics of MS Medicaid Members with Sickle Cell Disease (January 2025 - December 2025)

Member Characteristics		TOTAL		Program									
				FFS		UHC		MAG		MOL		TRU	
TOTAL		**1663**		**603**		**55**		**524**		**289**		**192**	
Age (in years)	0 - 4	182	10.94%	26	4.31%	5	9.09%	77	14.69%	58	20.07%	16	8.33%
	5 - 11	266	16.00%	40	6.63%	5	9.09%	112	21.37%	62	21.45%	47	24.48%
	12 - 17	237	14.25%	50	8.29%	12	21.82%	105	20.04%	40	13.84%	30	15.63%
	18 - 35	515	30.97%	179	29.68%	23	41.82%	154	29.39%	93	32.18%	66	34.38%
	36 - 50	275	16.54%	158	26.20%	10	18.18%	54	10.31%	27	9.34%	26	13.54%
	51 - 64	127	7.64%	89	14.76%	0	0.00%	22	4.20%	9	3.11%	7	3.65%
	65+	61	3.67%	61	10.12%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
Sex	Female	953	57.31%	343	56.88%	33	60.00%	295	56.30%	182	62.98%	100	52.08%
	Male	710	42.69%	260	43.12%	22	40.00%	229	43.70%	107	37.02%	92	47.92%
Race	White	17	1.02%	10	1.66%	1	1.82%	5	0.95%	0	0.00%	1	0.52%
	Black	1205	72.46%	463	76.78%	42	76.36%	352	67.18%	224	77.51%	124	64.58%
	Other	441	26.52%	130	21.56%	12	21.82%	167	31.87%	65	22.49%	67	34.90%

Notes: *FFS = Fee-for-service; UHC = UnitedHealthcare; MAG = Magnolia Health; MOL = Molina Healthcare; TRU = TrueCare*

1. Age, sex, race, and program were assessed on the index date. The index date was the last occurrence of a sickle cell disease diagnosis in the study period.

2. Baseline demographics were missing for 1 member.

3. 9 members with α-thalassemia (D56.0).

To identify Medicaid members diagnosed with SCD who would be eligible for gene therapy, modeling based on clinical criteria listed in the prior authorization packets for both Casgevy® and Lyfgenia® were evaluated in claims data. Hydroxyurea treatment failure, vaso-occlusive crises, and chronic transfusion for recurrent VOCs were identified in Table 2. While both therapies have minimum age restrictions, no age limits were utilized in this analysis. Distributions across age categories were provided.

Among the 1,663 members identified with SCD, 137 (8.3%) had treatment failure with hydroxyurea between January 2024 and December 2025. Each gene therapy product has different definitions for recurrent VOCs. The Casgevy® prior authorization criteria defines recurrent VOCs as 2 or more documented VOCs per year in the previous 24 months. Using that definition, 524 members (31.5%) experienced recurrent VOCs. The Lyfgenia® criteria defines recurrent VOCs as 4 or more events in the previous 24 months. Using this definition, 660 members (39.7%) experienced recurrent VOCs. Two thresholds were set for defining chronic transfusion: 6 or more transfusions in the previous year and 8 or more transfusions in the previous year. Based on those thresholds, 158 (9.5%) and 115 (6.9%) members experienced chronic transfusions, respectively. When combining all criteria together, 43 members (2.6%) were identified as being eligible to receive Casgevy® and 123 members (7.4%) were eligible for Lyfgenia®. These figures do not exclude eligibility due to age restrictions.

TABLE 2: Modeling Gene Therapy Eligibility Criteria Among the Sickle Cell Disease Population											
Member Characteristics		Study Population	HU Treatment Failure[1]	VOCs		Chronic Transfusions in Previous Year		Casgevy Criteria[2]		Lyfgenia[3]	
				≥ 2/yr in 24 mos	≥ 4 in 24 mos	≥ 6	≥ 8	HU Fail + VOCs OR CT*		HU Fail + VOCs OR CT*	
Total		1663	137	524	660	158	115	43	2.59%	123	7.40%
Age (in years)	0 - 4	182	10	14	27	4	1	1	0.55%	5	2.75%
	5 - 11	266	31	53	79	22	17	8	3.01%	27	10.15%
	12 - 17	237	20	47	61	27	25	8	3.38%	16	6.75%
	18 - 35	515	51	225	272	65	51	18	3.50%	50	9.71%
	36 - 50	275	18	135	156	31	16	5	1.82%	18	6.55%
	51 - 64	127	7	44	57	5	3	3	2.36%	7	5.51%
	65+	61	0	6	8	4	2	0	0.00%	0	0.00%
Gender	Female	953	65	273	352	81	55	18	1.89%	58	6.09%
	Male	710	72	251	308	77	60	25	3.52%	65	9.15%
Race	White	17	0	2	2	0	0	0	0.00%	0	0.00%
	Black	1205	82	336	434	83	58	24	1.99%	71	5.89%
	Other	441	55	186	224	75	57	19	4.31%	52	11.79%
Pharmacy Program	FFS	603	32	228	282	53	40	8	1.33%	29	4.81%
	UHC	55	0	2	5	0	0	0	0.00%	0	0.00%
	MAG	524	58	148	188	52	37	19	3.63%	54	10.31%
	MOL	289	22	70	93	30	20	7	2.42%	19	6.57%
	TRU	192	25	76	92	23	18	9	4.69%	21	10.94%

Notes: *FFS = Fee-for-service; UHC = UnitedHealthcare; MAG = Magnolia Health; MOL = Molina Healthcare; TRU = TrueCare; ACS = acute chest syndrome; VOCs = vaso-occlusive crises; HU - hydroxyurea; CT = Chronic Transfusion ; yr = years; mos = months;*

1. Hydroxyurea treatment failure was operationalized as having 2 or more VOCs or 1 or more ACS events during the time the individual was treatment persistent to hydroxyurea (persistence was defined as staying on HU therapy for 84 days or longer with an allowable gap of no more than 15 days).

2. For Casgevy, ≥ 2 VOCs per year in a 24-month period (2024 and 2025) were identified.

3. For Lyfgenia, ≥ 4 VOCs in a 24-month period were identified between Jan 2024 and Dec 2025. This was done in accordance with the PA criteria for both gene therapies.

** The number of members meeting the Casgevy and Lyfgenia eligibility criteria was identical under both definitions of CT (≥ 6 or ≥ 8 in the previous year).*

CONCLUSIONS

This report identified a measurable subset of Mississippi Medicaid members with sickle cell disease who may meet modeled eligibility criteria for newly approved gene therapies, although final eligibility will depend on age restrictions, clinical evaluation, and prior authorization requirements. While only a small proportion of members met all combined criteria for Casgevy® or Lyfgenia®, the findings highlight the need for early planning, care coordination, and access-support services as the Mississippi Division of Medicaid implements the CGT Access Model and prepares for the potential budget and operational impact of these high-cost therapies.

RECOMMENDATIONS

This report is presented for informational purposes with no formal recommendations included.

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Prior Authorization Criteria

MISSISSIPPI DIVISION OF MEDICAID

CASGEVY® (*exagamglogene autotemcel*) PA CRITERIA for Sickle Cell Disease:

CASGEVY® (*exagamglogene autotemcel*) is an autologous genome edited hematopoietic stem cell-based gene therapy indicated for the treatment of patients aged 12 years and older with sickle cell disease (SCD) with recurrent vaso-occlusive crises (VOCs) or transfusion-dependent β-thalassemia (TDT).

Prior authorization is required for CASGEVY® (*exagamglogene autotemcel*) in sickle cell disease (SCD). Prior authorization approval will be considered when the following criteria are met. Along with the Universal PA Form, please submit any supporting clinical documentation.

Initial Authorization: 12 Months. One single dose per lifetime.

1. Age of the patient is 12 years and older; **AND**

2. Patient has a diagnosis of sickle cell disease confirmed by genetic testing; **AND**

3. Patient has one of the following based on provider attestation:
    a. Experienced recurrent vaso-occlusive crises (VOCs), defined as 2 or more documented VOCs per year in the previous 24 months**; or**
    b. Currently receiving chronic transfusion therapy for recurrent VOCs; **AND**

4. Patient has prior use of or intolerance to hydroxyurea (as determined by healthcare professional judgement) at any point in the past; **AND**

5. Prescribed by or in consultation with a board-certified hematologist with sickle cell disease expertise; **AND**

6. Prescriber attests that patient is clinically stable and fit for transplantation.

CASGEVY® Dosing:

- Dosing is based on body weight. The minimum recommended dose is 3 x 10^6 CD34+ cells/kg. CASGEVY® is for autologous use only. Please see the full prescribing information for further details.

Formulation:

- CASGEVY® is a cell suspension for intravenous infusion.

Prior Authorization Criteria

MISSISSIPPI DIVISION OF MEDICAID

LYFGENIA® (*lovotibeglogene autotemcel*) PA CRITERIA for Sickle Cell Disease:

LYFGENIA® (*lovotibeglogene autotemcel*) is an autologous hematopoietic stem cell-based gene therapy indicated for the treatment of patients 12 years of age or older with sickle cell disease (SCD) and a history of vaso-occlusive events.

Prior authorization is required for LYFGENIA® (*lovotibeglogene autotemcel*) in sickle cell disease (SCD). Prior authorization approval will be considered when the following criteria are met. Along with the Universal PA Form, please submit any supporting clinical documentation.

Initial Authorization: 12 Months. One single dose per lifetime.

1. Age of the patient is 12 years and older at the expected time of gene therapy administration; **AND**

2. Patient has a diagnosis of sickle cell disease confirmed by genetic testing; **AND**

3. Patient has one of the following based on prescriber attestation:
    a. Experienced 4 or more vaso-occlusive events (VOEs) in the previous 24 months as determined by the treating clinician; **or**
    b. Currently receiving chronic transfusion therapy for recurrent VOEs**; AND**

4. Patient has failure or intolerance to hydroxyurea (defined as being unable to take hydroxyurea per healthcare professional judgement) at any point in the past; **AND**

5. Prescribed by or in consultation with a board-certified hematologist with sickle cell disease expertise; **AND**

6. Patient's treatment center has a Sickle Cell Center**; AND**

7. Prescriber attests that the patient is clinically stable and fit for transplantation.

LYFGENIA® Dosing: Dosing is based on the number of CD34+ cells in the infusion bag(s) per kg of body weight. The minimum recommended dose is 3 x 10^6 CD34+ cells/kg. LYFGENIA® is for autologous use only. Please see the full prescribing information for further details.

Formulation: LYFGENIA® is a cell suspension for intravenous infusion.

FDA DRUG SAFETY COMMUNICATIONS

March 2026 – May 2026

- **3-20-2026: FDA Is Requiring Warning about Vitamin B6 Deficiency and Associated Seizures for Drug Products Containing Carbidopa/Levodopa**
- **3-31-2026: FDA Identifies Cases of Serious Liver Injury in Patients Taking Tavneos (avacopan) for Severe Active Anti-neutrophil Cytoplasmic Autoantibody (ANCA)-associated Vasculitis**

FDA Is Requiring Warning about Vitamin B6 Deficiency and Associated Seizures for Drug Products Containing Carbidopa/Levodopa

What Is FDA Doing?

The U.S. Food and Drug Administration (FDA) has notified application holders for all drug products containing carbidopa/levodopa that the Agency is requiring the addition of a warning, and corresponding revisions, to the prescribing information to state that these medications, approved to treat symptoms of Parkinson's disease, can cause vitamin B6 deficiency and vitamin B6 deficiencyassociated seizures. The warning directs health care professionals to evaluate baseline vitamin B6 levels prior to starting treatment with carbidopa/levodopa therapies and periodically while on treatment and to supplement with vitamin B6 as necessary.

What Are Drug Products Containing Carbidopa/Levodopa?

Drug products containing carbidopa/levodopa are approved to treat symptoms of Parkinson's disease, a progressive nervous system disorder. Levodopa is the metabolic precursor to dopamine, a neurotransmitter in the brain that declines in patients with Parkinson's disease, leading to motor symptoms such as tremors, rigidity and bradykinesia (slow movements). Carbidopa inhibits the decarboxylation of peripheral levodopa, making more levodopa available for delivery to the brain.

Drug products containing carbidopa/levodopa approved to treat symptoms of Parkinson's disease may contain both carbidopa and levodopa (trade names: Crexont, Dhivy, Duopa, Rytary, Sinemet, and Sinemet CR); carbidopa/levodopa/entacapone (trade name: Stalevo); or foscarbidopa/foslevodopa (trade name: Vyalev), which is converted to active carbidopa/levodopa in the body. These products are available in multiple formulations and may be administered by several different routes, including oral tablets, an enteral (intestinal) suspension, and a subcutaneous injection for continuous infusion.

Drug products containing carbidopa/levodopa can deplete vitamin B6 levels during the process by which levodopa is converted to dopamine. Additionally, carbidopa binds to the active form of vitamin B6, which creates additional functional loss of vitamin B6.

What Should Patients and Caregivers Do?

Patients and caregivers should be aware that taking drug products containing carbidopa/levodopa can lead to vitamin B6 deficiency, which can increase the risk of seizures. To monitor for vitamin B6 deficiency, your health care professional should evaluate your vitamin B6 levels before starting treatment with a drug product containing carbidopa/levodopa, periodically during treatment, and if symptoms of vitamin B6 deficiency appear during treatment. These symptoms include seizures, as well as depression; confusion; inflammation of the lips, tongue, and skin; and nerve damage causing numbness, tingling, sharp pain, or muscle weakness. Patients should take vitamin B6 supplements as recommended in consultation with a health care professional. Higher doses of carbidopa/levodopa may increase the risk of vitamin B6 deficiency. Many of the cases of seizures reported with carbidopa/levodopa use did not respond to traditional anti- seizure medications but resolved after vitamin B6 administration.

What Should Health Care Professionals Do?

Health care professionals should evaluate vitamin B6 levels before starting patients on treatment with drug products containing carbidopa/levodopa, periodically during treatment, and if symptoms of vitamin B6 deficiency appear during treatment. Health care professionals should consider whether vitamin B6 supplementation is necessary. Higher doses of carbidopa/levodopa may increase the risk of vitamin B6 deficiency. Health care professionals should be aware that seizures associated with the use of a product containing carbidopa and levodopa do not respond to traditional anti- seizure medications but resolve after vitamin B6 administration. Furthermore, select anti- seizure medications may further worsen a vitamin B6 deficiency. Health care professionals should inform patients of these risks.

What Did FDA Find?

FDA conducted a safety review and identified 14 cases of seizures linked to vitamin B6 deficiency in patients using drug products containing carbidopa/levodopa. The 14 cases included postmarketing reports submitted to FDA1 (13 reports) or found in the medical literature (1 report), so there are likely additional cases about which we are unaware. All of the reviewed cases involved levodopa doses exceeding 1,000 mg daily, with higher doses (>1,500

mg levodopa) associated with shorter duration from treatment initiation to identification of vitamin B6 deficiency. The seizure cases were split among oral formulations and an enteral suspension, with latency periods ranging from 23 to 132 months. The seizures have typically presented as focal onset seizures with secondary generalization, consistent with seizures observed with vitamin B6- dependent epilepsy, and progression to status epilepticus was observed in some cases, indicating an urgent need for rapid identification and treatment.

In these cases of reported seizures, there was additional clinical evidence supportive of vitamin B6 deficiency, including elevated homocysteine levels in four cases, microcytic or normocytic anemia in three cases, and neuropsychiatric symptoms in four cases. Of the nine patients treated with vitamin B6 supplementation, all nine had resolution of their seizures, despite the majority of these patients previously demonstrating a lack of response to multiple antiseizure medications. Two fatalities occurred, both with documented low vitamin B6 levels and poorly controlled seizures.

The review found no cases of vitamin B6- associated seizures associated with carbidopa/levodopa/entacapone products or with the injectable carbidopa/levodopa product, which may reflect lower usage patterns, more recent approval dates, and/or different dosing and administration requirements. However, biological plausibility suggests there may be a similar risk across all drug products containing carbidopa/levodopa, as vitamin B6 deficiency was also observed in the clinical trials that supported the original approval of the injectable carbidopa/levodopa product. Based on the available data, FDA concluded there is reasonable evidence of a causal association between drug products containing carbidopa/levodopa and vitamin B6 deficiency- associated seizures.

FDA Identifies Cases of Serious Liver Injury in Patients Taking Tavneos (avacopan) for Severe Active Anti-neutrophil Cytoplasmic Autoantibody (ANCA)-associated Vasculitis

What Is FDA Doing?

FDA is alerting patients and health care professionals about serious postmarketing cases, including fatal cases, of drug-induced liver injury (DILI) associated with Tavneos (avacopan). Some cases involved vanishing bile duct syndrome (VBDS), which is characterized by progressive destruction and disappearance of the bile ducts in the liver. This condition can slow or stop the flow of bile and may lead to permanent liver damage. VBDS is often accompanied by the yellowing of skin or eyes (jaundice), itchiness, and tiredness. Although hepatotoxicity is a serious adverse reaction for Tavneos identified in premarket clinical trials and described in product labeling, VBDS and DILI cases with fatal outcomes represent new safety concerns. FDA is continuing to monitor postmarketing cases of DILI, including VBDS, involving Tavneos and will provide updates as appropriate.

What Is Tavneos (avacopan)?

Tavneos was approved on October 7, 2021, and is used together with glucocorticoids and other standard-of-care medications to treat adults with severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis and microscopic polyangiitis), a group of rare diseases that cause inflammation in small-to-medium-sized blood vessels. Tavneos does not eliminate glucocorticoid use.

What Should Patients Do?

Patients should contact their health care professional immediately if they develop any signs or symptoms that may indicate liver injury, such as: feeling more tired than usual; nausea; vomiting; unusual itching; light-colored stools; yellowing of skin or eyes; dark urine; swelling in the stomach or abdomen; or pain in the right upper abdomen. Patients should talk to their health care professional about the safety risks associated with Tavneos and whether to continue therapy or switch to alternative treatments.

What Should Health Care Professionals Do?

When treating patients who take Tavneos, health care professionals should:

- Conduct liver panel testing every 2 weeks in the first month of treatment, monthly for the next 5 months, and then as clinically indicated.

- Promptly discontinue Tavneos treatment, evaluate patients, and consider alternative treatments for patients with severe active ANCA-associated vasculitis if:
    - Alanine aminotransferase (ALT) or aspartate aminotransferase (AST) is >3 times the upper limit of normal (ULN) or alkaline phosphatase (ALP) is >2 times the ULN;
    - A patient presents with evidence of symptomatic cholestasis such as jaundice or pruritus.
- If liver test abnormalities or symptoms of liver injury do not improve, patients should be referred to a hepatologist for further evaluation. Professionals should consult the American College of Rheumatology treatment guidelines for more information.

What Did FDA Find?

After reviewing postmarketing data from the applicant's submission (cases from their global safety database), the literature, and the FDA Adverse Event Reporting System (FAERS) database, which has been incorporated into the FDA Adverse Event Monitoring System (AEMS) database, through October 9, 2024, FDA identified 76 cases of DILI with reasonable evidence of a causal association with avacopan use. A total of 74 cases reported a serious outcome, including hospitalization (n=54) and death (n=8). A total of 60 cases provided laboratory information to determine the initial pattern of liver injury; the majority (n=38) had a cholestatic or mixed pattern often marked by substantial elevations in ALP and total bilirubin. A total of 73 cases provided time from avacopan initiation to DILI onset, and the median time-to-onset was 46 days (range 22 to 140 days). Most cases (n=66) were reported from Japan, followed by the United States (n=5), Europe (n=4), and Canada (n=1).

Of the 76 cases, 7 reported biopsy-confirmed VBDS as a complication of DILI with reasonable evidence of a causal association with avacopan use. All cases reported hospitalization (n=7), of which 3 had a fatal outcome. The initial pattern of liver injury was cholestatic or mixed in 4 cases and hepatocellular in 3 cases. The median time from avacopan initiation to DILI onset among the 7 cases was 46 days (range 33 to 59 days). Cases were reported from Japan (n=6) and Canada (n=1).

FDA is continuing to monitor postmarketing cases of DILI, including VBDS, involving avacopan and will provide updates as appropriate.

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