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

MISSISSIPPI DIVISION OF
MEDICAID

**December 7, 2023 at 1:00pm**

**Zoom Video Conferencing**

Prepared by:

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

# Drug Utilization Review Board

**Joseph Austin, MD**
Vicksburg Women's Care
100 Maxwell Drive
Vicksburg, MS 39180
*Term Expires: June 30, 2025*

**Amy Catherine Baggett, PharmD**
Love's Pharmacy of Diamondhead
45000 E Aloha Dr., Suite B
Diamondhead, MS 39525
*Term Expires: June 30, 2024*

**Terrence Brown, PharmD**
BioScrip Infusion Services
187 Country Place Pkwy, Suite C
Pearl, MS 39208
*Term Expires: June 20, 2026*

**Chrysanthia Davis, PharmD (Vice-Chair)**
Omnicare Pharmacy
100 Business Park Dr, Ste D
Ridgeland, MS 39157
*Term Expires: June 30, 2025*

**Tanya Fitts, MD (Chair)**
Lafayette Pediatric Clinic
1300 Access Road, Suite 400
Oxford, MS 38655
*Term Expires: June 30, 2024*

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

**Jahanzeb Khan, MD**
University Hospital
2500 N. State Street
Jackson, MS 39216
*Term Expires: June 30, 2024*

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

**Kristi Phelps, RPh**
Burnham Drugs
12500 Hwy 57
Vancleave, MS 39565
*Term Expires: June 30, 2026*

**Joshua Pierce, PharmD**
McGuffee Drugs
102 Main St.
Magee, MS 39111
*Term Expires: June 30, 2024*

**Bobbie West, MD**
MEA Medical Clinic
342 Gilchrist Drive
Pearl, MS 39208
*Term Expires: June 30, 2025*

## 2023 DUR Board Meeting Dates

March 2, 2023
June 15, 2023
September 7, 2023
December 7, 2023

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**
**December 7, 2023**

**Welcome**

**Old Business**



**Resource Utilization Review** **FFS ONLY*



**Follow-up and Discussion from the Board**

**New Business**



**Pharmacy Program Update**

**Next Meeting Information**
Proposed 2024 Meeting Dates:
March 7, 2024; June 13, 2024; September 12, 2024; December 5, 2024

# DUR Board Meeting Minutes

**MISSISSIPPI DIVISION OF MEDICAID**
**DRUG UTILIZATION REVIEW (DUR) BOARD**
**MINUTES OF THE SEPTEMBER 7, 2023 MEETING**

| DUR Board Roster: State Fiscal Year 2023 (July 1, 2023 – June 30, 2024) | Dec 2022 | Mar 2023 | Jun 2023 | Sep 2023 |
|---|---|---|---|---|
| Joseph Austin, MD | ✓ | | ✓ | ✓ |
| Amy Catherine Baggett, PharmD | | | | ✓ |
| Terrence Brown, PharmD | ✓ | ✓ | ✓ | ✓ |
| Chrysanthia Davis, PharmD | ✓ | ✓ | ✓ | ✓ |
| Tanya Fitts, MD | | | ✓ | ✓ |
| Dena Jackson, MD | | | | ✓ |
| Jahanzeb Khan, MD | ✓ | ✓ | ✓ | ✓ |
| Holly Moore, PharmD | ✓ | ✓ | ✓ | |
| Kristi Phelps, RPh | ✓ | ✓ | | |
| Joshua Pierce, PharmD | ✓ | | ✓ | ✓ |
| Bobbie West, MD | | ✓ | | |
| **TOTAL PRESENT**** | **8** | **7** | **7** | **8** |

** *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:**
Terri Kirby, RPH, CPM, Pharmacy Director; Dennis Smith, RPH, DUR Coordinator; Gail McCorkle, RPH, Clinical Pharmacist; Vanessa Banks, RN, Program Integrity; Roxanne Coulter, RN, Program Integrity

**University of Mississippi School of Pharmacy - MS-DUR Staff:**
Eric Pittman, PharmD, MS-DUR Project Director; Kaustuv Bhattacharya, PhD, MS-DUR Research Assistant Professor; Ben Banahan, PhD, Research Staff; Claire Lin, Graduate Student; Arman Arabshomali, Graduate Student; Alfred Eriakha, Graduate Student; Emily Gravlee, Graduate Student;

**Medimpact Staff:**
Chris Benton, PharmD, Clinical Account Manager;

**Coordinated Care Organization (CCO) Staff:**
Jenni Grantham, PharmD, Director of Pharmacy, Magnolia Health; Heather Odem, PharmD, Director of Pharmacy - Mississippi, UnitedHealthcare Community & State;

**Gainwell Staff:**
Tricia Banks, PharmD, MS Pharmacy Services Manager;

**Alliant Health Staff:**

Catherine Brett, MD, Quality Director, MS UM/QIO; Buddy Ogletree, PharmD, Pharmacist;

**Visitors:**

Gene Wingo, Biogen; Michele Shirley, Indivior; Shawn Headley, Gilead; Paula Whatley, Novo Nordisk; Pete Smith, Capital Resources; Floyd Holmes, Lilly; Chasity Caston, Bioscrips; Meg Pearson, MSDH; Todd Dear, MSBOP; Stephanie Mueller, MSBOP; Cindy Noble, Independent Contractor; Griffin Sublet; Pharmacy Student; Devin Demaree, Pharmacy Student; Ann Sublett, Pharmacy Student;

**Call to Order/Welcome:**

Dr. Fitts called the meeting to order at 1:02 pm.

**OLD BUSINESS:**

Dr. Austin moved to approve the minutes from the June 2023 DUR Board Meeting, seconded by Dr. Khan, and unanimously approved by the DUR Board.

**Resource Utilization Review:**

Dr. Pittman presented the resource utilization report for September 2023. Dr. Pittman noted that MS-DUR continues to experience data transfer issues with the encounter claims from Gainwell therefore the resource report only included data from the Fee-for-Service Program. DOM continues to work with Gainwell to resolve the issues.

**NEW BUSINESS:**

**Appointment of Vice-Chair**

Following a discussion by the Board, Dr. Chrysanthia Davis volunteered to serve as Vice-Chair for the upcoming year.

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

Dr. Pittman provided an overview of all DUR mailings and educational notices that occurred between June 2023 – July 2023. He also provided members with an update on the mailing on the preventive use of low-dose aspirin in pregnant beneficiaries at risk of preeclampsia. The final edits have been made by DOM and the mailing will be sent out soon.

**Special Analysis Projects:**

**PMP Data Trends**

When analyzing PMP data for Medicaid beneficiaries, MS-DUR found that approximately 7% of patient inquiries each month resulted in what were considered to be invalid or questionable linkages to claims. Except for the period during the height of COVID, the total number of claims for reportable drugs and for opioids has remained somewhat constant during the three-year period examined. There has been a shift in payment source for these prescription claims with a decrease in payments by Medicaid and an almost equally large increase in payment by “other

payers." The use of cash payments has increased slightly among Medicaid beneficiaries, but the primary shift has been to other types of insurance. Approximately 42% of opioid claims for individuals enrolled in Medicaid are paid by a source other than Medicaid. With only 58% of opioid prescriptions being processed by Medicaid, it is extremely difficult, if not impossible, for Medicaid agencies to appropriately monitor opioid use among their beneficiaries using traditional prospective and retrospective DUR activities. It is important for state Medicaid agencies to have consistent access to PMP data for DUR purposes. Without these data, abuse detection and intervention programs will only have knowledge about 58% of opioid claims.

The following recommendations were presented:

1. DOM is encouraged to use PMP data cautiously to identify potential misuse. Invalid linkages of claims to beneficiaries and errors in recording prescriber identification can contribute to false positives in programs designed to detect misuse. Retrospective DUR reports can use PMP to better identify patients potentially at risk, but DOM will need to evaluate each case carefully to avoid acting on false positives.

2. DOM and others should encourage MS PMP to include unique patient identifiers as required fields, if possible, to reduce the problems with patient linkages to claims.

*During the discussion, Stephanie Mueller from the Board of Pharmacy provided insights into some of the difficulties with including a unique patient identifier into the PMP system. Following extensive discussion, Dr. Davis made a motion to accept the recommendations, seconded by Dr. Brown, and unanimously approved by the Board.*

**Opioid Guidelines and Trends**

Recognizing the need to establish a national guideline on pain management to combat the opioid epidemic, the CDC issued guidance in 2016 for the prescribing of opioids for chronic pain. This guidance ushered in sweeping regulatory and policy changes across the US targeting opioid prescribing. In 2019, Mississippi Medicaid implemented their Opioid Initiatives based on the CDC's recommendations and the SUPPORT Act requirements. Criteria implemented by DOM effectively altered prescribing patterns to comply with the Opioid Initiatives. Medicaid also utilizes quantity limits to manage opioid use, however, little evidence supports the use of quantity limits. An alternative approach to using quantity limits could be the use of cumulative MEDD limits. With the CDC's updated 2022 Guideline's, DOM should examine their current opioid initiatives and determine if any changes need to be made.

The following recommendations were presented:

1. DOM is encouraged to seek input from the DUR Board on current Medicaid policies related to opioid prescribing and the updated 2022 CDC Guideline for Prescribing Opioids in Chronic Pain.
2. DOM is encouraged to explore the possibility of replacing quantity limit criteria for opioids with cumulative MEDD criteria.

During their discussion, the Board felt current Medicaid policies were in line with the Mississippi Board of Medical licensure's current regulations. Medicaid was encouraged to examine their opioid policies if and when the Board of Medical Licensure changes their regulations. The Board also discussed nonpharmacologic therapies for pain and provided an additional recommendation:

3. DOM is encouraged to explore covering nonpharmacologic therapies for chronic pain management.

*Following a robust discussion, Dr. Pierce made a motion to accept the recommendations, seconded by Dr. Austin, and unanimously approved by the Board.*

**Naloxone Trends**

Opioid-related overdose deaths have risen dramatically across Mississippi and the US in recent years. Naloxone is a safe and effective treatment that can reverse the effects of opioids and prevent deaths. Although many efforts have taken place at both the state and national levels to increase naloxone access, utilization continues to be low. More work needs to be done to decrease stigma and improve access to this life-saving treatment for those at high-risk of experiencing adverse opioid events.

The following recommendations were presented:

1. DOM is encouraged to pursue efforts to increase the utilization of naloxone, especially among those at high-risk of experiencing an adverse opioid event. These efforts could include:
    a. Conducting an educational intervention targeting pharmacists to increase the availability of naloxone in community pharmacies and improve the rates of dispensing naloxone through MSDH's Naloxone Standing Order.
    b. Conducting an educational intervention targeting prescribers to increase their rates of prescribing naloxone among Medicaid beneficiaries considered high-risk of experiencing an opioid overdose.

During the Board's discussion, an additional recommendation was added:

    c. Develop an educational flyer targeting patients prescribed opioids that can be displayed in prescribers' offices or pharmacies.

*Following a brief discussion, Dr. Brown made a motion to accept the recommendations, seconded by Dr. Baggett, and unanimously approved by the Board.*

**Buprenorphine Trends**

The prescribing of buprenorphine products among Medicaid beneficiaries continues to increase. The inclusion of buprenorphine containing products as preferred agents not requiring prior authorization for use in MAT as well as the removal of limits on the length of therapy are

steps DOM has taken to improve access to buprenorphine products. With passage of the MAT Act in 2022 removing waiver requirements to prescribe buprenorphine, access to these products should continue to improve.

The following recommendation was presented:

1. DOM is encouraged to continue working internally and expand their reach to external stakeholders in efforts to improve access to MAT across the state.

*Following a brief discussion, Dr. Jackson made a motion to accept the recommendations, seconded by Dr. Austin, and unanimously approved by the Board.*

**FDA Drug Safety Updates:**
No new FDA drug safety communications were published between June 2023 – August 2023.

**Pharmacy Program Update:**
Ms. Kirby provided a pharmacy program update highlighting the following items:

- All generic Vyvanse was coded as preferred on the UPDL.
- In October 2023, Magnolia is changing to a new PBM with a new BIN number.
- DOM is working with CMS to acquire Medicare Part D claims information for dual eligible Medicaid beneficiaries.
- DOM has updated their RSV Synagis PA language.

**Next Meeting Information:**
The next Board meeting is scheduled for December 7, 2023.

Dr. Brown adjourned the meeting at 3:35 pm

Submitted,

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

**Meeting Location**: Woolfolk Building, 501 North West Street, Conference Room 145, Jackson, MS 39201, unless otherwise noted by the corresponding date of the meeting listed below.

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

Notice details:

**State Agency:** MS Division of Medicaid

**Public Body:** Drug Utilization Board (DUR) Meeting

**Subject:** Quarterly Meeting

**Dates and Times:**

2023 dates:

- March 2, 2023 (1-3pm; Room 117, Woolfolk Building)
- June 15, 2023 (1-3pm; Room 145)
- September 7, 2023 (1-3pm; Room 145)
- December 7, 2023 (1-3pm; Room 145)

**Description:** The Mississippi Division of Medicaid's Drug Utilization Review (DUR) Board is a quality assurance body which seeks to assure appropriate drug therapy to include optimal beneficiary outcomes and appropriate education for physicians, pharmacists, and the beneficiary. The Drug Utilization Review (DUR) Board is composed of twelve participating physicians and pharmacists who are active MS Medicaid providers and in good standing with their representative organizations.

The Board reviews utilization of drug therapy and evaluates the long-term success of the treatments.

The Drug Utilization Review (DUR) Board meets quarterly.


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PUBLIC MEETING NOTICES
Mississippi Public Meeting Notices
NOTICE DETAILS
NOTICE DETAILS
State Agency: Division of Medicaid
Public Body: Division of Medicaid
Title: Division of Medicaid Drug Utilization Review Board Meeting
Subject: Division of Medicaid Drug Utilization Review Board Meeting
Date and Time: 9/7/2023 1:00:00 PM
Description:
Please see attached for more information regarding Drug Utilization Review Board Meeting. Meeting will take place in Room 145.
Back
MEETING LOCATION
501 N. West Street
Jackson MS 39201
Map this!
CONTACT INFORMATION
Terri Kirby
601-359-9803
terri.kirby@medicaid.ms.gov
DOWNLOAD ATTACHMENTS
Notification to DFA 2023 Pharmacy meetings - DUR.docx
Added 1/25/2023
SUBSCRIPTION OPTIONS
Subscription options will send you alerts regarding future notices posted by this public body.
RSS

# Resource Utilizaton Review

| TABLE 04A: ENROLLMENT STATISTICS FOR LAST 6 MONTHS<br>April 1, 2023 through September 30, 2023 | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | Apr-23 | May-23 | Jun-23 | Jul-23 | Aug-23 | Sep-23 |
| Total enrollment | | 906,531 | 909,855 | 912,335 | 891,043 | 873,322 | 851,147 |
| Dual-eligibles | | 168,450 | 168,735 | 168,786 | 168,279 | 167,884 | 167,123 |
| Pharmacy benefits | | 796,121 | 799,148 | 801,498 | 780,293 | 762,796 | 741,110 |
| LTC | | 15,753 | 15,876 | 15,892 | 15,875 | 15,867 | 15,662 |
| PLAN % | FFS | 49.6% | 49.5% | 49.3% | 49.0% | 47.8% | 46.1% |
| PLAN % | MSCAN-UHC | 19.5% | 19.6% | 19.6% | 19.8% | 20.2% | 20.8% |
| PLAN % | MSCAN-Magnolia | 20.0% | 20.0% | 20.1% | 20.2% | 20.7% | 21.3% |
| PLAN % | MSCAN-Molina | 10.9% | 10.9% | 11.0% | 11.0% | 11.3% | 11.8% |

| TABLE 04B: PHARMACY UTILIZATION STATISTICS FOR LAST 6 MONTHS<br>April 1, 2023 through September 30, 2023 | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | Apr-23 | May-23 | Jun-23 | Jul-23 | Aug-23 | Sep-23 |
| # Rx Fills | FFS | 182,875 | 191,553 | 176,639 | 165,042 | 192,458 | 166,293 |
| # Rx Fills / Bene | FFS | 0.5 | 0.5 | 0.4 | 0.4 | 0.5 | 0.5 |
| $ Paid Rx | FFS | $24,481,148 | $27,412,384 | $26,821,685 | $24,583,183 | $27,311,704 | $24,086,926 |
| $/Rx Fill | FFS | $133.87 | $143.11 | $151.84 | $148.95 | $141.91 | $144.85 |
| $/Bene | FFS | $62.00 | $69.30 | $67.88 | $64.30 | $74.91 | $70.50 |

## TABLE C: TOP 10 DRUG CATEGORIES BY NUMBER OF CLAIMS IN SEP 2023 (FFS)

| Category | Month Year | Rank Volume | # RXs | $ Paid | # Unique Benes |
|---|---|---|---|---|---|
| CNS stimulants | Sep 2023 | 1 | 7,914 | $1,167,132 | 6,085 |
| | Aug 2023 | 1 | 8,554 | $1,346,478 | 6,631 |
| | Jul 2023 | 1 | 6,986 | $1,117,060 | 5,723 |
| SSRI antidepressants | Sep 2023 | 2 | 5,225 | $68,823 | 4,356 |
| | Aug 2023 | 3 | 6,217 | $85,941 | 5,057 |
| | Jul 2023 | 3 | 5,889 | $79,472 | 4,886 |
| contraceptives | Sep 2023 | 3 | 5,211 | $263,091 | 4,305 |
| | Aug 2023 | 2 | 6,275 | $339,967 | 5,033 |
| | Jul 2023 | 2 | 6,253 | $364,909 | 5,108 |
| aminopenicillins | Sep 2023 | 4 | 5,200 | $73,698 | 4,896 |
| | Aug 2023 | 4 | 6,148 | $86,922 | 5,710 |
| | Jul 2023 | 10 | 3,256 | $48,087 | 3,118 |
| vitamins | Sep 2023 | 5 | 4,871 | $50,898 | 3,478 |
| | Aug 2023 | 6 | 5,417 | $57,726 | 3,777 |
| | Jul 2023 | 5 | 4,884 | $49,022 | 3,532 |
| nonsteroidal anti-inflammatory agents | Sep 2023 | 6 | 4,811 | $67,955 | 4,355 |
| | Aug 2023 | 5 | 5,525 | $79,749 | 4,936 |
| | Jul 2023 | 4 | 5,125 | $74,885 | 4,644 |
| atypical antipsychotics | Sep 2023 | 7 | 4,239 | $869,464 | 3,126 |
| | Aug 2023 | 9 | 4,696 | $982,152 | 3,385 |
| | Jul 2023 | 6 | 4,388 | $1,054,252 | 3,252 |
| adrenergic bronchodilators | Sep 2023 | 8 | 4,061 | $230,334 | 3,315 |
| | Aug 2023 | 7 | 5,127 | $343,354 | 4,081 |
| | Jul 2023 | 8 | 3,711 | $278,021 | 3,021 |
| macrolides | Sep 2023 | 9 | 3,879 | $90,649 | 3,645 |
| | Aug 2023 | 8 | 4,973 | $99,571 | 4,693 |
| | Jul 2023 | 22 | 2,307 | $67,150 | 2,177 |
| proton pump inhibitors | Sep 2023 | 10 | 3,721 | $108,037 | 3,102 |
| | Aug 2023 | 11 | 4,184 | $128,972 | 3,463 |
| | Jul 2023 | 7 | 3,948 | $126,244 | 3,303 |

## TABLE D: TOP 10 DRUG CATEGORIES BY DOLLARS PAID IN SEP 2023 (FFS)

| Category | Month Year | Rank Paid Amt | # RXs | $ Paid | # Unique Benes |
|---|---|---|---|---|---|
| interleukin inhibitors | Sep 2023 | 1 | 428 | $2,690,746 | 242 |
| | Aug 2023 | 1 | 500 | $2,835,737 | 268 |
| | Jul 2023 | 1 | 425 | $2,370,197 | 257 |
| factor for bleeding disorders | Sep 2023 | 2 | 108 | $1,768,823 | 77 |
| | Aug 2023 | 3 | 108 | $1,823,460 | 78 |
| | Jul 2023 | 3 | 114 | $1,353,903 | 84 |
| TNF alpha inhibitors | Sep 2023 | 3 | 169 | $1,525,721 | 122 |
| | Aug 2023 | 2 | 247 | $2,331,371 | 147 |
| | Jul 2023 | 2 | 237 | $2,246,526 | 149 |
| CFTR combinations | Sep 2023 | 4 | 56 | $1,212,660 | 36 |
| | Aug 2023 | 5 | 60 | $1,228,369 | 39 |
| | Jul 2023 | 4 | 51 | $1,120,861 | 36 |
| CNS stimulants | Sep 2023 | 5 | 7,914 | $1,167,132 | 6,085 |
| | Aug 2023 | 4 | 8,554 | $1,346,478 | 6,631 |
| | Jul 2023 | 5 | 6,986 | $1,117,060 | 5,723 |
| antiviral combinations | Sep 2023 | 6 | 310 | $1,115,400 | 247 |
| | Aug 2023 | 6 | 376 | $1,158,072 | 292 |
| | Jul 2023 | 6 | 301 | $1,091,146 | 237 |
| atypical antipsychotics | Sep 2023 | 7 | 4,239 | $869,464 | 3,126 |
| | Aug 2023 | 7 | 4,696 | $982,152 | 3,385 |
| | Jul 2023 | 7 | 4,388 | $1,054,252 | 3,252 |
| GLP-1 receptor agonists | Sep 2023 | 8 | 902 | $853,157 | 683 |
| | Aug 2023 | 8 | 979 | $929,344 | 743 |
| | Jul 2023 | 8 | 850 | $774,555 | 685 |
| insulin | Sep 2023 | 9 | 1,851 | $651,851 | 1,168 |
| | Aug 2023 | 10 | 1,961 | $691,372 | 1,259 |
| | Jul 2023 | 9 | 2,040 | $756,728 | 1,290 |
| selective immunosuppressants | Sep 2023 | 10 | 160 | $528,847 | 118 |
| | Aug 2023 | 11 | 187 | $579,577 | 133 |
| | Jul 2023 | 10 | 205 | $685,344 | 138 |

## TABLE E: TOP 25 DRUG MOLECULES
## BY NUMBER OF CLAIMS IN SEP 2023 (FFS)

| Drug Molecule<br>Therapeutic Category | Aug 2023 # Claims | Sep 2023 # Claims | Sep 2023 $ Paid | Sep 2023 # Unique Benes |
|---|---|---|---|---|
| amoxicillin / aminopenicillins | 6,118 | 5,178 | $73,243 | 4,876 |
| albuterol / adrenergic bronchodilators | 4,557 | 3,759 | $149,392 | 3,115 |
| azithromycin / macrolides | 4,835 | 3,745 | $59,809 | 3,547 |
| ondansetron / 5HT3 receptor antagonists | 3,392 | 3,032 | $45,504 | 2,815 |
| fluticasone nasal / nasal steroids | 2,768 | 2,455 | $40,519 | 2,317 |
| ergocalciferol / vitamins | 2,745 | 2,452 | $21,755 | 1,880 |
| methylphenidate / CNS stimulants | 2,598 | 2,367 | $460,202 | 1,950 |
| amphetamine-dextroamphetamine / CNS stimulants | 2,646 | 2,311 | $96,988 | 1,909 |
| gabapentin / gamma-aminobutyric acid analogs | 2,464 | 2,250 | $34,411 | 1,793 |
| ibuprofen / nonsteroidal anti-inflammatory agents | 2,618 | 2,241 | $27,947 | 2,105 |
| montelukast / leukotriene modifiers | 2,487 | 2,174 | $31,672 | 2,022 |
| amoxicillin-clavulanate / penicillins/beta-lactamase inhibitors | 2,385 | 2,097 | $44,144 | 1,980 |
| sertraline / SSRI antidepressants | 2,364 | 2,028 | $25,561 | 1,684 |
| cetirizine / antihistamines | 2,081 | 2,009 | $39,064 | 1,763 |
| amlodipine / calcium channel blocking agents | 2,143 | 1,967 | $23,354 | 1,575 |
| ethinyl estradiol-norgestimate / contraceptives | 2,147 | 1,771 | $27,447 | 1,549 |
| cefdinir / third generation cephalosporins | 2,066 | 1,769 | $41,690 | 1,665 |
| acetaminophen-hydrocodone / narcotic analgesic combinations | 2,140 | 1,753 | $25,706 | 1,578 |
| clonidine / antiadrenergic agents, centrally acting | 1,899 | 1,701 | $20,341 | 1,495 |
| folic acid / vitamins | 1,866 | 1,684 | $12,506 | 1,132 |
| atorvastatin / HMG-CoA reductase inhibitors (statins) | 1,698 | 1,602 | $17,939 | 1,205 |
| pantoprazole / proton pump inhibitors | 1,783 | 1,597 | $20,697 | 1,295 |
| medroxyprogesterone / progestins | 1,927 | 1,567 | $55,960 | 1,466 |
| fluconazole / azole antifungals | 1,852 | 1,542 | $19,976 | 1,345 |
| omeprazole / proton pump inhibitors | 1,717 | 1,515 | $18,560 | 1,327 |

## TABLE F: TOP 25 DRUG MOLECULES BY DOLLARS PAID IN SEP 2023 (FFS)

| Drug Molecule<br>Therapeutic Category | Aug 2023<br>$ Paid | Sep 2023<br>$ Paid | Sep<br>2023<br># Claims | Sep<br>2023<br>#<br>Unique<br>Benes |
|---|---|---|---|---|
| adalimumab / TNF alpha inhibitors | $1,935,386 | $1,239,850 | 120 | 84 |
| elexacaftor/ivacaftor/tezacaftor / CFTR combinations | $1,228,369 | $1,212,660 | 56 | 36 |
| dupilumab / interleukin inhibitors | $1,303,476 | $1,085,455 | 303 | 176 |
| emicizumab / factor for bleeding disorders | $1,047,862 | $872,180 | 29 | 21 |
| ustekinumab / interleukin inhibitors | $567,568 | $786,791 | 36 | 17 |
| antihemophilic factor / factor for bleeding disorders | $167,963 | $661,199 | 17 | 10 |
| bictegravir/emtricitabine/tenofovir / antiviral combinations | $557,468 | $605,110 | 129 | 100 |
| methylphenidate / CNS stimulants | $525,381 | $460,202 | 2,367 | 1,950 |
| dulaglutide / GLP-1 receptor agonists | $371,939 | $374,084 | 418 | 333 |
| cannabidiol / miscellaneous anticonvulsants | $388,046 | $367,566 | 112 | 77 |
| lisdexamfetamine / CNS stimulants | $462,983 | $367,119 | 1,436 | 975 |
| paliperidone / atypical antipsychotics | $383,184 | $344,405 | 123 | 105 |
| ixekizumab / interleukin inhibitors | $369,362 | $342,938 | 40 | 22 |
| insulin glargine / insulin | $291,013 | $264,548 | 630 | 526 |
| empagliflozin / SGLT-2 inhibitors | $238,071 | $256,573 | 333 | 272 |
| liraglutide / GLP-1 receptor agonists | $317,973 | $251,405 | 282 | 214 |
| asciminib / BCR-ABL tyrosine kinase inhibitors | $40,233 | $235,403 | 12 | 2 |
| aripiprazole / atypical antipsychotics | $282,426 | $232,463 | 1,038 | 873 |
| somatropin / growth hormones | $237,298 | $217,840 | 48 | 38 |
| lenalidomide / other immunosuppressants | $105,054 | $213,148 | 12 | 9 |
| apixaban / factor Xa inhibitors | $240,265 | $208,649 | 507 | 369 |
| semaglutide / GLP-1 receptor agonists | $213,795 | $204,191 | 174 | 120 |
| risankizumab / interleukin inhibitors | $248,433 | $201,432 | 12 | 5 |
| dapagliflozin / SGLT-2 inhibitors | $245,498 | $193,268 | 287 | 236 |
| etanercept / TNF alpha inhibitors | $233,631 | $192,320 | 34 | 26 |

## TABLE G: TOP 25 DRUG MOLECULES
## BY CHANGE IN NUMBER OF CLAIMS FROM JUL 2023 TO SEP 2023 (FFS)

| Drug Molecule | Jul 2023 # Claims | Aug 2023 # Claims | Sep 2023 # Claims | Sep 2023 $ Paid | Sep 2023 # Unique Benes |
|---|---|---|---|---|---|
| amoxicillin / aminopenicillins | 3,219 | 6,118 | 5,178 | $73,243 | 4,876 |
| azithromycin / macrolides | 2,198 | 4,835 | 3,745 | $59,809 | 3,547 |
| fluticasone nasal / nasal steroids | 1,722 | 2,768 | 2,455 | $40,519 | 2,317 |
| cetirizine / antihistamines | 1,362 | 2,081 | 2,009 | $39,064 | 1,763 |
| cefdinir / third generation cephalosporins | 1,127 | 2,066 | 1,769 | $41,690 | 1,665 |
| amoxicillin-clavulanate / penicillins/beta-lactamase inhibitors | 1,471 | 2,385 | 2,097 | $44,144 | 1,980 |
| ondansetron / 5HT3 receptor antagonists | 2,414 | 3,392 | 3,032 | $45,504 | 2,815 |
| prednisolone / glucocorticoids | 850 | 1,504 | 1,447 | $39,164 | 1,317 |
| albuterol / adrenergic bronchodilators | 3,211 | 4,557 | 3,759 | $149,392 | 3,115 |
| influenza virus vaccine, inactivated / viral vaccines | 0 | 109 | 440 | $18,612 | 406 |
| methylphenidate / CNS stimulants | 2,049 | 2,598 | 2,367 | $460,202 | 1,950 |
| lisdexamfetamine / CNS stimulants | 1,165 | 1,317 | 1,436 | $367,119 | 975 |
| benzonatate / antitussives | 305 | 610 | 483 | $6,523 | 452 |
| dexmethylphenidate / CNS stimulants | 1,153 | 1,476 | 1,305 | $64,066 | 1,043 |
| prednisone / glucocorticoids | 939 | 1,389 | 1,073 | $11,419 | 1,005 |
| oseltamivir / neuraminidase inhibitors | 148 | 434 | 272 | $8,688 | 260 |
| budesonide / inhaled corticosteroids | 395 | 559 | 479 | $52,632 | 390 |
| dextroamphetamine / CNS stimulants | 183 | 245 | 262 | $89,807 | 212 |
| amphetamine-dextroamphetamine / CNS stimulants | 2,235 | 2,646 | 2,311 | $96,988 | 1,909 |
| polymyxin b-trimethoprim ophthalmic / ophthalmic anti-infectives | 220 | 276 | 284 | $4,608 | 262 |
| methylprednisolone / glucocorticoids | 807 | 1,120 | 870 | $12,513 | 837 |
| cephalexin / first generation cephalosporins | 1,016 | 1,306 | 1,077 | $19,772 | 1,008 |
| montelukast / leukotriene modifiers | 2,117 | 2,487 | 2,174 | $31,672 | 2,022 |
| semaglutide / GLP-1 receptor agonists | 134 | 184 | 174 | $204,191 | 120 |
| clarithromycin / macrolides | 48 | 88 | 85 | $7,508 | 68 |

## TABLE H: TOP 25 DRUG MOLECULES
## BY CHANGE IN AMOUNT PAID FROM JUL 2023 TO SEP 2023 (FFS)

| Drug Molecule | Jul 2023 $ Paid | Aug 2023 $ Paid | Sep 2023 $ Paid | Sep 2023 # Claims | Sep 2023 # Unique Benes |
|---|---|---|---|---|---|
| antihemophilic factor / factor for bleeding disorders | $416,321 | $167,963 | $661,199 | 17 | 10 |
| asciminib / BCR-ABL tyrosine kinase inhibitors | $40,233 | $40,233 | $235,403 | 12 | 2 |
| ustekinumab / interleukin inhibitors | $608,641 | $567,568 | $786,791 | 36 | 17 |
| lenalidomide / other immunosuppressants | $70,036 | $105,054 | $213,148 | 12 | 9 |
| emicizumab / factor for bleeding disorders | $730,663 | $1,047,862 | $872,180 | 29 | 21 |
| coagulation factor ix / factor for bleeding disorders | $67,671 | $143,931 | $177,992 | 12 | 7 |
| cabozantinib / multikinase inhibitors | $50,091 | $119,674 | $150,261 | 5 | 3 |
| cladribine / antimetabolites | $39,316 | $314,493 | $137,589 | 2 | 2 |
| elexacaftor/ivacaftor/tezacaftor / CFTR combinations | $1,120,861 | $1,228,369 | $1,212,660 | 56 | 36 |
| risankizumab / interleukin inhibitors | $115,385 | $248,433 | $201,432 | 12 | 5 |
| lonapegsomatropin / growth hormones | $25,618 | $42,953 | $107,310 | 14 | 6 |
| semaglutide / GLP-1 receptor agonists | $134,172 | $213,795 | $204,191 | 174 | 120 |
| guselkumab / interleukin inhibitors | $25,726 | $77,177 | $77,177 | 6 | 4 |
| lenvatinib / multikinase inhibitors | $0 | $0 | $46,911 | 2 | 1 |
| methylphenidate / CNS stimulants | $413,362 | $525,381 | $460,202 | 2,367 | 1,950 |
| deutetrabenazine / VMAT2 inhibitors | $50,767 | $78,197 | $92,735 | 12 | 9 |
| deferiprone / chelating agents | $115,731 | $165,875 | $156,697 | 5 | 3 |
| ocrelizumab / CD20 monoclonal antibodies | $0 | $131,474 | $37,562 | 1 | 1 |
| nintedanib / multikinase inhibitors | $25,016 | $25,016 | $62,540 | 5 | 2 |
| canakinumab / interleukin inhibitors | $35,304 | $88,849 | $71,307 | 4 | 2 |
| rituximab / CD20 monoclonal antibodies | $0 | $13,551 | $35,562 | 4 | 2 |
| pegvaliase / miscellaneous metabolic agents | $0 | $34,871 | $34,871 | 1 | 1 |
| dulaglutide / GLP-1 receptor agonists | $340,471 | $371,939 | $374,084 | 418 | 333 |
| amoxicillin / aminopenicillins | $43,985 | $86,389 | $73,243 | 5,178 | 4,876 |
| odevixibat / miscellaneous GI agents | $0 | $0 | $28,971 | 1 | 1 |

## TABLE I: TOP 15 DRUG SOLID DOSAGE FORM HIGH VOLUME (100+ RX FILLS LAST MONTH) PRODUCTS WITH UNIT COST > $1
## BY PERCENT CHANGE IN AMOUNT PAID PER UNIT JUL 2023 TO SEP 2023 (FFS)

| Drug Product<br>Therapeutic Category | Sep 2023 # Claims | Sep 2023 $ Paid | Sep 2023 Avr. Paid Per Rx | Sep 2023 Avr. Units Per Rx | Jul 2023 Paid Per Unit | Aug 2023 Paid Per Unit | Sep 2023 Paid Per Unit | Percent Change |
|---|---|---|---|---|---|---|---|---|
| dexmethylphenidate 10 mg capsule, extended release / CNS stimulants (Y) | 264 | $14,737 | $55.82 | 30 | $1.01 | $1.05 | $1.51 | 49.3% |
| dexmethylphenidate 20 mg capsule, extended release / CNS stimulants (Y) | 206 | $12,421 | $60.30 | 30 | $1.53 | $1.49 | $1.65 | 8.1% |
| Xarelto (rivaroxaban) 20 mg tablet / factor Xa inhibitors (Y) | 137 | $57,453 | $419.36 | 25 | $16.05 | $16.41 | $16.51 | 2.9% |
| Biktarvy (bictegravir/emtricitabine/tenofovir) 50 mg-200 mg-25 mg tablet / antiviral combinations (Y) | 129 | $605,110 | $4,690.77 | 38 | $113.84 | $115.42 | $116.29 | 2.2% |
| Jardiance (empagliflozin) 10 mg tablet / SGLT-2 inhibitors (Y) | 169 | $127,621 | $755.15 | 38 | $18.54 | $18.36 | $18.74 | 1.0% |
| Eliquis (apixaban) 5 mg tablet / factor Xa inhibitors (Y) | 416 | $171,952 | $413.35 | 47 | $8.58 | $8.61 | $8.67 | 1.0% |
| scopolamine 1 mg/72 hr film, extended release / anticholinergics/antispasmodics | 137 | $9,468 | $69.11 | 8 | $7.24 | $7.52 | $7.31 | 1.0% |
| Jardiance (empagliflozin) 25 mg tablet / SGLT-2 inhibitors (Y) | 164 | $128,952 | $786.29 | 40 | $18.08 | $18.03 | $18.19 | 0.6% |
| QuilliChew ER (methylphenidate) 30 mg/24 hr tablet, chewable, extended release / CNS stimulants (Y) | 271 | $98,860 | $364.80 | 30 | $11.77 | $11.77 | $11.81 | 0.3% |
| Suboxone (buprenorphine-naloxone) 8 mg-2 mg film / narcotic analgesic combinations (Y) | 301 | $118,785 | $394.64 | 45 | $8.62 | $8.62 | $8.62 | 0.0% |
| QuilliChew ER (methylphenidate) 40 mg/24 hr tablet, chewable, extended release / CNS stimulants (Y) | 177 | $64,603 | $364.99 | 30 | $11.95 | $11.92 | $11.86 | ( 0.8%) |
| Farxiga (dapagliflozin) 10 mg tablet / SGLT-2 inhibitors (Y) | 239 | $163,821 | $685.44 | 40 | $17.70 | $17.50 | $17.56 | ( 0.8%) |
| QuilliChew ER (methylphenidate) 20 mg/24 hr tablet, chewable, extended release / CNS stimulants (Y) | 374 | $129,376 | $345.92 | 29 | $11.85 | $11.78 | $11.67 | ( 1.5%) |

**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 JUL 2023 TO SEP 2023 (FFS)

| Drug Product<br>Therapeutic Category | Sep 2023 # Claims | Sep 2023 $ Paid | Sep 2023 Avr. Paid Per Rx | Sep 2023 Avr. Units Per Rx | Jul 2023 Paid Per Unit | Aug 2023 Paid Per Unit | Sep 2023 Paid Per Unit | Percent Change |
|---|---|---|---|---|---|---|---|---|
| Slynd (drospirenone) 4 mg tablet / progestins (Y) | 153 | $38,992 | $254.85 | 38 | $6.64 | $6.62 | $6.49 | ( 2.3%) |
| Xulane (ethinyl estradiol-norelgestromin) 35 mcg-150 mcg/24 hr film, extended release / contraceptives (Y) | 1,370 | $153,650 | $112.15 | 3 | $34.80 | $33.81 | $33.42 | ( 4.0%) |

**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**

**August 2023 – November 2023**

Ongoing Intervention(s):

| PROVIDER SHOPPING FOR OPIOIDS (≥4 Prescribers AND ≥4 Pharmacies) | | | | CONCOMITANT USE OF OPIOIDS AND ANTIPSYCHOTICS | | |
|---|---|---|---|---|---|---|
| **Month** | **Prescribers Mailed** | **Pharms Mailed** | **Benes Addressed** | **Month** | **Prescribers Mailed** | **Benes Addressed** |
| 22-Dec | 3 | 3 | 6 | 22-Dec | 27 | 28 |
| 23-Jan | 1 | 1 | 2 | 23-Jan | 19 | 19 |
| 23-Feb | 4 | 4 | 8 | 23-Feb | 14 | 17 |
| 23-Mar | 4 | 2 | 6 | 23-Mar | 16 | 16 |
| 23-Apr | 2 | 2 | 4 | 23-Apr | 9 | 10 |
| 23-May | 6 | 7 | 13 | 23-May | 37 | 40 |
| 23-Jun | 3 | 4 | 7 | 23-Jun | 19 | 21 |
| 23-Jul | 1 | 1 | 2 | 23-Jul | 4 | 4 |
| 23-Aug | 1 | 1 | 2 | 23-Aug | 12 | 13 |
| 23-Sep | 1 | 1 | 2 | 23-Sep | 17 | 17 |
| 23-Oct | 1 | 1 | 2 | 23-Oct | 12 | 12 |
| 23-Nov | 1 | 2 | 3 | 23-Nov | 11 | 11 |

Note: data for all CCOs was incomplete due to issues receiving encounter claims

One-time mailing:

| HORMONE THERAPY DIAGNOSIS EDIT | | |
|---|---|---|
| | Prescribers Mailed | Benes Addressed |
| 23-Oct | 3,730 | NA |

{Date}

**IMPORTANT INFORMATION REGARDING NALOXONE PRESCRIBING AND PATIENT EDUCATION**

Dear Dr. {Prescriber Name},

Despite decreases in opioid prescribing in recent years, opioid-involved overdose deaths continue to rise across the United States. In fact, in Mississippi, overdose deaths due to opioids increased 127% between 2019 and 2021.[1] Opioid antagonists, such as naloxone, can reverse the effects of opioids and prevent opioid-involved deaths. Extensive efforts have been made to increase the accessibility of naloxone for those at risk of opioid overdose. The Mississippi Division of Medicaid (DOM) has multiple naloxone products listed on their Universal Preferred Drug List (UPDL). In 2017, the Naloxone Standing Order Act was passed in Mississippi allowing pharmacists to dispense naloxone without an individual prescription. In December 2022, through the Mississippi Opioid and Substance Use Disorder Program, the Mississippi State Department of Health began distributing naloxone kits free to individuals upon request. Most recently, the first over-the-counter naloxone nasal spray products received FDA approval in early 2023.

Even with extensive efforts to improve naloxone availability, getting naloxone into the hands of individuals needing this life-saving medication has proven to be challenging. A recent study examining naloxone prescription claims among Mississippi Medicaid beneficiaries found that less than 3% of individuals considered to be at high risk for experiencing an adverse opioid event had a prescription claim for naloxone.

We support and encourage the prescribing of naloxone as a rescue medication for patients taking opioids, especially those considered at increased risk of overdose such as individuals prescribed opioids in combination with other psychotropic agents, those prescribed more than one type of opioid, or those prescribed high daily doses of opioids.

**To help facilitate discussions with your patients about naloxone, we have included a flyer that can be duplicated and displayed in your practice. A link to an electronic version can also be found by scanning the QR code below.**

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

[1] Reports and Data - Mississippi State Department of Health. https://msdh.ms.gov/page/44,0,382,740.html#overdose

MISSISSIPPI DIVISION OF MEDICAID

# HAVE YOU BEEN PRESCRIBED OPIOIDS?

## Naloxone Can Save Your Life in the Case of an Opioid Emergency.

### What Is Naloxone?

Naloxone is an agent that can reverse the effects of opioids on your body. This medication can be lifesaving in the event of opioid overdose.

### Did You Know?

Mississippi Medicaid pays for Naloxone and a Statewide Naloxone Standing Order authorizes pharmacists to dispense Naloxone by request. A prescription from a physician/other medical practitioner is not required.

### How Can I Get Naloxone?

Your provider can write you a prescription or you can ask your pharmacist who can dispense Naloxone to you per the standing order and educate you on how to use it.

### Am I At Risk Of Opioid Overdose?

Anyone with an opioid prescription is at risk for an overdose; but especially patients prescribed more than one opioid, high doses of opioids, or opioids in combination with certain other medications. Ask your provider for more information.

### What Are Signs Of Opioid Overdose ?

Shallow or slow breathing, confusion, lessened alertness, bluish lips and nose, and unconsciousness can all be signs of an opioid overdose.

If you cannot afford Naloxone or have reached your Medicaid prescription limit,
Naloxone can be obtained for free through
**ODFREE.ORG.**
*Scan the QR Code for more information*

MISSISSIPPI DIVISION OF MEDICAID

# A MATTER OF LIFE OR DEATH

## Increase Naloxone Access to Patients Under the Naloxone Standing Order

**Did you know?**

The Mississippi Statewide Naloxone Standing Order authorizes pharmacists to dispense naloxone by request. A prescription from a physician/other medical practitioner is not required.

### Why Is This Important?

A recent study found that out of 591 pharmacies in Mississippi, just over 36% had naloxone available to purchase under the standing order.

### How Can Pharmacists Help Increase Access?

- Have Naloxone readily available on your shelf.
- Identify and educate patients at risk for opioid overdose that naloxone is available to purchase by request without a prescription.

### Simple Steps To Dispense:

1. Complete the board approved training and maintain proof.
2. Maintain a copy of the standing order.
3. Reduce the standing order to a prescription. Dispense and file the prescription as a legend medication
4. Provide proper counseling on the use of the medication.

### Per the Standing Order use

Dr. Kathyrn Taylor as prescriber
NPI:1235339516
Interim State Epidemiologist

### FOR MORE INFORMATION

**Scan the QR code to view the current Naloxone Statewide Standing Order and the Naloxone Training required by the MS Board of Pharmacy.**

# PALIVIZUMAB UTILIZATION UPDATE: 2022-2023 SEASON

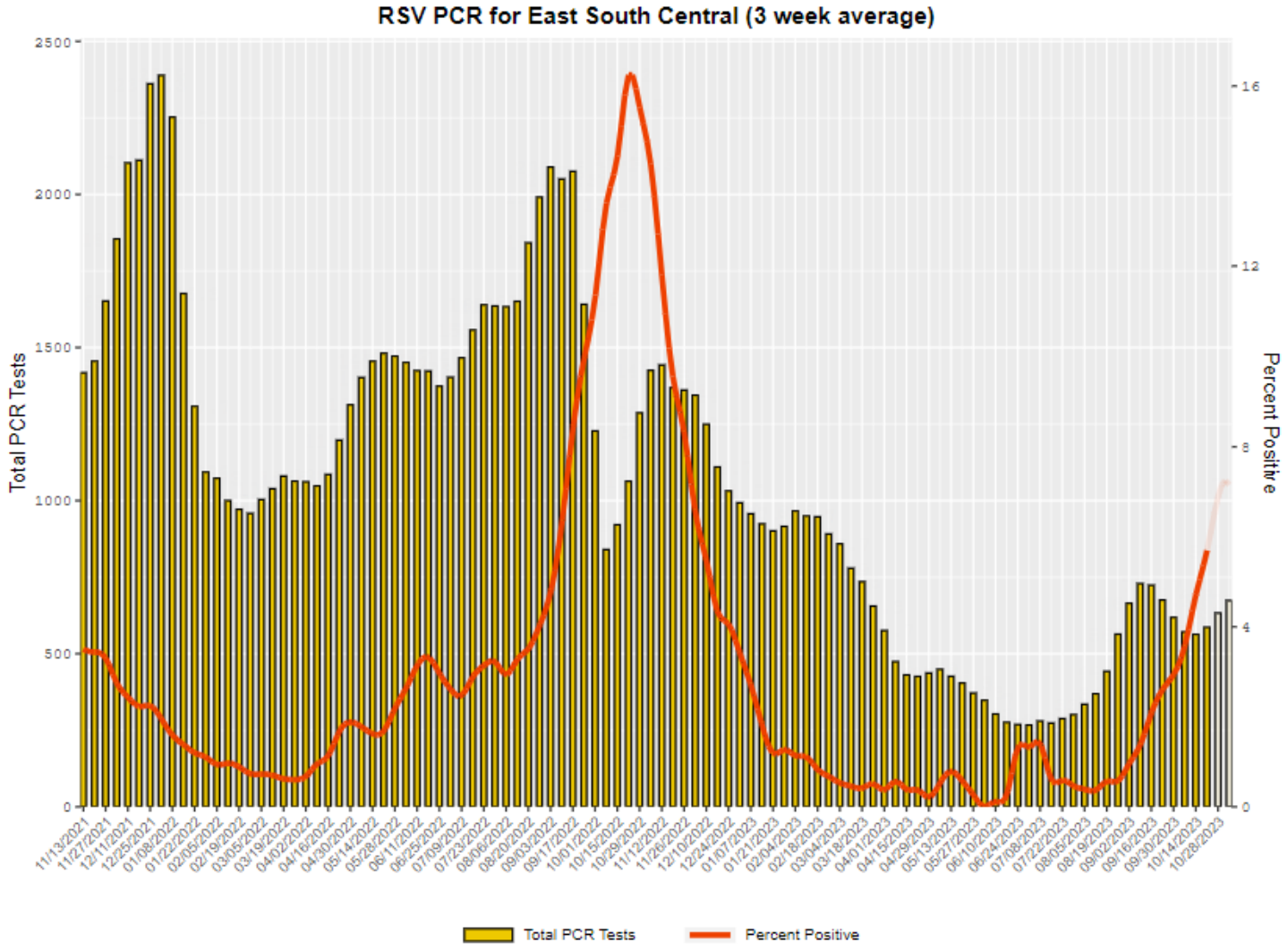
**BACKGROUND**

Respiratory syncytial virus (RSV) is a common respiratory virus typically causing cold-like symptoms, but RSV can be serious for infants and older adults. RSV can lead to the development of bronchiolitis and pneumonia in young children. Annually in the United States (U.S.), it is estimated that RSV leads to 58,000 hospitalizations among children under 5 years of age.[1] Palivizumab (Synagis®) was licensed in June 1998 by the Food and Drug Administration for the prevention of serious lower respiratory tract disease (LRTD) caused by RSV in children at increased risk of severe disease.[2] The Mississippi Division of Medicaid (DOM) has supported the administration of palivizumab for children meeting the American Academy of Pediatrics (AAP) criteria for RSV immunoprophylaxis.

Although palivizumab (Synagis) has been the mainstay of therapy for the prevention of RSV in infants, the FDA recently approved a new, single-dose monoclonal antibody, nirsevimab (Beyfortus).[3] Beyfortus is the first RSV prevention approved to protect all infants in the U.S. during their first RSV season and those up to 24 months who remain vulnerable to severe RSV through their second RSV season and is included in the Vaccines for Children program.[4] In addition to the newly approved Beyfortus, in early 2023 the FDA approved an RSV vaccine (Abryvso) to provide active immunization of pregnant individuals from 32-36 weeks gestational age for the prevention of LRTD caused by RSV in infants.[5,6] Furthermore, Abryvso and another recently approved RSV vaccine, Arexvy, are also indicated for active immunization for the prevention of LRTD caused by RSV in individuals 60 years of age and older.[6,7] With the approval of these new agents for the prevention of RSV-related complications, the therapeutic landscape in this area is rapidly evolving.

Prior to the COVID-19 pandemic, RSV infections in the U.S. routinely occurred during the fall and winter months concurrently with the typical cold and flu seasons beginning around October annually and ending the following March. In recent years, however, RSV infections have not followed traditional patterns. During 2020, RSV activity remained extremely low. In 2021, an unusual interseasonal rise began in late spring and continued through the fall months. Again, during the summer of 2022, RSV cases were reported outside of the typical season. Although the 2022/2023 season began earlier than prepandemic seasons typically occurred, RSV activity showed evidence of shifting back toward prepandemic patterns with no interseasonal spike.[9] (Figure 1)

FIGURE 1: East South Central Division Percent Positive PCR Tests[10]



**PALIVIZUMAB UTILIZATION**

Table 1 displays a summary of beneficiaries and claims associated with palivizumab utilization during state fiscal year (SFY) 2023 (July 1, 2022 – June 30, 2023). A total of 1,353 claims representing 378 unique beneficiaries occurred during SFY 2023.

**TABLE 1. Demographic Summary of Beneficiaries and Claims Associated with Palivizumab Utilization State Fiscal Year 2023 (July 1, 2022 - June 30, 2023)**

| | FFS | UHC | MAG | MOL | *Total* |
|---|---|---|---|---|---|
| Beneficiaries | 19 | 105 | 123 | 131 | ***378*** |
| POS Claims | 73 | 421 | 479 | 380 | ***1,353*** |
| Age at fill (in months) | | | | | |
| <6 | 6 | 148 | 173 | 123 | ***450*** |
| 6-12 | 13 | 225 | 204 | 173 | ***615*** |
| 13-18 | 28 | 40 | 79 | 50 | ***197*** |
| 19-24 | 19 | 8 | 19 | 30 | ***76*** |
| >24 | 7 | 0 | 4 | 4 | ***15*** |
| Race* | | | | | |
| White | 10 | | | | |
| Black | 2 | | | | |
| Other | 61 | | | | |
| Sex** | | | | | |
| Female | 40 | 234 | 240 | 212 | ***726*** |
| Male | 33 | 184 | 239 | 168 | ***624*** |

Notes: FFS = Fee for Service; UHC = United HealthCare; MAG = Magnolia; MOL = Molina
* Race data is not available in CCO claims data.
** 3 beneficiaries were missing a sex variable.

As seen in Table 2, claims for palivizumab began appearing in August 2022 as a result of the early rise in RSV reported during the 2022/2023 season. Palivizumab claims continued through the typical end of RSV season in March 2023.

**TABLE 2. Utilization and Paid Amounts for Palivizumab during State Fiscal Year 2023 (July 1, 2022 - June 30, 2023)**

| | FFS | | UHC | | MAG | | MOL | | *Total* | |
|---|---|---|---|---|---|---|---|---|---|---|
| Fill month | #Claims | Paid | #Claims | Paid | #Claims | Paid | #Claims | Paid | ***#Claims*** | ***Paid*** |
| Jul-22 | 0 | $0 | 0 | $0 | 0 | $0 | 0 | $0 | ***0*** | ***$0*** |
| Aug-22 | 3 | $6,694 | 12 | $35,443 | 22 | $58,254 | 12 | $32,993 | ***49*** | ***$133,384*** |
| Sep-22 | 6 | $15,164 | 29 | $76,406 | 40 | $123,063 | 22 | $72,303 | ***97*** | ***$286,936*** |
| Oct-22 | 5 | $13,410 | 39 | $113,335 | 57 | $163,794 | 33 | $106,622 | ***134*** | ***$397,161*** |
| Nov-22 | 15 | $45,744 | 60 | $165,728 | 62 | $177,205 | 55 | $174,799 | ***192*** | ***$563,476*** |
| Dec-22 | 12 | $37,788 | 61 | $174,294 | 65 | $178,017 | 51 | $161,457 | ***189*** | ***$551,556*** |
| Jan-23 | 10 | $24,398 | 90 | $260,594 | 87 | $252,774 | 77 | $220,501 | ***264*** | ***$758,267*** |
| Feb-23 | 13 | $46,575 | 70 | $202,218 | 75 | $222,938 | 63 | $187,088 | ***221*** | ***$658,819*** |
| Mar-23 | 9 | $22,961 | 60 | $180,472 | 71 | $227,124 | 67 | $200,781 | ***207*** | ***$631,338*** |
| ***Total*** | ***73*** | ***$212,734*** | ***421*** | ***$1,208,490*** | ***479*** | ***$1,403,169*** | ***380*** | ***$1,156,544*** | ***1,353*** | ***$3,980,937*** |

Notes: FFS = Fee for Service; UHC = United HealthCare; MAG = Magnolia; MOL = Molina

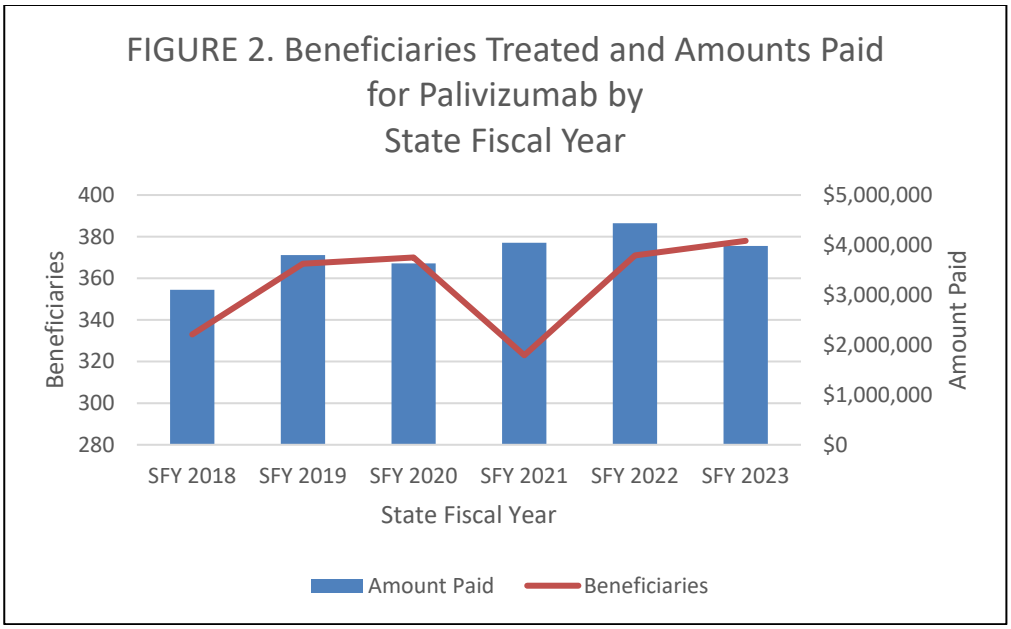
Table 3 shows a summary of palivizumab utilization for the last five SFYs. The total number of beneficiaries treated during SFY 2023 rose slightly compared to the previous year. However, the average paid amount per beneficiary treated dropped slightly compared to SFY 2022 to $10,532 and the total dollars paid decreased to $3,980,937. Trends in the number of beneficiaries treated and the total amounts paid by SFY are presented in Figure 2.

**TABLE 3. Palivizumab Utilization Summary by Season and Pharmacy Program**

| Season | Pharmacy Program | | | | |
|---|---|---|---|---|---|
| | FFS | UHC | MAG | MOL | *Total* |
| **Number of Unique Beneficiaries*** | | | | | |
| SFY 2018 | 18 | 164 | 165 | 0 | ***333*** |
| SFY 2019 | 34 | 155 | 168 | 27 | ***367*** |
| SFY 2020 | 22 | 108 | 101 | 150 | ***370*** |
| SFY 2021 | 22 | 109 | 79 | 131 | ***323*** |
| SFY 2022 | 25 | 126 | 117 | 119 | ***371*** |
| SFY 2023 | 19 | 105 | 123 | 131 | ***378*** |
| **Total Dollars Paid** | | | | | |
| SFY 2018 | $93,812 | $1,283,588 | $1,725,471 | $0 | ***$3,102,871*** |
| SFY 2019 | $270,004 | $1,385,769 | $2,018,792 | $123,795 | ***$3,798,360*** |
| SFY 2020 | $230,222 | $883,547 | $1,023,409 | $1,494,976 | ***$3,632,335*** |
| SFY 2021 | $314,219 | $1,262,651 | $925,021 | $1,542,600 | ***$4,044,491*** |
| SFY 2022 | $252,758 | $1,372,309 | $1,372,113 | $1,438,411 | ***$4,435,591*** |
| SFY 2023 | $212,734 | $1,208,490 | $1,403,169 | $1,156,544 | ***$3,980,937*** |
| **Mean Number of Claims/Beneficiary** | | | | | |
| SFY 2018 | 3.3 | 3.6 | 4.2 | 0 | ***3.7*** |
| SFY 2019 | 4.1 | 4 | 4.8 | 2.3 | ***3.8*** |
| SFY 2020 | 4.3 | 3.6 | 4.1 | 4.3 | ***4.1*** |
| SFY 2021 | 4 | 4.4 | 4.4 | 4.3 | ***4.3*** |
| SFY 2022 | 3.7 | 3.9 | 4.2 | 4.4 | ***4.1*** |
| SFY 2023 | 3.8 | 4 | 3.9 | 2.9 | ***3.6*** |
| **Dollars Paid/Beneficiary** | | | | | |
| SFY 2018 | $5,212 | $7,827 | $10,457 | $0 | ***$9,318*** |
| SFY 2019 | $7,941 | $8,940 | $12,017 | $4,585 | ***$10,350*** |
| SFY 2020 | $10,473 | $8,181 | $10,133 | $9,967 | ***$9,817*** |
| SFY 2021 | $14,283 | $11,584 | $11,709 | $11,776 | ***$12,522*** |
| SFY 2022 | $10,110 | $10,891 | $11,727 | $12,087 | ***$11,956*** |
| SFY 2023 | $11,197 | $11,509 | $11,408 | $8,829 | ***$10,532*** |

Notes: FFS = Fee for Service; UHC = United HealthCare; MAG = Magnolia; MOL = Molina; SFY - state fiscal year

*Some beneficiaries may be enrolled in multiple plans in a particular season; the sum of beneficiaries in each plan may not be equal to the total number of beneficiaries with Synagis utilization.




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

**REFERENCES**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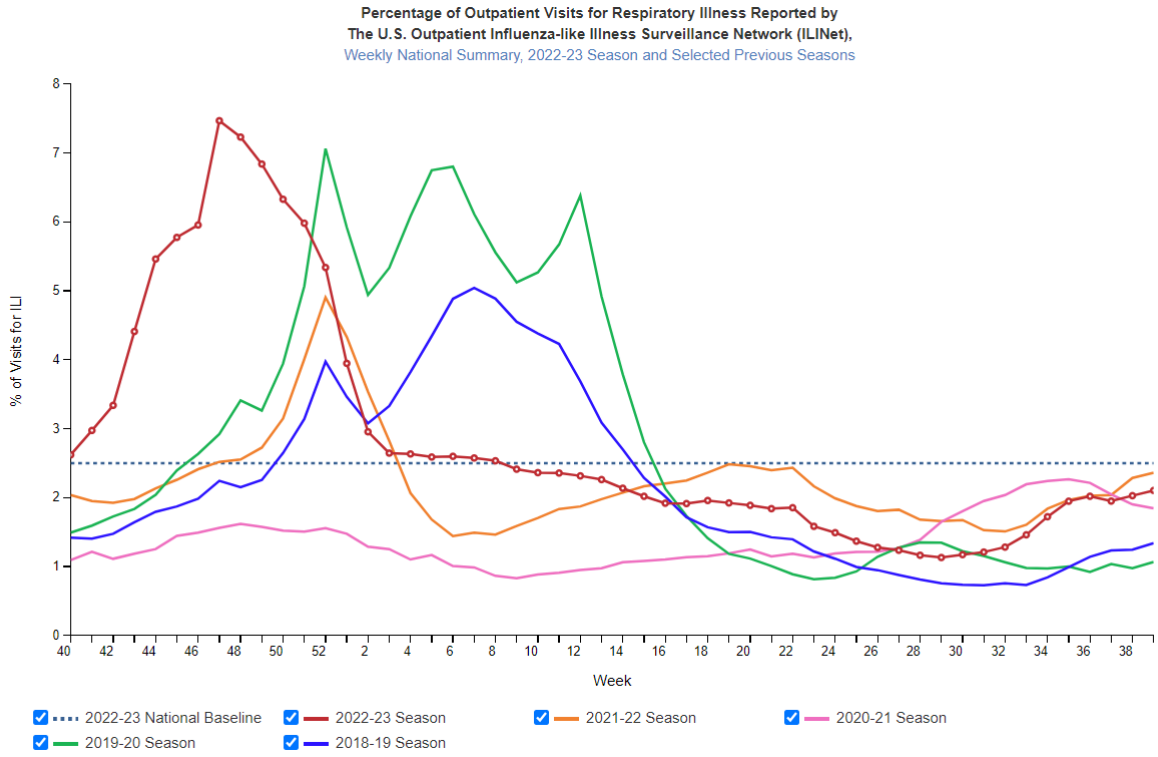
# INFLUENZA VACCINATION AND TREATMENT UPDATE
# 2022-2023 SEASON

## BACKGROUND

Influenza (Flu) is a contagious respiratory illness that can cause mild to severe illness and can even lead to death. While infection from the influenza virus can occur at any time, influenza viruses typically circulate in the United States (US) from late fall through early spring. In recent years, beginning with the COVID-19 pandemic, influenza activity did not follow typical trends. For the 2022-2023 season, influenza activity returned to pre-COVID-19 levels but occurred earlier in the season than traditionally anticipated.[1] Activity for the 2022-2023 season was moderate and the peak of the season occurred between late November to December of 2022.[2] The overall hospitalization rate during the 2022-2023 season was similar to those in the previous 4 seasons.[1]

Figure 1: Nationwide Percent of Visits for Influenza Like-Illness (ILI) [2]



## METHODS

Pharmacy claims data for fee-for-service and all CCOs [UnitedHealthcare (UHC), Magnolia Health (MAG), and Molina Healthcare (MOL)] for influenza vaccines and anti-influenza agents were compiled for state fiscal year (SFY) 2023 (July 1, 2022 to June 30, 2023). Due to issues with the claims data extract, MS-DUR was unable to analyze influenza vaccinations submitted as medical claims for SFY 2023. This analysis included pharmacy claims for influenza vaccines and all anti-influenza agents listed on the MS Division of Medicaid's Universal Preferred Drug List (Tamiflu®, oseltamivir, rimantadine, Rapivab®, Relenza®, Xofluza®). The number of beneficiaries taking these agents, the number of prescriptions filled, and the amounts paid for these claims were determined for SFY 2023.

## RESULTS

Table 1 displays the number of Medicaid beneficiaries who received influenza vaccinations through pharmacy claims during SFY 2023.

- 4,978 beneficiaries were identified in pharmacy claims data.
- FFS had the highest number of claims with Molina having the lowest.
- This number represents a 17% increase in the number of influenza vaccines administered through pharmacy claims compared to SFY 2022 data (Table 1b/Figure 2).[3]

**TABLE 1. Influenza Vaccination Utilization in Mississippi Medicaid for State Fiscal Year 2023 (Point of Sale Pharmacy Claims Only) July 2022 - June 2023**

| Age at time of vaccination | FFS | UHC | MAG | MOL | *Total* |
|---|---|---|---|---|---|
| ≤ 18 years | 269 | 99 | 54 | 0 | ***422*** |
| ≥ 19 years | 1,763 | 1,183 | 1,366 | 244 | ***4,556*** |
| ***Total*** | ***2,032*** | ***1,282*** | ***1,420*** | ***244*** | ***4,978*** |

Notes: FFS = Fee for service, UHC = UnitedHealthcare, MAG = Magnolia, Mol = Molina

**TABLE 1b. Total Influenza Vaccination Utilization by State Fiscal Year (Point of Sale Pharmacy Claims Only) SFY 2021 - SFY 2023**

| Age at time of vaccination | SFY 2021 | SFY 2022 | *SFY 2023* |
|---|---|---|---|
| ≤ 18 years | 116 | 318 | 422 |
| ≥ 19 years | 4,509 | 3,939 | 4,556 |
| ***Total*** | ***4,625*** | ***4,257*** | ***4,978*** |

Notes: FFS = Fee for service, UHC = UnitedHealthcare, MAG = Magnolia, Mol = Molina, SFY = State Fiscal Year

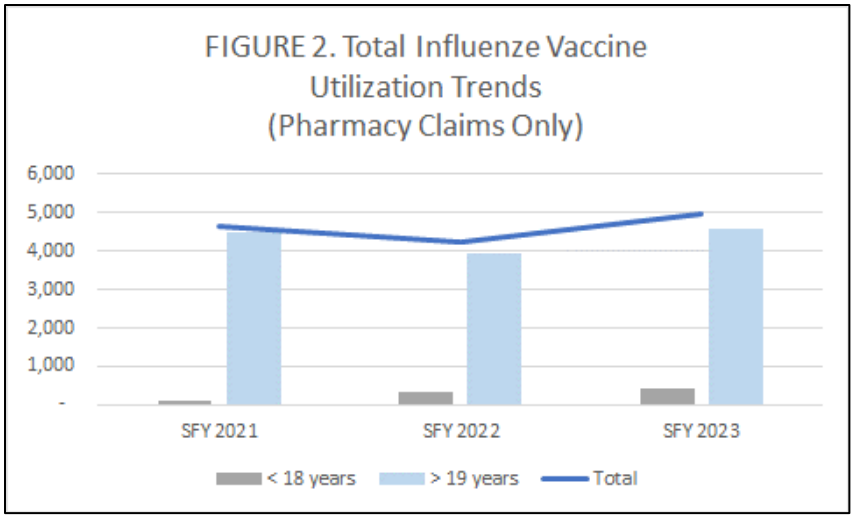



Table 2 displays the number of anti-influenza prescriptions filled, beneficiaries treated, and the amounts paid for each antiviral agent during SFY 2023.

- Number of claims and dollars paid during SFY 2023 were all roughly 3 times the amounts reported for SFY 2022 (Table 2b). While these numbers represent a substantial increase over the previous year, they are in line with numbers reported in years prior to the start of the COVID-19 pandemic.
    - Generic oseltamivir made up over 99% of claims for anti-influenza agents.

**TABLE 2. Utilization of Anti-Influenza Agents in Mississippi Medicaid (July 2022 - June 2023)**

| Drug | Plan | Claims | Beneficiaries | Paid Amount |
|---|---|---|---|---|
| **Oseltamivir Phosphate** | FFS | 25,556 | 22,675 | $1,031,573 |
| | UHC | 20,604 | 19,506 | $867,605 |
| | MAG | 17,218 | 16,790 | $716,097 |
| | MOL | 8,357 | 8,357 | $353,960 |
| **Rimantadine Hydrochloride** | FFS | 0 | 0 | $0 |
| | UHC | 0 | 0 | $0 |
| | MAG | 0 | 0 | $0 |
| | MOL | 0 | 0 | $0 |
| **Tamiflu** | FFS | 5 | 2 | $348 |
| | UHC | 1 | 1 | $158 |
| | MAG | 0 | 0 | $0 |
| | MOL | 1 | 1 | $99 |
| **Xofluza** | FFS | 99 | 88 | $15,721 |
| | UHC | 22 | 21 | $3,137 |
| | MAG | 4 | 4 | $550 |
| | MOL | 1 | 1 | $159 |
| **Grand total (across all plans and drugs)** | | **71,868** | **67,446** | **$2,989,407** |

Note: FFS = Fee-for-Service, UHC = United HealthCare, MAG = Magnolia, MOL = Molina
Other anti-influenza agents, namely Rapivab (peramivir) and Relenza did not have any pharmacy or medical claims during the study period.
Paid amounts represent amount reported on claims as paid to pharmacy. These amounts do not reflect final actual costs after rebates etc.
Total number of beneficiaries may not equal sum of beneficiaries for each product and plan, since certain beneficiaries may have had utilization of multiple products or enrolled in multiple pharmacy plans during the analysis period.

| TABLE 2b. Total Anti-Influenza Agent Utilization by State Fiscal Year (Point of Sale Pharmacy Claims Only) SFY 2021 - SFY 2023 | | | | | | |
|---|---|---|---|---|---|---|
| Drug | SFY 2021 | | SFY 2022 | | SFY 2023 | |
| | Claims | Paid Amount | Claims | Paid Amount | Claims | Paid Amount |
| **Oseltamivir** | 3,028 | $143,188 | 24,094 | $999,044 | 71,735 | $2,969,235 |
| **Rimantadine** | **0** | $0 | 1 | $23 | 0 | $0 |
| **Tamiflu** | **8** | $1,450 | 1 | $57 | 7 | $605 |
| **Xofluza** | **4** | $515 | 33 | $5,024 | 126 | $19,567 |
| ***Total*** | ***3,040*** | ***$145,153*** | ***24,129*** | ***$1,004,148*** | ***71,868*** | ***$2,989,407*** |

Notes: FFS = Fee for service, UHC = UnitedHealthcare, MAG = Magnolia, MoI = Molina, SFY = State Fiscal Year

## CONCLUSIONS AND RECOMMENDATIONS

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

**REFERENCES**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**FDA DRUG SAFETY COMMUNICATIONS**

**September 2023 – November 2023**

- 11/28/2023 FDA warns of rare but serious drug reaction to the antiseizure medicines levetiracetam (Keppra, Keppra XR, Elepsia XR, Spritam) and clobazam (Onfi, Sympazan).

# FDA Drug Safety Communication

FDA warns of rare but serious drug reaction to the antiseizure medicines levetiracetam (Keppra, Keppra XR, Elepsia XR, Spritam) and clobazam (Onfi, Sympazan)

*Seek immediate medical attention if unexplained rash, fever, or swollen lymph nodes develop*

**11-28-2023 FDA Drug Safety Communication**

**What safety concern is FDA announcing?**

The U.S. Food and Drug Administration (FDA) is warning that the antiseizure medicines levetiracetam (Keppra, Keppra XR, Elepsia XR, Spritam) and clobazam (Onfi, Sympazan), can cause a rare but serious reaction that can be life-threatening if not diagnosed and treated quickly. This reaction is called Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). It may start as a rash but can quickly progress, resulting in injury to internal organs, the need for hospitalization, and even death. As a result, we are requiring warnings about this risk to be added to the prescribing information and patient Medication Guides for these medicines.

This hypersensitivity reaction to these medicines is serious but rare. DRESS can include fever, rash, swollen lymph nodes, or injury to organs including the liver, kidneys, lungs, heart, or pancreas.

**What is FDA doing?**

We are requiring manufacturers of these medicines to add new warnings about DRESS to the prescribing information and the Medication Guide for patients and caregivers. For levetiracetam (Keppra, Keppra XR, Elepsia XR, and Spritam), this involves adding a new warning in the *Warnings and Precautions* section of the prescribing information, which describes the most serious and significant potential safety issues.[1] Currently the symptoms associated with this condition are described less prominently. For clobazam (Onfi and Sympazan), we are requiring a new warning specifically about DRESS to be added to the prescribing information. Symptoms related to this risk are already described more generally in other sections of the clobazam prescribing information.

The warnings for both levetiracetam and clobazam medicines will include information that early symptoms of DRESS such as fever or swollen lymph nodes can be present even when a rash cannot be seen. This is different from other serious skin-related reactions that can happen with these medicines and where a rash is present early on, including Stevens-Johnson Syndrome (SJS) and toxic epidermal necrolysis (TEN). We are also requiring information on this risk to be added to the Medication Guides to help inform patients and caregivers about this risk.

**What are levetiracetam (Keppra, Keppra XR, Elepsia XR, Spritam) and clobazam (Onfi, Sympazan), and how can these medicines help me?**

Levetiracetam is an antiseizure medicine approved for use alone or with other medicines to control certain types of seizures. It has been FDA-approved for 24 years and is available in multiple formulations under the brand names Keppra, Keppra XR, Elepsia XR, and Spritam, and as generics.

Clobazam is a type of medicine called a benzodiazepine that is FDA-approved for use with other

[1] https://www.fda.gov/about-fda/oncology-center-excellence/how-do-i-use-prescription-drug-labeling#Section-5

medicines to control seizures associated with a specific severe form of epilepsy called Lennox-Gastaut Syndrome. Benzodiazepines are a class of medicines that depress the central nervous system. DRESS and other serious skin reactions reported with clobazam have generally been associated only with clobazam and not with other benzodiazepines. Clobazam has been FDA-approved for 12 years. It is available in multiple formulations under the brand names Onfi and Sympazan, and as generics.

**What should patients and caregivers do?**

Do not stop taking levetiracetam or clobazam without talking with your health care professional. Stopping these medicines suddenly can lead to uncontrolled seizures. It is important to seek immediate medical attention for DRESS. Patients who develop any unusual symptoms or reactions, including a rash, at any time while taking levetiracetam or clobazam should go to an emergency room immediately. Fever with a rash and swollen lymph nodes or swelling in the face are common with DRESS, but some patients may not develop a rash. Symptoms of DRESS generally start 2 weeks to 8 weeks after starting on the medicine, but these symptoms may occur earlier or later. A physical examination, laboratory blood tests, and other evaluations are used to diagnose DRESS.

**What should health care professionals do?**

Health care professionals should be aware that prompt recognition and early treatment is important for improving DRESS outcomes and decreasing mortality. Diagnosis is often difficult because early signs and symptoms such as fever and swollen lymph nodes may be present without evidence of a rash. DRESS can develop 2 weeks to 8 weeks after starting the medicines, and symptoms and intensity can vary widely. DRESS can also be confused with other serious skin reactions such as SJS and TEN. Advise patients of the signs and symptoms of DRESS and to stop taking their medicine and seek immediate medical attention if DRESS is suspected during treatment with levetiracetam or clobazam.

**What did FDA find?**

FDA's cumulative review found serious cases of DRESS in children and adults worldwide (32 for levetiracetam and 10 for clobazam, see Data Summary). Most patients in these cases required hospitalization and received medical treatments, and two patients treated with levetiracetam died. These numbers include only reports submitted to FDA* and found in the medical literature, so there are likely additional cases about which we are unaware. We determined there was reasonable evidence that levetiracetam** and clobazam± were the cause of DRESS in these cases based on the timing of the onset of these events after receiving the medicines and the order in which they occurred. The majority of cases for which information about discontinuation was available reported that DRESS symptoms improved when the medicines were discontinued.

*The cases were reported to the FDA Adverse Event Reporting System (FAERS) database.
**We previously communicated safety information associated with levetiracetam in December 2008 (suicidal behavior and ideation and antiepileptic drugs).
±We previously communicated safety information associated with clobazam in August 2016 (serious risks and death when combining opioid pain or cough medicines with benzodiazepines), September 2017 (caution about withholding opioid addiction medicines from patients taking benzodiazepines or CNS depressants), and December 2013 (rare but serious skin reactions called SJS and TEN).

**What is my risk?**

All medicines have side effects even when used correctly as prescribed. It is important to know that people respond differently to all medicines depending on their health, the diseases they have, genetic factors, other medicines they are taking, and many other factors. As a result, we cannot determine how likely it is that someone will experience DRESS, a rare but serious reaction, when taking levetiracetam or

clobazam. Your health care professional knows you best, so talk to them if you have questions or concerns about the risks of taking these medicines.

**How do I report side effects from levetiracetam or clobazam?**
To help FDA track safety issues with medicines, we urge patients and health care professionals to report side effects involving levetiracetam or clobazam, or other medicines, to the FDA MedWatch program using the information in the "Contact FDA" box at the bottom of this page.

**How can I get new safety information on medicines I'm prescribing or taking?**
You can sign up for email alerts about Drug Safety Communications on medicines or medical specialties of interest to you.

**Facts about Levetiracetam (Keppra, Keppra XR, Elepsia XR, Spritam)**

- Levetiracetam is an antiseizure medicine indicated for use alone or together with other medicines to control certain types of seizures in adults and children such as partial seizures, myoclonic seizures, or tonic-clonic seizures.
- Levetiracetam is available as a liquid solution, immediate- and extended-release tablets, and a tablet that must be dissolved in a small amount of water on the tongue.
- Common side effects of levetiracetam include unusual irritability or aggression, confusion, loss of balance or coordination, and extreme drowsiness.
- In 2022, an estimated 12 million levetiracetam prescriptions were dispensed from U.S. outpatient pharmacies.[1]

**Facts about Clobazam (Onfi, Sympazan)**

- Clobazam is a benzodiazepine indicated for use in combination with other medicines to control seizures in adults and children 2 years and older who have a specific severe form of epilepsy called Lennox-Gastaut syndrome.
- Clobazam is available as a tablet and a liquid suspension (a powder mixed in a liquid) taken by mouth, and as a film applied on the tongue to dissolve.
- Common side effects of clobazam include difficulty speaking or swallowing, tiredness, change in appetite, and problems with muscle control or coordination.
- In 2022, an estimated 779,000 clobazam prescriptions were dispensed from U.S. outpatient pharmacies.[1]

**Additional Information for Patients and Caregivers**

- The medicines levetiracetam (Keppra, Keppra XR, Elepsia XR, Spritam) and clobazam (Onfi, Sympazan) prescribed to reduce seizures have been associated with a rare but serious reaction called Drug Reaction with Eosinophilia and Systemic Symptoms, or DRESS.
- This serious sensitivity is a reaction of the immune system that can cause severe swelling (inflammation)) throughout the body, or injury to organs, including the liver, kidneys, lungs, heart, or pancreas. It can lead to hospitalization and damage or failure of these organs and may progress to death, especially if treatment is delayed.
- Do not stop taking your levetiracetam or clobazam medicines without first talking to your health care professional. Stopping suddenly can cause uncontrolled seizures.
- Signs and symptoms of DRESS have been reported to occur 2 weeks to 8 weeks after starting to take levetiracetam or clobazam, but may occur earlier or later.

- Call your health care professional and seek immediate medical attention if you develop any of the following symptoms at any time while taking levetiracetam or clobazam:
    - Fever
    - Swollen lymph nodes
    - Sore throat
    - Skin rash (may or may not be present)
    - Swelling of your face, or eyes
    - Painful sores in the mouth or around your eyes
    - Trouble swallowing or breathing
    - Yellowing of your skin or eyes
    - Unusual bruising or bleeding
    - Severe fatigue or weakness
    - Shortness of breath or exercise intolerance
    - Severe muscle pain
- Read the patient Medication Guide every time you receive a prescription for your medicines because there may be new or important additional information about them. The Medication Guide explains the important things you need to know about the medicine. These include the side effects, what the medicine is used for, how to take and store it properly, and things to watch for when you are taking the medicine.
- To help FDA track safety issues with medicines, report side effects from levetiracetam or clobazam, or other medicines, to the FDA MedWatch program using the information in the "Contact FDA" box at the bottom of this page.
- You can sign up for email alerts about Drug Safety Communications on medicines and medical specialties of interest to you.

**Additional Information for Health Care Professionals**

- Levetiracetam (Keppra, Keppra XR, Elepsia XR, Spritam) and clobazam (Onfi, Sympazan) have been associated with a rare but serious and potentially life-threatening sensitivity reaction called Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) that typically occurs 2 weeks to 8 weeks after starting these medicines.
- This reaction can cause severe inflammation and organ injury throughout the body that may require hospitalization or lead to death, particularly if diagnosis and treatment are delayed. Eosinophilia is often but not always present.
- We are requiring the risk of DRESS to be added to the *Warnings and Precautions* sections of the prescribing information and to the Medication Guides. The risk of DRESS is currently in the Adverse Reactions; Postmarketing Experience section of the levetiracetam prescribing information, and symptoms related to this risk are already described more generally in other sections of the clobazam prescribing information.
- When prescribing levetiracetam or clobazam, inform patients about the risk of DRESS.
- Explain the signs and symptoms of DRESS and tell patients when to seek immediate medical care if any of these occur.
- DRESS consists of a combination of the following:
    - Cutaneous reaction (such as generalized rash or exfoliative dermatitis, which may or may not be present)
    - Eosinophilia
    - Fever

  - Lymphadenopathy
  - One or more systemic complications such as hepatitis, myocarditis, pericarditis, pancreatitis, nephritis, and pneumonitis
- If DRESS is suspected, discontinue levetiracetam or clobazam immediately and restart only if an alternative etiology for the signs or symptoms cannot be established.
- Important ways to manage DRESS are early recognition, discontinuation of the offending agent as soon as possible, supportive care, and/or other interventions commonly used to treat DRESS such as systemic corticosteroids.
- Encourage patients to read the Medication Guide they receive with their prescriptions because there may be new or important additional information about the medicine.
- To help FDA track safety issues with medicines, report adverse events involving levetiracetam or clobazam, or other medicines, to the FDA MedWatch program using the information in the "Contact FDA" box at the bottom of this page.
- You can sign up for email alerts about Drug Safety Communications on medicines and medical specialties of interest to you.

**Data Summary**

FDA reviewed worldwide cases of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) associated with levetiracetam and clobazam in children and adults reported to the FDA Adverse Event Reporting System (FAERS) database and found in the medical literature.

**Levetiracetam**

A search of FAERS and the medical literature through March 2023 identified 32 serious cases of DRESS worldwide. Three cases occurred in the U.S. and 29 abroad. In all 32 cases, the patients were hospitalized and received medical treatment; in two cases the patients died. The median time to onset was 24 days (range 7 to 170 days). The reported signs and symptoms included skin rash (n=22), fever (n=20), eosinophilia (n=17), lymph node swelling (n=9), and atypical lymphocytes (n=4). Twenty-two cases reported injury to one or more organs, including the liver (n=20), lungs (n=4), kidneys (n=3), and gallbladder (n=1). Twenty-five of the 29 cases for which information on treatment discontinuation was available reported that DRESS symptoms resolved when levetiracetam was discontinued.

**Clobazam**

A search of FAERS and the medical literature through July 2023 identified 10 serious cases of DRESS worldwide, one in the U.S. and nine abroad. In all 10, the patients were hospitalized and received medical treatment. No deaths were reported. The median time to onset was 21.5 days (range 7 to 103 days). The reported signs and symptoms included skin rash (n=10), fever (n=8), eosinophilia (n=7), facial swelling (n=7), leukocytosis (n=4), lymph node swelling (n=4), and leukopenia/thrombocytopenia (n=1). Nine cases reported injury to one or more organs, including the liver (n=7), kidneys (n=3), and gastrointestinal tract (n=1). DRESS symptoms resolved in all 10 when clobazam was discontinued. DRESS and other serious skin reactions reported with clobazam have not generally been associated with other benzodiazepines.

**Reference**

1. IQVIA. U.S. National Data, National Prescription Audit (NPA) database. Data Extracted November 2023. https://www.iqvia.com/insights/the-iqvia-institute/available-iqvia-data

**Related Information**

- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)
- Seizures
- The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective
- Think It Through: Managing the Benefits and Risks of Medicines

# APPENDIX


# Division of Medicaid
# Drug Utilization Review Board
# By-Laws

## Article I. Purpose

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

## Article II. Membership

### Section 1 – Board Composition

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

## Section 2 – Appointment selection methodology

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

## Section 3 - Term of Office

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

## Section 4 - Attendance

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

## Section 5 - Resignation

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

## Section 6 - Removal

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

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

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

### Section 7 - Board Officers

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

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

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

### Section 8 – Reimbursement

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

## Article III. Meetings

### Section 1 – Frequency

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

### Section 2 – Regular Meetings

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

### Section 3 – Special Meetings

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

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

### Section 4 – Meeting Notice

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

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

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

## Section 5 – Meeting Sign-In

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

## Section 6 – Quorum

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

## Section 7 – Voting

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

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

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

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

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

## Section 8 – Minutes

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

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

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

## Section 9 – Speakers & Special Topics

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

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

## Section 10 – Executive Session

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

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

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

### Section 11 – Conduct of Participants

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

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

## Article IV. Public Participation

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

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

## Article V. Conflicts of Interest

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

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

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

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

## Article VI. Confidentiality

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

## Article VII. Amendments

### Proposed Amendments of By-Laws

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

# MS-DUR BOARD
# COMMON ABBREVIATIONS

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