North Dakota Medicaid
Drug Utilization Review Board Meeting
March 4, 2026
Conference Room 210/212

NORTH Dakota | Health & Human Services
Be Legendary.

NORTH Dakota | Health & Human Services
Be Legendary.

Meeting Notice

North Dakota Medicaid Drug Use Review Board

Wednesday, March 4, 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 virtually: Click here to join the meeting
Join by phone: 701-328-0950, Conference ID 285 859 251 492 31

Agenda

1. Call to Order
2. Roll Call
3. Review and Approval of Minutes
4. Reports from Department
    - Administrative Report: Core Measures, Cost of Dispensing Survey, Website Overview
    - Financial Report: Top Drugs
    - Retrospective DUR Report
    - Clinical Report:
        - Prior Authorization and Criteria Updates: Anemia, Chronic Kidney Disease (IgA Nephropathy, C3 Glomerulopathy, Diabetic Kidney Disease), Cluster Headache, Heart Failure, Interstitial Lung Disease, Juvenile Idiopathic Arthritis, Myasthenia Gravis
5. New business
    - Second Reviews of Alzheimer's Disease, Non-Cystic Fibrosis Bronchiectasis, and Phenylketonuria
    - First Reviews of Acromegaly, Calcium Channel Blockers, Graft vs Host Disease, and Malaria
    - Review Antipsychotic Prescribing Patterns
    - Review of Retrospective DUR Criteria Recommendations
    - Provider suggestions for clinical practice education or RDUR ICER criteria
6. Announcements: Next Meeting (June 3, 2026)
7. Adjourn

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

Meeting Minutes

North Dakota Medicaid Drug Use Review (DUR) Board
Meeting Date: December 3rd, 2025
Time and Location: 1:00 pm CST in Bismarck, North Dakota

Call to Order:
A regular quarterly meeting of the North Dakota Medicaid Drug Use Review (DUR) Board meeting was convened at 1:01 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, Andrea Honeyman, Laura Kroetsch, Kevin Martian, Paige Adkins, Kristen Peterson, Jessica Ziegler, Matthew Zimny
Absent: Amy Werremeyer, Kurt Datz
Quorum Present: Yes

Board Members Non-Voting:
Absent: Kathleen Traylor

Medicaid Pharmacy Department:
Present: Brendan Joyce, Alexi Murphy, LeNeika Roerich, Katie Steig
Absent: Jeff Hostetter
Approval of Meeting Minutes:
Motion: Moved by K. Martian to approve the minutes of the September 3, 2025 meeting, motion was seconded by A. Dahl **Motion carried.**
The minutes of the September 3, 2025, meeting were approved as distributed.

Reports:
Administrative Report: A. Murphy

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

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

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

Clinical Report and Annual PDL Review: Prior Authorization and Criteria Updates by J. McKee
J. McKee presented prior authorization and criteria updates with emphasis on the following sections in the PDL: Chronic Kidney Disease, Epidermolysis Bullosa, Heart Failure, Hemophilia, and Pulmonary Hypertension.

Unfinished business:
RDUR DDI Update presented to the board by J. McKee.

New business:

Second Reviews presented by J. McKee
J. McKee presented group prior authorization criteria for ANCA-Associated Vasculitis
Motion: Moved by K. Martian to place ANCA-Associated Vasculitis on prior authorization, motion was seconded by K. Peterson. **Motion carried.**

J. McKee presented group prior authorization criteria for Niemann-Pick Type C
Motion: Moved by K. Peterson to place Niemann-Pick Type C on prior authorization, motion was seconded by K. Martian. **Motion carried.**

First Reviews presented by J. McKee
J. McKee presented an overview of non-cystic fibrosis bronchiectasis. The presented material can be found in the handout.
Motion: Moved by K. Martian to draft prior authorization for non-cystic fibrosis bronchiectasis, motion was seconded by L. Kroestch. **Motion carried.**

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

First Reviews presented by J. McKee
J. McKee presented an overview of Alzheimer's Disease. The presented material can be found in the handout.
Motion: Moved by K. Martian to draft prior authorization for Alzheimer's Disease, motion was seconded by S. Antony. **Motion carried.**

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

Announcements:
Next meeting is March 4, 2026.

Adjournment:
Meeting adjourned by K. Martian at 2:37 pm CST.

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

Core Measures

Antibiotic Related Measures

Measure AAB-AD: Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis: Age 18 or Older

Percentage of episodes for beneficiaries age 18 and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.

Measure AAB-CH: Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis: Ages 3 Months to 17 Years

Percentage of episodes for beneficiaries ages 3 months to 17 years with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.

Substance Use Related Measures

Measure COB-AD: Concurrent Use of Opioids and Benzodiazepine

Percentage of beneficiaries age 18 and older with concurrent use of prescription opioids and benzodiazepines. Beneficiaries with a cancer diagnosis, receiving treatment for cancer-related pain, sickle cell disease diagnosis, or in hospice or palliative care are excluded.

Measure IET-AD: Initiation and Engagement of Substance Use Disorder Treatment

Percentage of new substance use disorder (SUD) episodes that result in treatment initiation and engagement. Two rates are reported:

• Initiation of SUD Treatment. The percentage of new SUD episodes that result in treatment initiation through an inpatient SUD admission, outpatient visit, intensive outpatient encounter, partial hospitalization, telehealth visit, or medication treatment within 14 days.

• Engagement of SUD Treatment. The percentage of new SUD episodes that have evidence of treatment engagement within 34 days of initiation

Measure OUD-AD: Use of Pharmacotherapy for Opioid Use Disorder

Percentage of Medicaid beneficiaries age 18 and older with an opioid use disorder (OUD) who filled a prescription for or were administered or dispensed an FDA-approved medication for the disorder during the measurement year. Five rates are reported:

• A total (overall) rate capturing any medications used in medication assisted treatment of opioid dependence and addiction (Rate 1).

• Four separate rates representing the following types of FDA-approved drug products: - Buprenorphine (Rate 2) - Oral naltrexone (Rate 3) - Long-acting, injectable naltrexone (Rate 4) - Methadone (Rate 5)

Psychotropic Related Measures

Measure SAA-AD: Adherence to Antipsychotic Medications for Individuals with Schizophrenia

Percentage of beneficiaries age 18 and older during the measurement year with schizophrenia or schizoaffective disorder who were dispensed and remained on an antipsychotic medication for at least 80 percent of their treatment period.

Measure SSD-AD: Diabetes Screening For People with Schizophrenia or Bipolar Disorder Who Are Using Antipsychotic Medications

Percentage of beneficiaries ages 18 to 64 with schizophrenia, schizoaffective disorder, or bipolar disorder, who were dispensed an antipsychotic medication and had a diabetes screening test during the measurement year.

Measure APM-CH: Metabolic Monitoring for Children and Adolescents on Antipsychotics

The percentage of children and adolescents ages 1 to 17 years who had two or more antipsychotic prescriptions and had metabolic testing. Three rates are reported:

• The percentage of children and adolescents on antipsychotics who received blood glucose testing.

• The percentage of children and adolescents on antipsychotics who received cholesterol testing.

• The percentage of children and adolescents on antipsychotics who received blood glucose and cholesterol testing

Measure APP-CH: Use of First-Line Psychosocial Care for Children and Adolescents on Antipsychotics

Percentage of children and adolescents ages 1 to 17 who had a new prescription for an antipsychotic medication and had documentation of psychosocial care as first-line treatment.

Measure ADD-CH: Follow-Up Care for Children Prescribed Attention Deficit/Hyperactivity Disorder (ADHD) Medication

The percentage of children newly prescribed attention deficit/hyperactivity disorder (ADHD) medication who had at least three follow-up care visits within a 300-day (10 month) period, one of which was within 30 days of when the first ADHD medication was dispensed. Two rates are reported.

• Initiation Phase. The percentage of children ages 6 to 12 with a prescription dispensed for ADHD medication, who had one follow-up visit with a practitioner with prescribing authority during the 30-day initiation phase.

• Continuation and Maintenance (C&M) Phase. The percentage of children ages 6 to 12 with a prescription dispensed for ADHD medication, who remained on the medication for at least 210 days and who, in addition to the visit in the initiation phase, had at least two follow-up visits with a practitioner within 270 days (9 months) after the initiation phase ended

Contraception Related Measures

Measure CCW-AD: Contraceptive Care – All Women Ages 21 to 44

Among women ages 21 to 44 at risk of unintended pregnancy, the percentage that:

1. Were provided a most effective or moderately effective method of contraception.

2. Were provided a long-acting reversible method of contraception (LARC).

Measure CCW-CH: Contraceptive Care – All Women Ages 15 to 20

Among women ages 15 to 20 at risk of unintended pregnancy, the percentage that:

1. Were provided a most effective or moderately effective method of contraception.

2. Were provided a long-acting reversible method of contraception (LARC)

Measure CCP-AD: Contraceptive Care – Postpartum Women Ages 21 to 44

Among women ages 21 to 44 who had a live birth, the percentage that:

1. Were provided a most effective or moderately effective method of contraception within 3 days of delivery and within 90 days of delivery.

2. Were provided a long-acting reversible method of contraception (LARC) within 3 days of delivery and within 90 days of delivery

Measure CCP-CH: Contraceptive Care – Postpartum Women Ages 15 to 20

Among women ages 15 to 20 who had a live birth, the percentage that:

1. Were provided a most effective or moderately effective method of contraception within 3 days of delivery and within 90 days of delivery.

2. Were provided a long-acting reversible method of contraception (LARC) within 3 days of delivery and within 90 days of delivery

Cost of Dispensing Survey

North Dakota Medicaid is conducting a pharmacy cost of dispensing survey. The survey results will be used to evaluate the professional dispensing fee in the North Dakota Medicaid pharmacy program.

North Dakota Medicaid has engaged Myers and Stauffer LC, a national Certified Public Accounting firm with extensive experience in government healthcare and pharmacy reimbursement issues, to perform the pharmacy cost of dispensing study.

The survey was mailed February 17, 2026. Pharmacies must return the completed survey(s) directly to Myers and Stauffer no later than March 31, 2026.

For more information: ND Medicaid Provider Portal | Myers & Stauffer

Website Overview

Pharmacy Program State Website

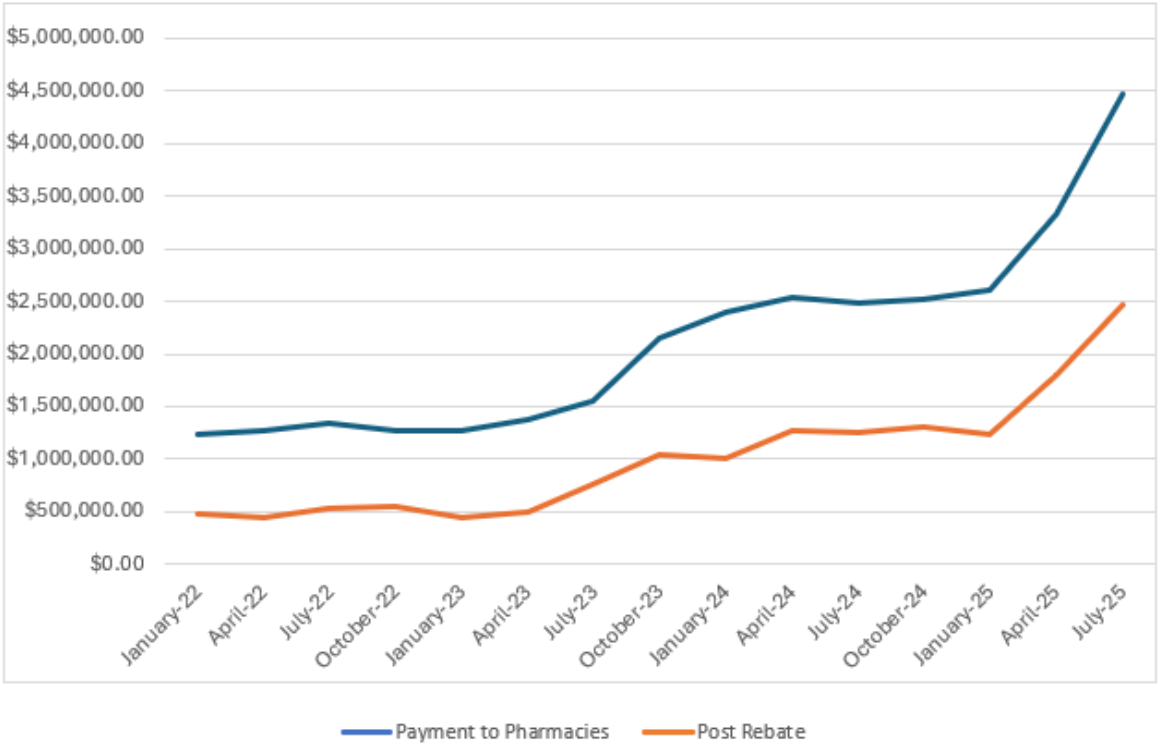
1. Payer Sheets
2. Naloxone Standing Order
3. ND Medicaid Drug Rebate Program Information
    a. Guide for Labelers
    b. Contact Information
    c. Drug Coverage Information
        i. New Labelers
        ii. Clinical Presentations
        iii. DUR Board Review Information and Public Comment
        iv. Supplemental Rebate
4. 340B Information
5. Other resources
    a. Pharmacy Provider Manual
    b. Procedure Code Look-Up

Drug Use Review State Website

1. Link to Acentra and Secretary of State Websites
2. DUR Board information
3. DUR Board procedures

Financial Report

Traditional Medicaid Cost Drivers



Traditional and Expansion

1. Increasing utilization
    - **Bimzelx, Dupixent** - Cytokine Modulators – Multiple Indications (see PDL)
    - **Liraglutide (due to brand shortage) -** Diabetes
2. Increasing utilization and increasing net cost
    - **Auvelity –** Depression
    - **Ingrezza -** Tardive Dyskinesia
    - **Vivitrol –** Substance Use Disorder

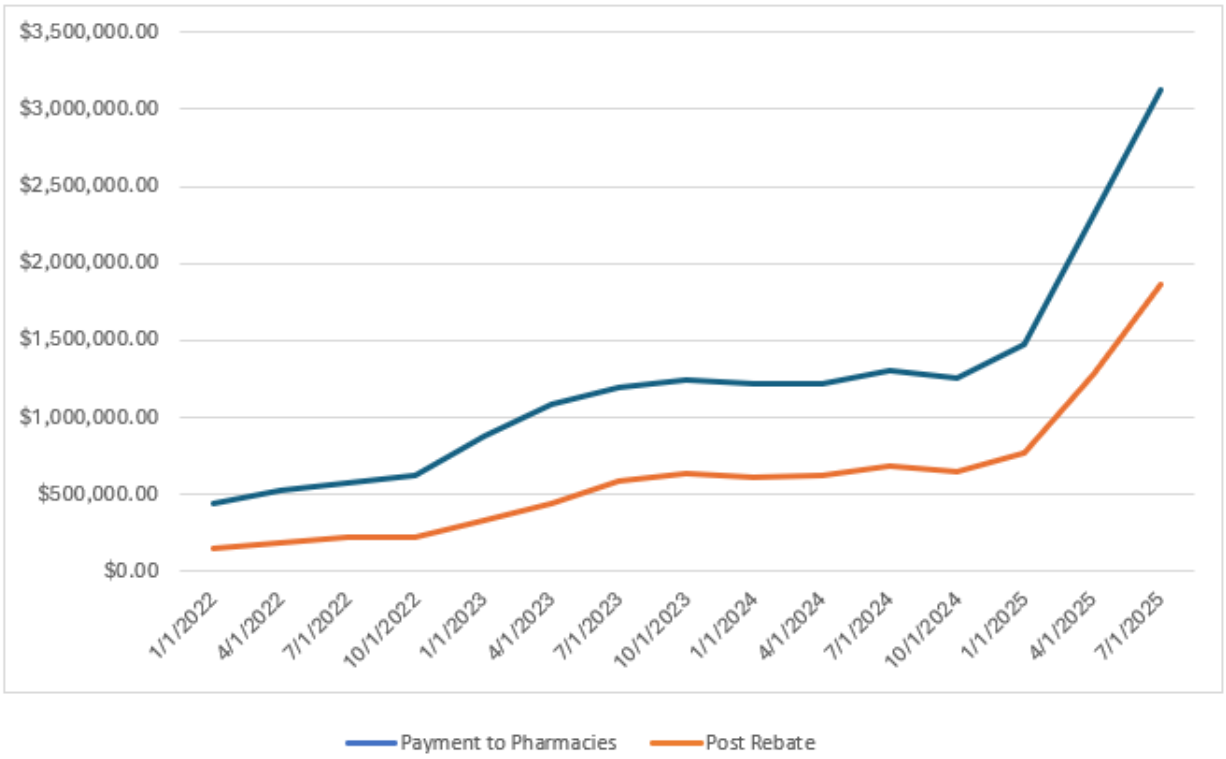
Traditional Only

1. Increasing utilization
    - **Crenessity -** Classic Congenital Adrenal Hyperplasia
    - **Fasenra, Xolair** – Cytokine Modulators – Multiple Indications (see PDL)
    - **Kesimpta –** Multiple Sclerosis
    - **Vraylar -** Antipsychotic
    - **Winrevair -** COPD
    - **Zurzuvae -** Postpartum Depression
2. Increasing utilization and increasing net cost

- **Cosentyx** – Cytokine Modulators – Multiple Indications (see PDL)
- **Daybue -** Rett Syndrome
- **Gattex –** Short Bowel Syndrome
- **Livmarli –** Cholestatic Pruritus
- **Lybalvi –** Antipsychotic (olanzapine + samidorphan)
- **Tyvaso DPI** – Pulmonary Hypertension
- **Valtoco** – Seizure Rescue

3. Loss of primary insurance payments
    - **Enbrel** – Cytokine Modulators – Multiple Indications (see PDL)
4. Increasing utilization and decreasing primary insurance payments
    - **Epidiolex –** Seizure Prevention
5. Increasing net cost and decreasing primary insurance payments
    - **Norditropin** – Growth Hormone
6. Increasing net cost, increasing utilization, decreasing primary insurance payments
    - **Trikafta –** Cystic Fibrosis

Expansion Medicaid Cost Drivers



Traditional and Expansion

1. Increasing utilization
    - **Bimzelx, Dupixent** - Cytokine Modulators – Multiple Indications (see PDL)
    - **Liraglutide (due to brand shortage) -** Diabetes
2. Increasing utilization and increasing net cost
    - **Auvelity –** Depression
    - **Ingrezza -** Tardive Dyskinesia
    - **Vivitrol –** Substance Use Disorder

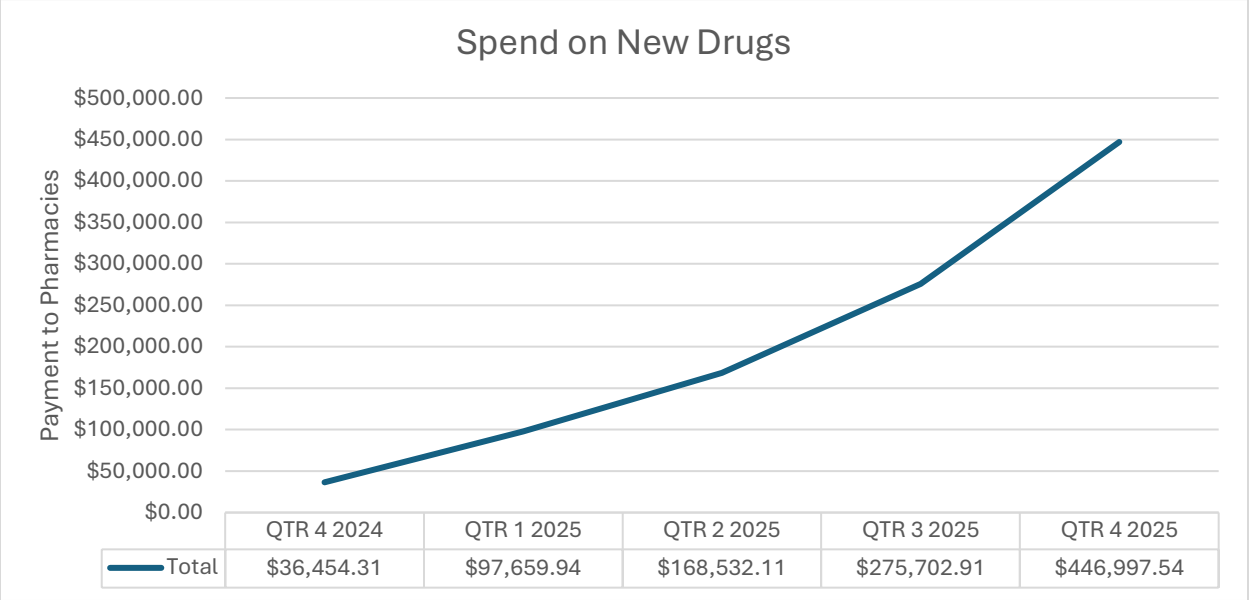
Expansion Only

1. Increasing net cost, increasing utilization, decreasing primary insurance payments
    - **Aimovig -** Migraine
    - **Vyvanse -** ADHD
2. Increasing net cost and increasing utilization
    - **Arnuity Ellipta (due to AMP cap removal of Flovent) -** Asthma
    - **Braftovi, Fruzaqla, Lonsurf, Nubeqa, Vanflyta -** Oncology
    - **Cresemba –** Invasive Aspergillosis
    - **Skyrizi –** Cytokine Modulators – Multiple Indications (see PDL)
3. Increased utilization
    - **Kisqali, Revuforj, Verzenio –** Oncology

- **Sivextro –** Acute Bacterial Skin and Skin Structure Infections
- **Qelbree -** ADHD
- **Sublocade –** Substance Use Disorder
- **Takhzyro –** Hereditary Angioedema

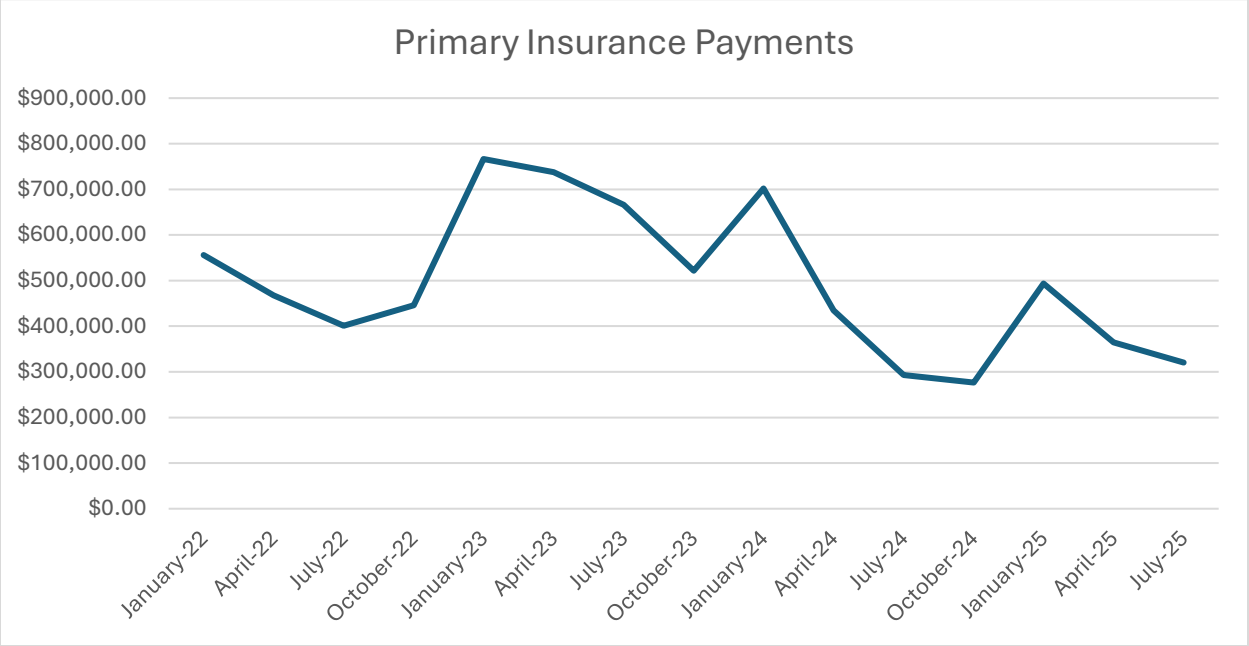
Spend on New Drugs

- **Livmarli -** Cholestatic Pruritus
- **Crenessity -** Classic Congenital Adrenal Hyperplasia
- **Ebglyss, Adbry –** Cytokine Modulators

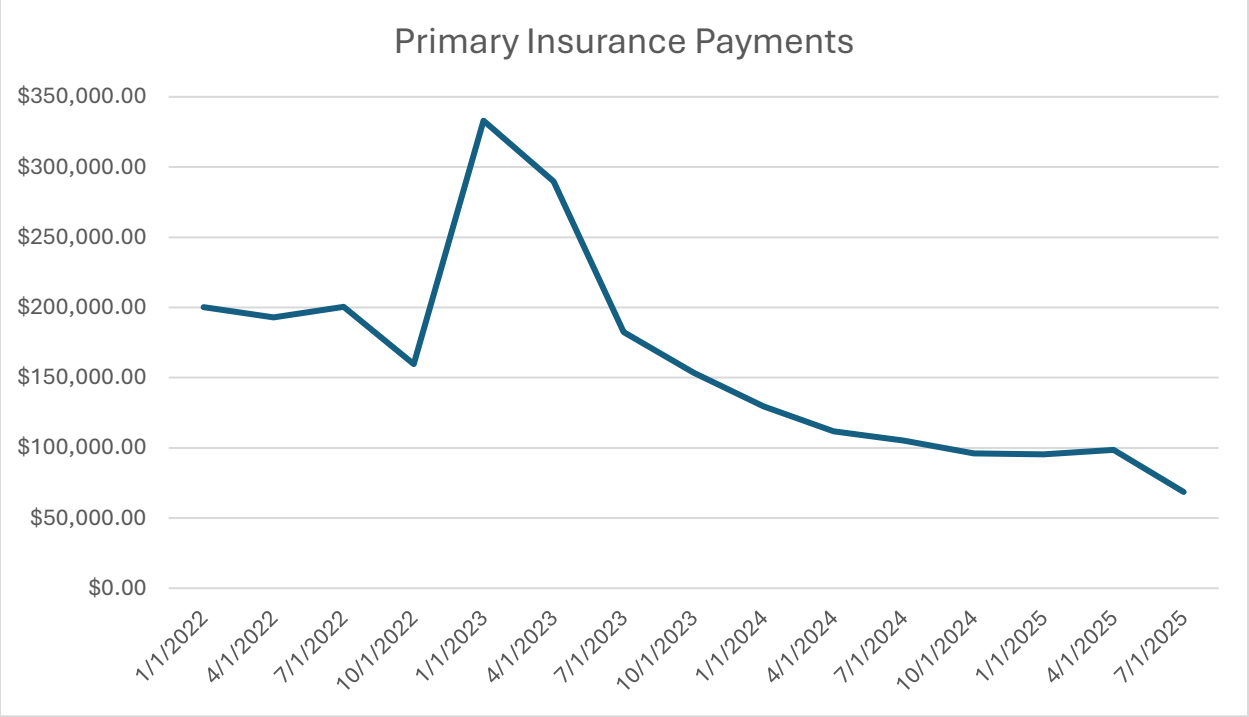


Decreasing Primary Insurance Payments

Traditional Medicaid

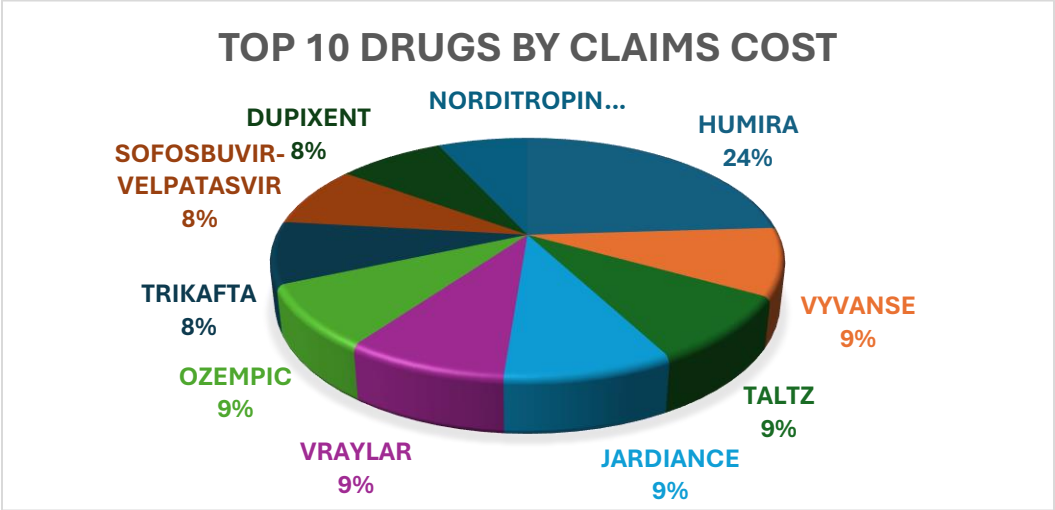


Expansion Medicaid



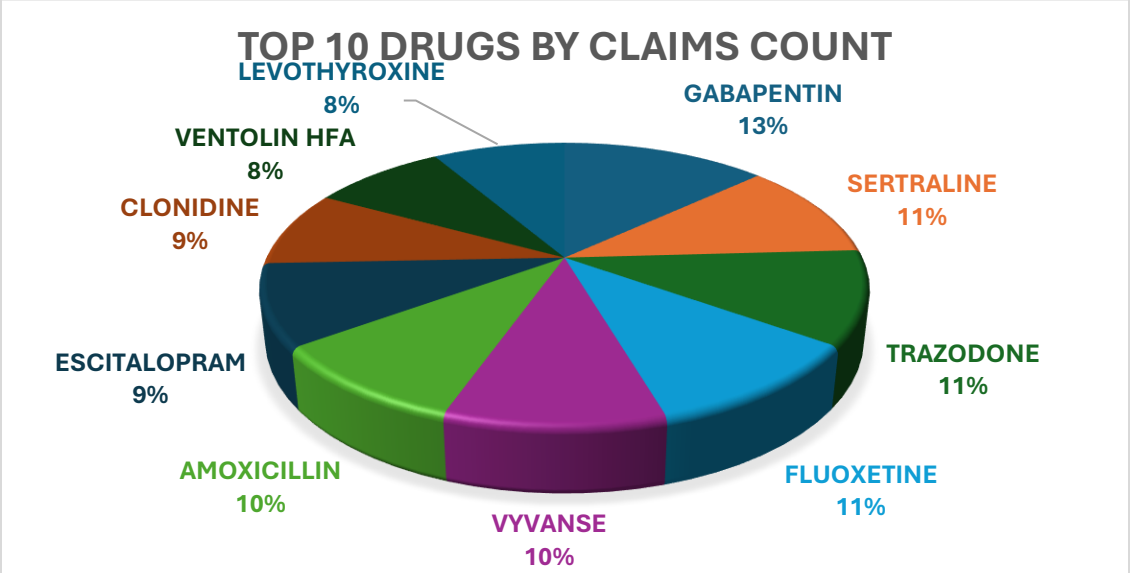
Top 25 Drugs Based on Total Claims Cost from 10/1/25 – 12/31/25

#	Drug Name	Claims	Claims Cost	Patients	Cost/Patient	% Cost	Dif
1	HUMIRA	291	$2,589,479.49	112	$23,120.35	6.76%	NC
2	VYVANSE	3253	$985,521.84	1328	$742.11	2.57%	↑2
3	TALTZ	128	$975,423.82	49	$19,906.61	2.55%	NC
4	JARDIANCE	1233	$972,805.90	674	$1,443.33	2.54%	↑1
5	VRAYLAR	841	$937,503.16	342	$2,741.24	2.45%	↑1
6	OZEMPIC	957	$914,288.39	540	$1,693.13	2.39%	↑19
7	TRIKAFTA	36	$906,687.98	12	$75,557.33	2.37%	↑1
8	SOFOSBUVIR-VELPATASVIR	39	$890,146.79	39	$22,824.28	2.32%	↓6
9	DUPIXENT	228	$871,293.65	105	$8,298.03	2.27%	↓2
10	NORDITROPIN FLEXPRO	98	$737,450.47	41	$17,986.60	1.92%	↓1
11	BIKTARVY	276	$608,116.60	135	$4,504.57	1.59%	↓1
12	COSENTYX	53	$560,549.04	22	$25,479.50	1.46%	NC
13	BIMZELX	30	$553,106.17	13	$42,546.63	1.44%	↑4
14	INVEGA SUSTENNA	188	$523,455.38	80	$6,543.19	1.37%	↓3
15	ELIQUIS	713	$466,099.25	348	$1,339.37	1.22%	↓1
16	INGREZZA	53	$441,028.92	21	$21,001.38	1.15%	↓3
17	SUBLOCADE	169	$358,822.73	84	$4,271.70	0.94%	↑1
18	ENBREL	41	$328,247.88	18	$18,235.99	0.86%	NC
19	ABILIFY MAINTENA	119	$315,174.86	50	$6,303.50	0.82%	↑2
20	DULERA	892	$290,656.37	582	$499.41	0.76%	↑3
21	CRENESSITY	7	$276,468.22	2	$138,234.11	0.72%	↑37
22	INSULIN LISPRO	1019	$255,331.89	630	$405.29	0.67%	NC
23	KESIMPTA PEN	26	$253,520.41	10	$25,352.04	0.66%	↑3
24	VIVITROL	155	$253,182.48	80	$3,164.78	0.66%	NC
25	XELJANZ	30	$245,643.78	12	$20,470.32	0.64%	↑2
Total							**$16,510,005.47**



Top 25 Drugs Based on Number of Claims from 10/1/25 – 12/31/25

#	Drug Name	Claims	Claims Cost	Patients	Cost/Claim	% Claims	Dif
1	GABAPENTIN	4,276	62,994.90	1,806	$14.73	1.76%	NC
2	SERTRALINE	3,571	48,390.60	2,022	$13.55	1.47%	NC
3	TRAZODONE	3,488	46,642.72	1,860	$13.37	1.43%	NC
4	FLUOXETINE	3,452	46,220.90	1,889	$13.39	1.42%	NC
5	VYVANSE	3,253	985,521.84	1,328	$302.96	1.34%	NC
6	AMOXICILLIN	3,117	50,633.22	2,935	$16.24	1.28%	↑9
7	ESCITALOPRAM	3,043	40,864.67	1,754	$13.43	1.25%	↓1
8	CLONIDINE	2,799	34,202.74	1,400	$12.22	1.15%	↑2
9	VENTOLIN HFA	2,790	181,865.40	2,759	$65.18	1.15%	↓2
10	LEVOTHYROXINE	2,755	39,164.36	1,501	$14.22	1.13%	↓1
11	OMEPRAZOLE	2,710	36,320.33	1,708	$13.40	1.11%	↓3
12	BUPROPION XL	2,699	45,306.04	1,498	$16.79	1.11%	↑1
13	HYDROXYZINE	2,677	37,405.66	1,607	$13.97	1.10%	NC
14	ATORVASTATIN	2,549	37,115.28	1,547	$14.56	1.05%	↓2
15	METHYLPHENIDATE ER	2,529	74,104.49	1,051	$29.30	1.04%	↑4
16	DEXTROAMPHETAMINE-AMPHET ER	2,490	72,253.79	1,071	$29.02	1.02%	↓2
17	PREDNISONE	2,483	28,643.18	1,974	$11.54	1.02%	NC
18	AMOXICILLIN-CLAVULANATE POTASS	2,428	41,740.43	2,249	$17.19	1.00%	↑10
19	LISINOPRIL	2,302	31,290.40	1,459	$13.59	0.95%	↓3
20	PANTOPRAZOLE	2,285	33,066.60	1,356	$14.47	0.94%	↓2
21	ONDANSETRON ODT	2,272	34,909.27	1,741	$15.36	0.93%	↑3
22	LAMOTRIGINE	2,253	30,989.41	931	$13.75	0.93%	↓2
23	BUSPIRONE	2,194	33,135.46	1,166	$15.10	0.90%	↓3
24	ARIPIPRAZOLE	2,160	32,102.87	1,092	$14.86	0.89%	↓3
25	HYDROCODONE-ACETAMINOPHEN	2,140	33,032.55	1,347	$15.44	0.88%	↓3
Total							**68,715**



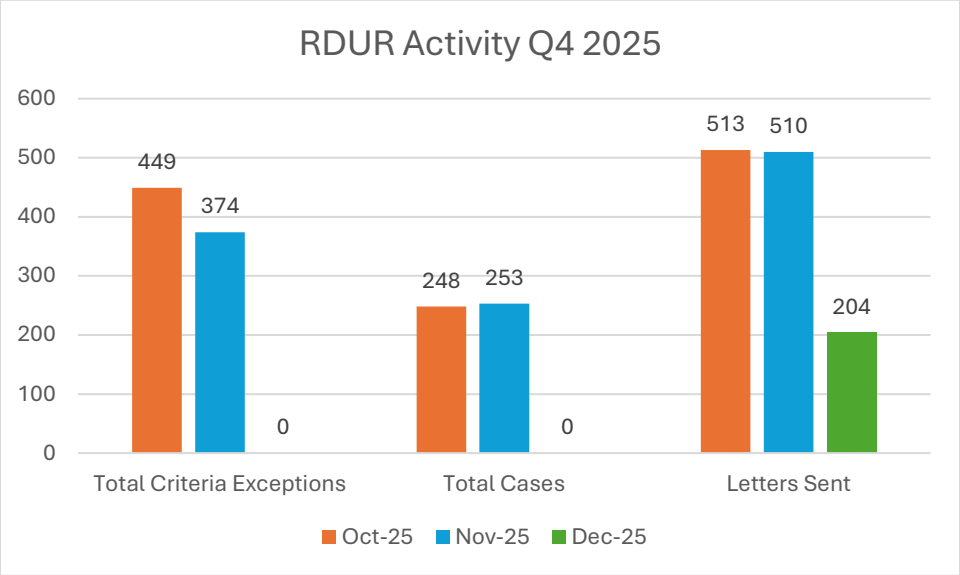
Top 15 Therapeutic Classes Based on Number of Claims from 10/1/25 – 12/31/25

#	Therapeutic Class Description	Claims	Claims Cost	Patients	Cost/Claim	% Claims	Dif
1	ANTIDEPRESSANTS	24,859	$612,679.39	10,603	$24.65	10.22%	NC
2	ANTIPSYCHOTIC AGENTS	9,712	$2,946,724.65	3,904	$303.41	3.99%	NC
3	AMPHETAMINES	7,343	$1,100,706.76	2,999	$149.90	3.02%	NC
4	RESPIRATORY AND CNS STIMULANTS	6,903	$339,842.18	2,652	$49.23	2.84%	↑1
5	GABA-MEDIATED ANTICONVULSANTS	6,662	$175,642.52	2,749	$26.36	2.74%	↓1
6	BETA AGONISTS	5,886	$778,108.32	4,084	$132.20	2.42%	↓1
7	PENICILLIN ANTIBIOTICS	5,775	$96,727.72	5,125	$16.75	2.37%	↑7
8	OPIOID AGONISTS	5,583	$104,256.43	2,876	$18.67	2.30%	↓1
9	CENTRAL ALPHA-AGONISTS	5,531	$77,107.74	2,490	$13.94	2.27%	↑1
10	NSAIDs	5,425	$74,191.12	3,667	$13.68	2.23%	↓1
11	PROTON-PUMP INHIBITORS	5,383	$98,672.81	3,223	$18.33	2.21%	↓3
12	ADRENALS	4,919	$168,994.56	3,635	$34.36	2.02%	↑3
13	ANTICONVULSANTS	4,888	$328,200.57	2,036	$67.14	2.01%	↑2
14	BETA-BLOCKERS	4,788	$81,851.92	2,755	$17.10	1.97%	↓1
15	STATINS	4,783	$68,915.20	2,897	$14.41	1.97%	↓3
Total							**108,440**

Top 15 Therapeutic Classes Based on Claims Cost from 10/1/25 to 12/31/25

#	Therapeutic Class Description	Claims	Claims Cost	Patients	Cost/Patient	% Cost	Dif
1	TUMOR NECROSIS FACTOR INHIBITORS	423	3,227,850.50	168	$19,213.40	8.42%	NC
2	ANTIPSYCHOTIC AGENTS	9712	2,946,724.65	3904	$754.80	7.69%	NC
3	ANTINEOPLASTIC AGENTS	581	1,737,806.39	245	$7,093.09	4.54%	NC
4	INTERLEUKIN-MEDIATED AGENTS	212	1,642,085.87	84	$19,548.64	4.29%	NC
5	INCRETIN MIMETICS	1966	$1,435,114.66	941	$1,525.10	3.75%	↑7
6	SGLT2 INHIB	1623	1,238,651.14	883	$1,402.78	3.23%	↓1
7	AMPHETAMINES	7343	1,100,706.76	2999	$367.02	2.87%	↓1
8	IMMUNOMODULATORY AGENTS	228	1,017,769.61	174	$5,849.25	2.66%	↑6
9	CFTR CORRECTORS	40	1,004,858.98	14	$71,775.64	2.62%	NC
10	ANTIRETROVIRALS	630	965,976.67	245	$3,942.76	2.52%	↓2
11	HCV ANTIVIRALS	42	906,037.43	41	$22,098.47	2.36%	↓5
12	SKIN AGENTS	240	871,642.36	116	$7,514.16	2.27%	↓3
13	BETA-ADRENERGIC AGONISTS	5886	778,108.32	4084	$190.53	2.03%	↓1
14	PITUITARY	332	754,675.75	144	$5,240.80	1.97%	↓4
15	ANTIDEPRESSANTS	24859	612,679.39	10603	$57.78	1.60%	↑1
Total							**$20,240,688.48**

RDUR Report: Q4 2025



October 2025 Cases by Type of Criteria		
Criteria Description	**# of Cases**	**% of Cases**
Drug Disease Precaution	152	61.29%
Drug-Drug Marker and/or Diagnosis	76	30.65%
Drug-Drug Interactions	9	3.63%
High Dose Alert	7	2.82%
Overutilization	4	1.61%

November 2025 Cases by Type of Criteria		
Criteria Description	**# of Cases**	**% of Cases**
Drug Disease Precaution	123	48.62%
Underutilization	76	30.04%
Drug-drug Interactions	24	9.49%
Therapeutic Appropriateness	20	7.91%
Drug-Drug Marker and/or Diagnosis	9	3.56%
High Dose Alert	1	0.40%

December 2025 Special Mailing

204 Letters Sent

Dear Prescriber,

SUBJECT: ND MEDICAID UPCOMING COVERAGE CHANGES

ND Medicaid will be changing the preferred agents for glucagon-like peptide 1 (GLP-1) agonists effective January 1, 2026.

- Liraglutide (generic) will become non-preferred status and require prior authorization (PA).
- Ozempic, Rybelsus, and Victoza (brand) remain preferred GLP-1 agonists and do not require PA. Victoza (brand) has market availability issues.
- Trulicity remains non-preferred status and requires PA.

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

Thank you for your professional consideration.

Sincerely,

ND Medicaid

Clinical Report

Prior Authorization Updates

Drug	PA Status	Class
amlodipine/atorvastatin	PA	Lipid-Lowering Therapy
Aqvesme	PA	Anemia
Belsomra	Remove PA	Sedative / Hypnotics
Betaseron	PA	Multiple Sclerosis
Cablivi	PA	Medications that cost > $3000
Cardura XL	PA	Benign Prostatic Hyperplasia
darifenacin ER	Remove PA	Genitourinary Smooth Muscle Relaxants
Daybue Stix	PA	Medications that cost > $3000
Divigel	Remove PA	Menopause
febuxostat	Remove PA	Uloric
formoterol	PA	COPD
Hulio	PA	Biosimilars
Jascayd	PA	Idiopathic Pulmonary Fibrosis
Javadin	PA	Non-Preferred Dosage Forms
Juluca	PA	Non-Preferred Dosage Forms
Jynarque	PA	Chronic Kidney Disease
Lanthanum chew tab	PA	Phosphate Binders
Menostar	PA	Menopause
Minivelle	PA	Menopause
Movantik	PA	Irritable Bowel Syndrome
Otezla XR	PA	Otezla
Premarin injection	Remove PA	Menopause
Pyzchiva	Remove PA	Biosimilars
Rebif	PA	Multiple Sclerosis
Silodosin	PA	Benign Prostatic Hyperplasia
Striverdi Respimat	PA	COPD
Suflave	PA	Bowel Preparation Agents
Sumatriptan Vial	PA	Migraine treatment
Suprep	PA	Bowel Preparation Agents
Trulance	PA	Irritable Bowel Syndrome
Tyruko	PA	Biosimilars
Voyxact	PA	Chronic Kidney Disease
Zycubo	PA	Medications that cost > $3000

Summary of Changes

Anemia

Aqvesme was added to the category for the treatment of alpha- and beta-thalassemia for those who are either transfusion dependent or non-transfusion dependent.

Disease-Modifying Agents

Pyruvate Kinase Activator

PA REQUIRED
AQVESME (mitapivat)

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 member must have a documented diagnosis of thalassemia (β-thalassemia with or without α-globin gene mutations, hemoglobin E (HbE)/β-thalassemia, or α-thalassemia/hemoglobin H (HbH) disease) based on Hb electrophoresis, Hb high-performance liquid chromatography (HPLC), and/or deoxyribonucleic acid (DNA) analysis
- The requested medication must be prescribed by, or in consult with, a hematologist or oncologist, or prescriber specializing in the treatment of thalassemia
- The member must not have a diagnosis of cirrhosis (Child Pugh Class A, B, or C)
- The member has transfusion-dependent thalassemia, defined as 6 to 20 red blood cell (RBC) units transfused over a 24-week period
- The member has non-transfusion-dependent thalassemia, defined as ≤ 5 red blood cell units over a 24-week period and an average baseline Hb concentration ≤10.0 g/dL

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced stabilization, slowing of disease progression, or improvement of the condition since starting treatment with the requested medication including:
  - For transfusion-dependent thalassemia, a reduction in transfusion requirements from pretreatment baseline achieving one of the following:
    - At least 2 units packed red blood cells in any consecutive 12 weeks
    - By one-half from baseline
  - For non-transfusion-dependent thalassemia, both of the following:
    - An increase in average Hb level ≥ 1 g/dL
    - An attestation of decreased fatigue-related symptoms from baseline

Chronic Kidney Disease

Chronic Kidney Disease split into additional categories and step therapy added to trial cost-effective products first for the following: C3 glomerulopathy, diabetic kidney disease, and IgA nephropathy.

- Xphozah and tolvaptan criteria updated based on indication and tolvaptan additionally updated for markers of high risk of kidney progression.
- Ozempic added to diabetic kidney disease.
- IgA nephropathy criteria updated to require biopsy and levels of proteinuria and UPCR per diagnostic criteria and treatment goals in KDIGO guidelines. New product added for IgA Nephropathy.

Kappa-opioid agonist

PA REQUIRED
KORSUVA (difelikefalin) – *Medical Billing*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months (one time)

- The member must be on renal dialysis.
- Medicare eligibility must be ruled out (6-month approval may be allowed to determine eligibility).
- The member must have failed a 60-day trial of pregabalin or gabapentin in addition to an oral antihistamine, as evidenced by paid claims or pharmacy printouts

Vasopressin V2-receptor (V2R) Antagonist

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

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member has autosomal dominant polycystic kidney disease.
- The member must not be on renal dialysis or have a kidney transplant
- The requested medication must be prescribed by, or in consult with, a nephrologist.
- The member does not have liver disease.
- The member has eGFR ≥ 25
- The prescriber has provided clinical justification that the member is at high risk of kidney progression by submitting one of the following (subject to clinical review):
  - Autosomal dominant polycystic kidney disease mayo classes 1C, 1D, or 1E
  - Kidney length > 16.5 cm (by ultrasound, MRI, or CT scan) for patients aged < 50 years
  - An annual eGFR decline of at least 3 mL/min/1.73 m2 per year over a period of five years
  - Total kidney volume > 750 mL and age < 51
  - Prognostic Tools - PROPKD Score | ADPKDSim > 6

Sodium/Hydrogen Exchanger 3 (NHE3)

PA REQUIRED

XPHOZAH (tenapanor)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months (one time)

- The member must be on renal dialysis
- Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.
- The member must have failed 30-day trials of sevelamer carbonate and sucroferric oxyhydroxide, as evidenced by paid claims or pharmacy printouts.

References:

1. Stevens, Paul E., et al. "KDIGO 2024 Clinical practice guideline for the evaluation and management of chronic kidney disease." Kidney international 105.4 (2024): S117-S314.

C3 Glomerulopathy (C3G)

Therapeutic Duplication

- Medication classes not payable together:
  - Empaveli and Fabhalta are not allowed together

C3 Inhibitors

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

Factor B Inhibitors

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

Renin-Angiotensin-Aldosterone System (RAAS) Inhibitors

NO PA REQUIRED
ACE (angiotensin-converting enzyme) inhibitors – all oral agents preferred
ARBs (angiotensin receptor blockers) – all oral agents preferred

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- If member is on renal dialysis or post kidney transplant, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.
- The member must have eGFR ≥ 30.
- The member must be experiencing proteinuria > 1 g/day or UPCR ≥ 1 g/g despite a 3-month trial with good compliance with an ACE inhibitor or an ARB at the target or maximally tolerated dose, as evidenced by paid claims or pharmacy printouts.

Empaveli Only:

- The member must have a diagnosis of native kidney or post-kidney transplant recurrent C3 glomerulopathy (C3G) or native kidney primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN)

*Fabhalt*a Only

- The member must also have failed a 6-month trial of Empaveli, as evidenced by paid claims or pharmacy printouts and proteinuria > 1 g/day or UPCR ≥ 1 g/g

Renewal Criteria – Approval Duration: 12 months (clinical justification required for treatment longer than 1.5 years such as relapse upon discontinuation – subject to clinical review)

- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.
- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by both of the following (A or B):
    A. A stable or improved eGFR
    B. a reduction of proteinuria or UPCR of 30% from baseline proteinuria <0.5 g/day or UPCR < 0.5 g/g or reduction of 30% from baseline

Diabetic Kidney Disease

GLP-1 receptor agonist

NO PA REQUIRED
OZEMPIC (semaglutide)

Non-steroidal selective mineralocorticoid receptor antagonist (MRA)

PA REQUIRED
KERENDIA (finerenone)

Renin-Angiotensin-Aldosterone System (RAAS) Inhibitors

NO PA REQUIRED
ACE (angiotensin-converting enzyme) inhibitors – all oral agents preferred
ARBs (angiotensin receptor blockers) – all oral agents preferred
TEKTURNA (aliskiren)

SGLT-2 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FARXIGA (dapagliflozin) – *Brand Required*	dapagliflozin
JARDIANCE (empagliflozin)	INVOKANA (canagliflozin)
	INVOKAMET (canagliflozin/metformin)

	INVOKAMET XR (canagliflozin/metformin)

SGLT-1/SGLT-2 Inhibitor

PA REQUIRED
INPEFA (sotagliflozin)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

Kerendia Only

- The member must have type 2 diabetes and chronic kidney disease.
- The member must be on the following at the target or maximally tolerated dose, as evidenced by paid claims or pharmacy printouts:
  - An ACE-inhibitor or an ARB
  - A SGLT-2 inhibitor
- The member has an estimated glomerular filtration rate (eGFR) ≥ 25 mL/min/1.73 m^2
- The member has one of the following (1 or 2) despite a 6-month trial with an ACE inhibitor or ARB in combination with a SGLT-2 inhibitor and a GLP1-agonist, as evidenced by paid claims or pharmacy printouts:
  1. urinary albumin-to-creatinine ratio (UACR) ≥ 30 mg/g (≥3 mg/mmol)
  2. albuminuria ≥ 300 mg/day

Inpefa Only:

- The requested medication must be prescribed by, or in consult with, a cardiologist or nephrologist.
- If member is on renal dialysis, Medicare eligibility must be ruled out. *(6-month approval allowed to determine eligibility)*
- The member has type 2 diabetes and chronic kidney disease.
- The member has a history of a cardiovascular event (e.g., heart failure, myocardial infarction, cerebrovascular event) or two or more risk factors (e.g., elevated cardiac and inflammatory biomarker, obesity, hyperlipidemia, hypertension)
- The member is receiving concurrent Entresto, a beta-blocker, a GLP-1 agonist, and a mineralocorticoid receptor antagonist.

Renewal Criteria – Approval Duration: 12 months

- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.

Kerendia Only:

- The member has experienced a stabilization in eGFR or one of the following:
  - albuminuria <0.3 g/day or reduction of 30% from baseline
  - UACR < 0.3 g/g or reduction of 30% from baseline

References:

1. de Boer, Ian H., et al. “Diabetes management in chronic kidney disease: a consensus report by the American Diabetes Association (ADA) and Kidney Disease: Improving Global Outcomes (KDIGO).” *Diabetes care* 45.12 (2022): 3075-3090.

IgA Nephropathy

Electronic Duration Verification:

- Tarpeyo is payable for 9 months every 3 years.

Therapeutic Duplication

- Medication classes not payable together:
  - Filspari, ACE Inhibitors, ARBs, and Renin Inhibitors are not allowed with each other.
  - Fabhalta Filspari, Vanrafia and Voyxact and are not allowed together

APRIL inhibitor

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
VOYXACT (sibeprenlimab-szsi)	

Dual endothelin angiotensin receptor antagonist

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

Endothelin receptor antagonist

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

Factor B Inhibitors

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

Renin-Angiotensin-Aldosterone System (RAAS) Inhibitors

NO PA REQUIRED
ACE (angiotensin-converting enzyme) inhibitors – all oral agents preferred
ARBs (angiotensin receptor blockers) – all oral agents preferred

SGLT-2 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FARXIGA (dapagliflozin) – *Brand Required*	dapagliflozin
JARDIANCE (empagliflozin)	INVOKANA (canagliflozin)
	INVOKAMET (canagliflozin/metformin)
	INVOKAMET XR (canagliflozin/metformin)

Systemic Corticosteroids

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
methylprednisolone	TARPEYO (budesonide-targeted release)
prednisone	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must have eGFR ≥ 30.
- The member must biopsy-proven IgA Nephropathy
- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.
- The member must be experiencing proteinuria > 0.5 g/day or UPCR ≥ 0.5 g/g despite a 3-month trial of a combination of (ACE inhibitor or an ARB + SGLT-2 inhibitor) with good compliance of the following at the target or maximally tolerated dose, as evidenced by paid claims or pharmacy printouts

*Fabhalt*a Only

- The member must also have failed a 6-month trial of Tarpeyo and mycophenolate mofetil (MMF), as evidenced by paid claims or pharmacy printouts and proteinuria > 0.5 g/day or UPCR ≥ 0.5 g/g

Vanrafia Only

- The member must also have failed a 6-month trial of Filspari, as evidenced by paid claims or pharmacy printouts and proteinuria > 0.5 g/day or UPCR ≥ 0.5 g/g

Renewal Criteria – Approval Duration: 12 months

- The member has experienced one of the following:
  - proteinuria <0.5 g/day or reduction of 30% from baseline
  - UPCR < 0.5 g/g or reduction of 30% from baseline

References:

1. Stevens, Paul E., et al. "KDIGO 2025 Clinical practice guideline for the management of Immunoglobulin A Nepropathy (igAN) and Immunogobulin A Vasculitis (IgAV)." Kidney International (2025) 108 (Suppl 4S), S1–S71

Cluster Headache

Cluster headache prevention criteria updated to reflect definition of cluster headache, symptoms, and to trial cost-effective treatment options first.

Cluster Headache Prevention

PA REQUIRED
EMGALITY (galcanazumab-gnlm)

- Emgality is to be used as preventative treatment during episodic cluster headache episodes (cluster periods usually last between 2 weeks and 3 months with pain-free periods lasting at least 3 months), as it is not indicated for chronic use

Prior Authorization Criteria

Prior Authorization Form – Migraine Prophylaxis/Treatment

Initial Criteria – Approval Duration: 3 months

- The member has had at least five attacks fulfilling criteria A-D
  - A. Severe or very severe unilateral orbital, supraorbital and/or temporal pain lasting at least 15 minutes
  - B. Occurring with a frequency of at least every other day
  - C. At least two cluster periods lasting longer than one month and separated by pain-free remission periods of at least three months.
  - D. The member must have at least one of the following:
    - A sense of restlessness or agitation
    - Any of the following symptoms or signs, ipsilateral to the headache:
      - Conjunctival injection and/or lacrimation
      - Nasal congestion and/or rhinorrhea
      - Eyelid edema
      - Forehead and facial swelling
      - Miosis and/or ptosis
- The member must have had 2-month trials with each of the following, as evidenced by paid claims or pharmacy printouts:
  - *A.* Topiramate
  - *B.* Verapamil

Heart Failure

Heart Failure criteria updated to more specifically and objectively define failure for each agent, align with FDA approved indications, and to maximize cost-effective treatment options first.

Solid Dosage Forms

First Line Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ACE (angiotensin-converting enzyme) inhibitors – *all oral agents preferred*	dapagliflozin
ARBs (angiotensin receptor blockers) – *all oral agents preferred*	ENTRESTO (sacubitril/valsartan)
Beta blockers – *all oral agents preferred*	INPEFA (sotagliflozin)
Diuretics	SAMSCA (tolvaptan)
FARXIGA (dapagliflozin) – *Brand Required*	tolvaptan
JARDIANCE (empagliflozin)	
sacubitril/valsartan	

Second Line Agents

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ivabradine	CORLANOR (ivabradine)
KERENDIA (finerenone)	
VERQUVO (vericiguat)	

Non-Solid Dosage Forms

First Line Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
enalapril oral solution	ENTRESTO (sacubitril/valsartan) SPRINKLE
	EPANED (enalapril) SOLUTION

Electronic Diagnosis Verification

- Corlanor, Entresto, and Verquvo: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Electronic Duration Verification:

- tolvaptan is payable for 30 days every year.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Corlanor Only:
  - The requested medication must be prescribed by, or in consult with, a cardiologist.
  - The member's heart rate must not be determined exclusively by a pacemaker.
  - The member must have a resting HR ≥ 70 beats per minute despite a 30-day trial of each of the following on maximally tolerated or target beta blocker dose in sinus rhythm, as evidenced by paid claims or pharmacy printouts:
    - Metoprolol
    - Bisoprolol
    - Carvedilol
- Entresto Sprinkle
  - See Non-Solid Dosage Form criteria
  - The member has a diagnosis of heart failure with left ventricular ejection fraction of ≤ 45 %
  - The member has failed a 3-month trial of enalapril, as evidenced by paid claims or pharmacy printouts and a NT-proBNP that failed to decrease by 60%.
- Inpefa Only:
  - The requested medication must be prescribed by, or in consult with, a cardiologist or nephrologist.
  - The member is receiving concurrent Entresto, a beta-blocker, and a mineralocorticoid receptor antagonist as evidenced by paid claims or pharmacy printouts.
  - The member must have diabetes type 2, and must not have diabetes type 1

- The member has failed 30-day trials of dapagliflozin and empagliflozin, as evidenced by paid claims or pharmacy printouts. Failure is defined by being admitted to the hospital, a heart failure unit, infusion center, or emergency department for worsening heart failure within the past 3 months.

- Kerendia Only:
  - The requested medication must be prescribed by, or in consult with, a cardiologist.
  - The member has a diagnosis of heart failure with left ventricular ejection fraction of ≥ 40%
  - The member has been admitted to the hospital, a heart failure unit, infusion center, or emergency department for worsening heart failure within the past 3 months despite 2-month trials each of spironolactone and eplerenone in combination with a SLGT-2 inhibitor and a GLP-1 agonist, as evidenced by paid claims or pharmacy printouts.
- Tolvaptan Only:
  - The requested medication must be prescribed by, or in consult with, a cardiologist
  - The member is experiencing sodium levels less than 120 mEq/L despite a 30-day trial of an ACE inhibitors or ARBs in combination with a loop diuretic, as evidenced by paid claims or pharmacy printouts.
  - The member does not have liver disease.
- Verquvo Only:
  - The requested medication must be prescribed by, or in consult with, a cardiologist.
  - The member must have left ventricular ejection fraction (LVEF) < 45% at initiation.
  - The member must have had a hospitalization or need for IV diuretics within the past 3 months despite 2-month trial of Entresto, a beta-blocker, a SGLT-2 Inhibitor, a mineralocorticoid receptor antagonist, and vasodilator therapy (e.g., isosorbide and hydralazine or amlodipine)

Interstitial Lung Disease

Criteria was updated to align with study inclusion criteria of Ofev and new drug Jascayd.

First Line Therapy - Orals

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
azathioprine	
cyclophosphamide	
mycophenolate mofetil (MMF)	

First Line Therapy - Biologics

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

Progressive Disease

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
rituximab - See Biosimilar Agents	JASCAYD (nerandomilast)
	OFEV (nintedanib)

Prior Authorization

Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a pulmonologist or rheumatologist.
- The member must have forced vital capacity (FVC) ≥ 45% of predicted within prior 60 days
- The member must have carbon monoxide diffusing capacity (DLCO, corrected for hemoglobin) of 30% to 79% of predicted.
- If the member is a current smoker, the member must have received smoking cessation counseling in the past year
- The member must have one of the following within the past 24 months:
  - a FVC decline of ≥10%
  - a FVC decline of ≥ 5% and worsening respiratory symptoms or fibrotic changes
  - worsening respiratory symptoms and fibrotic changes

Juvenile Idiopathic Arthritis

Required trials have been updated for Juvenile Idiopathic Arthritis – Polyarticular Course

Juvenile Idiopathic Arthritis – Polyarticular Course

Interleukin (IL) -6 Receptor Inhibitors

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

Janus Kinase (JAK) Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XELJANZ IR (tofacitinib) 5 MG TABLET, SOLUTION	RINVOQ ER TABLET, SOLUTION
	XELJANZ IR (tofacitinib) 10 MG TABLET
	XELJANZ XR (tofacitinib)

T-cell Costimulation Blocker

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ORENCIA (abatacept) – 125 mg/mL syringe	ORENCIA (abatacept) - 50 mg/0.4 mL and 87.5 mg/0.7 ml syringes
	ORENCIA (abatacept) – *Medical Billing*

TNF Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab - See Biosimilar Agents	CIMZIA (certolizumab) SYRINGE
ENBREL (etanercept)	CIMZIA (certolizumab) VIAL – *Medical Billing*
	SIMPONI ARIA (golimumab) – *Medical Billing*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member has failed all preferred agents in the same class as requested product
- The member has failed a 3-month trial of a TNF inhibitor, as evidenced by paid claims or pharmacy print outs.
- Cimzia, Orencia, and Toclizumab Only: The member has failed a 3-month trial of a TNF inhibitor and a 30-day trial of Xeljanz, as evidenced by paid claims or pharmacy print outs.
- Kevzara, Rinvoq, and Simponi Aria Only: The member has failed a 3-month trial of a TNF inhibitor, toclizumab, and Orencia, and a 30-day trial of Xeljanz, as evidenced by paid claims or pharmacy print outs.
- Xeljanz IR 10mg, Xeljanz XR Only: See Preferred Dosage Form criteria
- Medical billing only agents: In addition to above criteria, clinical justification must be provided why a self-administered agent cannot be used (subject to clinical review)

Myasthenia Gravis

Uplinza was given a new indication for generalized Myasthenia Gravis, preferred agents were adjusted to account for receptor status and cost considerations.

Glucocorticoid-Sparing Therapy

Oral Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
azathioprine	
cyclosporine	
mycophenolate mofetil	
tacrolimus	

Biologic Agents

Acetylcholine Receptor (AChR) Antibody Positive

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
rituximab - See Biosimilar Agents	eculizumab - See Biosimilar Agents
PREFERRED AGENTS (PA REQUIRED)	
IMAAVY (nipocalimab-aahu) – *Medical Billing*	
RYSTIGGO (rozanolixizumab-noli) – *Medical Billing*	
UPLIZNA (inebilizumab) – *Medical Billing*	
ULTOMIRIS (ravulizumab-cwvz) – *Medical Billing*	
VYVGART (ergartigimod alfa) – *Medical Billing*	
VYVGART HYTRULO (efgartigimod alfa/hyaluronidase) syringes	
VYVGART HYTRULO (efgartigimod alfa/hyaluronidase) – *Medical Billing*	
ZILBRYSQ (zilucoplan)	

Muscle Specific Kinase (MuSK) Positive

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
rituximab - See Biosimilar Agents	IMAAVY (nipocalimab-aahu) – *Medical Billing*
	RYSTIGGO (rozanolixizumab-noli) – *Medical Billing*
	UPLIZNA (inebilizumab) – *Medical Billing*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months (1 year total for bridge therapy)

- 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 neurologist or neuromuscular specialist.
- The member must have all of the following:
  - Myasthenia Gravis Foundation of America (MGFA) clinical classification class of II, III, or IV
  - Positive serological lab test for one of the following (A or B):
    A. Anti-AchR antibodies
    B. Anti-MuSK antibodies
- The member must have Myasthenia Gravis-specific Activities of Daily Living (MG-ADL) total score of one of the following:
  - For Zilbrysq (zilucoplan), eculizumab, Imaavy (nipocalimab-aahu), Uplizna (inebilizumab-cdon), or Ultomiris (ravulizumab-cwvz) requests: ≥ 6
  - For Vyvgart (efgartigimod alfa-fcab) or Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) requests: ≥ 5
  - For Rystiggo (rozanolixizumab-noli) requests: ≥ 3 (with at least 3 points from non-ocular symptoms)

Acetylcholine Receptor (AChR) Antibody Positive

- One of the following (A or B):
  A. The member is unable to complete glucocorticoid bridge therapy (e.g., diabetes) while waiting for efficacy of oral immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus)
  B. The member required chronic intravenous immunoglobulin (IVIG) or chronic plasmapheresis/plasma exchange (i.e., at least every 3 months over 12 months without symptom control), despite a 12-month trial (total duration) of immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus), as evidenced by paid claims or pharmacy printouts.
- Soliris Only:
  - The member required chronic intravenous immunoglobulin (IVIG) or chronic plasmapheresis/plasma exchange (i.e., at least every 3 months over 12 months without symptom control), despite a 90-day trial or recommended cycle duration of each of the following, as evidenced by paid claims or pharmacy printouts:
    A. Rituximab
    B. Ultomiris
    C. Vyvgart or Rystiggo

Muscle Specific Kinase (MuSK) Positive

- The member required chronic intravenous immunoglobulin (IVIG) or chronic plasmapheresis/plasma exchange (i.e., at least every 3 months over 12 months without symptom control), despite a 90-day trial of rituximab, as evidenced by paid claims or pharmacy printouts.

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 scores and symptoms (subject to clinical review):
  - Decreased rate of Myasthenia Gravis exacerbations
  - A 2-point improvement in the member's total MG-ADL score

Second Review

Alzheimer's Disease

Cholinesterase Inhibitors

Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
donepezil 5 mg, 10 mg tablet	ARICEPT (donepezil)
galantamine tablet	donepezil 23 mg tablet
galantamine ER	donepezil ODT
rivastigmine capsule	RAZADYNE (galantamine)
	RAZADYNE ER (galantamine)
	ZUNVEYL (benzgalantamine)

Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EXELON (rivastigmine) PATCH – *Brand Required*	ADLARITY (donepezil) PATCH
	galantamine oral solution
	rivastigmine patch

NMDA Receptor Antagonists

Solid Dosage Forms

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

Non-Solid Dosage Forms

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
memantine ER capsule sprinkle	memantine oral solution
	NAMENDA XR (memantine) CAPSULE SPRINKLE

Cholinesterase Inhibitors / NMDA Receptor Antagonist Combinations

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	memantine/donepezil
	NAMZARIC (memantine/donepezil)

Therapeutic Duplication

- One memantine medication is allowed at a time
- Anticholinergic medications are not covered with acetylcholinesterase inhibitors (donepezil, rivastigmine, galantamine, pyridostigmine).
    - The effects of an anticholinergic (blocks the effect of acetylcholine) and acetylcholinesterase inhibitors (prevents breakdown of acetylcholine) oppose each other, and the therapeutic effect of both products is diminished.

Electronic Diagnosis Verification

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

Electronic Age Verification

- Submit chart notes to verify diagnosis for members less than 30 years old

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of a pharmaceutically equivalent preferred agent, as evidenced by paid claims or pharmacy printouts.
- The member must not reside in facility where medications are managed such as skilled nursing care.
- Donepezil 23 mg/Zunveyl: Clinical justification must be provided explaining why the member is unable to use the preferred products (subject to clinical review).
- Memantine ER capsule sprinkle: Must meet Non-Solid Dosage Forms criteria

Amyloid Beta-Directed Monoclonal Antibody

PA REQUIRED
KISUNLA (donanemab-azbt) – *Medical Billing*
LEQEMBI (lecanemab-irmb) – *Medical Billing*
LEQEMBI IQLIK (lecanemab-irmb)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a neurologist, geriatric psychiatrist, or geriatrician specializing in dementia.
- The member must have been diagnosed with mild cognitive impairment or mild Alzheimer's disease dementia, with documented evidence of beta-amyloid plaque on the brain.
- The member has a physician who participates in a qualifying registry with an appropriate clinical team and follow-up care.

Leqembi Iqlik only

- The member must have completed 18 months of maintenance treatment with Leqembi IV infusions

Renewal Criteria – Approval Duration: 1 year

- The member continues to show positive clinical response, such as stable or improved cognitive function

Phenylketonuria (PKU)

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
JAVYGTOR (sapropterin)	KUVAN (sapropterin)
sapropterin	PALYNZIQ (pegvaliase-pqpz)
	SEPHIENCE (sepiapterin)
	ZELVYSIA (sapropterin)

Underutilization

- Sapropterin and Palynziq must be used adherently and will reject on point of sale for late fill

Prior Authorization Criteria

Prior Authorization Form – Phenylketonuria

Initial Criteria – Approval Duration: 2 months (sapropterin and Sephience); 12 months (Palynziq)

- The member must have been compliant with a PHE restricted diet for past 6 months
- The requested medication must be prescribed by, or in consult with, a geneticist or endocrinologist.
- Baseline PHE levels must meet one of the following:
  - For members of childbearing potential and children ≤ 12 years old: PHE levels must be above 360 µmoles/liter (6 mg/dL)
  - For members without childbearing potential, and children > 12 years old: PHE levels must be above 600 µmoles/liter 10 mg/dL)
- The member is known to have two null mutations in trans
- Sapropterin Only:
  - The member's weight must be provided. Requested initial dose must be 10 mg/kg.
- Palynziq and Sephience Only: One of the following must be met:
  - PHE levels must be attached documenting the member was unable to achieve a PHE level less than 600 µmoles/liter (10 mg/dL) despite a 3-month trial of 20 mg/kg dose of sapropterin with good compliance, as evidenced by paid claims or pharmacy printouts.
  - Sephience Only: One of the following must apply:
    - The member's weight must be provided and must be less than 16 kg.
    - PHE levels must be attached documenting the member was unable to achieve a PHE level less than 600 µmoles/liter (10 mg/dL) or less than 360 µmoles/liter (6 mg/dL) if childbearing potential or child ≤ 12 years old, despite a 4-month trial of 60 mg per day of Palynziq with good compliance, as evidenced by paid claims or pharmacy printouts.
  - Palynziq Only: Requested initial dose must be 20 mg
    - 40 mg: PHE levels must be attached documenting the member was unable to achieve a PHE level less than 600 µmoles/liter (10 mg/dL) or less than 360 µmoles/liter (6 mg/dL) if childbearing potential or child ≤ 12 years old, despite a 6-month trial of 20 mg per day of Palynziq with good compliance, as evidenced by paid claims or pharmacy printouts.
    - 60 mg: PHE levels must be attached documenting the member was unable to achieve a PHE level less than 600 µmoles/liter (10 mg/dL) or less than 360 µmoles/liter (6 mg/dL)

if childbearing potential or child ≤ 12 years old, despite a 4-month trial of 40 mg per day of Palynziq with good compliance, as evidenced by paid claims or pharmacy printouts.

Renewal Criteria:

- For same or reduced dose from previous trial:
  Approval Duration: 12 months – if dose is the same or less than previous trial
  - PHE level must be between 60 and 600 µmoles per liter
  - Sapropterin Only: The member's weight must be provided.

- For a dose increase from previous trial
  Approval Duration: 4 months – for a dose increase from previous trial
  - PHE level must be attached that were taken after previous trial (1 month for Kuvan, 4 months for Palynziq)
    - For members of childbearing potential and children ≤ 12 years old: PHE levels must be above 360 µmoles/liter (6mg/dL)
    - For members without childbearing potential, and children > 12 years old: PHE levels must be above 600 µmoles/liter 10mg/dL)
  - Sapropterin Only: The member's weight must be provided.

Non-Cystic Fibrosis Bronchiectasis

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 (NCFBE) (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.
- The member must have eosinophils ≤ 300 cells/microL
- If the member is a current tobacco user, the member must have received tobacco cessation counseling in the past year
- Documentation must be submitted of a baseline quality of life score, as assessed by the QoL bronchiectasis questionnaire, respiratory domain

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

First Review of Acromegaly

Overview

Definition[1]: A clinical syndrome that results from excessive secretion of growth hormone (GH) and high serum concentrations of liver-derived insulin-like growth factor (IGF-1). Progression is very slow and average time from onset of symptoms to until diagnosis is typically 12 years.

Prevalence[1,2]**:**

- Annual incidence is 6 to 8 per million people.
- Mean age at diagnosis is 40 to 45 years.
- 30 to 70 individuals per million in Europe.

Causes[1]**:**

- Somatotroph adenomas, which is an adenoma of the anterior pituitary, are the most common cause.
    - Accounts for approximately one-third of all hormone-secreting pituitary adenomas.
    - If GH excess occurs before fusion of epiphyseal growth plates it is known as pituitary gigantism
- Genetic Causes
    - Activating mutation of the alpha subunit of the guanine nucleotide stimulatory protein (Gs-alpha) gene
        - Found in 40% of somatotroph adenomas
    - Pituitary tumor transforming gene is overexpressed
    - Microduplications on chromosome Xq26.3
        - Found in younger children with gigantism
        - Disease onset prior to 5 years of age
- Other causes (very rare):
    - Excess secretion of GH-releasing hormone (GHRH) by hypothalamic tumors
    - Ectopic GHRH secretion by neuroendocrine tumors
    - Ectopic secretion of GH by neuroendocrine tumors

Clinical Features[1]**:**

- Somatic effects: stimulation of growth of skin (including skin thickening), connective tissue, cartilage, bone, viscera, and many epithelial tissues.
    - Enlarged jaw, hands, and feet
    - Deepening of voice
    - Carpal tunnel syndrome
    - Adults do NOT have increased linear growth. They experience enlargement of synovial tissue and cartilage causing hypertrophic arthropathy of knees, ankles, hips, spine, and other joints.
- Metabolic effects: Nitrogen retention and protein anabolism, insulin resistance, glucose dysregulation, and lipolysis.
- Common comorbidities: sleep apnea, cardiovascular dysfunction, neuropathy, hypogonadism, hyperglycemia, fatigue, and general weakness.
- Direct effects of pituitary adenoma:
    - Headache/vision loss

- Pituitary dysfunction
  - Hypogonadism which leads to menstrual dysfunction, hot flashes, and vaginal atrophy in females and erectile dysfunction, loss of libido, decreased facial hair growth, and decrease in testicular volume in males.
  - Hyperprolactinemia
  - Thyroid-stimulating hormone (TSH) and corticotropin (ACTH deficiencies.

Diagnosis[2]: Based on elevated age-adjusted serum IGF-1 concentration in patients with typical manifestations of acromegaly. Normal IGF-1 strongly suggests the patient does not have acromegaly. GH concentrations are also tested. Almost all patients with acromegaly have elevated IGF-1 and GH concentrations. Serum IGF-1 concentration is the best single test for diagnosis because concentrations do not vary from hour to hour based on food intake, exercise, and sleep.

Test	
Serum IGF-1 concentration	• Preferred testing method • Not affected by food intake, exercise, or sleep
Oral Glucose Tolerance Test	• Most specific dynamic test • Standard for determining control after surgical treatment
Pituitary MRI	• Performed after confirming GH hypersecretion
Random Serum Growth Hormone Measurements	• NOT useful for diagnosis • Levels affected by food intake, exercise, stress, and sleep

FDA Approval

Sandostatin (octreotide): October 21, 1988; 505(b) New Drug Application (NDA) pathway; Type 1 – New Molecular Entity; Priority

Bynfezia (octreotide): September 27, 2024; 505(b) New Drug Application (NDA) pathway; Type 5 – New Formulation or New Manufacturer; Standard

Mycapssa (octreotide): June 26, 2020; 505(b) New Drug Application (NDA) pathway; Type 5 – New Formulation or New Manufacturer; Standard; Orphan

Somatuline Depot (lanreotide): August 30, 2007; 505(b) New Drug Application (NDA) pathway; Type 1 – New Molecular Entity; Standard; Orphan

Signifor (pasireotide): December 14, 2012; 505(b) New Drug Application (NDA) pathway; Type 1 – New Molecular Entity; Standard; Orphan

Palsonify (paltusotine): September 25, 2025; 505(b) New Drug Application (NDA) pathway; Type 1 – New Molecular Entity; Standard; Orphan

Somavery (pegvisomant): March 25, 2003; 505(b) New Drug Application (NDA) pathway; Orphan

Dostinex (cabergoline): December 23, 1996; 505(b) New Drug Application (NDA) pathway; Type 1 – New Molecular Entity; Standard

Current Utilization

Quarter 4 2024 – Quarter 3 2025

Medication	Rx Count	% of Rx	Reimb Amount
Bynfezia	**0**	**0**	**0**
Cabergoline	**72**	**0.03%**	**$1929.55**
Dostinex	**0**	**0**	**0**
Lanreotide	**0**	**0**	**0**
Mycapssa	**0**	**0**	**0**
Octreotide	**25**	**0.01%**	**$7,981.77**
Palsonify	**0**	**0**	**0**
Sandostatin	**0**	**0**	**0**
Signifor	**0**	**0**	**0**
Somatuline	**0**	**0**	**0**
Somavert	**2**	**0.001%**	**$10,202.84**

Treatment Overview[3]

Goal of therapy is to lower IGF-1 concentrations, control adenoma size, improve symptoms, and reverse metabolic abnormalities.

Transsphenoidal surgery: treatment of choice for patients with adenomas that are small, large but still resectable, or large adenomas causing visual impairment.

- This is the preferred initial step for most patients.

Pharmacotherapy:

- Primary therapy option for the following patients:
- Have an adenoma that does not appear to be fully resectable
- Poor surgical candidates or decline surgery
- Would benefit from preoperative medication to allow easier intubation by reducing severe laryngeal swelling and macroglossia and to improve obstructive apnea or cardiac dysfunction.
- **Somatostatin receptor ligands - SRLs (Octreotide, lanreotide, pasireotide, and paltusotine, Mycapssa, Bynfezia)**
    - Analogs of somatostatin (GH-inhibitory hormone) that inhibit GH secretion. Also causes somatotroph adenoma shrinkage in some patients.
    - Preferred first-line treatment due to effects on adenoma size and secretion of GH.
    - IGF-1 should be measured every 3 to 4 months for the first year.
    - If IGF-1 is not normalized at maximum dose of SRL, alternative therapy should be considered.
    - Octreotide and lanreotide appear to be equivalent
    - Pasireotide often causes or worsens hyperglycemia.
    - Octreotide and paltusotine can be used orally for members who are stable on octreotide or lanreotide injections.

- **Pegvisomant**
  - Blocks native GH from binding and interferes with GH signal transduction.
  - May also be used first-line but SRLs are preferred first-line as they have effects on both adenoma size and GH secretion.
  - Efficacy determined by measuring IGF-1
- **Combination therapy** – indicated for patient with a suboptimal response in IGF-1 to analog alone.
- **Dopamine agonists (cabergoline)** – inhibit GH secretion in patients with very mild acromegaly.
  - Not as effective as SRLs
  - Can be used as first-line therapy for patients with mild IGF-1 elevation and small adenoma.
  - Can also be used in combination with SRLs or pegvisomant in patients with GH concentrations < 1.3 mcg/L and very mild symptoms of GH excess.

Medication	Mycapssa (octreotide)[11]	Bynfezia (octreotide)[12]
Mechanism of Action	Inhibits growth hormone, glucagon, and insulin by suppressing luteinizing hormone's response to GnRH.	
Dosing	20mg by mouth twice daily with a max dose of 80mg/day.	100mcg subcutaneously three times daily with a max dose of 500mcg three times daily.
Special Considerations	• Indicated for long-term maintenance in patients who have responded to and tolerated treatment with octreotide or lanreotide.	• Doses greater than 300 mcg/day rarely result in additional biochemical benefit • Therapy should be stopped for 4 weeks every year to reassess disease activity.
Clinical Trials	• 58% of patients maintained biochemical response at the end of 9 months.	
Cost (AWP)/	$8151.66 (28 days)	$912.00 (1 pen of 7000 mcg)

References:

1. *Melmed, Shlomo, et al. Causes and clinical manifestations of acromegaly. UpToDate. November 17, 2025. Causes and clinical manifestations of acromegaly - UpToDate*
2. *Melmed, Shlomo, et al. Diagnosis of acromegaly. UpToDate. November 17, 2025. Diagnosis of acromegaly - UpToDate*
3. *Melmed, Shlomo, et al. Treatment of acromegaly. UpToDate. November 17, 2025. Treatment of acromegaly - UpToDate*
4. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Sandostatin NDA 019667 approval letter, October 21, 1988. Drugs@FDA: FDA-Approved Drugs*
5. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Bynfezia NDA 213224 approval letter, September 27, 2024.* Approval Letter_213224Orig1s000ltr.pdf
6. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Mycapssa NDA 208232 approval letter, June 26, 2020.* Mycapssa (octreotide)*U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Somatuline Depot NDA 022074 approval letter, August 30, 2007. 022074s000ltr.pdf*

7. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Signifor NDA 022074 approval letter, December 14, 2012.* *Signifor (pasireotide) injection, for subcutaneous use, 0.3 mg/mL, 0.6 mg/mL, 0.9 mg/mL.*
8. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Palsonify NDA 219070 approval letter, September 25, 2025.* *Palsonify (paltusotine) tablets*
9. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Somavert NDA 021106 approval letter, March 25, 2003.* *NDA-I1: NDA Approval Letter*
10. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Dostinex NDA 020664 approval letter, December 23, 1996.* *Drugs@FDA: FDA-Approved Drugs*
11. *Mycapssa (octreotide). IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI.. https://www.Micromedexsolutions.com*
12. *Bynfezia (octreotide). IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI.. https://www.Micromedexsolutions.com*

First Review of Calcium Channel Blockers

Overview

Types[1,2]:

- **Dihydropyridines**
  - Amlodipine, felodipine, isradipine, nifedipine, nicardipine
  - Potent vasodilators with little or no negative effect upon cardiac contractility or conduction
  - Used to treat hypertension, coronary artery disease, and chronic stable angina
- **Non-dihydropyridines**
  - Diltiazem and verapamil
  - Less potent vasodilators but have a greater depressive effect on cardiac conduction and contractility
  - Used to treat hypertension, paroxysmal supraventricular tachycardia (PSVT) conversion, PSVT prophylaxis, atrial fibrillation/flutter, chronic stable angina, and vasospastic angina.

Mechanism of Action[3]:

- **Dihydropyridines**
  - Inhibits the influx of calcium ions across cellular membranes in vascular smooth muscle which results in arterial vasodilation. It is more selective for calcium channels in vascular smooth muscle than cardiac muscle therefore vasodilation mainly occurs in coronary and peripheral arteries.
  - Exert minimal effects on the myocardium[1].
- **Non-dihydropyridines**
  - Blocks calcium ion influx during depolarization of cardiac and vascular smooth muscle. They decrease vascular resistance and cause relaxation of the vascular smooth muscle.

Adverse Effects[3]:

- Bradyarrhythmia
- Peripheral edema (dihydropyridines)
- Dizziness
- Headache
- Cough
- Fatigue
- Serious ADRs: congestive heart failure, heart block, myocardial infarction, hepatotoxicity

Contraindications[3]:

- Acute MI with pulmonary congestion
- Wolff-Parkinson-White or short PR syndromes
- Cardiogenic shock
- 2nd or 3rd degree heart block
- Sick sinus syndrome without functioning pacemaker

- Symptomatic hypotension (SPB 90 mmHg or less)
- Ventricular tachycardia

Precautions for use[3]:
- Supraventricular arrhythmias
- Impaired ventricular function
- Hypotension
- Heart failure with reduced ejection fraction (non-dihydropyridine CCB not recommended)
- Avoid concurrent oral therapy with beta-blockers or digitalis
- Dermatologic reactions leading to erythema multiforme or exfoliative dermatitis
- Hepatic impairment
- Renal impairment
- Elderly patients with heart failure with reduced ejection fraction

Dosing of Diltiazem formulations[4]:
- **Immediate-release formulations:** dosed 3 to 4 times per day
  - Should be administered before meals and at bedtime
  - May be swallowed whole, crushed, or chewed
- **Sustained-release formulations:** dosed every 12 hours
- **Extended-release formulations:** dosed every 24 hours
  - Cardizem LA, Matzim LA, Cardizem CD, Cartia XT, Dilt-XR, Tiazac, Taztia XT
  - Should be swallowed whole and administered at the same time each day
  - Dilt-XR should be administered on an empty stomach in the morning
  - Taztia XT and Tiazac may be opened and sprinkled on a spoonful of applesauce.

Current Utilization

Inexpensive Non-dihydropyridines: Quarter 4 2024 – Quarter 3 2025

Medication	Dosing	Cost for 30 days	Rx Count	Reimb Amount
Cartia XT Capsule	180-240 mg once daily	$4.389 – $9.258	16	$210.86
Dilt XR	180-240 mg once daily	$11.382 – $16.866	51	$1170.14
Diltiazem 120mg tablet	120 mg four times daily	$11.652	1	$25.09
Diltiazem 12hr ER Capsule	120 – 180 mg twice daily	$104.172 - $142.08	6	$752.58
Diltiazem 24hr ER (CD)	180-240 mg once daily	$4.389 – $10.803	557	$10392.62
Diltiazem 24hr ER(LA)	120-420 mg once daily	$51.054 – $69.39	28	$1967.89
Diltiazem 24hr ER(XR)	180-240 mg once daily	$11.382 – $16.866	24	$586.41
Diltiazem 30mg tablet	30 mg four times daily	$6.444	16	$235.82

Diltiazem 60mg tablet	60 mg four times daily	$9.168	26	$430.67
Matzim LA	180-360 mg once daily	$27.465 - $69.39	0	0
Tiadylt ER	180-240 mg once daily	$2.652 - $31.443	49	$1039.44
Verapamil IR	80 mg three times daily (Max 480mg/day)	$10.596	99	$1,706.08
Verapamil SR	180 mg once daily (Max 240mg twice daily)	$5.82 - $10.602	327	$9,315.45
Verapamil ER (Verelan PM)	200 mg once daily at bedtime	$110.911	0	0

Expensive Non-dihydropyridines: Quarter 4 2024 – Quarter 3 2025

Medication	Dosing	Cost for 30 days	Rx Count	Reimb Amount
Diltiazem 12hr ER Capsule	120 – 180 mg twice daily	$104.172 - $142.08	6	$752.58
Diltiazem 24hr ER(LA)	120-420 mg once daily	$51.054 – $69.39	28	$1967.89
Verapamil ER (Verelan PM)	200 mg once daily at bedtime	$110.911	0	0

Inexpensive Dihydropyridines: Quarter 4 2024 – Quarter 3 2025

Medication	Dosing	Cost for 30 days	# of Rx ‘s	Reimb Amount
Amlodipine	5-10 mg once daily	$0.333 - $0.48	8251	$106,219.10
Felodipine	5 mg once daily (Max 10mg/day)	$4.047	38	$582.80
Nifedipine ER	30-60 mg once daily (Max 120mg/day)	$41.82 - $77.53	931	$15,134.99

Expensive Dihydropyridines: Quarter 4 2024 – Quarter 3 2025

Medication	Dosing	Cost for 30 days	# of Rx ‘s	Reimb Amount
Isradipine	2.5 mg twice daily (Max 20mg/day)	$255.888	0	0
Nicardipine IR	20-40 mg three times daily	$238.68	0	0
Nisoldipine ER	17-34 mg once daily	$139.77 - $171.18	0	0
Norliqva (6 to 17 years of age)	2.5-5 mg once daily	$246.623 - $493.245	12	$7,025.15

References:

1. *McKeever, Rita, et al. Calcium Channel Blockers. National Library of Medicine. February 22, 2024. Calcium Channel Blockers - StatPearls - NCBI Bookshelf*
2. *Bloch, Michael, et al. Major side effects and safety of calcium channel blockers. UpToDate. September 12, 2025.* Major side effects and safety of calcium channel blockers - UpToDate
3. *Diltiazem, Isradipine, Nicardipine, Nisoldipine. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI.. https://www.Micromedexsolutions.com*
4. *Diltiazem. Facts and Comparisons. February 2, 2026. DilTIAZem Oral (Drug Facts And Comparisons)*

First Review of Graft vs Host Disease (GVHD)

Overview

Definition[1]: Multisystem disorder that are common complications of allogenic hematopoietic cell transplant (HCT). Occurs when the graft recognizes the host as foreign which leads to an immune reaction that causes disease in the transplant recipient. Divided into acute and chronic using a cutoff of 100 days and/or clinical findings.

Classifications[1]**:**

- Classic acute GVHD – present within 100 days of HCT and display features of acute GVHD. **Distinctive features of chronic GVHD are absent.
- Persistent, recurrent, late-onset acute GVHD – present more than 100 days post-HCT with features of acute GVHD. **Distinctive features of chronic GVHD are absent.
- Classic chronic GVHD – presents at any time post-HCT, has diagnostic and distinctive features of chronic GVHD, and no features of acute GVHD.
- Overlap syndrome (aka acute on chronic GVHD) – presents at any time post-HCT with features of both chronic and acute GVHD.

Prevalence[1]**:** Occurs in 9-50% of patients who receive HCT

Clinical Features[1]**:**

- **Acute GVHD**
  - Maculopapular rash typically involves the nape of the neck, ears, shoulders, palms of hands, and soles of feet.
  - Persistent nausea and/or vomiting
  - Abdominal cramps with diarrhea
  - Rising serum bilirubin concentration
- **Chronic GVHD**
  - Lichen planus or cutaneous manifestations of scleroderma
  - Dry oral mucosa with ulcerations and sclerosis of GI tract
  - Rising serum bilirubin concentrations

Grading[1]**:**

- **aGVHD (International Bone Marrow Transplant Registry Severity Index)**
  - **Grade I (A) –** Mild; Stage 1 skin involvement alone (maculopapular rash < 25% of body) with no liver or GI involvement
  - **Grade II (B) –** Moderate; Stage 2 skin involvement; Stage 1 to 2 gut or liver involvement
  - **Grade III (C) –** Severe; Stage 3 involvement of any organ system (generalized erythroderma; bilirubin 6.1 to 15 mg/dL; diarrhea 1500 to 2000 mL/day)
  - **Grade IV (D) –** Life-threatening; Stage 4 involvement of any organ system (generalized erythroderma with bullous formation; bilirubin > 15 mg/dL; diarrhea > 2000 mL/day or pain or ileus)
  - **Steroid-resistant aGVHD –** disease that progresses by day 5 or no response to treatment by day 7
- **cGVHD**
  - **Mild** – Involvement of one or two organs with score ≤1 **plus** lung score 0 and no significant functional impairment (eg, ECOG PS ≤2)

- **Moderate** –
  - Involvement of ≥3 organs with score ≤1
  - Lung score 1
  - Any non-lung organ score 2
  - Functional impairment (eg, ECOG PS ≥3)
- **Severe** – Major disability caused by cGVHD
  - Lung score ≥2
  - Any non-lung score 3
  - Platelet count <100,000/microL
- **Steroid-resistant cGVHD** – disease that does not respond to full-dose prednisone or patients who are intolerant or have unacceptable complications with prednisone.
  - Progressive disease despite prednisone 1mg/kg/day for two weeks
  - Stable disease after four to six weeks of prednisone ≥ 0.5 mg/kg/day
  - Inability to taper prednisone < 0.5 mg/kg/day

FDA Approval

Niktimvo (axatilimab-csfr): August 14, 2024; Biologics License Application (BLA); Orphan

Rezurock (belumosudil): July 1, 2021; 505(b) New Drug Application (NDA) pathway; Type 1 – New Molecular Entity; Priority; Orphan

Jakafi (ruxolitinib): November 16, 2011; 505(b) New Drug Application (NDA) pathway; Type 1 – New Molecular Entity; Priority; Orphan

Imbruvica (ibrutinib): November 13, 2012; 505(b) New Drug Application (NDA) pathway; Type 1 – New Molecular Entity; Priority; Orphan

Gattex (Teduglutide): December 21, 2012; 505(b) New Drug Application (NDA) pathway; Type 1 – New Molecular Entity; Standard; Orphan

Adcetris (Brentuximab vedotin): August 19, 2011; Biologics License Applications (BLA) pathway; Orphan

Simulect (Basiliximab): May 12, 1998; Biologics License Application (BLA) pathway; Orphan

Tyenne, Actemra (Tocilizumab): March 5, 2024; Biologics License Application (BLA) pathway; Orphan

Lemtrada (Alemtuzumab): May 7, 2001; Biologics License Application (BLA) pathway; Orphan

Ryoncil (remestmecel-L-rknd): December 18, 2024; Biologics License Application (BLA) pathway

Current Utilization

Quarter 4 2024 – Quarter 3 2025

Medication	Rx Count	% of Rx	Reimb Amount
Adcetris	**0**	**0**	**0**
Gattex	**0**	**0**	**0**

Imbruvica	**0**	**0**	**0**
Jakafi**	**7**	**0.003%**	**$123,152.22**
Lemtrada	**0**	**0**	**0**
Niktimvo	**0**	**0**	**0**
Rezurock	**0**	**0**	**0**
Ryoncil	**0**	**0**	**0**
Simulect	**0**	**0**	**0**
Tyenne	**0**	**0**	**0**

**One member is on Jakafi for PCV.

Treatment Overview

Acute GVHD Treatment[2]

- **Grade 1 aGVHD**
  - Topical steroid
  - Optimize prophylaxis regimen
- **Grade ≥ 2 aGVHD**
  - Systemic glucocorticoid
- **Steroid-resistant aGVHD**
  - Ruxolitinib – 1st line therapy
  - 2nd-line treatments include
    - Mycophenolate mofetil (MMF)**
    - Teduglutide (Gattex)**
    - Etanercept (Enbrel)**
    - Alpha-1 antitrypsin**
    - Sirolimus**
    - Brentuximab vedotin**
    - Interleukin-2 receptor (CD25 alpha) antibodies – basiliximab (Simulect)**
    - Tocilizumab (Tyenne, Actemra)
    - Alemtuzumab (Lemtrada) – indicated for patients receiving allogenic stem cell transplant for hematologic malignancies, steroid-refractory

**Not compendia supported but listed in Up-To-Date as possible second-line treatments.

Chronic GVHD Treatment[3]

- **Mild cGVHD**
  - Localized/topical treatment
  - If BSA > 50%, oral glucocorticoids or other immunosuppressive agents may be required
- **Moderate cGVHD**
  - Prednisone
- **Severe cGVHD**
  - Prednisone plus ruxolitinib
- **Steroid-resistant cGVHD**
  - Prednisone plus ruxolitinib
  - Belumosudil – used after failure of 2 or more prior lines of systemic therapy in patients ≥ 12 years.
  - Ibrutinib – used after failure of 1 or more prior therapies for cGVHD in patients ≥ 1 year.
  - Axatilimab - used after failure of 2 or more prior lines of systemic therapy in patients ≥ 40 kg.
  - Other agents if the patient is refractory to prednisone plus one or more of the agents above: cyclosporine, tacrolimus, mycophenolate mofetil**, sirolimus**, rituximab, imatinib**, bortezomib**, entanercept**, thalidomide**, and pentostatin**.

****Not compendia supported but listed in Up-To-Date as possible treatments for SR-cGVHD.

Medication	**Niktimvo (Axatilimab-csfr)[4]**	**Rezurock (belumosudil) [5]**	**Ryoncil (remestemcel-L-rknd)[14]**
Mechanism of Action	Binds to colony stimulating factor-1 receptors (CSF-1R) expressed on monocytes and macrophages which reduces the levels of circulating proinflammatory and profibrotic monocytes and monocyte-derived macrophages.	Inhibits rho-associated, coiled-coil containing protein kinase (ROCK) which inhibits ROCK2 and ROCK1.	MOA unclear but may be related to immunomodulatory effects such as inhibition of T cell activation
Dosing	At least 40 kg: 0.3 mg/kg up to a max of 35mg every 2 weeks until	200mg daily until progression of cGVHD that	$2x10^6$ MSC/kg body weight IV twice weekly for 4 consecutive

	progression of cGVHD or unacceptable toxicity.	requires new systemic therapy.	weeks. **An additional 4 weeks may be needed if the patient has a partial or mixed response or for recurrence after a complete response.
Special Considerations	• For adults and pediatric patients at least 40 kg after failure of at least 2 prior lines of systemic therapy	• For ages 12 years and older after failure of 2 or more prior lines of systemic therapy. • Dose must be increased to 200mg twice daily when administered with CYP3a inducers or PPIs.	• Indicated for treatment of steroid refractory acute graft vs host disease in pediatric patients 2 months and older.
Clinical Trials	• AGAVE-201 trial – median time to first response was 1.5 months. Median duration of response was 1.9 months. • In patients who achieved response, no death or new systemic therapy initiation occurred in 60% of patients for at least 12 months.	• The overall response rate in clinical trials was 75%. • Median time to response was 1.8 months and median duration of response was 1.9 months. • In patients who achieved response, no death or new systemic therapy initiation occurred in 62% of patients for at	• Overall response rate at day 28 was 50% (Grade B), 70% (grade C), and 76% (Grade D). • 30% had a complete response. • 41% had a partial response.

		least 12 months.	
Cost (AWP)/30 days	$55,440.00 (2 - 22mg vials)	$22,403.98	$465,600.00

References:

1. *Chao, Nelson, et al. Clinical manifestations, diagnosis, and grading of acute graft-versus-host disease. UpToDate. August 27, 2024.* Clinical manifestations, diagnosis, and grading of acute graft-versus-host disease - UpToDate
2. *Zeiser, Robert, et al. Treatment of acute graft-versus-host disease. UpToDate. December 4, 2025.* Treatment of acute graft-versus-host disease - UpToDate
3. *Zeiser, Robert, et al. Treatment of chronic graft-versus-host disease. UpToDate. September 25, 2024.* Treatment of chronic graft-versus-host disease - UpToDate
4. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Niktimvo BLA 761411 approval letter, August 14, 2024.* Approval Letter_761411Orig1s000ltr.pdf
5. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Rezurock NDA 214783 approval letter, July 16, 2021.* REZUROCK (belumosudil)
6. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Jakafi NDA 202192 approval letter, November 16, 2011.* Jakafi (ruxolitinib) Tablets.im
7. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Imbruvica NDA 205552 approval letter, November 13, 2013.* Imbruvica® (ibrutinib) Capsules, 140 mg.
8. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Gattex NDA 203441 approval letter, December 21, 2012.* GATTEX (teduglutide [rDNA origin]) for injection, for subcutaneous use, 5 mg.
9. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Adcetris BL 125388/0 and BL 125399/0 approval letter, August 19, 2011.* 125388s000,125399s000ltr.pdf
10. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Simulect BL 103764/5040 approval letter, May 12, 1998.* 103764-5040ltr.pdf
11. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Tyenne BL 761275 approval letter, March 5, 2024.* Approval Letter_761275Orig1s000Correctedltr.pdf
12. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Lemtrada BL 103948/0 approval letterMay 7, 2001.* CBER - Alemtuzumab (Campath), Millennium and ILEX Partners, LP
13. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Ryoncil BL 125706/0 approval letter, December 18, 2024.* December 18, 2024 Approval Letter - RYONCIL
14. *Ryoncil. Package insert. Mesoblast, Inc. December 2024.* *prescribing-information.pdf*
15. *Niktimvo (axatilimab-csfr). Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. https://www.Micromedexsolutions.com*

16. *Rezurock (belumosudil). Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI.. https://www.Micromedexsolutions.com*
17. *Ryoncil (remestemcel-l-rknd). Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI.. https://www.Micromedexsolutions.com*

First Review of Malaria

Overview

Definition[1]: A parasitic disease caused by the *Plasmodium* species which is transmitted by the bite of an infected *Anopheles* female mosquito throughout the tropics. Some rare routes of transmission include congenitally acquired infection, blood transfusion, sharing of contaminated needles, and organ transplantation. Infants and children < 5 years of age, pregnant patients, and patients with HIV infection are at highest risk of developing severe malaria.

Prevalence[1]**:**

- Occurs in 83 countries
- 263 million cases and 597,000 deaths reported by the WHO in 2023
- 33 cases per 1000 population at risk each year
- The WHO African Region accounts for 94% of cases globally
- Transmission eliminated in the US in the mid-1950s
- Approximately 2000 imported cases in the US each year with 85% of those coming from Africa

Clinical Features[2]**:**

- Typically, asymptomatic for 12 to 35 days after infection.
- Initial symptoms: fever, tachycardia, tachypnea, chills, malaise, fatigue, diaphoresis, headache, cough, anorexia, nausea, vomiting, abdominal pain, diarrhea, arthralgias, myalgias
- Ruptured infected red blood cells
- Concomitant lower respiratory tract, intestinal, or bloodstream bacterial or viral infections
- Splenic enlargement and anemia
- Severe malaria:
    - *P. falciparum* parasitemia and one or more of the following:
        - Altered consciousness
        - Seizures
        - Severe anemia
        - Hypoglycemia
        - Coagulopathy
        - Metabolic acidosis
        - Circulatory collapse
        - Renal failure, hemoglobinuria (“blackwater fever”)
        - Hepatic failure
- Cerebral malaria – encephalopathy that presents with impaired consciousness, delirium, and/or seizures.

FDA Approval

chloroquine: August 29, 2003; Abbreviated New Drug Application ANDA

hydroxychlorquine: September 30, 1994; Abbreviated New Drug Application ANDA; Standard

quinine: September 28, 2012; Abbreviated New Drug Application ANDA

atovaquone/proguanil: January 12, 2011; Abbreviated New Drug Application ANDA

Coartem: April 7, 2009; Type 1 – New Molecular Entity; Priority; Orphan; NDA

Krintafel: July 20, 2018; Type 1 – New Molecular Entity; Priority; Orphan; NDA

Malarone (atovaquone-proguanil): July 14, 2000; Type 4 – New Combination; Priority; NDA

Mefloquine: May 2, 1989; Type 1 – New Molecular Entity; Priority; NDA

primaquine: January 23, 1952; Type 5 – New Formulation or New manufacturer; Standard; NDA

Sovuna: January 14, 2022; Type 5 – New Formulation or New Manufacturer; Standard; NDA

artesunate: May 26, 2020; Type 1 – New Molecular Formulation; Priority; Orphan; NDA

Fansidar (pyrimethamine-sulfadoxine): October 28, 1981; Type 1 – New Molecular Entity and Type 4 New Combination; Priority; NDA **Not commercially available for general use. **

Current Utilization

Quarter 4 2024 – Quarter 3 2025

Medication	Rx Count	% of Rx	Reimb Amount
Aralen**	**0**	**0**	**0**
Artesunate	**0**	**0**	**0**
Atovaquone**	**50**	**0.02%**	**$10,552.11**
Atovaquone-Proguanil	**0**	**0**	**0**
Chloroquine**	**0**	**0**	**0**
Coartem	**1**		**$98.26**
Fansidar	**0**	**0**	**0**
Hydroxychloroquine**	**597**	**0.25%**	**$14,311.66**
Krintafel	**0**	**0**	**0**
Lariam	**0**	**0**	**0**
Malarone	**0**	**0**	**0**
Mefloquine	**0**	**0**	**0**
Mepron**	**0**	**0**	**0**
Plaquenil**	**0**	**0**	**0**
Primaquine**	**0**	**0**	**0**
Quinine**	**0**	**0**	**0**
Sovuna**	**0**	**0**	**0**

**Please note, these medications are used for other indications therefore utilization likely represents those indications.

Treatment Overview

Prevention:[1]

- Vector control with insecticides, bed nets, insecticide-treated fabrics, insect repellants, and housing modifications.
- **Chemoprevention:**
    - **Mass Drug Administration** – administration of full course of antimalarial medication across a population in a defined geographical area. Combination medications different from first-line treatments are preferred. Single dose medications are also preferred over multiday regimens.
    - **Intermittent preventative treatment of school-age children (IPTsc)** – Used in areas of seasonal or moderate-to-high perennial transmission.
    - **Post-discharge malaria chemoprevention (PDMC)** – For children < 5 years of age hospitalized for severe anemia in moderate-to-high malaria transmission areas.
    - **Perennial transmission settings** – Used in areas of moderate-to-high perennial malaria transmission in children up to 24 months.
    - **Seasonal transmission settings** – Administration of antimalarial medications to children < 5 years of age in areas of seasonal transmission.
    - **Targeted drug administration** – for pregnant patients, infants with congenital HIV exposure, patients with HIV, and patients with sickle cell disease.
        - Trimethoprim-sulfamethoxazole is used for infants with HIV exposure and patients with HIV infection.
    - **Vaccination**
    - **Monoclonal antibodies** – novel approach to providing immune protection

Treatment:[3]

- First-line therapy should consider local guidelines, drug sensitivity patterns, and drug availability.
- Uncomplicated malaria:
    - Combination of 2 drugs (in case of chloroquine resistance) or chloroquine/hydroxychloroquine monotherapy (in case of chloroquine sensitivity) if artemisinin combination therapy (ACT) is not available.
    - ACT is preferred when available despite chloroquine sensitivity.
    - Patients who have received prophylaxis and still get infected should receive different medications from those used as prophylaxis.
    - ACT:
        - ACT has the lowest side effect profile, is effective against all blood stages, and has the most rapid clearance time.
        - All ACT therapies are similar in efficacy and local drug resistance patterns should be used to choose treatment option.
            - Artemether-lumefantrine (AL)
                - Efficacy can diminish with body weight > 65kg.
            - Artesunate-mefloquine (ASMQ)
            - Artesunate-sulfadoxine-pyrimethamine (AS+SP) – in areas with known SP sensitivity

- Recurrent infection
  - If ≤ 28 days following initial treatment, choose an alternative ACT regimen.
  - If > 28 days following initial treatment, the first-line ACT regimen.
    - Reuse of mefloquine within 60 days of initial treatment can increased risk of neuropsychiatric reactions so an alternative regimen should be used.
- Primaquine and artemether-lumefantrine can be used to treat gametocytes that may persist in the blood after successful treatment which reduces transmission.
  - Primaquine is only effective against mature gametocytes.
- Treatment outside endemic areas:
  - ACT regimens
  - Atovaquone-proguanil
    - Good alternative to artemether-lumefantrine in patients with higher BMI.
  - Quinine-based regimens
    - Quinine sulfate plus doxycycline, tetracycline, or clindamycin
    - Less preferrable due to bitter taste, cinchonism, and GI side effects.
    - Doxycycline and tetracycline are preferred as they have greater efficacy than clindamycin.
  - Mefloquine-based regimens
    - Should only be used

- Severe malaria
  - High risk of death within the first 24 hours after clinical presentation.
  - IV therapy should be initiated as soon as possible with artesunate, artemether, quinine, or quinidine.
  - Patients can switch to oral therapy after 24 hours if they can tolerate oral medications.
  - A single dose of artesunate is preferred.
  - If IM artesunate is not available:
    - Patients ≥ 6 years: IM artemether, then IM quinine if artemether not available
    - Patients < 6 years: rectal artesunate, then IM artemether, then IM quinine.
  - In areas of artemisinin resistance, a combination of parenteral artesunate and quinine is preferred.
  - Empiric antibiotic therapy against gram-negative bacilli, e.g. ceftriaxone, should be started and blood cultures obtained as concomitant bacteremia is common in severe malarial infections. Empiric therapy should be continued until bacteremia is excluded (48 to 72 hours of negative blood cultures).
- Pregnancy
  - Parenteral artesunate is preferred in all trimesters.
  - Artemether is preferred over quinine due to increased risk of hypoglycemia with quinine.
- Primary medications used per CDC guidelines: chloroquine, hydroxychloroquine, Coartem (artemether-lumefantrine), atovaquone-proguanil, quinine, tetracycline, doxycycline, clindamycin, and primaquine.[16]
  - For CDC Treatment Algorithm please visit: Appendix B: Algorithm for Diagnosing and Treatment for Malaria in the United States | Malaria | CDC.

Medication	Dose	Cost/recommended treatment duration
Artesunate	**2.4 mg/kg at 0 hours, 12 hours, 24 hours, and then once daily for 7 total days**	**$10,757.00**

Atovaquone-Proguanil	**1000mg/400mg (4 tablets) daily x 3 days**	**$85.77**
Chloroquine	**1000mg LD, 500mg after 6-8 hours, 500mg once daily x 2 days (2500mg in 3 days)**	**$119.27**
Coartem	**80mg/480mg x 2 (8 hours apart), then 80mg/480mg twice daily x 2 days (total 6 doses)**	**$161.72**
Hydroxychloroquine	**800mg LD, 400mg at 6, 24, and 48 hours after LD**	**$40.71**
Krintafel	**300mg x 1 dose on the first or second day of chloroquine therapy (for Vivax malaria)**	**$38.40**
Mefloquine	• **1250mg x 1 dose followed by treatment with primaquine** • **750mg LD, 500mg 6-12 hours after LD (for Plasmodium vivax or P ovale malaria) to be used in combination with primaquine**	**$52.95**
Primaquine	**For prevention of relapse/adjunct: 52.6mg once daily x 14 days**	**$50.37**
Quinine	• **648mg every 8 hours x 7 days** • **650mg three times daily for 3 or 7 days in combination with doxycycline 100mg twice daily for 7 days or tetracycline 250mg four times daily for 7 days**	**$127.30 (3 days)** **$297.04 (7 days)**
Sovuna	**800mg LD, 400mg at 6, 24, and 48 hours after LD**	**$209.79**

References:

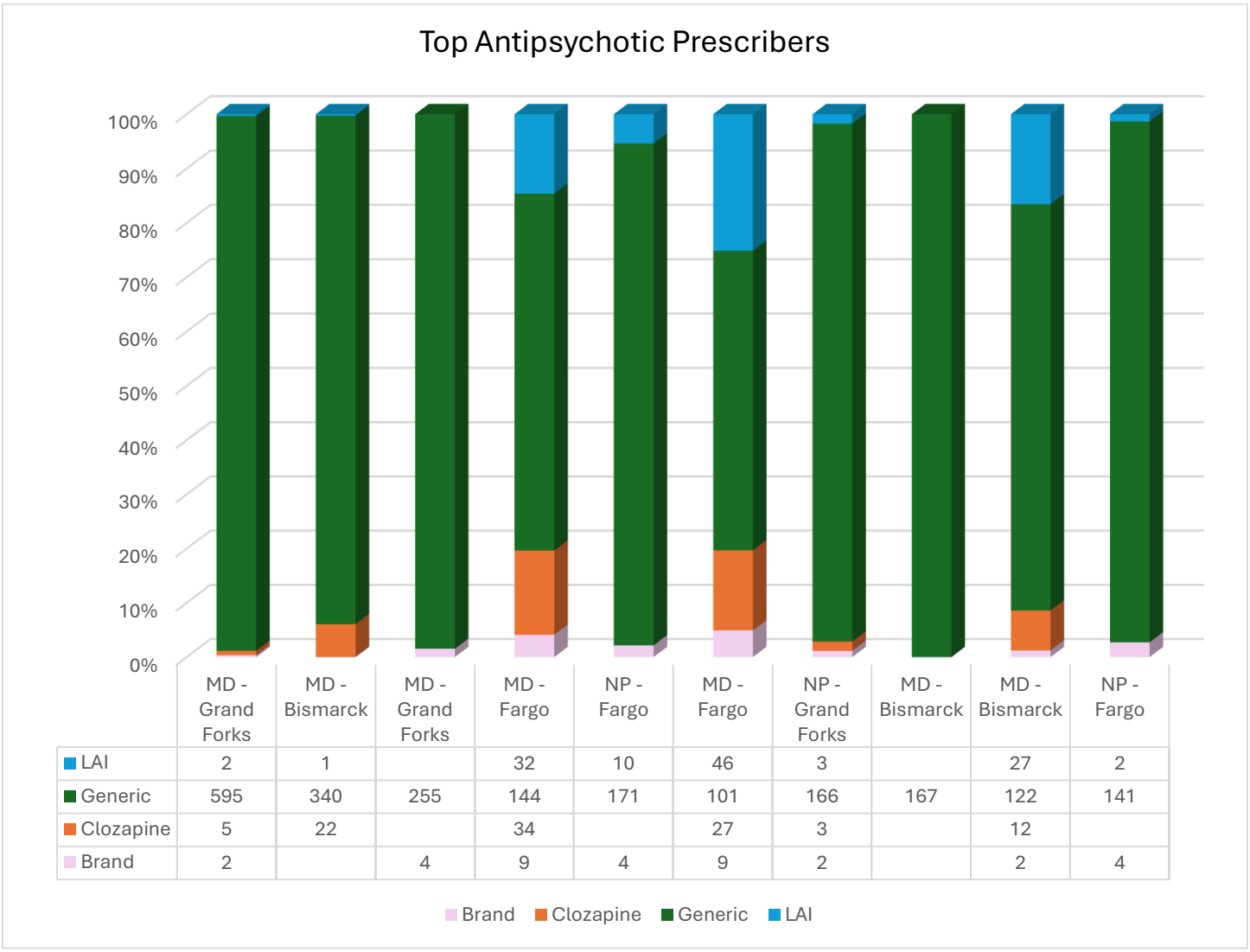
1. *Lindblade, Kim A, et al. Malaria: Epidemiology, prevention, and elimination. UpToDate. Oct 1, 2025.* Malaria: Epidemiology, prevention, and elimination - UpToDate
2. *Cohee, Lauren, et al. Malaria: Clinical manifestations and diagnosis in nonpregnant adults and children. UpToDate. January 8, 2026.* Malaria: Clinical manifestations and diagnosis in nonpregnant adults and children - UpToDate
3. *Daily, Johanna, et al. Treatment of uncomplicated falciparum malaria in nonpregnant adults and children. UpToDate. October 1, 2025.* *Treatment of uncomplicated falciparum malaria in nonpregnant adults and children - UpToDate*
4. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Chloroquine ANDA 040516 approval letter, August 29, 2003.* Drugs@FDA: FDA-Approved Drugs
5. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Hydroxychloroquine ANDA 040081 approval letter September 30, 1994.* Drugs@FDA: FDA-Approved Drugs

6. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Hydroxychloroquine ANDA 091661 approval letter, September 28, 2012 Drugs@FDA: FDA-Approved Drugs.*
7. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Atovaquone/Proguanil ANDA 091211 approval letter, January 12, 2011.* Drugs@FDA: FDA-Approved Drugs
8. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Coartem NDA 022268 approval letter, April 7, 2009.* Drugs@FDA: FDA-Approved Drugs
9. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Krintafel NDA 210795 approval letter, July 20, 2018.* 210795Orig1s000Ltr.pdf
10. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Malarone NDA 021078 approval letter, July 14, 2000.* 21-078 Malarone Final Print Label
11. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Mefloquine NDA 019578 approval letter, May 2, 1989.* Drugs@FDA: FDA-Approved Drugs
12. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Primaquine NDA 008316 approval letter January 23, 1952.* Drugs@FDA: FDA-Approved Drugs
13. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Sovuna NDA 214581. Approval letter January 14, 2022.* hydroxychloroquine sulfate tablets
14. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Artesunate NDA 213036. Approval letter May 26, 2020.* Drugs@FDA: FDA-Approved Drugs
15. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Fansidar NDA 018557. Approval letter October 28, 1981.* Drugs@FDA: FDA-Approved Drugs
16. *Clinical Guidance: Malaria Diagnosis & Treatment in the U.S. June 5, 2024. Clinical Guidance: Malaria Diagnosis & Treatment in the U.S. | Malaria | CDC*
17. *Artesunate. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. https://www.Micromedexsolutions.com*
18. *Atovaquone-proguanil. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI.. https://www.Micromedexsolutions.com*
19. *Chloroquine. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI.. https://www.Micromedexsolutions.com*
20. *Coartem. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI.. https://www.Micromedexsolutions.com*
21. *Hydroxychloroquine. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI.. https://www.Micromedexsolutions.com*
22. *Krintafel. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI.. https://www.Micromedexsolutions.com*
23. *Primaquine. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI.. https://www.Micromedexsolutions.com*
24. *Quinine. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI.. https://www.Micromedexsolutions.com*
25. *Quinine. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI.. https://www.Micromedexsolutions.com*
26. *Sovuna. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI.. https://www.Micromedexsolutions.com*

Top Antipsychotic Prescribers by # of Patients

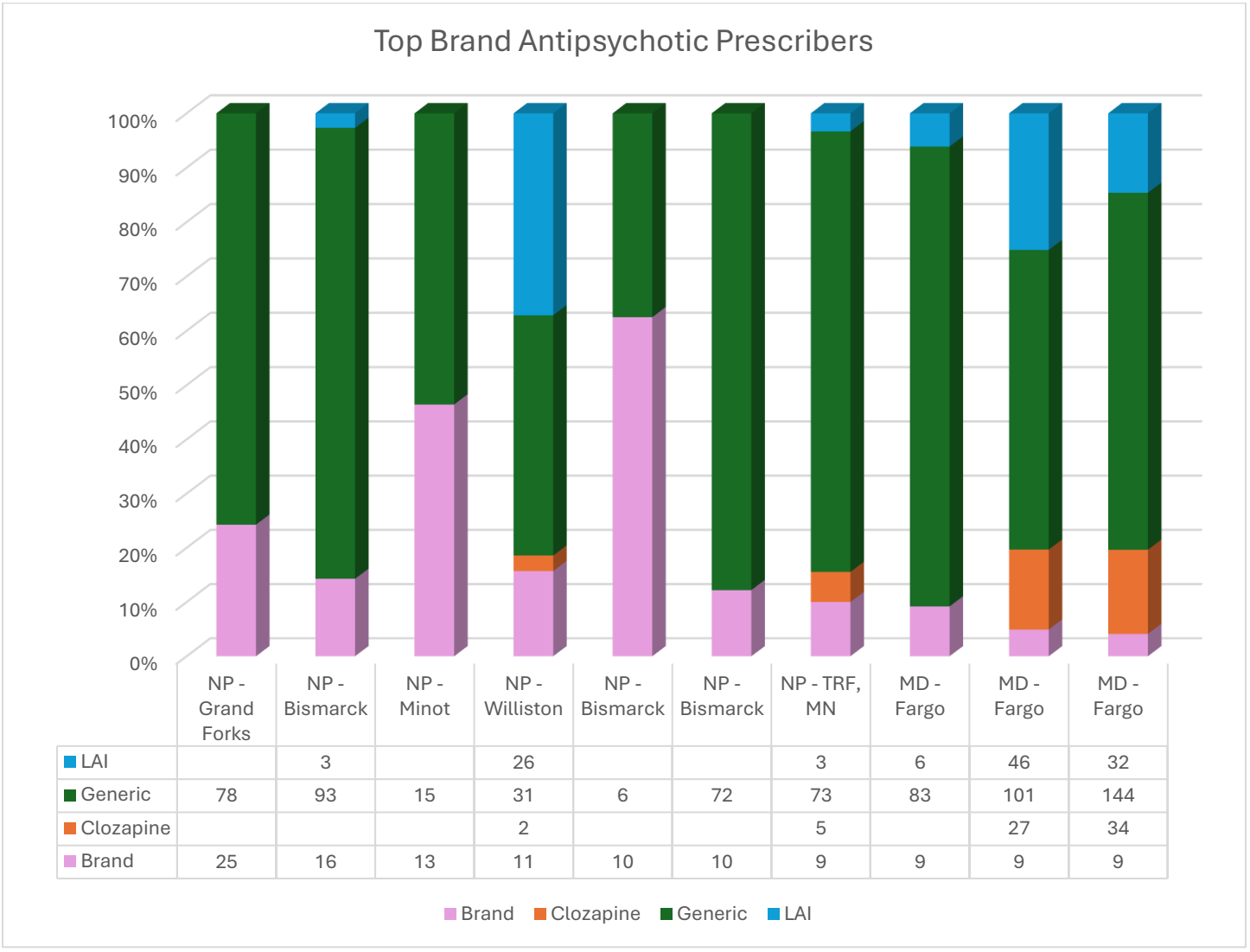
Total Volume

Row Labels	Brand	Clozapine	Generic	LAI	Grand Total	% Brand
Grand Total	**400**	**375**	**13145**	**596**	**14516**	2.76%
MD - Grand Forks	2	5	595	2	604	0.33%
MD - Bismarck		22	340	1	363	0.00%
MD - Grand Forks	4		255		259	1.54%
MD - Fargo	9	34	144	32	219	4.11%
NP - Fargo	4		171	10	185	2.16%
MD - Fargo	9	27	101	46	183	4.92%
NP - Grand Forks	2	3	166	3	174	1.15%
MD - Bismarck			167		167	0.00%
MD - Bismarck	2	12	122	27	163	1.23%
NP - Fargo	4		141	2	147	2.72%



Brand Name Drugs

Row Labels	Brand	Clozapine	Generic	LAI	Grand Total	% Brand
Grand Total	**400**	**375**	**13145**	**596**	**14516**	2.76%
NP - Grand Forks	25		78		103	24.27%
NP - Bismarck	16		93	3	112	14.29%
NP - Minot	13		15		28	46.43%
NP - Williston	11	2	31	26	70	15.71%
NP - Bismarck	10		6		16	62.50%
NP - Bismarck	10		72		82	12.20%
NP - TRF, MN	9	5	73	3	90	10.00%
MD - Fargo	9		83	6	98	9.18%
MD - Fargo	9	27	101	46	183	4.92%
MD - Fargo	9	34	144	32	219	4.11%



Top 5 Brand Prescribers by Drug and Indication

Prescriber / Indication	Rexulti	Vraylar	Caplyta	Lybalvi	Grand Total
NP – Grand Forks	**10**	**19**	**5**		**34**
Depression	10	11			21
Bipolar Disorder		6	5		11
Schizophrenia		1			1
Schizoaffective Disorder		1			1
NP – Bismarck #2	**5**	**17**		**3**	**25**
Depression	5	11		1	17
Bipolar Disorder		4		2	6
Schizophrenia		2			2
NP – Williston	**1**	**11**	**8**	**1**	**21**
Bipolar Disorder		4	8		12
Depression	1	4			5
Schizophrenia		1		1	2
Schizoaffective Disorder		1			1
Unspecified Psychosis		1			1
NP – Bismarck #5	**3**	**5**		**2**	**10**
Depression	3	3			6
Bipolar Disorder		2		1	3
Schizoaffective Disorder				1	1
NP – Minot	**6**			**2**	**8**
Bipolar Disorder	4			2	4
Depression	1				3
Schizoaffective Disorder	1				1
Schizophrenia	1				1

NORTH DAKOTA MEDICAID RETROSPECTIVE DRUG UTILIZATION REVIEW

CRITERIA RECOMMENDATIONS

1ST QUARTER 2026

Criteria Recommendations ***Approved Rejected***

1. Atrasentan/Overuse _____ _____

Alert Message: Vanrafia (atrasentan) may be over-utilized. The recommended dosage of atrasentan is 0.75 mg once daily.

Drugs/Diseases

Util A Util B Util C
Atrasentan

Max Dose: 1.75 mg/day

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Vanrafia Prescribing Information, April 2025, Novartis Pharmaceuticals Corp.

2. Atrasentan/Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A Util B Util C
Atrasentan

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Vanrafia Prescribing Information, April 2025, Novartis Pharmaceuticals Corp.

3. Atrasentan/Contraindication Box Warning _____ _____

Alert Message: The use of Vanrafia (atrasentan) is contraindicated in patients who are pregnant. Based on animal reproductive toxicity studies, atrasentan may cause fetal harm when administered to a pregnant patient. When pregnancy is detected, atrasentan should be discontinued as soon

as possible.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Atrasentan	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Vanrafia Prescribing Information, April 2025, Novartis Pharmaceuticals Corp.

4. Atrasentan/Therapeutic Appropriateness _____ _____

Alert Message: Patients who can become pregnant while using Vanrafia (atrasentan) should use effective contraception prior to initiation of treatment, during treatment, and for two weeks after discontinuation. Based on animal reproductive toxicity studies, atrasentan may cause fetal harm when administered to a pregnant patient.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Atrasentan		Contraception

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Vanrafia Prescribing Information, April 2025, Novartis Pharmaceuticals Corp.

5. Atrasentan/Severe Hepatic Impairment _____ _____

Alert Message: The use of Vanrafia (atrasentan) should not be initiated in patients with severe hepatic impairment. Asymptomatic and transient transaminase elevations have been observed with atrasentan use. If clinically relevant aminotransferase elevations occur, or if elevations are accompanied by an increase in bilirubin > 2 x ULN, or by clinical symptoms of hepatotoxicity, discontinue atrasentan. Consider re-initiation of atrasentan when hepatic enzyme levels normalize in patients who have not experienced clinical symptoms of hepatotoxicity or jaundice.

Drugs/Diseases

Util A	Util B	Util C
Atrasentan	Cirrhosis	
	Liver Failure	

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Vanrafia Prescribing Information, April 2025, Novartis Pharmaceuticals Corp.

6. Atrasentan/Elevated Liver Function Levels _____ _____

Alert Message: Asymptomatic and transient transaminase elevations have been observed with the use of Vanrafia (atrasentan). Obtain liver enzyme testing before initiating atrasentan. If clinically relevant aminotransferase elevations occur, or if elevations are accompanied by an increase in bilirubin > 2 x ULN, or by clinical symptoms of hepatotoxicity, discontinue atrasentan. Consider re-initiation of atrasentan when hepatic enzyme levels normalize in patients who have not experienced clinical symptoms of hepatotoxicity or jaundice. The use of atrasentan should not be initiated in patients with severe hepatic impairment.

Drugs/Diseases

Util A	Util B	Util C
Atrasentan	Elevated LFT	

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Vanrafia Prescribing Information, April 2025, Novartis Pharmaceuticals Corp.

7. Atrasentan/Strong and Moderate CYP3A Inducers _____ _____

Alert Message: The concurrent use of Vanrafia (atrasentan) with a strong or moderate CYP3A inducer should be avoided. Atrasentan is a CYP3A substrate and the use with a strong or moderate CYP3A inducer is expected to decrease atrasentan exposure, which may reduce atrasentan efficacy.

Drugs/Diseases

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

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Vanrafia Prescribing Information, April 2025, Novartis Pharmaceuticals Corp.

8. Atrasentan/OATP1B1/B3 Inhibitors _____ _____

Alert Message: The concurrent use of Vanrafia (atrasentan) with an OATP1B1/1B3 inhibitor should be avoided. Atrasentan is an OATP1B1/1B3 substrate, and its use with an OATP1B1/1B3 inhibitor is expected to increase atrasentan exposure, which may increase the risk of atrasentan-related adverse reactions.

Drugs/Diseases

Util A	Util B	Util C
Atrasentan	Asciminib	
	Atazanavir	
	Clarithromycin	
	Cyclosporine	
	Darolutamide	
	Eltrombopag	
	Gemfibrozil	
	Glecaprevir	
	Lopinavir	
	Sofosbuvir/Velpatasvir/Voxilaprevir	
	Teriflunomide	

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Vanrafia Prescribing Information, April 2025, Novartis Pharmaceuticals Corp.

9. Atrasentan/Lactation _____ _____

Alert Message: There are no data on the presence of Vanrafia (atrasentan) in human milk, effects on the breastfed infant, or effect on milk production. Because of the potential for adverse reactions, such as fluid retention, advise patients not to breastfeed during treatment with atrasentan.

Drugs/Diseases

Util A	Util B	Util C
Atrasentan	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Vanrafia Prescribing Information, April 2025, Novartis Pharmaceuticals Corp.

10. Atrasentan/Non-adherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Vanrafia (atrasentan). Nonadherence to the prescribed dosing regimen may result in subtherapeutic effects, which

may lead to decreased patient outcomes and additional healthcare costs.

Drugs/Diseases

Util A	Util B	Util C
Atrasentan		

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

11. Brensocatib/Overuse _____ _____

Alert Message: Brinsupri (brensocatib) may be over-utilized. The maximum recommended dose of brensocatib is 25 mg once daily.

Drugs/Diseases

Util A	Util B	Util C
Brensocatib		

Max Dose: 25 mg/day

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Brinsupri Prescribing Information, August 2025, Insmed Inc.

12. Brensocatib/Therapeutic Appropriateness _____ _____

Alert Message: The safety and efficacy of Brinsupri (brensocatib) in pediatric patients younger than 12 years of age have not been established.

Drugs/Diseases

Util A	Util B	Util C
Brensocatib		

Age Range: 0 – 12 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Brinsupri Prescribing Information, August 2025, Insmed Inc

13. Brensocatib/Dermatologic Adverse Reactions _____ _____

Alert Message: Treatment with Brinsupri (brensocatib) is associated with an increase in dermatologic adverse reactions, including rash, dry skin, and hyperkeratosis. Monitor patients

for the development of new rashes or skin conditions and refer patients to a dermatologist for evaluation of new dermatologic findings.

Drugs/Diseases

Util A	Util B	Util C
Brensocatib	Dermatitis	
	Erythema	
	Hyperkeratosis	
	Palmoplantar keratoderma	
	Rash	

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Brinsupri Prescribing Information, August 2025, Insmed Inc.

14. Brensocatib/Periodontal Adverse Reactions _____ _____

Alert Message: Treatment with Brinsupri (brensocatib) is associated with an increase in gingival and periodontal adverse reactions. Refer patients to dental care services for regular dental checkups while taking brensocatib. Advise patients to perform routine dental hygiene.

Drugs/Diseases

Util A	Util B	Util C
Brensocatib	Gingivitis	
	Periodontal Disease	

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Brinsupri Prescribing Information, August 2025, Insmed Inc.

15. Brensocatib/Non-adherence _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Brensocatib		

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.

16. Dihydroergotamine Nasal/Overuse _____ _____

Alert Message: Atzumi (dihydroergotamine nasal powder) may be over-utilized. The recommended dose of nasal dihydroergotamine is one 5.2 mg spray (contents of one nasal device) into one nostril. The dose (one 5.2 mg spray in one nostril) may be repeated, if needed, a minimum of 1 hour after the first dose. The maximum dose in a 24-period is 10.4 mg.

Drugs/Diseases

Util A	Util B	Util C
Dihydroergotamine Nasal		

Max Dose: 10.4 mg/day

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Atzumi Prescribing Information, April 2025, Satsuma Pharmaceuticals, Inc.

17. Dihydroergotamine Nasal/Therapeutic Appropriateness _____ _____

Alert Message: The safety and efficacy of Atzumi (dihydroergotamine nasal powder) in pediatric patients have not been established.

Drugs/Diseases

Util A	Util B	Util C
Dihydroergotamine Nasal		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Atzumi Prescribing Information, April 2025, Satsuma Pharmaceuticals, Inc.

18. Dihydroergotamine Nasal/Therapeutic Appropriateness _____ _____

Alert Message: The safety of taking more than 4 doses of Atzumi (dihydroergotamine nasal powder) in a 7-day period or 12 doses within a 30-day period has not been established.

Drugs/Diseases

Util A	Util B	Util C
Dihydroergotamine Nasal		

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Atzumi Prescribing Information, April 2025, Satsuma Pharmaceuticals, Inc.

19. Dihydroergotamine SubQ/Overuse _____ _____

Alert Message: Brekiya (dihydroergotamine subcutaneous injection) may be over-utilized. The recommended dose of subcutaneous dihydroergotamine is 1 mg. The dose may be repeated, as needed, at 1-hour intervals to a total maximum of 3 mg (3 doses) in a 24-hour period. Do not exceed 6 mg (6 doses) in a week.

Drugs/Diseases

Util A	Util B	Util C
Dihydroergotamine SubQ		

Max Dose: 3 mg/day

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Brekiya Prescribing Information, May 2025, Amneal Pharmaceuticals, Inc.

20. Dihydroergotamine SubQ/Therapeutic Appropriateness _____ _____

Alert Message: The safety and efficacy of Brekiya (dihydroergotamine subcutaneous injection) in pediatric patients have not been established.

Drugs/Diseases

Util A	Util B	Util C
Dihydroergotamine SubQ		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Brekiya Prescribing Information, May 2025, Amneal Pharmaceuticals, Inc.

21. Aripiprazole Tablets/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of aripiprazole tablets. Aripiprazole tablets are approved for the treatment of schizophrenia in patients 13 years of age and older, bipolar mania in patients 10 years and older, major depressive disorder in adults, irritability associated with autistic disorder in patients 6 to 17 years of age, and Tourette's disorder in patients 6 to 18 years. The long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Aripiprazole Tabs		Schizophrenia Manic and Mixed Episodes Bipolar I Disorder Major Depressive Disorder

Irritability w/ Autistic Disorder
Tourette's Disorder

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Merative Micromedex DRUGDEX (electronic version). Merative, Ann Arbor, Michigan, USA. 2025.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

22. Aripiprazole Asimtufii Injection/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of Abilify Asimtufii (aripiprazole extended-release injectable suspension). Aripiprazole ER injectable suspension is approved for the treatment of adults with schizophrenia or bipolar I disorder. The long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Aripiprazole ER Susp		Schizophrenia
		Bipolar 1 Disorder

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

23. Aripiprazole Maintena Injection/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of Abilify Maintena (aripiprazole extended-release injectable suspension). Aripiprazole extended-release injection is approved for the treatment of adults with schizophrenia or bipolar I disorder. The long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Aripiprazole ER Susp		Schizophrenia
		Bipolar 1 Disorder

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

23. Aripiprazole Maintena Injection/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of Abilify Maintena (aripiprazole extended-release injectable suspension). Aripiprazole extended-release injection is approved for the treatment of adults with schizophrenia or bipolar I disorder. The long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Aripiprazole ER Susp		Schizophrenia
		Bipolar 1 Disorder

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

24. Aripiprazole Lauroxil Injection/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of Aristada (aripiprazole lauroxil extended-release injectable suspension). Aripiprazole lauroxil ER injectable suspension is approved for the treatment of adults with schizophrenia. The long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Aripiprazole Lauroxil		Schizophrenia

Age Range: 198 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

25. Aripiprazole Film/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of Opipza (aripiprazole oral film). Aripiprazole oral films are approved for the treatment of schizophrenia in patients 13 years of age and older, adjunctive treatment of major depressive disorder in adults, irritability associated with autistic disorder in patients 6 and older, and Tourette's disorder in patients 6 and older. The long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Aripiprazole Films		Schizophrenia Major Depressive Disorder Irritability w/ Autistic Disorder Tourette's Disorder

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

26. Aripiprazole Oral Solution/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of aripiprazole oral solution. Aripiprazole oral solution is approved for the treatment of schizophrenia in patients 13 years of age and older, acute treatment of manic and mixed episodes in bipolar 1 disorder in patients 10 years and older, irritability associated with autistic disorder in pediatric patients 6 to 17 years of age, and Tourette's disorder in patients 6 to 18 years. The long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Aripiprazole Oral Solution		Schizophrenia Manic and Mixed Episodes Bipolar I Disorder Major Depressive Disorder Irritability w/ Autistic Disorder Tourette's Disorder

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Aripiprazole Oral Solution, Jan. 2025, Atlantic Biologicals Corp.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

27. Aripiprazole Mycite Tablets/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of Abilify Mycite (aripiprazole tablets with sensor). Aripiprazole sensor tablets are approved for the treatment of adults with schizophrenia, adults with bipolar I disorder, and as adjunctive treatment for adults with major depressive disorder. The long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)

Aripiprazole Mycite Tabs		Schizophrenia Bipolar I Disorder Major Depressive Disorder

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

28. Asenapine Tablets/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of asenapine sublingual tablets. Asenapine sublingual tablets are approved for the treatment of schizophrenia in adults, bipolar I disorder in adults, and acute monotherapy of manic and mixed episodes in adults and pediatric patients (10 to 17 years). The long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Asenapine Tabs		Schizophrenia Bipolar I Disorder

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

29. Asenapine Transdermal/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of asenapine transdermal. Asenapine transdermal patches are approved for the treatment of schizophrenia in adults. The long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Asenapine Transdermal		Schizophrenia

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

30. Brexpiprazole/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of Rexulti (brexpiprazole). Brexpiprazole is approved for the treatment of schizophrenia in adults and pediatric patients (13 years and older), agitation associated with dementia due to Alzheimer's disease, and adjunctive treatment of major depressive disorder in adults. The long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Brexpiprazole		Schizophrenia
		Dementia due to Alzheimer's Disease
		Major Depressive Disorder

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

31. Cariprazine/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of Vraylar (cariprazine). Cariprazine is approved for the treatment of schizophrenia in adult and pediatric patients 13 years of age and older, acute treatment of manic or mixed episodes associated with bipolar I disorder in adults and pediatric patients 10 years of age and older, depressive episodes associated with bipolar I disorder, and adjunctive therapy to antidepressants for major depressive disorder. The long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Cariprazine		Schizophrenia
		Bipolar I Disorder
		Major Depressive Disorder

Age Range: 19 - 999

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024

32. Clozapine Tablets/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of clozapine tablets. Clozapine tablets are approved for the treatment of treatment-resistant schizophrenia and for reducing the risk of recurrent suicidal behavior in

schizophrenia or schizoaffective disorder. The long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Clozapine Tabs		Schizophrenia
		Schizoaffective

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Clozapine Tablet, July 2025, Aurobindo Pharma Limited.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

33. Clozapine ODT/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of clozapine oral disintegrating tablets (ODT). Clozapine ODT is approved for the treatment of treatment-resistant schizophrenia and reducing the risk of recurrent suicidal behavior in schizophrenia or schizoaffective disorder. The long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Clozapine ODT		Schizophrenia
		Schizoaffective

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Clozapine Tablet, Orally Disintegrating, June 2025, Aurobindo Pharma Limited.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

34. Iloperidone/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of iloperidone. Iloperidone is approved for the treatment of adults with schizophrenia or acute treatment of manic or mixed episodes associated with bipolar I disorder in adults. The long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Iloperidone		Schizophrenia
		Bipolar I Disorder

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

35. Lumateperone/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of Caplyta (lumateperone). Lumateperone is approved for the treatment of adults with schizophrenia, depressive episodes associated with bipolar I or II disorder (bipolar depression), and major depressive disorder. The long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Lumateperone		Schizophrenia
		Bipolar I Disorder, Depressed
		Bipolar II Disorder, Depressed
		Major Depressive Disorder

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

36. Lurasidone/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of Latuda (lurasidone). Lurasidone is approved for the treatment of schizophrenia in adults and adolescents (ages 13 to 17), monotherapy for depressive episodes associated with bipolar I disorder (bipolar depression) in adults and pediatric patients (ages 10 to 17), and for adjunctive therapy in adults with major depressive episodes associated with bipolar I disorder (bipolar depression). The long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Lurasidone		Schizophrenia
		Bipolar I Disorder, Depressed

Age Range: 19 – 999 yoa

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

Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

37. Olanzapine Tabs/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of olanzapine tablets. Olanzapine tablets are approved for the treatment of schizophrenia in adults and adolescents (ages 13 to 17), for acute treatment of manic or mixed episodes associated with bipolar disorder in adults and adolescents (ages 13 to 17), as adjunct treatment of manic or mixed episodes associated with bipolar disorder in adults, for the adjunct treatment of depressive episodes associated with bipolar I disorder, bipolar depression in combination with fluoxetine in adults and children (ages 10 to 17), and for the use in combination with fluoxetine for treatment-resistant depression in adults. The long-term safety and efficacy of this agent in the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Olanzapine Tabs		Schizophrenia
		Bipolar I Disorder, Manic & Mixed
		Bipolar I Disorder, Depressed
		Major Depressive Disorder

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

38. Olanzapine IR Injection/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of olanzapine injection. Olanzapine injection is approved for the treatment of acute agitation associated with schizophrenia and bipolar I mania in adults. The long-term safety and efficacy of this agent in the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Olanzapine IR Inj		Schizophrenia
		Bipolar I Disorder Mania

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

39. Olanzapine ODT/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis

for the use of Zyprexa Zydis (olanzapine oral disintegrating tablets (ODT)). Olanzapine ODTs are approved for the treatment of schizophrenia in adults and adolescents (ages 13 to 17), for acute treatment of manic or mixed episodes associated with bipolar disorder in adults and adolescents (ages 13 to 17), as adjunct treatment of manic or mixed episodes associated with bipolar disorder in adults, for the adjunct treatment of depressive episodes associated with bipolar I disorder, bipolar depression in combination with fluoxetine in adults and children (ages 10 to 17), and for the use in combination with fluoxetine for treatment-resistant depression in adults. The long-term safety and efficacy of this agent in the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Olanzapine ODT		Schizophrenia
		Bipolar I Disorder, Manic & Mixed
		Bipolar Disorder, Depressed
		Major Depressive Disorder

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

40. Olanzapine ER Injection/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of Zyprexa Relprevv (olanzapine extended-release injection). Olanzapine ER injection is approved for the treatment of schizophrenia. The long-term safety and efficacy of this agent in the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Olanzapine ER Inj		Schizophrenia

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

41. Olanzapine/Fluoxetine/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of olanzapine/fluoxetine tablets. Olanzapine/fluoxetine tablets are approved for the treatment of treatment-resistant depression in adults and depressive episodes associated with bipolar I disorder in adults and children 10 years and older. The long-term safety and efficacy of this agent in the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Olanzapine /Fluoxetine		Bipolar I Disorder, Depressed Treatment Resistant Depression

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

42. Olanzapine/Samidorphan Tabs/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of Lybalvi (olanzapine/samidorphan). Olanzapine/samidorphan is approved for the treatment of schizophrenia and bipolar I disorder in adults. The long-term safety and efficacy of this agent in the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Olanzapine/Samidorphan		Schizophrenia Bipolar I Disorder

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

43. Paliperidone Oral/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for paliperidone. Paliperidone is approved for the treatment of schizophrenia in patients 12 years and older and schizoaffective disorder in adults. The long-term safety and efficacy of this agent in the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Paliperidone		Schizophrenia Schizoaffective Disorder

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

44. Paliperidone ER Injection/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for Erzofri (paliperidone extended-release injection). Paliperidone extended-release injection is approved for the treatment of adults with schizophrenia or schizoaffective disorder. The long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Paliperidone ER Injection		Schizophrenia
		Schizoaffective Disorder

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Erzofri Prescribing Information, Jan. 2025, Luye Innomind Pharma Shijiazhuang Co., Ltd.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

45. Paliperidone Palmitate ER Injection/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for Invega Sustenna (paliperidone palmitate extended-release injection). Paliperidone palmitate extended-release injection is approved for the treatment of adults with schizophrenia or schizoaffective disorder. The long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Paliperidone ER Injection		Schizophrenia
		Schizoaffective Disorder

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

46. Paliperidone Palmitate ER Inj 3 mo/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for Invega Trinza (paliperidone palmitate extended-release injection suspension). Paliperidone palmitate extended-release suspension injection is approved for the treatment of schizophrenia in patients after they have been adequately treated with Invega Sustenna (1-month paliperidone ER injection) for at least 4 months. The long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Paliperidone ER Injection		Schizophrenia
		Schizoaffective Disorder

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

47. Paliperidone Palmitate Gluteal IM ER Inj 6 mo/FDA Indications _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for Invega Hafyera (paliperidone palmitate extended-release injection). The once-every-six-month paliperidone palmitate extended-release injection is approved for the treatment of adults with schizophrenia after the patients have been adequately treated with once-a-month paliperidone ER injectable for at least 4 months or every-three-month paliperidone ER injection for at least one three-month cycle. The long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Paliperidone ER Injection		Schizophrenia

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

48. Pimavanserin/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for Nuplazid (pimavanserin). Pimavanserin is approved for the treatment of hallucinations and delusions associated with Parkinson’s disease psychosis. The long-term safety and efficacy of this agent in the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Pimavanserin		Parkinsons Disease

Age Range: 19 – 999 yoa

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

Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

49. Pimozide/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of pimozide. Pimozide is approved for the treatment of motor and phonic tics in patients Tourette's disorder. The long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Pimozide		Tourette's Disorder

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

50. Quetiapine/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for quetiapine. Quetiapine is approved for the treatment of schizophrenia and bipolar I disorder, manic episodes, and bipolar disorder, depressive episodes. The long-term safety and efficacy of this agent in the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Quetiapine		Schizophrenia
		Bipolar I Disorder, Manic
		Bipolar Disorder, Depressive

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

51. Quetiapine XR/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for quetiapine extended-release. Quetiapine extended-release is approved for the treatment of schizophrenia, bipolar I disorder manic or mixed episodes, bipolar disorder, depressive episodes, and major depressive disorder. The long-term safety and efficacy of this agent in the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Quetiapine		Schizophrenia Bipolar I Disorder, Manic Bipolar Disorder, Depressive Major Depressive Disorder

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

52. Risperidone Oral/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for risperidone. Risperidone is approved for the treatment of schizophrenia in patients 13 years and older, acute manic or mixed episodes associated with bipolar I disorder in patients 10 years of age and older, and irritability associated with autistic disorder in patients 5 years of age and older. The long-term safety and efficacy of this agent in the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Risperidone Oral		Schizophrenia Bipolar I Disorder, Manic & Mixed Episodes Irritability Autistic Disorder

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

53. Risperidone LA Injection/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of Risperdal Consta (risperidone long-acting injection). Risperidone long-acting injection is approved for the treatment of schizophrenia and bipolar I disorder. The long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Risperidone LA Inj		Schizophrenia Bipolar I Disorder

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

54. Risperidone ER Suspension Inj/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of Rykindo (risperidone extended-release injectable suspension). Risperidone extended-release injectable suspension is approved for the treatment of adults with schizophrenia and bipolar I disorder. The long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Risperidone ER Susp Inj		Schizophrenia
		Bipolar I Disorder

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

55. Risperidone ER Subcutaneous Inj/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of Uzedy (risperidone extended-release subcutaneous injectable suspension). Risperidone ER subcutaneous injectable suspension is approved in adults for the treatment of schizophrenia and bipolar I disorder. The long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Risperidone ER SubQ Inj.		Schizophrenia
		Bipolar I Disorder

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

56. Risperidone ER Subcutaneous Inj/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of Perseris (risperidone extended-release subcutaneous injectable suspension). Risperidone ER subcutaneous injectable suspension is approved for the treatment of

schizophrenia in adults. The long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Risperidone ER SubQ Inj.		Schizophrenia

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

57. Ziprasidone Oral/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of oral ziprasidone. Ziprasidone oral capsules are approved for the treatment of adults with schizophrenia, acute treatment of adults with manic or mixed episodes associated with bipolar I disorder, and as adjunct to lithium or valproate for the maintenance treatment of bipolar I disorder in adults. The long-term safety and efficacy of this agent in the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Ziprasidone Caps		Schizophrenia Bipolar I Disorder

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

58. Ziprasidone Injection/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of ziprasidone injection. Ziprasidone injection is approved for the treatment of acute agitation in schizophrenia in adults. The long-term safety and efficacy of this agent in the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Ziprasidone Inj		Schizophrenia

Age Range: 19 – 999 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

59. Fluphenazine Oral/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of fluphenazine. Fluphenazine is approved for the treatment of manifestations of psychotic disorders. The long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Fluphenazine Oral		Delusional Disorders
		Schizophrenia
		Schizoaffective Disorder
		Schizotypal Disorder
		Other or Unspecified Psychotic Disorders

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Fluphenazine Hydrochloride Tablets, Nov. 2024, ANI Pharmaceuticals, Inc.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

60. Fluphenazine Decanoate Inj/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of fluphenazine decanoate injections. Fluphenazine decanoate is approved for the treatment of schizophrenia. The long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Fluphenazine Decanoate		Schizophrenia

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Fluphenazine Decanoate Injection, Jan. 2025, Hikma Pharmaceuticals USA Inc.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

61. Chlorpromazine/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of chlorpromazine. Chlorpromazine is approved for the treatment of schizophrenia, psychotic disorders, intractable hiccups, nausea and vomiting, acute intermittent porphyria, tetanus, manic-depressive illness, and restlessness and apprehension before surgery. It is also

approved for severe behavioral problems in children 1 to 12 years of age marked by combativeness and/or explosive hyperexcitable behavior, and in the short-term treatment of hyperactive children who show excessive motor activity with accompanying conduct disorders. The long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Chlorpromazine		Schizophrenia
		Psychotic Disorders
		Intractable Hiccups
		Nausea & Vomiting
		Acute Intermittent Porphyria
		Treatment of Tetanus
		Manic-Depressive Illness
		Restless and Apprehension Before Surgery
		Conduct Disorders
		ADHD

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Chlorpromazine Hydrochloride Tablet, June 2025, Aurobindo Pharma Limited.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

62. Chlorpromazine Injection/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of chlorpromazine injection. Chlorpromazine injection is approved for the treatment of schizophrenia, psychotic disorders, intractable hiccups, nausea and vomiting, acute intermittent porphyria, tetanus, manic-depressive illness, and restlessness and apprehension before surgery. It is also approved for severe behavioral problems in children 1 to 12 years of age marked by combativeness and/or explosive hyperexcitable behavior, and in the short-term treatment of hyperactive children who show excessive motor activity with accompanying conduct disorders. The long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Chlorpromazine Injection		Schizophrenia
		Psychotic Disorders
		Intractable Hiccups
		Nausea & Vomiting
		Acute Intermittent Porphyria
		Treatment of Tetanus
		Manic-Depressive Illness
		Restless and Apprehension Before Surgery
		Conduct Disorders

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Chlorpromazine Hydrochloride Injection, Nov. 2024, Camber Pharmaceuticals, Inc.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

63. Haloperidol Oral/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of haloperidol. Haloperidol is approved for the treatment of manifestations of psychotic disorders, tic and vocal utterances of Tourette's disorder in children and adults, severe behavioral problems in children with combative, explosive hyperexcitability, and hyperactivity in children who show excessive motor activity with accompanying conduct disorders. The long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Haloperidol Oral		Delusional Disorders
		Conduct Disorders
		Schizophrenia
		ADHD
		Schizoaffective Disorder
		Schizotypal Disorder
		Other or Unspecified Psychotic Disorders
		Tourette's Disorder

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

64. Haloperidol Decanoate Inj/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of haloperidol decanoate injection. Haloperidol decanoate is approved for the treatment of schizophrenia. The long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Haloperidol Decanoate		Schizophrenia

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

65. Haloperidol Lactate Inj/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of haloperidol lactate injection. Haloperidol lactate injection is approved for the treatment of schizophrenia. The long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Haloperidol Lactate		Schizophrenia

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

66. Loxapine Oral/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of oral loxapine. Oral loxapine is approved for the treatment of schizophrenia in adults. The long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Loxapine Oral		Schizophrenia

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

67. Loxapine Nasal/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of Adasuve (loxapine inhalation). Loxapine inhalation is approved for the acute treatment of agitation associated with schizophrenia and bipolar I disorder in adults. The long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Loxapine Nasal		Schizophrenia
		Bipolar I Disorder

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

68. Molindone/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of molindone. Molindone is approved for the treatment of schizophrenia. The long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Molindone		Schizophrenia

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

69. Perphenazine/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of perphenazine. Perphenazine is approved for the treatment of schizophrenia and nausea and vomiting. The long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Perphenazine		Schizophrenia
		Nausea & Vomiting

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

70. Perphenazine-Amitriptyline/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of perphenazine/amitriptyline. Perphenazine/amitriptyline is approved for the treatment of schizophrenia with depressive symptoms. It is also approved to treat patients with moderate to severe anxiety and /or agitation and depressed mood, depression in whom anxiety and/or agitation are severe, and depression and anxiety in association with chronic physical disease. The long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Perphenazine/Amitriptyline		Schizophrenia w/ Depressive
		Major Depressive Disorder
		Anxiety Disorders

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

71. Pimozide/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of pimozide. Pimozide is approved for the treatment of motor and phonic tics in patients with Tourette's disorder. The long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Pimozide		Tourette's Disorder

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

72. Prochlorperazine Oral/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of prochlorperazine. Prochlorperazine is approved for the treatment of schizophrenia, anxiety, and nausea and vomiting. The long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Prochlorperazine Oral		Anxiety

Nausea & Vomiting
Schizophrenia

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

73. Prochlorperazine Edisylate Inj/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of prochlorperazine edisylate injection. Prochlorperazine edisylate injection is approved for the treatment of schizophrenia and nausea and vomiting. The long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Prochlorperazine		Schizophrenia
		Nausea & Vomiting

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

74. Thioridazine/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of thioridazine. Thioridazine is approved for the treatment of schizophrenia. The long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Thioridazine		Schizophrenia

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

75. Thiothixene/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of thiothixene. Thiothixene is approved for the treatment of schizophrenia. The long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Thiothixene		Schizophrenia

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

76. Trifluoperazine/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of trifluoperazine. Trifluoperazine is approved for the treatment of schizophrenia and anxiety. The long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Conflict Code: TA - Therapeutic Appropriateness

Drugs/Diseases

Util A	Util B	Util C (Negate)
Trifluoperazine		Schizophrenia
		Anxiety

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

77. Xanomeline-Trospium/Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of Cobenfy (xanomeline/trospium). Xanomeline/Trospium is approved for the treatment of schizophrenia. The long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Xanomeline/Trospium		Schizophrenia

Age Range: 19 – 999 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

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?