North Dakota Medicaid

Drug Use Review Board Meeting

September 2, 2026

HHS Hoteling Space, Room 308, State Capitol

NORTH Dakota | Health & Human Services
Be Legendary.

Meeting Notice

North Dakota Medicaid Drug Use Review Board

Wednesday, June 3, 2026
1 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 277 413 230 644 78

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 gervingashley@nd.gov.

Agenda

1. Call to Order
2. Roll Call
3. Review and Approval of Minutes
4. Reports from Department
   - Administrative Report: Prescription Drug Monitoring Program Data, Brand Antipsychotic report card
   - Financial Report
   - Retrospective Drug Utilization Review (DUR) Report
   - Clinical Report:
     - Prior Authorization and Criteria Updates: Allergic Fungal Rhinosinusitis, Biosimilar agents, General Rules, Imcivree, Interstitial Lung Disease, Non-Cystic Fibrosis Bronchiectasis, NSAIDs, Pulmonary Hypertension
5. New Business
   - Second Reviews of Familial Chylomicronemia Syndrome, Nausea and Vomiting, Thrombotic Microangiopathies (TMA)
   - First Reviews of Antipsychotics, Human Immunodeficiency Virus, Human Coronavirus, Hypertension, Long-acting Opioids, Pheochromocytoma
   - Review of Retrospective DUR Criteria Recommendations
   - Provider suggestions for clinical practice education or Retrospective Drug Utilization Review (RDUR) Incremental Cost-Effectiveness Ratio (ICER) criteria
6. Announcements: Next Meeting (December 2, 2026)
7. Adjourn

Meeting Minutes
North Dakota Medicaid Drug Use Review (DUR) Board
Meeting Date: June 3, 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 1:02 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
Absent: Kristen Peterson, Matthew Zimny
Quorum Present: Yes

Board Members Non-Voting:
Absent: Kathleen Traylor

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 March 4, 2026, meeting, motion was seconded by A. Honeyman. Motion carried.
The minutes of the March 4, 2026, meeting were approved as distributed.

Reports:
Administrative Report: K. Steig
K. Steig shared with the Board Cost of Dispensing Survey, Acentra NDMA Website Overview

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

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

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

Clinical Report: 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: Alzheimer’s Disease, Heart Failure, Imcivree, and Mounjaro.

Special Orders: Elections completed for Presiding Officer and Vice Presiding Officer

K. Martian nominated K. Datz for Vice Presiding Officer. A. Werremeyer seconded. K. Datz re-elected as Vice Presiding Officer.

K. Martian nominated K. Martian for Presiding Officer. A. Werremeyer seconded. K. Martian re-elected as Presiding Officer.

Unfinished Business:

K. Steig presented updated information for Aqvesme, Ozempic for Type 1 Diabetes and chronic kidney disease, Leqembi renewal criteria, Sapropterin non-responsive after 1 month at 20 mg/kg.

New business:

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

J. McKee presented group prior authorization criteria for Calcium-Channel Blockers
Motion: Moved by K. Datz to place Calcium-Channel Blockers on prior authorization, motion was seconded by K. Martian. Motion carried.

J. McKee presented group prior authorization criteria for Graft vs. Host Disease
Motion: Moved by K. Martian to place Graft vs. Host Disease on prior authorization, motion was seconded by A. Werremeyer. Motion carried with change to add specialist treating disease to the criteria.

J. McKee presented group prior authorization criteria for Malaria
Motion: Moved by K. Datz to place Malaria on prior authorization, motion was seconded by A. Dahl. Motion carried.

First Reviews presented by J. McKee
J. McKee presented an overview of Familial Chylomicronemia Syndrome (FCS). The presented material can be found in the handout.
Motion: Moved by K. Martian to draft prior authorization for Acromegaly, motion was seconded by K. Datz. Motion carried.

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

First Reviews presented by J. McKee
J. McKee presented an overview of Thrombotic Microangiopathies (TMA). The presented material can be found in the handout.
Motion: Moved by K. Martian to draft prior authorization for Thrombotic Microangiopathies (TMA), motion was seconded by K. Datz. 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 K. Martian. Motion carried.

Announcements:
Next meeting is September 2, 2026.

Adjournment:
Meeting adjourned by K. Martian at 2:17 pm CST.

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

PDMP rules

Provider Requirements

Pharmacy Provider Manual

Providers are required to check the Prescription Drug Monitoring Programs (PDMPs) before prescribing or dispensing controlled substances to a Medicaid member. ND Medicaid defines “before prescribing or dispensing” as one or more of the following:

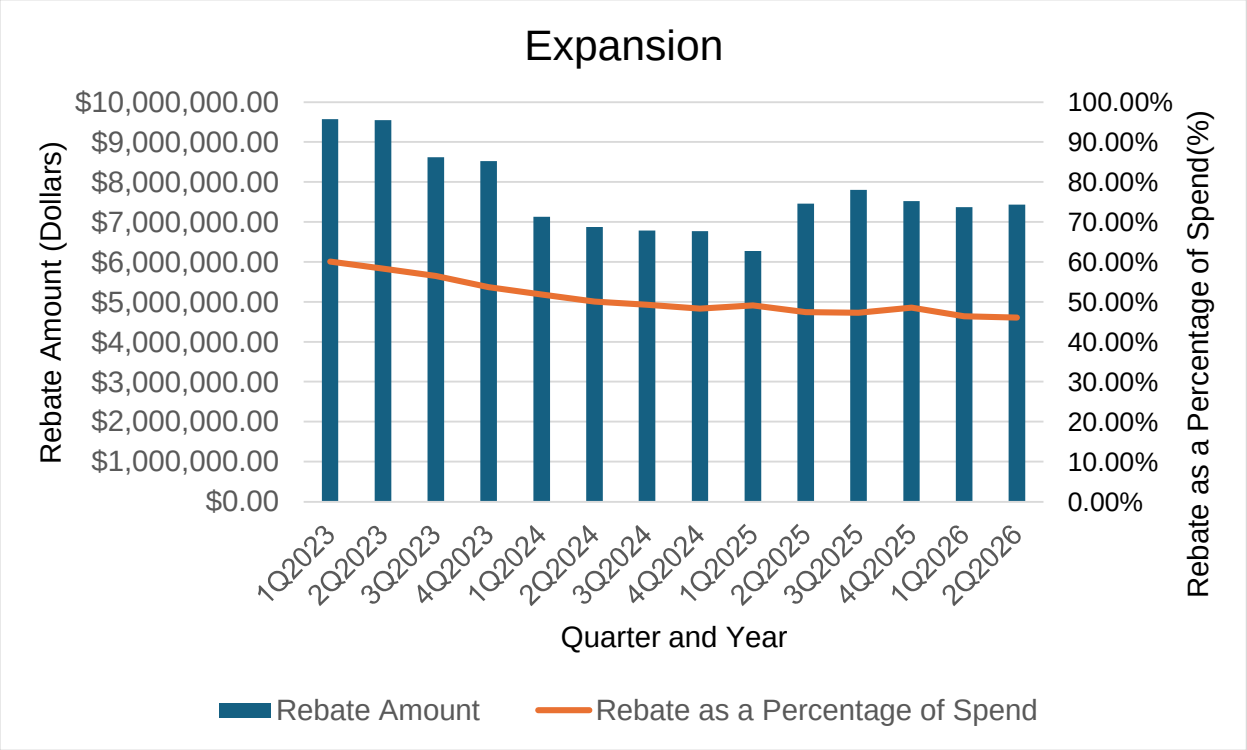
- New or unestablished treatment;
- Every six months during established treatment;
- For early refills or patterns of taking more than prescribed dosage; and
- Upon suspicion or known drug overuse, diversion or abuse.

PDMP Data will be presented at the December 2026 meeting

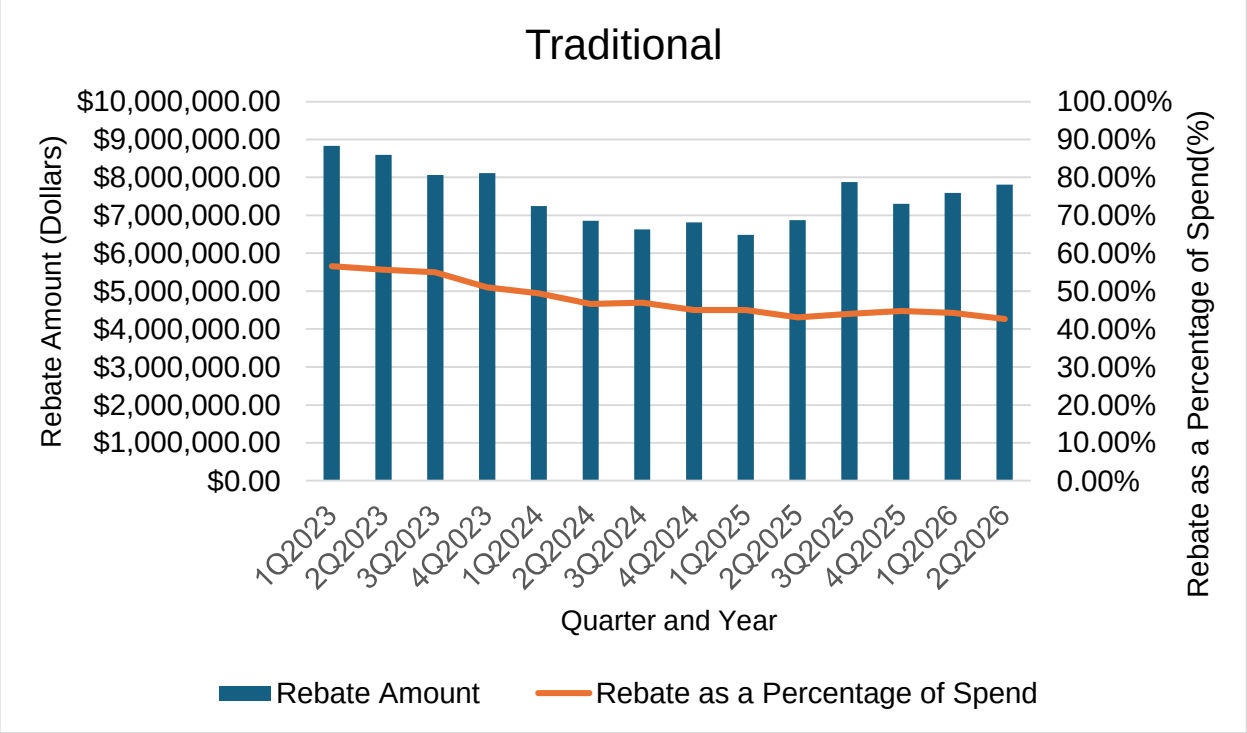
Brand Antipsychotic Report Card

Follow-up to be presented at the December 2026 meeting

Rebate Percent of Spend



Detailed Description:
A mixed bar and line graph for expansion. The expansion graph bars reflect the total rebates collected for each quarter from 1Q2023 to 2Q2026 starting at $9.5 million and decreasing to $7.5 million. The bars indicate a decrease until 2Q2025 where there is a slight increase before decreasing again in 3Q2025. The line on the expansion graph shows the total rebate as a percentage of spend collected for each quarter from 1Q2023 to 2Q2026 starting at 60% and decreasing to 46%.



Detailed Description:
A mixed bar and line graph for traditional. The traditional graph bars also reflect the total rebates collected for each quarter from 1Q2023 to 2Q2026 starting at $8.8 million and decreasing to $7.8 million. The bars indicate a decrease until 2Q2025 where there is a slight increase which is mostly maintained until 2Q2026. The line on the traditional graph also shows the total rebate as a percentage of spend collected for each quarter from 1Q2023 to 2Q2026 starting at 56% and decreasing to 42%.

GENEROUS Model Supplemental Rebates

A new type of supplemental rebate is available to North Dakota (ND). Under the GENErating cost Reductions fOr U.S. Medicaid (GENEROUS) Model, manufacturers will provide supplemental rebates on select drugs to align Medicaid net prices with what certain other countries pay.

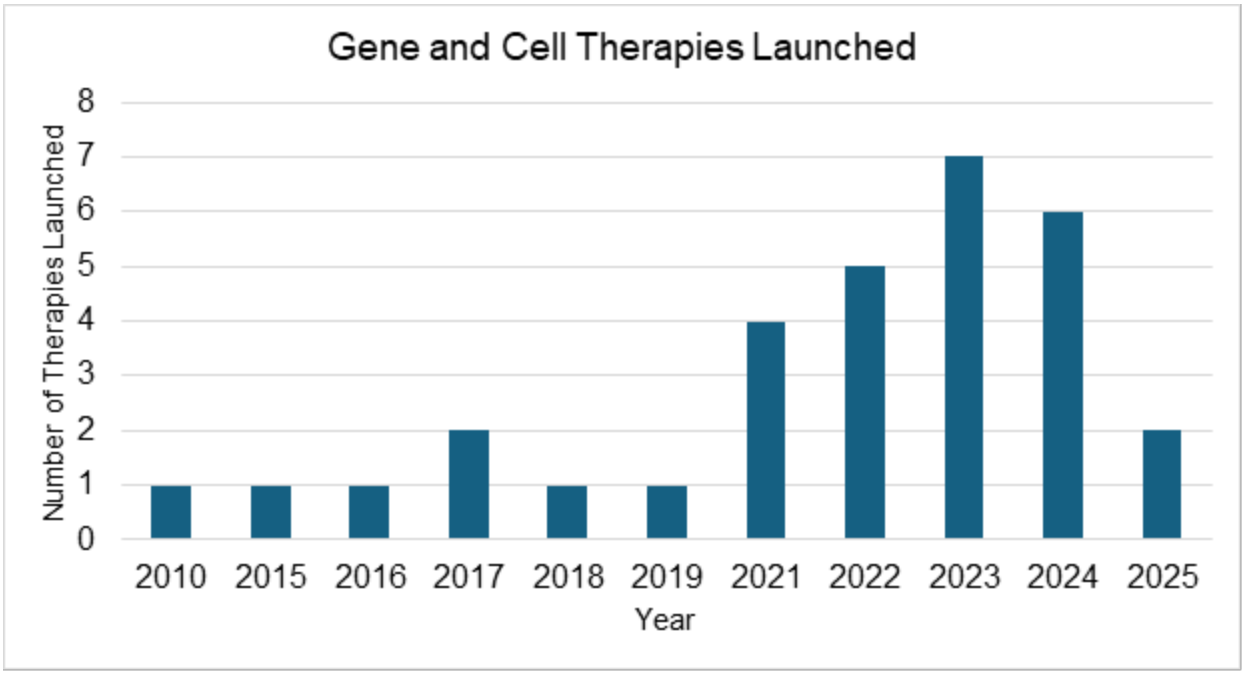
Reimbursement Methodology Preference

Some products do not have a national average drug acquisition cost (NADAC) on all national drug codes (NDCs). When a branded product doesn't have a NADAC, it is typically reimbursed on wholesale cost (WAC). WAC is typically higher than NADAC. Typically, autoinjectors have NADAC while syringes may not (e.g., Taltz, Bimzelx).

ND Medicaid plans to prefer dosage forms based on reimbursement and net cost for injections.

Increased Gene and Cell Therapy Launches

Gene and cell therapies are extremely expensive, with prices as high as $4.25 million for a single dose. There continues to be increasing numbers of gene and cell therapies launched increasing the potential impact for ND Medicaid.



Detailed Description:

A bar graph showing 1 or 2 gene and cell therapy launched between 2010 and 2019 and increases to 4 in 2021 and further increases to 7 in 2023. In 2024, there are 6 launches and in 2025 there are 2 launches.

Reimbursement to Rebate Gap for 5i Drugs

The Average Manufacturer Price (AMP) calculation for 5i (injectable, instilled, inhaled, implanted, or infused) drugs includes pharmacy benefit manager (PBM) rebates which decrease the rebate owed to the state. PBM rebates are not included in the standard methodology for other drugs.
AMP was 42% lower, on average, under the 5i methodology than under the standard methodology. From 2013–2017, Medicaid rebates under the 5i methodology were 82% lower than under the standard methodology, resulting in manufacturers of 15 drugs reducing their Medicaid rebate liability by $1.1 billion in five years.

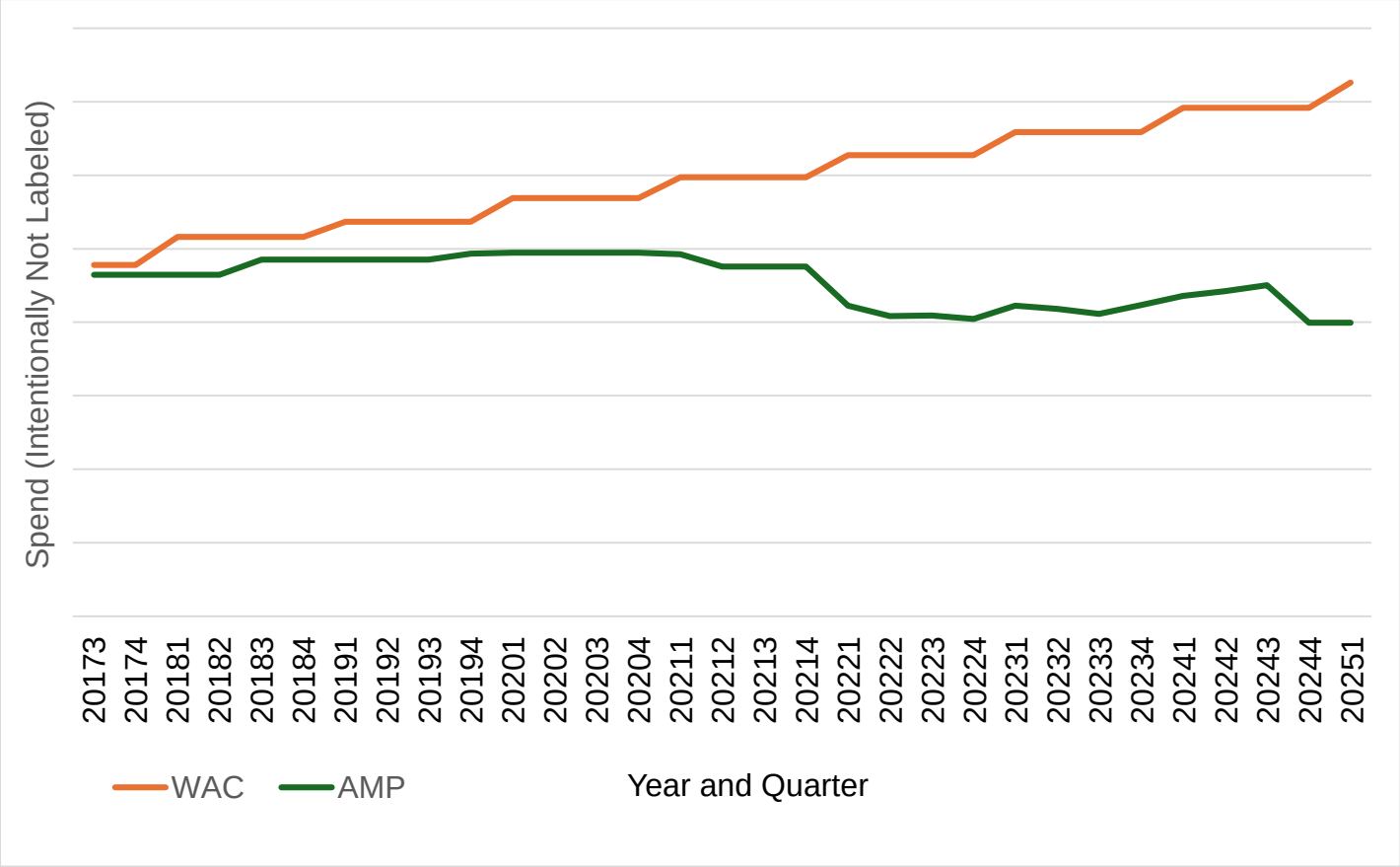
Inclusion into the 5i definition is determined by nonretail sales which may incentivize manufacturers to shift sales to nonretail channels.

References

1. Reduction in Medicaid Rebates Paid by Pharmaceutical Manufacturers for Outpatient Infused, Injected, Implanted, Inhaled, or Instilled Drugs: The 5i Loophole. Journal of Health Politics, Policy and Law. December 1, 2022. https://doi.org/10.1215/03616878-10041219

Effect of Inclusion of PBM rebates on AMP

The difference between wholesale acquisition cost (WAC) and AMP is largely driven by the inclusion of PBM rebates in the AMP calculation. WAC closely follows Medicaid reimbursement while AMP is a large part of the calculation of Medicaid rebates.

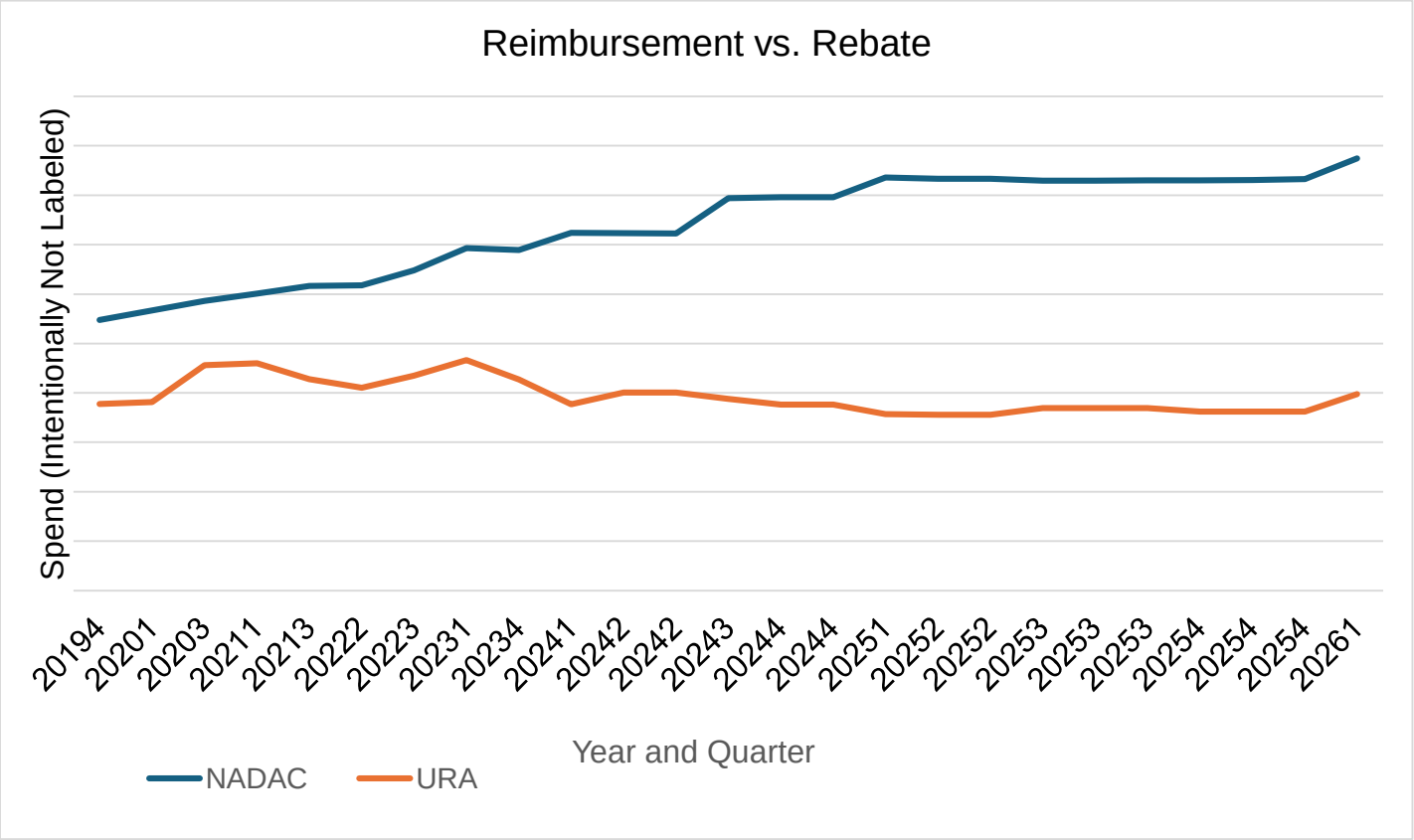


Detailed Description:

This is a line graph showing the WAC and AMP are tightly aligned at drug launch in 2017. WAC continues to increase incrementally each year. The AMP stays flat until 1Q2022 and then decreases. AMP again decreases in 4Q2024. The difference between WAC and AMP increases through time.

Effect of 5i AMP Calculation on Rebates

The difference between NADAC and URA is our net spend for the medication.



Detailed Description:

This is a line graph showing the National Average Drug Acquisition Cost (NADAC) increasing steadily from 4Q2019 to 1Q2025 where the line flattens until it again increases in 1Q2026. The unit rebate amount (URA) slightly decreasing in 1Q2024 and remaining flat. The graph shows a widening difference between NADAC and URA through time.

Top 25 Drugs Based on Total Claims Cost from 4/1/26 to 6/30/26

Total Claims Cost - $18,405,166.17

#	Drug Name	Claims	Claims Cost	Patients	Cost/Patient	% Cost	Dif
1	OZEMPIC	2,348	$2,336,529.14	1,043	$2,240.20	5.72%	↑1
2	HUMIRA	255	$2,207,951.00	108	$71,093.00	5.41%	↓1
3	SOFOSBUVIR-VELPATASVIR	49	$1,144,554.74	49	$23,358.26	2.80%	NC
4	VYVANSE	3,733	$1,136,809.36	1,466	$775.45	2.78%	NC
5	DUPIXENT	274	$1,087,438.00	125	$16,570.00	2.66%	NC
6	TALTZ	123	$1,064,754.00	54	$83,302.00	2.61%	↑1
7	VRAYLAR	885	$1,041,055.36	343	$3,035.15	2.55%	↓1
8	TRIKAFTA	37	$972,228.38	16	$60,764.27	2.38%	NC
9	NORDITROPIN	123	$868,044.57	49	$17,715.20	2.13%	↑1
10	COSENTYX	56	$641,493.00	20	$62,418.00	1.57%	↑3
11	DULERA	1,841	$623,035.05	1,137	$547.96	1.53%	↑4
12	BIKTARVY	282	$618,004.18	144	$4,291.70	1.51%	↓3
13	JARDIANCE	1,266	$570,930.50	667	$855.97	1.40%	↓1
14	INVEGA SUSTENNA	170	$499,042.86	70	$7,129.18	1.22%	↓3
15	INGREZZA	54	$442,034.70	20	$22,101.74	1.08%	↑1
16	SUBLOCADE	199	$438,669.02	99	$4,431.00	1.07%	↑1
17	KESIMPTA PEN	34	$371,954.98	13	$28,611.92	0.91%	↑3
18	CRENESSITY	9	$355,459.14	3	$118,486.38	0.87%	↑12
19	ENBREL	43	$350,692.00	19	$42,693.00	0.86%	↓1
20	BIMZELX	18	$292,180.00	10	$77,035.00	0.72%	↓5
21	ABILIFY MAINTENA	106	$282,039.86	44	$6,410.00	0.69%	NC
22	INVEGA TRINZA	31	$280,329.86	29	$9,666.55	0.69%	↑5
23	ELIQUIS	732	$276,253.97	372	$742.62	0.68%	↓1
24	XELJANZ	48	$257,272.26	23	$11,185.75	0.63%	↑21
25	VIVITROL	144	$246,410.24	69	$3,571.16	0.60%	↑1

Top 25 Drugs Based on Number of Claims from 4/1/26 to 6/30/26

Total Number of Claims - 69,947

#	Drug Name	Claims	Claims Cost	Patients	Cost/Claim	% Claims	Dif
1	GABAPENTIN	4,351	$65,280.48	1,847	$15.00	1.75%	NC
2	VYVANSE	3,733	$1,136,809.36	1,466	$304.53	1.50%	↑3
3	TRAZODONE	3,610	$48,413.36	1,931	$13.41	1.45%	NC
4	SERTRALINE	3,574	$49,244.10	2,021	$13.78	1.44%	NC
5	FLUOXETINE	3,203	$42,833.37	1,786	$13.37	1.29%	↓1
6	ESCITALOPRAM	3,158	$42,240.98	1,813	$13.38	1.27%	↑1
7	CLONIDINE	3,029	$36,965.32	1,540	$12.20	1.22%	↑1
8	AMOXICILLIN	2,891	$43,578.37	2,729	$15.07	1.16%	↓6
9	HYDROXYZINE	2,795	$38,623.50	1,671	$13.82	1.13%	NC
10	LEVOTHYROXINE	2,767	$38,882.74	1,521	$14.05	1.12%	↑1
11	BUPROPION XL	2,762	$45,139.11	1,569	$16.34	1.11%	↑1
12	VENTOLIN HFA	2,637	$174,851.76	2,595	$66.31	1.06%	↓2
13	ATORVASTATIN	2,635	$38,706.62	1,575	$14.69	1.06%	↑6
14	OMEPRAZOLE	2,622	$36,221.43	1,677	$13.81	1.06%	↓1
15	DEXTROAMPH-AMPHET ER	2,533	$71,296.34	1,088	$28.15	1.02%	↑2
16	METHYLPHENIDATE ER	2,481	$68,707.06	1,072	$27.69	1.00%	↓2
17	PREDNISONE	2,454	$28,899.68	1,981	$11.78	0.99%	↑1
18	LAMOTRIGINE	2,441	$33,668.04	999	$13.79	0.98%	↑2
19	ONDANSETRON ODT	2,431	$34,695.36	1,897	$14.27	0.98%	↓4
20	OZEMPIC	2,348	$2,336,529.14	1,043	$995.11	0.95%	↑17
21	PANTOPRAZOLE	2,336	$32,058.08	1,413	$13.72	0.94%	NC
22	ARIPIPRAZOLE	2,325	$34,454.59	1,142	$14.82	0.94%	↑1
23	BUSPIRONE	2,297	$35,421.53	1,230	$15.42	0.93%	↑2
24	AMOXICILLIN-CLAV	2,284	$39,118.47	2,134	$17.13	0.92%	↓8
25	HYDROCODONE-ACETAMINOPHEN	2,250	$35,670.42	1,402	$15.85	0.91%	↑1

Top 15 Therapeutic Classes Based on Number of Claims from 4/1/26 to 6/30/26

Total Number of Claims = 110,158

#	Therapeutic Class Description	Claims	Claims Cost	Patients	Cost/Claim	% Claims	Dif
1	ANTIDEPRESSANTS	25,148	$715,617.48	10,699	$28.46	10.13%	NC
2	ANTIPSYCHOTICS	10,133	$3,280,762.88	4,116	$323.77	4.08%	NC
3	AMPHETAMINES	8,023	$1,258,209.44	3,250	$156.83	3.23%	NC
4	RESPIRATORY AND CNS STIMULANTS	6,889	$330,160.76	2,724	$47.93	2.78%	NC
5	GABA-MEDIATED ANTICONVULSANTS	6,827	$143,817.59	2,828	$21.07	2.75%	NC
6	CENTRAL ALPHA-AGONISTS	5,905	$84,145.27	2,684	$14.25	2.38%	↑1
7	OPIOID AGONISTS	5,727	$110,773.23	2,964	$19.34	2.31%	↑3
8	NONSTEROIDAL ANTI-INFLAMMATORY AGENTS	5,578	$75,990.08	3,815	$13.62	2.25%	↑1
9	BETA-ADRENERGIC AGONISTS	5,573	$847,628.48	3,839	$152.10	2.25%	↓1
10	PENICILLIN ANTIBIOTICS	5,409	$86,910.48	4,791	$16.07	2.18%	↓4
11	PROTON-PUMP INHIBITORS	5,357	$91,729.82	3,249	$17.12	2.16%	NC
12	ANTICONVULSANTS, MISCELLANEOUS	5,203	$277,083.14	2,119	$53.25	2.10%	NC
13	HMG-COA REDUCTASE INHIBITORS	4,916	$72,636.55	2,957	$14.78	1.98%	↑1
14	BETA-ADRENERGIC BLOCKING AGENTS	4,769	$80,197.31	2,776	$16.82	1.92%	↑1
15	ADRENALS	4,701	$157,187.35	3,441	$33.44	1.89%	↓2

Top 15 Therapeutic Classes Based on Claims Cost from 4/1/26 to 6/30/26

Total Claims Cost = $21,872,164.00

#	Therapeutic Class Description	Claims	Claims Cost	Patients	Cost/Patient	% Cost	Dif
1	ANTIPSYCHOTICS	10,133	$3,280,762.88	4,116	$797.08	8.03%	NC
2	TNF INHIBITORS	449	$2,856,945.68	178	$16,050.26	7.00%	NC
3	INCRETIN MIMETICS	2,759	$2,651,474.62	1,216	$2,180.49	6.49%	NC
4	INTERLEUKIN-MEDIATED AGENTS	218	$1,871,898.81	89	$21,032.57	4.58%	↑1
5	ANTINEOPLASTIC AGENTS	541	$1,595,059.62	230	$6,935.04	3.91%	↓1
6	HCV ANTIVIRALS	53	$1,261,539.18	52	$24,260.37	3.09%	NC
7	AMPHETAMINES	8,023	$1,258,209.44	3,250	$387.14	3.08%	NC
8	SKIN AGENTS	298	$1,088,068.86	143	$7,608.87	2.66%	↑1
9	ANTIRETROVIRALS	635	$1,049,613.45	250	$4,198.45	2.57%	↓1
10	CYSTIC FIBROSIS CORRECTORS	39	$1,018,731.26	16	$63,670.70	2.49%	↑1
11	PITUITARY	364	$890,256.98	154	$5,780.89	2.18%	↑2
12	BETA-ADRENERGIC AGONISTS	5,573	$847,628.48	3,839	$220.79	2.08%	NC
13	IMMUNOMODULATORY AGENTS	235	$823,919.03	180	$4,577.33	2.02%	↓3
14	ANTIDEPRESSANTS	25,148	$715,617.48	10,699	$66.89	1.75%	↑1
15	SGLT2 INHIBITORS	1,618	$662,438.23	857	$772.97	1.62%	↓1

RDUR Report: Q2 2026

Date	Total Criteria Exceptions	Total Cases	Letters Sent
April 2026	416	268	629
May 2026	0	0	62
June 2026	567	284	622

April 2026 Cases by Type of Criteria

Criteria Description	# of Cases	% of Cases
Drug Disease Precaution	18	6.72%
Drug-Drug Interactions	156	58.21%
Drug-Drug Marker and/or Diagnosis	34	12.69%
High Dose Alert	3	1.12%
Overuse Precaution	45	16.79%
Therapeutic Appropriateness	12	4.48%

June 2026 Cases by Type of Criteria

Criteria Description	# of Cases	% of Cases
Drug Disease Precaution	33	11.62%
Drug-Drug Interactions	84	28.87%
Drug-Drug Marker and/or Diagnosis	42	14.79%
High Dose Alert	1	0.35%
Overuse Precaution	1	0.35%
Therapeutic Appropriateness	125	44.01%

Dear Prescriber,

SUBJECT: ND MEDICAID LEGISLATIVELY MANDATED PSYCHOTROPIC CERTIFICATION

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

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

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

Thank you for your professional consideration.

Sincerely,

ND Medicaid

Clinical Report

Prior Authorization Updates

Drug	PA Status	Class
Adempas	PA	Pulmonary Hypertension
Arynta	PA	Preferred Dosage Forms
Awiqli	PA	Insulin
Atoncy	PA	ADHD Stimulants
Cerdelga	PA	Medications that cost > $3000
Ctexli	PA	Medications that cost > $3000
Epoprostenil (all forms)	PA	Pulmonary Hypertension
Fetroja	PA	Anti-infectives Resistance Prevention
Filkri	PA	Biosimilars
Hepcludex	PA	Medications that cost > $3000
Idvynso	PA	Anti-infectives Resistance Prevention
nitisinone	PA	Medications that cost > $3000
Orfadin	PA	Medications that cost > $3000
phenoxybenzamine	PA	Medications that cost > $3000
Pyrimethamine	PA	Medications that cost > $3000
Revcovi	PA	Medications that cost > $3000
Secuado	PA	Preferred Dosage Forms
Strensiq	PA	Medications that cost > $3000
Thiola EC	PA	Preferred Dosage Forms
Tiopronin ER	PA	Preferred Dosage Forms
Treprostinil (all forms)	PA	Pulmonary Hypertension
Tryngolza	PA	Lipid-Lowering Agents
Uptravi	PA	Pulmonary Hypertension
Xtoro	PA	Otic Anti-infectives
Waskyra	PA	Medications that cost > $3000
Zolymbus	PA	Glaucoma

Allergic Fungal Rhinosinusitis (AFRS)

Discussion: Dupixent added AFRS as a new indication, so the section was added similarly to Chronic Rhinosinusitis with Nasal Polyps.

Steroids – Nasal Spray

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
See Steroid – Nasal Spray	XHANCE (fluticasone)

Initial Criteria - Approval Duration: 12 months

- Xhance (fluticasone) Only: The member has failed two 30-day trials of steroid nasal sprays of different active ingredients; one must be fluticasone.

Biologics

Anti-IL-4/13 biologics

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

Prior Authorization Criteria

Prior Authorization Form - Nasal Polyps

Initial Criteria - Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, an ear/nose/throat specialist or allergist/immunologist.
- The member must have a history of sino-nasal surgery.
- The member must meet one of the following:
  - The member must have failed a 12-week trial of intranasal corticosteroids, as evidenced by paid claims or pharmacy printouts.
  - The member must have trialed at least two courses of a 10-day trial of oral glucocorticoids in the past year, as evidenced by paid claims or pharmacy printouts.
- The member must have polyps (unilateral or bilateral) confirmed by sinus CT, anterior rhinoscopy, or nasal endoscopy.

Renewal Criteria - Approval Duration: 12 months

- The member must have received a therapeutic response as evidenced by a significant reduction in nasal polyp size and symptoms since treatment initiation.
- The member must be receiving intranasal steroids.

Biosimilar Agents:

Discussion: MedWatch form is now required to document failed trials of biosimilar products

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 90-day trial of each preferred medication, 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).
- A MedWatch form for each trial of each NDC from the available manufacturer(s) is filled out and attached to request.

Rules

Discussion: Rule number 5 was added requesting expected benefit of a medication.

1. Requests for non-preferred brand name agents with a generic formulation available must meet the Dispense as Written (DAW1) criteria for approval in addition to as any other applicable coverage criteria/rule (unless otherwise noted).
2. Non-solid dosage preparations must meet Non-Solid Dosage Preparations prior authorization criteria even if they are preferred in the clinical category.
3. Renewal Request Criteria must be met for all renewal requests.
4. The use of all preferred and non-preferred agents must meet recommendations found in the FDA label or compendia (e.g., diagnosis, age, dosage, frequency, route). Compendia supported use is defined as at least of level of IIa efficacy rating and IIb recommendation. ND Medicaid uses DrugDex ® compendia. Requests outside of FDA approved or compendia supported use are not reviewable by prior authorization and the request will be dismissed on PA review. Sec. 1927. [42 U.S.C. 1396r-8] (d).
5. Clinical justification must be provided explaining how the requested drug is expected to benefit or has benefited the member's condition based on available evidence and outcomes of the drug (subject to clinical review).
6. Clinical justification may be provided when criteria does not encompass a standard of care or guideline supported therapy or a member's unique scenario, by faxing supporting chart notes and evidence using the General Prior Authorization Form.
7. Grandfathering may be allowed in cases where the clinical condition has been verified by a specialist, member is currently receiving FDA or compendia approved medication, and there is clinical evidence for decompensation of member's condition if agent is switched (subject to clinical review).
8. A trial will be considered a failure if a product was not effective at the maximum therapeutic dose with good compliance (defined as the condition is continuously being treated) with most recent trial within the past 3 months, as evidenced by paid claims or pharmacy print outs. If unable to titrate dose to maximum therapeutic dose due to contraindication, intolerance, or lack of effect; trial requirements must be met with alternative preferred product(s) when applicable. Mitigation efforts must be provided, as applicable, with a request to bypass a trial for a preferred product(s) due to intolerance (subject to clinical review). A preferred product must be trialed prior to a non-preferred product approval.

9. The use of pharmaceutical samples or direct to consumer sales will not be considered when evaluating the member's medical condition or prior prescription history for drugs that require prior authorization.
10. Unless otherwise specified, the listing of a brand or generic name includes all legend formulations of that drug. OTC drugs are not covered unless specified. All drugs are pharmacy billed medications unless otherwise specified.
11. Please use the following forms unless otherwise indicated:
    - Pharmacy Point of Sale: General Prior Authorization Form
    - Medical Office Billing: Provider Administered Drug (Medical Billing) PA Form
    - Requested product is same active ingredient as preferred product: MedWatch Form
12. For pharmacy billed medication: please use the prior authorization website to access PA forms, NDC Drug Lookup, quantity limits, and prior authorization information for all medications.
13. For medical billed medications: Please use the Procedure Code Look-up Tool to search for the HCPCS codes that require prior authorization.
14. All requirements outlined in the Pharmacy Provider Manual and any other federal or ND Medicaid manuals, policies, or guidance still apply. For example, when the PDL says a drug is covered without prior authorization, that does not imply that ND Medicaid will pay for that drug if someone has Medicare coverage.
15. If member is 65 years or older, on chronic renal dialysis or has had a kidney transplant within the past 3 years, Medicare eligibility must be ruled out (6-month approval may be allowed to determine eligibility).

Imcivree

Discussion: Imcivree added hypothalamic obesity as a labeled indication, so it was added to criteria

PA REQUIRED	
IMCIVREE (setmelanotide)	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 4 months (6 months for Bardet-Bidel syndrome)

- The member must have a diagnosis of obesity (BMI > 30 kg/m2 for adults or > 95th percentile using growth chart assessments for pediatric members)
- The member's weight and body mass index (BMI) must be provided within the last 60 days.
- The requested medication must be prescribed by, or in consult with, endocrinologist or medical geneticist.
- The member's obesity must be due to one of the following:
  - Genetic testing confirms one of the following variants that is pathogenic, likely pathogenic, or of unknown significance:
    - Proopiomelanocortin (POMC) deficiency
    - Proprotein convertase subtilisin/kexin type 1 (PCSK1) deficiency
    - Leptin receptor (LEPR) deficiency
  - Bardet-Biedl syndrome as evidenced by three or more of the following:
    - Rod-cone dystrophy

        - Polydactyly
        - Genital anomalies
        - Renal anomalies
        - Intellectual impairment
    - Hypothalamic obesity due to injury to the hypothalamus

Renewal Criteria – Approval Duration: 12 months

For Bardet-Biedl Syndrome

- One of the following must be met since starting treatment with Imcivree:
    - Members ≥ 18 years old:
        - First renewal – a weight reduction has been achieved or maintained.
        - Subsequent renewal – a 5% weight reduction has been achieved or maintained.
    - Members < 18 years old:
        - First renewal – a weight reduction has been achieved or maintained.
        - Subsequent renewal - a 5% reduction in BMI has been achieved or maintained.

For POMC, PCSK1, or LEPR deficiency and Hypothalamic obesity

- One of the following must be met since starting treatment with Imcivree:
    - Members ≥ 18 years old:
        - First renewal – a 5% weight reduction has been achieved or maintained.
        - Subsequent renewal – a 10% weight reduction has been achieved or maintained.
    - Members < 18 years old: a 5% reduction in BMI has been achieved or maintained.

Non-Cystic Fibrosis Bronchiectasis

Discussion: The previous eosinophil level requirement was removed from initial criteria, language added to QoL bronchiectasis questionnaire point (it is not required, unless it is planned to be used as a measure of progress)

DPP-1 Inhibitor

PA REQUIRED
BRINSUPRI (brensocatib)

Underutilization

- Brinsupri must be used adherently and will reject on point of sale for late fill.

Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a pulmonologist
- The member must have a clinical history consistent with non-cystic fibrosis bronchiectasis (NCFB) (cough, chronic sputum production and/or recurrent respiratory infections) that is confirmed by chest computerized tomography (CT) scan.
- The member must have documented at least 2 pulmonary exacerbations despite antibiotic therapy in the past 12 months, or be unable to tolerate ongoing antibiotic therapies
    - Pediatric members over the age of 12 are required to have at least 1 pulmonary exacerbation in the prior 12 months.

- If the member is a current tobacco user, the member must have received tobacco cessation counseling in the past year
- For ages 18 and older: Documentation must be submitted of a baseline quality of life score, as assessed by the QoL bronchiectasis questionnaire, respiratory domain if this will be the chosen method for showing future clinical benefit
- The member's baseline current Forced Vital capacity (FVC and FEV1) via Pulmonary Function Test must be provided

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by one of the following (subject to clinical review):
  - The member has experienced a decrease in the number or frequency of pulmonary exacerbations
  - The member shows improvement in pulmonary function (FEV1)
  - The member reports an increased quality of life, as assessed by the QoL bronchiectasis questionnaire, respiratory domain, with an increase from baseline of at least 8 points

NSAIDS

Discussion: The 2nd bullet point under initial criteria for non-preferred agents with no same active ingredient available as preferred was added, requiring trial of mefenamic acid for dysmenorrhea

Oral Solid Dosage Forms

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

Electronic Diagnosis Verification

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

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

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

Therapeutic Duplication

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

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

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

Pulmonary Hypertension

Discussion: Prostacyclin and soluble guanylate cyclase stimulator categories were added, so criteria was developed.

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.
     - 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.

Non-Preferred Agent Criteria

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

Renewal Criteria – Approval Duration: 12 months

- The member has experienced stabilization or improvement in exercise tolerance, WHO functional class, 6-meter walking distance (< 15% decline), pulmonary artery pressure, or pulmonary vascular resistance.

Soluble Guanylate Cyclase Stimulators

PA REQUIRED
ADEMPAS (riociguat)

Electronic Diagnosis Verification

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

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must meet one of the following:
  - The member must have failed a 3-month trial of ambrisentan and bosentan, as evidenced by paid claims or pharmacy printouts.
    - 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 3-month trial with another dual combination therapy.
  - The member has persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) WHO group 4 that is inoperable or post-surgical treatment.

Renewal Criteria – Approval Duration: 12 months

- The member has experienced stabilization or improvement in exercise tolerance, WHO functional class, 6-meter walking distance (< 15% decline), pulmonary artery pressure, or pulmonary vascular resistance.

References:

Humbert, Marc, et al. "2022 ESC/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension: Developed by the task force for the diagnosis and treatment of pulmonary hypertension

of the European Society of Cardiology (ESC) and the European Respiratory Society (ERS). Endorsed by the International Society for Heart and Lung Transplantation (ISHLT) and the European Reference Network on rare respiratory diseases (ERN-LUNG)." *European heart journal* 43.38 (2022): 3618-3731.

Familial Chylomicronemia Syndrome (FCS)

Antisense oligonucleotides

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TRYNGOLZA (olezarsen)	this space intentionally left blank

si RNAs

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
this space intentionally left blank	REDEMPLO (plozasiran)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, an endocrinologist, geneticist, or clinical lipid specialist
- The member must have genetically confirmed FCS (also known as monogenic chylomicronemia)
- The member must have a fasting TG ≥ 880 mg/dL or 10 mmol/L
- The member must remain compliant with a FCS recommended diet, including all the following:
  - Low fat diet (e.g., ≤ 20 grams of fat per day)
  - alcohol avoidance
  - limit simple sugars

Redemplo Only:

- The member must also have failed a 6-month trial of Tryngolza, as evidenced by paid claims or pharmacy printouts

Renewal Criteria – Approval Duration: 12 months

- The member has a reduced fasting TG level at least 25% from baseline

Nausea/Vomiting

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)
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 chemotherapy

- The requested medication must be prescribed by, or in consult with, an oncologist.
- The member must be receiving moderately or highly emetogenic chemotherapy.
- The final date of chemotherapy 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 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.

Motion Sickness-Induced

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
meclizine	NEREUS (tradipitant)
promethazine	this space intentionally left blank
scopolamine patch	this space intentionally left blank

Electronic Age Verification

- Nereus capsules are approved for use in adults only

Electronic Diagnosis Verification

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

Prior Authorization Criteria

Initial Criteria – Approval Duration: 3 months

- Clinical justification must be provided why the member is unable to participate in medically necessary activities or daily responsibilities (subject to clinical review)
- The member has failed a 3-month trial of each preferred agent, as evidenced by paid claims or pharmacy printouts.

Renewal Criteria – Approval Duration: 12 months
- Clinical justification must be provided (subject to clinical review), including activities of daily living are positively impacted by drug therapy.

Post-operative prophylaxis/treatment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
dronabinol	this space intentionally left blank
meclizine	this space intentionally left blank
ondansetron	this space intentionally left blank
scopolamine patch	this space intentionally left blank

Pregnancy-induced

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DICLEGIS (doxylamine/vitamin B6) – Brand Required	BONJESTA (doxylamine/vitamin B6)
meclizine	doxylamine/vitamin B6
metoclopramide	this space intentionally left blank
ondansetron	this space intentionally left blank

Prior Authorization Criteria

Initial Criteria – Approval Duration: until due date
- The member's due date must be provided
- See Preferred Dosage Form criteria

Transplant-Associated Thrombotic Microangiopathy (TA-TMA)

PA REQUIRED
YARTEMLEA (narsoplimab) – Medical Billing

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 hematologist or nephrologist.
- The member has all the following:
  - Low platelet count, as defined by laboratory reference range or member requires dialysis.
  - Evidence of hemolysis such as an elevation in serum lactate dehydrogenase (LDH), elevated indirect bilirubin, reduced haptoglobin, or increased reticulocyte, as defined by laboratory reference range or member requires dialysis.

- Serum creatinine above the upper limits of normal, as defined by laboratory reference range or member requires dialysis.
- If member is on chronic renal dialysis (for at least 3 months), Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.

<u>Renewal Criteria – Approval Duration:</u> 12 months

- The member must have experienced clinical benefit since starting treatment with the requested medication, subject to clinical review, including one of the following scores and symptoms:
- Normalization of platelet count, as defined by laboratory reference range.
- Normalization of lactate dehydrogenase (LDH), as defined by laboratory reference range.
- ≥ 25% improvement in serum creatinine from baseline or ability to discontinue dialysis.

First Review of Antipsychotics

Overview

Purpose of Review:

Bysanti new to market. Reviewing class as supplemental rebate offers allow for prior authorization in class per NDCC 50-24.6-04 (3)(c).

Classifications:

- Second Generation Antipsychotics (SGA) or Atypical Antipsychotics[1]:
  - Lower risk of extrapyramidal symptoms and tardive dyskinesia
- First Generation Antipsychotics (FGA)[2]
  - High-potency FGAs (fluphenazine, haloperidol, loxapine, perphenazine, pimozide, thiothixene, trifluoperazine)
    - Associated with little sedation, weight gain, or anticholinergic activity
  - Low-potency FGAs (chlorpromazine and thioridazine)
    - High prevalence of sedation and anticholinergic effects but have a lower risk of EPS.
- Others:
  - Xanomeline-trospium[1]

Mechanism of Action[1]:

- Both SGAs and FGAs exhibit postsynaptic blockage of brain dopamine D2 receptors.
  - SGAs have a higher affinity for 5HT2 receptor binding than dopamine D2 receptor binding which is thought to be the reason for the lower risk of extrapyramidal symptoms.
- Aripiprazole and brexpiprazole are D2 receptor partial agonists.
- Cariprazine is a D3-preferring D3/D2 receptor partial agonist.
- Lumateperone is a serotonin 5HT2A antagonist and has moderate affinity for D2 receptors.
- Pimavanserin is a serotonin 5HT2A antagonist and has 5HT2 inverse agonist activity and no dopamine D2 affinity.
- Xanomeline-trospium has muscarinic agonism at M1 and M4 acetylcholine receptors in the central nervous system and muscarine antagonism in peripheral receptors.

Common Side Effects:

- SGAs[1]:
  - Metabolic effects
  - Hypotension
  - Sedation
  - Anticholinergic symptoms
  - Hyperprolactinemia
  - Extrapyramidal symptoms (EPS)
  - Cardiac effects
  - Cardiomyopathies
  - Cataracts
  - Sexual dysfunction

- FGAs[2]:
  - Extrapyramidal symptoms (significant)
  - Tardive dyskinesia (significant)
  - Metabolic syndrome
  - Anticholinergic effects
  - Cardiovascular effects
    - QT interval prolongation and sudden death
    - Orthostatic hypotension
    - Increased risk of mortality
  - Agranulocytosis
  - Cholestatic jaundice
  - Neuroleptic malignant syndrome
  - Ocular issues
  - Prolactin elevation
  - Sedation
  - Falls
  - Seizure

FDA Approval

Bysanti (milsaperidone): February 20, 2026; 505(b) New Drug Application (NDA) pathway; Type 1 – New Molecular Entity; Standard;

Current Utilization

Quarter 2 2025 – Quarter 1 2026

Medication	Rx Count	% of Rx	Reimb Amount
Abilify Asimutufii	54	0.02%	$293,892.82
Abilify Maintena	451	0.18%	$1,196,469.44
Aripiprazole	9,345	3.77%	$142,124.14
Aristada ER	253	0.10%	$741,883.18
Aristada Initio	7	0.003%	$15,070.49
Asenapine	16	0.006%	$1,992.14
Bysanti	0	0	0
Caplyta	397	0.16%	$485,077.83
Clozapine	1782	0.71%	$67,303.48
Cobenfy	90	0.04%	$86,385.03
Fanapt	25	0.01%	$66,350.76
Invega ER	16	0.006%	$1,491.74
Invega Hafyera	17	0.007%	$269,725.68
Invega Sustenna	860	0.35%	$2,402,598.10
Invega Trinza	101	0.04%	$922,932.82
Latuda	14	0.006%	$312.21
Lurasidone	1,966	0.79%	$41,690.83
Lybalvi	208	0.08%	$318,019.83
Olanzapine	3,873	1.56%	$55,995.18
Paliperidone ER	836	0.34%	$43,026.00
Quetiapine ER	1,237	0.50%	$20,783.43

Quetiapine	7,523	3.03%	$104,901.74
Rexulti	651	0.26%	$491,550.04
Risperdal Consta	70	0.03%	$103,030.90
Risperidone	6,146	2.48%	$82,454.67
Uzedy	112	0.05%	$346,856.65
Vraylar	3,511	1.42%	$3,955,333.19
Ziprasidone	555	0.22%	$12,146.73
Zyprexa Relprevv	3	0.001%	$2,552.12

Treatment Overview

- SGAs are preferred initial therapy due to the lower risk of EPS.
- Aripiprazole, olanzapine, or risperidone are appropriate first choices due to their efficacy, tolerability, and side effect profile.
- Haloperidol may also be used as an initial option.
- For members with a sensitivity to EPS despite use of agents with a low risk, xanomeline-trospium may be the best option.
- Clozapine is first-line for treatment-resistant schizophrenia.
- Olanzapine and haloperidol are preferred for agitation treatment.
- Quetiapine is preferred for patients who also exhibit insomnia.
- Aripiprazole may be the best option for patients with diabetes, obesity, dyslipidemia, or uncontrolled cardiovascular risks.
- Avoid ziprasidone, quetiapine, chlorpromazine, and IV haloperidol in patients with QT prolongation.
- IM or IV treatment are preferred for patients who refuse to take medications regularly.

Medication Overview[5,6]:

- Bysanti (milsaperidone)
  - Indications:
    - Bipolar I disorder, acute treatment of manic or mixed episodes
    - Schizophrenia
  - Mechanism of action: Dopamine (D2) and serotonin type 2 (5-HT2) receptor antagonist.
  - Dosing: 1mg twice daily; Maintenance and Max dose 12mg twice daily
    - Titration required to reduce risk of orthostatic hypotension.
  - Restart initial dosing and titration if more than 3 days of therapy is missed.
  - Clinical trials[6]:
    - Patients who remained on iloperidone (active metabolite of milsaperidone) for the full treatment period (42 weeks) had comparable efficacy to risperidone (active control antipsychotic drug). Risperidone was shown to be superior to iloperidone in the first 2 weeks, likely due to the more rapid titration with risperidone.
    - Iloperidone was found to be comparable to ziprasidone (both have slow titration periods).
    - Patients treated with iloperidone had a statistically significant longer time to relapse or impending relapse compared to placebo.
  - Cost/month: $3775.58 (all strengths for 30 days)
- Risperdal Consta (risperidone)
  - Mechanism of action: Exact mechanism is unknown. Blocks cortical serotonin receptors and limbic dopamine systems.

    - Side effects: rash, gastrointestinal symptoms (higher with intramuscular injection), Parkinsonism, tremor
    - Administration: intramuscular injection every 2 weeks
    - Cost/month: $2,658.78
- Uzedy (risperidone)
    - Mechanism of action: Exact mechanism is unknown. Blocks cortical serotonin receptors and limbic dopamine systems.
    - Side effects: weight gain (higher with subcutaneous injection), injection site pruritus, skin nodule at injection site
    - Administration: subcutaneous injection every one to two months
    - Cost/month: $1,365.73
- Aripiprazole:
    - Mechanism of action: Partial agonist activity at dopamine D2 and serotonin 5-HT2(1A) receptors and antagonism of serotonin 5-HT2(2A) receptors.
    - Side effects: weight gain, akathisia, extrapyramidal disease, headache, insomnia, sedation, somnolence, hyperglycemia.
    - Cost/month: $8.50
- Rexulti (brexpiprazole):
    - Mechanism of action: Exact mechanism unknown. Partial agonist of serotonin 5-HT-1A activity and dopamine D2 receptors, and antagonist of serotonin 5-HT-2A activity.
    - Side effects: hyperglycemia, increase in triglycerides, weight gain, akathisia
    - Cost/month: $1,555.86
- Olanzapine:
    - Mechanism of action: Dopamine and serotonin type 2 (5HT2) antagonist
    - Side effects: orthostatic hypotension, hypercholesterolemia, hyperglycemia, increased triglycerides, constipation, xerostomia, akathisia, asthenia, dizziness, somnolence, tremor, weight gain, hyperprolactinemia, increased appetite
    - Cost/month: Olanzapine (20mg tablets): $33.75
- Lybalvi (olanzapine/samidorphan):
    - Mechanism of action: Dopamine and serotonin type 2 (5HT2) antagonist. Samidorphan is an opioid receptor antagonist.
    - Side effects: weight gain, xerostomia, headache, hyperglycemia, hyperprolactinemia, somnolence
    - Cost/month: $1,729.54
- Vraylar (cariprazine):
    - Mechanism of action: Partial agonist of serotonin 5-HT-1A activity and dopamine D2 receptors, and serotonin 5-HT-2A antagonist
    - Side effects: constipation, nausea, increased appetite, akathisia, dizziness, extrapyramidal sign, insomnia, somnolence
    - Cost/month: Vraylar: $1,594.82

Considerations for Discussion:

- Should we implement criteria and gold card exceptions for certain providers?
- What is the place in therapy for branded orals?
- Should generics be trialed prior to brands?

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First Review of Human Immunodeficiency Virus (HIV)

Overview

Purpose of Review:

Idvynso new to market. Supplemental rebate offers allow for prior authorization in class per NDCC 50-24.6-04 (3)(c).

Definition[1]: HIV is treated with antiretroviral therapy (ART).

- Early HIV refers to both acute and recent infection.
  - Considered a period of high infectivity.
- Acute HIV occurs soon after transmission and is characterized by the presence of HIV RNA alone or with positive p24 antigen and nonreactive or indeterminate HIV antibody results.
- Recent HIV refers to the first 6 months after infection. Anti-HIV antibodies and HIV RNA become detectable during this time.

Treatment Goals[1]**:**

- Maximally and durably suppress plasma HIV RNA
- Restore and preserve immunologic function
- Reduce HIV-associated morbidity and prolong the duration and quality of survival
- Prevent HIV transmission

FDA Approval

Idvynso (doravirine/islatravir): April 20, 2026; Type 1 – New Molecular Entity and Type 4 – New Combination; 505(b) New Drug Application (NDA); Standard

Current Utilization

Quarter 2 2025 – Quarter 1 2026

Medication	Rx Count	% of Rx	Reimb Amount
Abacavir	4	0.002%	$223.39
Abacavir-lamivudine	11	0.004%	$49.60
Atazanavir	11	0.004%	$49.60
Biktarvy	1,252	0.505%	$2,837,036.21
Darunavir	104	0.042%	$6,895.56
Delstrigo	22	0.009%	$7,582.63
Descovy	153	0.062%	$154,870.12
Dovato	136	0.055%	$228,365.05
Efavir/emtri/tenof	24	0.010%	$1,482.13
Efavirez	13	0.005%	%1,779.33
Emtricitabine/tenofovir	179	0.072%	$5,052.75
Emtricit/rilp/tenof	4	0.002%	$6,764.58
Etravirine	36	0.015%	$17,218.14
Evotaz	6	0.002%	$9,435.87

Genvoya	237	0.96%	$555,598.04
Isentress	33	0.013%	$64,919.77
Juluca	11	0.004%	$11,470.99
Kaletra	5	0.002%	$1,803.00
Lamivudine	7	0.003%	$700.64
Lamivudine/zidovudine	12	0.005%	$432.80
Lopinavir/ritonavir	4	0.002%	$1,319.23
Odefsey	23	0.009%	$17,790.50
Prescobix	35	0.014%	$31,150.29
Prezista	10	0.004%	$2,714.12
Ritonavir	130	0.052%	$3,632.80
Rukobia	9	0.004%	$81,899.60
Stribild	24	0.010%	$52,400.83
Symtuza	44	0.018%	$87,352.50
Tenofovir disop fum	73	0.029%	$1,726.68
Tivicay	137	0.055%	$139,179.43
Tivicay PD	5	0.002%	$4,700.34
Triumeq	94	0.038%	$177,288.18
Yeztugo	2	0.001%	$4,727.92
Zidovudine	5	0.002%	$470.00

Treatment Overview[1]

- ART should be initiated as soon as possible after HIV diagnosis.
- More than 30 antiretroviral (ARV) drugs in nine mechanistic classes are available in the United States.
- Recommended initial regimens for most patients with HIV include an oral second-generation integrase stand transfer inhibitor (INSTI) plus two nucleos(t)ide reverse transcriptase inhibitor (NRTIs).
    - Bictegravir/tenofovir alfenamide (TAF)/emtricitabine
    - Dolutegravir plus tenofovir alafenamide/emtricitabine or tenofovir disoproxil fumurate (TDF)/emtricitabine or tenofovir/lamivudine
- Some patients can use the two drug regimen of dolutegravir/lamivudine.
- Nine classes of antiretroviral medications[1,2]:
    - Nucleos(t)ide reverse transcriptase inhibitors (NRTIs)
        - Block HIV reverse transcriptase which prevents HIV from replicating
        - Abacavir (Ziagen), emtricitabine (Emtriva), lamivudine (Epivir), tenofovir disoproxil fumarate (Viread), tenofovir alafenamide (Vemlidy), and zidovudine (Retrovir).
        - Tenofovir alafenamide (TAF) was shown to be superior to tenofovir disoproxil fumarate (TDF) in clinical trials.
        - TAF was found to be less likely to cause reductions in bone mineral density than TDF.
        - TAF affected eGFR and renal biomarkers less than TDF.
        - TAF caused higher increases in low-density lipoprotein, high-density lipoprotein, and triglycerides than TDF.
    - Non-nucleoside reverse transcriptase inhibitors (NNRTIs)
        - Block HIV reverse transcriptase which prevents HIV from replicating

        - Doravirine (Pifeltro), efavirenz (Sustiva), etravirine (Intelence), nevirapine, and rilpivirine (Edurant, Edurant PED).
    - Protease inhibitors (PIs)
        - Block protease which prevents new (immature)HIV from becoming a mature virus that can infect other CD4 cells.
        - Atazanavir (Reyataz), darunavir (Prezista), fosamprenavir (Lexiva), ritonavir (Norvir), and tipranavir (Aptivus).
    - Integrase strand transfer inhibitors (INSTIs)
        - Block integrase which prevents HIV from inserting its viral DNA into the host CD4 cell and prevents replication.
        - Cabotegravir (Apretude), dolutegravir (Tivicay, Tivicay PD), and raltegravir (Isentress, Isentress HD).
    - Fusion inhibitor
        - Blocks the HIV envelope from merging with the host CD4 cell membrane and entering the CD4 cell.
        - Enfuviratide (Fuzeon)
    - CCR5 antagonist
        - Block CCR5 corecptor on the surface of certain immune cells and prevents HIV from entering the cell
        - Maraviroc (Selzentry)
    - CD4 T lymphocyte (CD4) cell post-attachment inhibitor
        - Blocks HIV from attaching to the CCR5 and CXCR4 coreceptors and entering the cell.
        - Ibalizumab-uiyk (Trogarzo)
    - gp120 attachment inhibitor
        - bind to the gp120 protein on the outer surface which prevents HIV from entering the CD4 cells.
        - Fostemsavir (Rukobia)
    - Capsid inhibitor
        - Disrupts the HIV capsid, protein shell that protects the genetic material and enzymes needed for replication, during multiple stages of the viral life cycle.
        - Lenacpavir (Sunlenca, Yeztugo)
- Ritonavir and cobicistat are used as pharmacokinetic enhancers (or boosters) to improve the pharmacokinetic profiles of PIs and the INSTI, elvitegravir.
- If INSTI resistance is possible, use boosted darunavir with two NRTIs (tenofovir (TAF or TDF) plus emtricitabine or lamivudine.

Medication Overview[4, 5]:

- Idvynso (doravirine/islatravir):
    - Place in therapy: treatment of HIV-1 infection in adults to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of virologic treatment failure and no known substitutions associated with resistance to doravirine.
    - Mechanism of action:
        - Doravirine inhibits HIV-1 replication by non-competitive inhibition of HIV-1 reverse transcriptase (RT).
        - Islatravir inhibits reverse transcriptase following incorporation into the nascent viral DNA by blocking translocation and inducing structural changes in viral DNA that prevent further nucleotide incorporation.

    - Dose: 1 tablet (doravirine 100mg/islatravir 0.25mg) orally once daily
        - Avoid use if eGFR < 30 ml/min
        - Avoid use in severe hepatic impairment (Child-Pugh Class C)
    - Contraindicated with strong CYP3A enzyme inducers and coadministration with lamivudine or emtricitabine.
    - Cost: $4,455.00
- Genvoya (elvitegravir/cobicistat/emtrictabine/tenofovir alafenamide)
    - Place in therapy: Considered a complete antiretroviral regimen for treatment-naïve or as a replacement regimen in patients who have been on a stable regimen for at least 6 months with virologic suppression and no history of treatment failure or resistance to any components.
    - Mechanism of action:
        - Elvitegravir inhibits the strand transfer activity of HIV-1 integrase
        - Cobicistat enhances the systemic exposure of elvitegravir by inhibiting CYP3A metabolism.
        - Emtricitabine inhibits HIV-1 reverse transcriptase
        - Tenofovir alafenamide inhibits HIV-1 replication through incorporation into viral DNA by the HIV reverse transcriptase which results in DNA chain-termination.
    - Dose: 1 tablet daily with food
    - Contraindicated with drugs that require CYP3A for clearance.
    - Cost: $4,422.69
- Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide):
    - Place in therapy: Considered a complete regimen for treatment of HIV-1 infection in adults and pediatrics weighing at least 14 kg who are treatment-naïve or as a replacement regimen in patients who have been on a stable regimen for at least 6 months with virologic suppression and no history of treatment failure or resistance to any components.
    - Mechanism of action:
        - Bictegravir is an integrase strand transfer inhibitor which prevents HIV-1 DNA integration into host DNA, inhibiting viral propagation.
        - Emtricitabine and tenofovir alafenamide are nucleoside analog reverse transcriptase inhibitors that result in termination of the HIV DNA chain.
    - Dose: 1 tablet daily
    - Cost: $4,216.10

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First Review of Human Coronavirus Prevention and Treatment

Overview

Purpose of Review: Xocova, a new medication to the market.

Definition[1]: Coronaviruses are RNA viruses that can be found in bats and other animals. Seven coronaviruses have been found to affect humans. Human coronaviruses infect human cells of the airways and other tissues.

Four common human coronaviruses (common cold)[1]:

- 229E
- NL63
- OC43
- HKU1

Severe human coronaviruses[1]:

- SARS-CoV: caused the Severe Acute Respiratory Distress Syndrome (SARS) epidemic from 2002 to 2004.
- MERS-CoV: causes Middle East Respiratory Syndrome (MERS). First reported in 2012.
- SARS-CoV-2: causes Coronavirus Disease 2019 (COVID-19).

Clinical Features[2]:

- Common human coronaviruses cause mild to moderate upper-respiratory tract illnesses.
    - Runny nose
    - Sore throat
    - Headache
    - Fever
    - Cough
    - Feeling generally unwell

Prevalence[3]:

- Common cold human coronaviruses cause 15 to 30% of all mild upper respiratory infections.
- SARS-CoV-2 was related to hospitalization rates among infants less than 6 months old of 320 per 100,000 and adults 75 years of age and older of 940 per 100,000.

FDA Approval

Paxlovid (nirmatrelvir/ritonavir): May 25, 2023; 505(b) New Drug Application (NDA) pathway; Type 1 – New Molecular Entity; Priority

Xocova (ensitrelvir): May 29, 2026; 505(b) New Drug Application (NDA) pathway; Type 1 – New Molecular Entity; Standard

Current Utilization

Quarter 2 2025 – Quarter 1 2026

Medication	Rx Count	% of Rx	Reimb Amount
Paxlovid	80	0.03%	$113,174.50
Xocova	0	0	0

Treatment Overview

Prophylaxis Medication Overview[3,6,7]:

- Ensitrelvir (Xocova)
  - Protease inhibitor with antiviral activity against SARS-CoV-2.
  - Approved for postexposure prophylaxis for ages 12 years and older.
  - Recommended for patients who are at high risk for severe disease.
    - People 65 years of age and older
    - Medical comorbidities
    - Immunocompromising conditions
  - Dose: 375mg on day 1, then 125mg on days 2 through 5
    - Should be started as soon as possible and within 72 hours of initial exposure.
  - Should not be used during pregnancy and pregnancy should be ruled out prior to taking and contraception should be used for two weeks after use.
  - Strong CYP3A inhibitor with effects lasting 4 days after the final dose.
  - Clinical trials showed a reduced incidence of laboratory-confirmed COVID-19 within 10 days in the treatment group compared with placebo (2.9% versus 9%).
  - Cost/treatment course: $1400.00

Treatment Medication Overview[6,7]:

- Paxlovid (nirmatrelvir/ritonavir)
  - Mechanism of action:
    - Nirmatrelvir is a peptidomimetic inhibitor of SARS-Cov-2 main protease (Mpro) which renders in incapable of processing polyprotein precursors, preventing viral replication.
    - Ritonavir: an HIV-1 protease inhibitor that inhibits CYP3A-mediated metabolism of nirmatrelvir.
  - Dose: Nirmatrelvir 300mg (2 150mg tablets) with ritonavir 100mg (1 100mg tablet) twice daily for 5 days.
    - Should be initiated within 5 days of symptom onset.
  - Cost/treatment course: $1,496.13
- Veklury (given only in medical settings)
  - Dose 200mg IV infusion on day 1, then 100mg IV on days 2 and 3.

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First Review of Hypertension

Overview

Purpose of Review:

Baxfendy is new to market.

Definition[1]:

- Normal blood pressure: Systolic less than 120 mmHg and diastolic less than 80 mmHg
- Elevated blood pressure: Systolic 120 to 129 mmHg and diastolic less than 80 mmHg
- Stage 1 Hypertension: Systolic 130 to139 mmHg and diastolic 80 to 89 mmHg
- Stage 2 Hypertension: Systolic greater than or equal to 140 mmHg or diastolic greater than or equal to 90 mmHg
- Severe Hypertension: Systolic greater than 180 mmHg or diastolic greater than 120 mmHg
- Hypertension in pregnancy: Systolic greater than or equal to 140 mmHg or diastolic greater than or equal to 90 mmHg.

Prevalence[1,2]**:**

- Higher prevalence in males, older adults, black adults, patients with obesity, chronic kidney disease, and/or diabetes, and in those living in rural areas.
- 32% of the world's population (aged 30 to 79 years) has hypertension.
- Nearly half of adults in the United States have hypertension.

FDA Approval

Baxfendy (baxdrostat): May 15, 2026; 505(b) New Drug Application (NDA) pathway; Type 1 – New Molecular Entity; Priority

Current Utilization

Quarter 2 2025 – Quarter 1 2026

Medication	Rx Count	% of Rx	Reimb Amount
Amilodride	52	0.21%	$1,062.67
Baxfendy	0	0	0
Carospir	2	0.001%	$494.93
Eplerenone	65	0.026%	$1,815.62
Spironolactone	5015	2.021%	$96,510.62

Treatment Overview[3, 4, 5]

- Stage 1 Hypertension
  - Monotherapy with an angiotensin-converting enzyme (ACE) Inhibitor, angiotensin receptor blocker (ARB), a dihydropyridine calcium channel blocker, or a thiazide-like diuretic.
- Stage 2 Hypertension

    - Initial therapy with low to moderate doses of two agents
    - Examples include:
        - ACE inhibitor or ARB plus a dihydropyridine calcium channel blocker
        - ACE inhibitor or ARB plus a thiazide-like diuretic
        - Dihydropyridine calcium channel blocker plus thiazide-like diuretic
    - Combinations to avoid:
        - ACE inhibitor plus ARB
        - Beta blocker plus diltiazem or verapamil
        - Alpha-1 adrenergic blocker plus clonidine
        - Beta-blocker plus clonidine
- Resistant Hypertension:
    - Blood pressure that remains above goal despite concurrent use of three antihypertensive agents of different classes, including a diuretic, taken at maximally tolerated doses.
    - Triple therapy generally consists of an ACE inhibitor or ARB plus a dihydropyridine calcium channel blocker and a thiazide-like diuretic.
    - Initial approach is to switch to a more potent thiazide-like diuretic like chlorthalidone or indapamide.
    - If increased blood pressure persists with triple therapy including a potent diuretic the addition of a mineralocorticoid receptor antagonist is recommended.
        - Potassium-sparing diuretics can be used as alternative to mineralocorticoids.
    - The next addition would be a beta blocker.
        - Labetalol, carvedilol, and nebivolol provide vasodilating effects and may be preferred over other beta blockers.
    - Additions to regimens of five or more agents include clonidine, guanfacine, aprocitentan, alpha-1 antagonists, and direct vasodilators.
    - Baxdrostat, an aldosterone synthase inhibitor, was shown to reduce seated systolic pressure by 8.7 to 9.8 mmHg compared to placebo.
- Hypertension in pregnancy:
    - Labetalol and nifedipine ER are preferred for patients who are pregnant or plant to become pregnant.
        - Found to be more effective than methyldopa.
    - Should not use atenolol, ACE inhibitors, ARBs, direct renin inhibitors, nitroprusside, or MRA to avoid fetal harm.

Medication Overview:

- Initial therapies:
    - Thiazide-like diuretics (chlorthalidone, hydrochlorthiazide, indapamide)
    - ACE inhibitors (benazepril, captopril, enalapril, fosinopril, lisinopril, moexipril, perindopril, quinapril, ramipril, trandolapril)
    - ARBs (azilsartan, candesartan, eprosartan, irbesartan, losartan, Olmesartan, telmisartan, valsartan)
    - Dihydropyridine calcium channel blockers (amlodipine, felodipine, isradipine, nicardipine SR, nifedipine LA, nisoldipine)
- Alternative therapies
    - Non-dihydropyridine calcium channel blockers (diltiazem ER and verapamil IR/SR/ER)
    - Loop diuretics (bumetanide, furosemide, and torsemide)
    - Potassium-sparing diuretics (amiloride and triamterene)
    - Aldosterone antagonists (eplerenone and spironolactone)

    - Beta blockers (atenolol, betaxolol, bisoprolol, metoprolol, nebivolol, propranolol, acebutolol, penbutolol, pindolol, carvedilol, labetalol)
    - Direct renin inhibitor (aliskiren)
    - Alpha-1 blockers (doxazosin, prazosin, terazosin)
    - Central alpha-2 agonists (clonidine, methyldopa, guanfacine)
    - Direct vasodilators (hydralazine and minoxidil)
    - Dual endothelin receptor antagonist (aprocitentan)
- Baxdrostat (Baxfendy)[6]
    - Mechanism of action: Inhibits human aldosterone synthase which decreases plasma aldosterone concentrations and reduces blood pressure.
    - Dose: 2mg orally once daily.
    - May cause hyperkalemia and hyponatremia.
    - Cost/month: $900.00

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First Review of Long-Acting Opioids

Overview

Purpose of Review:

Previous reviews targeted specific individual agents within the long-acting opioids class. We are now transitioning to a class-wide review of all long-acting opioids in line with other related recently reviewed classes: short acting opioids and non-opioid pain medications.

Definition[1]:

Long-acting opioids should be reserved for management of cancer pain, palliative care, or conditions relating to persistent pain that is disabling or associated with significant functional impairment. Long-acting opioids should only be initiated in patients who have been taking short-acting opioids for at least one week.

Regulation and Guidance Overview:

- The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act[2]
    - Enacted October 24, 2018
    - Imposes a tighter oversight of prescription opioid production and distribution; requires additional reporting and safeguards to address fraudulent prescribing of opioid medications; and limits coverage of prescription opioids, while expanding coverage of and access to opioid use disorder treatment services.
- Center for Disease Control (CDC) 2022 Clinical Practice Guidelines[3]
    - Areas of consideration:
        - Determining whether or not to initiate opioids for pain.
        - Selecting opioids and determining opioid dosages.
        - Deciding duration of initial opioid prescription and conducting follow-up.
        - Assessing risk and addressing potential harms of opioid use.
    - Recommendations:
        - Nonopioid therapies are at least as effective as opioids for many common types of acute pain.
        - Nonopioid therapies are preferred for subacute and chronic pain.
        - When initiating opioid therapy, providers should prescribe immediate-release opioids.
        - Opioids should be prescribed at the lowest effective dose.
        - Providers should carefully weigh benefits and risks and exercise care when changing opioid dosage for those who have already initiated therapy.
        - Prescribe only the quantity needed for the expected duration of pain severe enough to require opioids.
        - Evaluate benefits and risk of therapy within one to four weeks after starting and regularly thereafter for continued use.
        - Evaluate the risk for opioid-related harms and discuss risk with patients.
        - Review the patient's history of controlled substance prescriptions using the state prescription drug monitoring program (PDMP) data.
        - Providers should consider toxicology testing to assess for prescribed medications as well as other prescribed and nonprescribed controlled substances.

        - Providers should use caution when prescribing opioids and benzodiazepines concurrently.
        - Providers should offer or arrange treatment with evidence-based medications to treat patients with opioid use disorder.
    - FDA has also made labeling changes that along with many other changes includes the following: “Long-acting or extended-release opioids should only be considered when other treatments, including short-acting opioids, are inadequate.” [4]

Medications[1]:

- Buprenorphine transdermal patch and buccal film
    - Associated with less opioid-induced hyperalgesia, produces less respiratory depression than other long-acting opioids.
- Fentanyl transdermal patch
- Hydrocodone ER 12-hour and 24-hour
- Hydromorphone ER 24-hour
- Methadone
    - Should not be first choice for a long-acting opioid.
- Morphine ER
- Oxycodone ER 12-hour
- Oxymorphone ER 12-hour
- Tapentadol ER
- Tramadol ER

Mechanism of Action[1]:

Produce analgesia by acting on central and peripheral mu-, kappa-, and delta-opioid receptors to inhibit the transmission of nociceptive input and the perception of pain.

Adverse Reactions[1]:

- Constipation
- Nausea and vomiting
- Sedation
- Impaired psychomotor function
- Urinary retention
- Opioid-induced hyperalgesia
- Respiratory depression
- Seizures
- Long-term use may lead to hypogonadism, immunosuppression, increased risk of myocardial infarction, and osteoporosis.

Misue and Overdose Risk Factors[1]:

- Personal or family history of substance use disorder
- Younger age (< 40 to 45 years of age)
- More severe pain
- Co-occurring mental health disorders
- High average daily dose
- Uncontrolled pain
- Multiple prescribers or prescriptions
- Prolonged use

- Use of long-acting opioids

Current Utilization

Quarter 1 2025 – Quarter 4 2025

Medication	Rx Count	% of Rx	Reimb Amount
Belbuca	9		$3,315.77
Butrans	57		$20,762.38
Fentanyl	126		$9,366.45
Methadone	4		$50.66
Morphine ER	160		$4,732.64
Oxycontin	158		$69,833.06

Treatment Overview

Nociceptive Pain Treatment[5]:

- Non-steroidal anti-inflammatory drugs (NSAIDs) are the first-line option.
- If NSAIDs are ineffective, a pain-relieving antidepressant like duloxetine, antiseizure drugs like gabapentin or pregabalin, acetaminophen, or opioids may be used.

Neuropathic or Nociplastic Pain Treatment[5]:

- Tricyclic antidepressants, serotonin-norepinephrine reuptake inhibitors, or antiseizure drugs (gabapentin or pregabalin) are first-line.
    - These can be used with adjunctive topical therapy (lidocaine or capsaicin) when pain is localized.
- Opioids should be a second or third-line option due to the uncertainty of efficacy for this type of pain.

Cancer-related Pain[6]:

- Typically involves management with a pure-mu receptor agonist.
- Buprenorphine, an agonist-antagonist, can be used for cancer-related pain.
    - Typically reserved for patients with new-onset, moderate or severe cancer pain due to it potentially inducing withdrawal in opioid-tolerant patients.
- Oxymorphone and fentanyl may be less likely to cause itching and rash than other opioids as they have a low propensity to release histamine.
- Fentanyl may be beneficial in patients with constipation, those unable to take medications orally, and those with kidney impairment.
- Methadone may be useful for patients with kidney disease.
- Inappropriate candidates for methadone include:
    - Patient who lives alone or has poor cognitive function and no responsible caregiver.
    - Obstructive or central sleep apnea
    - Prognosis less than 5 to 7 days
    - History of or high risk of QTc prolongation
    - Clinical instability

Opioid Use[5]:

- Long-term opioid use should not routinely be used for chronic pain.
- The medications should be used at the lowest effective dose for the shortest duration possible.
- The medications should only be used when other non-opioid therapies are ineffective.
- Patients should be carefully assessed for potential substance use disorder and co-occurring conditions that increase risk of adverse effects.

References:

1. Rosenquist, Richard, et al. Use of opioids in the management of chronic pain in adults. April 15, 2026. Use of opioids in the management of chronic pain in adults - UpToDate
2. Duff, Johnathan H, et al. The SUPPORT for Patients and Communities Reauthorization Act of 2025: Section-by-Section Summary. Feb 26, 2026. R48864.3.pdf
3. Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95. DOI: http://dx.doi.org/10.15585/mmwr.rr7103a1.
4. FDA Requires Major Changes to Opioid Pain Medication Labeling to Emphasize Risks. July 31, 2025. FDA Requires Major Changes to Opioid Pain Medication Labeling to Emphasize Risks | FDA
5. Tauben, David, et al. Overview of pharmacologic management of chronic pain in adults. May 4, 2026. Overview of pharmacologic management of chronic pain in adults - UpToDate
6. Portenoy, Russel K, et al. Cancer pain management with opioids: Optimizing analgesia. Jan 5, 2026. Cancer pain management with opioids: Optimizing analgesia - UpToDate

First Review of Pheochromocytoma

Overview

Purpose of Review:

Reviewing to consider adding prior authorization criteria to class, specifically we are considering phenoxybenzamine.

Definition[1]:

Catecholamine-secreting tumors that arise from chromaffin cells of the adrenal medulla and the sympathetic ganglia.

Prevalence[1]:

- Annual incidence is 0.8 per 100,000 person-years.

Clinical Features[1]:

- Classic Triad: episodic headache, sweating, and tachycardia
- One-half of patients have paroxysmal hypertension while the other half have primary hypertension or normal blood pressure
- 95% of catecholamine-secreting tumors are in the abdomen, 85-90% of these are intra-adrenal (pheochromocytoma)

Diagnosis[1]:

- Diagnosis is made based upon biochemical confirmation of catecholamine hypersecretion, followed by identifying the tumor with imaging studies.
- Should be suspected in patients with one or more of the following:
    - The classic triad
    - Hyperadrenergic spells
    - Onset of hypertension at a young age
    - A familial syndrome that predisposes to catecholamine-secreting tumors
    - A family history of pheochromocytoma
    - Lipid-poor adrenal incidentaloma
    - Pressor response during anesthesia, surgery, or angiography
    - Idiopathic dilate cardiomyopathy
    - A history of gastric stromal tumor or pulmonary chondromas (Carney triad)

FDA Approval

Phenoxybenzamine: July 16, 2012; Abbreviated New Drug Application (ANDA)

Current Utilization

Quarter 2 2025 – Quarter 1 2026

Medication	Rx Count	% of Rx	Reimb Amount
Amlodipine**	8,076	3.25%	$102,236.86

Doxazosin**	240	0.10%	$3,565.29
Metoprolol Succinate**	6,225	2.51%	$103,352.26
Metoprolol tartrate**	1,893	0.76%	$24,752.66
Metyrosine	0	0	0
Nicardipine**	0	0	0
Phenoxybenzamine	0	0	0
Prazosin**	5,984	2.41%	$94,253.25
Terazosin**	30	0.01%	$2,053.30

**The indicated medications may have been filled for indications other than pheochromocytoma.

Treatment Overview

- Surgical resection of the pheochromocytoma should occur in all patients following diagnosis.[2]
- The following medications should be avoided in patients with pheochromocytoma: beta-blockers in the absence of alpha-adrenergic blockade, glucagon, histamine, metoclopramide, and high-dose corticosteroids.[2]

Medication Overview[2]:

- Alpha-adrenergic blockade
  - Should be started 7 days preoperatively
  - Selective alpha-1 blockers (doxazosin, terazosin, and prazosin)
    - Preferred due to similar outcomes as phenoxybenzamine at a considerably lower cost.
    - Doxazosin is preferred.
  - Phenoxybenzamine
    - Irreversible, long-acting, nonspecific alpha-adrenergic blocking agent.
    - Found to be more effective than selective alpha-1 blockers at preventing intraoperative blood pressure fluctuations but high cost has limited use.
    - Should be used if blood pressure is not controlled with a selective alpha-1 blocker.
    - Dose: 10mg twice daily, may increase to 20 to 40mg two to three times daily
    - Cost: $1,650.00 (10mg twice daily)
- Beta-adrenergic blockade
  - Beta-blockers are added once alpha-adrenergic blockade has been achieved.
  - Typically added 2 to 3 days prior to surgery
  - Should never be started first.
  - Use caution if the patient has asthma or heart failure.
- Calcium channel blockers
  - Can be used to supplement alpha- and beta-adrenergic blockades if blood pressure control is inadequate or to replace alpha-1 blockers in patients with intolerable side effects
  - Nicardipine and amlodipine are the most used.
- Metyrosine
  - Inhibits catecholamine synthesis.
  - Typically reserved for patients who cannot be treated with alpha and beta-adrenergic blockade protocols.

- May be added to alpha- and beta-blockers when the resection will be difficult or if destructive therapy is planned.
- Associated with potentially disabling side effects including sedation, depression, anxiety, nightmares, crystalluria and urolithiasis, galactorrhea, and extrapyramidal signs.

References:

1. Young, William F, et al. Clinical presentation and diagnosis of pheochromocytoma. March 31, 2026. Clinical presentation and diagnosis of pheochromocytoma - UpToDate
2. Young, William F, et al. Treatment of pheochromocytoma in adults. March 3, 2026. Treatment of pheochromocytoma in adults - UpToDate
3. U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Phenoxybenzamine ANDA 201050 approval letter, July 2012. Phenoxybenzamine Hydrochloride Capsules USP, 10 mg.
4. Phenoxybenzamine. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. https://www.Micromedexsolutions.com

NORTH DAKOTA MEDICAID RETROSPECTIVE DRUG UTILIZATION REVIEW

CRITERIA RECOMMENDATIONS

3RD QUARTER 2026

1. Resmetirom / Overuse
Alert Message: Rezdiffra (resmetirom) may be over-utilized. The recommended dosage of resmetirom is based on actual weight. For patients weighing < 100 kg, the recommended dosage is 80 mg orally once daily, and for patients weighing 100 kg or more, the recommended dosage is 100mg once daily.

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

2. Resmetirom / Therapeutic Appropriateness
Alert Message: The safety and efficacy of Rezdiffra (resmetirom) in pediatric patients have not been established.

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

3. Resmetirom / Decompensated Cirrhosis
Alert Message: Avoid the use of Rezdiffra (resmetirom) in patients with decompensated cirrhosis (consistent with moderate to severe hepatic impairment). Moderate or severe hepatic impairment (Child-Pugh Class B or C) increases resmetirom Cmax and AUC, which may increase the risk of adverse reactions. The safety and effectiveness of resmetirom have not been established in patients with NASH cirrhosis.

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

4. Resmetirom / Gallbladder-Related Adverse Reactions
Alert Message: In clinical trials, cholelithiasis, acute cholecystitis, and obstructive pancreatitis (gallstones) were observed more often in Rezdiffra (resmetirom)-treated patients than in placebo-treated patients. If cholelithiasis is suspected, diagnostic studies of the gallbladder and appropriate clinical follow-up are indicated. If an acute gallbladder event is suspected, interrupt resmetirom treatment until the event is resolved.

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

5. Resmetirom / Strong CYP2C8 Inhibitors

Alert Message: The concurrent use of Rezdiffra (resmetirom) with strong CYP2C8 inhibitors is not recommended. Resmetirom is a CYP2C8 substrate, and concomitant use with a strong CYP2C8 inhibitor may increase resmetirom Cmax and AUC, increasing the risk of resmetirom-related adverse effects.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Rezdiffra Prescribing Information, Dec. 2025, Madrigal Pharmaceuticals.
FDA: Drug Development and Drug Interactions: Tables of Substrates, Inhibitors and Inducers. Available at:
http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/DrugInteractionaLabeling/ucm093664.htm

6. Resmetirom 100 mg / Moderate CYP2C8 Inhibitors
Alert Message: Rezdiffra (resmetirom) is a CYP2C8 substrate, and concomitant use with a moderate CYP2C8 inhibitor may increase resmetirom Cmax and AUC, increasing the risk of resmetirom-related adverse effects. When resmetirom is co-administered with a moderate CYP2C8 inhibitor reduce the dosage of resmetirom. For patients weighing < 100 kg, the recommended dosage is 60 mg orally once daily, and for patients weighing 100 kg or more, the recommended dosage is 80 mg once daily.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Rezdiffra Prescribing Information, Dec. 2025, Madrigal Pharmaceuticals.
FDA: Drug Development and Drug Interactions: Tables of Substrates, Inhibitors and Inducers. Available at:
http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/DrugInteractionaLabeling/ucm093664.htm

7. Resmetirom / Atorvastatin 80 mg
Alert Message: The dose of atorvastatin should not exceed 40 mg per day when co-administered with Rezdiffra (resmetirom). In pharmacokinetic studies, the concurrent use of resmetirom with atorvastatin resulted in increased plasma concentrations of atorvastatin. The Cmax of the parent drug atorvastatin was unchanged, and AUC increased 1.4-fold following the concomitant use of a single dose of atorvastatin 20 mg with resmetirom. The Cmax of the atorvastatin lactone active metabolite increased 2.0-fold, and the AUC increased 1.8-fold.

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

8. Resmetirom / Pravastatin 80 mg
Alert Message: The dose of pravastatin should not exceed 40 mg per day when co-administered with Rezdiffra (resmetirom). In drug studies, the concurrent use of resmetirom with pravastatin resulted in increased plasma concentrations of pravastatin. Pravastatin Cmax increased 1.3-fold and AUC 1.4-fold following concomitant use of a single dose of pravastatin 40 mg with resmetirom.

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

Rezdiffra Prescribing Information, Dec. 2025, Madrigal Pharmaceuticals.

9. Resmetirom / Rosuvastatin 40 mg
Alert Message: The dose of rosuvastatin should not exceed 20 mg per day when co-administered with Rezdiffra (resmetirom). In pharmacokinetic studies, the concurrent use of resmetirom with rosuvastatin resulted in increased plasma concentrations of rosuvastatin. Rosuvastatin Cmax increased 1.8-fold and AUC 1.4-fold following concomitant use of a single dose of rosuvastatin 20 mg with resmetirom.

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

10. Resmetirom / Simvastatin 40 & 80 mg
Alert Message: The dose of simvastatin should not exceed 20 mg per day when co-administered with Rezdiffra (resmetirom). In pharmacokinetic studies, the concurrent use of resmetirom with simvastatin resulted in increased plasma concentrations of simvastatin. Simvastatin Cmax increased 1.4-fold and AUC 1.7-fold following concomitant use of a single dose of simvastatin 20 mg with resmetirom.

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

11. Resmetirom / Sensitive CYP2C8 Substrates
Alert Message: Rezdiffra (resmetirom) is a weak CYP2C8 inhibitor, and concurrent use with a sensitive CYP2C8 substrate may lead to serious substrate-related adverse reactions. Monitor patients more frequently for substrate-related adverse reactions if resmetirom is co-administered with a sensitive CYP2C8 substrate.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Rezdiffra Prescribing Information, Dec. 2025, Madrigal Pharmaceuticals.
FDA: Drug Development and Drug Interactions: Tables of Substrates, Inhibitors and Inducers. Available at:
http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/DrugInteractionaLabeling/ucm093664.htm

12. Resmetirom / Pregnancy / Pregnancy Negating
Alert Message: There are no adequate and well-controlled studies of Rezdiffra (resmetirom) during human pregnancy to determine a drug-associated risk of adverse maternal or fetal outcomes. Resmetirom should be used during pregnancy only if the benefit outweighs the risk to the fetus. There are risks to both the pregnant patient and the fetus related to underlying maternal MASH with liver fibrosis, including an increased risk of gestational diabetes, hypertensive complications, preterm birth, and postpartum hemorrhage.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.

Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Rezdiffra Prescribing Information, Dec. 2025, Madrigal Pharmaceuticals.

13. Resmetirom / Lactation
Alert Message: There is no information regarding the presence of Rezdiffra (resmetirom) in human or animal milk, the effects on the breast-fed infant, or the effects on milk production.The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for resmetirom and any potential adverse effects on the breastfed infant from resmetirom or from the underlying maternal condition.

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

14. Resmetirom / Non-adherence
Alert Message: Based on refill history, your patient may be under-utilizing Rezdiffra (resmetirom). 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.
Achterbosch M, Aksoy N, Obeng GD, Ameyaw D, Ágh T, van Boven JFM. Clinical and economic consequences of medication nonadherence: a review of systematic reviews. Front Pharmacol. 2025 Jun 25;16:1570359. doi: 10.3389/fphar.2025.1570359. PMID: 40635744; PMCID: PMC12237677.

15. Celecoxib Oral Suspension / Overuse - Adults
Alert Message: Vyscoxa (celecoxib oral suspension) may be over-utilized. The recommended maximum dose of celecoxib oral suspension is 400 mg (200 mg twice daily). The maximum single dose of celecoxib oral suspension in adults is 200 mg (20 mL). Administering more than 200 mg in a single dose of celecoxib oral suspension may result in higher than intended concentrations of celecoxib. For patients requiring a single dose greater than 200 mg (20 ml), a different celecoxib product should be used.

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Vyscoxa Prescribing Information, July 2025, Carwin Pharmaceutical Associates LLC.

16. Celecoxib Oral Suspension / Therapeutic
Alert Message: The safety and effectiveness of Vyscoxa (celecoxib oral suspension) have not been established in pediatric patients for the treatment of osteoarthritis or ankylosing spondylitis.

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Vyscoxa Prescribing Information, July 2025, Carwin Pharmaceutical Associates LLC.

17. Celecoxib Oral Suspension / Overuse - Pediatric
Alert Message: Vyscoxa (celecoxib oral suspension) may be over-utilized. For the treatment of juvenile rheumatoid arthritis (JRA) in patients 2 years and older, the dosage is weight-based. For

patients 2 years and older weighing 10 kg to 25 kg, the recommended dose is 50 mg (5 mL) twice daily. For patients 2 years and older weighing more than 25 mg, the recommended dose is 100 mg (10 mL) twice daily.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Vyscoxa Prescribing Information, July 2025, Carwin Pharmaceutical Associates LLC.

18. Celecoxib Oral Suspension / Therapeutic Appropriateness
Alert Message: The safety and effectiveness of Vyscoxa (celecoxib oral suspension) have not been established in pediatric patients with JRA less than 2 years of age, in patients with a body weight of less than 10 kg, and in patients with active systemic features.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Vyscoxa Prescribing Information, July 2025, Carwin Pharmaceutical Associates LLC.

19. Semaglutide Tablets / Overuse
Alert Message: Wegovy tablets (semaglutide) may be over-utilized. The recommended maintenance dose of semaglutide tablets is 25 mg orally once daily for cardiovascular risk reduction and weight reduction in adults.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Wegovy Prescribing Information, Dec. 2025, Nono Nordisk Inc.

20. Semaglutide Tablets / Therapeutic
Alert Message: The safety and efficacy of Wegovy tablets (semaglutide) in pediatric patients have not been established.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Wegovy Prescribing Information, Dec. 2025, Nono Nordisk Inc.

21. Semaglutide Tablets / Lactation
Alert Message: Advise patients that breastfeeding is not recommended during treatment with Wegovy tablets (semaglutide). Semaglutide tablets contain salcaprozate sodium (SNC), an absorption enhancer, and it or its metabolites are present in human milk. Since the activity of enzymes involved in SNAC clearance may be lower in infants compared to adults, higher SNAC plasma levels may occur in neonates and infants, potentially leading to serious adverse reactions. Alternative semaglutide formulations exist that do not contain SNAC and can be used during lactation.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Wegovy Prescribing Information, Dec. 2025, Nono Nordisk Inc.

22. Dupilumab / Therapeutic Appropriateness

Alert Message: The safety and efficacy of Dupixent (dupilumab) in pediatric patients with allergic fungal rhinosinusitis (AFRS) have not been established.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Dupixent Prescribing Information, Feb. 2026, Regeneron.

23. Bempedoic Acid / Fibrates
Alert Message: The concurrent use of Nexletol (bempedoic acid) with a fibrate (e.g., fenofibrate or gemfibrozil) may result in increased triglycerides and decreased high-density lipoprotein cholesterol (HDL-C). Both increased triglycerides and decreased HDL-C levels are reversed to baseline if bempedoic acid or the fibrate therapy is discontinued. Monitor triglycerides and HDL-C for 4 weeks after initial concomitant use of bempedoic acid and periodically thereafter. If increased triglycerides or decreased HDL-C levels are detected, discontinue bempedoic acid or fibrate therapy. Monitor triglycerides and HDL-C levels until levels return to baseline.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Nexletol Prescribing Information, Jan. 2026, Esperion.

24. Bempedoic Acid-Ezetimibe / Fibrates
Alert Message: The concurrent use of Nexlizet (bempedoic acid/ezetimibe) with a fibrate (e.g., fenofibrate or gemfibrozil) may result in increased triglycerides and decreased high-density lipoprotein cholesterol (HDL-C). Both increased triglycerides and decreased HDL-C levels are reversed to baseline if the bempedoic acid-containing agent or the fibrate therapy is discontinued. Monitor triglycerides and HDL-C levels for 4 weeks after the initial concomitant use of bempedoic acid/ezetimibe, and periodically thereafter. If increased triglycerides or decreased HDL-C levels are detected, discontinue bempedoic acid/ezetimibe or fibrate therapy. Monitor triglycerides and HDL-C levels until levels return to baseline.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Nexlizet Prescribing Information, Jan. 2026, Esperion.

25. Taletrectinib / Overuse
Alert Message: Ibtrozi (taletrectinib) may be over-utilized. The recommended dosage of taletrectinib is 600 mg once daily on an empty stomach (no food intake at least 2 hours before and 2 hours after taking taletrectinib).

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Ibtrozi Prescribing Information, June 2025, Nuvation Bio Inc.

26. Taletrectinib / Therapeutic Appropriateness
Alert Message: The safety and efficacy of Ibtrozi (taletrectinib) in pediatric patients have not been established.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Ibtrozi Prescribing Information, June 2025, Nuvation Bio Inc.

27. Taletrectinib / Hepatotoxicity
Alert Message: Ibtrozi (taletrectinib) can cause hepatotoxicity, including drug-induced liver injury and fatal adverse reactions. Monitor liver function tests prior to administration of taletrectinib, every 2 weeks during the first 2 months of treatment, then monthly thereafter as clinically indicated. Based on the severity of hepatic adverse reaction and resolution, withhold taletrectinib until recovery, then resume at a reduced dose or permanently discontinue taletrectinib.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Ibtrozi Prescribing Information, June 2025, Nuvation Bio Inc.

28. Taletrectinib / QTc Interval Prolongation
Alert Message: Ibtrozi (taletrectinib) can cause QTc interval prolongation, which can increase the risk for ventricular tachyarrhythmias or sudden death. Taletrectinib prolongs the QTc interval in a concentration-dependent manner. Withhold taletrectinib in patients with Grade 2 or 3 severity, correct electrolytes and/or change concomitant medications, then resume taletrectinib at the same dose for Grade 2 and at a reduced dose for Grade 3 when recovered to Grade 1 or less. For patients with Grade 4 severity, permanently discontinue taletrectinib.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Ibtrozi Prescribing Information, June 2025, Nuvation Bio Inc.

29. Taletrectinib / Interstitial Lung Disease/Pneumonitis
Alert Message: Ibtrozi (taletrectinib) can cause severe, life-threatening, or fatal interstitial lung disease/pneumonitis (ILD) or pneumonitis. Monitor patients for signs and symptoms indicative of ILD/ pneumonitis (e.g., dyspnea, cough,fever). Immediately withhold taletrectinib in patients with suspected ILD/pneumonitis. Withhold, then resume at the same or reduced dose, or permanently discontinue taletrectinib if Grade 2 or higher ILD/pneumonitis is confirmed.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Ibtrozi Prescribing Information, June 2025, Nuvation Bio Inc.

30. Taletrectinib / Hyperuricemia
Alert Message: Ibtrozi (taletrectinib) can cause hyperuricemia. Monitor serum uric acid levels prior to administration of taletrectinib, and periodically during treatment. Initiate treatment with urate-lowering medications as clinically indicated. For hyperuricemia severity Grade 3 or 4, withhold taletrectinib until improved signs and symptoms, then resume at the same or reduced dose, or permanently discontinue taletrectinib based on severity.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.

Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Ibtrozi Prescribing Information, June 2025, Nuvation Bio Inc.

31. Taletrectinib / Moderate & Strong CYP3A Inhibitors
Alert Message: The current use of Ibtrozi (taletrectinib) with strong and moderate CYP3A inhibitors should be avoided. Taletrectinib is a CYP3A substrate. Concomitant use of taletrectinib with a strong or moderate CYP3A inhibitor increases taletrectinib exposure, which may increase the risk of taletrectinib adverse reactions.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Ibtrozi Prescribing Information, June 2025, Nuvation Bio Inc.

32. Taletrectinib / Moderate & Strong CYP3A Inducers
Alert Message: The current use of Ibtrozi (taletrectinib) with strong and moderate CYP3A inducers should be avoided. Taletrectinib is a CYP3A substrate. Concomitant use of taletrectinib with a strong or moderate CYP3A inducer decreases taletrectinib exposure, which may reduce taletrectinib efficacy.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Ibtrozi Prescribing Information, June 2025, Nuvation Bio Inc.

33. Taletrectinib / QTc Prolongation Drugs
Alert Message: Ibtrozi (taletrectinib) can cause QTc interval prolongation, which can increase the risk for ventricular tachyarrhythmias or sudden death. Avoid the concurrent use of taletrectinib with other drugs with a known potential to prolong the QTc interval. If concomitant use cannot be avoided, increase the frequency of monitoring as recommended.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Ibtrozi Prescribing Information, June 2025, Nuvation Bio Inc.

34. Taletrectinib / Gastric Acid Reducing Agents
Alert Message: Ibtrozi (taletrectinib) oral absorption is pH dependent, and concurrent use with proton pump inhibitors (PPIs) or H2 receptor antagonists (H2RAs) should be avoided. Concomitant use of a PPI or H2RA with taletrectinib may decrease taletrectinib exposure, which may decrease taletrectinib efficacy. Locally acting antacids may be used as long as administration of the antacids is taken at least 2 hours before or 2 hours after taking taletrectinib.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Ibtrozi Prescribing Information, June 2025, Nuvation Bio Inc.

35. Taletrectinib / Antacids
Alert Message: Ibtrozi (taletrectinib) oral absorption is pH dependent, and concurrent use with an antacid may decrease taletrectinib exposure, potentially reducing taletrectinib effectiveness.If antacid

use is clinically warranted, administer the antacid at least 2 hours before or 2 hours after taking taletrectinib.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Ibtrozi Prescribing Information, June 2025, Nuvation Bio Inc.

36. Taletrectinib / Pregnancy / Pregnancy Negating
Alert Message: Based on literature reports in humans with congenital mutations leading to changes in TRK signaling, findings from animal studies, and its mechanism of action, Ibtrozi (taletrectinib) 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 animal reproduction studies, oral administration of taletrectinib to pregnant animals during the period of organogenesis resulted in embryo-fetal mortalities and structural fetal malformations at exposures below or equal to human exposure.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Ibtrozi Prescribing Information, June 2025, Nuvation Bio Inc.

37. Taletrectinib / Lactation
Alert Message: There are no data on the presence of Ibtrozi (taletrectinib) or its metabolites in human milk or their effects on the breastfed infant or milk production. Because of the potential for serious adverse reactions in breastfed infants, advise women not to breastfeed during treatment with taletrectinib and for 3 weeks after the final dose.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Ibtrozi Prescribing Information, June 2025, Nuvation Bio Inc.

38. Taletrectinib / Therapeutic Appropriateness
Alert Message: Advise females of reproductive potential to use effective contraception during treatment with Ibtrozi (taletrectinib) and for 3 weeks after the last dose. Taletrectinib can cause fetal harm when administered to a pregnant woman.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Ibtrozi Prescribing Information, June 2025, Nuvation Bio Inc.

39. Taletrectinib / Therapeutic Appropriateness
Alert Message: Advise male patients with female partners of reproductive potential to use effective contraception during treatment with Ibtrozi (taletrectinib) and for 3 weeks after the last dose.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Ibtrozi Prescribing Information, June 2025, Nuvation Bio Inc.

40. Taletrectinib / FDA Approved Indications

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for Ibtrozi (taletrectinib). Taletrectinib is indicated for the treatment of adult patients with locally advanced or metastatic ROSI-positive non-small cell lung cancer (NSCLC). The long-term safety and efficacy of this agent in the treatment of disease states other than the FDA-approved indications are unknown.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Ibtrozi Prescribing Information, June 2025, Nuvation Bio Inc.
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

41. Taletrectinib / Non-adherence
Alert Message: Based on refill history, your patient may be under-utilizing Ibtrozi (taletrectinib). 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.

42. Apremilast XR / Overuse
Alert Message: The manufacturer’s recommended maximum daily maintenance dose of Otezla XR (apremilast extended-release) in adults (after a 5-day titration schedule) is 75 mg. Titration is intended to reduce the gastrointestinal symptoms associated with initial therapy.

References:
Otezla/Otezla XR Prescribing Information, Dec. 2025, Amgen Inc.
Clinical Pharmacology, 2026 Elsevier/Gold Standard.

43. Apremilast XR / Therapeutic Appropriateness
Alert Message: The safety and effectiveness of Otezla XR (apremilast extended-release) have not been established in pediatric patients below the age of 6 years or weighing less than 50 kg with moderate to severe plaque psoriasis or psoriatic arthritis.

References:
Otezla/Otezla XR Prescribing Information, Dec. 2025, Amgen Inc.
Clinical Pharmacology, 2026 Elsevier/Gold Standard.

44. Apremilast XR / Severe Renal Impairment - Adult

Alert Message: Otezla XR (apremilast extended-release) use is not recommended in adult patients with severe renal impairment (CrCl < 30 mL/min estimated by Cockcroft-Gault equation). In a pharmacokinetic study, the administration of apremilast 30 mg in patients with severe renal impairment resulted in an increase in the AUC and Cmax of approximately 88% and 42%, respectively.

References:
Otezla/Otezla XR Prescribing Information, Dec. 2025, Amgen Inc.
Clinical Pharmacology, 2026 Elsevier/Gold Standard.

45. Apremilast XR / Severe Renal Impairment - Pediatric
Alert Message: Otezla XR (apremilast extended-release) use is not recommended in pediatric patients with severe renal impairment (CrCl < 30 mL/min estimated by Cockcroft-Gault equation). In a pharmacokinetic study, the administration of apremilast 30 mg in patients with severe renal impairment resulted in an increase in the AUC and Cmax of approximately 88% and 42%, respectively.

References:
Otezla/Otezla XR Prescribing Information, Dec. 2025, Amgen Inc.
Clinical Pharmacology, 2026 Elsevier/Gold Standard.

46. Apremilast XR / Therapeutic Appropriateness
Alert Message: The safety and effectiveness of Otezla XR (apremilast extended release) have not been established in pediatric patients with oral ulcers associated with Behcet's Disease.

References:
Otezla/Otezla XR Prescribing Information, Dec. 2025, Amgen Inc.
Clinical Pharmacology, 2026 Elsevier/Gold Standard.

47. Imlunestrant / Overuse
Alert Message: Inluriyo (imlunestrant) may be over-utilized. The maximum recommended dose of imlunestrant is 400 mg once daily.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Inluriyo Prescribing Information, Sept. 2025, Eli Lilly and Company.

48. Imlunestrant / Therapeutic Appropriateness
Alert Message: The safety and efficacy of Inluriyo (imlunestrant) in pediatric patients have not been established.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Inluriyo Prescribing Information, Sept. 2025, Eli Lilly and Company.

49. Imlunestrant / Overuse – Hepatic Impairment
Alert Message: Inluriyo (imlunestrant) may be over-utilized. The recommended maintenance dose of imlunestrant in patients with moderate (Child-Pugh B) or severe (Child-Pugh C) hepatic impairment is

200 mg once daily. No dosage modification is recommended for patients with mild hepatic impairment (Child-Pugh A).

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Inluriyo Prescribing Information, Sept. 2025, Eli Lilly and Company.

50. Imlunestrant / Sensitive P-gp or BCRP Substrates

Alert Message: Avoid the use of Inluriyo (imlunestrant) with sensitive substrates of P-gp and BCRP transport. Imlunestrant is an inhibitor of both P-gp and BCRP transport, and concomitant use with a sensitive P-gp or BCRP substrate may increase substrate exposure and the risk of substrate-related adverse reactions.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Inluriyo Prescribing Information, Sept. 2025, Eli Lilly and Company.

51. Imlunestrant / Strong CYP3A4 Inhibitors
Alert Message: The concurrent use of Inluriyo (imlunestrant) with strong CYP3A4 inhibitors should be avoided. Imlunestrant is a CYP3A4 substrate, and concomitant use with a strong CYP3A4 inhibitor may increase imlunestrant exposure, increasing the risk of imlunestrant-associated adverse reactions. If concomitant use cannot be avoided, decrease the imlunestrant dosage to 200 mg once daily.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Inluriyo Prescribing Information, Sept. 2025, Eli Lilly and Company.

52. Imlunestrant / Strong CYP3A4 Inducers
Alert Message: The concurrent use of Inluriyo (imlunestrant) with strong CYP3A4 inducers should be avoided. Imlunestrant is a CYP3A4 substrate, and concomitant use with a strong CYP3A4 inducer may decrease imlunestrant exposure. If concomitant use cannot be avoided, increase the imlunestrant dosage to 600 mg once daily.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Inluriyo Prescribing Information, Sept. 2025, Eli Lilly and Company.

53. Imlunestrant / Pregnancy / Pregnancy Negating
Alert Message: Based on findings in animals and its mechanism of action, Inluriyo (imlunestrant) can cause fetal harm when administered to a pregnant woman. In an animal reproduction study, oral administration of imlunestrant to pregnant rats during the period of organogenesis led to embryo-fetal mortality and structural abnormalities at maternal exposures that were below the human exposure at the recommended dose, based on AUC.

References:

Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Inluriyo Prescribing Information, Sept. 2025, Eli Lilly and Company.

54. Imlunestrant / Lactation
Alert Message: There is no data on the presence of Inluriyo (imlunestrant) or its metabolites in human milk, its effects on the breastfed child, or on milk production. Because of the potential for serious reactions in the breastfed child, advise lactating women not to breastfeed during treatment with imlunestrant and for 1 week after the last dose.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Inluriyo Prescribing Information, Sept. 2025, Eli Lilly and Company.

55. Imlunestrant / Therapeutic Appropriateness
Alert Message: Advise females of reproductive potential to use effective contraception during treatment with Inluriyo (imlunestrant) and for 1 week after the final imlunestrant dose. Imlunestrant can cause fetal harm.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Inluriyo Prescribing Information, Sept. 2025, Eli Lilly and Company.

56. Imlunestrant / Therapeutic Appropriateness
Alert Message: Advise male patients receiving Inluriyo (imlunestrant) with female partners of reproductive potential to use effective contraception during treatment with Inluriyo (imlunestrant) and for 1 week after the final imlunestrant dose. Imlunestrant can cause fetal harm.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Inluriyo Prescribing Information, Sept. 2025, Eli Lilly and Company.

57. Imlunestrant / Non-adherence
Alert Message: Based on refill history, your patient may be under-utilizing Inluriyo (imlunestrant). 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.

58. Dextromethorphan/Bupropion / Overuse

Alert Message: Auvelity (dextromethorphan/bupropion) may be over-utilized. The maximum recommended dosage of dextromethorphan/bupropion, starting on Day 15 of the dose titration schedule, for the treatment of agitation associated with dementia due to Alzheimer's disease is one 45 mg/105 mg tablet twice daily (total 90 mg/210 mg daily), given at least 8 hours apart. Do not exceed two doses within the same day.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Auvelity Prescribing Information, April 2026, Axsome Therapeutics, Inc.

59. Elinzanetant / Overuse
Alert Message: Lynkuet (elinzanetant) may be over-utilized. The recommended dosage of elinzanetant is 120 mg (two 60 mg capsules) orally once daily at bedtime.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Lynkuet Prescribing Information, Oct. 2025, Bayer HealthCare Pharmaceuticals.

60. Elinzanetant / Therapeutic Appropriateness
Alert Message: The safety and efficacy of Lynkuet (elinzanetant) in pediatric patients have not been established.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Lynkuet Prescribing Information, Oct. 2025, Bayer HealthCare Pharmaceuticals.

61. Elinzanetant / Pregnancy / Pregnancy Negating - Contraindication
Alert Message: Lynkuet (elinzanetant) is contraindicated in pregnancy. If pregnancy occurs during the use of elinzanetant, discontinue treatment. Exposure to elinzanetant may cause pregnancy loss or stillbirth when administered during pregnancy.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Lynkuet Prescribing Information, Oct. 2025, Bayer HealthCare Pharmaceuticals.

62. Elinzanetant / End Stage Renal Disease
Alert Message: The use of Lynkuet (elinzanetant) is not recommended in patients with end-stage renal disease (with or without hemodialysis). Elinzanetant has not been studied in this patient population.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Lynkuet Prescribing Information, Oct. 2025, Bayer HealthCare Pharmaceuticals.

63. Elinzanetant / Moderate & Severe Hepatic Impairment

Alert Message: The use of Lynkuet (elinzanetant) is not recommended in patients with moderate or severe hepatic impairment (Child-Pugh B & C). In a pharmacokinetic study, patients with moderate hepatic impairment (Child-Pugh B) who received elinzanetant experienced a 2.3-fold increase in the elinzanetant Cmax and AUC(0-24). Elinzanetant has not been studied in this patient with severe hepatic impairment.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Lynkuet Prescribing Information, Oct. 2025, Bayer HealthCare Pharmaceuticals.

64. Elinzanetant / Hepatic Transaminase Elevations
Alert Message: The use of Lynkuet (elinzanetant) can cause elevations in serum transaminase (ALT and AST) concentrations. Baseline blood work should be performed prior to initiation of therapy to determine if the patient can safely take elinzanetant. Advise patients to discontinue elinzanetant immediately and seek medical attention, including hepatic laboratory testing, if they experience signs and symptoms suggesting liver injury (new-onset fatigue, decreased appetite, nausea, vomiting, pruritus, jaundice, pale feces, dark urine, or abdominal pain).

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Lynkuet Prescribing Information, Oct. 2025, Bayer HealthCare Pharmaceuticals.

65. Elinzanetant / CNS Depressant Effects
Alert Message: The use of Lynkuet (elinzanetant) can cause CNS depressant effects and daytime impairment. Inform patients about the potential for somnolence and other nervous system effects. Advise patients who experience these effects to refrain from driving or engaging in hazardous activities until the effects have been resolved.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Lynkuet Prescribing Information, Oct. 2025, Bayer HealthCare Pharmaceuticals.

66. Elinzanetant / Seizures
Alert Message: Lynkuet (elinzanetant) should be used with caution in patients with a history of seizures or conditions that potentially lower the seizure threshold. Seizure was reported in one patient with a history of seizures in the clinical trials. In addition, convulsions were observed in studies conducted on male and female rats.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Lynkuet Prescribing Information, Oct. 2025, Bayer HealthCare Pharmaceuticals.

67. Elinzanetant / Strong CYP3A4 Inhibitors
Alert Message: The concurrent use of Lynkuet (elinzanetant) with a strong CYP3A4 inhibitor should be avoided. Elinzanetant is a CYP3A4 substrate, and co-administration with a strong CYP3A4 inhibitor may result in elevated elinzanetant exposure, which may increase the risk of elinzanetant-associated adverse reactions.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Lynkuet Prescribing Information, Oct. 2025, Bayer HealthCare Pharmaceuticals.

68. Elinzanetant / Moderate CYP3A4 Inhibitors
Alert Message: The concurrent use of Lynkuet (elinzanetant), a CYP3A4 substrate, and a moderate CYP3A4 inhibitor may result in elevated elinzanetant exposure, which may increase the risk of elinzanetant-associated adverse reactions. If co-administration use cannot be avoided, reduce the dose of elinzanetant to 60 mg once daily at bedtime. After discontinuation of the moderate CYP3A4 inhibitor, wait 3 to 5 half-lives and return to the usual dosage of elinzanetant (120 mg once daily).

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Lynkuet Prescribing Information, Oct. 2025, Bayer HealthCare Pharmaceuticals.

69. Elinzanetant / Strong & Moderate CYP3A4 Inducers
Alert Message: The concurrent use of Lynkuet (elinzanetant) with a moderate or strong CYP3A4 inducer should be avoided. Elinzanetant is a CYP3A4 substrate, and coadministration with a moderate or strong CYP3A4 inducer may decrease elinzanetant exposure, which may reduce elinzanetant effectiveness.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Lynkuet Prescribing Information, Oct. 2025, Bayer HealthCare Pharmaceuticals.

70. Elinzanetant / Sensitive CYP3A4 Substrates
Alert Message: Avoid the concurrent use of Lynkuet (elinzanetant) and a drug that is a CYP3A4 substrate, where minimal concentration changes may lead to serious substrate-related adverse reactions. Elinzanetant is a weak CYP3A4 inhibitor, and concurrent use with a CYP3A4 substrate with a narrow therapeutic index may result in increased substrate concentrations.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Lynkuet Prescribing Information, Oct. 2025, Bayer HealthCare Pharmaceuticals.

71. Elinzanetant / Lactation
Alert Message: There are no data on the presence of Lynkuet (elinzanetant) or its active metabolites in human milk, effects on the breastfed child, or the effects on milk production. Elinzanetant is present in animal milk. When a drug is present in animal milk, it is likely that the drug will be present in human milk.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Lynkuet Prescribing Information, Oct. 2025, Bayer HealthCare Pharmaceuticals.

72. Elinzanetant / Therapeutic Appropriateness

Alert Message: Advise females of reproductive potential to use effective contraception during treatment and for 2 weeks after stopping Lynkuet (elinzanetant). Elinzanetant can cause pregnancy loss or stillbirth.

References:
Clinical Pharmacology, 2026 Elsevier/Gold Standard.
Facts & Comparisons, 2026 Updates, Wolters Kluwer Health.
Lynkuet Prescribing Information, Oct. 2025, Bayer HealthCare Pharmaceuticals.

73. Elinzanetant / Non-adherence
Alert Message: Based on refill history, your patient may be under-utilizing Lynkuet (elinzanetant). 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 F. The Unmet Challenge of Medication Nonadherence. Perm Jrnl. 2018;22:18-033. doi:10.7812/TPP/18-033.

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?