North Dakota Medicaid
Drug Utilization Review Board Meeting
September 3, 2025
Conference Room 210/212

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Meeting Notice

North Dakota Medicaid Drug Use Review Board

Wednesday, September 3rd, 2025
1:00 p.m. to 4:00 p.m. CT

In-Person Information

Conference Room 210/212, 2nd Floor, Judicial Wing, State Capitol
600 e. Boulevard Ave. Bismarck ND, 58505

Virtual Information

Join by computer: Click here to join the meeting
Join by phone: 701-328-0950, Conference ID #227 173 260 751

Agenda

- Call to Order
- Roll Call
- Review and Approval of Minutes
- Reports from Department
    - Administrative Report: Member Updates, Core Measures, PDMP, Utilization Review
    - Financial Report: Top Drugs
    - Retrospective DUR Report
    - Clinical Report:
        - Prior Authorization Update
        - Criteria updates: Bullous Pemphigoid, Chronic Kidney Disease, Giant Cell Arteritis (Temporal Arteritis), Uveitis
- Unfinished Business – 5th psychotropics RDUR letter discussion follow up
- New business
    - Second Review of Non-Opioid Analgesia
    - First Review of ANCA-Associated Vasculitis
    - First Review of Niemann-Pick Type C
    - Review of retrospective DUR criteria recommendations
    - Provider suggestions for clinical practice education or RDUR ICER criteria
- Announcements: Next Meeting (December 3, 2025)
- Adjourn

Individuals who need accommodations in order to participate or who would like information about joining the meeting can contact Ashley Gerving at 701-328-2354, 711 (TTY) or gervingashley@nd.gov.

Date Posted: 02/11/2025
Date Revised: 08/07/2025 (agenda/meeting details added)

Meeting Minutes

North Dakota Medicaid Drug Use Review (DUR) Board
Meeting Date: June 4th, 2025
Time and Location: 1:00 pm CST in Bismarck, North Dakota

Call to Order:
A regular quarterly meeting of the North Dakota Medicaid Drug Use Review (DUR) Board meeting was convened at 1:13 pm CST with T. Schmidt presiding as Presiding Officer. DUR Board Coordinator, J. McKee recording minutes.

Roll Call:
Board Members Voting:
Present: Stephanie Antony, Gabriela Balf, Amanda Dahl, Kurt Datz, Andrea Honeyman, Laura Kroetsch, Kevin Martian, Kristen Peterson, Tanya Schmidt, Amy Werremeyer, Jessica Ziegler, Matthew Zimny
Absent:
Quorum Present: Yes

Board Members Non-Voting: Kathleen Traylor
Absent:

Medicaid Pharmacy Department:
Present: Jeff Hostetter, Brendan Joyce, Alexi Murphy, LeNeika Roerich, Katie Steig
Absent:
Approval of Meeting Minutes:
Motion: Moved by M. Zimny to approve the minutes of the March 5, 2025 meeting, motion was seconded by K. Datz. **Motion carried.**
The minutes of the March 5, 2025, meeting were approved as distributed.

Reports:
Administrative Report: B. Joyce
B. Joyce introduced Dr. Matthew Zimny to the board and announced that this was the last board meeting for Tanya Schmidt as she is rolling off of the board.

Financial Report: Budget provided by B. Joyce
B. Joyce shared with the Board trends of reimbursement amount vs net spend for pharmacy drug claims. This information can be found in the handout.

Financial Report: Top Drugs provided by B. Joyce
B. Joyce presented the quarterly review of the top 25 drugs based on total number and cost of claims and the top 15 therapeutic classes based on number and cost of claims. This report can be found in the handout.

Retrospective Drug Utilization Review (RDUR) Report by J. McKee
J. McKee reviewed the quarterly RDUR criteria that were selected for review of each month and information from a targeted mailing. This material can be found in the handout.

Clinical Report and Annual PDL Review: Prior Authorization and Criteria Updates by J. McKee
J. McKee presented prior authorization and criteria updates with emphasis on the following sections in the PDL: Amyloidosis, Chronic Kideny Disease, Hemophilia

New business:

Special Orders: Presiding office and Vice-presiding Officer Elections.

*Kevin Martian was nominated for Presiding officer. Motion m*oved by M. Zimny and seconded by A. Werremeyer. **Motion carried**
Kurt Datz nominated for Vice-Presiding Officer. Motion moved by K. Martian and seconded by M. Zimny. **Motion carried.**

Second Reviews presented by J. McKee
J. McKee presented group prior authorization criteria for Diabetes Mellitus
Motion: Moved by K. Datz to place Diabetes Mellitus on prior authorization, motion was seconded by K. Martian. **Motion carried.**

First Reviews presented by J. McKee
J. McKee presented an overview of Non-Opioid Analgesics. The presented material can be found in the handout.
Motion: Moved by K. Datz to draft prior authorization for Non-Opioid Analgesics, motion was seconded by L. Kroetsch. **Motion carried.**

Retrospective Drug Utilization Review (RDUR) Criteria Recommendations:
RDUR criteria recommendations were reviewed. The presented material can be found in the handout.
Motion: Moved by K. Martian to approve the RDUR criteria, motion was seconded by M. Zimny. **Motion carried.**

Announcements:
Next meeting is September 3rd, 2025.

Adjournment:
Meeting adjourned by T. Schmidt at 2:34 pm CST.

Date of Minutes Approval:
Minutes submitted by: Julie McKee, Acentra Health

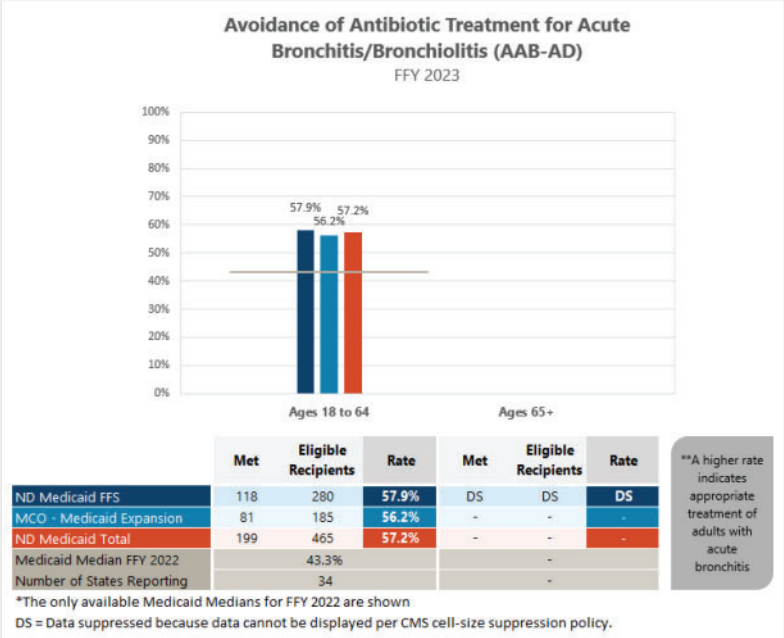
Administrative Report

New Members- Paige Adkins

Migraine Prophylaxis Utilization Review
Since July 2024

Type of Prophylaxis	ER visits use due to Migraine	Average Qty of Rescue Doses
Non-CGRP	1 person in July 2024	34.0
CGRP		58.5

Core Measures / Quality Measures



	Met	Eligible Recipients	Rate	Met	Eligible Recipients	Rate
ND Medicaid FFS	118	280	57.9%	DS	DS	DS
MCO - Medicaid Expansion	81	185	56.2%	-	-	-
ND Medicaid Total	199	465	57.2%	-	-	-
Medicaid Median FFY 2022		43.3%			-	
Number of States Reporting		34			-	

**A higher rate indicates appropriate treatment of adults with acute bronchitis

*The only available Medicaid Medians for FFY 2022 are shown

DS = Data suppressed because data cannot be displayed per CMS cell-size suppression policy.

MEASURE DESCRIPTION

This measure shows a percentage of episodes for adults ages 18 and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.

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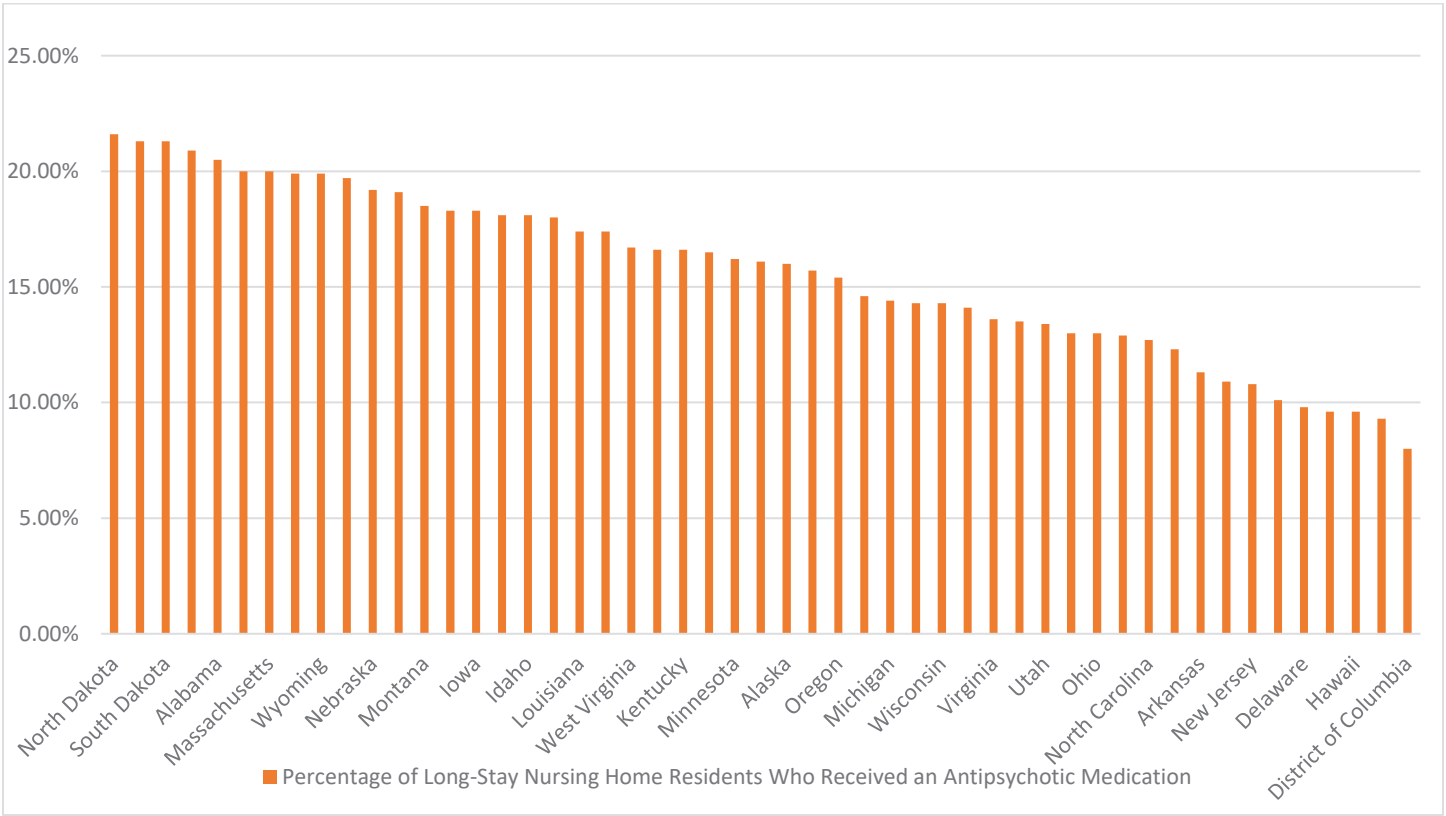
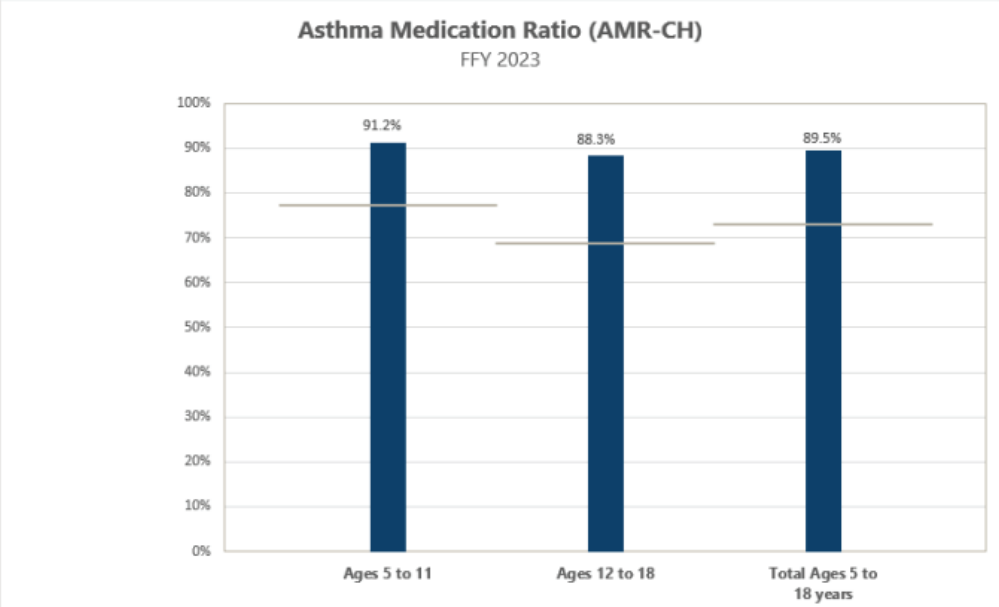
Percentage of Long-Stay Nursing Home Residents Who Received an Antipsychotic Medication





	Met	Eligible Recipients	Rate	Met	Eligible Recipients	Rate	Met	Eligible Recipients	Rate
ND Medicaid FFS	134	147	**91.2%**	189	214	**88.3%**	323	361	**89.5%**
Medicaid Median FFY 2022		77.3%			68.8%			73.1%	
Number of States Reporting		47			47			48	

MEASURE DESCRIPTION

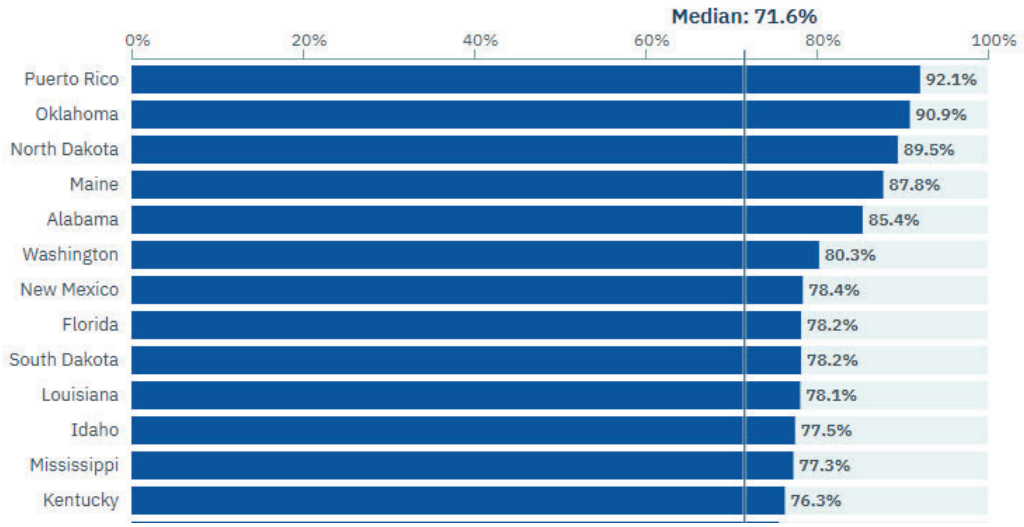
This measure shows the percentage of children ages 5 to 18 with persistent asthma and were dispensed appropriate asthma controller medications during the measurement year.

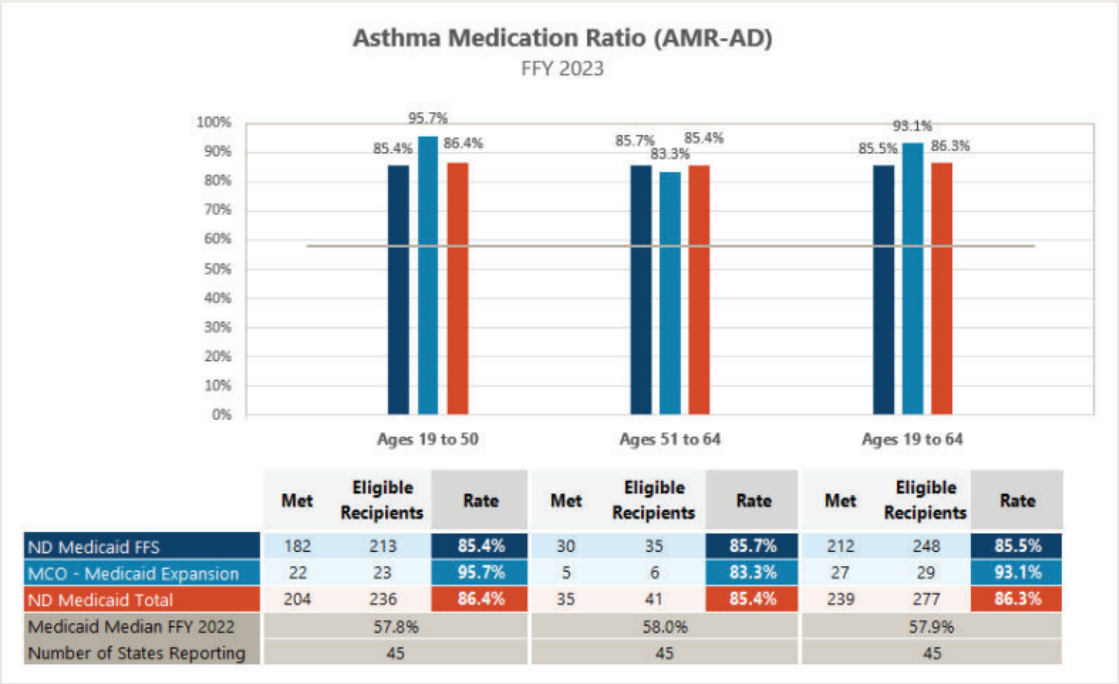
ASTHMA MEDICATION RATIO: AGES 5 TO 18 (AMR-CH)

Percentage with Persistent Asthma who had a Ratio of Controller Medications to Total Asthma Medications of 0.50 or Greater: Ages 5 to 18

Age: **Total (Ages 5-18)**
Population: **All states view (mixed populations)**
Methodology: **Administrative**
Core Set Year: **2023**

Sort by: Alphabetical **Values: High to Low** Values: Low to High





	Met	Eligible Recipients	Rate	Met	Eligible Recipients	Rate	Met	Eligible Recipients	Rate
ND Medicaid FFS	182	213	85.4%	30	35	85.7%	212	248	85.5%
MCO - Medicaid Expansion	22	23	95.7%	5	6	83.3%	27	29	93.1%
ND Medicaid Total	204	236	86.4%	35	41	85.4%	239	277	86.3%
Medicaid Median FFY 2022		57.8%			58.0%			57.9%	
Number of States Reporting		45			45			45	

MEASURE DESCRIPTION

This measure assesses the percentage of adults with persistent asthma who were dispensed appropriate asthma controller medications by the percentage of beneficiaries ages 19 to 64 who were identified as having persistent asthma and had a ratio of controller medications to total asthma medications of 0.50 or greater during the measurement year.

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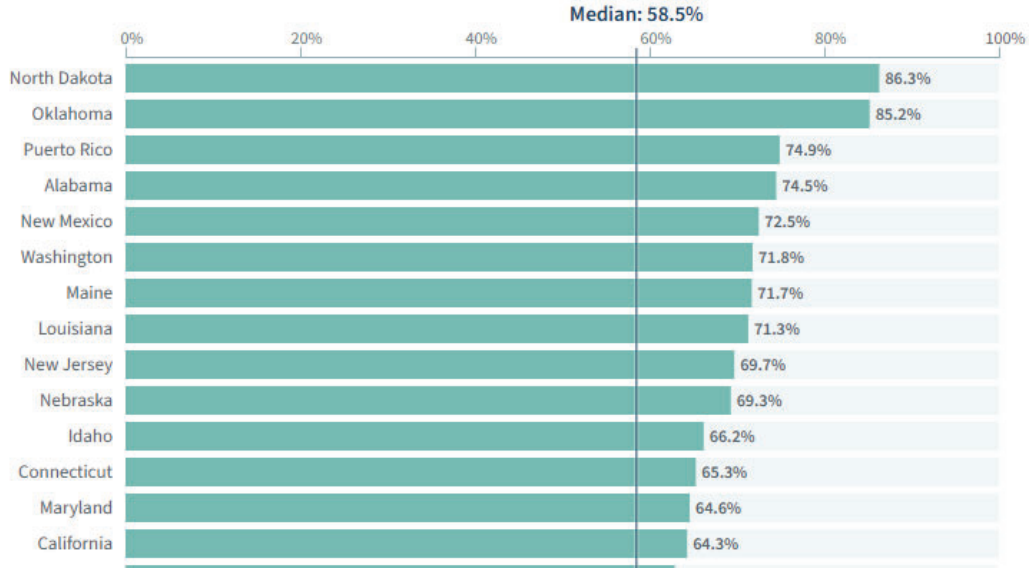
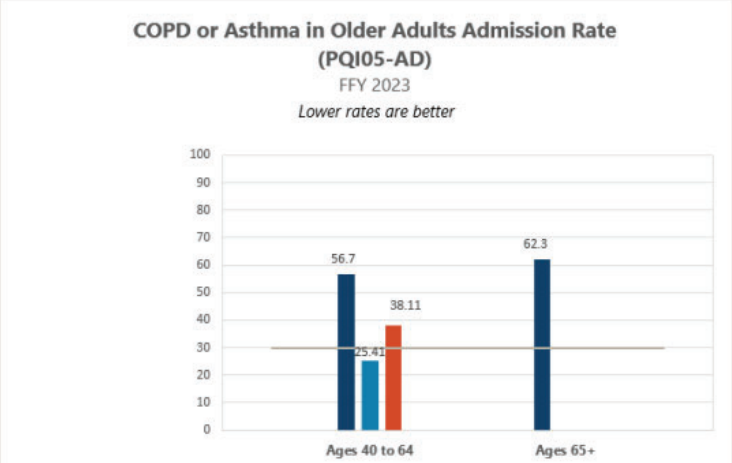
ASTHMA MEDICATION RATIO: AGES 19 TO 64

Percentage with persistent asthma who were dispensed appropriate asthma controller medications

Age: **Total (Ages 19 to 64)**
Population: **All states view (mixed populations)**
Methodology: **Administrative**
Core Set Year: **2023**

Sort by: Alphabetical **Values: High to Low** Values: Low to High





	Admits	Member Months	Rate	Admits	Member Months	Rate
ND Medicaid FFS	67	118,150	**56.7**	57	91,565	**62.3**
MCO - Medicaid Expansion	44	173,128	**25.41**	-	-	-
ND Medicaid Total	111	291,278	**38.11**	-	-	-
Medicaid Median FFY 2022	29.8					
Number of States Reporting	34					

MEASURE DESCRIPTION

This measure assesses the frequency of hospital admissions to treat COPD or asthma among Medicaid adults ages 40 and older by the number of inpatient hospital admissions for chronic obstructive pulmonary disease (COPD) or asthma per 100,000 beneficiary months for beneficiaries ages 40 and older.

Note: A lower rate indicates better performance.

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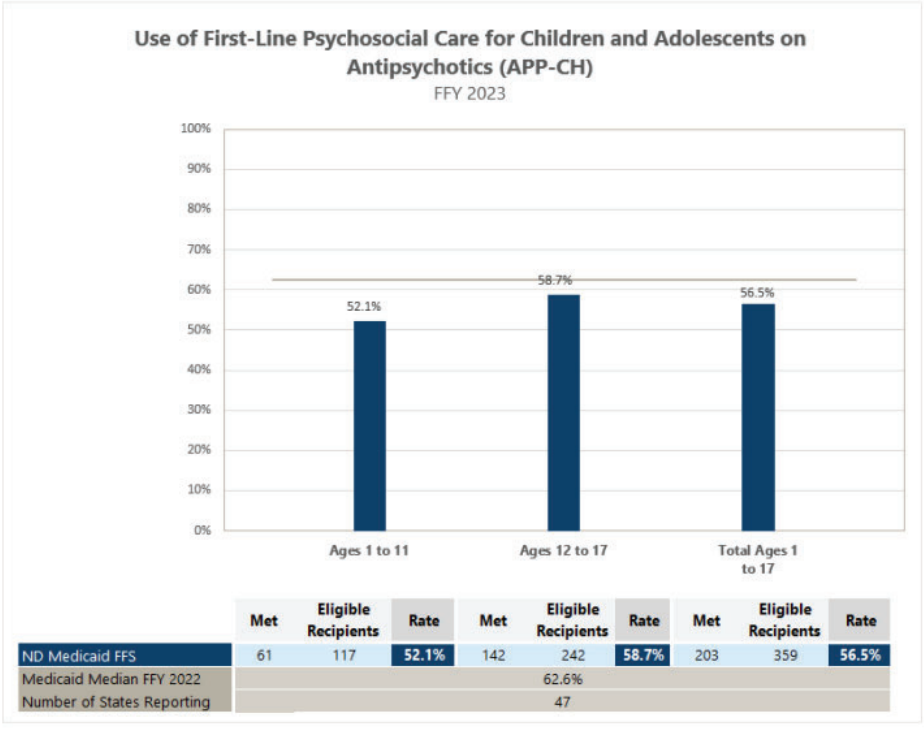
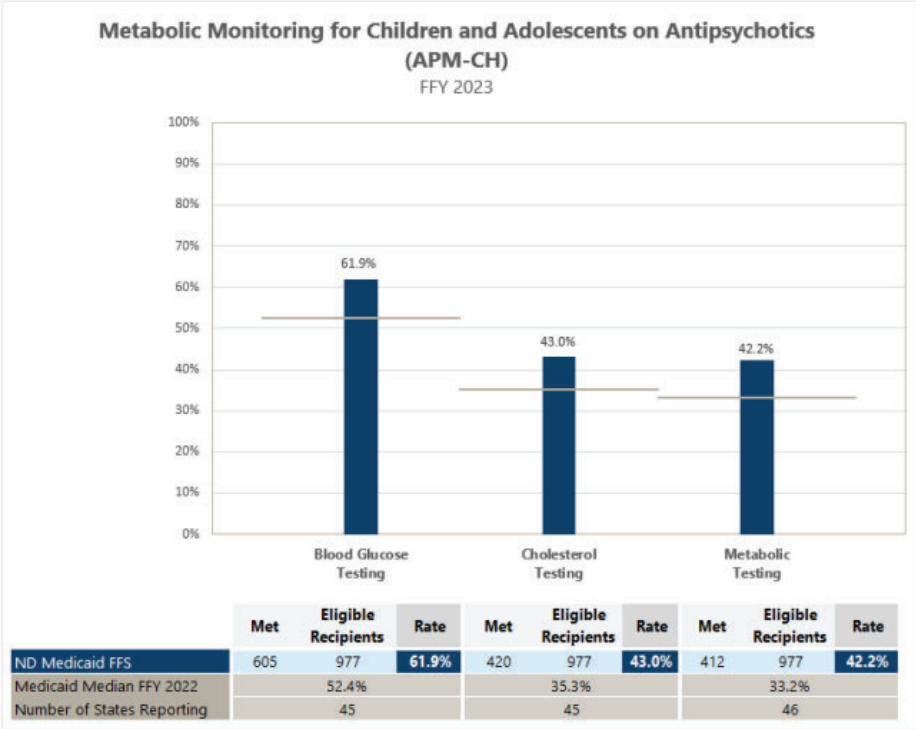


	Met	Eligible Recipients	Rate	Met	Eligible Recipients	Rate	Met	Eligible Recipients	Rate
ND Medicaid FFS	61	117	**52.1%**	142	242	**58.7%**	203	359	**56.5%**
Medicaid Median FFY 2022	62.6%								
Number of States Reporting	47								

MEASURE DESCRIPTION

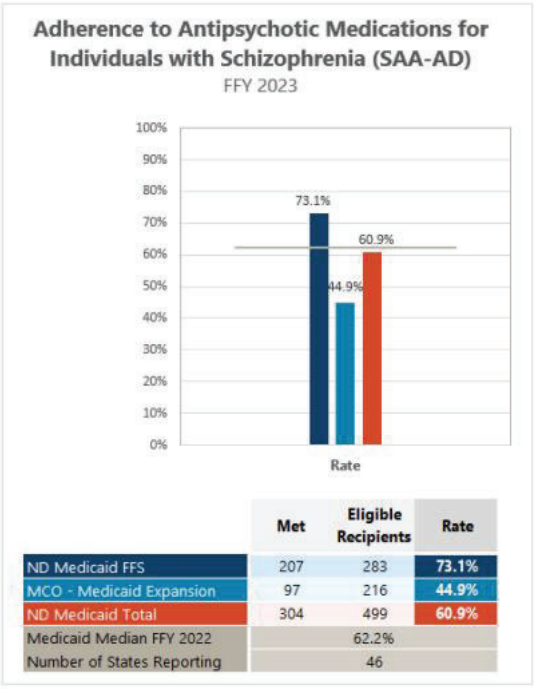
This measure assesses the percentage of children and adolescents ages 1 to 17 who had a new prescription for an antipsychotic medication *and had documentation* of psychosocial care as first-line treatment.



	Met	Eligible Recipients	Rate	Met	Eligible Recipients	Rate	Met	Eligible Recipients	Rate
ND Medicaid FFS	605	977	61.9%	420	977	43.0%	412	977	42.2%
Medicaid Median FFY 2022		52.4%			35.3%			33.2%	
Number of States Reporting		45			45			46	

MEASURE DESCRIPTION

This measure assesses the percentage of children and adolescents ages 1 to 17 who had two or more antipsychotic prescriptions and had metabolic testing for blood glucose, cholesterol, and both blood glucose and cholesterol.



	Met	Eligible Recipients	Rate
ND Medicaid FFS	207	283	73.1%
MCO - Medicaid Expansion	97	216	44.9%
ND Medicaid Total	304	499	60.9%
Medicaid Median FFY 2022		62.2%	
Number of States Reporting		46	

MEASURE DESCRIPTION

Adherence to antipsychotics for the treatment of schizophrenia can reduce the risk of relapse or hospitalization. This measure shows the percentage of adults ages 18 and older with schizophrenia or schizoaffective disorder who were dispensed and remained on an antipsychotic medication for at least 80 percent of their treatment period.

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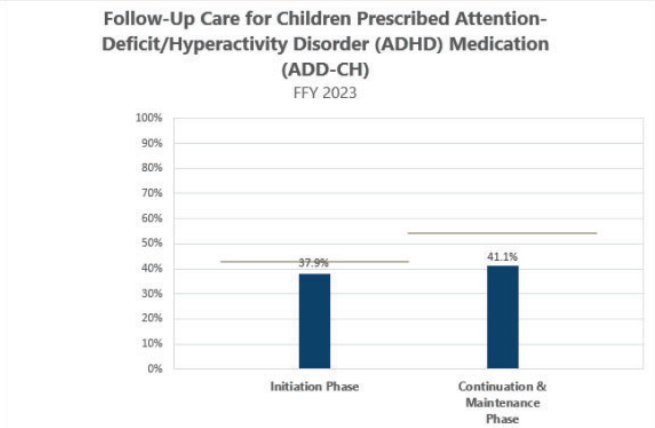
Behavioral Health Care



	Met	Eligible Recipients	Rate	Met	Eligible Recipients	Rate
ND Medicaid FFS	323	852	37.9%	146	355	41.1%
Medicaid Median FFY 2022		43.0%			54.1%	
Number of States Reporting		50			49	

MEASURE DESCRIPTION

This measure shows the percentage of children ages 6 to 12 who were newly prescribed medication for ADHD and who had *at least one visit* during the 30-Day Initiation Phase and *at least two visits* During the 9-Month Continuation and Maintenance Phase.

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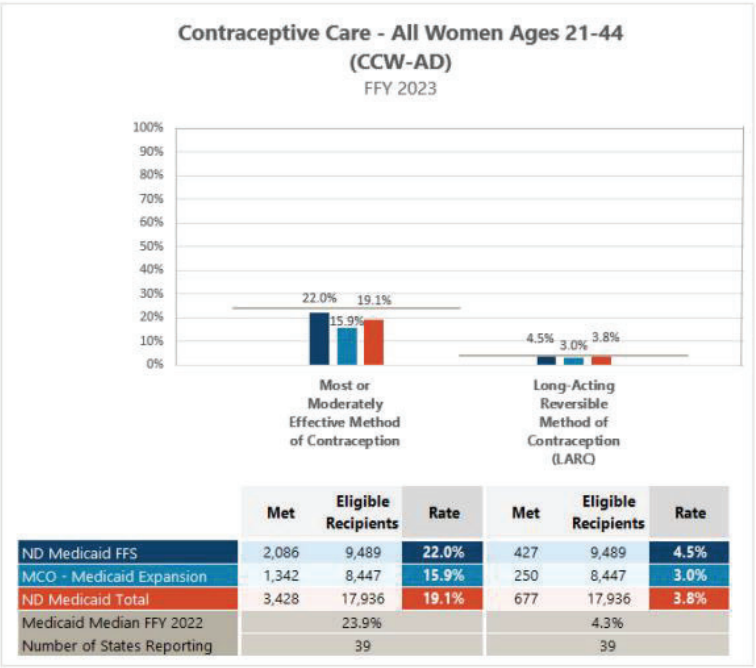

	Met	Eligible Recipients	Rate	Met	Eligible Recipients	Rate
ND Medicaid FFS	2,086	9,489	22.0%	427	9,489	4.5%
MCO - Medicaid Expansion	1,342	8,447	15.9%	250	8,447	3.0%
ND Medicaid Total	3,428	17,936	19.1%	677	17,936	3.8%
Medicaid Median FFY 2022		23.9%			4.3%	
Number of States Reporting		39			39	

MEASURE DESCRIPTION

This measure assesses the percentage of women ages 21 to 44 at risk of unintended pregnancy who were provided a most or moderately effective method of contraception as well as the percentage who were provided a long-acting reversible method of contraception (LARC).

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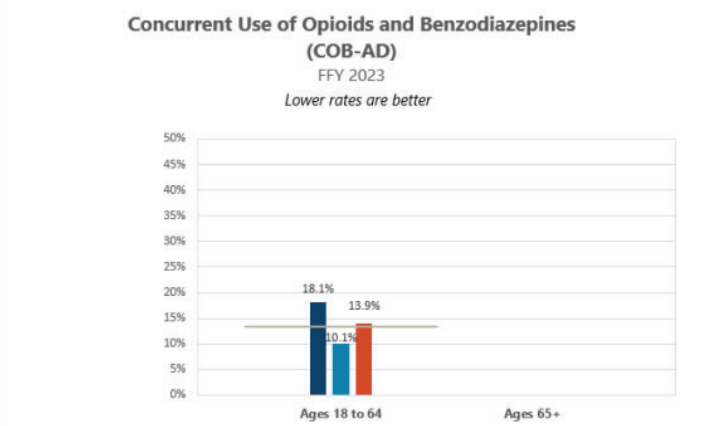

	Met	Eligible Recipients	Rate	Met	Eligible Recipients	Rate
ND Medicaid FFS	126	696	18.1%	DS	DS	DS
MCO - Medicaid Expansion	79	784	10.1%	-	-	-
ND Medicaid Total	205	1,480	13.9%	-	-	-
Medicaid Median FFY 2022		13.3%			-	
Number of States Reporting		36			-	

*The only available Medicaid Medians for FFY 2022 are shown
DS = Data suppressed because data cannot be displayed per CMS cell-size suppression policy.

MEASURE DESCRIPTION

This measure assesses the percentage of adults age 18 and older that were prescribed both opioids and benzodiazepines for 30 or more cumulative days during the measurement year.

Note: A lower rate indicates better performance.

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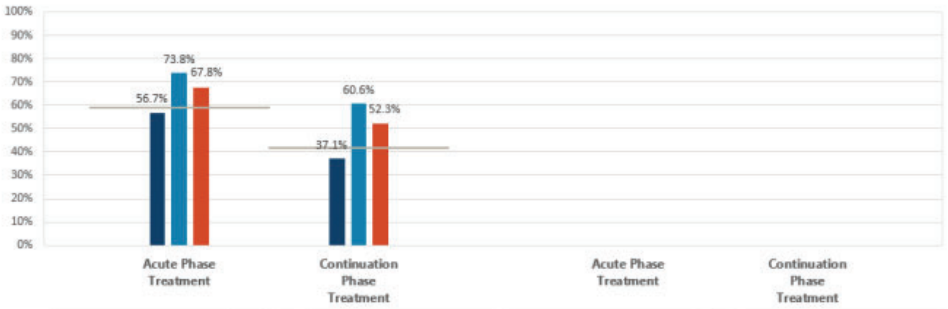

	Ages 18 to 64						Ages 65+					
	Met	Eligible Recipients	Rate	Met	Eligible Recipients	Rate	Met	Eligible Recipients	Rate	Met	Eligible Recipients	Rate
ND Medicaid FFS	473	834	56.7%	309	834	37.1%	DS	DS	DS	DS	DS	DS
MCO - Medicaid Expansion	1,132	1,534	73.8%	930	1,534	60.6%	-	-	-	-	-	-
ND Medicaid Total	1,605	2,368	67.8%	1,239	2,368	52.3%	-	-	-	-	-	-
Medicaid Median FFY 2022		58.8%			41.8%			-			-	
Number of States Reporting		44			43			-			-	

*The only available Medicaid Medians for FFY 2022 are shown
DS = Data suppressed because data cannot be displayed per CMS cell-size suppression policy.

MEASURE DESCRIPTION

This measure shows the percentage of adults ages 18 and older diagnosed with major depression who were treated with antidepressant medication and who remained on antidepressant medication treatment. Two rates are reported: (1) the percentage who remained on antidepressant medication treatment for the 12-week *effective acute phase treatment*; and (2) the percentage who remained on antidepressant medication treatment for the 6-month effective *continuation phase* treatment.

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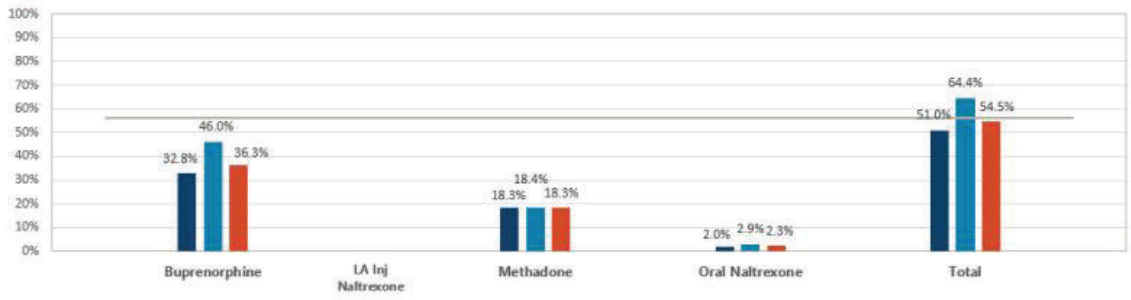

	Met	Eligible Recipients	Rate	Met	Eligible Recipients	Rate	Met	Eligible Recipients	Rate	Met	Eligible Recipients	Rate	Met	Eligible Recipients	Rate
ND Medicaid FFS	289	881	32.8%	DS	DS	DS	161	881	18.3%	18	881	2.0%	449	881	51.0%
MCO - Medicaid Expansion	145	315	46.0%	DS	DS	DS	58	315	18.4%	9	315	2.9%	203	315	64.4%
ND Medicaid Total	434	1,196	36.3%	DS	DS	DS	219	1,196	18.3%	27	1,196	2.3%	652	1,196	54.5%
Medicaid Median FFY 2022								56.2%							
Number of States Reporting								33							

DS = Data suppressed because data cannot be displayed per CMS cell-size suppression policy.

MEASURE DESCRIPTION

This measure shows the percentage of adults age 18 to 64 with an opioid use disorder (OUD) who filled a prescription for or were administered or dispensed an FDA-approved medication for the disorder during the measurement year. Five rates are reported:

- A total (overall) rate capturing any medications used in medication assisted treatment of opioid dependence and addiction (Rate 1)
- Four separate rates representing the following types of FDA-approved drug products:
    - Buprenorphine (Rate 2)
    - Oral naltrexone (Rate 3)
    - Long-acting, injectable naltrexone (Rate 4)
    - Methadone (Rate 5)

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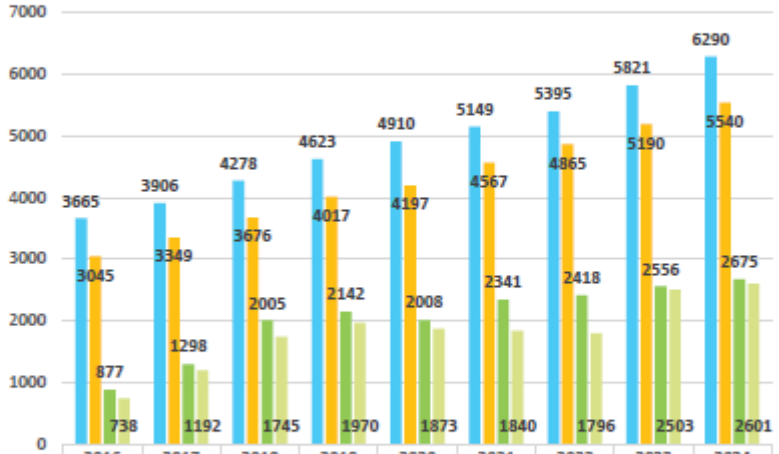
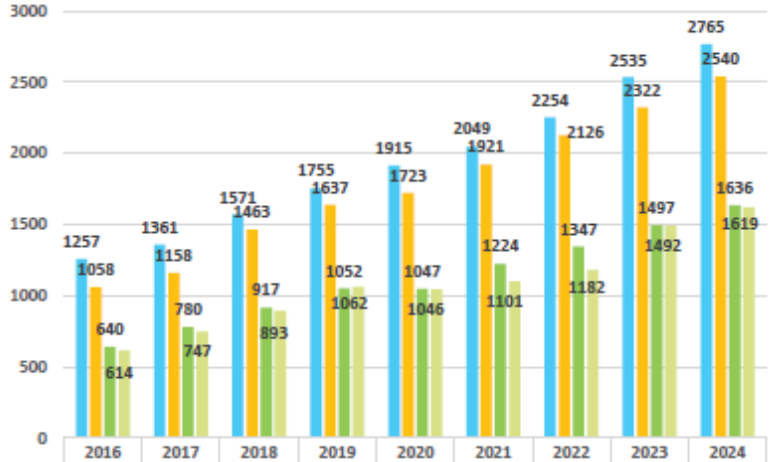
Doctors – Authorization vs. Utilization

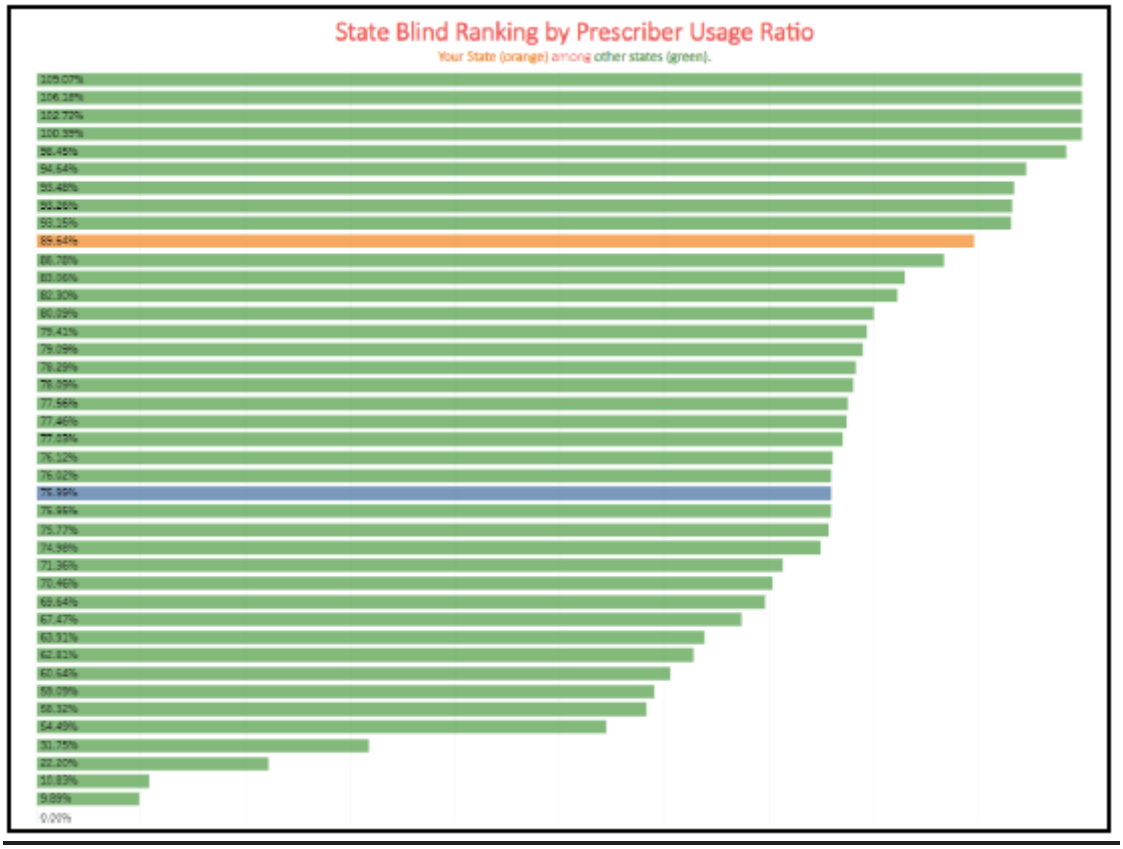


	2016	2017	2018	2019	2020	2021	2022	2023	2024
ND DEA Registered Doctors	3665	3906	4278	4623	4910	5149	5395	5821	6290
ND Doctors who authorized prescriptions	3045	3349	3676	4017	4197	4567	4865	5190	5540
ND Doctors also registered with ND PDMP	877	1298	2005	2142	2008	2341	2418	2556	2675
ND Doctor/their appointed delegate who accessed the system on their behalf (counts as 1)	738	1192	1745	1970	1873	1840	1796	2503	2601

Advanced Practice Providers - Authorization vs. Utilization



	2016	2017	2018	2019	2020	2021	2022	2023	2024
DEA Registered	1257	1361	1571	1755	1915	2049	2254	2535	2765
Authorized prescriptions	1058	1158	1463	1637	1723	1921	2126	2322	2540
Registered with ND PDMP	640	780	917	1052	1047	1224	1347	1497	1636
Practitioner/their appointed delegate who Accessed the System on their behalf (counts as 1)	614	747	893	1062	1046	1101	1182	1492	1619



Avg. MME per Patient per County for the 2024 year

County	Average MME Per Patient Per Day
Adams	8.79
Barnes	5.53
Benson	5.93
Billings	2.57
Bottineau	5.49
Bowman	6.12
Burke	8.95
Burleigh	6.08
Cass	4.08
Cavalier	5.56
Dickey	6.40
Divide	12.38
Dunn	7.74
Eddy	7.59
Emmons	6.33
Foster	7.78
Golden Valley	5.52
Grand Forks	6.34

County	Average MME Per Patient Per Day
Grant	7.71
Griggs	4.09
Hettinger	7.13
Kidder	8.05
LaMoure	3.62
Logan	4.71
McHenry	6.06
McIntosh	6.68
McKenzie	4.31
McLean	6.76
Mercer	7.62
Morton	7.15
Mountrail	6.31
Nelson	6.75
Oliver	7.91
Pembina	6.78
Pierce	5.13
Ramsey	6.76

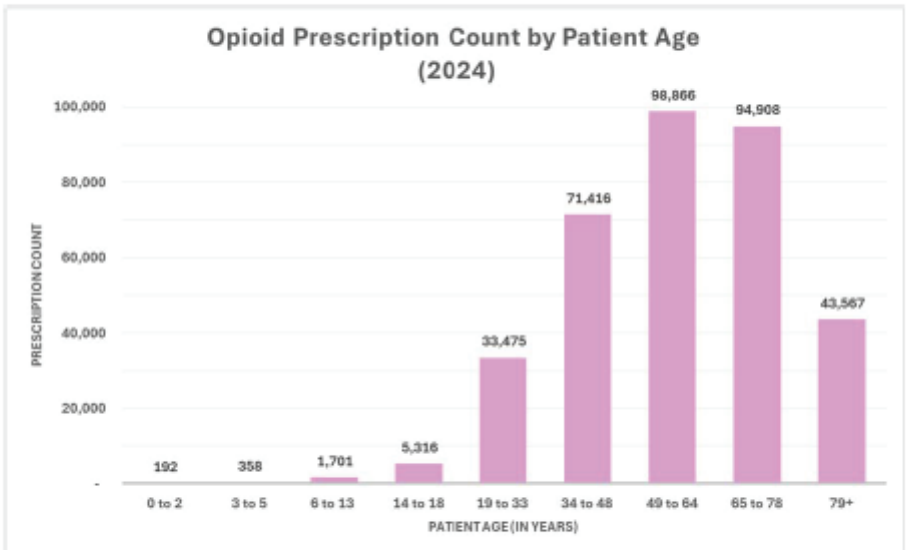
County	Average MME Per Patient Per Day
Ransom	4.65
Renville	3.91
Richland	4.35
Rolette	5.52
Sargent	3.09
Sheridan	9.79
Sioux	5.70
Slope	9.25
Stark	6.68
Steele	4.88
Stutsman	5.29
Towner	8.98
Traill	4.02
Walsh	6.95
Ward	4.91
Wells	7.05
Williams	6.89

Avg. MME per Patient per County for the 2024 Year

County	Average MME Per Patient Per Day
Divide	12.38
Sheridan	9.79
Slope	9.25
Towner	8.98
Burke	8.95
Adams	8.79
Kidder	8.05
Oliver	7.91
Foster	7.78
Dunn	7.74
Grant	7.71
Mercer	7.62
Eddy	7.59
Morton	7.15
Hettinger	7.13
Wells	7.05
Walsh	6.95

County	Average MME Per Patient Per Day
Williams	6.89
Pembina	6.78
McLean	6.76
Ramsey	6.76
Nelson	6.75
Stark	6.68
McIntosh	6.68
Dickey	6.40
Grand Forks	6.34
Emmons	6.33
Mountrail	6.31
Bowman	6.12
Burleigh	6.08
McHenry	6.06
Benson	5.93
Sioux	5.70
Cavalier	5.56
Barnes	5.53

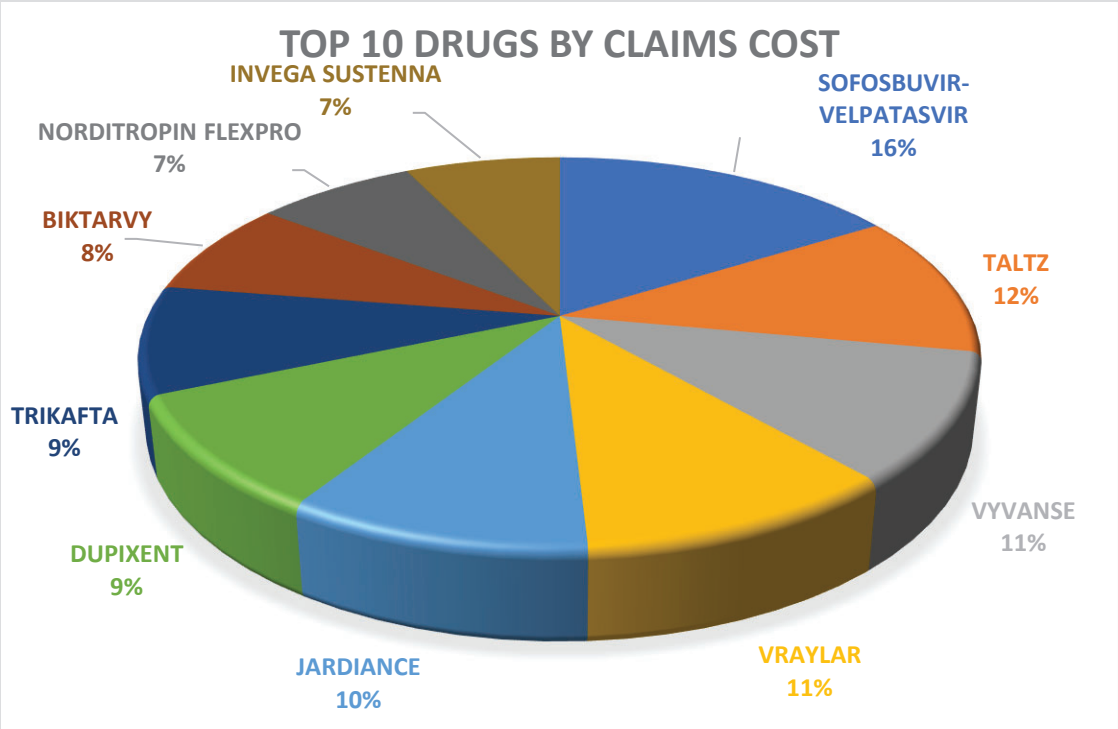
County	Average MME Per Patient Per Day
Golden Valley	5.52
Rolette	5.52
Bottineau	5.49
Stutsman	5.29
Pierce	5.13
Ward	4.91
Steele	4.88
Logan	4.71
Ransom	4.65
Richland	4.35
McKenzie	4.31
Griggs	4.09
Cass	4.08
Traill	4.02
Renville	3.91
LaMoure	3.62
Sargent	3.09
Billings	2.57



Financial Report

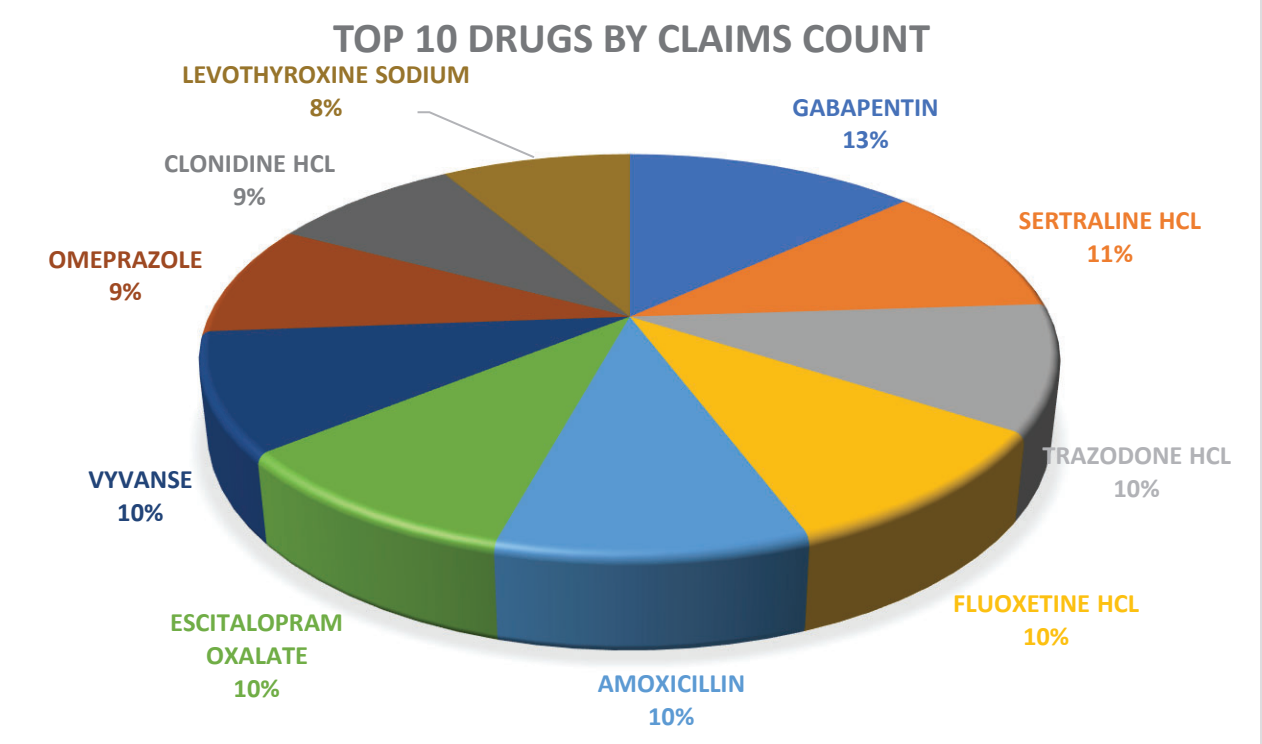
Top 25 Drugs Based on Total Claims Cost from 4/1/25 – 6/30/25

#	Drug Name	Claims	Claims Cost	Patients	Cost/Patient	% Cost	Dif
1	SOFOSBUVIR-VELPATASVIR	59	$1,375,708.91	59	$23,317.10	3.98%	↑1
2	TALTZ	129	$1,002,855.20	54	$75,744.96	2.90%	↑1
3	VYVANSE	3086	$904,034.67	1275	$709.05	2.61%	↑7
4	VRAYLAR	817	$898,463.92	340	$2,642.54	2.60%	NC
5	JARDIANCE	1085	$846,170.83	615	$1,375.89	2.45%	NC
6	DUPIXENT	209	$811,192.58	107	$14,590.61	2.34%	↑1
7	TRIKAFTA	31	$763,170.00	12	$63,597.50	2.21%	↓1
8	BIKTARVY	282	$670,216.50	143	$4,686.83	1.94%	↑1
9	NORDITROPIN FLEXPRO	85	$631,765.30	37	$17,074.74	1.83%	↓1
10	INVEGA SUSTENNA	222	$610,835.38	93	$6,568.12	1.77%	↑1
11	HUMIRA	282	$609,243.56	127	$101,648.79	1.76%	↓10
12	ELIQUIS	683	$427,501.22	347	$1,231.99	1.24%	↑1
13	SUBLOCADE	193	$409,780.96	96	$4,268.55	1.18%	↑1
14	COSENTYX	43	$407,521.24	16	$50,468.27	1.18%	↑1
15	INGREZZA	48	$382,787.81	19	$20,146.73	1.11%	↑1
16	LIRAGLUTIDE	894	$326,117.44	498	$654.85	0.94%	↑98
17	STELARA	13	$325,057.42	10	$32,505.74	0.94%	NC
18	VERZENIO	19	$309,867.45	7	$44,266.78	0.90%	NC
19	XIFAXAN	104	$276,302.79	53	$5,213.26	0.80%	NC
20	ENBREL	41	$275,429.53	18	$32,219.54	0.80%	↑10
21	INSULIN LISPRO	1223	$266,231.29	756	$579.84	0.77%	NC
22	DULERA	731	$231,984.62	458	$506.52	0.67%	↓2
23	ABILIFY MAINTENA	88	$231,847.06	36	$6,440.20	0.67%	↓1
24	FARXIGA	345	$227,143.93	188	$1,208.21	0.66%	↓1
25	OZEMPIC	239	$220,362.05	101	$2,181.80	0.64%	↑10
Total						**$13,441,591.66**	



Top 25 Drugs Based on Number of Claims from 4/1/25 – 6/30/25

#	Drug Name	Claims	Claims Cost	Patients	Cost/Claim	% Claims	Dif
1	GABAPENTIN	4,226	$ 61,819.49	1,873	$14.63	1.82%	↑1
2	SERTRALINE HCL	3,435	$ 46,277.13	1,948	$13.47	1.48%	↑3
3	TRAZODONE HCL	3,266	$ 43,869.68	1,813	$13.43	1.41%	↑1
4	FLUOXETINE HCL	3,237	$43,845.42	1,850	$13.55	1.40%	↓1
5	AMOXICILLIN	3,194	$ 49,440.88	3,015	$ 15.48	1.38%	↓4
6	ESCITALOPRAM	3,166	$ 42,029.53	1,842	$13.28	1.36%	NC
7	VYVANSE	3,086	$ 904,034.67	1,275	$292.95	1.33%	↑12
8	OMEPRAZOLE	2,871	$39,172.73	1,782	$ 13.64	1.24%	↓1
9	CLONIDINE HCL	2,772	$33,947.05	1,440	$12.25	1.19%	↑1
10	LEVOTHYROXINE	2,737	$ 39,318.57	1,492	$14.37	1.18%	↑2
11	VENTOLIN HFA	2,701	$ 74,454.66	2,688	$64.59	1.16%	↓3
12	BUPROPION XL	2,601	$ 42,948.48	1,488	$16.51	1.12%	↑2
13	HYDROXYZINE HCL	2,511	$35,050.68	1,549	$ 13.96	1.08%	NC
14	ATORVASTATIN	2,480	$35,406.72	1,498	$ 14.28	1.07%	↑1
15	LISINOPRIL	2,385	$ 30,635.25	1,517	$ 12.84	1.03%	↑2
16	DEXTRO-AMPHET ER	2,358	$ 72,199.22	1,071	$30.62	1.02%	NC
17	PREDNISONE	2,351	$ 28,590.48	1,905	$12.16	1.01%	↓6
18	METHYLPHENIDATE ER	2,321	$70,531.94	1,057	$ 30.39	1.00%	↑2
19	AMOXICILLIN-CLAV	2,316	$ 39,973.15	2,174	$17.26	1.00%	↓12
20	LAMOTRIGINE	2,196	$ 30,770.68	953	$14.01	0.95%	↑2
21	PANTOPRAZOLE SODIUM	2,196	$ 30,652.48	1,353	$13.96	0.95%	↑2
22	ARIPIPRAZOLE	2,177	$33,450.88	1,107	$15.37	0.94%	↓1
23	ONDANSETRON ODT	2,157	$31,728.85	1,697	$14.71	0.93%	↓5
24	HYDROCODONE-APAP	2,132	$ 33,271.12	1,386	$15.61	0.92%	↓1
25	DULOXETINE HCL	2,112	$35,020.41	1,149	$16.58	0.91%	NC
Total							**66,984**

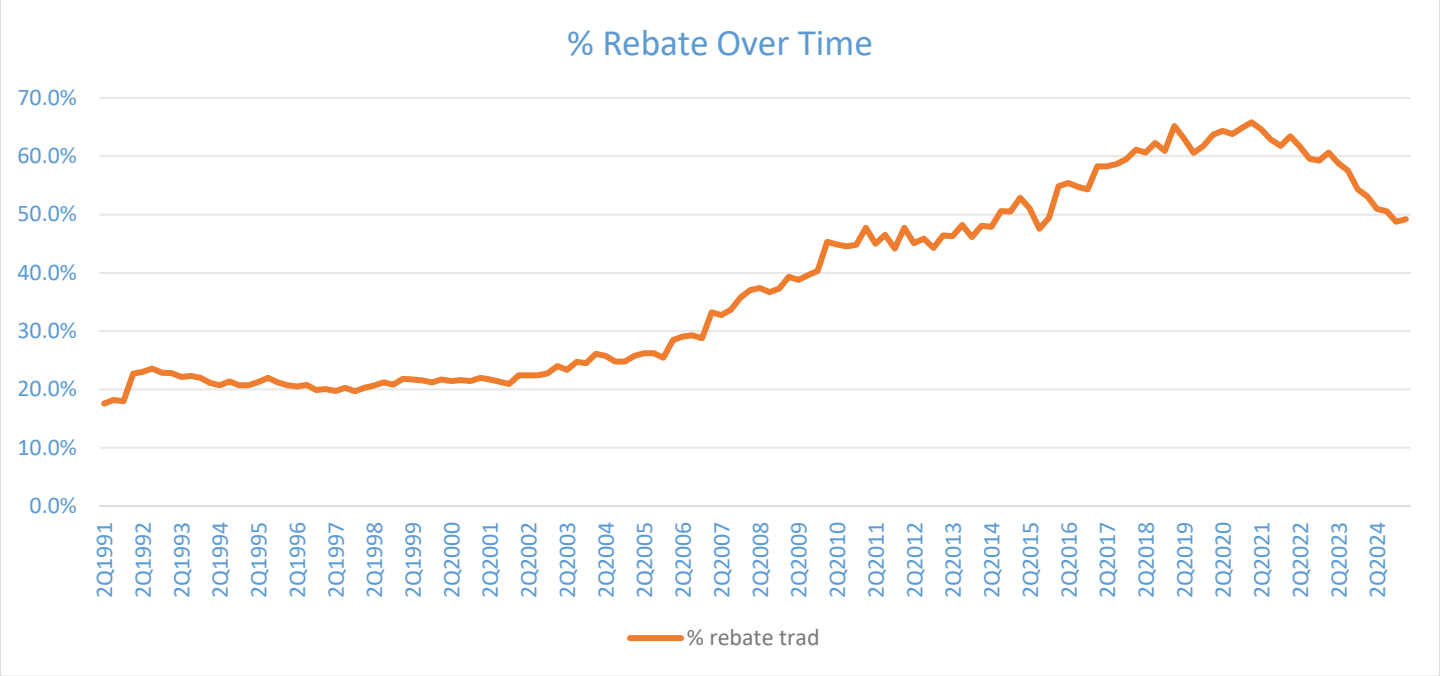


Top 15 Therapeutic Classes Based on Number of Claims from 4/1/25 – 6/30/25

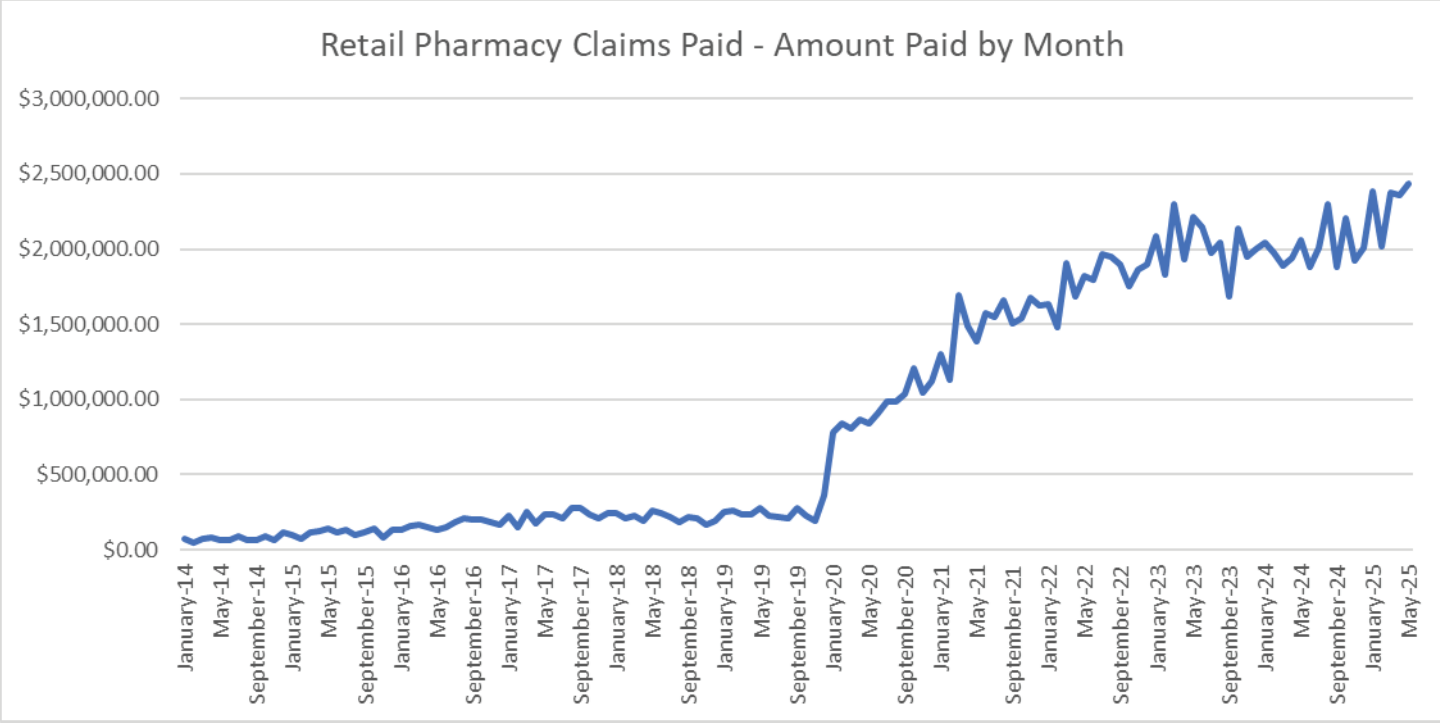
#	Therapeutic Class Description	Claims	Claims Cost	Patients	Cost/Claim	% Claims	Dif
1	ANTIDEPRESSANTS	24,203	564,534	10,526	$23.32	10.43%	NC
2	ANTIPSYCHOTIC AGENTS	9,502	2,754,587	3,987	$289.90	4.10%	NC
3	AMPHETAMINES	6,934	1,026,701	2,929	$148.07	2.99%	↑1
4	GABA-MEDIATED ANTICONVULSANTS	6,511	140,234	2,792	$21.54	2.81%	↑2
5	RESPIRATORY AND CNS STIMULANTS	6,374	347,575	2,662	$54.53	2.75%	NC
6	PENICILLIN ANTIBIOTICS	5,773	95,072	5,188	$16.47	2.49%	↓3
7	BETA-ADRENERGIC AGONISTS	5,694	733,129	3,962	$128.75	2.45%	NC
8	OPIOID AGONISTS	5,541	104,160	2,928	$18.80	2.39%	NC
9	PROTON-PUMP INHIBITORS	5,381	94,973	3,276	$17.65	2.32%	↑2
10	CENTRAL ALPHA-AGONISTS	5,353	76,880	2,491	$14.36	2.31%	↓1
11	NSAIDs	5,257	74,437	3,616	$14.16	2.27%	↑1
12	ANTICONVULSANTS	4,866	302,925	2,086	$62.25	2.10%	↑1
13	ADRENALS	4,707	180,272	3,472	$38.30	2.03%	↓3
14	STATINS	4,587	66,281	2,833	$14.45	1.98%	NC
15	BETA-BLOCKERS	4,509	77,491	2,636	$17.19	1.94%	NC

Top 15 Therapeutic Classes Based on Claims Cost from 4/1/25 – 6/30/25

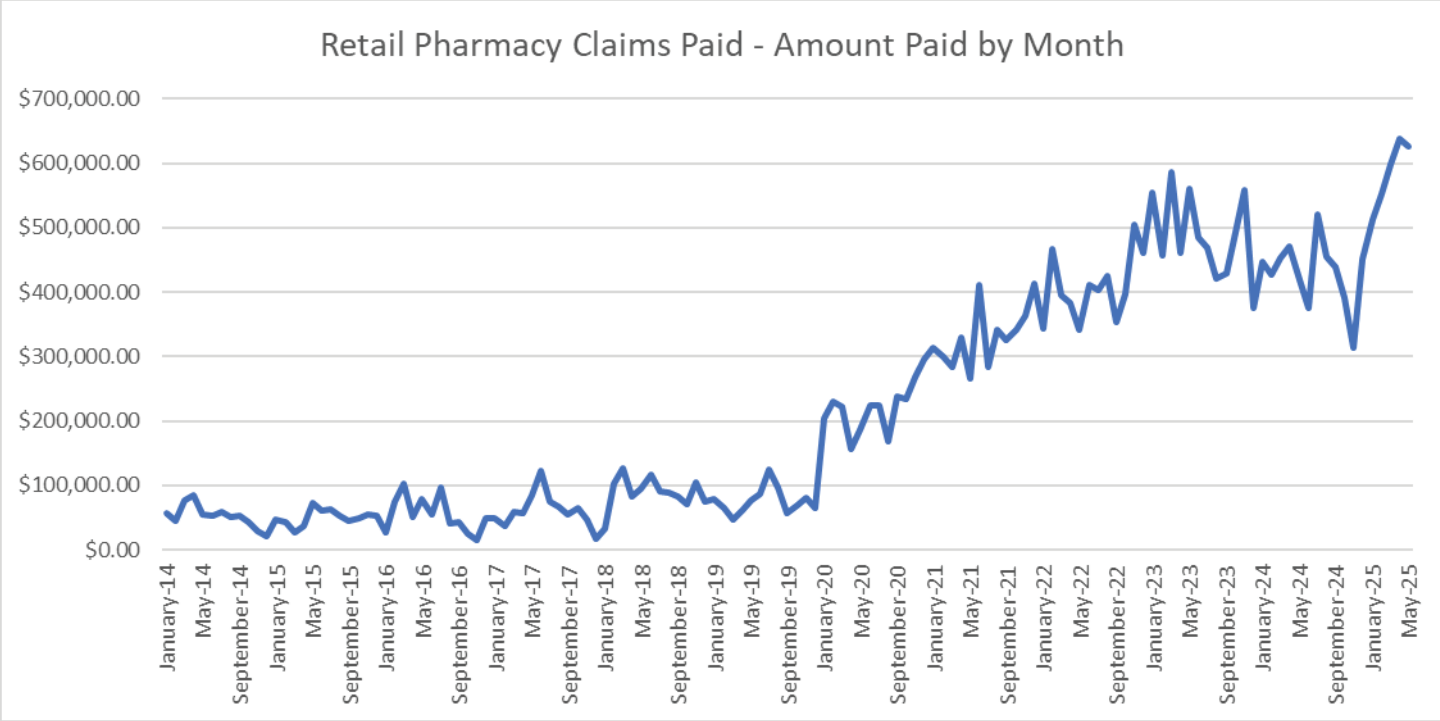
#	Therapeutic Class Description	Claims	Claims Cost	Patients	Cost/Patient	% Cost	Dif
1	TUMOR NECROSIS FACTOR INHIBITORS	370	$ 2,976,706.38	162	$ 18,374.73	8.60%	NC
2	ANTIPSYCHOTIC AGENTS	9502	$ 2,754,586.63	3987	$ 690.89	7.96%	NC
3	INTERLEUKIN-MEDIATED AGENTS	188	$ 1,749,046.15	76	$ 23,013.77	5.06%	NC
4	ANTINEOPLASTIC AGENTS	570	$ 1,735,396.77	236	$ 7,353.38	5.02%	NC
5	HCV ANTIVIRALS	60	$ 1,386,281.85	60	$ 23,104.70	4.01%	↑1
6	SGLT2 INHIBITORS	1472	$ 1,100,669.32	825	$ 1,334.14	3.18%	↑1
7	ANTIRETROVIRALS	644	$ 1,059,413.84	268	$ 3,953.04	3.06%	↓2
8	AMPHETAMINES	6934	$ 1,026,700.71	2929	$ 350.53	2.97%	NC
9	CFTR CORRECTORS	35	$ 856,175.76	14	$ 61,155.41	2.47%	NC
10	SKIN AGENTS	222	$ 811,632.76	117	$ 6,937.03	2.35%	↑2
11	BETA AGONISTS	5694	$ 733,128.90	3962	$ 185.04	2.12%	NC
12	INCRETIN MIMETICS	1320	$ 685,123.94	666	$ 1,028.71	1.98%	↑1
13	PITUITARY	302	$ 675,505.41	139	$ 4,859.75	1.95%	↓3
14	INSULINS	2842	$ 574,417.83	1260	$ 455.89	1.66%	NC
15	ANTIDEPRESSANTS	24203	$ 564,533.84	10526	$ 53.63	1.63%	NC



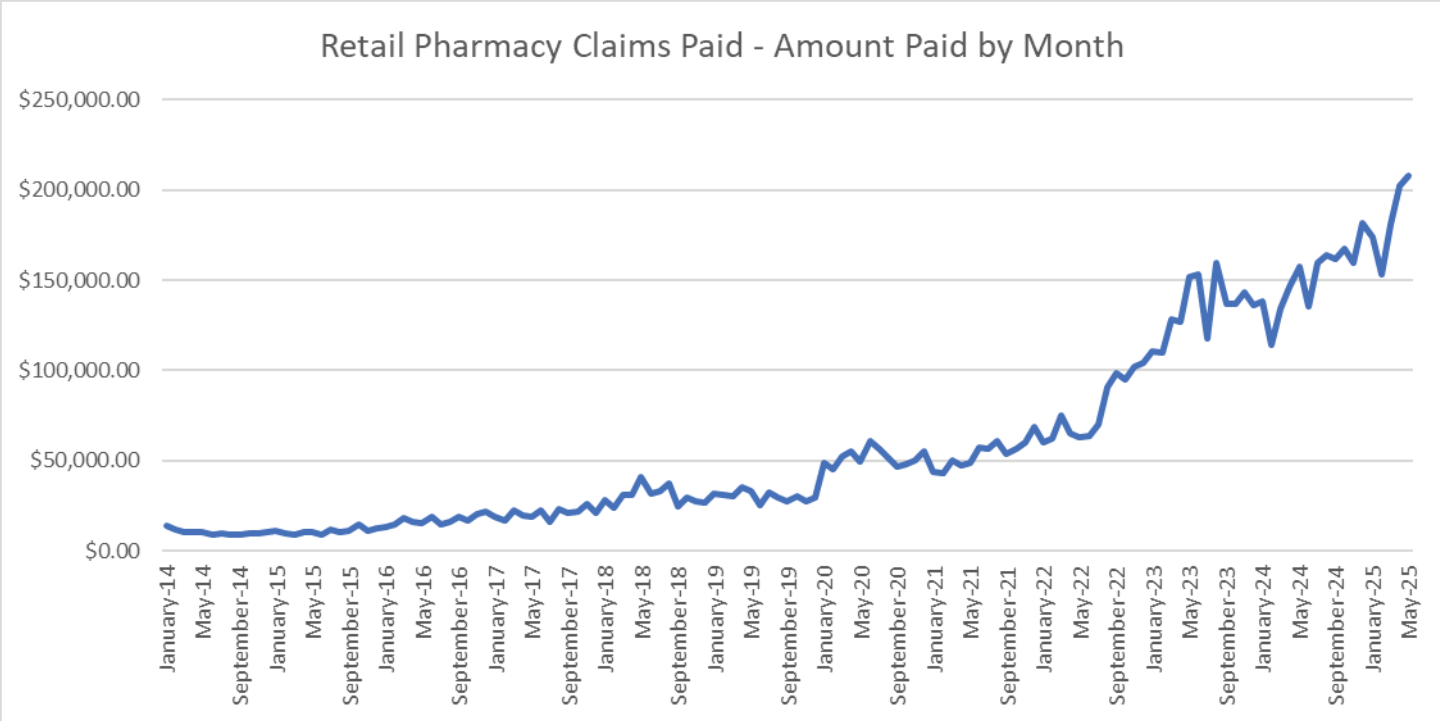
Immunomodulators



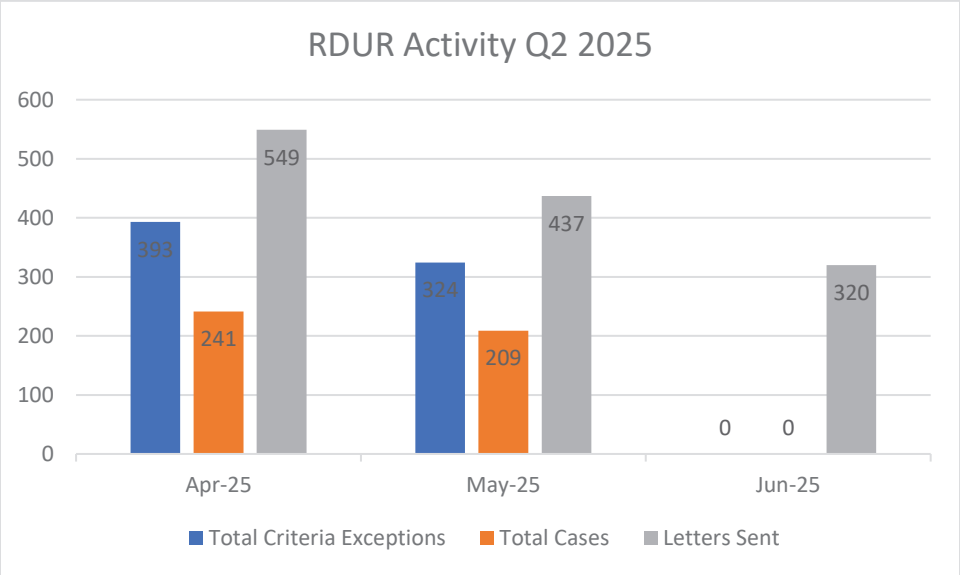
Oncology



Opioid Use Disorder



RDUR Report: Q2 2025 - Julie



April Cases by Type of Criteria		
Criteria Description	**# of Cases**	**% of Cases**
Drug-Drug Interactions	98	40.66%
Therapeutic Appropriateness	55	22.82%
Overutilization	37	15.35%
Drug-Disease Precaution	33	13.69%
Underutilization	15	6.22%
Drug-Drug Marker And/Or Diagnosis	3	1.24%

May Cases by Type of Criteria		
Criteria Description	**# of Cases**	**% of Cases**
Overutilization	71	33.97%
Underutilization	60	28.71%
Drug-Drug Interactions	39	18.66%
Therapeutic Appropriateness	39	18.66%

June Special Mailing

320 Letters Sent

Dear Prescriber,

SUBJECT: ND MEDICAID UPCOMING COVERAGE CHANGES

ND Medicaid will be changing the preferred agents for the following drug classes:

1. Dipeptidyl peptidase-4 (DPP-4) inhibitors effective July 1, 2025
2. Inhaled corticosteroid/long-acting beta agonists (ICS/LABA) effective October 1, 2025

A summary of the Preferred Drug List (PDL) changes and a list of your patients who will potentially be affected are enclosed for your review. Please transition to a preferred agent or submit prior authorization (PA) before the changes are effective to minimize treatment disruption.

Thank you for your professional consideration.

Sincerely,

Brendan K. Joyce, PharmD

Administrator, Pharmacy Services

Prior Authorization Updates

Drug	PA Status	Class
Merilog	PA	Diabetes
Avmapki/Fakzynja	PA	> $3000
Bomyntra	PA	Biosimilars
Brynovin	PA	DPP-4 inhibitors
Conexxence	PA	Biosimilars
Edurant PED	PA	Preferred Dosage Forms
Emblaveo	PA	> $3000
Enflonsia	PA	Medical Billing Only
Imuldosa	PA	Biosimilars
Khindivi	PA	Preferred Dosage Forms
Osenvelt	PA	Biosimilars
Perseris	PA	Preferred Dosage Forms
Soliqua	Remove PA	Insulin/GLP-1 Agonists
Stoboclo	PA	Biosimilars
Tryngolza	PA	> $3000
Tryptyr	PA	Dry Eye Syndrome
Xultrophy	Remove PA	Insulin/GLP-1 Agonists

Criteria Updates

Summary of Changes

Bullous Pemphigoid

Dupixent received FDA approval for the treatment of Bullous Pemphigoid. Using Dupixent can reduce the need for corticosteroids, improving itch and overall disease severity. It will be considered for those who haven't responded to conventional therapy or for those unable to tolerate high doses of corticosteroids.

PREFERRED AGENTS (PA REQUIRED)
DUPIXENT (dupliumab)

Initial Criteria - Approval Duration: 4 months

- The member has a diagnosis of bullous pemphigoid
  - Drug-induced disease must be assessed/ruled out by prescriber attestation
- The requested medication must be prescribed by, or in consult with, a dermatologist
- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).
- Current symptoms (e.g., extent or spread of the blisters/pruritus) have been submitted
- The member has experienced new development of nontransient lesions, extension of current lesions, failure of lesion healing, or continued pruritus despite at least 3 weeks of prednisone or prednisolone at 0.75 mg/kg/day within the past 2 months

Chronic Kidney Disease

Like SGLT2 inhibitors, GLP-1 receptor agonists have kidney and cardiovascular benefits in patients with diabetic kidney disease.

GLP-1 receptor agonist

PA REQUIRED
Ozempic (semaglutide)

Semaglutide Only

- The member has type 2 diabetes
- The member has one of the following (1 or 2) despite a 3-month trial with an ACE inhibitor or a 6-month trial with an ARB in combination with a SGLT-2 inhibitor and liraglutide at the target or maximally tolerated dose, as evidenced by paid claims or pharmacy printouts:
  1. urinary albumin-to-creatinine ratio (UACR) ≥ 30 mg/g (≥3 mg/mmol)
  2. eGFR < 60 mL/min/1.73 m^3

Giant Cell Arteritis (Temporal Arteritis)

Rinvoq received FDA approval to treat GCA. It is the only JAK-inhibitor to receive this indication so far, giving another option for treatment. It will be another option for those unable to tolerate high doses of corticosteroids.

Janus Kinase (JAK) inhibitor

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
RINVOQ ER (upadacitinib) TABLET	

Interleukin (IL) -6 Receptor Inhibitors

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
tocilizumab – See Biosimilar Agents	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in the area of the member's diagnosis.
- The member must meet one of the following conditions:
  - A minimum 7-day trial of high dose glucocorticoids
  - At high risk of glucocorticoid side effects or complications, including osteoporosis, diabetes, hypertension, or glaucoma

Uveitis

Adalimumab is the only agent currently FDA approved for the treatment of non-infective uveitis, however both infliximab and tocilizumab have compendia support, so they were added to this section.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab - See Biosimilar Agents	tocilizumab - See Biosimilar Agents
infliximab - See Biosimilar Agents	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, an ophthalmologist or rheumatologist.
- The member has failed a 6-month trial of a preferred agent, as evidenced by paid claims or pharmacy printouts.

Psychotropic Certification

Dear Prescriber,

SUBJECT: ND MEDICAID LEGISLATIVELY MANDATED PSYCHOTROPIC CERTIFICATION

ND Medicaid is required by state law N.D.C.C. § 50-24.6-04(7) to implement a certification program verifying medical necessity of each psychotropic drug when the regimen contains five or more concurrent prescriptions for the following drugs:

1. Antipsychotic
2. Antidepressant
3. Anticonvulsant
4. Benzodiazepine
5. Mood stabilizer
6. Sedative hypnotic
7. Attention Deficit Hyperactivity Disorder (ADHD)

Coverage of the psychotropic drug may be denied if you fail to certify within 90 days of the date of this notification. A list of your patients and their psychotropic drugs are enclosed for your review. Please complete the certification response for each psychotropic drug you prescribed for each of the enclosed patients within 90 days to minimize treatment disruption.

Thank you for your professional consideration.

Sincerely,

ND Medicaid

State law requires ND Medicaid to implement a psychotropic certification program

Psychotropic certification of medical necessity is required annually for each drug within a regimen containing five or more concurrent prescriptions for the following drugs:

Antipsychotic	Anticonvulsant	Mood stabilizer	ADHD
Antidepressant	Benzodiazepine	Sedative hypnotic	

Psychotropic certification **must be completed within 90 days** of the notice date to minimize treatment disruption.

Each prescriber of a medication in an impacted regimen must certify the medical necessity of each psychotropic drug they prescribed within the regimen.

Psychotropic Polypharmacy

Although psychotropic polypharmacy is common in clinical practice, there is limited data to assess the safety and efficacy of using multiple agents concurrently in certain populations (e.g., pediatric).[1, 2]

Polypharmacy can contribute to negative consequences, including:

- Adverse effects
- Drug-drug interactions
- Nonadherence
- Therapeutic duplication
- Increased healthcare costs[1, 2]

Safe & effective psychotropic treatment should include evaluation of:

- Guideline recommendations
- Appropriate indications for use
- Non-pharmacological interventions
- Patient education
- Continuous monitoring[1, 2]

Prior to using multiple agents, implement non-pharmacological interventions and consider alternative monotherapy.

References

1. Medhekar R, Fujimoto K, Aparasu RR, Bhatara VS, Johnson ML, Alonzo JP, Schwarzwald HL, Chen H. Physician care coordination and the use of psychotropic polypharmacy in the management of pediatric mental disorders. J Manag Care Spec Pharm. 2019 Jan;25(1):29-39. doi: 10.18553/jmcp.2019.25.1.029.
2. Libowitz MR, Nurmi EL. The Burden of Antipsychotic-Induced Weight Gain and Metabolic Syndrome in Children. Front Psychiatry. 2021 Mar 12;12:623681. doi: 10.3389/fpsyt.2021.623681. PMID: 33776816; PMCID: PMC7994286.

Psychotropic drugs where you have been identified as the prescriber through pharmacy claims data are highlighted within each member's psychotropic drug list (may not include medications paid out-of-pocket or fully covered by another payer). If there are multiple prescribers involved with the regimen, each will receive this information.

You must certify each psychotropic drug that you prescribed **within 90 days** to minimize treatment disruption.

TO CERTIFY MEDICAL NECESSITY:

1. Complete the Certification of Medical Necessity column
2. Initial in the Prescriber column for each drug you prescribed
3. Submit certification using one of the following options:
    a. Fax this completed form to 866-798-4904
    b. Mail this completed form in the envelope provided

Member: John Smith (DOB: 07/24/2010)		
Psychotropic Drug	**Prescriber**	**Certification of Medical Necessity**
Methylphenidate ER 36 mg		☐ Yes ☐ No, I am not the current prescriber ☐ No, the drug was/will be discontinued Time needed to taper: _____
Methylphenidate 10 mg		☐ Yes ☐ No, I am not the current prescriber ☐ No, the drug was/will be discontinued Time needed to taper: _____
Clonidine 0.1 mg	PCP name	[redacted]
Aripiprazole 5 mg	Psychiatrist name	
Sertraline 50 mg	Psychiatrist name	

1. Were you aware of these other prescribers?
    ☐ Yes, I was aware of ALL the other prescribers
    ☐ Yes, I was aware of SOME of the other prescribers
    ☐ No

2. Did you do anything additional with this information?
    ☐ Yes. What action did you take? _____
    ☐ No. Why not? _____

Second Review

Non-Opioid Pain Medications

Lidocaine Patch

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
lidocaine 5% patch	LIDODERM (lidocaine) 5% PATCH
PREFERRED AGENTS (PA REQUIRED)	
ZTLIDO (lidocaine) 1.8% PATCH	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of lidocaine 5% patch, as evidenced by paid claims or pharmacy printouts.

Lidocaine Topical Cream

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The request must be for injection pain from a medically necessary procedure

NSAIDS

Oral Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
celecoxib	ARTHROTEC (diclofenac/misoprostol)
diclofenac potassium 50 mg tablet	CELEBREX (celecoxib)
diclofenac sodium DR 50 mg, 75 mg	DAYPRO (oxaprozin)
etodolac	diclofenac potassium 25 mg tablet
flurbiprofen	diclofenac potassium 25 mg capsule
ibuprofen	diclofenac sodium 25 mg DR
indomethacin	diclofenac sodium 100 mg ER tablet
indomethacin ER	diclofenac/misoprostol
ketoprofen IR	DUEXIS (famotidine/ibuprofen)
ketorolac	etodolac ER
meclofenamate	famotidine/ibuprofen
mefenamic acid	FELDENE (piroxicam)
meloxicam	fenoprofen
nabumetone	ketoprofen ER 200 mg
naproxen	LOFENA (diclofenac potassium)
piroxicam	meloxicam, submicronized
sulindac	NALFON (fenoprofen)
tolmetin	NAPRELAN (naproxen)
	naproxen ER 500 mg

	naproxen/esomeprazole
	oxaprozin
	RELAFEN DS (nabumetone)
	SEGLENTIS (celecoxib/tramadol)
	VIMOVO (naproxen/esomeprazole)

Electronic Diagnosis Verification

- Mefenamic acid and Meclofenamate: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- *Non-preferred agents with no same active ingredient preferred:*
  - The member must have failed a 7-day trial of 3 different oral generic NSAIDs including a COX-2 inhibitor if member has experienced GI intolerances, as evidenced by paid claims or pharmacy print outs
- *Non-preferred agents with same active ingredient preferred*:
  - See Preferred Dosage Form Criteria

Therapeutic Duplication

- One strength of one medication is allowed at a time (topical and oral formulations are not allowed together)

If the following conditions apply, please call for an override by calling provider relations at 1-800-755-2604:

- The member is prescribed ketorolac and will stop regular NSAID therapy during course of ketorolac

Oral Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ibuprofen suspension	indomethacin solution
naproxen suspension	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of each preferred agent, as evidenced by paid claims or pharmacy print outs.

Nasal Dosage Forms

PA REQUIRED
ketorolac nasal spray

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of 3 different oral generic NSAIDs including a COX-2 inhibitor if member has experienced GI intolerances, as evidenced by paid claims or pharmacy print outs

- Clinical justification must be provided explaining why the member is unable to use another dosage form (subject to clinical review).

Topical Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
diclofenac gel	diclofenac 1.3% patch
diclofenac topical solution (all other labelers)	diclofenac 2% pump
	diclofenac topical solution (labeler 59088)

Prior Authorization Criteria

- See *Preferred Dosage Form* Criteria

Sodium Channel Blockers

PREFERRED AGENTS (NO PA REQUIRED)
JOURNAVX (suzetrigine)

Electronic Duration Verification

- One 14-day fill allowed per 60 days

Therapeutic Duplication

- Concurrent use with opioid medication is not covered

First Review of Nieman-Pick Type C

Overview

Definition: an autosomal recessive disorder associated with splenomegaly, variable neurologic deficits, and the storage of lipids including sphingomyelin and cholesterol.[1]

Niemann-Pick Type C (NPC) is caused by variants of the NPC1 and NPC2 genes that cause impaired processing and transport of LDL cholesterol and other macromolecules. It affects approximately 1:120,000 worldwide. It can present from the perinatal period until late adulthood. Greater than 85% of patients have liver, spleen, or lung involvement which precedes the development of neurologic symptoms. Acid sphingomyelinase deficiency (ASMD) types A and B were previously known as Niemann-Pick disease types A and B. ASMD is caused by pathogenic variants ins the SMPD1 gene. ASMD-A is the more severe, early-onset form of the two types. Differential diagnosis should include Gaucher disease, lysosomal acid lipase deficiency, hepatosplenomegaly associated with infection, and hematologic malignancies.[1]

Most Common Clinical Features:[1]

- Vertical supranuclear gaze palsy: an eye movement disorder characterized by an inability to move the eyes up or down due to a problem in the brain
- Gelastic cataplexy: a sudden, brief loss of muscle tone triggered by strong emotions, especially laughter.
- Isolated unexplained splenomegaly with or without hepatomegaly
- Prolonged neonatal jaundice or cholestasis
- Premature cognitive decline or dementia

FDA Approval

Miplyffa (arimoclomol)[2]: September 20, 2024; 505(b) New Drug Application (NDA) pathway; Type 1 – New Molecular Entity; Priority; Orphan

Aqneursa (levacetylleucine)[3]: September 24, 2024; 505(b) New Drug Application (NDA) pathway Type 1 New Molecular Entity, Priority; Orphan

Current Utilization

	Quarter 3 2024 – Quarter 2 2025		
Medication	**Rx Count**	**Rx Count**	**% of Rx**
Miplyffa	**0**	**0**	**0**
Aqneursa	**0**	**0**	**0**

Medication Overview

Medication	Miplyffa (arimoclomol)	Aqneursa (levacetylleucine)
Dosing	**Adults:** 62-124mg three times daily based on actual body weight **Pediatrics (2 years or older):** 47-124mg three times daily based on actual body weight	**Adults:** 1-2g three times daily based on actual body weight **Pediatrics:** 1g twice daily to 2g three times daily based on actual body weight
Special Considerations	• Can cause an increase in creatinine without affecting GFR so other measures should be used to assess renal function • May cause embryo-fetal harm and impair fertility • Dosage adjustments required for eGFR < 50 ml/min • Should be used in combination with miglustat Common ADRs: weight decrease, upper respiratory infection, urticaria	• May cause fetal harm • No dosage adjustments required Common ADRs: rosacea, abdominal pain, dysphagia, vomiting, thrombocytopenia, upper respiratory infection
Clinical Trials	Evaluated safety only. Common adverse effects of each medication found in trials listed above.	
Cost (AWP)/month[4]	**47mg – 124mg**: $40,185.00 to $127,224.00	**1gm**: $34,682.40 to 104,587.20
Place in Therapy[1]	• Therapy should be initiated at the earliest evidence of neurologic manifestations • Choice between Aqneursa or Miplyffa plus miglustat should be individualized • Patients without neurologic manifestations do not require treatment	

References:

1. *Schiffmann, Raphael, et al. Niemann-Pick type C disease. UpToDate. May 15, 2025. Niemann-Pick type C disease - UpToDate*
2. *Aqneursa (levacetylleucine). [prescribing information]. Zevra Therapeutics, Inc. US Food and Drug Administration. Celebration, FL Sept 2024. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/219209Orig1s000lbl.pdf*
3. *Miplyffa (arimoclomol). [prescribing information]. IntraBio Inc. US Food and Drug Administration. Austin, TX Sept 2024. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/219209Orig1s000lbl.pdf*
4. *Miplyffa (arimoclomol), Aqneursa (levacetylleucine) Red Book. IBM Micromedex Solutions. Tuven Health Analytics, Inc. Ann Arbor, MI. March 4, 2025. https://www. Micromedexsolutions.com*

First Review of ANCA-Associated vasculitis

Overview

Definition:
Antineutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (AAV) includes granulomatosis with polyangiitis (GPA), microscopic polyangiitis (MPA), renal-limited vasculitis, and eosinophilic granulomatosis with polyangiitis (EGPA), previously called Churg-Strauss syndrome (CSS) or allergic granulomatosis and angiitis. All affect small-sized arteries and have similar effects on kidney histology. [1]

Prevalence[1,2]:
GPA:
- 2.3 to 146 cases per million persons
- Mostly affects people of European ancestry

MPA:
- 9-94 cases per million persons
- Mostly affects people of Asian ancestry

EGPA:
- 12 to 15 cases per million persons

Clinical Features:
GPA and MPA[1]:
- Can involve small blood vessels in almost any organ or tissue but mostly affects the respiratory tracts and kidneys
    - May develop interstitial lung disease complicated by pulmonary fibrosis and pulmonary arterial hypertension.
    - Kidney involvement includes rapidly progressive glomerulonephritis.
        - Asymptomatic hematuria with normal kidney function
        - Increase in serum creatinine over days or weeks with hematuria and cellular casts
- Initial presentation includes fever, malaise, anorexia, weight loss, myalgias, and arthralgias.
- May also see urinary abnormalities with or without kidney function impairment, purpuric skins kidney function impairment, purpuric skins lesions, and neurologic dysfunction (foot or wrist drop).
- Approximately one-fourth of patients present with migratory polyarthropathy, nasal crusting, or other findings that do not include organ-threatening manifestations.
    - Typically younger at disease onset and more likely to be women.
    - More likely to have chronic, recurring disease and destructive upper respiratory tract disease
- Ear, nose, and throat manifestations can occur in 90% of GPA patients and 35% in MPA patients.
- GPA patients typically have more bone and cartilage destruction.

EGPA[2]:
- Asthma
- Rhinitis
- Nasal polyps
- Prominent peripheral blood and tissue eosinophilia
- Commonly involved organs: lungs, skin, nervous system
- Vasculitis of small and medium sized arteries

Diagnosis[1]: Patients who present with constitutional symptoms along with clinical evidence of glomerulonephritis, upper or lower respiratory tract involvement, or multiple mononeuropathy. Detection of antineutrophil cytoplasmic autoantibody (ANCA) should increase suspicion of GPA or MPA. Approximately 82 to 94% of patients have a positive ANCA. GPA is primarily associated with PR3-ANCA and MPA is associated with MPO-ANCA.

Asthma and eosinophilia may distinguish EGPA from GPA and MPA. Vasculitis is indistinguishable in all three.

FDA Approval

Tavneos (avacopan)[3]**:** October 7, 2021; 505(b) New Drug Application (NDA) pathway; Type 1 – New Molecular Entity; Standard; Orphan; Approved for GPA and MPA

Current Utilization

	Quarter 3 2024 – Quarter 2 2025		
Medication	**Rx Count**	**Rx Count**	**% of Rx**
Tavneos (avacopan)	**0**	**0**	**0**

Medication Overview [4]

Treatment for organ or life-threatening disease[4]**:**
Organ- or life-threatening disease is characterized by active glomerulonephritis, pulmonary hemorrhage, cerebral vasculitis, progressive peripheral or cranial neuropathy, orbital pseudotumor, scleritis, GI bleeding due to vasculitis, or cardiac disease due to vasculitis (pericarditis, myocarditis). Induction therapy includes treatment with glucocorticoids combined with either rituximab or cyclophosphamide. If the patient achieves remission after 3 to 6 months, maintenance therapy with rituximab, azathioprine, methotrexate, or mycophenolate should be initiated. Rituximab is the preferred choice for maintenance therapy after remission of newly diagnosed disease.

Avacopan can be used as an adjunctive agent with standard induction therapy to limit the use of glucocorticoids. Glucocorticoids should be tapered over 4 to 6 weeks based on patient response. It is indicated for use in severe, active disease which is defined as vasculitis with organ- or life-threatening manifestations (e.g. alveolar hemorrhage, glomerulonephritis, CNS vasculitis, mononeuritis multiplex, cardiac involvement, mesenteric ischemia, limb/digit ischemia). Active disease is defined as new, persistent, or worsening clinical signs and symptoms attributed to GPA or MPA and not related to prior damage.[5]

Treatment for non-organ or non-life-threatening disease[4]**:**
Induction therapy includes glucocorticoids combined with weekly methotrexate. Rituximab is the suggested alternative for patients with an eGFR below 60 mL/min per 1.73m^2. Methotrexate, rituximab, or azathioprine can be used for maintenance therapy.

First-line treatment for non-severe EGPA is systemic glucocorticoids which typically results in remission within the first few weeks. If the patient does not experience remission with system glucocorticoids alone, mepolizumab or benralizumab should be added.[6]

Medication	Avacopan (Tanveos)
Mechanism of Action[3]	Complement 5a receptor antagonist that inhibits the interaction between C5aR and the anaphylatoxin C5a. It blocks C5a-mediated neutrophil activation and migration. Exact mechanism in AAV is not definitively established.
Dosing[4]	30mg twice daily
Special Considerations[4]	• Avoid in patients with chronic liver disease and those taking strong CYP3A4 inducers. • Liver function tests should be obtained at baseline and then monitored periodically.
Clinical Trials[4]	A trial of 331 patients with newly diagnosed or relapsing AAV found that at 52 weeks sustained remission was higher in the avacopan group than in the prednisone group (66 vs 55%).
Cost (AWP)/month[7]	$21,457.37

References:

5. *Falk, Ronald J, et al. Granulomatosis with polyangiitis and microscopic polyangiitis: Clinical manifestations and diagnosis. UpToDate. March 20, 2025. Granulomatosis with polyangiitis and microscopic polyangiitis: Clinical manifestations and diagnosis – UpToDate*
6. *Khoury, Paneez, et al. Epidemiology, pathogeneiss, and pathology of eosinophilic granulomatosis with polyangiitis. UpToDate. Oct 30, 2024. Epidemiology, pathogenesis, and pathology of eosinophilic granulomatosis with polyangiitis - UpToDate*
7. *Tavneos (avacopan). [prescribing information]. Thermo Fisher Scientific. US Food and Drug Administration. Cincinnati, OH Oct 2021.* https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214487s000lbl.pdf
8. *Merkel, Peter A, et al. Granulomatosis with polyangiiis and microscopic polyangiitis: Induction and maintenance therapy. UpToDate. Jul 14, 2025. Granulomatosis with polyangiitis and microscopic polyangiitis: Induction and maintenance therapy - UpToDate*
9. *Chung, Sharon A, et al. 2021 American College of Rheumatology/Vasculitis Foundation Guideline for the Management of Antineutrophil Cytoplasmic Antibody-Associated Vasculitis. Arthritis & Rheumatology. 2021. 2021-ACR-VF-Guideline-for-Management-of-ANCA-Associated-Vasculitis.pdf*
10. *Khoury, Paneez, et al. Eosinophilic granulomatosis with polyangiitis: Treatment and prognosis. UpToDate. May 2, 2025. Eosinophilic granulomatosis with polyangiitis: Treatment and prognosis - UpToDate*
11. *Tavneos (avacopan) Red Book. IBM Micromedex Solutions. Tuven Health Analytics, Inc. Ann Arbor, MI. March 4, 2025. https://www.Micromedexsolutions.com*

NORTH DAKOTA MEDICAID

RETROSPECTIVE DRUG UTILIZATION REVIEW

CRITERIA RECOMMENDATIONS

3RD QUARTER 2025

Criteria Recommendations ***Approved*** ***Rejected***

1. Nirogacestat / Overuse _____ _____

Alert Message: Ogsiveo (nirogacestat) may be over-utilized. The recommended dosage nirogacestat is 150 mg administered orally twice daily until disease progression or unacceptable toxicity.

Drugs/Diseases

Util A	Util B	Util C
Nirogacesta		

Max Dose: 300 mg/day

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Ogsiveo Prescribing Information, April 2024, SpringWorks Therapeutics Inc.

2. Nirogacestat / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Ogsiveo (nirogacestat) have not been established in pediatric patients.

Drugs/Diseases

Util A	Util B	Util C
Nirogacesta		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Ogsiveo Prescribing Information, April 2024, SpringWorks Therapeutics Inc.

3. Nirogacestat / Diarrhea _____ _____

Alert Message: Diarrhea, sometimes severe, can occur in patients treated with Ogsiveo (nirogacestat). In the clinical trial for nirogacestat efficacy, diarrhea occurred in 84% of patients treated with nirogacestat, including Grade 3 events in 16% of patients. For diarrhea persisting for greater than 3 days despite maximal medical therapy, withhold nirogacestat until resolved to Grade 1 or baseline, then restart at a dose of 100 mg twice daily.

Drugs/Diseases

Util A	Util B	Util C
Nirogacesta	Diarrhea	

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Ogsiveo Prescribing Information, April 2024, SpringWorks Therapeutics Inc.

4. Nirogacestat / Elevated Liver Enzymes - Dose _____ _____

Alert Message: ALT or AST elevations occurred in 30% and 33% of patients who received Ogsiveo (nirogacestat) in the clinical trial, respectively. Grade 3 ALT or AST elevations (> 5 × ULN) occurred in 6% and 2.9% of patients, respectively. Monitor liver function tests regularly and modify dose as recommended for patients with Grade 2 (>/= 3 to 5 x ULN) ALT or AST increased withhold nirogacestat until ALT, AST, or both are resolved to < 3 x ULN or baseline, then restart at a dose of 100 mg twice daily. Permanently discontinue nirogacestat if the patient has Garde 3 or 4 (> 5 x ULN).

Drugs/Diseases

Util A	Util B	Util C
Nirogacesta	Abnormal Liver Function Studies	

Max Dose: 200 mg/day

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Ogsiveo Prescribing Information, April 2024, SpringWorks Therapeutics Inc.

5. Nirogacestat / Electrolyte Abnormalities _____ _____

Alert Message: Electrolyte abnormalities can occur in patients treated with Ogsiveo (nirogacestat). In the clinical trial, electrolyte abnormalities included decreased phosphate (65%) and decreased potassium (22%). If Grade 3 or 4 hypophosphatemia persists for >/= 3 days despite maximal replacement therapy, withhold nirogacestat until resolved to Grade 1 or lower or baseline, then restart at a dose of 100 mg twice daily. If Grade 3 or 4 hypokalemia occurs despite maximal replacement therapy, withhold nirogacestat until resolved to Grade 1 or lower, or baseline, then restart at a dose of 100 mg twice daily.

Drugs/Diseases

Util A	Util B	Util C
Nirogacesta	Hypokalemia	
	Hypophosphatemia	

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Ogsiveo Prescribing Information, April 2024, SpringWorks Therapeutics Inc.

6. Nirogacestat / Ovarian Toxicity _____ _____

Alert Message: Female reproductive function and fertility may be impaired in patients being treated with Ogsiveo (nirogacestat). The long-term effects of nirogacestat on fertility have not been established. Advise patients on the potential risks for ovarian toxicity before initiating treatment with nirogacestat. Monitor patients for changes in menstrual cycle regularity or the development of symptoms of estrogen deficiency, including hot flashes, night sweats, and vaginal dryness.

Drugs/Diseases

Util A	Util B	Util C
Nirogacesta		

Gender: Female
Age Range: 18 – 50 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Ogsiveo Prescribing Information, April 2024, SpringWorks Therapeutics Inc.

7. Nirogacestat / Strong or Moderate CYP3A4 Inhibitors _____ _____

Alert Message: The concomitant use of Ogsiveo (nirogacestat) with a strong or moderate CYP3A inhibitor should be avoided. Nirogacestat is a CYP3A substrate, and concomitant use with a strong or moderate CYP3A inhibitor may increase nirogacestat exposure, which may increase the risk of nirogacestat adverse reactions.

Drugs/Diseases

Util A	Util B		Util C
Nirogacesta	Atazanavir	Idelalisib	
	Aprepitant	Itraconazole	
	Clarithromycin	Ketoconazole	
	Cobicistat	Nefazodone	
	Crizotinib	Nelfinavir	
	Diltiazem	Posaconazole	
	Dronedarone	Ritonavir	
	Erythromycin	Tipranavir	
	Fluconazole	Verapamil	
	Fluvoxamine	Voriconazole	
	Fosamprenavir		

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Ogsiveo Prescribing Information, April 2024, SpringWorks Therapeutics Inc.

8. Nirogacestat / Strong or Moderate CYP3A4 Inducers _____ _____

Alert Message: The concomitant use of Ogsiveo (nirogacestat) with a strong or moderate CYP3A inducer should be avoided. Nirogacestat is a CYP3A substrate, and concomitant use with a strong or moderate CYP3A inducer may decrease nirogacestat exposure, which may reduce the effectiveness of nirogacestat.

Drugs/Diseases

Util A	Util B	Util C
Nirogacesta	Apalutamide	
	Bosentan	
	Carbamazepine	
	Efavirenz	
	Etravirine	
	Phenobarbital	
	Phenytoin	
	Primidone	
	Rifabutin	
	Rifampin	
	Rifapentine	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Ogsiveo Prescribing Information, April 2024, SpringWorks Therapeutics Inc.

9. Nirogacestat / PPIs & H-s Antagonists _____ _____

Alert Message: The concomitant use of Ogsiveo (nirogacestat) with proton pump inhibitors and H2 blockers should be avoided. Nirogacestat is poorly soluble at pH ≥ 6. Gastric acid-reducing agents may decrease serum nirogacestat exposure, which may reduce the effectiveness of nirogacestat. If concomitant use cannot be avoided, nirogacestat can be staggered with antacids (e.g., administer nirogacestat 2 hours before or 2 hours after antacid use).

Drugs/Diseases

Util A	Util B		Util C
Nirogacesta	Dexlansoprazole	Cimetidine	
	Esomeprazole	Famotidine	
	Lansoprazole	Nizatidine	
	Omeprazole		
	Rabeprazole		

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Ogsiveo Prescribing Information, April 2024, SpringWorks Therapeutics Inc.

10. Nirogacestat / CYP3A4 Substrates w/NTI _____ _____

Alert Message: Avoid the concomitant use of Ogsiveo (nirogacestat) with CYP3A4 substrates where minimal concentration changes may lead to serious adverse substrate-related reactions. Nirogacestat is a CYP3A4 inhibitor, and concurrent use with a CYP3A4 substrate with a narrow therapeutic index may increase CYP3A substrate exposure, which may increase the risk of substrate-related adverse reactions.

Drugs/Diseases

Util A	Util B					Util C
Nirogacesta	Avanafil	Eletriptan	Lurasidone	Simvastatin	Vardenafil	
	Budesonide	Eplerenone	Maraviroc	Sirolimus		
	Buspirone	Everolimus	Midazolam	Tacrolimus		
	Conivaptan	Felodipine	Naloxegol	Ticagrelor		
	Darifenacin	Ibrutinib	Nisoldipine	Tipranavir		
	Darunavir	Lomitapide	Quetiapine	Tolvaptan		
	Dronedarone	Lovastatin	Sildenafil	Triazolam		

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Ogsiveo Prescribing Information, April 2024, SpringWorks Therapeutics Inc.

11. Nirogacestat / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on findings from animal studies and its mechanism of action, Ogsiveo (nirogacestat) can cause fetal harm or loss of pregnancy when administered to a pregnant woman. Oral administration of nirogacestat to pregnant rats during the period of organogenesis resulted in embryo-fetal toxicity and embryo-fetal death at maternal exposures below the human exposure at the recommended dose of 150 mg twice daily. Advise pregnant women of the potential risk to a fetus.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Nirogacesta	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Ogsiveo Prescribing Information, April 2024, SpringWorks Therapeutics Inc.

12. Nirogacestat / Lactation _____ _____

Alert Message: There are no data on the presence of Ogsiveo (nirogacestat) or its metabolites in human milk or the effects of nirogacestat on a breastfed child or milk production. Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment with nirogacestat and for 1 week after the last dose.

Drugs/Diseases

Util A	Util B	Util C
Nirogacesta	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

13. Nirogacestat /Therapeutic Appropriateness _____ _____

Alert Message: Advise females of reproductive potential to use effective contraception during treatment with Ogsiveo (nirogacestat) and for 1 week after the last dose. Ogsiveo (nirogacestat) can cause fetal harm or loss of pregnancy when administered to a pregnant woman.

Drugs/Diseases

Util A	Util B	Util C
Nirogacesta		

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

14. Nirogacestat /Therapeutic Appropriateness _____ _____

Alert Message: Advise males with female partners of reproductive potential to use effective contraception during treatment with Ogsiveo (nirogacestat) and for 1 week after the last dose.

Drugs/Diseases

Util A	Util B	Util C
Nirogacesta		

Gender: Male

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

15. Nirogacesta / Non-adherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Ogsiveo (nirogacestat). Nonadherence to the prescribed dosing regimen may result in subtherapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Drugs/Diseases

Util A	Util B	Util C
Nirogacesta		

References:

Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Ruddy K, Mayer E, Partridge A. Patient Adherence and Persistence With Oral Anticancer Treatment. CA Cancer J Clin 2009;59:56-66.
Barillet M, Prevost V, Joly F, Clarisse B. Oral Antineoplastic Agents: How do We Care About Adherence?. Br J Clin Pharmacol. 2015;80(6):1289–1302. doi:10.1111/bcp.12734
Greer JA, Amoyal N, Nisotel L, et al. Systemic Review of Adherence to Oral Antineoplastic Therapies. The Oncologist. 2016;21:354-376.

16. Paliperidone ER Injection / Overuse _____ _____

Alert Message: Erzofri (paliperidone extended-release injection) may be over-utilized. The maximum recommended dose of paliperidone extended-release injection is 234 mg monthly.

Drugs/Diseases

Util A	Util B	Util C (Exclude)
Paliperidone ER Injection		Renal Impairment

Max Dose: 234 mg/month

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Erzofri Prescribing Information, Jan. 2025, Luye Innomind Pharma Shijiazhuang Co., Ltd.

17. Paliperidone ER Injection / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Erzofri (paliperidone extended-release injection) in pediatric patients have not been established.

Drugs/Diseases

Util A	Util B	Util C
Paliperidone ER Injection		

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Erzofri Prescribing Information, Jan. 2025, Luye Innomind Pharma Shijiazhuang Co., Ltd.

18. Paliperidone ER Injection / Therapeutic Appropriateness _____ _____

Alert Message: The use of Erzofri (paliperidone extended-release injection) is not recommended in patients with moderate or severe renal impairment (creatinine clearance < 50 mL/min). Paliperidone is substantially excreted by the kidney, and clearance is decreased in patients with renal impairment.

Drugs/Diseases

Util A	Util B	Util C (Include)
Paliperidone ER Injection		CKD Stage 3b
		CKD Stage 4
		CKD Stage 5
		ESRD

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Erzofri Prescribing Information, Jan. 2025, Luye Innomind Pharma Shijiazhuang Co., Ltd.

19. Paliperidone ER Injection / Mild Renal Impairment _____ _____

Alert Message: Dose reduction of Erzofri (paliperidone extended-release injection) is recommended for patients with mild renal impairment. Paliperidone is substantially excreted by the kidney, and clearance is decreased in patients with renal impairment. For patients with mild renal impairment (creatinine clearance >/= 50 mL/min to < 80 mL/min (Cockcroft-Gault Formula), initiate paliperidone extended-release injection with a dose of 234 mg on treatment Day 1 in the deltoid muscle. Follow with the recommended monthly dosage of 78 mg, administered in either the deltoid or gluteal muscle. Adjust monthly dosage based on tolerability and/or response within the strengths of 39 mg, 78 mg, 117 mg, or 156 mg. The maximum monthly dosage is 156 mg for patients with mild renal impairment.

Drugs/Diseases

Util A	Util B	Util C (Include)
Paliperidone ER Injection		Mild Renal Impairment

Max Dose: 156 mg/day

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Erzofri Prescribing Information, Jan. 2025, Luye Innomind Pharma Shijiazhuang Co., Ltd.

20. Semaglutide Tabs / Overuse _____ _____

Alert Message: Rybelsus (semaglutide formulation R2) may be over-utilized. The recommended maximum daily dose of oral semaglutide is 9 mg once daily.

Drugs/Diseases

Util A	Util B	Util C
Semaglutide R2 Tabs		

Max Dose: 9 mg/day

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Rybelsus Prescribing Information, Dec. 2024, Novo Nordisk, Inc.

21. Topiramate Oral Solution / Overuse - Migraine _____ _____
Alert Message: The recommended total daily dose of topiramate oral solution for the preventive treatment of migraine in patients 12 years of age and older is 100 mg per day in two divided doses.

Drugs/Diseases

Util A	Util B	Util C (Include)
Topiramate Sol		Migraine

Max Dose: 100 mg/day

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

22. Aripiprazole / Overuse _____ _____
Alert Message: Opipza (aripiprazole) may be over-utilized. The manufacturer's recommended maximum dose of aripiprazole for the treatment of; schizophrenia is 30 mg/day, major depressive disorder or irritability associated with autistic disorder is 15 mg/day, and for Tourette's disorder it is 10 mg/day in patients < 50 kg or 15 mg/day for patients 50 kg or more.

Drugs/Diseases

Util A	Util B	Util C
Aripiprazole Film		

Max Dose: 30 mg/day

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Opipza Prescribing Information, March 2025, Carwin Pharmaceutical Associates.

23. Benzgalantamine / Overuse _____ _____
Alert Message: Zunveyl (benzgalantamine delayed-release) may be over-utilized. The maximum recommended dose of benzgalantamine is 15 mg twice a day (a total of 30 mg/day).

Drugs/Diseases

Util A	Util B	Util C (Negating)
Benzgalantamine		Moderate to Severe Hepatic Impairment
		Moderate to Severe Renal Impairment

Max Dose: 30 mg/day

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Zunveyl Prescribing Information, July 2024, Alpha Cognition, Inc.

24. Benzgalantamine / Overuse – Moderate Hepatic Impairment _____ _____ Alert Message:
Zunveyl (benzgalantamine delayed-release) may be over-utilized. The maximum recommended dose of benzgalantamine in patients with moderate hepatic impairment is 10 mg twice a day (a total of 20 mg/day).

Drugs/Diseases

Util A	Util B	Util C (Include)
Benzgalantamine		Moderate Hepatic Impairment

Max Dose: 20 mg/day

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Zunveyl Prescribing Information, July 2024, Alpha Cognition, Inc.

25. Benzgalantamine / Severe Hepatic Impairment _____ _____
Alert Message: Zunveyl (benzgalantamine delayed-release) use is not recommended in patients with severe hepatic impairment.

Drugs/Diseases

Util A	Util B	Util C (Include)
Benzgalantamine		Severe Hepatic Impairment

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Zunveyl Prescribing Information, July 2024, Alpha Cognition, Inc.

26. Benzgalantamine / Overuse – Mod to Severe Renal Impairment _____ _____
Alert Message: Zunveyl (benzgalantamine delayed-release) may be over-utilized. The maximum recommended dose of benzgalantamine in patients with creatinine clearance of 9 to 59 mL/min is 10 mg twice a day (total 20 mg/day). In patients with creatinine clearance of less than 9mL/min, the use of benzgalantamine is not recommended. In pharmacokinetic studies, the AUC increased by 37% and 67% in patients with moderate and severe renal impairment, respectively, compared with normal volunteers.

Drugs/Diseases

Util A	Util B	Util C (Include)
Benzgalantamine		CKD Stage 3
		CKD Stage 3a
		CKD Stage 3b
		CKD Stage 4
		CKD Stage 5
		ESRD

Max Dose: 20 mg/day

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Zunveyl Prescribing Information, July 2024, Alpha Cognition, Inc.

27. Benzgalantamine / Therapeutic Appropriateness _____ _____
Alert Message: The safety and effectiveness of Zunveyl (benzgalantamine delayed-release) in pediatric patients have not been established.

Drugs/Diseases
Util A Util B Util C
Benzgalantamine

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Zunveyl Prescribing Information, July 2024, Alpha Cognition, Inc.

28. Benzgalantamine / Non-adherence _____ _____
Alert Message: Based on refill history, your patient may be under-utilizing Zunveyl (benzgalantamine delayed-release). Nonadherence to the prescribed dosing regimen may result in subtherapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Drugs/Diseases
Util A Util B Util C
Benzgalantamine

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Brown MT, Bussell J, Suparna D, et al. Medication Adherence: Truth and Consequences. Am J Med Sci. 2016 Apr;351(4):387-399.

Arlt S, Lindner R, Rosler A, et al., Adherence to Medication in Patients with Dementia, Predictors and Strategies for Improvement. Drugs Aging 2008;25(12):1033-1047.

29. Topiramate XR / Overuse - Migraine _____ _____
Alert Message: The recommended total daily dose of topiramate extended-release for the preventive treatment of migraine in patients 12 years of age and older is 100 mg once daily.

Drugs/Diseases
Util A Util B Util C
Topiramate XR Migraine

Max Dose: 100 mg/day

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

30. Seladelpar / Overuse _____ _____
Alert Message: Livdelzi (seladelpar) may be over-utilized. The recommended dosage of seladelpar is 10 mg orally once daily.

Drugs/Diseases

Util A	Util B	Util C
Seladelpar		

Max Dose: 10 mg/day

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Livdelzi Prescribing Information, August 2024, Gilead Sciences, Inc.

31. Seladelpar / Therapeutic Appropriateness _____ _____
Alert Message: The safety and effectiveness of Livdelzi (seladelpar) in pediatric patients have not been established.

Drugs/Diseases

Util A	Util B	Util C
Seladelpar		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Livdelzi Prescribing Information, August 2024, Gilead Sciences, Inc.

32. Seladelpar / Therapeutic Appropriateness _____ _____
Alert Message: The safety and efficacy of Livdelzi (seladelpar) in patients with decompensated cirrhosis have not been established. Use of seladelpar is not recommended in patients who have or develop decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy). Monitor patients with cirrhosis for evidence of decompensation. Consider discontinuing seladelpar if the patient progresses to moderate or severe hepatic impairment (Child-Pugh B or C).

Drugs/Diseases

Util A	Util B	Util C
Seladelpar	Ascites	
	Cirrhosis	
	Hepatic Encephalopathy	
	Variceal Bleeding	

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Livdelzi Prescribing Information, August 2024, Gilead Sciences, Inc.

33. Seladelpar / Biliary Obstruction _____ _____

Alert Message: Avoid the use of Livdelzi (seladelpar) in patients with complete biliary obstruction. If biliary obstruction is suspected, interrupt seladelpar and treat as clinically indicated.

Drugs/Diseases

Util A	Util B	Util C
Seladelpar	Biliary Obstruction	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Livdelzi Prescribing Information, August 2024, Gilead Sciences, Inc.

34. Seladelpar / OAT3 Inhibitors _____ _____

Alert Message: Concomitant administration of Livdelzi (seladelpar) with OAT3 inhibitors (e.g., probenecid) can increase seladelpar (an OAT3 substrate) exposure. Avoid concomitant administration of seladelpar with OAT3 inhibitors.

Drugs/Diseases

Util A	Util B	Util C
Seladelpar	Gemfibrozil	
	Leflunomide	
	Probenecid	
	Pretomanid	
	Teriflunomide	
	Vadadustat	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Livdelzi Prescribing Information, August 2024, Gilead Sciences, Inc.

35. Seladelpar / Rifampin _____ _____

Alert Message: Co-administration of Livdelzi (seladelpar) with rifampin, an inducer of seladelpar metabolizing enzymes (CYP2D6, CY2C8, and CYP3A4), may reduce systemic seladelpar exposure and result in delayed or suboptimal biochemical response. Monitor the biochemical response (e.g., ALP and bilirubin) when patients initiate rifampin during treatment with seladelpar.

Drugs/Diseases

Util A	Util B	Util C
Seladelpar	Rifampin	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Livdelzi Prescribing Information, August 2024, Gilead Sciences, Inc.

36. Seladelpar / Dual Moderate CYP2C9 and Mod to Strong CYP3A4 Inh _____ _____

Alert Message: Co-administration of Livdelzi (seladelpar) with a drug that is a dual moderate CYP2C9 and moderate or strong CYP3A4 inhibitor may result in increased seladelpar exposure. Seladelpar is a substrate of both CYP2C9 and CYP3A4. Patients receiving seladelpar with a dual inhibitor should be closely monitored for seladelpar adverse effects.

Drugs/Diseases

Util A	Util B	Util C
Seladelpar	Adagrasib	
	Mifepristone	

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Livdelzi Prescribing Information, August 2024, Gilead Sciences, Inc.

37. Seladelpar / BCRP Inhibitors _____ _____

Alert Message: Concomitant administration of Livdelzi (seladelpar) with a BCRP inhibitor may increase seladelpar exposure. When seladelpar is concomitantly administered with drugs that inhibit BCRP, patients should be closely monitored for adverse effects.

Drugs/Diseases

Util A	Util B			Util C
Seladelpar	Acalabrutinib	Leflunomide	Vemurafenib	
	Brigatinib	Osimertinib	Voxilaprevir	
	Capmatinib	Pibrentasvir		
	Cyclosporine	Regorafenib		
	Darolutamide	Rolapitant		
	Eltrombopag	Safinamide		
	Fostamatinib	Sulfasalazine		
	Grazoprevir	Tafamidis		
	Ibrutinib	Tedizolid		
	Itraconazole	Teriflunomide		
	Ledipasvir	Velpatasvir		

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Livdelzi Prescribing Information, August 2024, Gilead Sciences, Inc.

38. Seladelpar / Bile Acid Sequestrants _____ _____

Alert Message: Bile acid sequestrants may interfere with the action of Livdelzi (seladelpar) by reducing its absorption and systemic exposure, which may reduce seladelpar efficacy. Administer seladelpar at least 4 hours before or 4 hours after taking a bile acid sequestrant, or at as great an interval as possible.

Drugs/Diseases

Util A	Util B	Util C
Seladelpar	Cholestyramine	
	Colesevelam	
	Colestipol	

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Livdelzi Prescribing Information, August 2024, Gilead Sciences, Inc.

39. Seladelpar / Lactation _____ _____

Alert Message: There are no data on the presence of Livdelzi (seladelpar) or its metabolite in either human or animal milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for seladelpar and any potential adverse effects on the breastfed infant from seladelpar or the underlying maternal condition.

Drugs/Diseases

Util A	Util B	Util C
Seladelpar	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Livdelzi Prescribing Information, August 2024, Gilead Sciences, Inc.

40. Seladelpar / Non-adherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Livdelzi (seladelpar). Nonadherence to the prescribed dosing regimen may result in subtherapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Drugs/Diseases

Util A	Util B	Util C
Seladelpar		

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Kim J, Combs K, Downs J, Tillman F., Medication Adherence: The Elephant in the Room. US Pharm. 2018;43(1)30-34.
Kleinsinger F. The Unmet Challenge of Medication Nonadherence. Perm Jrnl. 2018;22:18-033. doi:10.7812/TPP/18-033.

41. Metaxalone 640 mg / Overuse _____ _____

Alert Message: Metaxalone may be over-utilized. The recommended dosage of metaxalone 640 mg tablets in adults and pediatric patients 13 years of age and older is 2,560 mg (640 mg four times a day).

Drugs/Diseases

Util A	Util B	Util C
Metaxalone 640		

Max Dose: 2560 mg/day

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Metaxalone Tablet Prescribing Information, Feb. 2025, INA Pharmaceuticals Inc.

42. Metaxalone 640 mg/ Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of metaxalone 640 mg tablets in pediatric patients less than 13 years of age have not been established.

Drugs/Diseases

Util A	Util B	Util C
Metaxalone 640		

Age Range: 0 – 12 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Metaxalone Tablet Prescribing Information, Feb. 2025, INA Pharmaceuticals Inc.

43. Metaxalone 640 mg / Severe Hepatic Impairment _____ _____

Alert Message: Metaxalone 640 mg tablets use is contraindicated in patients with severe hepatic impairment. The effect of hepatic impairment on metaxalone pharmacokinetics is unknown; however, metaxalone undergoes extensive hepatic metabolism. Metaxalone 640 mg tablets should be used with caution and additional monitoring in patients with mild to moderate renal impairment.

Drugs/Diseases

Util A	Util B	Util C
Metaxalone 640	Cirrhosis	
	Hepatic Failure	

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Metaxalone Tablet Prescribing Information, Feb. 2025, INA Pharmaceuticals Inc.

44. Metaxalone 640 mg / Severe Renal Impairment _____ _____

Alert Message: Metaxalone 640 mg tablets use is contraindicated in patients with severe renal impairment. The effect of renal impairment on metaxalone pharmacokinetics is unknown. Metaxalone undergoes renal excretion as unidentified metabolites. Metaxalone 640 mg tablets should be used with caution, and additional monitoring should be considered in patients with mild to moderate renal impairment.

Drugs/Diseases

Util A	Util B	Util C
Metaxalone 640	CKD Stage 4	
	CKD Stage 5	

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Metaxalone Tablet Prescribing Information, Feb. 2025, INA Pharmaceuticals Inc.

45. Meloxicam/Rizatriptan / Overuse _____ _____
Alert Message: Symbravo (meloxicam/rizatriptan) may be over-utilized. The recommended maximum daily dose of meloxicam/rizatriptan is one tablet (20 mg meloxicam/10 mg rizatriptan).

Drugs/Diseases

Util A	Util B	Util C
Meloxicam/Rizatriptan		

Max Dose: 1 Tablet per day

References:
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Symbravo Prescribing Information, Jan. 2025, Axsome Therapeutics.

46. Meloxicam/Rizatriptan / Therapeutic Appropriateness _____ _____
Alert Message: The safety and effectiveness of Symbravo (meloxicam/rizatriptan) in pediatric patients have not been established.

Drugs/Diseases

Util A	Util B	Util C
Meloxicam/Rizatriptan		

Age Range: 0 – 17 yoa

References:
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Symbravo Prescribing Information, Jan. 2025, Axsome Therapeutics.

47. Meloxicam/Rizatriptan / Therapeutic Appropriateness _____ _____
Alert Message: The concurrent use of Symbravo (meloxicam/rizatriptan) with propranolol is contraindicated. Propranolol has been shown to increase the plasma AUC (area under the curve) of rizatriptan, a component of the combination medication. The combination formulation cannot be divided, and therefore, the recommended dose adjustment of rizatriptan is not possible.

Drugs/Diseases

Util A	Util B	Util C
Meloxicam/Rizatriptan	Propranolol	

References:
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Symbravo Prescribing Information, Jan. 2025, Axsome Therapeutics.

48. Aripiprazole Film / Overuse _____ _____
Alert Message: Mezofy (aripiprazole oral film) may be over-utilized. The maximum recommended dose of aripiprazole for the treatment of schizophrenia is 30 mg/day.

Drugs/Diseases
Util A Util B Util C
Aripiprazole Film

Max Dose: 30mg/day

References:
Mezofy Prescribing Information, April 2025, CMG Pharmaceutical Co., Ltd.

49. Aripiprazole Film / Therapeutic Appropriateness _____ _____
Alert Message: The safety and effectiveness of Mezofy (aripiprazole oral film) have not been established in pediatric patients less than 13 years of age. This formulation of aripiprazole is only approved for the treatment of schizophrenia in adult and pediatric patients 13 years and older.

Drugs/Diseases
Util A Util B Util C
Aripiprazole Film

Age Range: 0 – 12 yoa

References:
Mezofy Prescribing Information, April 2025, CMG Pharmaceutical Co., Ltd.

50. Aripiprazole Film / Non-adherence _____ _____
Alert Message: Based on refill history, your patient may be under-utilizing Mezofy (aripiprazole oral film). Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects, which may lead to decreased patient outcomes and additional medical cost.

Drugs/Diseases
Util A Util B Util C
Aripiprazole Film

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Higashi k, Medic G, Littlewood K, et al., Medication Adherence in Schizophrenia: Factors Influencing Adherence and Consequences of Nonadherence, A Systemic Literature Review. Ther Adv Psychopharmacol. 2013 2(4):200-218.

Acsher-Svanum H, Zhu B, Faries DE, et al., The Cost of Relapse and the Predictors of Relapse in the Treatment of Schizophrenia. BMC Psychiatry 2010, 10:2.

51. Vadadustat / Overuse _____ _____
Alert Message: Vafseo (vadadustat) may be over-utilized. The maximum recommended dose of vadadustat is 600 mg per day.

Drugs/Diseases

Util A	Util B	Util C
Vadadustat		

Max Dose: 600 mg/day

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Vafseo Prescribing Information, March 2024, Akebia Therapeutics, Inc.

52. Vadadustat / Therapeutic Appropriateness _____ _____
Alert Message: The safety and effectiveness of Vafseo (vadadustat) in pediatric patients have not been established.

Drugs/Diseases

Util A	Util B	Util C
Vadadustat		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Vafseo Prescribing Information, March 2024, Akebia Therapeutics, Inc.

53. Vadadustat / Therapeutic Appropriateness _____ _____
Alert Message: Vafseo (vadadustat) is not recommended in patients with cirrhosis or active, acute liver disease. Vadadustat may cause hepatotoxicity. In clinical trials, hepatocellular injury attributed to vadadustat was reported in less than 1% of patients, including one case of severe hepatocellular injury with jaundice. All events were asymptomatic and resolved after discontinuation of vadadustat. The time to onset was generally within the first 3 months of treatment.

Drugs/Diseases

Util A	Util B	Util C
Vadadustat	Acute Liver Disease Cirrhosis	

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Vafseo Prescribing Information, March 2024, Akebia Therapeutics, Inc.

54. Vadadustat / Box Warning _____ _____

Alert Message: Vafseo (vadadustat) increases the risk of arterial and venous thrombotic events, that may be fatal, including myocardial infarction, stroke, venous thromboembolism and vascular access thrombosis. Patients with cardiovascular or cerebrovascular disease are at increased risk of these events. Avoid use in patients with a history of myocardial infarction, cerebrovascular event, or acute coronary syndrome within the 3 months prior to starting vadadustat.

Drugs/Diseases

Util A	Util B	Util C (Include)
Vadadustat		Cardiovascular Disease
		Cerebrovascular Disease

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Vafseo Prescribing Information, March 2024, Akebia Therapeutics, Inc.

55. Vadadustat / Gastrointestinal Erosion Risk _____ _____

Alert Message: In clinical trials with Vafseo (vadadustat), gastric or esophageal erosions occurred in 6.4% and 5.3% of darbepoetin alfa-treated patients. Serious gastrointestinal erosions, including gastrointestinal bleeding and the need for red blood cell transfusions were reported in 3.4% and 3.3% of those receiving vadadustat and darbepoetin alfa, respectively. Consider this risk particularly in patients at increased risk for gastrointestinal erosions, such as those with a history of gastrointestinal erosion, peptic ulcer disease, use of concomitant medications that increase the risk of gastrointestinal erosion, and current tobacco smokers and alcohol drinkers.

Drugs/Diseases

Util A	Util B	Util C
Vadadustat	Gastrointestinal Erosion	
	Peptic Ulcer Disease	
	Tobacco Use	
	Alcohol Consumption	
	NSAIDS	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Vafseo Prescribing Information, March 2024, Akebia Therapeutics, Inc.

56. Vadadustat / Malignancy _____ _____

Alert Message: Because increased hypoxia inducible factor (HIF)-1 levels may be associated with unfavorable effects on cancer growth, Vafseo (vadadustat) has not been studied and is not recommended in patients with active malignancies.

Drugs/Diseases

Util A	Util B	Util C
Vadadustat	Malignancy	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Vafseo Prescribing Information, March 2024, Akebia Therapeutics, Inc.

57. Vadadustat / Therapeutic Appropriateness _____ _____

Alert Message: The safety of Vafseo (vadadustat) has not been established for the treatment of anemia due to CKD in adults not on dialysis and its use is not recommended in this setting.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Vadadustat		Dialysis

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Vafseo Prescribing Information, March 2024, Akebia Therapeutics, Inc.

58. Vadadustat / Iron Supplements & Phosphate Binders _____ _____

Alert Message: Co-administration of Vafseo (vadadustat) with oral iron supplements, products containing iron, or phosphate binders decreases the exposure of vadadustat, which may reduce the effectiveness of vadadustat. Stagger administration when vadadustat is used with oral iron supplements, products containing iron, iron-containing phosphate binders, or non-iron containing phosphate binders.

Drugs/Diseases

Util A	Util B	Util C
Vadadustat	Iron Supplements	
	Phosphate Binders	

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Vafseo Prescribing Information, March 2024, Akebia Therapeutics, Inc.

59. Vadadustat / OAT1/OAT3 Inhibitors _____ _____

Alert Message: Co-administration with OAT1/OAT3 (Organic Anion Transporter) inhibitors may increase the area under the concentration curve (AUC) of Vafseo (vadadustat), which may increase the risk of vadadustat adverse reactions. Closely monitor for too large or too rapid an increase in Hb response and for adverse reactions.

Drugs/Diseases

Util A	Util B	Util C
Vadadustat	Clarithromycin	
	Cobicistat	
	Cyclosporine	
	Gemfibrozil	
	Probenecid	
	Rifampin	
	Teriflunomide	
	Velpatasvir	

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Vafseo Prescribing Information, March 2024, Akebia Therapeutics, Inc.

60. Vadadustat / Sulfasalazine _____ _____

Alert Message: The concurrent use of Vafseo (vadadustat) with sulfasalazine can result in increased exposure of sulfasalazine, which may increase the risk of sulfasalazine-related adverse reactions. Dosage reduction of sulfasalazine may be needed.

Drugs/Diseases

Util A	Util B	Util C
Vadadustat	Sulfasalazine	

References:

Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Vafseo Prescribing Information, March 2024, Akebia Therapeutics, Inc.

61. Vadadustat / Rosuvastatin 10, 20 & 40 mg _____ _____

Alert Message: In pharmacokinetic studies, concurrent use of Vafseo (vadadustat) with rosuvastatin resulted in increases the maximal concentration (Cmax) and AUC of rosuvastatin. The maximum daily dose of rosuvastatin should not exceed 5 mg/day when used concurrently with vadadustat.

Drugs/Diseases

Util A	Util B	Util C
Vadadustat	Rosuvastatin 10 mg	
	Rosuvastatin 20 mg	
	Rosuvastatin 40 mg	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Vafseo Prescribing Information, March 2024, Akebia Therapeutics, Inc.

62. Vadadustat / Simvastatin 40 & 80 mg _____ _____

Alert Message: In pharmacokinetic studies, concurrent use of Vafseo (vadadustat) with simvastatin resulted in increases the maximal concentration (Cmax) and AUC of simvastatin. The maximum daily dose of simvastatin should not exceed 20 mg/day when used concurrently with vadadustat.

Drugs/Diseases

Util A	Util B	Util C
Vadadustat	Simvastatin 40 mg	
	Simvastatin 80 mg	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

63. Vadadustat / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Available data with Vafseo (vadadustat) use in pregnant women are insufficient to establish a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. Vadadustat should only be used during pregnancy if the benefit justifies the potential risk to the fetus.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Vadadustat	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Vafseo Prescribing Information, March 2024, Akebia Therapeutics, Inc.

64. Vadadustat / Lactation _____ _____

Alert Message: There are no data on the presence of Vafseo (vadadustat) in human milk, the effects of vadadustat on the breastfed child, or the effects on milk production. Vadadustat is present in the milk of lactating rats. When a drug is present in animal milk, it is likely that the drug will be present in human milk. Given the serious adverse reactions seen in adults treated with vadadustat, such as thrombotic vascular events, advise patients not to breastfeed during treatment with vadadustat, and for 2 days after the final dose.

Drugs/Diseases

Util A	Util B	Util C
Vadadustat	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Vafseo Prescribing Information, March 2024, Akebia Therapeutics, Inc.

65. Ropinirole XR / Overuse – Parkinson's Disease _____ _____

Alert Message: Ropinirole extended-release may be over-utilized. The maximum recommended dose of ropinirole ER for the treatment of Parkinson's disease is 24 mg per day.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Ropinirole XR		Dialysis

Max Dose: 24 mg/day

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Ropinirole Hydrochloride Tablet Extended-Release Prescribing Information, Sept. 2023, AvKARE.

66. Ropinirole XR / Severe Renal Impairment _____ _____
Alert Message: Ropinirole extended-release may be over-utilized. The maximum recommended dose of ropinirole ER for the treatment of Parkinson's disease in patients with end-stage renal disease on dialysis is 18 mg per day.

Drugs/Diseases

Util A	Util B	Util C (Include)
Ropinirole XR		Dialysis

Max Dose: 18 mg/day

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Ropinirole Hydrochloride Tablet Extended-Release Prescribing Information, Sept. 2023, Solco Healthcare US, LLC.

67. Ropinirole XR / Therapeutic Appropriateness _____ _____
Alert Message: Safety and effectiveness of ropinirole extended-release in pediatric patients have not been established.

Drugs/Diseases

Util A	Util B	Util C
Ropinirole XR		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Ropinirole Hydrochloride Tablet Extended-Release Prescribing Information, Sept. 2023, Solco Healthcare US, LLC.

68. Ropinirole XR / Dyskinesia _____ _____
Alert Message: Ropinirole extended-release may cause or exacerbate pre-existing dyskinesia in patients treated with L-dopa for Parkinson's disease. Decreasing the dose of dopaminergic medications may ameliorate this adverse reaction.

Util A	Util B	Util C (Include)
Ropinirole XR	Levodopa	Dyskinesia

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Ropinirole Hydrochloride Tablet Extended-Release Prescribing Information, Sept. 2023, Solco Healthcare US, LLC.

69. Ropinirole XR / Impulse Control _____ _____

Alert Message: Reports suggest that patients can experience intense urges to gamble, increased sexual urges, intense urges to spend money, binge or compulsive eating, and/or other intense urges, and the inability to control these urges while taking medications that increase central dopaminergic tones, including ropinirole extended-release. Because patients may not recognize these behaviors as abnormal, it is important for prescribers to specifically ask patients or their caregivers about the development of new or increased gambling urges, sexual urges, uncontrolled spending, binge or compulsive eating, or other urges while being treated with ropinirole tablets for Parkinson's disease. Physicians should consider dose reduction or stopping the medication if a patient develops such urges while taking ropinirole extended-release.

Drugs/Diseases

Util A	Util B	Util C
Ropinirole XR	Pathological Gambling	
	Other Impulse Disorders	
	Binge Eating Disorder	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Ropinirole Hydrochloride Tablet Extended-Release Prescribing Information, Sept. 2023, Solco Healthcare US, LLC.

70. Ropinirole XR / Hallucinations & Psychotic-Like Behavior _____ _____

Alert Message: Postmarketing reports indicate that patients with Parkinson's disease may experience new or worsening mental status and behavioral changes, which may be severe, including psychotic-like behavior during treatment with ropinirole extended-release or after starting or increasing the dose of ropinirole. This abnormal thinking and behavior can consist of one or more of a variety of manifestations including paranoid ideation, delusions, hallucinations, confusion, psychotic-like behavior, mania, disorientation, aggressive behavior, agitation, and delirium. Patients with a major psychotic disorder should ordinarily not be treated with ropinirole ER because of the risk of exacerbating the psychosis.

Drugs/Diseases

Util A	Util B	Util C
Ropinirole XR	Paranoid ideation	
	Delusions	
	Hallucinations	
	Confusion	
	Psychotic-like behavior	
	Mania	
	Disorientation	
	Aggressive behavior	
	Agitation	
	Delirium	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Ropinirole Hydrochloride Tablet Extended-Release Prescribing Information, Sept. 2023, Solco Healthcare US, LLC.

71. Ropinirole XR / Dopamine Antagonists _____ _____

Alert Message: Ropinirole extended-release is a dopamine agonist, and concurrent use with a dopamine antagonist such as neuroleptics (e.g., phenothiazines, butyrophenones, thioxanthenes) or metoclopramide may reduce the efficacy of ropinirole.

Drugs/Diseases

Util A	Util B		Util C
Ropinirole XR	Chlorpromazine	Aripiprazole	
	Fluphenazine	Asenapine	
	Haloperidol	Iloperidone	
	Loxapine	Lumateperone	
	Molindone	Lurasidone	
	Perphenazine	Olanzapine	
	Pimozide	Paliperidone	
	Prochlorperazine	Risperidone	
	Thioridazine	Ziprasidone	
	Thiothixene		
	Trifluoperazine		
	Metoclopramide		

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Ropinirole Hydrochloride Tablet Extended-Release Prescribing Information, Sept. 2023, Solco Healthcare US, LLC.

72. Ropinirole XR / Higher Dose Estrogen _____ _____

Alert Message: Concomitant use of ropinirole extended-release and higher doses of estrogens may increase the exposure of ropinirole. A dose adjustment of ropinirole ER may be needed when estrogen therapy is initiated or discontinued.

Drugs/Diseases

Util A	Util B	Util C
Ropinirole XR	Conjugated Estrogen	
	Esterified Estrogen	
	Estradiol	
	Estropipate	
	Ethinyl Estradiol	

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Ropinirole Hydrochloride Tablet Extended-Release Prescribing Information, Sept. 2023, Solco Healthcare US, LLC.

73. Ropinirole XR / CYP1A2 Inhibitors _____ _____

Alert Message: Ropinirole is a CYP1A2 substrate, and concurrent use with a CYP1A2 inhibitor may result in increased ropinirole concentrations. Therefore, if therapy with a drug known to be a potent inhibitor of CYP1A2 is initiated or discontinued during treatment with ropinirole extended-release, adjustment of ropinirole ER dose may be required.

Drugs/Diseases

Util A	Util B	Util C
Ropinirole XR	Ciprofloxacin	
	Fluvoxamine	
	Viloxazine	

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Ropinirole Hydrochloride Tablet Extended-Release Prescribing Information, Sept. 2023, Solco Healthcare US, LLC.

74. Ropinirole XR / Pregnancy / Pregnancy Negating _____ _____

Alert Message: There are no adequate data on the developmental risk associated with the use of ropinirole extended-release in pregnant patients. In animal studies, ropinirole had adverse effects on development when administered to pregnant rats at doses similar to (neurobehavioral impairment) or greater than (teratogenicity and embryolethality at >36 times) the MRHD for Parkinson's disease. Ropinirole should be used in pregnancy only if the potential benefit to the mother outweighs the potential risk to the fetus.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Ropinirole XR	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Ropinirole Hydrochloride Tablet Extended-Release Prescribing Information, Sept. 2023, Solco Healthcare US, LLC.

75. Ropinirole XR / Lactation _____ _____

Alert Message: There are no data on the presence of ropinirole in human milk, the effects of ropinirole on the breastfed infant, or the effects of ropinirole on milk production. However, inhibition of lactation is expected because ropinirole inhibits secretion of prolactin in humans. Ropinirole or metabolites, or both, are present in rat milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ropinirole and any potential adverse effects on the breastfed infant from ropinirole or the underlying maternal condition.

Drugs/Diseases

Util A	Util B	Util C
Ropinirole XR	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Ropinirole Hydrochloride Tablet Extended-Release Prescribing Information, Sept. 2023, Solco Healthcare US, LLC.

76. Ropinirole XR/ Non-adherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing ropinirole extended-release. Nonadherence to the prescribed dosing regimen may result in subtherapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Drugs/Diseases

Util A	Util B	Util C
Ropinirole XR		

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Richy FF, Guilhem P, Moran, et al., Compliance with Pharmacotherapy and Direct Healthcare Costs with Parkinson's Disease: A Retrospective Claims Database Analysis. Appl Health Econ Health Policy. 2013 Aug;11(4):395-406.

Daley DJ, Myint PK, Gray RJ, Deane KH. Interventions for Improving Medication Adherence in Patients with Idiopathic Parkinson's Disease. Cochrane Database System Rev 2014. DOI:10.1002/14651858.CD011191

77. Mepolizumab / Therapeutic Appropriateness - COPD _____ _____
Alert Message: The safety and effectiveness of Nucala (mepolizumab) in patients less than 18 years of age with chronic obstructive pulmonary disease (COPD) have not been established.

Drugs/Diseases

Util A	Util B	Util C (Include)
Mepolizumab		COPD

Age Range: 0 – 17 yoa

References:
Nucala Prescribing Information, May 2025, GlaxoSmithKline

78. Mepolizumab / Overutilization - COPD _____ _____ Alert Message:
The manufacturer's recommended dosage of Nucala (mepolizumab) for the treatment of chronic obstructive pulmonary disease (COPD) in adults is 100 mg administered once every 4 weeks.

Drugs/Diseases

Util A	Util B	Util C (Include)
Mepolizumab		COPD

Max Dose: 1 injection/4 weeks

References:
Nucala Prescribing Information, May 2025, GlaxoSmithKline

79. Hydroxyurea Oral Solution / Overuse - Renal _____ _____
Alert Message: Xromi (hydroxyurea oral solution) may be over-utilized. Reduce the dose of hydroxyurea oral solution by 50% in patients with creatinine clearance of less than 60 mL/min or with end-stage renal disease (ESRD). The exposure to hydroxyurea is higher in patients with creatinine clearance of less than 60 mL/min. Closely monitor hematologic parameters when hydroxyurea is administered to this patient population.

Drugs/Diseases

Util A	Util B	Util C (Include)
Hydroxyurea Oral Solution		CKD Stage 3, 4 & 5 ESRD

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Xromi Prescribing Information, Dec. 2024, Rare Disease Therapeutics Inc.

Board Suggestions for clinical practice education or RDUR ICER criteria

1. Is there anything in clinical practice that you've seen that you feel needs to be addressed?
    a. New best practices?
    b. Fraud, waste, or abuse?
2. Is there any new guideline information?
3. Requests for Utilization Review topics?