North Dakota Medicaid
Drug Utilization Review Board Meeting
December 2, 2026
HHS Hoteling Space, Room 308, State Capitol

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Meeting Notice

North Dakota Medicaid Drug Use Review Board

Wednesday, December 2, 2026
1 p.m. to 4 p.m. Central Time

In-Person Information

HHS Hoteling Space, Room 308, State Capitol
600 E. Boulevard Ave., Bismarck

Virtual Information

Join the virtual meeting
Join by phone: 701-328-0950, Conference ID 288 179 943 233 45

Accommodations: Individuals with disabilities who need accommodations, including auxiliary aids, to participate may contact Ashley Gerving at 701-328-2354, toll-free 800-755-2604, 711 (TTY), or email at gervingashley@nd.gov.

Agenda

1. Call to Order
2. Roll Call
3. Review and Approval of Minutes
4. Reports from Department
   - Administrative Report: PDMP data
   - Financial Report
   - Retrospective Drug Utilization Review (DUR) Report
   - Clinical Report:
     - Prior Authorization and Criteria Updates: Anti-infectives/Anti-inflammatories – Fluroquinolones, Asthma/COPD, Cholestatic Pruritis, Diabetes, Diabetic Kidney Disease, Heart Failure, Hepatitis C Antiviral Treatments, Hypertrophic Cardiomyopathy, Lipid-Lowering Medication, Migraine, Spinal Muscular Atrophy, Systemic Lupus Erythematosus
     - Annual Prior Authorization Review
5. Unfinished Business – Nausea and Vomiting Criteria, Updated financial charts from Q3 meeting
6. New Business

- Second Reviews of Antipsychotics, Human Immunodeficiency Virus, Human Coronavirus, Hypertension, Long-acting Opioids, Pheochromocytoma
- First Reviews of Contraceptives, Fibrodysplasia ossificans progressiva (FOP)
- Brand Antipsychotic Report Card
- Review of Retrospective DUR Criteria Recommendations
- Provider suggestions for clinical practice education or Retrospective Drug Utilization Review (RDUR) Incremental Cost-Effectiveness Ratio (ICER) criteria

7. Announcements: Next Meeting (March 3, 2027)
8. Adjourn

Meeting Minutes
North Dakota Medicaid Drug Use Review (DUR) Board
Meeting Date: September 2, 2026
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 1:00 pm CST with K. Martian 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, Paige Adkins, Jessica Ziegler, Amy Werremeyer, Matthew Zimny, Kristen Peterson
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 K. Datz to approve the minutes of the June 3, 2026 meeting, motion was seconded by K. Martian. Motion carried.
The minutes of the June 3, 2026, meeting were approved as distributed.

Reports:
Administrative Report: K. Steig
K. Steig shared with the Board Prescription Drug Monitoring Program provider requirements and update on the brand antipsychotic report card.

Financial Report: A. Murphy
A. Murphy 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 A. Murphy
A. Murphy 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: 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: Allergic Fungal Rhinosinusitis, Biosimilar agents, General Rules, Imcivree, Non-Cystic Fibrosis Bronchiectasis, NSAIDs, Pulmonary Hypertension

New business:

Second Reviews presented by J. McKee
J. McKee presented group prior authorization criteria for Familial Chylomicronemia Syndrome
Motion: Moved by K. Datz to place Familial Chylomicronemia Syndrome
on prior authorization, motion was seconded by A. Werremeyer. Motion carried.

J. McKee presented group prior authorization criteria for Nausea and Vomiting
Motion: Moved by K. Martian to place Nausea and Vomiting on prior authorization with alignment of current guidelines, motion was seconded by G. Balf. Motion carried.

J. McKee presented group prior authorization criteria for Transplant-Associated Thrombotic Microangiopathy
Motion: Moved by A. Werremeyer to place Transplant-Associated Thrombotic Microangiopathy on prior authorization, motion was seconded by M. Zimny. Motion carried.

First Reviews presented by J. McKee
J. McKee presented an overview of Antipsychotics. The presented material can be found in the handout.
Motion: Moved by K. Martian to create a subcommittee to assist department in drafting prior authorization criteria for Antipsychotics, motion was seconded by K. Datz. Motion carried.

First Reviews presented by J. McKee
J. McKee presented an overview of Human Immunodeficiency Virus. The presented material can be found in the handout.
Motion: Moved by A. Werremeyer to draft prior authorization for Human Immunodeficiency Virus, motion was seconded by M. Zimny. Motion carried.

First Reviews presented by J. McKee
J. McKee presented an overview of Human Coronavirus. The presented material can be found in the handout.
Motion: Moved by K. Martian to draft prior authorization for Human Coronavirus, motion was seconded by A. Werremeyer. Motion carried.

First Reviews presented by J. McKee
J. McKee presented an overview of Hypertension. The presented material can be found in the handout.
Motion: Moved by A. Dahl to draft prior authorization for Hypertension, motion was seconded by G. Balf. Motion carried.

First Reviews presented by J. McKee
J. McKee presented an overview of Long-acting Opioids. The presented material can be found in the handout.
Motion: Moved by K. Martian to draft prior authorization for Long-acting Opioids, motion was seconded by K. Datz. Motion carried.

First Reviews presented by J. McKee

J. McKee presented an overview of Pheochromocytoma. The presented material can be found in the handout.
Motion: Moved by A. Werremeyer to draft prior authorization for Pheochromocytoma, motion was seconded by S. Antony. Motion carried.

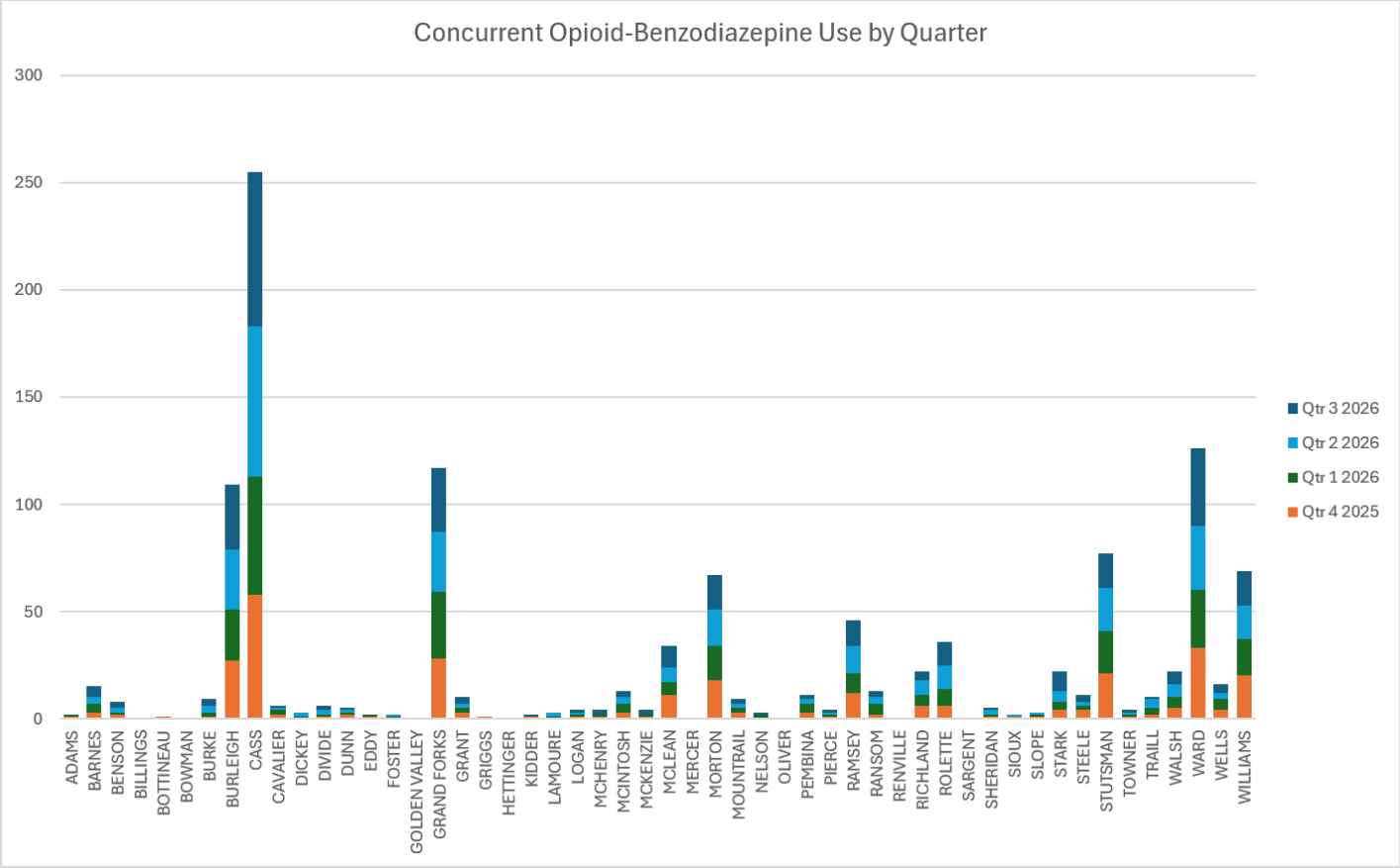
Retrospective Drug Utilization Review (RDUR) Criteria Recommendations:
RDUR criteria recommendations were reviewed. The presented material can be found in the handout.
Motion: Moved by K. Datz to approve the RDUR criteria, motion was seconded by A. Dahl. Motion carried.

Announcements:
Next meeting is December 2, 2026.

Adjournment:
Meeting adjourned by K. Martian at 2:33 pm CST.

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

PDMP Data

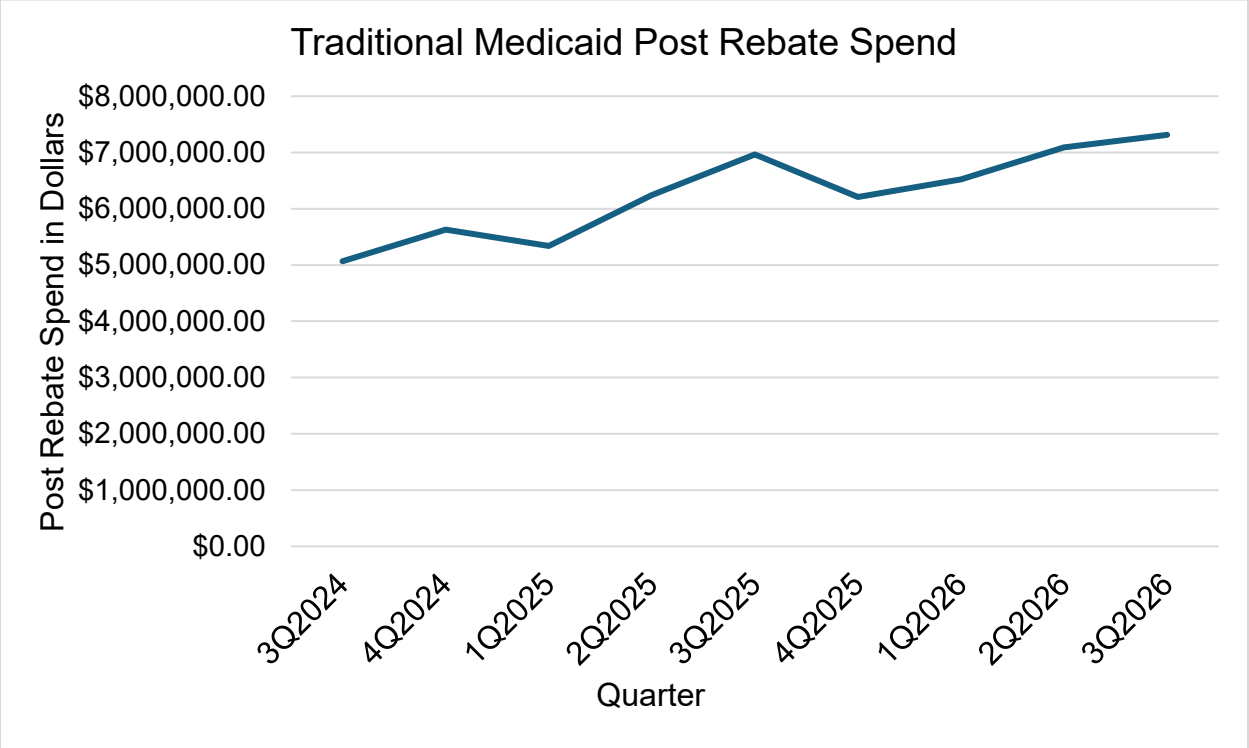


Detailed Description:

The graphic shows the data broken down by each county in North Dakota, with stacked bars representing the last four quarters. The totals represent the number of members in each quarter with claims paid through Medicaid who got at least a 30-day supply of both an opioid and a benzodiazepine during that quarter, indicating concurrent use.

Traditional Medicaid Post Rebate Spend

For calculation of the post rebate spend for 3Q2026, 3Q2026 federal rebate dollars and 2Q2026 supplemental rebate dollars were used as 3Q2026 supplemental rebate dollars were not yet available at the time of the graph creation.

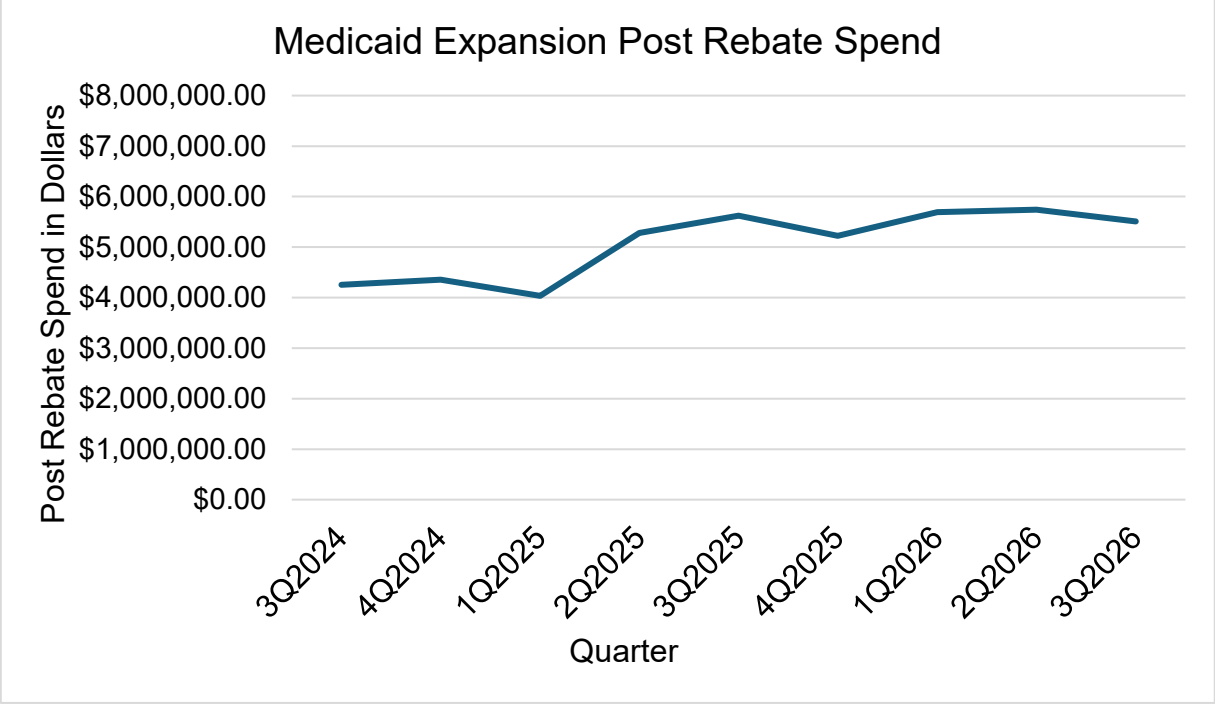


Detailed Description:

A line graph showing post rebate spend for traditional Medicaid between 3Q2024 and 3Q2026. There is a steep increase between 1Q2025 and 3Q2025 followed by a dip in 4Q2025 and then an increase until 3Q2026. The overall trend is an increase in post rebate spend between 3Q2024 and 3Q2026 by $2.3 million.

Medicaid Expansion Post Rebate Spend

For calculation of the post rebate spend for 3Q2026, 3Q2026 federal rebate dollars and 2Q2026 supplemental rebate dollars were used as 3Q2026 supplemental rebate dollars were not yet available at the time of the graph creation.

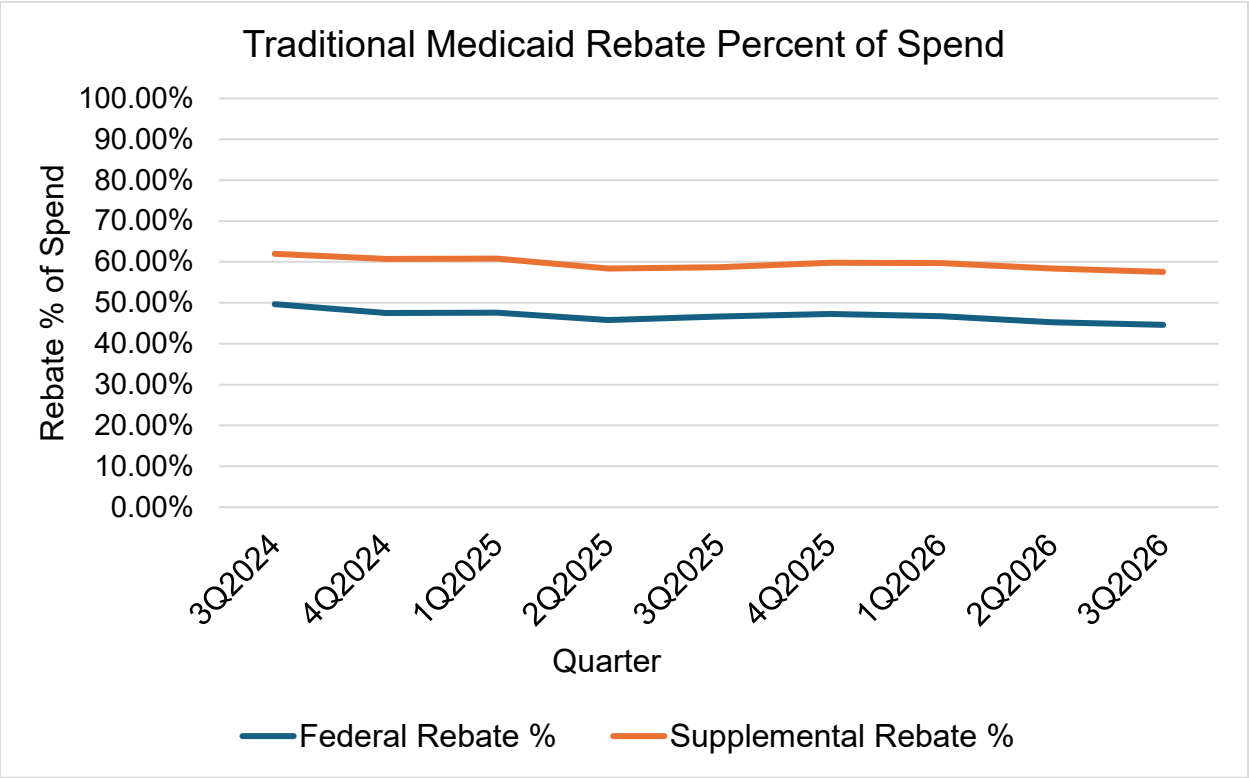


Detailed Description:

A line graph showing post rebate spend for Medicaid Expansion between 3Q2024 and 3Q2026. There is a slight dip in post rebate spend in 1Q2025 followed by a steep increase in 2Q2025. The overall trend is an increase in post rebate spend between 3Q2024 and 3Q2026 by over $1 million.

Traditional Medicaid Rebate Percent of Spend

For calculation of the post rebate percent of spend for 3Q2026, 3Q2026 federal rebate dollars and 2Q2026 supplemental rebate dollars were used as 3Q2026 supplemental rebate dollars were not yet available at the time of the graph creation.

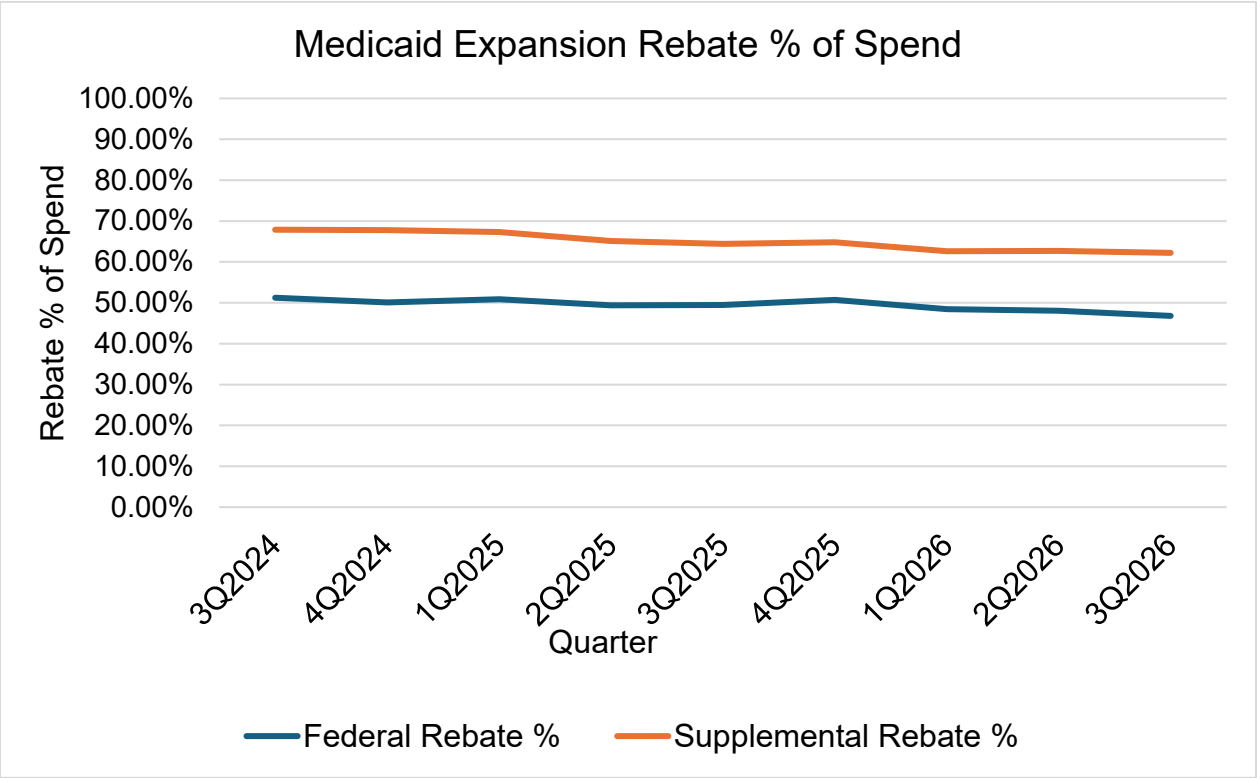


Detailed Description:

A stacked line graph showing post rebate percent of spend for traditional Medicaid between 3Q2024 and 3Q2026. The federal rebate percent of spend decreased nearly 5% during this timeframe and supplemental rebate percent of spend increased by 0.6% during this timeframe which resulted in an overall decrease in rebate percent of spend of 4.4%.

Medicaid Expansion Rebate Percent of Spend

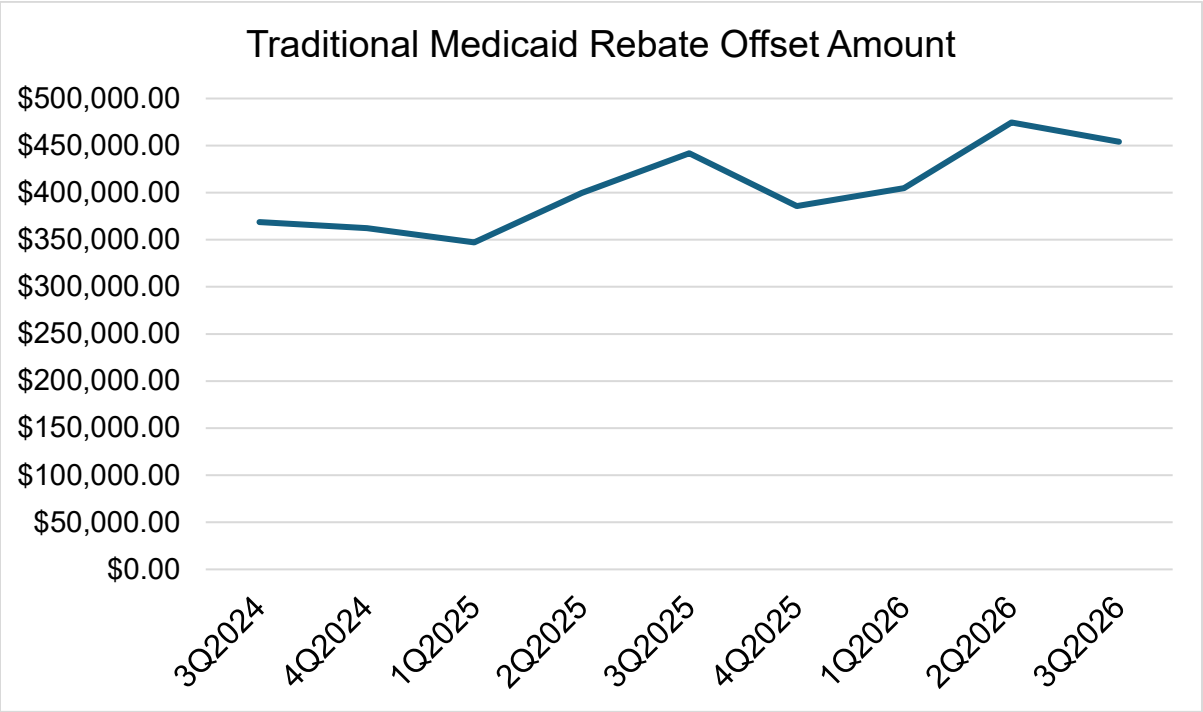
For calculation of the post rebate percent of spend for 3Q2026, 3Q2026 federal rebate dollars and 2Q2026 supplemental rebate dollars were used as 3Q2026 supplemental rebate dollars were not yet available at the time of the graph creation.



Detailed Description:

A stacked line graph showing post rebate percent of spend for Medicaid Expansion between 3Q2024 and 3Q2026. The federal rebate percent of spend decreased by 4.5% during this timeframe and supplemental rebate percent of spend decreased by 1.2% during this timeframe which resulted in an overall decrease in rebate percent of spend of 5.7%.

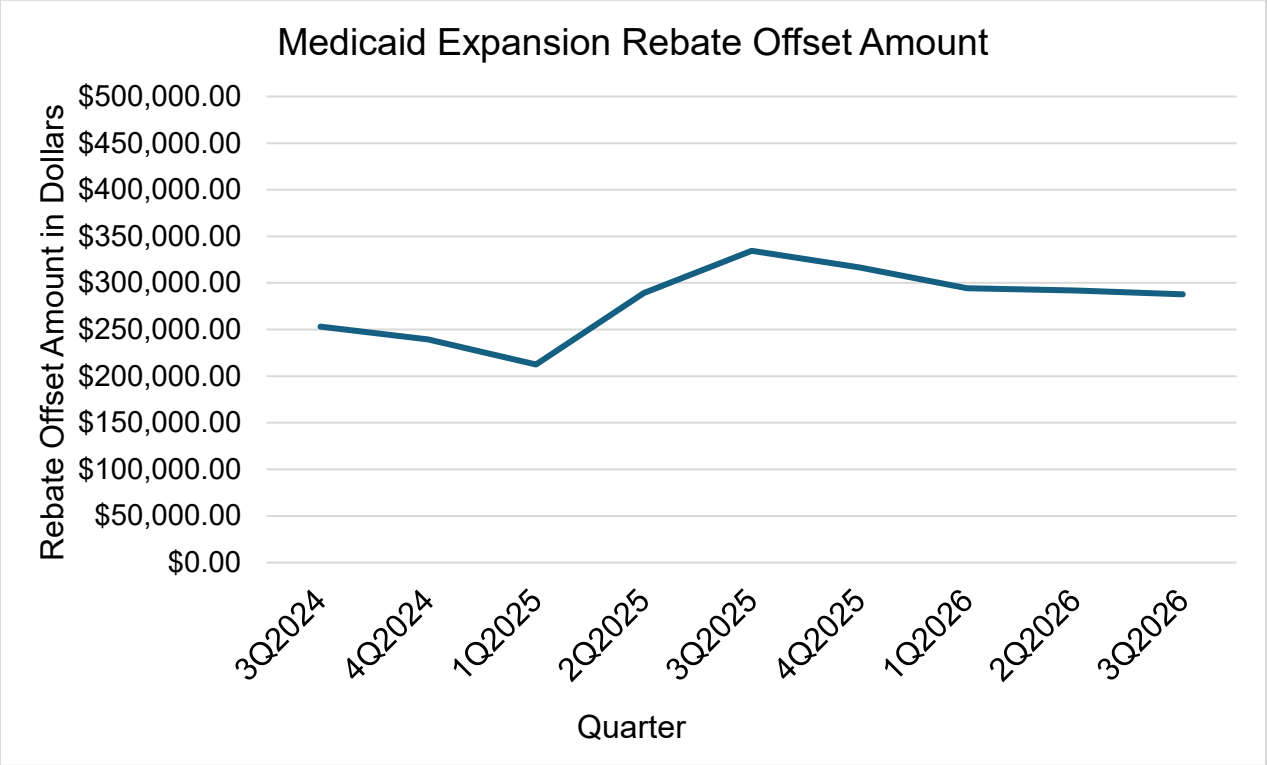
Traditional Medicaid Rebate Offset Amount



Detailed Description:

A line graph showing an overall increase of $85,000 per quarter in rebate offset amount for traditional Medicaid between 3Q2024 and 3Q2026. The rebate offset amount decreased slightly between 3Q2024 and 1Q2025 before steeply increasing between 1Q2025 and 3Q2025, decreasing between 3Q2025 and 4Q2025, increasing between 4Q2025 and 2Q2026, and slightly decreasing 3Q2026.

Medicaid Expansion Rebate Offset Amount



Detailed Description:

A line graph showing an overall increase of $35,000 in rebate offset amount for Medicaid Expansion between 3Q2024 and 3Q2026. The rebate offset amount decreased slightly between 3Q2024 and 1Q2025 before steeply increasing between 1Q2025 and 3Q2025 before decreasing slightly again.

Top 25 Drugs Based on Total Claims Cost from 7/1/26 to 9/30/26

Total Claims Cost - $ 18,231,915.89

#	Drug Name	Claims	Claims Cost	Patients	Cost/Patient	% Cost	Dif
1	OZEMPIC	2,566	$2,561,465.64	1,107	$2,313.88	6.35%	NC
2	HUMIRA	221	$2,060,434.00	97	$52,277.00	5.11%	NC
3	TALTZ	141	$1,270,150.00	60	$92,292.00	3.15%	↑3
4	DUPIXENT	272	$1,120,406.00	130	$16,574.00	2.78%	↑1
5	TRIKAFTA	41	$1,106,374.74	14	$79,026.77	2.74%	↑3
6	VRAYLAR	818	$1,005,238.23	331	$3,036.97	2.49%	↑1
7	VYVANSE	2,902	$884,158.03	1,368	$646.31	2.19%	↓3
8	NORDITROPIN	110	$865,435.57	46	$18,813.82	2.15%	↑1
9	BIKTARVY	299	$780,507.13	140	$5,575.05	1.94%	↑3
10	SOFOSBUVIR-VELPATASVIR	33	$748,033.47	32	$23,376.05	1.86%	↓7
11	DULERA	1,770	$592,767.18	1,089	$544.32	1.47%	NC
12	COSENTYX	55	$532,649.00	32	$84,072.00	1.32%	↑2
13	SUBLOCADE	226	$500,474.74	112	$4,468.52	1.24%	↑3
14	INVEGA SUSTENNA	166	$485,773.85	65	$7,473.44	1.20%	NC
15	INGREZZA	57	$460,654.80	19	$24,244.99	1.14%	NC
16	JARDIANCE	1,346	$457,055.53	682	$670.17	1.13%	↓3
17	ENBREL	50	$441,087.00	19	$45,627.00	1.09%	↑2
18	BIMZELX	23	$371,979.00	11	$82,325.00	0.92%	↑2
19	VERZENIO	18	$311,802.12	6	$51,967.02	0.77%	↑7
20	KESIMPTA PEN	33	$305,293.10	13	$23,484.08	0.76%	↓3
21	ABILIFY MAINTENA	109	$295,375.45	46	$6,421.21	0.73%	NC
22	INVEGA TRINZA	30	$285,854.25	28	$10,209.08	0.71%	NC
23	ELIQUIS	714	$280,471.23	374	$749.92	0.70%	NC
24	CRENESSITY	7	$276,468.22	3	$92,156.07	0.69%	↓6
25	VIVITROL	135	$232,007.61	67	$3,462.80	0.58%	NC

Top 25 Drugs Based on Number of Claims from 7/1/26 to 9/30/26

Total Number of Claims – 66,656

#	Drug Name	Claims	Claims Cost	Patients	Cost/Claim	% Claims	Dif
1	GABAPENTIN	4,251.00	$62,997.91	1,797.00	$14.82	1.74%	NC
2	SERTRALINE	3,637.00	$49,128.83	2,055.00	$13.51	1.49%	↑2
3	TRAZODONE	3,504.00	$46,472.34	1,896.00	$13.26	1.44%	NC
4	ESCITALOPRAM	3,175.00	$42,653.42	1,808.00	$13.43	1.30%	↑2
5	FLUOXETINE	3,058.00	$40,815.99	1,709.00	$13.35	1.25%	NC
6	CLONIDINE	2,976.00	$36,602.14	1,525.00	$12.30	1.22%	↑1
7	VYVANSE	2,902.00	$884,158.03	1,368.00	$304.67	1.19%	↓5
8	HYDROXYZINE	2,753.00	$38,749.25	1,688.00	$14.08	1.13%	↑1
9	BUPROPION XL	2,661.00	$43,513.49	1,513.00	$16.35	1.09%	↑2
10	LEVOTHYROXINE	2,646.00	$36,687.37	1,465.00	$13.87	1.08%	NC
11	OMEPRAZOLE	2,602.00	$36,788.02	1,680.00	$14.14	1.07%	↑3
12	OZEMPIC	2,566.00	$2,561,465.64	1,107.00	$998.23	1.05%	↑8
13	DEXTROAMPHETAMINE-AMPHET ER	2,502.00	$64,621.30	1,076.00	$25.83	1.02%	↑2
14	ATORVASTATIN	2,461.00	$36,340.55	1,495.00	$14.77	1.01%	↑1
15	LAMOTRIGINE	2,379.00	$32,195.20	982.00	$13.53	0.97%	↑3
16	METHYLPHENIDATE ER	2,356.00	$62,925.71	1,020.00	$26.71	0.97%	NC
17	ONDANSETRON ODT	2,333.00	$32,205.06	1,769.00	$13.80	0.96%	↑2
18	BUSPIRONE	2,308.00	$33,638.95	1,215.00	$14.57	0.95%	↑5
19	PANTOPRAZOLE	2,284.00	$31,986.70	1,415.00	$14.00	0.94%	↑2
20	ARIPIPRAZOLE	2,265.00	$34,115.29	1,141.00	$15.06	0.93%	↑2
21	CYCLOBENZAPRINE	2,242.00	$27,731.28	1,392.00	$12.37	0.92%	↑8
22	HYDROCODONE-ACETAMINOPHEN	2,225.00	$35,081.96	1,376.00	$15.77	0.91%	↑3
23	PREDNISONE	2,220.00	$26,241.60	1,785.00	$11.82	0.91%	↑6
24	VENTOLIN HFA	2,184.00	$146,570.00	2,162.00	$67.11	0.89%	↓12
25	LISINOPRIL	2,166.00	$28,434.16	1,387.00	$13.13	0.89%	↑1

Top 15 Therapeutic Classes Based on Number of Claims from 7/1/26 to 9/30/26

Total Number of Claims = 107,150

#	Therapeutic Class Description	Claims	Claims Cost	Patients	Cost/Claim	% Claims	Dif
1	ANTIDEPRESSANTS	24,787	$735,066.25	10,609	29.66	10.15%	NC
2	ANTIPSYCHOTIC	9,952	$3,228,703.99	4,071	324.43	4.08%	NC
3	AMPHETAMINES	8,114	$1,065,327.31	3,266	131.29	3.32%	NC
4	GABA-MEDIATED ANTICONVULSANTS	6,764	$142,078.19	2,788	21.01	2.77%	↑1
5	RESPIRATORY AND CNS STIMULANTS	6,523	$297,780.22	2,624	45.65	2.67%	↓1
6	OPIOID AGONISTS	5,919	$114,567.35	3,007	19.36	2.42%	↑1
7	CENTRAL ALPHA-AGONISTS	5,707	$80,684.53	2,712	14.14	2.34%	↓1
8	NONSTEROIDAL ANTI-INFLAMMATORY AGENTS	5,629	$76,953.98	3,799	13.67	2.31%	NC
9	BETA-ADRENERGIC AGONISTS	5,372	$793,387.21	3,730	147.69	2.20%	NC
10	PROTON-PUMP INHIBITORS	5,293	$95,751.67	3,257	18.09	2.17%	↑1
11	ANTICONVULSANTS	5,120	$290,115.26	2,139	56.66	2.10%	↑1
12	HMG-COA REDUCTASE INHIBITORS	4,749	$69,487.05	2,895	14.63	1.95%	↑1
13	BETA-ADRENERGIC BLOCKING AGENTS	4,714	$80,255.14	2,765	17.02	1.93%	↑1
14	PENICILLIN ANTIBIOTICS	4,333	$72,454.22	3,839	16.72	1.77%	↓4
15	ADRENALS	4,174	$140,854.91	3,032	33.75	1.71%	NC

Top 15 Therapeutic Classes Based on Claims Cost from 7/1/26 to 9/30/26

Total Claims Cost = $21,538,955.84

#	Therapeutic Class Description	Claims	Claims Cost	Patients	Cost/Patient	% Cost	Dif
1	ANTIPSYCHOTIC	9,952	$3,228,703.99	4,071	$793.10	8.01%	NC
2	INCRETIN MIMETICS	2,888	$2,811,303.65	1,246	$2,256.26	6.97%	↑1
3	TNF INHIBITORS	421	$2,805,470.68	170	$16,502.77	6.96%	↓1
4	INTERLEUKIN-MEDIATED AGENTS	221	$1,904,035.24	92	$20,696.04	4.72%	NC
5	ANTINEOPLASTIC AGENTS	526	$1,576,540.46	224	$7,038.13	3.91%	NC
6	CYSTIC FIBROSIS CORRECTORS	44	$1,193,584.68	15	$79,572.31	2.96%	↑5
7	ANTIRETROVIRALS	608	$1,165,986.12	242	$4,818.12	2.89%	↑2
8	SKIN AGENTS	287	$1,120,765.40	141	$7,948.69	2.78%	NC
9	AMPHETAMINES	8,114	$1,065,327.31	3,266	$326.19	2.64%	↓2
10	PITUITARY	326	$883,807.02	145	$6,095.22	2.19%	↑1
11	IMMUNOMODULATORY AGENTS	256	$877,238.42	203	$4,321.37	2.18%	↑2
12	BETA-ADRENERGIC AGONISTS	5,372	$793,387.21	3,730	$212.70	1.97%	NC
13	HCV ANTIVIRALS	33	$748,033.47	32	$23,376.05	1.86%	↓7
14	ANTIDEPRESSANTS	24,787	$735,066.25	10,609	$69.29	1.82%	NC
15	OPIOID PARTIAL AGONISTS	2,017	$629,705.94	665	$946.93	1.56%	↑2

Retrospective Drug Utilization Review (DUR) Report: Q3 2026

Date	Total Criteria Exceptions	Total Cases	Letters Sent
July 2026	539	337	719
August 2026	534	310	665
September 2026	455	281	584

July 2026 Cases by Type of Criteria

Criteria Description	# of Cases	% of Cases
Drug Disease Precaution	24	7.12%
Drug-Drug Interactions	32	9.50%
Drug-Drug Marker and/or Diagnosis	28	8.37%
Overuse Precaution	17	5.04%
Therapeutic Appropriateness	236	70.03%

August 2026 Cases by Type of Criteria

Criteria Description	# of Cases	% of Cases
Drug Disease Precaution	30	9.68%
Drug-Drug Interactions	70	22.58%
Drug-Drug Marker and/or Diagnosis	5	1.61%
Therapeutic Appropriateness	205	66.13%

September 2026 Cases by Type of Criteria

Criteria Description	# of Cases	% of Cases
Drug Disease Precaution	65	23.13%
Drug-Drug Interactions	59	21.00%
Drug-Drug Marker and/or Diagnosis	1	0.36%
Overuse Precaution	1	0.36%
Therapeutic Appropriateness	106	37.72%
Underuse Precautions	49	17.44%

Clinical Report

Prior Authorization Updates

Drug	PA Status	Class
Adquey	PA	Eczema / Atopic Dermatitis
Armlupeg	PA	Biosimilars
Atebrioz	PA	Medications that cost > $3000
Epclusa (and generic)	Remove PA	Hepatitis C
Humira	PA	Biosimilars
Juvmo	PA	Parkinson's Disease
Langlara	PA	Biosimilars
Lipfendra	PA	Lipid-Lowering Agents
Lisraya	PA	Medications that cost > $3000
Lynavoy	PA	Cholestatic Pruritis
Mavyret	Remove PA	Hepatitis C
Myqorzo	PA	Hypertrophic Cardiomyopathy
Novolin Mix 70-30	PA	Insulin
Nuzolvence	PA	Anti-infectives Resistance Prevention
Risperdal Consta	PA	Preferred Dosage Forms
Selarsdi	PA	Biosimilars
Simlandi	PA	Biosimilars
Trulicity	Remove PA	Diabetes
Trutakna	PA	IgA Nephropathy
Zyprexa Relprevv	PA	Preferred Dosage Forms

Summary of Changes

Anti-infectives – Fluoroquinolones

Xtoro was added to the class for acute otitis externa.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ofloxacin otic drops	ciprofloxacin otic drops
this space intentionally left blank	XTORO (finafloxacin) SUSPENSION

For Xtoro only:

- The member must have a diagnosis of acute otitis externa with confirmed susceptible strains of *Pseudomonas aeruginosa* or *Staphylococcus aureus*

All other agents:

- The member must have failed a 7-day trial of each of the preferred agent, as evidenced by paid claims or pharmacy printouts.

Asthma/COPD

A biosimilar to Xolair was added. The criteria was updated to require eosinophil count of ≥ 150 cells/mcL for any biologic agents for COPD. Trelegy will no longer be preferred, and Breztri criteria has been updated in line with their label and clinical studies.

Biologics

Anti-IL-5 biologics

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FASENRA (benralizumab)	CINQAIR (reslizumab) – Medical Billing
NUCALA (mepolizumab) SYRINGE, AUTOINJECTOR	EXDENSUR (depemokimab-ulaa) – Medical Billing
NUCALA (mepolizumab) VIAL – Medical Billing	this space intentionally left blank

Anti-IL-4/13 biologics

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DUPIXENT (dupilumab)	this space intentionally left blank

Allergic Asthma-directed biologics

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
omalizumab – See Biosimilar Agents	this space intentionally left blank

Thymic Stromal Lymphopoietin (TSLP) blocker

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TEZSPIRE (tezepelumab-ekko) PENS	this space intentionally left blank
TEZSPIRE (tezepelumab-ekko) VIAL and SYRINGES – Medical Billing	this space intentionally left blank

Prior Authorization Criteria

Prior Authorization Form – Asthma

Initial Criteria – Approval Duration: 6 months

For Asthma Only

- The requested medication must be prescribed by, or in consult with, an allergist/immunologist or pulmonologist
- If the member is a current smoker, the member must have received smoking cessation counseling in the past year
- The member must have had at least one exacerbation requiring use of oral corticosteroids in the past year despite continued compliant use of a high dose inhaled steroid in combination with a long-acting beta agonist (LABA) for at least 3 months prior to the exacerbation, as evidenced by paid claims or pharmacy printouts
- Dupixent Only:
  - The member must have an eosinophil count of ≥ 150 cells/mcL or FeNO ≥ 25 ppb within the past year
- Omalizumab Only:
  - The member has a serum total IgE level, measured before the start of treatment within the past year, of ≥ 30 IU/mL and ≤ 700 IU/mL in members age ≥ 12 years or ≥ 30 IU/mL and ≤ 1300 IU/mL in members ages 6 to < 12 years.
  - The member has had a positive skin test or in vitro reactivity to a perennial aeroallergen
- Anti-IL-5 biologics:
  - The member has an eosinophil count ≥ 150 cells/mcL within the past year
  - Cinqair Only:
    - The member must have had at least one exacerbation requiring use of oral corticosteroids in the past year despite continued compliant use of a triple therapy regimen (high dose inhaled steroid + long-acting beta agonist (LABA) + long-acting muscarinic antagonist (LAMA)) in combination with each of the following for at least 4 months, as evidenced by paid claims or pharmacy printouts: Dupixent, Fasenra, Nucala, and Tezspire.
  - Exdensur Only:
    - The member must have had at least two exacerbations requiring use of oral corticosteroids in the past year despite continued compliant use of a triple therapy regimen (medium-to-high dose inhaled steroid + long-acting beta agonist (LABA) + long-acting muscarinic antagonist (LAMA)) in combination with each of the following for at least 4 months, as evidenced by paid claims or pharmacy printouts: Dupixent, Fasenra, Nucala, and Tezspire.

For COPD Only

- The requested medication must be prescribed by, or in consult with, an allergist/immunologist or pulmonologist

- If the member is a current smoker, the member must have received smoking cessation counseling in the past year
- The member must have had at least one exacerbation requiring use of oral corticosteroids in the past year months despite continued compliant use of an inhaled steroid AND long-acting beta agonist (LABA) AND long-acting muscarinic antagonist (LAMA) for at least 2 months, as evidenced by paid claims or pharmacy printouts
- The member has an eosinophil count of ≥ 150 cells/mcL within the past year

Renewal Criteria – Approval Duration: 12 months

- The member must have achieved a significant reduction in exacerbations and utilization of systemic steroids and rescue medications since treatment initiation since starting treatment with the requested medication (subject to clinical review).

Corticosteroid/Anticholinergics/Long-Acting Beta Agonists Combinations

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BREZTRI AEROSPHERE (budesonide/glycopyrrolate/formoterol)	TRELEGY ELLIPTA (fluticasone/umeclidinium/vilanterol)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- For COPD Only:
  - The member must have had at least one exacerbation in the past year while adherent to at least 6 weeks of double therapy (ICS, LAMA or LABA, as evidenced by paid claims or pharmacy printouts.
- For Asthma Only
  - The member must have failed 2 months of at least a medium dose inhaled corticosteroid/long-acting beta agonist (ICS/LABA), as evidenced by paid claims or pharmacy printouts.

Non-Preferred Agent Criteria:

- If the member is a current smoker, the member must have received smoking cessation counseling in the past year.
- The member must have had at least one exacerbation in the past year while adherent to at least 3 months of the preferred agent, as evidenced by paid claims or pharmacy printouts.

Cholestatic Pruritis

Lynavoy was added and criteria developed.

IBAT inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED (PA REQUIRED)
this space intentionally left blank	LYNAVOY (linerixibat)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 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 hepatologist or gastroenterologist
- The member is experiencing itch for greater than 6 weeks that has significantly diminished quality of life, including sleep disturbances.
- The member must have documented Primary Biliary Cholangitis
- The member must not have a history or current presence of decompensated cirrhosis
- The member must have failed at least a 3-month trial of each of the following, as evidenced by paid claims or pharmacy printouts:
  - cholestyramine, rifampin, naltrexone, sertraline

Renewal Criteria – Approval Duration: 12 months

- The member has experienced an improvement in pruritis, as evidenced by clinical documentation.

Diabetes

Tzield criteria was updated and adjusted to differentiate between stage 2 and stage 3 of type 1 diabetes, as well as adding a more "real-world" testing option with random/non-fasting C-peptide testing

Biologics

PA REQUIRED
TZIELD (teplizumab-mzwv) – Medical Billing

High-Cost Drug:

This 14-day treatment course costs $193,900.

- In study TN-10; 72 people were enrolled – 44 in active treatment group and 32 in placebo group. By month 36, 63.7% (28) in the active treatment group and 71.9% (23) in the placebo group had experienced Stage 3 Type 1 Diabetes onset.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months (1 approval per lifetime)

- The requested medication must be prescribed by, or in consult with, an endocrinologist.
- The member must meet one of the following:
  - A diagnosis of Stage 2 type 1 diabetes documented by all of the following:
    - The member has at least two of the following pancreatic islet cell autoantibodies:
      - Glutamic acid decarboxylase 65 (GAD) autoantibodies
      - Insulin autoantibody (IAA)
      - Insulinoma-associated antigen 2 autoantibody (IA-2A)
      - Zinc transporter 8 autoantibody (ZnT8A)
      - Islet cell autoantibody (ICA)
    - The member has no symptoms of Type 1 Diabetes (e.g., polyuria, polydipsia, weight loss, fatigue, DKA)
    - The member has abnormal blood sugar levels determined by one of the following:
      - an oral glucose tolerance test

        - Fasting glucose 100 to 125 mg/dL (5.6-6.9 mmol/L)
        - 2-hour post prandial glucose 140 to 199 mg/dL (7.8-11.0 mmol/L)
        - A1C 5.7 to 6.4%
    - A new diagnosis of Stage 3 type 1 diabetes (within the last 56 days) documented by all of the following:
        - The member must be between the ages of 8 and 17 years old
        - The member has at least one of the following pancreatic islet cell autoantibodies:
            - Glutamic acid decarboxylase 65 (GAD) autoantibodies
            - Insulin autoantibody (IAA)
            - Insulinoma-associated antigen 2 autoantibody (IA-2A)
            - Zinc transporter 8 autoantibody (ZnT8A)
            - Islet cell autoantibody (ICA)
        - The member has abnormal blood sugar levels determined by one of the following:
            - Fasting glucose ≥ 126 mg/dL (≥ 7.0 mmol/L)
            - 2-hour post prandial glucose ≥ 200 mg/dL (≥ 11.1 mmol/L)
            - Random plasma glucose ≥ 200 mg/dL with symptoms of hyperglycemia
            - A1C ≥ 6.5%
        - The member has preserved beta-cell function shown by Peak stimulated C-peptide level of ≥ 0.2 pmol/mL on Mixed-Meal Tolerance Test (MMTT) or random/non-fasting C-peptide testing

Diabetic Kidney Disease

Kerendia was approved for chronic kidney disease in type 1 diabetes, so the criteria was updated to include type 1.

Non-steroidal selective mineralocorticoid receptor antagonist (MRA)

PA REQUIRED
KERENDIA (finerenone)

Initial Criteria – Approval Duration: 6 months

Kerendia Only

- The member must have type 1 or type 2 diabetes and chronic kidney disease.
- The member has an estimated glomerular filtration rate (eGFR) ≥ 25 mL/min/1.73 m^2
- The member must not be on chronic kidney dialysis.
- If member is post-kidney transplant, Medicare eligibility must be ruled out (6-month approval may be allowed to determine eligibility).
- For members with Type 1 diabetes:
    - The member must be on an ACE-inhibitor or an ARB at the target or maximally tolerated dose, as evidenced by paid claims or pharmacy printouts
    - The member must have a urinary albumin-to-creatinine ratio (UACR) ≥ 200 mg/g (≥ 22.6 mg/mmol)
- For members with Type 2 diabetes:
    - The member must be on the following at the target or maximally tolerated dose, as evidenced by paid claims or pharmacy printouts:

        - An ACE-inhibitor or an ARB
        - A SGLT-2 inhibitor
    - The member has one of the following (a, b, or c) despite a 6-month trial with an ACE inhibitor or ARB in combination with a SGLT-2 inhibitor and a GLP1-agonist, as evidenced by paid claims or pharmacy printouts:
        a) urinary albumin-to-creatinine ratio (UACR) ≥ 30 mg/g (≥3 mg/mmol) with an eGFR < 60 mL/min/1.73 m^2
        b) urinary albumin-to-creatinine ratio (UACR) ≥ 300 mg/g (≥30 mg/mmol) with an eGFR ≥ 60 mL/min/1.73 m^2
        c) albuminuria ≥ 300 mg/day

Heart Failure

A new section was added to address new formulations of furosemide and bumetanide that were developed for emergent fluid overload or heart failure exacerbation to keep members out of the hospital.

Novel administration loop diuretics

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	ENBUMYST (bumetanide) NASAL SPRAY
this space intentionally left blank	FUROSCIX ON-BODY (furosemide)
this space intentionally left blank	FUROSCIX READYFLOW (furosemide)
this space intentionally left blank	LASIX ONYU (furosemide)

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Electronic Duration Verification:

- Enbumyst: up to 12 doses per 30 days
- Furoscix On-Body and ReadyFlow: up to 7 doses in 30 days
- Lasix ONYU: up to 10 doses per 30 days

Prior Authorization Criteria

Initial Criteria – Approval Duration: 3 months

- The requested medication must be prescribed by, or in consult with, a cardiologist, or nephrologist
    - The member has documented diagnosis of one of the following:
    - NYHA Class II/III chronic heart failure
    - Chronic Kidney Disease including nephrotic syndrome
    - The prescriber must provide attestation that the member has a history in the last 90 days of at least one prior hospitalization or emergency department visit due to heart failure exacerbation and/or fluid overload
    - The prescriber must submit clinical rationale for why intravenous furosemide treatment is inappropriate
    - The member has failed a 14-day trial in the last 30 days of at least one of the following:

- furosemide 160 mg daily
- torsemide 40 mg daily
- bumetanide 4 mg daily

Renewal Criteria – Approval Duration: 12 months

- The prescriber must attest that the member has not had a hospitalization due to fluid overload

Hepatitis C Antiviral Treatments

Mavyret was switched to a preferred agent and PA was removed from Mavyret and sofosbuvir/velpatasvir. Differentiation for initial treatment or after incomplete treatment less than 28 days versus initial treatment failure or incomplete treatment greater than 28 days is provided to guide selection for Vosevi per guidelines.

Direct Acting Antivirals

Initial Treatment or After Incomplete Treatment < 28 days

Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
MAVYRET (glecaprevir/pibrentasvir)	EPCLUSA (sofosbuvir/velpatasvir)
sofosbuvir/velpatasvir	HARVONI (ledipasvir/sofosbuvir)
this space intentionally left blank	ledipasvir/sofosbuvir 90mg/400mg tablet
this space intentionally left blank	SOVALDI (sofosbuvir)

Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
MAVYRET PELLET PACKET (glecaprevir/pibrentasvir)	EPCLUSA PALLET PACKET (sofosbuvir/velpatasvir)
this space intentionally left blank	HARVONI PALLET PACKET (ledipasvir/sofosbuvir)
this space intentionally left blank	SOVALDI PALLET PACKET (sofosbuvir)

After Initial Treatment Failure or After Incomplete Treatment ≥ 28 days

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
VOSEVI (sofosbuvir/velpatasvir/voxilaprevir)	this space intentionally left blank

Electronic Age Verification

- Mavyret Pellet Packet:
  - PA Not Required Criteria: The member is 11 years old or less.
  - PA Required Criteria: The member must meet Non-Solid Dosage Preparations criteria

- Epclusa (and its generic), Mavyret and Vosevi: The entire treatment course must be dispensed at the initial fill.
  - Please call pharmacy provider relations (1-701-328-4086) if a member has already partially completed their treatment course and needs less than a full course of therapy for their current fill.

Prior Authorization Criteria

Prior Authorization Form – Hepatitis C

Initial Criteria – Approval Duration: Based on label recommendations

Vosevi Only –
- The member has experienced Direct Acting Antiviral failure or incomplete therapy after receiving ≥ 28 days
- The member has Chronic Hepatitis C as evidenced by the submission of the date and value of 1 positive HCV RNA test since most recent DAA treatment (HCV RNA level must be within the last 24 months).

Non-Solid Dosage Form Agents Criteria Only:
- Epclusa, Harvoni, and Sovaldi pellets: All of the following are met (A or B)
  A. The member must meet Non-Solid Dosage Preparations criteria in addition to Hepatitis C criteria
  B. The member is unable to use Mavyret pellets (subject to clinical justification)

Non-Preferred Agents Criteria Only**:**
- Clinical justification must be provided explaining why the member is unable to use the preferred product (subject to clinical review).

Hypertrophic Cardiomyopathy

Myqorzo was added to the category, so criteria was added to differentiate from Camzyos.

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CAMZYOS (mavacamten)	MYQORZO (aficamten)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months
- The requested medication must be prescribed by, or in consult with, a cardiologist.
- The member must have both of the following:
  - NYHA class II or III
  - Valsava left ventricular outflow tract (LVOT) gradient ≥ 30 mmHg at rest or ≥ 50 mmHg with provocation.
- The member must have persistent symptoms despite maximally tolerated concurrent therapy with each of the following for 90 days, as evidenced by paid claims or pharmacy printouts.
  - Non-dihydropyridine calcium channel blocker

- beta blocker
- disopyramide

For Camzyos only:

- The member must have both of the following:
  - Left ventricular ejection fraction (LVEF) ≥ 55%
  - Resting oxygen saturation ≥ 90%

For Myqorzo only:

- The member must have both of the following:
  - Left ventricular ejection fraction (LVEF) ≥ 60%
  - Hemoglobin ≥ 10 g/dL
- The member must have failed a 6-month trial of Camzyos

Renewal Criteria – Approval Duration: 12 months

- The member has one of the following:
  - an improved pVO_2 by ≥ 1.5 mL/kg/min plus improvement in NYHA class by at least 1
  - an improvement of pVO_2 by ≥ 3 mL/kg/min and no worsening in NYHA class.
  - NYHA class I or II without exertion-induced syncope
  - Valsalva LVOT gradient < 50 mmHg at rest or with provocation.

References

1. Olivotto, Iacopo, et al. "Mavacamten for treatment of symptomatic obstructive hypertrophic cardiomyopathy (EXPLORER-HCM): a randomised, double-blind, placebo-controlled, phase 3 trial." The Lancet 396.10253 (2020): 759-769.
2. Desai, Milind Y., et al. “Mavacamten in patients with hypertrophic cardiomyopathy referred for septal reduction: week 56 results from the VALOR-HCM randomized clinical trial.” JAMA cardiology 8.10 (2023): 968-977.

Lipid-Lowering Agents

Tryngolza was added to the category, so criteria was developed.

Apolipoprotein C-III (apoC-III)-directed antisense oligonucleotide

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	TRYNGOLZA (olezarsen)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 3 months

- The member must have severe hypertriglyceridemia, defined by triglycerides greater than or equal to 500 mg/dL.
- Clinical justification must be provided explaining why the member is unable to use all other products to lower their cholesterol (subject to clinical review)

Migraine

Criteria was added to the prophylaxis section to better define episodic migraine versus chronic migraine. Aimovig and Qulipta have changed preferred positions and Aimovig, Qulipta, and Nurtec ODT have updated criteria. Changes reflect recent updates in guidelines.

Prophylaxis of Episodic Migraine

Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonist

PREFERRED AGENTS (PA REQUIRED)	PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AJOVY (fremanezumab-vfrm)	NURTEC ODT (rimegepant) TABLETS	AIMOVIG (erenumab-aooe)
EMGALITY (galcanazumab-gnlm)	QULIPTA (atogepant) TABLETS	VYEPTI (eptinezumab-jjmr) – Medical Billing

Prior Authorization Criteria

Prior Authorization Form – Migraine Prophylaxis/Treatment

Initial Criteria – Approval Duration: 6 months

- The member must experience 4 or more migraine days and less than 15 days per month.
- The member must have failed 2-month trials of at least two of the following agents, as evidenced by paid claims or pharmacy printouts:
  - divalproex sodium, propranolol, and topiramate.
- Aimovig Only:
  - The member must have failed a 3-month trial of a preferred agent or be stable on Aimovig, as evidenced by paid claims or pharmacy printouts.
- Nurtec ODT and Qulipta Only:
  - The member must have failed a 3-month trial of Ajovy or Emgality, as evidenced by paid claims or pharmacy printouts.
- Vyepti Only:
  - The member must have failed a 3-month trial of Ajovy, Emgality, Aimovig, Qulipta and Nurtec ODT, as evidenced by paid claims or pharmacy printouts.

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced at least a 50% reduction in migraine frequency, pain intensity, or duration from baseline.

Prophylaxis of Chronic Migraine

Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonist

PREFERRED AGENTS (PA REQUIRED)	PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)

AJOVY (fremanezumab-vfrm)	QULIPTA (atogepant) TABLETS	AIMOVIG (erenumab-aooe)
EMGALITY (galcanazumab-gnlm)	this space intentionally left blank	VYEPTI (eptinezumab-jjmr) – Medical Billing

Prior Authorization Criteria

Prior Authorization Form – Migraine Prophylaxis/Treatment

Initial Criteria – Approval Duration: 6 months

- The member must experience 15 or more migraine days per month.
- The member must have failed a 2-month trial of at least two of the following agents, as evidenced by paid claims or pharmacy printouts:
  - divalproex sodium, onabotulinumtoxinA, topiramate

Non-Preferred Agents Criteria:

- Aimovig Only:
  - The member must have failed a 3-month trial of a preferred agent or be stable on Aimovig, as evidenced by paid claims or pharmacy printouts.
- Qulipta Only:
  - The member must have failed a 3-month trial of Ajovy or Emgality, as evidenced by paid claims or pharmacy printouts.
- Vyepti Only:
  - The member must have failed a 3-month trial of Ajovy, Emgality, Aimovig, and Qulipta, as evidenced by paid claims or pharmacy printouts.

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced at least a 50% reduction in migraine frequency, pain intensity, or duration from baseline.

Spinal Muscular Atrophy

Nothing was added to this section for DUR Board Review. This was added to the agenda in error.

Systemic Lupus Erythematosus (SLE)

Saphnelo Pen was added, so criteria were written for non-preferred agents.

Biologics

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BENLYSTA (belimumab) – Medical Billing	SAPHNELO (anifrolumab-fnia) – Medical Billing
this space intentionally left blank	SAPHNELO (anifrolumab-fnia) PEN

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a rheumatologist or a specialist in the treatment of SLE
- The member must also be receiving standard therapy, defined as any of the following (alone or in combination): corticosteroids, antimalarials, NSAIDs, and/or immunosuppressives
- The member must have failed a 6-month trial of Benlysta, as evidenced by paid claims or pharmacy printouts
- The member must not have severe active lupus nephritis and/or severe active CNS lupus
- The member must test positive to one or more of the following autoantibodies relevant to SLE at the time of the request:
    - Antinuclear antibodies [ANA]
    - Anti-double-stranded DNA [anti-ds DNA]
    - Anti-Smith [anti-SM]
- The member must have a Safety of Estrogens in Lupus Erythematosus National Assessment-Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) or SLE Disease Activity Index 2000 (SLEDAI-2K) score ≥ 6
- The following baseline scores must be submitted:
    - British Isles Lupus Assessment Group (BILAG) A and BILAG B score
    - Physician's Global Assessment (PGA) score

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced disease stability and/or improvement as indicated by one or more of the following when compared to pre-treatment baseline:
    - No worsening in the SELENA-SLEDAI or SLEDAI-2K score where worsening is defined as > 0-point increase
    - A reduction of all BILAG A to B/C/D and baseline BILAG B to C/D, and no new organ system affected as defined by ≥ 1 new BILAG A or ≥ 2 new BILAG B items compared to baseline
    - No worsening (defined as ≥ 0.30-point increase) in PGA score
    - Seroconverted (negative)

PDL Annual Review

Please use the following link to review the most recently updated PDL:

Preferred Drug List (PDL) - North Dakota Medicaid

Nausea/Vomiting

Updated criteria to include radiation-induced language

Chemotherapy or Radiation-Induced

NK1 Receptor Antagonists

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
aprepitant tripack	AKYNZEO (netupitant/palonosetron) CAPSULE
EMEND (aprepitant) SUSPENSION	aprepitant capsules
this space intentionally left blank	EMEND (aprepitant) 125 MG-80 MG CAPSULE TRIPACK
this space intentionally left blank	EMEND (aprepitant) CAPSULES

5-HT3 Receptor Antagonists

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
granisetron tablet	AKYNZEO (netupitant/palonosetron) CAPSULE
granisetron vial – Medical Billing	SANCUSO (granisetron) PATCH
ondansetron	ZOFRAN (ondansetron)
palonosetron – Medical Billing	this space intentionally left blank
SUSTOL (granisetron) SYRINGE – Medical Billing	this space intentionally left blank

Cannabinoids

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
dronabinol capsule	MARINOL (dronabinol) CAPSULE

Other options

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
dexamethasone	this space intentionally left blank
olanzapine	this space intentionally left blank
prochlorperazine	this space intentionally left blank
promethazine	this space intentionally left blank

Electronic Diagnosis Verification

- Dronabinol Only: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months or until last day of treatment

- The requested medication must be prescribed by, or in consult with, an oncologist or radiologist
- The member must be receiving moderately or highly emetogenic chemotherapy, or emetogenic radiation therapy
- The final date of treatment must be provided with the request.

- The member must have failed a 3-day trial of each preferred product(s) in the same class in combination with a product in at least one other class within the last 6 months, as evidenced by paid claims or pharmacy printouts.
- The member must not have failed preferred chemical entity with same active ingredient as requested product due to side effects.

Pulmonary Hypertension

Adjusted trial length for prostacyclins from 3 months to 60 days within the last 90 days

Prostacyclins

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
epoprostenol	YUTREPIA (treprostinil)
FLOLAN (epoprostenol)	this space intentionally left blank
ORENITRAM ER (treprostinil) TABLET	this space intentionally left blank
REMODULIN (treprostinil) INJECTION – *Brand Co-Preferred*	this space intentionally left blank
treprostinil injection – *Generic Co-Preferred*	this space intentionally left blank
TYVASO (treprostinil) DPI	this space intentionally left blank
TYVASO (treprostinil) INHALATION	this space intentionally left blank
UPTRAVI (selexipag) TABLET	this space intentionally left blank
UPTRAVI (selexipag) VIAL	this space intentionally left blank
VELETRI (epoprostenol)	this space intentionally left blank

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a pulmonologist or cardiologist.
- One of the following must be met (1 or 2):
  1. The member has WHO functional class IV and is receiving dual combination therapy
  2. The member has failed a 60-day trial in the last 90 days of combination tadalafil and ambrisentan.
     1. If ambrisentan or tadalafil isn't tolerated or clinical justification has been provided why the member is not able to use ambrisentan and tadalafil (subject to clinical review), the member must have failed a 60-day trial in the last 90 days with another dual combination therapy.

Updated financial charts from Q3 meeting

Financial charts have been updated and reposted to DUR Board - North Dakota Medicaid with the corrected left access label of dollars instead of dollars (in millions).

New Business

Second Reviews

Antipsychotics

Antipsychotics Subcommittee Summary

The Antipsychotics Subcommittee met on November 19, 2026. Recommendations were to trial aripiprazole prior to Rexulti and otherwise use outlier prescriber prior authorization. The subcommittee asked for the board to be able to review and provide input into the Antipsychotics Brand Report Card language. The subcommittee requested another meeting to further the conversations regarding age related prior authorization and plans for outlier prescriber prior authorization after the Department compiles the requested information.

Oral

Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
aripiprazole	ABILIFY (aripiprazole)
clozapine	CLOZARIL (clozapine)
lurasidone	GEODON (ziprasidone)
olanzapine	INVEGA ER (paliperidone)
quetiapine	LATUDA (lurasidone)
quetiapine ER	RISPERDAL (risperidone)
paliperidone ER	SEROQUEL (quetiapine)
risperidone	SEROQUEL XR (quetiapine)
ziprasidone	ZYPREXA (olanzapine)
High-Cost Preferred Options (NO PA REQUIRED)	**High Cost Non—Preferred Options (REQUIRES PA)**
CAPLYTA (lumateperone)	BYSANTI (milsaperidone)
COBENFY (xanomeline/trospium)	olanzapine/fluoxetine
FANAPT (iloperidone)	this space intentionally left blank
LYBALVI (olanzapine/samidorphan)	this space intentionally left blank
VRAYLAR (cariprazine)	this space intentionally left blank
High-Cost Preferred Options (Electronic Lookback Required)	**High Cost Non—Preferred Options (REQUIRES PA)**
REXULTI (brexpiprazole)	this space intentionally left blank

Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
aripiprazole ODT	RISPERDAL (risperidone) ORAL SOLUTION
aripiprazole solution	SAPHRIS (asenapine)
asenapine	ZYPREXA ZYDIS (olanzapine)
clozapine ODT	this space intentionally left blank
olanzapine ODT	this space intentionally left blank
risperidone ODT	this space intentionally left blank
risperidone oral solution	this space intentionally left blank
High-Cost Preferred Options (NO PA REQUIRED)	**High Cost Non—Preferred Options (REQUIRES PA)**

this space intentionally left blank	OPIPZA FILM (aripiprazole)
this space intentionally left blank	SECUADO (asenapine) PATCH

Long-Acting Injectable (LAI)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ABILIFY ASIMTUFII (aripiprazole)	PERSERIS (risperidone)
ABILIFY MAINTENA (aripiprazole)	RISPERDAL CONSTA (risperidone microspheres) – *Brand Required*
ARISTADA (aripiprazole lauroxil)	risperidone ER (risperidone microspheres)
ARISTADA INITIO (aripiprazole lauroxil)	ZYPREXA RELPREVV (olanzapine)
ERZOFRI (paliperidone)	this space intentionally left blank
INVEGA HAFYERA (paliperidone)	this space intentionally left blank
INVEGA SUSTENNA (paliperidone)	this space intentionally left blank
INVEGA TRINZA (paliperidone)	this space intentionally left blank
UZEDY (risperidone)	this space intentionally left blank
WELTRUZA (olanzapine)	this space intentionally left blank

Electronic Step Therapy Required

Rexutli requires initiation titration:

- PA Not Required Criteria: A total of 100-day supply of aripiprazole has been paid within 130 days prior to Rexulti's date of service.
- PA Required Criteria: The member must have failed a 2-month trial of aripiprazole, as evidenced by paid claims or pharmacy printouts.

Vraylar requires initiation titration:

- For 3 mg dose: Initiation pack or 1 day of the 1.5 mg tablet is required
- For 4.5 mg dose: Initiation pack or 1 day of the 1.5 mg tablet plus 6 days of 3 mg tablets is required

Cobenfy requires initiation titration:

- For 100 mg/20 mg dose: Initiation pack or 2 days of the 50 mg/20 mg capsules is required
- For 125 mg/30 mg dose: Initiation pack or 5 days of the 100 mg/20 mg capsules is required

First Fill

- Caplyta, Cobenfy, Fanapt, Paliperidone ER, Rexulti, Saphris, Sacuado, and Vraylar must be filled with a 10-day supply if no previous fill within past 99 days

Therapeutic Duplication

Prior Authorization Form - Concurrent Antipsychotics

Please see **Appendix A** for clinical criteria for multiple oral antipsychotics and oral and injectable antipsychotic requests

- One strength of one medication is allowed at a time with the following exceptions:
  - risperidone 0.25 mg, 0.5 mg and 1 mg are allowed with other strengths of risperidone
  - quetiapine 25 mg and 50 mg are allowed with other strengths of quetiapine IR
  - quetiapine 50 mg ER is allowed with other strengths of quetiapine ER
  - olanzapine 2.5 mg is allowed with 10 mg, 15 mg, and 20 mg
  - olanzapine 5 mg is allowed with 7.5 mg and 20 mg

Underutilization

- Bysanti, Caplyta, Cobenfy, Fanapt, Latuda, Paliperidone ER, Rexulti, Saphris, Sacuado, and Vraylar must be used adherently and will reject on point of sale for late fill

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- Bysanti Only: Both of the following must be met:
  - The member must have failed a 60-day trial of 3 antipsychotics including Fanapt.
  - Clinical justification must be provided to explain the clinical meaningful difference between Fanapt and Bysanti and the reason why a different outcome is expected based on available evidence (subject to clinical review).
- All other agents: See Preferred Dosage Form Criteria

Human Immunodeficiency Virus (HIV)

Antiretrovirals – Pre-exposure Prophylaxis (PrEP)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
APRETUDE (cabotegravir) – Medical billing	TRUVADA (emtricitabine/tenofovir disoproxil fumarate)
DESCOVY (emtricitabine/tenofovir alafenamide)	this space intentionally left blank
emtricitabine/tenofovir disoproxil fumarate	this space intentionally left blank
YEZTUGO TABLETS (lenacapavir)	this space intentionally left blank
YEZTUGO INJECTION (lenacapavir) – Medical billing	this space intentionally left blank

Antiretrovirals – Treatment

References:

Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. Available at Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents With HIV Accessed (November 3, 2026)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BIKTARVY (bictegravir/emtricitabine/tenofovir)	emtricitabine capsule
CIMDUO (lamivudine/tenofovir)	EMTRIVA (emtricitabine) CAPSULE
darunavir	EPIVIR (lamivudine)
DESCOVY (emtricitabine/tenofovir alafenamide)	NORVIR (ritonavir)
DOVATO (dolutegravir/lamivudine)	PREZISTA (darunavir)
emtricitabine solution	TRUVADA (emtricitabine/tenofovir disoproxil fumarate)
emtricitabine/tenofovir disoproxil fumarate	VIREAD (tenofovir)
GENVOYA (elvitegravir/cobicistat/emtricitabine/tenofovir)	this space intentionally left blank
lamivudine	this space intentionally left blank
NORVIR (ritonavir) POWDER PACKET	this space intentionally left blank
PREZCOBIX (darunavir/cobicistat)	this space intentionally left blank
ritonavir	this space intentionally left blank
STRIBILD (elvitegravir/cobicistat/emtricitabine/tenofovir)	this space intentionally left blank

TEMIXYS (lamivudine/tenofovir)	this space intentionally left blank
tenofovir	this space intentionally left blank
TIVICAY (dolutegravir)	this space intentionally left blank
Not Recommended for First Line Use (in most scenarios)	
abacavir	APTIVUS (tipranavir)
abacavir/lamivudine	EDURANT (rilpivirine)
atazanavir	EDURANT PED (rilpivirine)
BIXLENVO (bictegravir/lenacapavir)	etravirine
CABENUVA (cabotegravir/rilprivirine) -- Medical Billing	fosamprenavir
COMPLERA (emtricitabine/rilpivirine/tenofovir) – Brand Required	IDVYNSO (doravirine/islatravir)
DELSTRIGO (doravirine/lamivudine/tenofovir)	INTELENCE (etravirine)
FUZEON (enfuvirtide)	JULUCA (dolutegravir/rilpivirine)
efavirenz	KALETRA (lopinavir/ritonavir)
efavirenz/emtricitabine/tenofovir	lamivudine/zidovudine
efavirenz/lamivudine/tenofovir	lopinavir/ritonavir
EVOTAZ (atazanavir/cobicistat)	nevirapine ER
ISENTRESS (raltegravir)	RETROVIR (zidovudine)
nevirapine	REYATAZ (atazanavir)
ODEFSEY (emtricitabine/rilpivirine/tenofovir)	rilpivirine
PIFELTRO (doravirine)	SELZENTRY (maraviroc)
REYATAZ (atazanavir) POWDER PACK	stavudine
RUKOBIA (fostemsavir)	SYMFI (efavirenz/lamivudine/tenofovir) – *Brand Required*
SUNLENCA (lenacapavir) INJECTION – Medical Billing	SYMFI LO (efavirenz/lamivudine/tenofovir) – *Brand Required*
SUNLENCA (lenacapavir) TABLET	VIRACEPT (nelfinavir)
SYMTUZA (darumavir/cobicistat/emtricitabine/tenofovir)	zidovudine capsule and tablet
TRIUMEQ (abacavir/dolutegravir/lamivudine)	this space intentionally left blank
TRIUMEQ PD (abacavir/dolutegravir/lamivudine)	this space intentionally left blank
TROGARZO (Ibalizumab-uiyk)	this space intentionally left blank
zidovudine syrup	this space intentionally left blank

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

See Preferred Dosage Form criteria

- For Idvynso only: the member must meet all of the following:
  - The member must be virologically suppressed on a stable antiretroviral regimen defined as HIV-1 RNA less than 50 copies per mL
  - The member must have a documented resistance or clinical justification must be provided why Biktarvy, Dovato, or Bixlenvo cannot be used (subject to clinical review)
- For any of the following medications or combinations, the request must include clinical justification to explain why the requested drug is expected to benefit the member's condition outside of guideline recommendations:

- abacavir/lamivudine/zidovudine – Guidelines do not recommend ABC/3TC/ZDU (as either a triple-NRTI combination regimen or in combination with tenofovir (TDF) as a quadruple-NRTI combination regimen) due to inferior virologic efficacy.
- didanosine – Guidelines do not recommend ddI/3TC or ddI/FTC regimens due to inferior virologic efficacy, limited trial experience in ART-naïve members, and ddI toxicities (including pancreatitis and peripheral neuropathy). ddI/TDF regimens are not recommended due to high rate of early virologic failure, rapid selection of resistance mutations, potential for immunologic nonresponse/CD4 cell decline, and increased ddI drug exposure and toxicities.
- etravirine – Guidelines do not recommend for treatment-naïve members due to insufficient data. FDA indication is for treatment experienced members and so should be reserved for salvage therapy, pretreated members with NNRTI resistance and PI exposure or who have ongoing adverse effects with first line therapies.
- fosamprenavir – Guidelines do not recommend use of unboosted FPV or FPV/r due to virologic failure with unboosted FPV-based regimens that may result in selection of mutations that confer resistance to FPV and DRV. There is also less clinical trial data for FPV/r than other RTV-boosted PIs.
- lopinavir/ritonavir – Guidelines do not recommend LPV/r due to GI intolerance, higher pill burden and higher RTV dose than other PI-based regimens
- lamivudine/zidovudine – Guidelines do not recommend ZDV/3TC due to greater toxicities than recommended NRTIs (including bone marrow suppression, GI toxicities, skeletal muscle myopathy, cardiomyopathy, and mitochondrial toxicities such as lipoatrophy, lactic acidosis and hepatic steatosis).
- maraviroc (CCR5 Antagonist) – Guidelines do not recommend MVC for initial therapy due to twice daily dosing, no virologic benefit compared to recommended regimens, and required CCR5 tropism testing.
- nelfinavir – Guidelines do not recommend use of NFV due to inferior virologic efficacy and diarrhea.
- nevirapine – Guidelines no longer recommend nevirapine for initial treatment of HIV infection in treatment-naïve members. In resource limited settings, it can be considered as a third agent. Nevirapine demonstrated inferiority relative to efavirenz and is associated with serious and fatal hepatic and rash events.
- stavudine – Guidelines do not recommend d4T/3TC due to significant toxicities (including lipoatrophy, peripheral neuropathy) and hyperlactatemia (including symptomatic and life-threatening lactic acidosis, hepatic steatosis, and pancreatitis)
- tipranavir – Guidelines do not recommend TPV/r due to inferior virologic efficacy, higher dose of RTV and higher rate of adverse events than other RTV-boosted PIs.

Human Coronavirus Prevention

Prevention

Antiviral

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XOCOVA (ensitrelvir)	this space intentionally left blank

Prior Authorization Criteria

Approval Duration: 1 month (each treatment course requires new approval)

- The requested medication must be prescribed by, or in consult with, an infection disease specialist, an antibiotic/antifungal stewardship program, or protocol.
- The member must have been exposed to COVID-19 within the last 72 hours
- Confirmation of a negative COVID-19 test must be submitted
- The member must be considered high-risk for severe COVID-19, defined as having at least one of the following common risk factors associated with severe COVID-19:
  - age 65 or older
  - cerebrovascular disease
  - chronic liver disease (cirrhosis, metabolic dysfunction-associated steatotic liver disease, alcohol-associated liver disease, autoimmune hepatitis)
  - chronic kidney disease
  - chronic lung disease (asthma, cystic fibrosis, interstitial lung disease, pulmonary embolism, pulmonary hypertension, bronchiectasis, COPD)
  - obesity (BMI ≥30 kg/m2) or overweight (BMI 25 to 29 kg/m2), or ≥95th percentile in children
  - current smoker diabetes
  - heart disease (e.g., heart failure, coronary artery disease, cardiomyopathies, congenital heart disease)
  - immunocompromised (e.g., HIV, cancer, post-transplant)

Hypertension

Aldosterone Synthase Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	BAXFENDY (baxdrostat)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 3 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The medication must be prescribed by, or in consultation with a cardiologist or other hypertension specialist
- The prescriber must include target blood pressure goal
- The member must not have a secondary cause of hypertension, such as obstructive sleep apnea, renal parenchymal disease, primary aldosteronism, or renal artery stenosis
- If member has a concurrent medication that is known to induce or exacerbate high blood pressure or hypertension, clinical justification must be provided why that medication cannot be discontinued (subject to clinical review).
- The member must have failed at least a 90-day trial of the following in combination: (failure defined as inability to achieve target blood pressure despite adherence to maximally tolerated dosing):
  - An ACE-inhibitor or an ARB
  - A long-acting dihydropyridine calcium channel blocker
  - A potent thiazide diuretic, such as chlorthalidone or indapamide, or addition of a loop diuretic along with a thiazide diuretic
  - An aldosterone inhibitor

Renewal Criteria – Approval Duration: 12 months

The member must have achieved target blood pressure goals

Calcium Channel Blockers

Solid oral dosage forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
amlodipine	diltiazem 12HR ER capsule
CARTIA XT (diltiazem) capsule	diltiazem ER(LA) tablet
diltiazem tablet	levamlodipine tablet
diltiazem ER(CD) capsule	isradipine capsule
diltiazem ER(XR) capsule	MATZIM LA (diltiazem) ER tablet
DILT-XR (diltiazem) capsule	nicardipine capsule
felodipine ER	nisoldipine ER
nifedipine	NORVASC (amlodipine)
nifedipine ER	PROCARDIA XL (nifedipine)
nimodipine capsule	SULAR ER (nisoldipine)
TIADYLT ER (diltiazem)	verapamil ER PM
verapamil tablet	this space intentionally left blank
verapamil ER/SR capsule	this space intentionally left blank
verapamil ER tablet	this space intentionally left blank

Non-solid oral dosage forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NORLIQVA (amlodipine) SOLUTION	KATERZIA (amlodipine) SUSPENSION
nimodipine solution – PA required for non-solid dosage form	NYMALIZE (nimodipine) SOLUTION

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 member must have failed a 30-day trial of each preferred medication of the same subtype (e.g., dihydropyridine, non-dihydropyridine), as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).

Electronic Diagnosis Verification

- Nimodipine and Nymalize: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale

Diuretics

Diuretics – Solid Dosage Forms

Diuretics - Loop

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
furosemide	ethacrynic acid
bumetanide	this space intentionally left blank
torsemide	this space intentionally left blank

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Ethacrynic acid: One of the following must be met:
  1. The member must have a documented sulfa allergy.
  2. The member must have failed a 30-day trial of each preferred agent, as evidenced by paid claims or pharmacy print outs.

Diuretics – Potassium Sparing / Sodium Channel Blocker

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
amiloride	triamterene

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

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

Diuretics – Potassium Sparing / Aldosterone Antagonist

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
amiloride	ALDACTONE (spironolactone)
eplerenone	INSPRA (eplerenone)
spironolactone	this space intentionally left blank

Diuretics - Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
furosemide oral solution	CAROSPIR (spironolactone) SUSPENSION
spironolactone suspension	INZIRQO (hydrochlorothiazide) ORAL SUSP

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

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

Long Acting Opioids

Partial Agonist/Antagonist Opioids

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)

BELBUCA (buprenorphine) FILM	buprenorphine patches
butorphanol	this space intentionally left blank
BUTRANS (buprenorphine) PATCHES - Brand Required	this space intentionally left blank

Abuse Deterrent Formulations/Unique Mechanisms from Full Agonists Opioids

Abuse-Deterrent Opioid Analgesics | FDA

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
OXYCONTIN (oxycodone) – Brand Required	CONZIP (tramadol ER) CAPSULES
this space intentionally left blank	hydrocodone ER tablets
this space intentionally left blank	HYSINGLA ER (hydrocodone)
this space intentionally left blank	levorphanol
this space intentionally left blank	methadone
this space intentionally left blank	tramadol ER

Full Agonist Opioids Without Abuse Deterrent Formulations

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
fentanyl 12 mcg/hr, 25 mcg/hr, 50 mcg/hr, 75 mcg/hr, 100 mcg/hr	fentanyl patch 37.5 mcg/hr, 62.5 mcg/hr, 87.5 mcg/hr
morphine ER tablets	hydrocodone ER capsules
this space intentionally left blank	hydromorphone ER tablets
this space intentionally left blank	morphine ER capsules
this space intentionally left blank	MS CONTIN (morphine)
this space intentionally left blank	oxycodone ER
this space intentionally left blank	oxymorphone ER tablets
this space intentionally left blank	tapentadol ER

Prior Authorization Criteria

Prior Authorization Form – Opioid Analgesics

Initial Criteria – Approval Duration: 12 months

- The past 3 months of the member's North Dakota PDMP reports must have been reviewed.
- One of the following criteria must be met:
  - The member has access to an opioid reversal medication and has been counseled on overdose risk.
  - The member resides in a facility with skilled nursing care.
- One of the following criteria must be met:
  - The member is currently on a long-acting opioid therapy.
  - The member must have been established on opioid therapy during hospitalization
  - Both of the following are met:
    - The member must have a diagnosis of cancer pain, palliative care, or sickle cell disease.

        - The member must currently be on around-the-clock opioid therapy of at least 30 Morphine Milligram equivalents (MME) for at least a week, as evidenced by paid claims or pharmacy printouts.
            - If member is unable to swallow (e.g., mucositis, head/neck radiation, head/neck cancers, uncontrollable vomiting) and has severe pain (>6/10), fentanyl patch 12 mcg/hr may be considered for approval for opioid naïve members (subject to clinical review).
    - Both of the following are met:
        - The member must currently be on around-the-clock opioid therapy of at least 30 Morphine Milligram equivalents (MME) for at least a week, as evidenced by paid claims or pharmacy printouts.
            - The member has not achieved therapeutic goal with non-narcotic medication (NSAIDs, TCAs, SNRIs, corticosteroids, etc.) and non-medication alternatives (weight loss, physical therapy, cognitive behavioral therapy, etc.).
- One of the following criteria must be met:
    - The member resides in a facility with skilled nursing care.
    - The member must have taper plan
    - The member must have a treatment plan including goals for pain and function, and urine and/or blood screens.

Fentanyl Patch:

- The member must have a BMI ≥17.

Non-Preferred Agents Criteria:

- Clinical justification must be provided explaining why the member is unable to use other opioid and non-opioid analgesic agents (subject to clinical review).

Renewal Criteria – Approval Duration: 12 months

- One of the following must be met:
    - Progress toward therapeutic goal must be included with request (e.g., improvement in pain level, quality in life, or function).
    - The member must be stable on long-acting opioid medication for 2 years or longer.

Underutilization

- Long-acting opioid analgesics must be used adherently and will reject on point of sale for late fill.

Pheochromocytoma

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
amlodipine	phenoxybenzamine
doxazosin	this space intentionally left blank
nicardipine	this space intentionally left blank
prazosin	this space intentionally left blank
terazosin	this space intentionally left blank

Non-Preferred Agent Criteria

Initial Criteria – Approval Duration: 3 months

- The member must fail a 7-day trial of a preferred agent, with failure defined as an inability to achieve low-normal target blood pressure based on age and comorbidity

- Clinical justification must be provided explaining why the member is unable to use a preferred agent (subject to clinical review).

First Review of Contraceptives

Overview

Purpose of Review:

Combined estrogen-progestin oral contraceptives (COCs)[1]

- Place in Therapy:
  - COCs are used to treat menstrual cycle disorders, pelvic pain disorders, ovarian cysts, and hyperandrogenism.
  - COCs regulate menstrual bleeding, decrease menstrual blood loss, dysmenorrhea, and population-level reductions in the risk of ovarian and endometrial cancers.
- Ingredients: An estrogen (ethinyl estradiol, estradiol valerate, 17-beta estradiol, estetrol) and one of a dozen different progestins
  - Estrogen dose ranges for 10mcg to 50mcg with 20 to 30mcg being the most common
    - Low-dose COCs contain less than 50 mcg of ethinyl estrogen
  - Progestin classes:
    - First generation: norethindrone acetate, ethynodiol diacetate, lynestrenol, norethynodrel
    - Second generation: dl-Norgestrel, levonorgestrel
    - Third generation: desogestral, gestodene, norgestimate
    - Fourth generation: drosperinone, cyproterone acetate
- Mechanisms of action:
  - Ethinyl estradiol suppresses FSH and prevents folliculogenesis.
  - Progestin renders the endometrium less suitable for implantation, causes thickening of cervical mucus which is less permeable to penetration by sperm, and impairs normal tubal motility and peristalsis.
- Monophasic –
  - Preferred due to ease of use and consistent hormone dose.
    - Helps to improve adherence.
  - Contain the same dose of estrogen and progestin in each of the 21 to 28 active pills with the following regimen options:
    - 28 active pills
    - 21/7 regimen is 21 active pills and 7 placebo pills.
    - 24/4 regimen is 24 active pills and 4 placebo or low estrogen pills.
      - The shorter the pill-free window, the less likely that folliculogenesis will occur.
      - Endometrial atrophy is more likely which can result in more unscheduled bleeding and early cycles.
      - May have increased efficacy due to less hormone withdrawal symptoms like mood symptoms, headache, and pelvic pain.
  - Can be transitioned to continuous or extended-cycle use
  - Placebo pills may contain folate or iron
- Multiphasic – requires more careful adherence to a specific sequential order
  - Developed to help reduce hormone dose and hormone-related side effects and unscheduled bleeding.

    - Consist of 21/7 or 24/4 regimens similar to monophasic OCPs.
    - Cyclic pill packs provide hormone for 21 days of the 28-day cycle (monophasic, biphasic, triphasic, or quadraphasic)
        - Biphasic formulations contain the same dose of estrogen and progestin dose changes halfway through the cycle
            - May be associated with more unscheduled bleeding than triphasic pills.
        - Triphasic have 3 different doses of progestin and estrogen that changes every 7 days.
        - Quadraphasic pills provide 4 different doses of progestin and estrogen.
            - developed to reduce adverse effects as they mimic the natural cycle more than other types or OCPs.
            - Increased risk of pill-taking errors due to different color pills and complicated directions for catching up if a pill is missed.
            - Clinical trials found that adverse effects were similar to monophasic OCPs but the patients taking quadraphasic OCPs had less bleeding/spotting days.
- Unacceptable risks for COC initiation:
    - Age greater than or equal to 35 and smoking greater than or equal to 15 cigarettes per day
        - May be continued until the age of menopause for healthy, nonsmoking women
    - Multiple risk factors for arterial cardiovascular disease
    - Hypertension
    - Ischemic heart disease
    - History of stroke
    - Complicated valvular heart disease
    - Breast cancer
    - Severe decompensated cirrhosis
    - Hepatocellular adenoma or malignant hepatoma
    - Migraine with aura
    - Diabetes mellitus of more than 20 years duration or with nephropathy, retinopathy, or neuropathy

Progestin-only pills (POPs)[2]

- Place in Therapy: Safe option for patients at high risk of coronary artery disease, cerebrovascular disease, venous thromboembolic disease, hypertension, and other conditions in which estrogen use is contraindicated.
- Ingredients: Norethindrone, drosperinone (Slynd) and norgestrel (Opill) are the main progestins used for POPs.
    - Norethindrone and norgestrol packs have 28 active days with no placebo pills
    - Drosperinone tablets have 24 active pills followed by 4 placebo pills
- Mechanism of action:
    - Norethindrone works by thickening cervical mucus and thinning the endometrium. Also inhibit sperm migration, lower the midcycle peaks of follicle-stimulating hormone (FSH) and luteinizing hormone (LH), and slows movement of egg through the fallopian tubes.
    - Drospirenone, norgestrel, and desogestrel suppress ovulation and change the cervical mucous and endometrial lining.
- Disadvantages
    - Fertility returns rapidly upon discontinuation of POPs.
    - Drospirenone carries a risk of hyperkalemia as it has anti-mineralocorticoid activity comparable to spironolactone 25 mg.

    - POPs should be taken at the same time of day, every day to maximize contraceptive efficacy.
        - If started on the first day of menses, back-up contraception in not needed.
- Patients who should not use POPs include:
    - Known or suspected breast cancer
    - Undiagnosed abnormal uterine bleeding
    - Benign or malignant liver tumors, severe cirrhosis, or acute liver disease
    - Patients who have undergone malabsorptive bariatric surgeries
    - Those taking certain anticonvulsants
- Side effects:
    - Unscheduled bleeding and changes in menses
    - Increased prevalence of follicular ovarian cysts
    - Acne flare

Other Formulations: Transdermal contraceptive patches and vaginal rings

- Patches and vaginal rings carry the same risks and contraindications as COCs.
- Vaginal rings
    - Etonogestrel and ethinyl estradiol (NuvaRing, EluRyng, Haloette, EnilloRing)
        - Provides an immediate increase in serum hormonal concentration after insertion with a slow decrease over the cycle
    - Segesterone and ethinyl estradiol (Annovera)
        - One-year reusable ring that is worn for 3 weeks and removed for one week; repeated for a total of 13 cycles.

Clinical and Cost Considerations

- Combined Oral Contraception higher cost options include:
    - Monophasic Options: Generally monophasic products, i.e. Ayuna, cost around $7/month.
        - Balcoltra and Minzoya (levonorgestrol/ethinyl estradiol/iron) – clinical consideration: iron containing placebo pills
            - Balcotra cost/month (WAC): $291.81
            - Minzoya cost/month (WAC): $200.26
        - Wymzya and Xelria (norethindrone/ethinyl estradiol/iron) - clinical consideration: lower dose norethindrone, and iron containing placebo pills
            - Wymzya FE cost/month (WAC): $58.54
            - Xelria cost/month (WAC): $24.06
        - Galbriela and Kaitlib (norethindrone/ethinyl estradiol/iron) chewable tablets – clinical consideration: lower dose ethinyl estradiol, chewable, and iron containing placebo pills
            - Galbriela cost/month (WAC): $97.60
            - Kaitlib FE cost/month (WAC): $97.70
        - Beyaz, Safyral and Tydemy (drospirenone/ethinyl estradiol/folate) -clinical consideration: folate containing placebo pills
            - Beyaz cost/month (WAC): $242.76
            - Safyral cost/month (WAC): $199.83
            - Tydemy cost/month (WAC): $148.91
    - Biphasic Options:
        - General cost of biphasic products is around $45 per month
        - Lo Loestrin FE 1/10– clinical consideration: lowest available estrogen dose
            - Lo Loestrin FE 1/10 cost/month (WAC): $198.01

- Quadphasic Options:
  - Natazia (estradiol valerate and dienogest) – clinical consideration: formulated for heavy bleeding, estradiol valerate is closer to ednogeneous estradiol to produce very strong endometrial control while dienogest suppresses and stabilizes the endometrium.
    - Natazia cost/month (WAC): $247.80

- Transdermal contraceptive patches
  - Ethinyl estradiol-norelgestromin (EE/N) patch:
    - Xulane and Zafemy
      - Cost/month (WAC): $122.15 (Xulane and Zafemy)
      - Releases approximately 35 mcg of EE and 150 mcg norelgestromin per day.
      - EE exposure is 60% higher compared with oral contraceptive pills (OCPs) of a similar dose
    - Gwyn Lo
      - Cost/month (WAC): $198.00
      - Releases approximately 20 mcg of EE and 220 mcg of norelgestromin per day.
      - Potential clinical ramifications of a lower estrogen patch, such as increased breakthrough bleeding or decreased VTE risk, are not yet known.
  - Ethinyl estradiol-levonorgestrel (EE/LNG) patch:
    - Twirla
      - Cost/month (WAC): $198.00
      - Releases approximately 10 mcg of EE and 40 mcg of LNG per day
      - Similar EE exposure to OCPs of a similar dose.

Current Utilization

Quarter 2 2026

Brand Name	Patients	Qty	Reimbursement	Cost per Month
ANNOVERA VAGINAL RING				$199.50
ARANELLE 28 TABLET				$35.41
AYUNA-28 TABLET				$6.96
BLISOVI 24 FE TABLET	1	84	$14.84	$10.54
BLISOVI FE 1.5-30 TABLET	1	0	$0.00	$5.16
CRYSELLE-28 TABLET	12	448	$235.14	$12.35
DROSP-EE-LEVOMEF 3-0.03-0.451	1	84	$288.14	$158.52
DROSPIRENONE-EE 3-0.03 MG TAB				$4.69
ELLA 30 MG TABLET	2	1	$49.56	$38.75
ENILLORING VAGINAL RING	34	89	$4,767.05	$61.69
ENPRESSE-28 TABLET				$8.61
ENSKYCE 28 TABLET	27	1,596	$503.54	$4.03
ESTARYLLA 0.25-0.035 MG TABLET	39	2,884	$913.95	$4.13
FEIRZA 1 MG-20 MCG TABLET	1	0	$0.00	$5.23
FEMLYV 1 MG-0.02 MG ODT				$281.43
GALBRIELA 0.8-0.025 MG CHEW TB				$59.66

KELNOR 1-35 28 TABLET	2	168	$64.96	$9.53
LEVONOR-ETH ESTRA 0.09-0.02 MG	1	0	$0.00	$22.75
LEVONOR-ETH ESTRAD 0.1-0.02 MG	8	532	$175.67	$3.80
LEVONOR-ETH ESTRAD 0.15-0.03	3	182	$51.52	$4.76
LEVONORGESTREL 1.5 MG TABLET				$226.20
LO LOESTRIN FE 1-10 TABLET	9	756	$5,306.92	$282.87
LOJAIMIESS 0.1-0.02-0.01 TAB				$6.42
LUIZZA 1 MG-20 MCG TABLET				$6.81
LUIZZA 1.5 MG-30 MCG TABLET				$13.83
MEDROXYPROGESTERONE 150 MG/ML	1	1	$38.05	$8.78
MEDROXYPROGESTERONE 150 MG/ML				$6.00
MELEYA 0.35 MG TABLET	1	84	$18.61	$2.93
NATAZIA 28 TABLET				$354.00
NEXTSTELLIS 3-14.2 MG TABLET	2	168	$1,250.29	$280.18
NIKKI 3 MG-0.02 MG TABLET	53	3,920	$1,343.16	$8.48
NORELGESTROM-EE 150-35 MCG/DAY	51	219	$6,782.96	$120.70
NORETH-EE-FE 1-0.02(24)-75 CAP				$44.91
NORETH-EE-FE 1-0.02(24)-75 CHW				$10.07
NORG-EE 0.18-0.215-0.25/0.035				$4.22
NORTREL 0.5-35-28 TABLET	2	196	$122.73	$19.00
NYLIA 1-35 28 TABLET	5	364	$142.07	$7.39
NYLIA 7-7-7-28 TABLET	1	84	$26.97	$6.91
OPILL 0.075 MG TABLET				$17.41
PHEXXI 1.8-1-0.4% VAGINAL GEL				$319.56
PHILITH 0.4-0.035 MG TABLET				$12.18
ROSYRAH TABLET				$45.45
SIMPESSE 0.15-0.03-0.01 MG TAB	11	1,001	$235.31	$7.55
SLYND 4 MG TABLET	22	1,792	$12,330.7	$242.50
TRI-LEGEST FE-28 DAY TABLET				$39.60
TRI-LO-MILI TABLET	12	924	$391.84	$3.72
TWIRLA 120-30 MCG/DAY PATCH	2	9	$415.74	$301.01
TYBLUME 0.1-0.02 MG CHEW TAB				$3.84
VALTYA 1 MG-50 MCG TABLET	2	112	$78.16	$19.02
VELIVET 28 DAY TABLET	2	168	$49.91	$17.83
VOLNEA 0.15-0.02-0.01 MG TAB	10	812	$233.11	$4.08
XELRIA FE 0.4-0.035 MG CHEW TB	1	84	$76.77	$18.75

References:

1. Allen, Rebecca H, et al. Combined estrogen-progestin oral contraceptives: Patient selection, counseling, and use. March 11, 2026. Combined estrogen-progestin oral contraceptives: Patient selection, counseling, and use - UpToDate
2. Kaunitz, Andrew M, et al. Contraception: Progestin-only pills (POPs). March 25, 2026. Contraception: Progestin-only pills (POPs) - UpToDate
3. Burkman, Ronald T, et al. Contraception: Transdermal contraceptive patches. August 24, 2026. Contraception: Transdermal contraceptive patches - UpToDate

4. Kerns, Jennifer, et al. Contraception: Hormonal contraceptive vaginal rings. June 19, 2026. Contraception: Hormonal contraceptive vaginal rings - UpToDate

First Review of Fibrodysplasia Ossificans Progressiva (FOP)

Overview

Purpose of Review: Pasatru and Atebrioz are new to market

Definition[1]:

- Rare connective tissue disorder is characterized by severe, progressive heterotopic ossificans of soft tissues that span joints and results in an ectopic skeleton.
- Severely decreases mobility and causes significant disability
- Caused by mutations in the ACVR1/ALK2 gene

Prevalence[1]:

- 1 in 2 million
- Average age of onset of heterotopic ossification is 5 years

Clinical Features[1]:

- Bilateral malformation of the great toes (short and laterally deviated)
- First metatarsals are malformed and first toes have absent or fused interphalangeal joint
- Short, malformed thumbs in approximately 50 percent of patients
- Clinodactyly: congenital curvature of a finger caused by abnormal bone shape or growth. Most commonly affects the pinky finger.[2]
- Neck stiffness
- Hearing loss in approximately 50 percent of patients
- Sporadic, painful episodes of rapidly progressive soft tissue swelling during the first decade of life which typically present as nodules on the head or back
- Heterotopic bone eventually extends across joints which results in progressive and irreversible immobility, weight loss, and thoracic insufficiency syndrome
- Most patients die of respiratory depression or pneumonia
    - The median lifespan is approximately 40 years.
    - 54% die from thoracic insufficiency
    - 15% die from pneumonia
    - Starvation in those with ankylosis of the jaw used to be a common cause of death but alternative feeding methods have led to a decrease in this cause.

Diagnosis[1]:

- Definitive diagnosis requires genetic confirmation showing missense mutations or in frame deletions in the protein-encoding region of the ACVR1 gene

FDA Approval

Atebrioz (zilurgisertib): September 25, 2026; 505(b) New Drug Application (NDA) pathway; Type 1 – New Molecular Entity; Priority; Orphan

Pasatru (garetosmab-grts): August 19, 2026; 505(b) New Drug Application (NDA) pathway; Type 1 – New Molecular Entity; Orphan

Sohonos (palovarotene): August 16, 2023; Biologics License Application (BLA); Priority; Orphan

Current Utilization

Quarter 4 2025 – Quarter 3 2026

Medication	Rx Count	% of Rx	Reimb Amount
Atebrioz	0	0	0
Pasatru	0	0	0
Sohonos	0	0	0

Treatment Overview

Medication Overview[1, 6, 7, 8]:

- Glucocorticoids
  - Prophylaxis may be needed to prevent flare-ups within 24 hours of severe soft tissue trauma or emergency, elective, major, or minor surgery
    - Dose 1 to 2 mg/kg once or twice daily (maximum of 100mg) for 3 to 4 days.
  - Short course may be needed for early symptomatic management of flare-ups affecting the jaw, submandibular area, or major joints
    - Not used for flare-ups in the neck or trunk due to these flare-ups being prolonged and recurrent.
- Ibuprofen may prevent heterotopic ossification because inflammatory prostaglandins are thought to stimulate induction of heterotopic bone.
- Palovarotene (Sohonos)
  - A selective retinoic acid receptor gamma agonist
  - Indicated for use in females 8 years and older and males 10 years and older
  - Can be used for chronic management with dose escalations for flare-ups or for flare-up treatment only
  - Contraindicated in pregnancy, breastfeeding, and those of childbearing potential.
  - May cause premature closure of physeal growth plates
  - Use with CYP3A4 inhibitors is not recommended but dose adjustments are available if concurrent use is unavoidable
  - Dose: 2.5 to 5 mg by mouth daily for maintenance dosing (pediatric dosing based on weight and age).
  - Clinical trials: The mean annualized new heterotopic ossification (HO) was 9.4 cubic centimeters per year in the Sohonos group and 20.3 cubic centimeters per year (cm^3) in the untreated group.
  - Cost (WAC per 28 days): $25,644.00 to $51,290.00
- Garetosmab (Pasatru)
  - An activin A antibody which blocks activation of fibrodysplasia ossificans progressiva-mutant activin receptor type 1 and reduces formation and progression of new heterotopic bone lesions.
  - Clinical trials:
    - Patients had a 90-94% reduction in new heterotopic ossifications with Pasatru versus placebo
    - The mean new HO volume at week 56 was 10.5 cm^3 in patients receiving placebo compared with 0.02 cm^3 in patients receiving Pasatru.
  - Dosing (for reduction of new HO and clinician-assessed flare-ups): 10 mg/kg IV over 60 minutes every 4 weeks

        - May decrease to 3 mg/kg if 10 mg/kg is not tolerated
    - Cost (based on 90kg patient; WAC per 28 days): $106,614.00
- Zilurgisertib (Atebrioz)
    - Mechanism of action: a selective inhibitor of wild-type ALK2 and pathogenic ALK2 (R206H mutation) which stops ALK2 mediated signaling and reduces endochondral bone formation.
    - Dosing: 100mg by mouth daily
        - Can be administered whole or crushed
        - Indicted for use in patients 12 years of age and older
    - Interacts with CYP3A4, MATE1, and MATE2-K substrates
    - Contraindicated in pregnancy
    - Clinical Studies: The mean change from baseline in total new HO lesions was -3.2 cm^3 in the zilurgisertib group and +24.6 cm^3 in the placebo group.
    - Cost (WAC/month): $141,666.67

References:

1. Tis John E, et al. Fibrodysplasia ossificans progressiva. Sep 4, 2026. Fibrodysplasia ossificans progressiva - UpToDate
2. Clinodactyly. Cleveland Clinic. Feb 21, 2022. Clinodactyly: Causes & Outlook
3. U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Atebrioz NDA 221198 approval letter, September 25, 2026. 221198Orig1s000ltr.pdf
4. U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Pasatru BLA 761508 approval letter, August 19, 2026. Approval Letter_761508Orig1s000ltr.pdf
5. U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Sohonos NDA 215559 approval letter, August 16, 2023. Sohonos (palovarotene) capsules
6. Pasatru, Sohonos. Drugdex. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. https://www.Micromedexsolutions.com
7. Pasatru, Sohonos. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. https://www.Micromedexsolutions.com
8. Atebrioz. Package Insert. Mirum Pharmaceuticals, INC. 9/2026. Atebrioz-USPI-MedGuide.pdf

Brand Antipsychotic Report Card

Balancing New Indications with Patient Safety and Efficacy:

The use of antipsychotic medications has expanded considerably beyond their traditional role in treating serious psychiatric conditions such as schizophrenia and bipolar disorder. Newer indications, including the use of certain antipsychotics as adjunctive treatment for major depressive disorder, as well as prescribing for off-label conditions such as Conduct Disorder or Oppositional Defiant Disorder (ODD), have contributed to a broader range of patient populations.[1, 2]

The growing number of approved indications and emerging prescribing practices may contribute to a perception that antipsychotics are relatively safe or routine treatment options. However, it is important to recognize that antipsychotics remain high-risk medications with potentially significant adverse effects. These risks are particularly important in children and adolescents, who may be prescribed antipsychotics for behavioral or mood-related symptoms and may require treatment over extended periods.

Balancing New Treatment Options with Patient Safety and Efficacy:

When selecting an antipsychotic, newer branded medications are not necessarily more effective or appropriate than established generic alternatives. Treatment guidelines emphasize selecting medications based on the patient's diagnosis, clinical history, treatment response, tolerability, and individual risk factors rather than new or brand status of the medication. For many shared indications, established generic antipsychotics remain effective treatment options with well-characterized safety profiles and extensive clinical experience.[3]

Second-generation antipsychotics that are commonly used due to their efficacy, tolerability, and side effect profile include aripiprazole, olanzapine, and risperidone, while first-generation agents such as haloperidol remain appropriate options for certain clinical circumstances.[4]

Established Generic Antipsychotics: Clinical Benefits and Considerations

Established generic antipsychotics offer several advantages, including extensive clinical experience, established evidence of efficacy, availability of multiple formulations, and lower treatment costs.

Generic antipsychotics with specific clinical considerations include[5]:

- Clozapine is first-line for treatment-resistant schizophrenia which is defined as patients who have failed two or more trials of antipsychotics at therapeutic doses.
- Olanzapine and haloperidol are preferred for agitation treatment.
- Quetiapine is preferred for patients who also exhibit insomnia due to their prominent sedating effects.
- Aripiprazole may be the best option for patients with diabetes, obesity, dyslipidemia, or uncontrolled cardiovascular risks due to it having a lower risk of metabolic side effects compared with other agents.

Newer Branded Antipsychotics: When Might They Be Appropriate?

Newer branded medications offer alternative mechanisms of action and different safety profiles to patients who have not responded adequately to established therapies or have experienced intolerable

adverse effects. However, these potential advantages should be evaluated against the available clinical evidence, patient-specific needs, and overall treatment costs.

When to consider newer branded agents:[5, 6, 7]

- Rexulti (Brexpipirazole) has lower akathisia rates, less sedation, and less weight gain than aripiprazole.
- Vraylar (Cariprazine) has a half-life of 1 to 3 weeks which may be beneficial to protect against rapid onset of relapse following non-adherence. Cariprazine is associated with less weight gain and somnolence but a higher risk of akathisia than aripiprazole and brexpiprazole.
- Caplyta (Lumateprerone) has a favorable side effect profile. Studies show that it has a lower risk of hyperprolactinemia, hyperglycemia, hyperlipidemia, and weight gain compared to risperidone.
- Cobenfy (xanomeline-trospium) is beneficial for patients with a sensitivity to EPS despite the use of agents with a low risk. [5]
- Lybalvi (olanzapine/samidorphan) is used in patients with a good response to olanzapine who are experiencing weight gain and have failed to respond to metformin.[7]

1. Agency for Healthcare Research and Quality. Safe and Judicious Use of Antipsychotic Medications in Children and Adolescents Toolkit. Accessed Nov 10, 2026. Other Resources | Agency for Healthcare Research and Quality.
2. World Health Organization. Pharmacological interventions for children with Disruptive Behaviour Disorders or Conduct Disorder or Oppositional Defiant Disorder. Mental Health, Brain Health and Substance Use
3. The American Psychiatric Association Practice Guideline for the Treatment of Patients With Schizophrenia
4. Differentiating the third generation of antipsychotics: a focus on lumateperone's similarities and differences - PubMed
5. Marder, Stephen. Psychosis in adults: Initial management. April 10, 2026. Psychosis in adults: Initial management - UpToDate
6. Newer antipsychotics: Brexpiprazole, cariprazine, and lumateperone: A pledge or another unkept promise? - PMC
7. Jarskog, L. Fredrik, et al. Prevention and management of antipsychotic-associated weight-gain and obesity. Oct 19, 2026. Prevention and management of antipsychotic-associated weight-gain and obesity - UpToDate

NORTH DAKOTA MEDICAID RETROSPECTIVE DRUG UTILIZATION REVIEW

CRITERIA RECOMMENDATIONS

4th QUARTER 2026

1. Milsaperidone / Overuse
Alert Message: Bysanti (milsaperidone) may be over-utilized. The maximum recommended maintenance dosage of milsaperidone for the treatment of schizophrenia or acute treatment of manic or mixed episodes associated with bipolar I disorder in adult patients who are normal CYP2D6 metabolizers is 12 mg twice daily. The maximum recommended maintenance dosage in poor metabolizers is 6 mg/day twice daily.

References:
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Bysanti Prescribing Information, Feb. 2026, Vanda Pharmaceuticals, Inc.

2. Milsaperidone / Therapeutic Appropriateness
Alert Message: The safety and efficacy of Bysanti (milsaperidone) in pediatric patients have not been established.

References:
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Bysanti Prescribing Information, Feb. 2026, Vanda Pharmaceuticals, Inc.

3. Milsaperidone / Severe Hepatic Impairment
Alert Message: Bysanti (milsaperidone) is hepatically metabolized. Milsaperidone has not been studied in patients with severe hepatic impairment, and use is not recommended in this patient population.

References:
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Bysanti Prescribing Information, Feb. 2026, Vanda Pharmaceuticals, Inc.

4. Milsaperidone / Moderate Hepatic Impairment
Alert Message: Bysanti (milsaperidone) is hepatically metabolized, and the use of milsaperidone in patients with moderate hepatic impairment may result in increased milsaperidone exposure. If milsaperidone is used in patients with moderate hepatic impairment, consider a lower maintenance dosage. Milsaperidone has not been studied in patients with severe hepatic impairment, and its use is not recommended. Patients with mild hepatic impairment take the same dosage as patients with normal hepatic function.

References:
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Bysanti Prescribing Information, Feb. 2026, Vanda Pharmaceuticals, Inc.

5. Milsaperidone / Seizures
Alert Message: Bysanti (milsaperidone) should be used with caution in patients with a history of seizures or with other conditions that lower seizure threshold. Like other antipsychotic drugs, milsaperidone may cause seizures. The risk of antipsychotic drug-associated seizure is greatest in patients with a history of seizures or with conditions that lower the seizure threshold.

References:
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Bysanti Prescribing Information, Feb. 2026, Vanda Pharmaceuticals, Inc.

6. Milsaperidone / QT Prolongation
Alert Message: Bysanti (milsaperidone) prolongs the QTc interval and may be associated with arrhythmias and sudden death. Milsaperidone should be avoided in patients who have significant risk of developing torsades de pointes, including those with congenital long QT syndrome, recent myocardial infarction, ischemic cardiomyopathy, unstable angina, bradyarrhythmias, uncontrolled hypertension, high degree atrioventricular block, severe aortic stenosis, or uncontrolled hypothyroidism.

References:
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Bysanti Prescribing Information, Feb. 2026, Vanda Pharmaceuticals, Inc.

7. Milsaperidone / Strong CY3A4 Inhibitors

Alert Message: Bysanti (milsaperidone) is a CYP3A4 substrate, and concurrent use with a strong CYP3A4 inhibitor may result in increased milsaperidone exposure, which may increase the risk of milsaperidone-associated adverse reactions. Reduce the milsaperidone dose by one-half when a strong CYP3A4 inhibitor is initiated in a patient treated with a maintenance dose of milsaperidone. No dose adjustments are required in patients treated with a strong CYP3A4 inhibitor initiating milsaperidone.

References:

Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.

Bysanti Prescribing Information, Feb. 2026, Vanda Pharmaceuticals, Inc.

8. Milsaperidone / Strong CYP2D6 Inhibitors
Alert Message: Bysanti (milsaperidone) is a CYP2D6 substrate, and concurrent use with a strong CYP2D6 inhibitor may result in increased milsaperidone exposure, which may increase the risk of milsaperidone-associated adverse reactions. Reduce the milsaperidone dose by one-half when a strong CYP2D6 inhibitor is initiated in a patient treated with a maintenance dose of milsaperidone. No dose adjustments are required in patients treated with a strong CYP2D6 inhibitor initiating milsaperidone.

References:
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Bysanti Prescribing Information, Feb. 2026, Vanda Pharmaceuticals, Inc.

9. Milsaperidone / Antihypertensives
Alert Message: The concurrent use of Bysanti (milsaperidone) with drugs that lower blood pressure could potentially cause symptomatic hypotension. Avoid concomitant administration of milsaperidone with alpha-adrenergic blocking agents and consider lowering the dosage of the other drugs that lower blood pressure.

References:
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Bysanti Prescribing Information, Feb. 2026, Vanda Pharmaceuticals, Inc.

10. Milsaperidone / QT Prolongation Drugs
Alert Message: Bysanti (milsaperidone) prolongs the QTc interval and may be associated with arrhythmias and sudden death. The concomitant use of milsaperidone should be avoided with other drugs that prolong the QTc interval.

References:
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Bysanti Prescribing Information, Feb. 2026, Vanda Pharmaceuticals, Inc.

11. Milsaperidone / Strong CYP3A4 Inhibitors / Strong 2D6 Inhibitors
Alert Message: Bysanti (milsaperidone) is a CYP2D6 and CYP3A4 substrate, and concurrent use with a strong CYP2D6 inhibitor and a strong CYP3A4 inhibitor may result in increased milsaperidone exposure, which may increase the risk of milsaperidone-associated adverse reactions. Reduce the milsaperidone dose by one-half when both a strong CYP2D6 inhibitor plus a strong CYP3A4 inhibitor are initiated in a patient treated with a maintenance dose of milsaperidone. When both of the strong inhibitors are discontinued in the milsaperidone-treated
patient, titrate milsaperidone to the recommended maintenance dose as described in the official prescribing information.

References:
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Bysanti Prescribing Information, Feb. 2026, Vanda Pharmaceuticals, Inc.

12. Milsaperidone / Pregnancy / Pregnancy Negating
Alert Message: Neonates exposed to antipsychotic drugs, including Bysanti (milsaperidone), during the third trimester of pregnancy are at risk for extrapyramidal and/or withdrawal symptoms following delivery. There are no available data with milsaperidone use during pregnancy, and available data from pharmacovigilance reports with iloperidone (iloperidone and milsaperidone rapidly interconvert in vivo) use during pregnancy are insufficient to inform a drug-associated risk for major birth defects and miscarriage. There are risks to the mother associated with untreated schizophrenia or bipolar I disorder.

References:
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Bysanti Prescribing Information, Feb. 2026, Vanda Pharmaceuticals, Inc.

13. Milsaperidone / Lactation
Alert Message: Because of the potential for serious adverse reactions in the breastfed infant, advise patients not to breastfeed during Bysanti (milsaperidone) treatment and for 6 days after the last dose in CYP2D6 normal metabolizers and 8 days after the last dose in CYP2D6 poor metabolizers. There are no data on the presence of (milsaperidone or its metabolite, P95, in either human or animal milk, the effects on the breastfed infant, or the effects on milk production. Milsaperidone is a prodrug of iloperidone, and iloperidone and milsaperidone rapidly interconvert in vivo. Iloperidone is present in animal milk after administration. When a drug is present in animal milk, it is likely present in human milk.

References:
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Bysanti Prescribing Information, Feb. 2026, Vanda Pharmaceuticals, Inc.

14. Milsaperidone / Non-adherence

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

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.

Berger A, Edelsbery J, Sanders KN, et al., Medication Adherence and Utilization in Patients with Schizophrenia or Bipolar Disorder Receiving Aripiprazole, Quetiapine, or Ziprasidone at Hospital Discharge: A Retrospective Cohort Study. BMC Psychiatry 2012;12:99.

Stephenson JJ, Tuncelli O, Gu T, et al. Adherence to Oral Second-Generation Antipsychotic Medications in Patients with Schizophrenia and Bipolar Disorder: Physicians' Perceptions of Adherence vs. Pharmacy Claims. Int J Clin Pract, June 2012, 66, 6, 565-573.
Morken G, Widen JH, Grawe RW. Non-adherence to Antipsychotic Medication, Relapse and Rehospitalisation in Recent-Onset Schizophrenia. BMC Psychiatry. 2008, 8:32.

15. Vepdegestrant / Overuse
Alert Message: Veppanu (vepdegestrant) may be over-utilized. The recommended maximum dose of vepdegestrant is 200 mg orally once daily with food.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Veppanu Prescribing Information, May 2026, Arvinas Inc.

16. Vepdegestrant / Therapeutic Appropriateness
Alert Message: The safety and efficacy of Veppanu (vepdegestrant) in pediatric patients have not been established.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Veppanu Prescribing Information, May 2026, Arvinas Inc.

17. Vepdegestrant / QT Prolongation
Alert Message: Veppanu (vepdegestrant) can cause QT (QTc) interval prolongation. Correct electrolyte abnormalities, including hypokalemia and hypomagnesemia, prior to and during treatment with vepdegestrant. Perform an ECG prior to initiation of treatment with vepdegestrant, and do not initiate vepdegestrant in patients with QTc >470 msec. In patients with congenital long QTc syndrome, congestive heart failure, electrolyte abnormalities, or those who are taking medications known to prolong the QTc interval, additional ECG monitoring may be necessary. Withhold, reduce dose, or permanently discontinue based on severity.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Veppanu Prescribing Information, May 2026, Arvinas Inc.

18. Vepdegestrant 200 mg / Strong CYP3A Inhibitors

Alert Message: Avoid the concomitant use of Veppanu (vepdegestrant) 200 mg once daily withstrong CYP3A inhibitors. Vepdegestrant is a CYP3A substrate, and concurrent use with a strong CYP3A inhibitor may result in increased vepdegestrant plasma concentrations. If concomitant use cannot be avoided, reduce the vepdegestrant dose from 200 mg once daily to 100 mg once daily. After a CYP3A inhibitor has been discontinued for 3 to 5 half-lives, resume vepdegestrant 200 mg once daily.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Veppanu Prescribing Information, May 2026, Arvinas Inc.

19. Vepdegestrant 100 mg / Strong CYP3A Inhibitors
Alert Message: Avoid the concomitant use of Veppanu (vepdegestrant) 100 mg once daily withstrong CYP3A inhibitors. Vepdegestrant is a CYP3A substrate, and concurrent use with a strong CYP3A inhibitor may result in increased vepdegestrant plasma concentrations. There is no lower vepdegestrant strength that allows for dosage reductions.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Veppanu Prescribing Information, May 2026, Arvinas Inc.

20. Vepdegestrant 200 mg / Strong CYP3A Inducers
Alert Message: Avoid the concomitant use of Veppanu (vepdegestrant) 200 mg once daily with strong CYP3A inducers. Vepdegestrant is a CYP3A substrate, and concurrent use with a strong CYP3A inducer may result in decreased vepdegestrant plasma concentrations, which may reduce the effectiveness of vepdegestrant. If concomitant use cannot be avoided, increase the vepdegestrant dose from 200 mg once daily to 300 mg once daily. After a strong CYP3A inducer has been discontinued for 7 to 14 days, resume vepdegestrant 200 mg once daily.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Veppanu Prescribing Information, May 2026, Arvinas Inc.

21. Vepdegestrant 100 mg / Strong CYP3A Inducers
Alert Message: Avoid the concomitant use of Veppanu (vepdegestrant) 100 mg once daily with strong CYP3A inducers. Vepdegestrant is a CYP3A substrate, and concurrent use with a strong CYP3A inducer may result in decreased vepdegestrant plasma concentrations, which may reduce the effectiveness of vepdegestrant.

References:

Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Veppanu Prescribing Information, May 2026, Arvinas Inc.

22. Vepdegestrant / Sensitive P-gp Substrates
Alert Message: Avoid the co-administration of Veppanu (vepdegestrant) with certain P-gp substrates, where minimal increases in the substrate concentration may lead to serious substrate-related adverse reactions. Vepdegestrant is a P-gp inhibitor, and concurrent use with the P-gp substrate may lead to increased substrate concentrations.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.

Veppanu Prescribing Information, May 2026, Arvinas Inc.

23. Vepdegestrant / Sensitive UGT1A9 Substrates
Alert Message: Avoid co-administration of Veppanu (vepdegestrant) with certain UGT1A9 substrates, where minimal increases in the substrate concentration may lead to serious substrate-related adverse reactions. Vepdegestrant is a UGT1A9 inhibitor, and concurrent use with the UGT1A9 substrate may lead to increased substrate concentrations.

References:

Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Veppanu Prescribing Information, May 2026, Arvinas Inc.

24. Vepdegestrant / QT Prolongation Drugs
Alert Message: Veppanu (vepdegestrant) can cause QT (QTc) interval prolongation. Avoid concomitant use of vepdegestrant with strong CYP3A inhibitors or drugs known to prolong the QTc interval. Reduce the vepdegestrant dose when concomitant use with strong CYP3A inhibitors cannot be avoided. If concomitant use with other QTc-prolonging agents cannot be avoided, increase the frequency of ECG monitoring.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Veppanu Prescribing Information, May 2026, Arvinas Inc.

25. Vepdegestrant / Pregnancy / Pregnancy Negating
Alert Message: Based on findings in animals and its mechanism of action, Veppanu (vepdegestrant) can cause fetal harm when administered to a pregnant woman. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. In an animal reproduction study, oral administration of vepdegestrant to pregnant rats during the period of organogenesis caused adverse developmental outcomes, including embryo-fetal mortality and structural abnormalities at maternal exposures below the recommended dose based on AUC. Advise pregnant women and females of reproductive potential of the potential risk to a fetus.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Veppanu Prescribing Information, May 2026, Arvinas Inc.

26. Vepdegestrant / Lactation

Alert Message: There are no data on the presence of Veppanu (vepdegestrant) or its metabolites in human milk, or its effects on milk production or the breastfed child. Because of the potential for serious adverse reactions in the breastfed child, advise lactating women not to breastfeed during treatment with vepdegestrant and for 2 weeks after the last dose.
References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Veppanu Prescribing Information, May 2026, Arvinas Inc.

27. Vepdegestrant / Therapeutic Appropriateness
Alert Message Advise females of reproductive potential to use effective contraception during treatment with Veppanu (vepdegestrant) and for 2 weeks after the last dose. Vepdegestrant can cause fetal harm when administered to a pregnant woman.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.

Veppanu Prescribing Information, May 2026, Arvinas Inc.

28. Vepdegestrant / Therapeutic Appropriateness

Alert Message: Advise male patients with female partners of reproductive potential to use effective contraception during treatment with Veppanu (vepdegestrant) and for 2 weeks after the last dose.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Veppanu Prescribing Information, May 2026, Arvinas Inc.

29. Vepdegestrant / Non-adherence

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

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.

30. Aficamten / Overuse

Alert Message: Myqorzo (aficamten) may be over-utilized. The maximum recommended dose of aficamten is 20 mg once daily.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Myqorzo Prescribing Information, Dec. 2025, Cytokinetics, Incorporated.

31. Aficamten / Therapeutic Appropriateness

Alert Message: The safety and efficacy of Myqorzo (aficamten) in pediatric patients have not been established.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Myqorzo Prescribing Information, Dec. 2025, Cytokinetics, Incorporated.

32. Aficamten / Rifampin

Alert Message: The concomitant use of Myqorzo (aficamten) with rifampin is contraindicated. Aficamten is primarily metabolized by CYP2C9, and to a lesser extent by CYP3A4, CYP2D6, and CYP2C19. Rifampin is a strong inducer of CYP3A4 and CYP2C19, and a moderate CYP2C9 inducer. Coadministration of rifampin decreases aficamten exposure, which may reduce the effectiveness of aficamten.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Myqorzo Prescribing Information, Dec. 2025, Cytokinetics, Incorporated.

33. Aficamten / Heart Failure Box Warning
Alert Message: Myqorzo (aficamten) can cause heart failure due to systolic dysfunctions. Echocardiogram assessments of left ventricular ejection fraction (LVEF) are required before and during aficamten use. Initiation in patients with LVEF < 55% is not recommended. Decrease the aficamten dose if LVEF is < 50% and =/> 40%. Interrupt the dose of aficamten for at least 7 days if LVEF is less than 40% or if the patient experiences heart failure symptoms or worsening clinical status due to systolic dysfunction.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Myqorzo Prescribing Information, Dec. 2025, Cytokinetics, Incorporated.

34. Aficamten / Fluvoxamine

Alert Message: Concurrent use of Myqorzo (aficamten) with fluvoxamine may result in increased aficamten concentrations. Aficamten is primarily metabolized by CYP2C9 and, to a lesser extent by CYP3A, CYP2D6, and CYP2C19. Fluvoxamine is a weak CYP2C9 inhibitor, weak CYP2D6 inhibitor, moderate CYP3A inhibitor, and strong CYP2C19 inhibitor. Initiate aficamten at 5 mg in patients on stable therapy with fluvoxamine. In patients currently receiving aficamten who intend to initiate fluvoxamine: reduce dose of aficamten (i.e., 20 mg to 10 mg, 15 mg to 5 mg or 10 mg to 5 mg) or continue 5 mg.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Myqorzo Prescribing Information, Dec. 2025, Cytokinetics, Incorporated.

35. Aficamten 15 & 20 mg / Fluconazole
Alert Message: Concurrent use of Myqorzo (aficamten) with fluconazole may result in elevated aficamten concentrations, increasing the risk of developing heart failure. Initiate aficamten at 5 mg in patients on stable therapy with fluconazole. In patients currently receiving aficamten who intend to initiate fluconazole (if used more than 3 days), reduce the aficamten dose to 5 mg if they are currently receiving aficamten 15 mg or 20 mg. Avoid concomitant use of fluconazole if the patient is currently receiving aficamten 5 mg or 10 mg. Aficamten is primarily metabolized by CYP2C9 and to a lesser extent by CYP3A, CYP2D6, and CYP2C19. Fluconazole is a moderate inhibitor of CYP2C9 and CYP3A and a strong CYP2C19 inhibitor.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Myqorzo Prescribing Information, Dec. 2025, Cytokinetics, Incorporated.

36. Aficamten 5 & 10 mg / Fluconazole
Alert Message: Concurrent use of Myqorzo (aficamten) with fluconazole may result in increased aficamten concentrations. Avoid concomitant of use of fluconazole if currently receiving aficamten 5

mg or 10 mg. Aficamten is primarily metabolized by CYP2C9 and, to a lesser extent by CYP3A, CYP2D6, and CYP2C19. Fluconazole is a moderate CYP2C9 inhibitor, moderate CYP3A inhibitor, and strong CYP2C19 inhibitor. Initiate aficamten at 5 mg in patients on stable therapy with fluconazole. In patients currently receiving aficamten who intend to initiate fluconazole (if used more than 3 days) reduce dose of aficamten to 5 mg if they are currently receiving aficamten 15 mg or 20 mg.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Myqorzo Prescribing Information, Dec. 2025, Cytokinetics, Incorporated.

37. Aficamten / Voriconazole

Alert Message: Concurrent use of Myqorzo (aficamten) with voriconazole is predicted to increase aficamten concentrations. Aficamten is primarily metabolized by CYP2C9 and, to a lesser extent by CYP3A, CYP2D6, and CYP2C19. Voriconazole is a strong CYP3A inhibitor, moderate CYP2C19 inhibitor, and weak CYP2C9 inhibitor. Initiate aficamten at 5 mg in patients on stable therapy with voriconazole. In patients currently receiving aficamten who intend to initiate voriconazole reduce dose of aficamten to 5 mg if they are currently receiving aficamten 15 mg or 20 mg. Avoid concomitant use if currently receiving aficamten 5 mg or 10 mg.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Myqorzo Prescribing Information, Dec. 2025, Cytokinetics, Incorporated.

38. Aficamten / Moderate to Strong CYP3A Inducers
Alert Message: Coadministration of Myqorzo (aficamten), a CYP3A substrate, with a moderate or strong CYP3A inducer may decrease aficamten exposure, which may decrease aficamten effectiveness. The risk of heart failure due to systolic dysfunction may increase with discontinuation of these inducers. When coadministration of aficamten and a moderate or strong CYP3A inducer is warranted, refer to the official prescribing information for dosage adjustment and administration.

References:

Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Myqorzo Prescribing Information, Dec. 2025, Cytokinetics, Incorporated.

39. Aficamten / Pregnancy / Pregnancy Negating
Alert Message: There are no available data on the use of Myqorzo (aficamten) during pregnancy to evaluate for a drug associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. The underlying maternal condition during pregnancy poses a risk to the mother and fetus. There is a pregnancy safety study for aficamten. If aficamten is administered during pregnancy, or if a patient becomes pregnant while receiving aficamten or within 3 weeks after the last dose of aficamten, healthcare providers should report aficamten exposure by contacting Cytokinetics, Inc. at 1-833-633-2986.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.

Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Myqorzo Prescribing Information, Dec. 2025, Cytokinetics, Incorporated.

40. Aficamten / Lactation
Alert Message: There are no data on the presence of Myqorzo (aficamten) in human milk, the effects on the breastfed infant, or the effects on milk production. Aficamten was detected in the plasma of rat pups when dams were dosed with the drug orally during the lactation period. When a drug is present in animal milk, it is likely that the drug will be present in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for aficamten and any potential adverse effects on the breastfed infant
from aficamten or from the underlying maternal condition.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Myqorzo Prescribing Information, Dec. 2025, Cytokinetics, Incorporated.

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

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, Fred. The Unmet Challenge of Medication Nonadherence. The Permanente Journal. Vol. 22 (2018): 18-033. doi:10.7812/TPP/18-033.

42. Icotrokinra / Overuse

Alert Message: Icotyde (icotrokinra) may be over-utilized. The recommended dosage of icotrokinra is 200 mg once daily.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Icotyde Prescribing Information, March 2026, Janssen Biotech, Inc.

43. Icotrokinra / Therapeutic Appropriateness
Alert Message: The safety and efficacy of Icotyde (icotrokinra) in pediatric patients less than 12 years of age or weigh less than 40 kg have not been established.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Icotyde Prescribing Information, March 2026, Janssen Biotech, Inc.

44. Icotrokinra / Moderate or Severe Renal Impairment

Alert Message: Patients receiving Icotyde (icotrokinra) who have moderate to severe renal impairment should be monitored for icotrokinra-related adverse reactions. In a pharmacokinetic study, icotrokinra AUC increased by 2.47-fold in patients with moderate renal impairment (eGFR 30 to < 60 mL/min) and 2.78-fold in severe renal impairment. No clinically significant differences in the pharmacokinetics of icotrokinra were observed in patients with mild renal impairment (eGFR 60 to < 90 mL/min).

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Icotyde Prescribing Information, March 2026, Janssen Biotech, Inc.

45. Icotrokinra / Infections
Alert Message: Icotyde (icotrokinra) use may increase the risk of infection. Avoid treatment with icotrokinra in patients with any clinically important active infection until the infection resolves or is adequately treated. In patients with a chronic infection or a history of recurrent infection, consider the risks and benefits prior to prescribing icotrokinra. Instruct patients to seek medical advice if signs or symptoms of clinically important infection occur. If a patient develops such an infection and/or is not responding to standard therapy, monitor the patient closely and discontinue icotrokinra until the infection resolves. Avoid treatment with icotrokinra in patients with any clinically important active infection until the infection resolves.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Icotyde Prescribing Information, March 2026, Janssen Biotech, Inc.

46. Icotrokinra / Tuberculosis
Alert Message: Consider evaluating patients for tuberculosis (TB) infection prior to initiating treatment with Icotyde (icotrokinra) based on clinical judgement. Consider anti-TB therapy prior to initiating icotrokinra in patients with a history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Monitor patients for signs and symptoms of active TB during and after icotrokinra treatment. Avoid administering icotrokinra to patients with active TB.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Icotyde Prescribing Information, March 2026, Janssen Biotech, Inc.

47. Icotrokinra / Pregnancy / Pregnancy Negating
Alert Message: The available data on the use of Icotyde (icotrokinra) during pregnancy are insufficient to evaluate for a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. There is a pregnancy safety study for icotrokinra. If a patient becomes pregnant while receiving icotrokinra, healthcare providers can report icotrokinra exposure by calling 1-800-526-7736 or visiting www.ICTOTYDE.com.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Icotyde Prescribing Information, March 2026, Janssen Biotech, Inc.

48. Icotrokinra / Lactation
Alert Message: There are no data on the presence of Icotyde (icotrokinra) in human milk, effects on the breastfed infant, or the effects on milk production. When administered to lactating rats in animal studies, icotrokinra was detected in the plasma of nursing pups. When a drug is present in animal milk, it is likely that the drug will be present in human milk.The development and health benefits of breastfeeding should be considered along with the mother's clinical need for icotrokinra and any potential icotrokinra-related adverse effects of the breastfed infant.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Icotyde Prescribing Information, March 2026, Janssen Biotech, Inc.

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

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, Fred. The Unmet Challenge of Medication Nonadherence. The Permanente Journal. Vol. 22 (2018): 18-033. doi:10.7812/TPP/18-033.

50. Sparsentan / Overuse
Alert Message: Filspari (sparsentan) may be over-utilized. The recommended maintenance dose of sparsentan in patients 8 years of age and older with focal segmental glomerulosclerosis weighing greater than 50 kg is 800 mg once daily. Patients weighing 50 kg or less should receive a maximum of 400 mg once daily.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Filspari Prescribing Information, April 2026, Travere Therapeutics, Inc.

51. Sparsentan / Therapeutic Appropriateness

Alert Message: The safety and efficacy of Filspari (sparsentan) for the treatment of focal segmental glomerulosclerosis in pediatric patients less than 8 years of age have not been established.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Filspari Prescribing Information, April 2026, Travere Therapeutics, Inc.

52. Sparsentan / CYP2B6, CYP2C9, and CYP2C Substrates
Alert Message: Filspari (sparsentan) induces CYP2B6, CYP2C9, and CYP2C19 enzymes. Concurrent use of sparsentan with a medication that is a CYP2B6, CYP2C9, and/or CYP2C19 substrate may result in decreased systemic concentrations of the substrates. Monitor patients for loss of therapeutic effect of substrates of these enzymes when co-administered with sparsentan.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Filspari Prescribing Information, April 2026, Travere Therapeutics, Inc.

53. Depemokimab-ulaa / Therapeutic Appropriateness
Alert Message: The safety and efficacy of Exdensur (depemokimab-ulaa) in pediatric patients younger than 12 years of age have not been established.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Exdensur Prescribing Information, Dec. 2025, GlaxoSmithKline.

54. Depemokimab-ulaa / Pregnancy / Pregnancy Negating

Alert Message: Available data from clinical trials with Exdensur (depemokimab-ulaa) use in pregnant women are insufficient to identify drug-associated major birth defects or other adverse maternal or fetal outcomes. Transport of endogenous IgG antibodies and monoclonal antibodies,such as depemokimab-ulaa, across the placenta increases as pregnancy progresses and peaks during the third trimester. The presence of the YTE modification may prolong and increase exposure to the infant in utero. The impact of depemokimab-ulaa transmission to the fetus should be considered.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Exdensur Prescribing Information, Dec. 2025, GlaxoSmithKline.

55. Depemokimab-ulaa / Lactation
Alert Message: There are no data on the presence of Exdensur (depemokimab-ulaa) in either human or animal milk, effects on the breastfed infant, or effects on milk production. However, depemokimab-ulaa is a humanized monoclonal antibody and material IgG is present in human milk in small amounts. The effects of local gastrointestinal exposure and the extent of depemokimab-ulaa systemic exposure in the breastfed infant are unknown.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Exdensur Prescribing Information, Dec. 2025, GlaxoSmithKline.

56. Belzutifan / Overuse
Alert Message: Welireg (belzutifan) may be over-utilized. The recommended dose of belzutifan in adults is 120 mg orally once daily with or without food.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Welireg Prescribing Information, June 2026, Merck Sharp & Dohme.

57. Belzutifan / Overuse
Alert Message: Welireg (belzutifan) may be over-utilized. The recommended dose of belzutifan in pediatric patients 12 years and older is weight-based. The maximum dose of belzutifan in patients

weighing 40 kg or more is 120 mg orally once daily. In patients weighing less than 40 kg, the max dose is 80 mg orally once daily.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Welireg Prescribing Information, June 2026, Merck Sharp & Dohme.

58. Belzutifan / Therapeutic Appropriateness
Alert Message: The safety and effectiveness of Welireg (belzutifan) have not been established in pediatric patients with von Hippel-Lindau (VHL) or renal cell carcinoma (RCC).

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Welireg Prescribing Information, June 2026, Merck Sharp & Dohme.

59. Belzutifan / Therapeutic Appropriateness
Alert Message: The safety and effectiveness of Welireg (belzutifan) have not been established in pediatric patients with VHL or ccRCC, or in pediatric patients younger than 12 years of age with PPGL.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Welireg Prescribing Information, June 2026, Merck Sharp & Dohme.

60. Belzutifan / Pregnancy / Pregnancy Negating (Box Warning)

Alert Message: Based on findings in animal studies, Welireg (belzutifan) can cause fetal harm when administered to a pregnant woman. In an animal reproduction study, oral administration of belzutifan to pregnant rats during the period of organogenesis caused embryo-fetal lethality, reduced fetal body weight, and fetal skeletal malformations at maternal exposures greater than or equal to 0.2 times the human exposure (AUC) at the recommended dose of 120 mg daily. Advise pregnant women and females of reproductive potential of the potential risk to a fetus.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Welireg Prescribing Information, June 2026, Merck Sharp & Dohme.

61. Belzutifan / Anemia
Alert Message: Welireg (belzutifan) can cause severe anemia which can require blood transfusion.Monitor patients for anemia before initiation of and periodically throughout treatment with belzutifan.Transfuse patients as clinically indicated. Withhold, reduce dose or permanently discontinue belzutifan based on severity.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Welireg Prescribing Information, June 2026, Merck Sharp & Dohme.

62. Belzutifan / Hypoxia
Alert Message: Welireg (belzutifan) can cause severe hypoxia that may require discontinuation, supplemental oxygen or hospitalization. Monitor oxygen saturation before initiation of, and periodically throughout, treatment with belzutifan. For decreased oxygen saturation with exercise (e.g., pulse oximeter < 88% or PaO2 </= 55 mm Hg) consider withholding belzutifan until pulse oximetry with exercise is greater than 88% then resume at the same dose or a reduced dose. For decreased oxygen saturation at rest (e.g., pulse oximeter < 88% or PaO2 </= 55 mm Hg) or urgent intervention indicated, withhold belzutifan until resolved and resume at a reduced dose or discontinue. For life-threating hypoxia or for recurrent symptomatic hypoxia, permanently discontinue belzutifan.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Welireg Prescribing Information, June 2026, Merck Sharp & Dohme.

63. Belzutifan / Moderate or Severe Hepatic Impairment

Alert Message: Welireg (belzutifan) should be used with caution in patients with moderate or severe hepatic impairment. In a pharmacokinetic study, the AUC of belzutifan increased by 1.5-fold in patients with moderate hepatic impairment receiving belzutifan. For patients with moderate and severe hepatic impairment, monitor patients for increased adverse reactions and modify the dosage as recommended, if required. Belzutifan has not been studied in patients with severe hepatic impairment.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Welireg Prescribing Information, June 2026, Merck Sharp & Dohme.

64. Belzutifan / UGT2B17 or CYP2C19 Inhibitors
Alert Message: Coadministration of Welireg (belzutifan), a UGT2B17 and CYP2C19 substrate, with inhibitors of UGT2B17 or CYP2C19 increases belzutifan exposure. Elevated belzutifan concentrations may increase the risk of adverse reactions, which include anemia and hypoxia.Patients should be monitored for anemia and hypoxia, and dose reduction may be considered.

References:
Welireg Prescribing Information, June 2026, Merck Sharp & Dohme.
DrugBank.UGT2B17 Inhibitors. https://go.drugbank.com/categories/DBCAT005522

65. Belzutifan / Hormonal Contraceptives
Alert Message: Coadministration of Welireg (belzutifan) with hormonal contraceptives may lead to contraceptive failure or an increase in breakthrough bleeding. Estrogens are CYP3A substrates, and belzutifan is a weak CYP3A inducer. The alternative or additional contraceptive agent may need to be continued for 1 month after discontinuation of belzutifan. Patients taking these hormones for other indications may need to be monitored for reduced clinical effect while on belzutifan, with dose adjustments made based on clinical efficacy.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.

Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Welireg Prescribing Information, June 2026, Merck Sharp & Dohme.

66. Belzutifan / Sensitive CYP3A4 Substrates

Alert Message: Avoid coadministration of Welireg (belzutifan) with sensitive CYP3A4 substrates, for which minimal decrease in concentration may lead to therapeutic failures of the substrate. Belzutifan is a weak CYP3A4 inhibitor. If coadministration cannot be avoided, increase the sensitive CYP3A4 substrate dosage in accordance with its Prescribing Information.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Welireg Prescribing Information, June 2026, Merck Sharp & Dohme.

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

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Welireg Prescribing Information, June 2026, Merck Sharp & Dohme.

68. Belzutifan / Therapeutic Appropriateness
Alert Message: Advise females of reproductive potential to use effective non-hormonalcontraception during treatment with Welireg (belzutifan) and for 1 week after the last dose.Belzutifan can render some hormonal contraceptives ineffective.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Welireg Prescribing Information, June 2026, Merck Sharp & Dohme.

69. Belzutifan / Therapeutic Appropriateness

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

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Welireg Prescribing Information, June 2026, Merck Sharp & Dohme.

70. Belzutifan / FDA Approved Indications

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for Welireg (belzutifan). Belzutifan is indicated for the treatment of adult patients with Hippel-Lindau (VHL) disease who require therapy for associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumors (pNET), not requiring

immediate surgery, and renal cell carcinoma with a clear cell component (ccRCC). Belzutifan is also approved for the treatment of adult and pediatric patients 12 years and older with locally advanced, unresectable, or metastatic pheochromocytoma or paraganglioma (PPGL). The long-term safety and efficacy of this agent in the treatment of disease states other than the FDA-approved indications are unknown.

References:

Welireg Prescribing Information, June 2026, Merck Sharp & Dohme.
National Cancer Institute. Off-Label Drug use in Cancer Treatment. [01-13-2022]. Available at: https://www.cancer.gov/about-cancer/treatment/drugs/off-label
Understanding Unapproved Use of Approved Drugs "Off Label". FDA U.S. Food and Drug Administration. [02/05/2018]. Available at: https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label

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

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.

72. Roflumilast Cream 0.15% / Therapeutic Appropriateness

Alert Message: The safety and efficacy of Zoryve 0.15% cream (roflumilast) in pediatric patients less than 6 years of age have not been established.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Zoryve Cream Prescribing Information, June 2026, Arcutis Biotherapeutics, Inc.

73. Roflumilast Cream 0.05% / Therapeutic Appropriateness
Alert Message: The safety and efficacy of Zoryve 0.05% cream (roflumilast) in pediatric patients less than 2 years of age have not been established.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Zoryve Cream Prescribing Information, June 2026, Arcutis Biotherapeutics, Inc.

74. Roflumilast Foam 0.3% / Therapeutic Appropriateness
Alert Message: The safety and efficacy of Zoryve 0.3% foam (roflumilast foam) for the treatment of seborrheic dermatitis in pediatric patients less than 9 years of age have not been established.

References:

Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Zoryve Foam Prescribing Information, June 2026, Arcutis Biotherapeutics, Inc.

75. Roflumilast Foam 0.3% / Therapeutic Appropriateness

Alert Message: The safety and efficacy of Zoryve 0.3% foam (roflumilast) for the treatment of plaque psoriasis in pediatric patients less than 12 years of age have not been established.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Zoryve Foam Prescribing Information, June 2026, Arcutis Biotherapeutics, Inc.

76. Enlicitide / Overuse
Alert Message: Lipfendra (enlicitide) may be overutilized. The recommended dose of enlicitide is 20 mg once daily.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Lipfendra Prescribing Information, July 2026, Merck Sharp & Dohme.

77. Enlicitide / Therapeutic Appropriateness
Alert Message: The safety and efficacy of Lipfendra (enlicitide) in pediatric patients have not been established.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Lipfendra Prescribing Information, July 2026, Merck Sharp & Dohme.

78. Enlicitide / Pregnancy / Pregnancy Negating

Alert Message: Discontinue Lipfendra (enlicitide) when pregnancy is recognized unless the benefits of therapy outweigh the potential risks to the fetus. Enlicitide is a PCSK9 inhibitor and may cause fetal harm when administered to pregnant patients based on the mechanism of action.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Lipfendra Prescribing Information, July 2026, Merck Sharp & Dohme.

79. Enlicitide / Lactation
Alert Message: There is no information on the presence of Lipfendra (enlicitide) in human milk, the effects on the breastfed infant, or the effects on milk production. Enlicitide was detected at low concentrations in the plasma of nursing pups from lactating rats administered subcutaneous enlicitide. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for enlicitide and any potential adverse effects on the breastfed child from enlicitide or from the underlying maternal condition.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.

Lipfendra Prescribing Information, July 2026, Merck Sharp & Dohme.

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

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Kumbhani DJ, Steg PG, Cannon CP, et al., Adherence to Secondary Prevention Medications for Four-Year Outcomes in Outpatients with Atherosclerosis. Am J Med. 2013 Aug;126(8):693-700.

Lindgren P, Eriksson J, Buxton M, et al., The Economic Consequences of Non-Adherence to Lipid-Lowering Therapy: Results from the Anglo-Scandinavian Cardia Outcomes Trial. Int J Clin Pract. 2010 May 24.

81. Mavacamten / Moderate CYP2C19 Inhibitors & Strong CYP3A Inhibitors

Alert Message: Concomitant use of Camzyos (mavacamten) with a moderate CYP2C19 inhibitor or a strong CYP3A4 inhibitor increases mavacamten exposure, which may increase the risk of adverse drug reactions. Discontinuing a moderate CYP2C19 inhibitor or a strong CYP3A4 inhibitor after long-term concomitant use with mavacamten may decrease mavacamten exposure, which may reduce mavacamten efficacy. Refer to the mavacamten official prescribing information for instructions for dosing modification when mavacamten is administered with a moderate CYP2C19 inhibitor or a strong CYP3A4 inhibitor.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Camzyos Prescribing Information, April 2025m Bristol-Myers Squibb.

82. Nerandomilast / Pirfenidone
Alert Message: The concurrent use of Jascayd (nerandomilast) with pirfenidone may result in decreased nerandomilast exposure and loss of nerandomilast efficacy. In clinical drug studies, the nerandomilast trough concentrations at steady state decreased by approximately 50% following concomitant use with pirfenidone. The recommended dosage of nerandomilast is 18 mg twice daily when used concomitantly with pirfenidone.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.

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?