North Dakota Medicaid

Drug Utilization Review Board Meeting

June 5, 2024

Conference Room 210/212

NORTH Dakota Be Legendary. | Health & Human Services

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Be Legendary.

Meeting Notice

North Dakota Medicaid Drug Use Review Board

Wednesday, June 5th, 2024
1 to 4 p.m. Central Time

In-Person Information

Conference Room 210/212, 2nd Floor, Judicial Wing, 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: 876 672 920 #

Agenda

1. Call to Order
2. Roll Call
3. Review and Approval of Minutes
4. Reports from Department
    - Administrative Report: Utilization Review
    - Financial Report: Top Drugs
    - Retrospective DUR Report
    - Clinical Report:
        - Prior Authorization Update
        - Criteria updates: Food Allergy (Xolair), Peanut Allergy (Palforzia), Reduce Risk of Major Adverse Cardiovascular Events (Wegovy), Pulmonary Hypertension (Winrevair), Tardive Dyskinesia (Ingrezza, Austedo)
5. Special Orders: Presiding Officer and Vice-Presiding Officer Elections
6. Unfinished Business: Update to Hyperkalemia
7. New business
    - Second Review of Acid Blockers (Voquezna)
    - Second Review of Seborrheic Dermatitis (Zoryve)
    - Second Review of Primary Hyperoxaluria Type 1 (Rivfloza)
    - Second Review of Myasthenia Gravis (Zilbrysq)
    - Second Review of Duchenne Muscular Dystrophy (Emflaza, Agamree)
    - Second Review of Paroxysmal Nocturnal Hemoglobinuria (Empaveli, Fabhalta)
    - First Review of Molluscum Contagiosum (Ycanth and Zelsuvmi)
    - First Review of Epidermolysis Bullosa (Filsuvez)
    - First Review of Metabolic Dysfunction–Associated Steatohepatitis (Rezdiffra)
    - Review of retrospective DUR criteria recommendations
8. Announcements: Next Meeting (September 4, 2024)
9. 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: March 6th, 2024
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 1:04 pm CST with A. Honeyman presiding as Presiding Officer. DUR Board Coordinator, C. Stauter recording minutes.

Roll Call:
Board Members Voting:
Present: Stephanie Antony, Gabriela Balf, Amanda Dahl, Kurt Datz, Andrea Honeyman, Laura Kroetsch, Kevin Martian, Kristen Peterson
Absent: Josh Askvig, Jennifer Iverson, Tanya Schmidt, Amy Werremeyer
Quorum Present: Yes

Board Members Non-Voting:
Absent: Kathleen Traylor

Medicaid Pharmacy Department:
Present: Jeff Hostetter, Brendan Joyce, Alexi Murphy, LeNeika Roehrich

Approval of Meeting Minutes:
Motion: Moved by K. Martian to approve the minutes of the December 6th, 2023 meeting, motion was seconded by K. Peterson. **Motion carried.**
The minutes of the December 6th, 2023 meeting were approved as distributed.

Reports:
*Administrative Report***:** *Member Update* provided by C. Stauter
C. Stauter introduced the new Board Member A. Dahl.

*Administrative Report***:** by A. Murphy
A. Murphy shared with the Board changes to distribution and patient assistance programs for COVID-19 treatments (Lagevrio and Paxlovid), information regarding a special mailing for prescriber PDMP utilization, and updated to covered agents for antipsychotic induced weight gain. This information can be found in the handout.

Financial Report: Budget provided by B. Joyce
B. Joyce shared with the Board trends of pharmacy claims from Quarter 1 2019 until Quarter 1 2023 for cost drivers and other classes. This information can be found in the handout.

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

Retrospective Drug Utilization Review (RDUR) Report by C. Stauter
C. Stauter reviewed the quarterly RDUR criteria that were selected for review of each month. This material can be found in the handout.

Clinical Report: Prior Authorization and Criteria Updates by C. Stauter
C. Stauter presented prior authorization and criteria updates with emphasis on the following sections in the PDL: inhaled corticosteroids, tardive dyskinesia, and phenylketonuria. The presented information can be found in the handout.

Unfinished business:
Criteria Updates provided by C. Stauter
C. Stauter presented criteria updates with emphasis on the following sections in the PDL: hyperkalemia, prophylaxis to migraine, eczema/atopic dermatitis, and cholestatic pruritis. The presented material can be found in the handout. Testimony was provided by the following: Christine Dubé from Astrazeneca on Lokelma, Erin Nowak from Abbvie on Rinvoq, and Phong Pham from Ipsen Biopharmaceuticals on Bylvay.

New business:
First Reviews presented by C. Stauter
C. Stauter presented an overview of acid blockers (Voquezna), seborrheic dermatitis (Zoryve), primary hyperoxaluria type 1 (Rivfloza), myasthenia gravis (Zilbrysq), Duchenne muscular dystrophy (Emflaza, Agamree), and paroxysmal nocturnal hemoglobinuria (Empaveli, Fabhalta). The presented material can be found in the handout. Testimony was provided by Jamie Tobitt from Apellis Pharmaceuticals on Empaveli and Shirley Quach from Novartis on Fabhalta.
Motion: Moved by K. Peterson to draft prior authorization for acid blockers, motion was seconded by A. Dahl. **Motion carried.**
Motion: Moved by K. Martian to draft prior authorization for seborrheic dermatitis, motion was seconded by A. Honeyman. **Motion carried.**
Motion: Moved by K. Peterson to draft prior authorization for primary hyperoxaluria type 1, motion was seconded by K. Martian. **Motion carried.**
Motion: Moved by K. Martian to draft prior authorization for myasthenia gravis, motion was seconded by G. Balf. **Motion carried.**
Motion: Moved by A. Honeyman to draft prior authorization for Duchenne muscular dystrophy, motion was seconded by K. Martian. **Motion carried.**
Motion: Moved by K. Martian to draft prior authorization for paroxysmal nocturnal hemoglobinuria, motion was seconded by K. Datz. **Motion carried.**

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

Announcements:
Next meeting is June 5th, 2024.

Adjournment:
Meeting adjourned by A. Honeyman at 2:22 pm CST.

Date of Minutes Approval:
Minutes submitted by: Claire Stauter, Acentra Health

Administrative Report

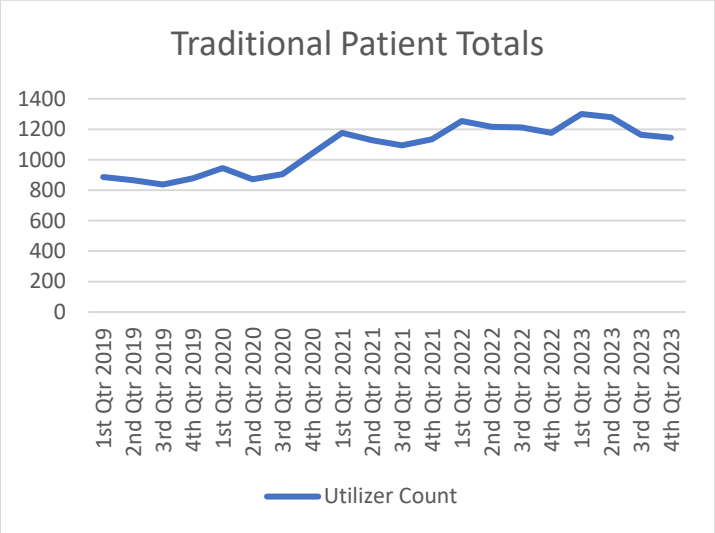
Utilization Review

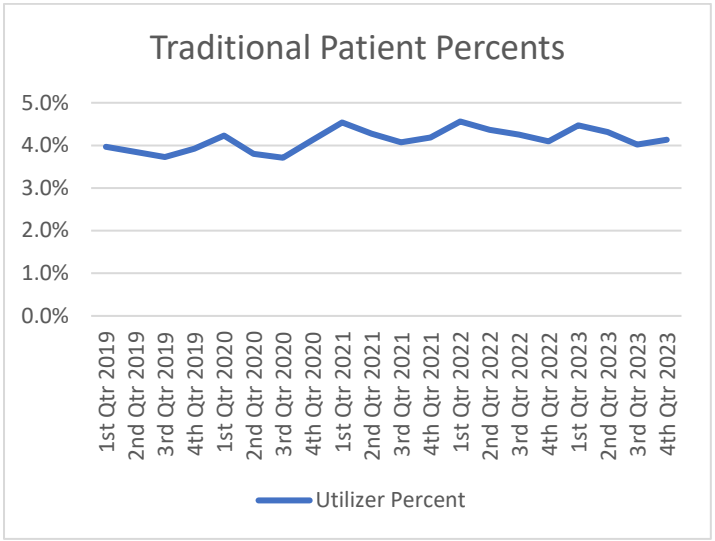
The following graphs depict pharmacy claims utilization of various agents for the specified indications. Pharmacy data is not available for expansion members in 2019.

Antidepressants: Pediatric Females (Ages 0-17)

Chua, Kao-Ping, et al. "Antidepressant dispensing to US adolescents and young adults: 2016–2022." *Pediatrics* 153.3 (2024).

- Data assessed antidepressant prescribing trends in teens and young adults from 2016 to 2022.
- After March 2020, the prescribing rate of antidepressants among female adolescents ages 12-17 increased 130% faster than prior to March 2020.





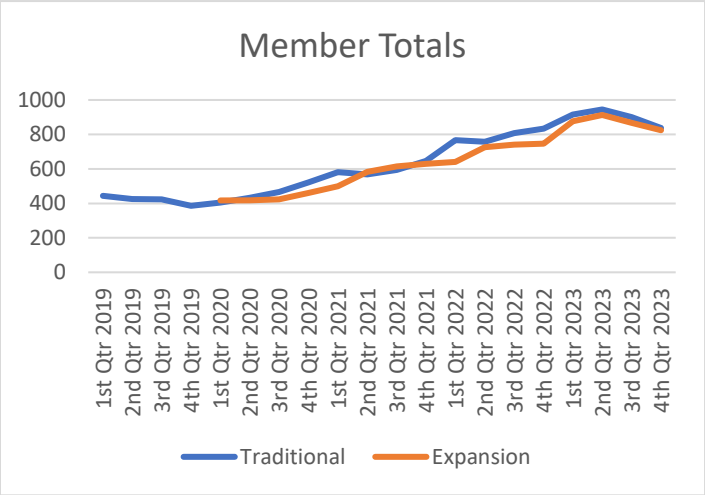
Quarter	Eligible Members	Number of Patients	Percent of Patients
2019 Q1	22,332	886	4.0%
2019 Q2	22,468	865	3.8%
2019 Q3	22,455	837	3.7%
2019 Q4	22,351	877	3.9%
2020 Q1	22,360	945	4.2%
2020 Q2	22,959	872	3.8%
2020 Q3	24,396	905	3.7%
2020 Q4	25,257	1,042	4.1%
2021 Q1	25,890	1,175	4.5%
2021 Q2	26,400	1,128	4.3%
2021 Q3	26,904	1,095	4.1%
2021 Q4	27,099	1,135	4.2%
2022 Q1	27,496	1,254	4.6%
2022 Q2	27,845	1,216	4.4%
2022 Q3	28,457	1,211	4.3%
2022 Q4	28,746	1,176	4.1%
2023 Q1	29,093	1,300	4.5%
2023 Q2	29,706	1,280	4.3%
2023 Q3	28,961	1,164	4.0%
2023 Q4	27,689	1,145	4.1%

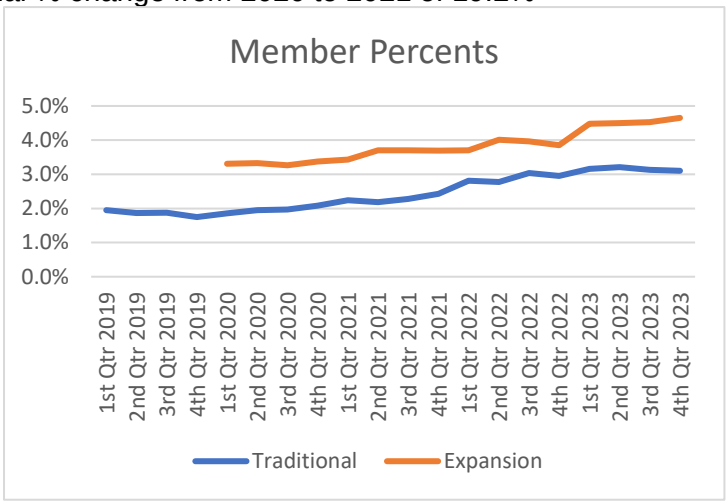
Eligible members: females aged 0-17 years old with traditional Medicaid

Attention-Deficit Hyperactivity Disorder: Adult Females (Ages 18+)

Danielson ML, Bohm MK, Newsome K, et al. Trends in Stimulant Prescription Fills Among Commercially Insured Children and Adults — United States, 2016–2021. MMWR Morb Mortal Wkly Rep 2023;72:327–332. DOI: http://dx.doi.org/10.15585/mmwr.mm7213a1

- Data published by the CDC evidences a rise in ADHD prescriptions during the COVID-19 pandemic, particularly in females aged 15 to 54 and males aged 30 to 39.
- For example, the average annual % change for females aged 20-24 saw an average annual % change from 2016 to 2020 of -1.8% in contrast to the annual % change from 2020 to 2021 of 19.2%





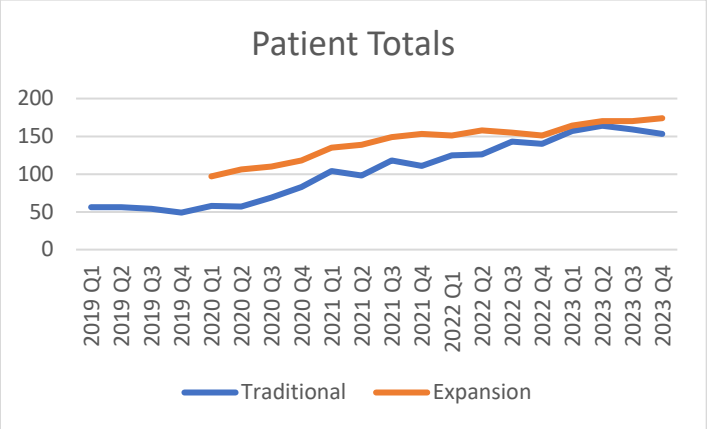
Quarter	Exp Eligible Members	Exp Number of Members	Exp Percent of Members	Trad Eligible Members	Trad Number of Members	Trad Percent of Members
2019 Q1	12,448			22,773	444	1.9%
2019 Q2	12,609			22,807	426	1.9%
2019 Q3	12,580			22,561	423	1.9%
2019 Q4	12,726			22,093	386	1.7%
2020 Q1	12,588	417	3.3%	21,872	405	1.9%
2020 Q2	12,567	418	3.3%	22,260	433	1.9%
2020 Q3	12,992	424	3.3%	23,750	467	2.0%
2020 Q4	13,650	461	3.4%	25,075	521	2.1%
2021 Q1	14,539	499	3.4%	25,910	581	2.2%
2021 Q2	15,759	583	3.7%	25,977	568	2.2%
2021 Q3	16,571	614	3.7%	26,171	595	2.3%
2021 Q4	17,055	629	3.7%	26,573	646	2.4%
2022 Q1	17,298	640	3.7%	27,214	766	2.8%
2022 Q2	18,122	726	4.0%	27,368	758	2.8%
2022 Q3	18,686	741	4.0%	26,573	807	3.0%
2022 Q4	19,396	747	3.9%	28,244	834	3.0%
2023 Q1	19,564	877	4.5%	28,967	915	3.2%
2023 Q2	20,281	913	4.5%	29,448	945	3.2%
2023 Q3	19,163	867	4.5%	28,714	900	3.1%
2023 Q4	17,715	824	4.7%	27,003	837	3.1%

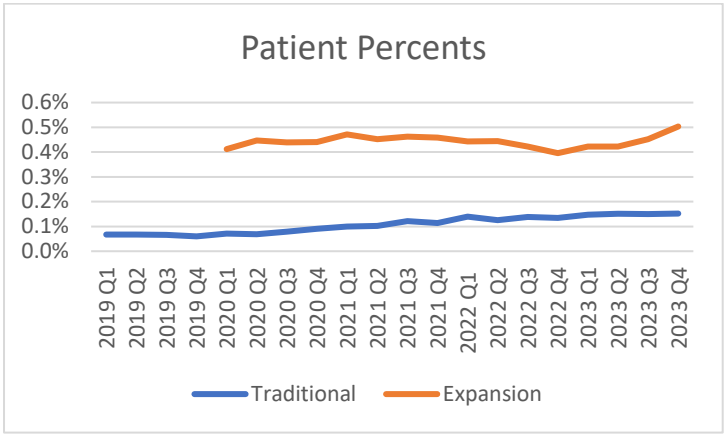
Eligible members: females aged 18+ years old

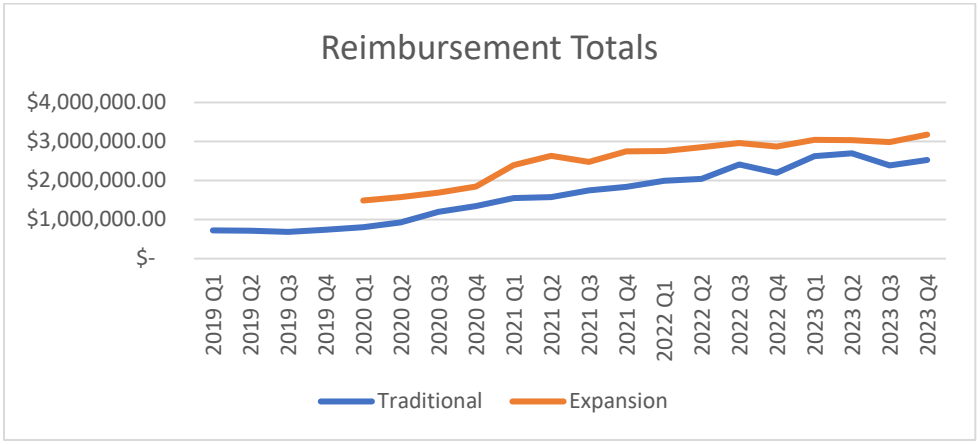
Cost Drivers

- Jornay PM - $75,745 (34% of methylphenidate spend) / 373 scripts (7.5% of methylphenidate utilization) = $203.07 per script (avg. $44.32/script for methylphenidate)

Biologics


Patient Totals
200
150
100
50
0
2019 Q1
2019 Q2
2019 Q3
2019 Q4
2020 Q1
2020 Q2
2020 Q3
2020 Q4
2021 Q1
2021 Q2
2021 Q3
2021 Q4
2022 Q1
2022 Q2
2022 Q3
2022 Q4
2023 Q1
2023 Q2
2023 Q3
2023 Q4
Traditional
Expansion


Patient Percents
0.6%
0.5%
0.4%
0.3%
0.2%
0.1%
0.0%
2019 Q1
2019 Q2
2019 Q3
2019 Q4
2020 Q1
2020 Q2
2020 Q3
2020 Q4
2021 Q1
2021 Q2
2021 Q3
2021 Q4
2022 Q1
2022 Q2
2022 Q3
2022 Q4
2023 Q1
2023 Q2
2023 Q3
2023 Q4
Traditional
Expansion


Reimbursement Totals
$4,000,000.00
$3,000,000.00
$2,000,000.00
$1,000,000.00
$-
2019 Q1
2019 Q2
2019 Q3
2019 Q4
2020 Q1
2020 Q2
2020 Q3
2020 Q4
2021 Q1
2021 Q2
2021 Q3
2021 Q4
2022 Q1
2022 Q2
2022 Q3
2022 Q4
2023 Q1
2023 Q2
2023 Q3
2023 Q4
Traditional
Expansion

Quarter	Exp Eligible Members	Exp Number of Members	Exp Percent of Members	Trad Eligible Members	Trad Number of Members	Trad Percent of Patients
2019 Q1	23,066			82,630	56	0.07%
2019 Q2	23,332			82,814	56	0.07%
2019 Q3	23,265			82,456	54	0.07%
2019 Q4	23,549			81,716	49	0.06%
2020 Q1	23,538	97	0.41%	81,479	58	0.07%
2020 Q2	23,730	106	0.45%	83,007	57	0.07%
2020 Q3	25,055	110	0.44%	87,997	69	0.08%
2020 Q4	26,774	118	0.44%	91,726	83	0.09%
2021 Q1	28,663	135	0.47%	104,590	104	0.10%
2021 Q2	30,783	139	0.45%	95,587	98	0.10%
2021 Q3	32,259	149	0.46%	96,987	118	0.12%
2021 Q4	33,358	153	0.46%	98,028	111	0.11%
2022 Q1	34,074	151	0.44%	89,583	125	0.14%
2022 Q2	35,545	158	0.44%	100,977	126	0.12%
2022 Q3	36,736	155	0.42%	103,217	143	0.14%
2022 Q4	38,149	151	0.40%	104,533	140	0.13%
2023 Q1	38,879	164	0.42%	106,361	157	0.15%
2023 Q2	40,269	170	0.42%	108,369	164	0.15%
2023 Q3	37,649	170	0.45%	105,759	159	0.15%
2023 Q4	34,569	174	0.50%	100,691	153	0.15%

New Cost Drivers:

4Q23

- Stelara - $454,415 for 20 scripts / 13 members = $22,720 per script (every 2-3 months)
- Skyrizi - $257,467 for 14 scripts / 14 members = $18,390 per script (every 2-3 months)
- Tremfya - $116,857 for 9 scripts / 5 members = $12,984 per script (every 2 months)
- **= $828,739 per quarter for 43 scripts / 32 members**

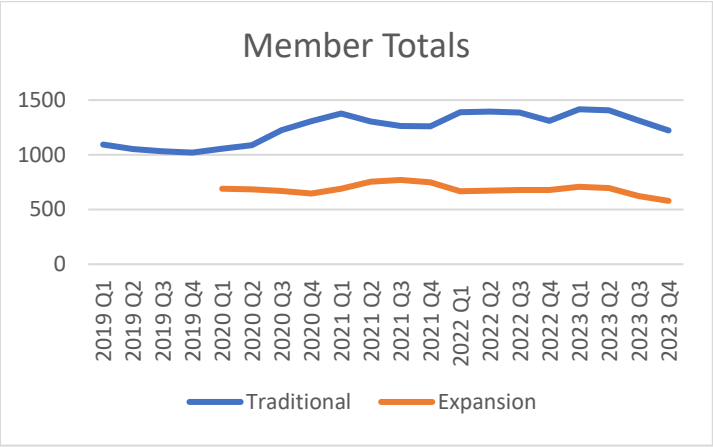
1Q20

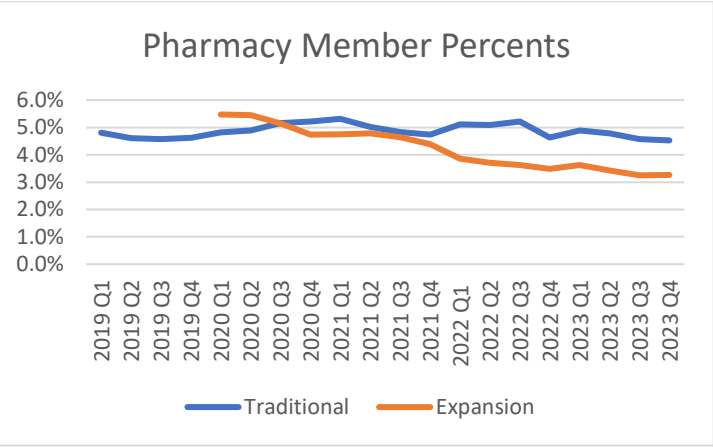
- Stelara – $73,107 for 5 scripts / 4 members = $14,621 per script (every 2-3 months)
- Skyrizi - 0 scripts / 0 members
- Tremfya – $11,404 for 1 script / 1 member = $11,404 for 1 script (every 2 months)
- **= $84,511 per quarter for 6 scripts / 5 members**

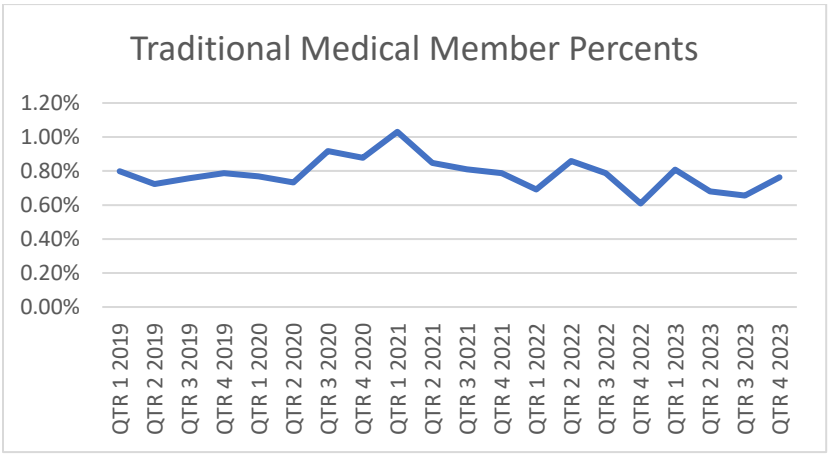
Contraceptives

Steenland, Maria W., et al. "Declines in contraceptive visits in the United States during the COVID-19 pandemic." *Contraception* 104.6 (2021): 593-599.

- Data has shown that the % decline in contraceptive visits between 2019 and April 2020 decreased and remained low through December 2020.
- Comparing levels in December 2019 with those in December 2020, the change in contraceptive visits was -18% for tubal ligation -11% for injectable contraceptives, -6% for LARC, and -5% for pill, patch and ring visits







Pharmacy Utilization

Quarter	Exp Eligible Members	Exp Number of Members	Exp Percent of Members	Trad Eligible Members	Trad Number of Members	Trad Percent of Members
2019 Q1	12,448			22,773	1,095	4.8%
2019 Q2	12,609			22,807	1,052	4.6%
2019 Q3	12,580			22,561	1,032	4.6%
2019 Q4	12,726			22,093	1,020	4.6%
2020 Q1	12,588	689	5.5%	21,872	1,055	4.8%
2020 Q2	12,567	685	5.5%	22,260	1,089	4.9%
2020 Q3	12,992	669	5.1%	23,750	1,224	5.2%
2020 Q4	13,650	646	4.7%	25,075	1,307	5.2%
2021 Q1	14,539	690	4.7%	25,910	1,377	5.3%
2021 Q2	15,759	754	4.8%	25,977	1,304	5.0%
2021 Q3	16,571	770	4.6%	26,171	1,264	4.8%
2021 Q4	17,055	749	4.4%	26,573	1,260	4.7%
2022 Q1	17,298	667	3.9%	27,214	1,390	5.1%

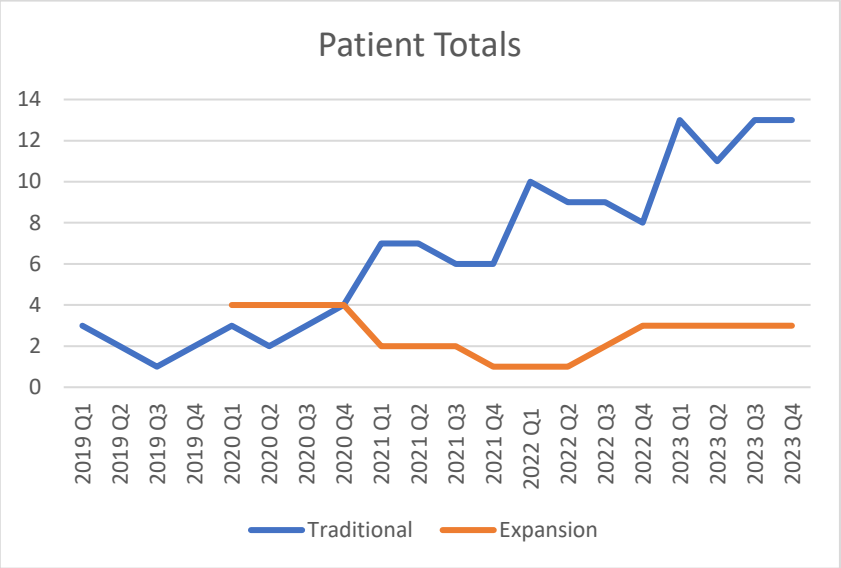
2022 Q2	18,122	673	3.7%	27,368	1,394	5.1%
2022 Q3	18,686	677	3.6%	26,573	1,386	5.2%
2022 Q4	19,396	677	3.5%	28,244	1,309	4.6%
2023 Q1	19,564	709	3.6%	28,967	1,416	4.9%
2023 Q2	20,281	696	3.4%	29,448	1,408	4.8%
2023 Q3	19,163	623	3.3%	28,714	1,314	4.6%
2023 Q4	17,715	579	3.3%	27,003	1,222	4.5%

Eligible members: females aged 18+ years old; IUD's included

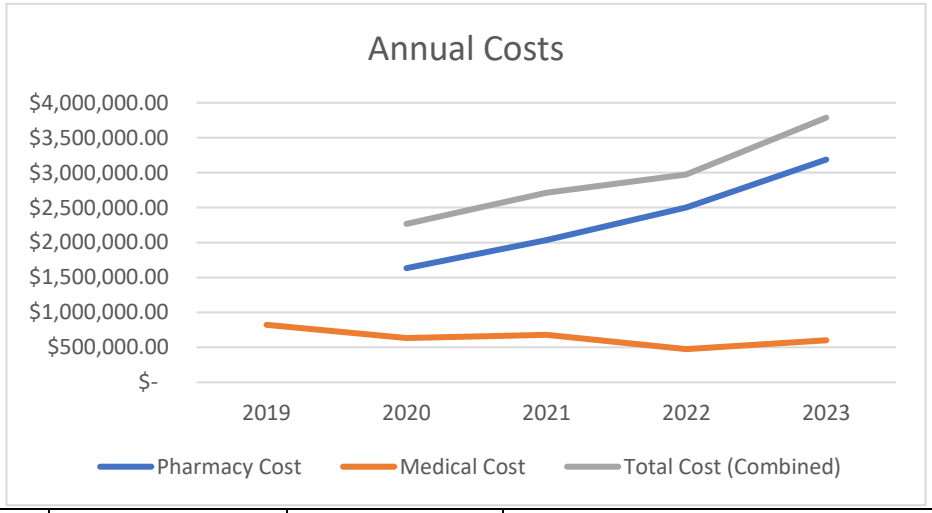
Medical Utilization

Quarter	Service Count	Trad Number of Members	Trad Percent of Members
QTR 1 2019	182	22,773	0.80%
QTR 2 2019	165	22,807	0.72%
QTR 3 2019	171	22,561	0.76%
QTR 4 2019	174	22,093	0.79%
QTR 1 2020	168	21,872	0.77%
QTR 2 2020	163	22,260	0.73%
QTR 3 2020	218	23,750	0.92%
QTR 4 2020	220	25,075	0.88%
QTR 1 2021	267	25,910	1.03%
QTR 2 2021	220	25,977	0.85%
QTR 3 2021	212	26,171	0.81%
QTR 4 2021	209	26,573	0.79%
QTR 1 2022	188	27,214	0.69%
QTR 2 2022	235	27,368	0.86%
QTR 3 2022	209	26,573	0.79%
QTR 4 2022	172	28,244	0.61%
QTR 1 2023	234	28,967	0.81%
QTR 2 2023	200	29,448	0.68%
QTR 3 2023	188	28,714	0.65%
QTR 4 2023	206	27,003	0.76%

Cystic Fibrosis



	Exp Number of Patients	Trad Number of Patients
2019 Q1		3
2019 Q2		2
2019 Q3		1
2019 Q4		2
2020 Q1	4	3
2020 Q2	4	2
2020 Q3	4	3
2020 Q4	4	4
2021 Q1	2	7
2021 Q2	2	7
2021 Q3	2	6
2021 Q4	1	6
2022 Q1	1	10
2022 Q2	1	9
2022 Q3	2	9
2022 Q4	3	8
2023 Q1	3	13
2023 Q2	3	11
2023 Q3	3	13
2023 Q4	3	13

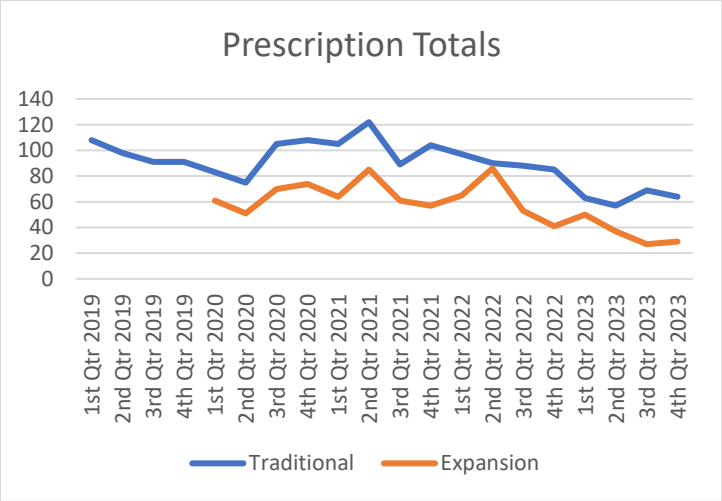


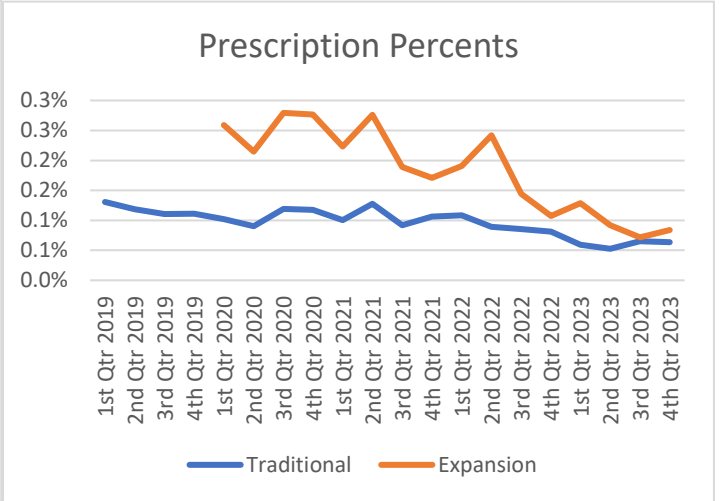
	Pharmacy Cost	Medical Cost	Total Cost (Pharmacy and Medical)
2019		$822,730.61	
2020	$1,633,456.80	$633,385.61	$2,266,842.41
2021	$2,033,262.88	$681,236.36	$2,714,499.24
2022	$2,500,280.01	$474,927.74	$2,975,207.75
2023	$3,186,849.04	$599,749.13	$3,786,598.17

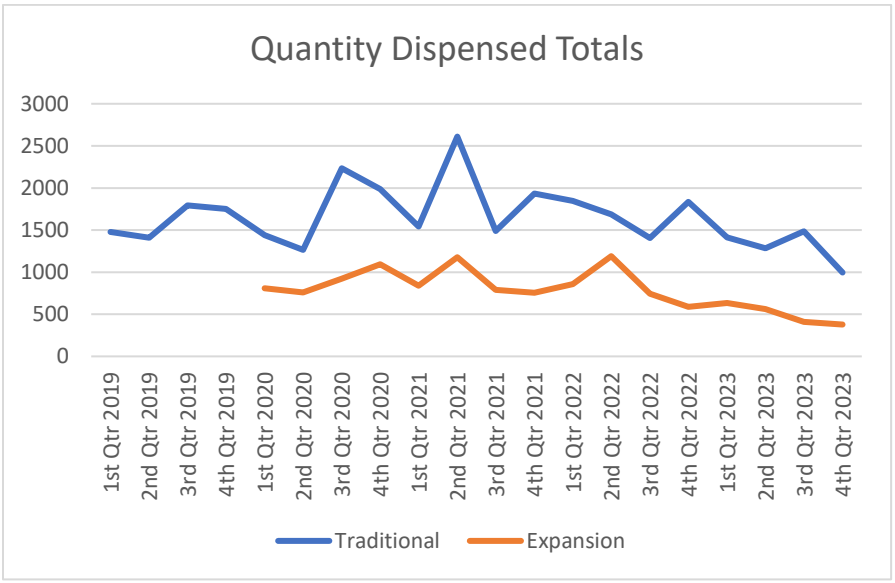
Pharmacy costs do not include costs for expansion members in 2019, so pharmacy claims have been omitted for 2019. Cost data includes both traditional and expansion members.

Dentist Prescribed Opioid Analgesics

- Okunev, Ilya, Julie Frantsve-Hawley, and Eric Tranby. "Trends in national opioid prescribing for dental procedures among patients enrolled in Medicaid." *The Journal of the American Dental Association* 152.8 (2021): 622-630.
- “Although the trends revealed in the analysis show declining opioid prescription patterns, these results suggest that the overall rate is still too high and prescriptions are being written unnecessarily”



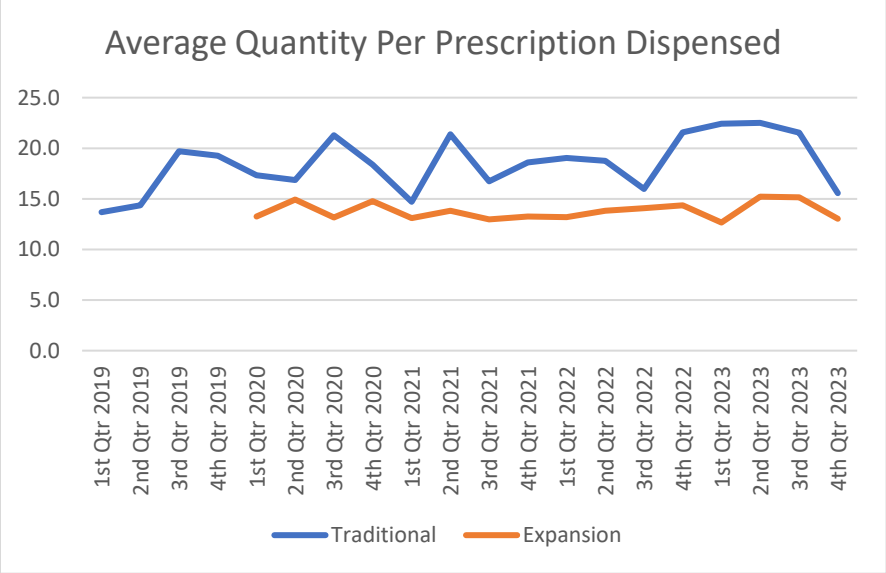




	Exp Eligible Members	Exp Number of Rx	Exp Percent of Members	Trad Eligible Members	Trad Number of Rx	Trad Percent of Members
2019 Q1	23,066			82,630	108	0.1%
2019 Q2	23,332			82,814	98	0.1%
2019 Q3	23,265			82,456	91	0.1%
2019 Q4	23,549			81,716	91	0.1%
2020 Q1	23,538	61	0.3%	81,479	83	0.1%
2020 Q2	23,730	51	0.2%	83,007	75	0.1%
2020 Q3	25,055	70	0.3%	87,997	105	0.1%
2020 Q4	26,774	74	0.3%	91,726	108	0.1%
2021 Q1	28,663	64	0.2%	104,590	105	0.1%
2021 Q2	30,783	85	0.3%	95,587	122	0.1%
2021 Q3	32,259	61	0.2%	96,987	89	0.1%

2021 Q4	33,358	57	0.2%	98,028	104	0.1%
2022 Q1	34,074	65	0.2%	89,583	97	0.1%
2022 Q2	35,545	86	0.2%	100,977	90	0.1%
2022 Q3	36,736	53	0.1%	103,217	88	0.1%
2022 Q4	38,149	41	0.1%	104,533	85	0.1%
2023 Q1	38,879	50	0.1%	106,361	63	0.1%
2023 Q2	40,269	37	0.1%	108,369	57	0.1%
2023 Q3	37,649	27	0.1%	105,759	69	0.1%
2023 Q4	34,569	29	0.1%	100,691	64	0.1%

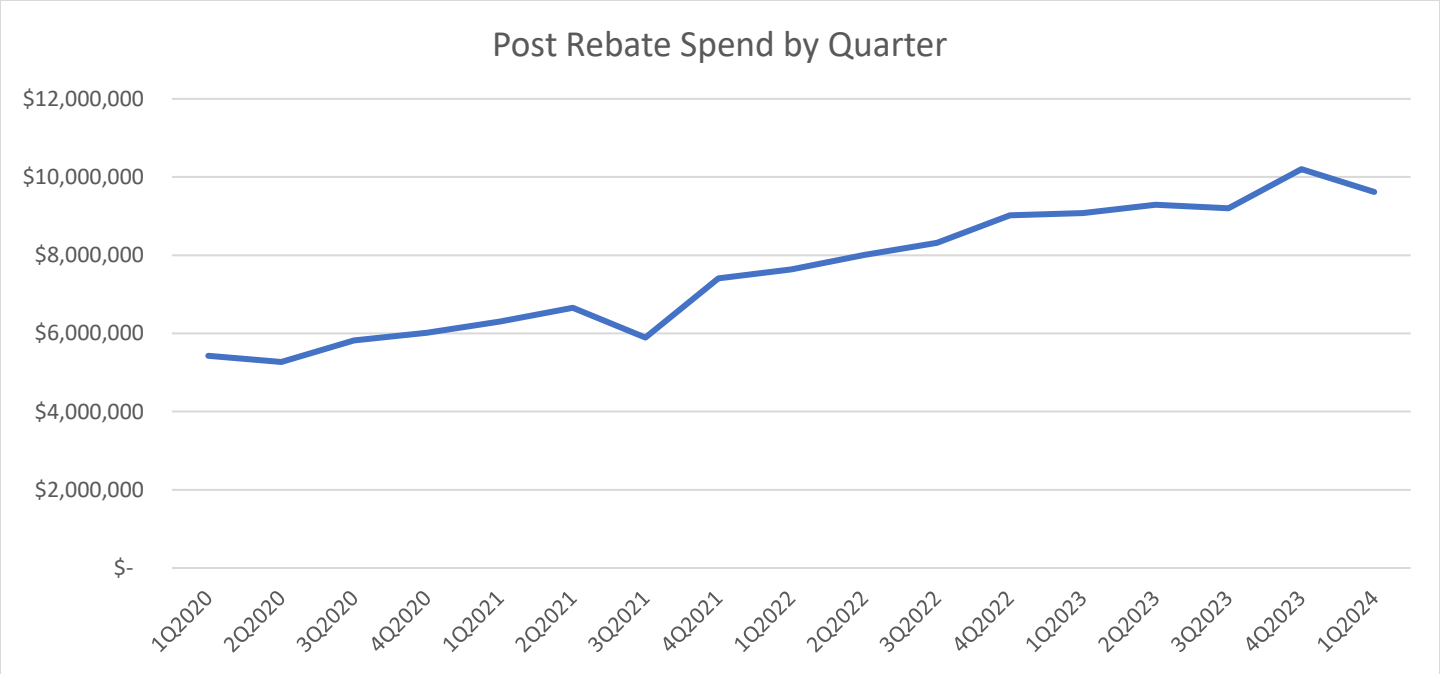
	Exp Quantity Dispensed	Exp Quantity Per Rx	Trad Quantity Dispensed	Trad Quantity Per Rx
2019 Q1			1,478	13.7
2019 Q2			1,408	14.4
2019 Q3			1,793	19.7
2019 Q4			1,753	19.3
2020 Q1	808	13.2	1,438	17.3
2020 Q2	761	14.9	1,265	16.9
2020 Q3	921	13.2	2,235	21.3
2020 Q4	1,092	14.8	1,985	18.4
2021 Q1	839	13.1	1,543	14.7
2021 Q2	1,176	13.8	2,610	21.4
2021 Q3	791	13.0	1,488	16.7
2021 Q4	755	13.2	1,934	18.6
2022 Q1	858	13.2	1,846	19.0
2022 Q2	1,190	13.8	1,687	18.7
2022 Q3	746	14.1	1,407	16.0
2022 Q4	589	14.4	1,833	21.6
2023 Q1	633	12.7	1,413	22.4
2023 Q2	563	15.2	1,283	22.5
2023 Q3	409	15.1	1,487	21.6
2023 Q4	378	13.0	996	15.6

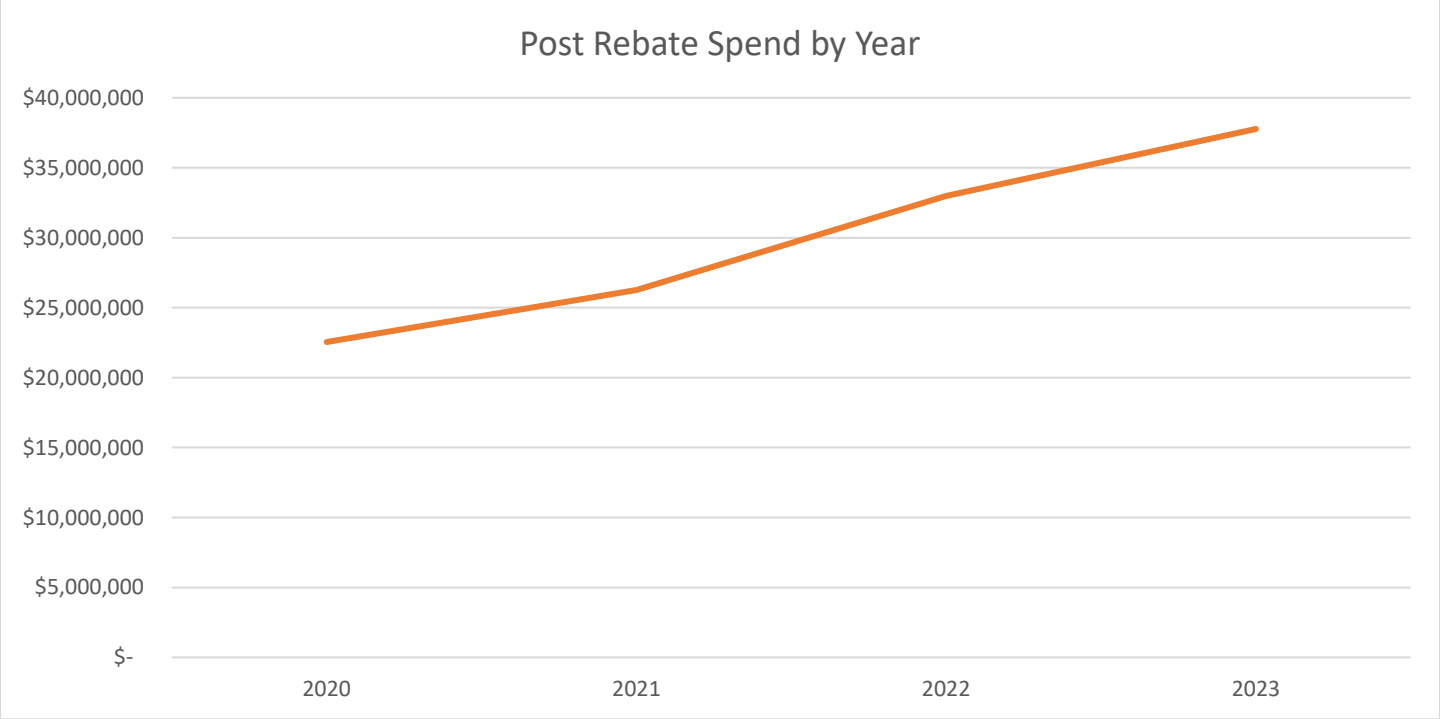


Financial Report

All graphs are only for traditional and expansion pharmacy claims.
ND Medicaid has experienced 67% growth in post rebate spend the past 4 years which equates to an increase of:

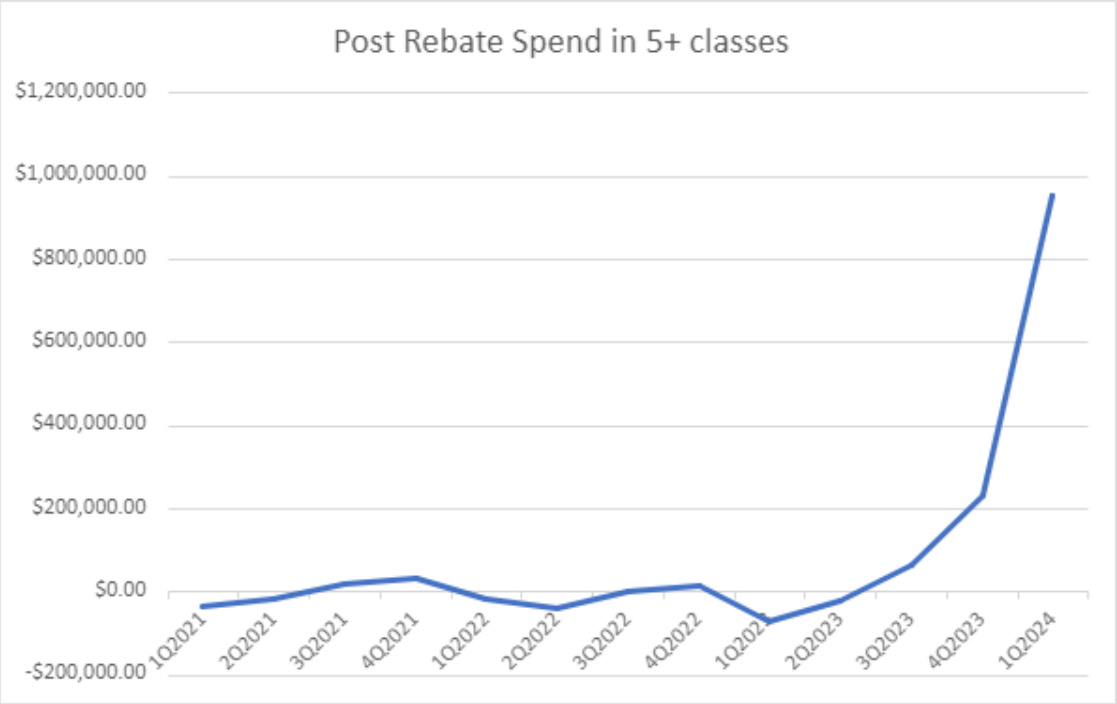
- $4.2 million dollar per quarter or $15.2 million per year



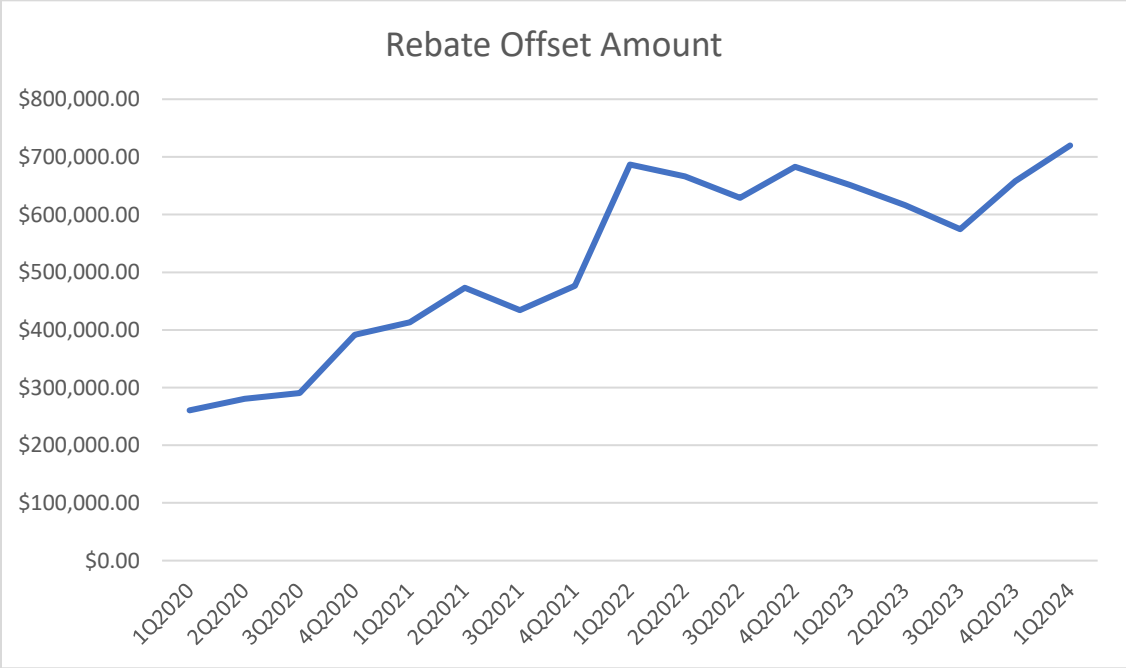


In addition to the long-term trend in growth due to increasing utilization of costly medication, there is additional increase in expenditure not fully captured in the above graphs due to rebate calculation changes.

AMP cap removal effect

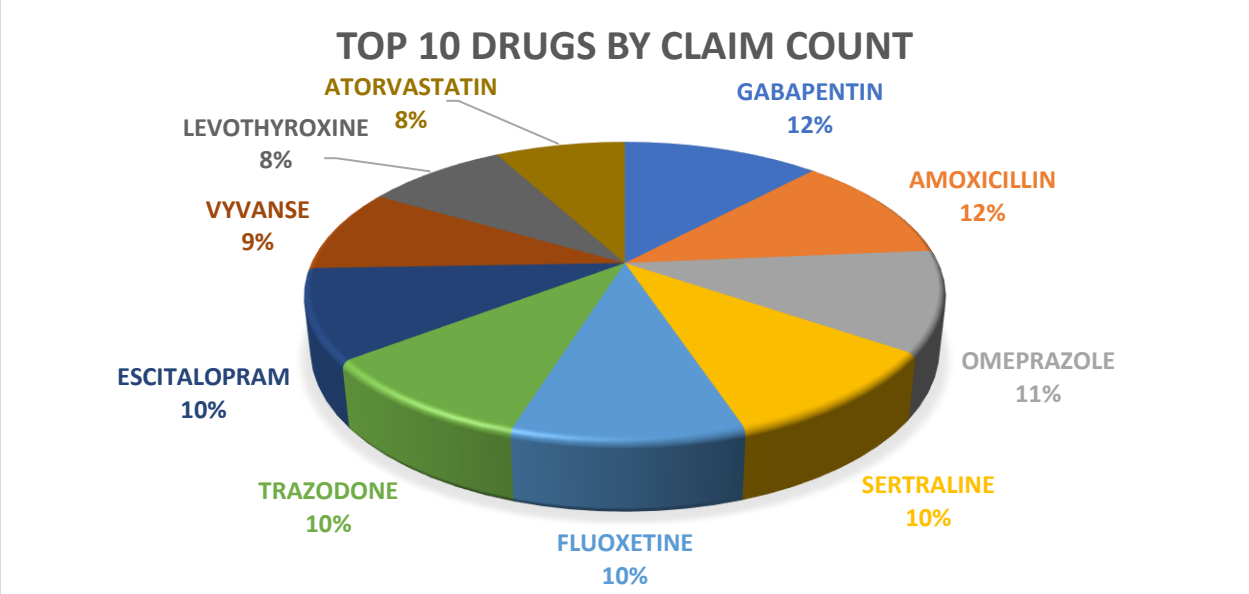


Offset Amount – Line Extension



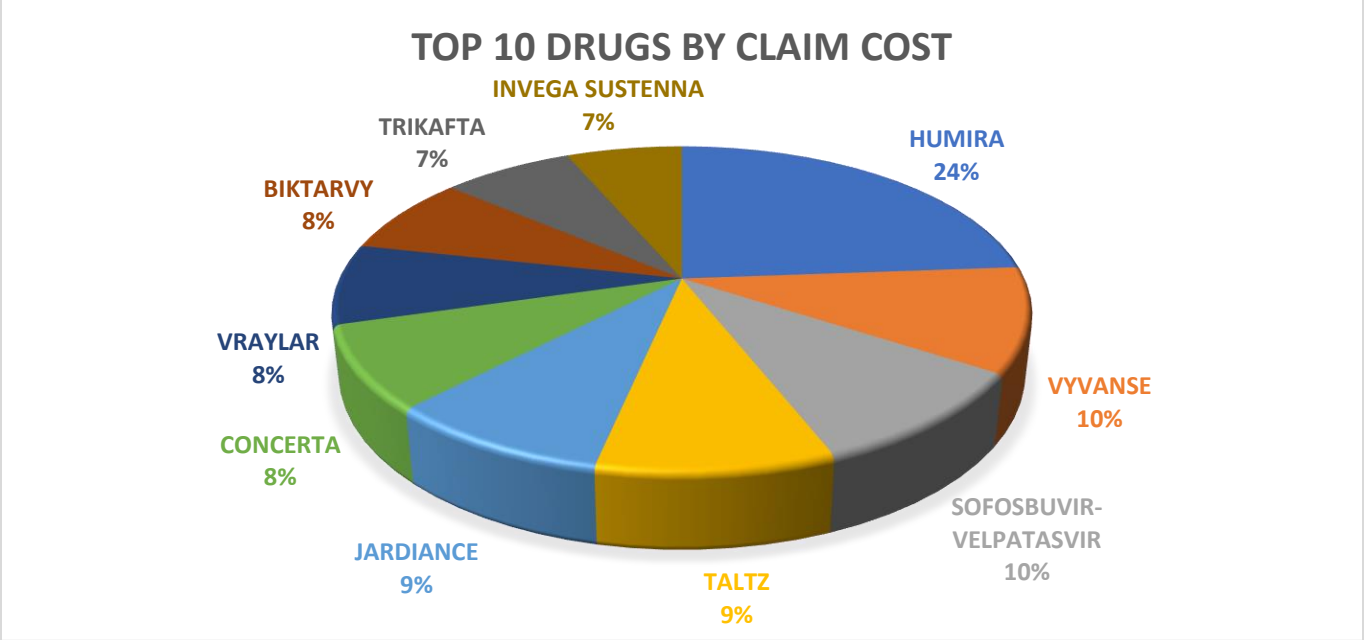
Top 25 Drugs Based on Number of Claims from 01/01/2024 – 03/31/2024

Drug	Claims	Claims Cost	Patients	Cost / Claim	% Claims	Dif.
1. GABAPENTIN	4,239	$62,373.24	1,828	$14.71	1.8%	NC
2. AMOXICILLIN	4,114	$62,936.07	3,844	$15.30	1.7%	↑2
3. OMEPRAZOLE	3,871	$49,806.16	2,048	$12.87	1.6%	↓1
4. SERTRALINE HCL	3,654	$49,168.72	2,091	$13.46	1.5%	↑1
5. FLUOXETINE HCL	3,530	$46,171.21	1,949	$13.08	1.5%	↑2
6. TRAZODONE HCL	3,471	$46,509.94	1,843	$13.40	1.5%	NC
7. ESCITALOPRAM	3,464	$46,348.87	1,984	$13.38	1.5%	↓2
8. VYVANSE	3,190	$916,793.04	1,318	$287.40	1.3%	↑2
9. LEVOTHYROXINE	3,049	$45,058.21	1,631	$14.78	1.3%	↓1
10. ATORVASTATIN	2,806	$40,698.63	1,696	$14.50	1.2%	↓1
11. LISINOPRIL	2,801	$37,352.72	1,755	$13.34	1.2%	↑1
12. BUPROPION XL	2,789	$45,312.46	1,529	$16.25	1.2%	↑1
13. VENTOLIN HFA	2,745	$175,538.27	2,718	$63.95	1.2%	↓2
14. CLONIDINE HCL	2,563	$31,530.10	1,299	$12.30	1.1%	↑3
15. PANTOPRAZOLE	2,493	$35,334.20	1,377	$14.17	1.0%	↑1
16. AMOXICILLIN-CLAV	2,491	$43,725.62	2,327	$17.55	1.0%	↓1
17. PREDNISONE	2,417	$28,013.17	1,943	$11.59	1.0%	↓1
18. LAMOTRIGINE	2,360	$33,408.82	995	$14.16	1.0%	↑2
19. DULOXETINE HCL	2,338	$38,576.15	1,290	$16.50	1.0%	NC
20. HYDROXYZINE HCL	2,311	$33,312.81	1,450	$14.41	1.0%	↑2
21. ONDANSETRON ODT	2,278	$32,090.57	1,828	$14.09	1.0%	↑3
22. ARIPIPRAZOLE	2,261	$33,381.55	1,120	$14.76	0.9%	↑3
23. HYDROCODONE-APAP	2,252	$33,166.82	1,435	$14.73	0.9%	↓5
24. CYCLOBENZAPRINE	2,226	$25,759.01	1,404	$11.57	0.9%	↓3
25. ADDERALL XR	2,112	$379,800.94	917	$179.83	0.9%	↑1
Total Claims						**238,051**



Top 25 Drugs Based on Total Claims Cost from 01/01/2024 – 03/31/2024

Drug	Claims	Claims Cost	Patients	Cost / Patient	% Cost	Dif.
1. HUMIRA	250	$2,103,532.98	114	$18,452.04	6.8%	NC
2. VYVANSE	3,190	$916,793.04	1,318	$695.59	2.9%	↑2
3. SOFOS-VELPATASVIR	37	$864,957.79	37	$23,377.24	2.8%	↑24
4. TALTZ	97	$823,407.50	50	$16,468.15	2.6%	↑1
5. JARDIANCE	1,054	$784,159.53	588	$1,333.60	2.5%	↑1
6. CONCERTA	2,045	$729,103.17	882	$826.65	2.3%	↑1
7. VRAYLAR	699	$704,788.32	294	$2,397.24	2.3%	↑3
8. BIKTARVY	309	$688,521.12	138	$4,989.28	2.2%	↑4
9. TRIKAFTA	33	$643,163.49	14	$45,940.25	2.1%	NC
10. INVEGA SUSTENNA	208	$568,689.32	91	$6,249.33	1.8%	↑3
11. NORDITROPIN	94	$540,683.17	41	$13,187.39	1.7%	↑4
12. DUPIXENT	150	$529,830.65	73	$7,257.95	1.7%	↓4
13. ENBREL	63	$436,395.60	28	$15,585.56	1.4%	↑7
14. ELIQUIS	661	$383,918.81	325	$1,181.29	1.2%	↑3
15. ADDERALL XR	2,112	$379,800.94	917	$414.18	1.2%	↑1
16. INGREZZA	47	$362,703.02	21	$17,271.57	1.2%	↑3
17. STELARA	16	$359,933.56	13	$27,687.20	1.2%	↓3
18. SKYRIZI	16	$319,976.58	14	$22,855.47	1.0%	↑8
19. SUBLOCADE	123	$247,649.47	66	$3,752.26	0.8%	↑6
20. ABILIFY MAINTENA	98	$242,013.93	43	$5,628.23	0.8%	↑4
21. SYMBICORT	981	$230,267.48	599	$384.42	0.7%	↓3
22. INVEGA TRINZA	27	$221,071.71	27	$8,187.84	0.7%	↑4
23. FARXIGA	333	$215,214.27	186	$1,157.07	0.7%	↑6
24. JIVI	2	$183,730.52	1	$183,730.52	0.6%	↑12
25. VENTOLIN HFA	2,745	$175,538.27	2,718	$64.58	0.6%	↑9
Total Claims Cost						**$31,129,344.12**



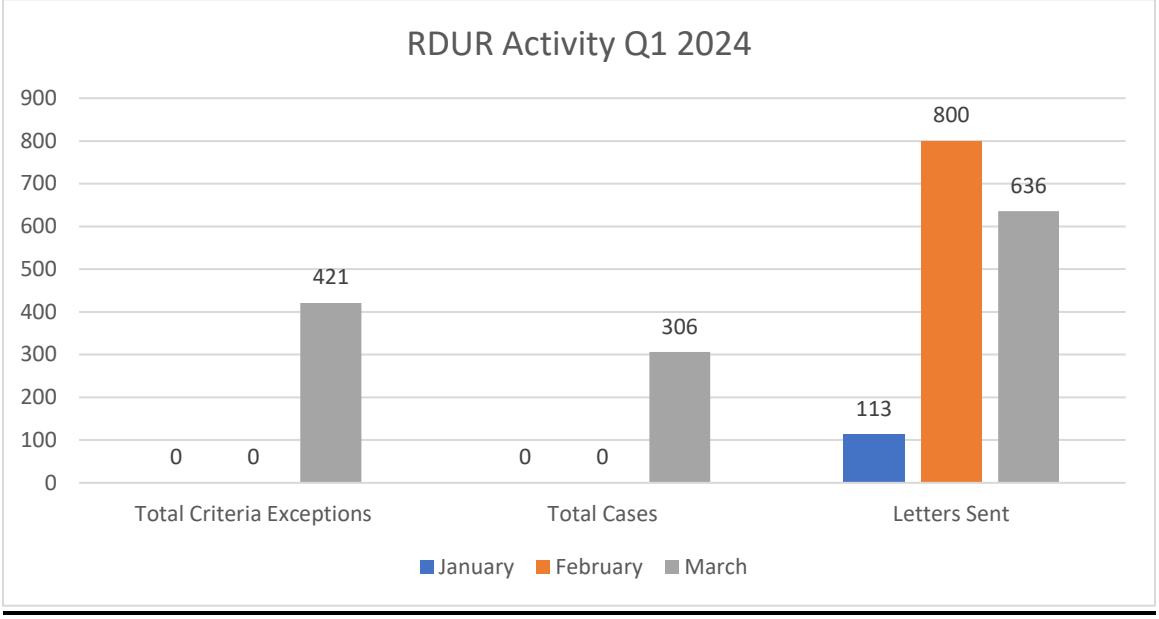
Top 15 Therapeutic Classes Based on Number of Claims from 01/01/2024 – 03/31/2024

Therapeutic Class Description	Claims	Claims Cost	Patients	Cost/Claim	% Claims	Dif.
1. ANTIDEPRESSANTS	25,951	$601,006.96	11,151	$23.16	10.9%	NC
2. ANTICONVULSANTS	12,924	$562,766.38	4,685	$43.54	5.4%	NC
3. ANTIPSYCHOTIC AGENTS	9,337	$2,405,679.06	3,802	$257.65	3.9%	NC
4. PENICILLIN ANTIBIOTICS	6,885	$111,290.27	6,116	$16.16	2.9%	↑2
5. ANXIOLYTICS, SEDATIVES, HYPNOTICS	6,828	$101,318.20	3,540	$14.84	2.9%	NC
6. PROTON-PUMP INHIBITORS	6,807	$161,366.00	3,610	$23.71	2.9%	↓2
7. AMPHETAMINES	6,737	$1,348,461.20	2,849	$200.16	2.8%	NC
8. RESP/CNS STIMULANTS	5,714	$997,464.73	2,183	$174.57	2.4%	↑2
9. OPIATE AGONISTS	5,652	$96,501.24	2,966	$17.07	2.4%	↓1
10. NSAIDS	5,590	$76,196.87	3,789	$13.63	2.3%	↓1
11. STATINS	5,046	$74,749.79	3,051	$14.81	2.1%	NC
12. BETA BLOCKING AGENTS	4,299	$71,517.60	2,462	$16.64	1.8%	NC
13. BETA AGONISTS	4,102	$231,639.81	3,718	$56.47	1.7%	↑1
14. ADRENALS	4,071	$55,788.34	3,242	$13.70	1.7%	↓1
15. BIGUANIDES	3,479	$48,266.58	2,055	$13.87	1.5%	NC

Top 15 Therapeutic Classes Based on Claims Cost from 01/01/2024 – 03/31/2024

Therapeutic Class Description	Claims	Claims Cost	Patients	Cost/Patient	% Cost	Dif.
1. DMARDS	492	$3,241,945.15	210	$15,437.83	10.4%	NC
2. ANTIPSYCHOTIC AGENTS	9,337	$2,405,679.06	3,802	$632.74	7.7%	NC
3. SKIN AGENTS	524	$1,788,798.46	297	$6,022.89	5.7%	NC
4. AMPHETAMINES	6,737	$1,348,461.20	2,849	$473.31	4.3%	↑3
5. ANTIRETROVIRALS	813	$1,307,586.66	308	$4,245.41	4.2%	↑4
6. ANTINEOPLASTIC AGENTS	548	$1,273,829.43	245	$5,199.30	4.1%	NC
7. INCRETIN MIMETICS	1,431	$1,065,462.24	705	$1,511.29	3.4%	↓2
8. SGLT2 INHIBITORS	1,474	$1,048,828.27	810	$1,294.85	3.4%	↑3
9. RESP/CNS STIMULANTS	5,714	$997,464.73	2,183	$456.92	3.2%	↑3
10. HCV ANTIVIRALS	38	$869,552.84	38	$22,882.97	2.8%	↓2
11. INSULINS	3,144	$669,578.43	1,307	$512.30	2.2%	↓7
12. CFTR CORRECTORS	33	$643,163.49	14	$45,940.25	2.1%	↑1
13. CORTICOSTEROIDS (RESP)	3,033	$628,082.92	1,863	$337.14	2.0%	↓3
14. PITUITARY	362	$627,479.21	158	$3,971.39	2.0%	↑1
15. ANTIDEPRESSANTS	25,951	$601,006.96	11,151	$53.90	1.9%	↓1

RDUR Report: Q1 2024



Exception Types:

Drug-drug conflicts: • Drug-drug interaction • Therapeutic duplication	**Overutilization:** • Overuse • High dose	**Clinical Appropriateness** • Therapeutic appropriateness
Drug-disease conflicts: • Drug-disease precaution, actual and inferred • Drug-drug and/or diagnosis	**Underutilization:** • Underuse	

January Special Mailing
113 letters sent to prescribers

Introduction

At the bottom of this report, you will see patients receiving multiple psychotropic medications concurrently in the past 120 days per pharmacy claims data. If multiple prescribers are involved, each will receive this information.

- *Please be aware that the North Dakota Medicaid Psychotropic Monitoring Program was created in response to the SUPPORT (Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment) for Patients and Communities Act; this act requires the state to monitor and manage safe and effective use of psychotropic agents, especially for pediatric patients in foster care.* [1]

Psychotropic Polypharmacy

Prior to considering the use of multiple agents, prescribers should implement non-pharmacological interventions and consider alternative monotherapy or non-psychotropic combinations. Polypharmacy can worsen adverse effects, increase the risk of drug interactions, decrease medication adherence, lead to therapy duplication, and may increase healthcare costs. Although psychotropic polypharmacy is commonly used in clinical practice, it is not supported by the literature and many agents are used off-label; there is insufficient data to assess the safety and efficacy of using multiple agents concurrently. [2]

Safe and effective psychotropic treatment should include evaluation of guideline recommendations, considerations of appropriate indications for use, implementation of non-pharmacological interventions including cognitive behavior therapy, patient education, and continuous monitoring.[3] To properly assess for medication efficacy and safety, prescribers should counsel patients and caregivers regarding their treatment regimen, monitoring plan, and expected outcomes; oftentimes, a medication is considered ineffective despite the inability of the medication to affect the assessed behavior.[4] Proper assessment of side effects is vital to decrease the risk of prescribing cascades to treat adverse effects. [5] The appropriateness of the patient's regimen should also be routinely assessed as well. [6]

For example, despite minimal data and no FDA approved medications for the treatment of Disruptive Behavior Disorders, psychotropic medication use has increased significantly in this patient population.[10] The strongest evidence for management of these disorders is the implementation of behavioral therapy for patients, parents, families, and teachers. These programs aim to implement consistent responses to behaviors, provide aggression and problem-solving training, and improve social skills.[11]

Monitoring for Metabolic Effects

The risk of metabolic effects from psychotropic medications increases with younger age, antipsychotic naïve patients, and longer duration of therapy; despite this increased risk, studies have shown that metabolic monitoring occurs less frequently during antipsychotic treatment for pediatric patients. [3]

Baseline and regular monitoring should include:

- Personal and familial history
- Modifiable risk factors
- Weight
- Body mass index
- Waist circumference
- Blood pressure
- Heart rate
- Fasting glucose
- Hemoglobin A1c
- Fasting lipid profiles

Key Takeaways:

Safe and effective psychotropic treatment should include:

- Evaluation of guideline recommendations and appropriate indications for use
- Considerations of alternative monotherapy or non-psychotropic combinations if current regimen is ineffective
- Implementation of non-pharmacological interventions including cognitive behavior therapy
- Patient and caregiver education regarding their treatment regimen, monitoring plan, and expected outcomes
- Continuous monitoring, especially for metabolic effects in pediatric patients [2, 3, 4]

References:

1. *North Dakota Health and Human Services. Monitoring Program for Psychotropic Medications [Internet]. Bismarck (ND): Medical Services Division; 2023 April. Available from: http://hidesigns.com/assets/files/ndmedicaid/2023/ND_Psychotropic%20Monitoring%20Program_042023.pdf*
2. *Gallego JA, Nielsen J, De Hert M, Kane JM, Correll CU. Safety and Tolerability of Antipsychotic Polypharmacy. Expert Opin Drug Saf. 2012;11(4):527-542. doi:10.1517/14740338.2012.683523*
3. *Libowitz MR, Nurmi EL. The burden of antipsychotic-induced weight gain and metabolic syndrome in children. Front Psychiatry [Internet]. 2021 Mar 12. 12:623681. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7994286/*
4. *McLaren JL, Lichtenstein JD. The Pursuit of the Magic Pill: The Overuse of Psychotropic Medications in Children with Intellectual and Development Disabilities in the USA. Epidemiol Psychiatr Sci. 2019 Aug;28(4):365-368.*
5. *Kukreja S, Kalra G, Shah N, Shrivastava A. Polypharmacy in psychiatry: a review. Mens Sana Monogr. 2013 Jan;11(1):82-99. doi: 10.4103/0973-1229.104497. PMID: 23678240; PMCID: PMC3653237.*
6. *Walkup J, Bernet W, Work Group on Quality Issues, et al. Practice Parameter on the use of Psychotropic Medication in Children and Adolescents. Journal of the American Academy of Child and Adolescent Psychiatry. 2009;48(9):961-973.*
7. *Wolraich ML, Hagan JF, Allan C, et al. AAP Subcommittee on Children and Adolescents with Attention-Deficit/Hyperactive Disorder. Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents. Pediatrics. 2019;144(4):e20192528*
8. *Solmi M et al. Safety of 80 Antidepressants, Antipsychotics, Anti-attention-deficit/hyperactivity Medications and Mood Stabilizers in Children and Adolescents with Psychiatric Disorders: A Large Scale Systematic Meta-Review of 78 Adverse Effects. World Psychiatry 2020 Jun; 19:214. (https://doi.org/10.1002/wps.20765)*
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11. *Agency for Healthcare Research and Quality. Consumer Summary: Treating Disruptive Behavior Disorders in Children and Teens [Internet]. Rockville, MD: Effective Health Care Program; 2016 Aug 31. Available from: https://effectivehealthcare.ahrq.gov/products/disruptive-behavior-disorder/consumer*

February Special Mailing
800 letters sent to prescribers

In accordance with the SUPPORT ACT under Section 5042 (effective October 1, 2021), all Medicaid providers authorized to prescribe controlled substances are required to assess the prescription drug history from a qualified prescription drug monitoring program (PDMP) before prescribing controlled substances to Medicaid members. Exclusions to this requirement include prescriptions written for the following members:

- Receiving hospice, palliative care, or cancer treatment
- Resident of a long-term care facility or facility with a single pharmacy contract[1,2]

A recent review of claims data indicated that you have written a prescription for a controlled substance from October 1, 2022 until September 30, 2023 for a Medicaid member. If there appears to be an error in the information provided, please note the discrepancy.

The PDMP should be checked prior to prescribing controlled substances for Medicaid members (except excluded member categories). State Medicaid programs are required to report provider PDMP use percentages to CMS annually. **Please respond to the attached questionnaire regarding your use of the PDMP for the period of October 1, 2022 through September 30, 2023 and fax it to 866-798-4904.**

References:

1. *Library of Congress. H.R.6 – SUPPORT for Patients and Communities Act (2017-2018). [Internet}. Available from: https://www.congress.gov/bill/115th-congress/house-bill/6/text*
2. *Department of Health and Human Services. Frequently Asked Questions: SUPPORT for Patients and Communities Act, Section 5042 – Medicaid PARTNERSHIP Act [Internet]. Baltimore (MD): Centers for Medicare & Medicare Services. Available from: https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/faq051519_199.pdf*

March Cases by Type of Criteria		
Criteria Description	**# of Cases**	**% of Cases**
Underuse	305	99.7%
High-dose	1	0.3%

Clinical Report

Prior Authorization Updates

Drug Name	PA Status	Class
Alvaiz	PA	Thrombocytopenia
Novolog	PA	Insulins
Opsynvi	PA	Pulmonary Hypertension
Revivasil Kit	PA	Kits
Rezdiffra	PA	Medications Over $3000
Symbicort	PA	Steroid/LABA
Spevigo	PA	Medications Over $3000
Voydeya	PA	Medications Over $3000
Winrevair	PA	Pulmonary Hypertension
Zymfentra	PA	Cytokine Modulators
Bivigam	Remove PA	Immune Globulins
Fiasp	Remove PA, electronic step	Insulins
Flebogamma Dif	Remove PA	Immune Globulins
Gammagard	Remove PA	Immune Globulins
Gammagard S-D	Remove PA	Immune Globulins
Gammaked	Remove PA	Immune Globulins
Gamunex-C	Remove PA	Immune Globulins
Hizentra	Remove PA	Immune Globulins
Hyqvia	Remove PA	Immune Globulins
Octagam	Remove PA	Immune Globulins
Privigen	Remove PA	Immune Globulins

Criteria Updates

Summary of Changes:

Xolair received a new indication of Food Allergy.

Allergy severity is defined since specifically we are looking to treat allergy that may result in anaphylaxis.

What constitutes a positive IgE test varies greatly depending on food specific allergen and age. The size of the skin test does not correlate with severity of clinical allergic reaction. IgE testing also does not correlate well with the severity of a reaction. IgE results also vary based on immunoassay used. A positive skin test to a particular food only indicates the possibility that the patient has a true allergy because of the low specificity of the test, as low as 50% with some foods. A positive IgE tests is indicative of a sensitization, not necessarily of an allergy. It is common to have a positive SPT or IgE test to a tolerated food. Both IgE and SPT is useful for excluding IgE-mediated food allergy.

Further studies are needed to evaluate ways to predict the risk of severe reactions. Although reviewing a patient's history of previous reactions and allergen-specific IgE levels can help provide patient-centered care, these methods are not good predictors of future anaphylaxis.

Resources:

1. *Muraro et al. World Allergy Organization Journal (2022) 15:100687 http://doi.org/10.1016/j.waojou.2022.100687*
2. *Ansotegui, Ignacio J., et al. "IgE allergy diagnostics and other relevant tests in allergy, a World Allergy Organization position paper." World allergy organization journal 13.2 (2020): 100080.*
3. *Sicherer, Scott H., et al. "Allergy testing in childhood: using allergen-specific IgE tests." Pediatrics 129.1 (2012): 193-197.*
4. *Burks, Wesley. "Diagnostic evaluation of IgE-mediated food allergy." Uptodate. Available online: https:// https://www.uptodate.com/contents/diagnostic-evaluation-of-ige-mediated-food-allergy (2023).*
5. *Stokes, Jeff, and Thomas B. Casale. "The relationship between IgE and allergic disease." Uptodate. Available online: https://www.uptodate.com/contents/the-relationship-between-ige-and-allergic-disease (2022).*

Food Allergy

Eosinophil-directed biologics

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XOLAIR (omalizumab) SYRINGES	
XOLAIR (omalizumab) VIAL – *Medical Billing Only*	

Oral Immunotherapy

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
PALFORZIA (peanut allergen powder)	

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, an allergist/immunologist.
- The provider must attest that the member has access to injectable epinephrine, and that the member/caregiver has been instructed and trained on its appropriate use.
- The member has one of the following:
    A. The member has a history of severe (type 1) allergic response requiring the use of epinephrine, an ER visit, or hospitalization.
    B. Allergic reaction produced during a provider observed intake of food allergen and attestation that food allergy is likely to produce anaphylaxis as determined by allergist/immunologist.
    C. The member has all the following:
        - History of urticaria, angioedemia, or wheeze
        - Skin prick wheal of at least 3 mm or positive IgE test as determined by allergist/immunologist (at least 0.35 kUA/L for Palforzia and at least 30 IU/mL for Xolair)
        - Attestation that food allergy is likely to produce anaphylaxis as determined by allergist/immunologist.

Renewal Criteria (Palforzia Only) - Approval Duration: 6 months for continued up-titration or 12 months for maintenance the 300 mg dose.

- The member must have been adherent with therapy (last 6 fills must have been on time).
- One of the following must be met:
    A. The member has been able to tolerate the maintenance dose of Palforzia (300 mg daily)
    OR
    B. An up-titration plan to a final dose of 300 mg daily by week 40 and this is a first request for an up-titration renewal.

Summary of Changes

GLP-1 Agonist semaglutide has received a new indication. Criteria is derived from the SELECT trial's confidence intervals for efficacy.

Age: Age inclusion criteria ≥ 55 years. Hazard ratio for ≥ 75 (0.67 to 1.25) was not statistically significant, so the age was set at ≥ 55 and <75, additionally most people > 65 will be on Medicare.

BMI: BMI inclusion criteria ≥ 27 kg/m^2. Hazard ratios for BMI ≥ 35 to <40 (0.74 to 1.18), BMI ≥ 40 to <45 (0.55 to 1.26) and ≥ 45 (0.51 to 1.65) were not statistically significant, so criteria was set at BMI that performed better than placebo: ≥ 27 kg/m^2 and < 35 kg/m^2

Established Cardiovascular Disease (CVD): Indication requires established CV disease. CV inclusion criteria requires one of the following: prior myocardial infarction (MI), prior stroke, or symptomatic peripheral arterial disease (PAD) as evidenced by intermittent claudication with ankle-brachial index >0.85, peripheral arterial revascularization procure, or amputation due to atherosclerotic disease. Hazard ratios for only stroke (0.75 to 1.27) and only PAD (0.36 to 1.48) were not statistically significant. Only MI and ≥ 2 CVD had statistically significant hazard ratios and are included in the criteria.

Lipid lowering and antiplatelet treatment: Lipid lowering therapy and antiplatelet therapy are indicated for reduction of cardiovascular events, as well as recommended therapy in each of the required co-morbid conditions.

Titration of semaglutide: The semaglutide molecule is marketed under two different brand names, Ozempic and Wegovy. The cost to the department is very different based on the marketed brand name for the exact same molecule. Semaglutide has a relatively high risk of adverse effects, so there is significant likelihood that a titration will not be tolerated. The only strength of semaglutide that is indicated for MACE is 2.4 mg which is only marketed under the brand name Wegovy. There is a required titration to reach the 2.4 mg dose, so we will use the most cost effective semaglutide NDCs for titration (this is congruent with other cost containment strategies similarly made for many other exact same molecules that are marketed under various brand names, e.g., non-preferred dosage forms, biosimilars).

Reduction of Major Adverse Cardiovascular Events (MACE)

Oral Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
See Lipid-Lowering Agents	
See Platelet Aggregation Inhibitors	

Injectable Agents - GLP-1 Agonists

CLINICAL PA REQUIRED
WEGOVY (semaglutide)

Prior Authorization Criteria

For reduction of MACE in members with diabetes, please see diabetes category for criteria on indicated agents.

Initial Criteria - Approval Duration: 12 months

- The member is ages of ≥ 55 and < 75.
- The member does not have diabetes.
- The member has an initial BMI of ≥ 27 kg/m^2 and < 35 kg/m^2

- The member has one of the following:
  - Prior myocardial infarction (MI)
  - Prior stroke and symptomatic peripheral arterial disease (PAD), as evidenced by intermittent claudication with ankle-brachial index >0.85, peripheral arterial revascularization procure, or amputation due to atherosclerotic disease.
- The member is concurrently taking lipid-lowering and antiplatelet therapy
- If the member qualifies for Wegovy, a dose escalation to 2 mg of Ozempic (semaglutide) must be tolerated before Wegovy will be authorized (2.4 mg is the only strength indicated for reduction of MACE)

Summary of Changes

Winrevair has been approved for pulmonary hypertension with a novel mechanism of action.

Pulmonary Hypertension

Activin Signaling Inhibitor

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
WINREVAIR (sotatercept-csrk)	

Electronic Diagnosis Verification

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

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a pulmonologist or cardiologist.
- The member must currently be on a dual therapy combination regimen.

Renewal Criteria - Approval Duration: 12 months

- Documentation of a therapeutic response as evidenced by stabilization or improvement from baseline in each of the following:
  - 6MWT (≤ 15% decline)
  - WHO functional class

Endothelin Receptor Antagonists

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ambrisentan	LETAIRIS (ambrisentan)
bosentan	OPSUMIT (macitentan)
TRACLEER (bosentan) SUSPENSION	OPSYNVI (macitentan/tadalafil)
	TRACLEER (bosentan) TABLETS

Electronic Diagnosis Verification

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

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

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

PDE-5 Inhibitors

Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
sildenafil tablet	ADCIRCA (tadalafil) TABLET
tadalafil tablet	ALYQ (tadalafil)
	OPSYNVI (macitentan/tadalafil)
	REVATIO (sildenafil) TABLET

Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
REVATIO (sildenafil) SUSPENSION – *Brand Required*	LIQREV (sildenafil) SUSPENSION
	sildenafil suspension
	TADLIQ (tadalafil) SUSPENSION

Electronic Age Verification

- Sildenafil/tadalafil: Prior authorization is not required for ages less than 18 years old.
- Revatio suspension: Prior authorization is not required for ages less than 9 years old.

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The request must include medical documentation (e.g., clinical notes) to verify diagnosis.

Non-Preferred Agents Criteria

- The member must have failed a 30-day trial of a preferred product, as evidenced by paid claims or pharmacy printouts.
- Liqrev Only: See Preferred Dosage Form criteria

Prostacyclins

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ORENITRAM ER (treprostinil) TABLET	
REMODULIN (treprostinil) INJECTION – *Brand Co-Preferred*	
treprostinil injection	
TYVASO (treprostinil) DPI	
TYVASO (treprostinil) INHALATION	
UPTRAVI (selexipag) TABLET	
UPTRAVI (selexipag) VIAL	
VENTAVIS (iloprost) INHALATION	

Electronic Diagnosis Verification

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

Soluble Guanylate Cyclase Stimulators

NO PA REQUIRED
ADEMPAS (riociguat)

Electronic Diagnosis Verification

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

Summary of Changes

APA recommends that patients who have moderate to severe or disabling tardive dyskinesia associated with antipsychotic therapy be treated with a reversible inhibitor of the vesicular monoamine transporter 2 (VMAT2).

APA also recommends regular assessment of patients for tardive syndromes, including the use of structured evaluative tools such as the clinician-administered Abnormal Involuntary Movement Scale (AIMS). Although AIMS is recommended for assessment of efficacy, there is not an established minimal clinically important difference (MCID). Clinicians may evaluate a change in AIMS score value or percentage from baseline. A change of 2 or 3 points from baseline may be indicative of efficacy. Clinical studies have defined efficacy as 30-50% reduction from baseline.
**AIMS: Item 8 is used to determine overall severity (3 = moderate). Item 9 is used to determine incapacitation due to abnormal movements (3 = moderate).*

Patients with more severe TD (AIMS total score ≥ 6) exhibit better clinical response. A review of the ARM-TD and AIM-TD studies evaluated the change in AIMS scores for patients with mild TD (AIMS score < 6) and more severe TD (AIMS score ≥ 6) who were treated with deutetrabenazine versus placebo:

- For mild TD, the change in AIMS score from baseline at week 12 was not statistically significant versus placebo (mean difference from placebo = -0.92; p = 0.08).
- For more severe TD, the change in AIMS score from baseline at week 12 was statistically significant (mean difference from placebo = -1.79; p < 0.0001).

North Dakota Medicaid paid $360,000 for 59 prescriptions in 2023 Quarter 4 for Ingrezza and Austedo.

Resources:

1. *Hauser RA, Barkay H, Anderson KE, et al. Efficacy and Safety of Deutetrabenazine in Patients With Mild Tardive Dyskinesia: Analysis of the ARM-TD and AIM-TD Studies. Presentation; June 16-19, 2019.*
2. *Kane JM, Correll CU, Nierenberg AA, et al. Revisiting the Abnormal Involuntary Movement Scale: proceedings from the Tardive Dyskinesia Assessment Workshop. J Clin Psychiatry. 2018;79(3):17cs11959.*

Tardive Dyskinesia

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AUSTEDO (deutetrabenazine)	tetrabenazine 25 mg
AUSTEDO XR (deutetrabenazine)	XENAZINE (tetrabenazine)
INGREZZA (valbenazine)	
tetrabenazine 12.5 mg	

Electronic Step Therapy Required

- The Initiation Pack or 40 mg x 7 days is required for titration to 80 mg capsules.

Prior Authorization Criteria

Prior Authorization Form – Tardive Dyskinesia

Initial Criteria – Approval Duration: 12 months
- The requested medication must be prescribed by, or in consult with, a psychiatric or neurology specialist.
- The member must have a history of treatment with dopamine receptor blocking agent (DRBA).
- The member must have a total AIMS score (items 1-7) of ≥ 6 or AIMS score on item 8 or item 9 ≥ 3

Renewal Criteria – Approval Duration: 12 months
- The member must have had improvement in AIMS score from baseline

Special Orders: Elections

Presiding Officer and Vice-Presiding Officer Elections

Unfinished Business

Summary of Changes

Cardiologist has been added as a specialist able to prescribe Lokelma and Veltassa. SPS has been added to PDL as a preferred drug not requiring prior authorization.

Hyperkalemia (Chronic)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
SPS (sodium polystyrene sulfonate) SUSPENSION	
PREFERRED AGENTS (CLINICAL PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
LOKELMA (sodium zirconium cyclosilicate)	VELTASSA (patiromer)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 3 months

- The requested medication must be prescribed by, or in consult with, a nephrologist or cardiologist.
- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.
- The member's current serum potassium level must be exceeding the upper limit of normal, as evidenced by documentation from at least two separate lab values, submitted with the request.
- The member must have failed 30-day trials with at least two of the following products:
  - bumetanide, chlorothiazide, fludrocortisone, furosemide, hydrochlorothiazide, indapamide, metolazone, torsemide
- The member must not be receiving nonsteroidal anti-inflammatory drugs (NSAIDs)

Non-Preferred Agent Criteria:

- The member must have failed a 30-day trial with Lokelma, as evidenced with paid claims or pharmacy print outs.

Renewal Criteria – Approval Duration: 12 months

- The member's current serum potassium level is within normal limits or has been significantly reduced from baseline, as evidenced by lab documentation submitted with the request.

Reference:

1. *Rossing, Peter, et al. "KDIGO 2022 clinical practice guideline for diabetes management in chronic kidney disease." Kidney International 102.5 (2022): S1-S127.*

New Business:

Second Reviews

Acid Blockers

Proton Pump Inhibitors

Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED STEP 1 AGENTS (ELECTRONIC STEP)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
DEXILANT (dexlansoprazole) *– Brand Required*	esomeprazole magnesium	ACIPHEX (rabeprazole)
Lansoprazole		dexlansoprazole
Omeprazole		NEXIUM (esomeprazole)
Pantoprazole		omeprazole-sodium bicarbonate
Rabeprazole		PREVACID (lansoprazole)
		PRILOSEC (omeprazole)
		PROTONIX (pantoprazole)
		ZEGERID (omeprazole/sodium bicarbonate)

Electronic Step Therapy Required

- Preferred Step 1 Agents: Member must have failed 14-day trial of at least 2 preferred agents at max dose within 365 days.

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- Non-Preferred Agents Criteria - Step 2 Agents:
  - Member must have failed a 30-day trial with all preferred agents (including Step 1 Agents), as evidenced by paid claims or pharmacy printouts.
  - Clinical justification must be provided explaining why the member is unable to use the other agents (subject to clinical review).

Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED (PA REQUIRED)
lansoprazole ODT	esomeprazole solution packet
NEXIUM (esomeprazole) PACKET- *Brand Required*	KONVOMEP (omeprazole/sodium bicarbonate)
PROTONIX (pantoprazole) PACKET *– Brand Required*	omeprazole-sodium bicarbonate packet
	pantoprazole packet
	PREVACID (lansoprazole) SOLUTAB
	PRILOSEC SUSPENSION (omeprazole)
	ZEGERID (omeprazole-sodium bicarbonate) PACKET

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- Member must have failed a 30-day trial with all preferred agents, as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the member is unable to use the other agents (subject to clinical review).

Electronic Age Verification

- Nexium 2.5 mg and 5 mg Packet: The member must be less than 1 years old (or less than 7.5 kg)

Therapeutic Duplication

- One strength of one medication is allowed at a time.
- Proton Pump Inhibitors is not allowed with:
  - Esomeprazole or omeprazole are not covered with clopidogrel.
    - Other PPIs such as pantoprazole are covered with clopidogrel. Clopidogrel is a substrate for 2C19 and esomeprazole and omeprazole are strong 2C19 inhibitors and can decrease effectiveness of clopidogrel.
  - Dextroamphetamine/Amphetamine ER:
    - Proton Pump Inhibitors increase blood levels and potentiate the action of amphetamine. Co-administration of Adderall XR and gastrointestinal or urinary alkalizing agents should be avoided.
  - H2 Blockers: If either of the following circumstances apply, please call for an override by calling provider relations at 1-800-755-2604:
    - Member is experiencing nocturnal symptoms after compliance with nighttime dose of proton pump inhibitor. A two-month override may be approved for concurrent H2 blocker use.
    - H2 blocker is being used concurrently with a H1 blocker for severe allergy prophylaxis, unrelated to PPI use for GI symptoms.

References

1. Katz PO, Gerson LB, Vela MF. Guidelines for the diagnosis and management of gastroesophageal reflux disease. Am J Gastroenterol 2013;108:308-28.
2. Fackler WK, Ours TM, Vaezi MF, Richter JE. Long-term effect of H2RA therapy on nocturnal gastric breakthrough. Gastroenterology. 2002;122:625-632.

Potassium Competitive Acid Blocker

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
VOQUEZNA (vonoprazan)	

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The member must meet one of the following criteria (A or B):
  A. The member has a diagnosis of erosive esophagitis and have failed an 8-week trial of each of the following:
     - Omeprazole twice daily
     - Rabeprazole or esomeprazole daily.
  B. The member has severe esophagitis (LA Grade C/D disease)

Paroxysmal Nocturnal Hemoglobinuria (PNH)

C5 inhibitors

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ULTOMIRIS (ravulizumab)	SOLIRIS (eculizumab) – *Medical Billing Only*
ULTOMIRIS (ravulizumab) – *Medical Billing Only*	

C3 Inhibitors

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

Factor B Inhibitors

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

Factor D Inhibitors

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	VOYDEYA (danicopan)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a hematologist.
- Diagnosis must be confirmed by flow cytometry demonstrating that the member's peripheral blood cells are deficient in glycosylphosphatidylinositol (GPI) – linked proteins (e.g., CD55, CD59)
- One of the following criteria must be met (A, B, or C):
  A. The member has had at least 1 transfusion in the past 6 months
  B. The member has symptoms of PNH (e.g., abdominal pain, anemia, shortness of breath, hemolysis, organ dysfunction, debilitating fatigue) and one of the following:
     - granulocyte PNH clone size > 10%
     - hemoglobin < 10 g/dL
  C. LDH level of 1.5 times the upper limit of normal (must include at least 2 different reagents tested on at least 2 cell lineages)

Non-Preferred Agent Criteria:

Fabhalta Only:

- The member must have failed a 6-month trial with Empaveli, as evidenced by paid claims or printouts, with one of the following criteria being met (A, B, C):
  A. The member has had at least 1 transfusion in the past 6 months
  B. The member has symptoms of PNH (e.g., abdominal pain, anemia, shortness of breath, hemolysis, organ dysfunction, debilitating fatigue) and one of the following:
     - granulocyte PNH clone size > 10%
     - hemoglobin < 10 g/dL
  C. LDH level of 1.5 times the upper limit of normal (must include at least 2 different reagents tested on at least 2 cell lineages)

Voydeya Only:

- The member must have failed a 6-month trial with Ultomiris, with at least one transfusion, persistent anemia (Hb < 9.5 g/dL) and absolute reticulocyte count ≥ 120 × 109 /L, as evidenced by paid claims or printouts.

Soliris Only:
- The member must have failed a 6-month trial with Ultomiris with Voydeya, as evidenced by paid claims or printouts, with at least one transfusion, persistent anemia (Hb < 9.5 g/dL) and absolute reticulocyte count ≥ 120 × 109 /L, as evidenced by paid claims or 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:
  - Member has not required transfusion in the past 6 months
  - Increase in hemoglobin by ≥ 2 g/dL from baseline
  - Normal LDH levels ≤ 280 U/L

Non-Preferred Agent Criteria:
Fabhalta Only:
- The member must have experienced one of the clinical benefit metrics defined in the renewal criteria that was not met Empaveli.

Voydeya Only:
- The member must have experienced one of the clinical benefit metrics defined in the renewal criteria that was not met Ultomiris.

Soliris Only:
- The member must have experienced one of the clinical benefit metrics defined in the renewal criteria that was not met Ultomiris with Voydeya.

References:

1. Parker, Charles J. "Update on the diagnosis and management of paroxysmal nocturnal hemoglobinuria." Hematology 2014, the American Society of Hematology Education Program Book 2016.1 (2016): 208-216.

Duchenne Muscular Dystrophy

Corticosteroids

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AGAMREE (vamorolone)	deflazacort
EMFLAZA (deflazacort) – *Brand Required*	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months
- Diagnosis must be confirmed by the documented presence of abnormal dystrophin or a confirmed mutation of the dystrophin gene
- The requested medication must be prescribed by, or in consult with, a neurologist

- Onset of weakness must have occurred before 2 years of age
- The member must have serum creatinine kinase activity of at least 10 times the upper limit of normal (ULN) prior to initiating treatment
- The member must have failed a 6-month trial of prednisone, as evidenced by paid claims or pharmacy printouts
- The provider must submit baseline assessment results from the following assessments (the member does not have to meet all of these parameters, but each assessment must be submitted, and provider must indicate which parameters are met and being preserved, must be at least one):
    - Stable cardiac function LVEF > 40% by ECHO
    - Scoliosis not requiring surgery
    - Stable respiratory function – FVC predicted > 50%, not requiring ventilatory assistance
    - The provider must submit baseline motor milestone score results from at least ONE the following assessments:
        - 6-minute walk test (6MWT)
        - North Star Ambulatory Assessment (NSAA)
        - Motor Function Measure (MFM)
        - Hammersmith Functional Motor Scale (HFMS)
        - Performance of Upper Limb (PUL)
- The member must have ONE of the following significant intolerable adverse effects supported by documentation:
    i. Cushingoid appearance
    ii. Central (truncal) obesity
    iii. Severe behavioral adverse effect
    iv. Undesirable weight gain (>10% of body weight gain increase over 6-month period)
    v. Diabetes and/or hypertension that is difficult to manage

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, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including the following assessments (the member does not have to meet all of these parameters, but each assessment must be submitted, and provider must indicate which parameters are met and being preserved, must be at least one):
    - Stable cardiac function LVEF > 40% by ECHO
    - Scoliosis not requiring surgery
    - Stable respiratory function – FVC predicted > 50%, not requiring ventilatory assistance
    - Motor function assessment
        - 6MWT – improvement of 20 meters from baseline
        - NSAA – improvement of 2 points from baseline
        - MFM – improvement of 2 points from baseline
        - HFMS – improvement of 2 points from baseline
        - PUL – improvement of 4 points from baseline
- The member must have had improvement of adverse effects experienced on prednisone supported by documentation:
    i. Cushingoid appearance
    ii. Central (truncal) obesity
    iii. Severe behavioral adverse effect
    iv. Undesirable weight gain (>10% of body weight gain increase over 6-month period)
    v. Diabetes and/or hypertension that is difficult to manage

Genetic Therapies

Exon 45 Skipping

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

AMONDYS 45 (casimersen) – *Medical Billing Only*	

Exon 51 Skipping

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EXONDYS 51 (eteplirsen) – *Medical Billing Only*	

Exon 53 Skipping

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
VILTEPSO (viltolarsen) – *Medical Billing Only*	VYONDYS 53 (golodirsen) – *Medical Billing Only*

High-Cost Drug:
Amondys 45, Exondys 51, and Vyondys 53 cost $758,000 per year for a 30 kg child.
Viltepso cost $733,200 per year for a 30 kg child.

- Amondys 45 is awaiting verification of clinical benefit in confirmatory trials. In Study 1 (NCT02500381), individuals treated with Amondys 45 observed an increase in mean dystrophin protein levels of 0.81%, while the placebo arm observed a mean increase of 0.22%.
- Exondys 51 is awaiting verification of clinical benefit in confirmatory trials. In Study 1, there was no significant difference in change in 6MWD in patients treated with Exondys 51 and placebo. All 12 individuals enrolled in Study 1, continued treatment with open-label Exondys 51 and were compared to an external control group. Study 2 failed to provide evidence of a clinical benefit of Exondys 51 compared to the external control group. In Study 3, the median increase in dystrophin level was 0.1% in 12 evaluable individuals receiving open-label Exondys 51.
- Viltepso is awaiting verification of clinical benefit in confirmatory trials. In Study 1 (NCT02740972), 8 individuals treated with Viltepso observed a mean increase in dystrophin of 5.3% of normal levels.
- Vyondys 53 is awaiting verification of clinical benefit in confirmatory trials. In Study 1 (NCT02310906), 25 individuals treated with Vyondys 53 observed a mean increase in dystropin of 0.92% of normal levels.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 8 weeks

- The member must be assigned male at birth between ages of 4 and 19 years old
- Diagnosis must be confirmed by the documented presence of abnormal dystrophin or a confirmed mutation of the dystrophin gene
- The requested medication must be prescribed by, or in consult with, a neurologist
- The member has had an inadequate treatment response with standard corticosteroid therapy for a minimum of 6 months with adherence, as evidenced by paid claims or pharmacy printouts
- Medical records must be provided confirming the member has:
  - A baseline 6-Minute Walk Time (6MWT) ≥ 300 meters while walking independently (e.g., without side-by-side assist, cane, walker, wheelchair, etc.)
  - Stable respiratory function – FVC predicted > 50%, not requiring ventilatory assistance
  - Stable cardiac function – LVEF > 40 % by ECHO
- Weight and calculated dose must be provided consistent with approved FDA dose
- The member must not be taking any other RNA antisense agent or any other gene therapy

Non-Preferred Agent Criteria (Initial)

- Please provide explanation with the request why the preferred agent cannot be used (subject to clinical review)

Renewal Criteria – Approval Duration: 12 months

- Medical records must be provided confirming the member has maintained:

- A 6MWT ≥ 300 meters while walking independently (e.g., without side-by-side assist, cane, walker, wheelchair, etc.)
- Stable respiratory function – FVC predicted > 50%, not requiring ventilatory assistance
- Stable cardiac function – LVEF > 40 % by ECHO

Primary Hyperoxaluria Type 1 (PH1)

RNA interference (RNAi)

CLINICAL PA REQUIRED
OXLUMO (lumasiran) – *Medical Billing Only*
RIVFLOZA (nedosiran)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a nephrologist, urologist or geneticist
- The member's diagnosis must be documented by one of the following:
  - Mutation in the alanine: glyoxylate aminotransferase (AGXT) gene confirmed by genetic testing
  - Liver enzyme analysis confirming absent or significant deficiency in alanine: glyoxylate aminotransferase (AGT) activity
- The member has a failed to achieve at least a 30% reduction in urinary oxalate excretion after a 90-day trial of pyridoxine (vitamin B6) of maximally tolerated doses (maximum dose, 20 mg/kg per day)
- The member has not received a liver transplant
- Documentation of the one of the following must be submitted:
  - Elevated urinary oxalate excretion > 1 mmol/1.73 m^2 per day or 90 mg/1.73 m^2 per day
  - Elevated urinary oxalate: creatinine ratio as defined by age defined laboratory reference range

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including one of the following scores and symptoms:
  - Reduced signs and symptoms of PH1 (e.g., nephrocalcinosis, formation of renal stones, renal impairment)
  - Decrease of 30% from baseline or normalization of urinary oxalate excretion
  - Decreased or normalized urinary oxalate: creatinine ratio relative to normative values for age

Myasthenia Gravis

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)	PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
RIABNI (rituximab-arrx) *– Medical Billing Only*	ULTOMIRIS (ravulizumab) *– Medical Billing Only*	SOLIRIS (eculizumab) *– Medical Billing Only*
RITUXAN (rituximab) *– Medical Billing Only*	RYSTIGGO (rozanolixizumab-noli) *– Medical Billing Only*	
RUXIENCE (rituximab-pvvr) *– Medical Billing Only*	VYVGART (ergartigimod alfa) *– Medical Billing Only*	
TRUXIMA (rituximab-abbs) *– Medical Billing Only*	VYVGART HYTRULO (efgartigimod alfa/hyaluronidase) *– Medical Billing Only*	
	ZILBRYSQ (zilucoplan)	

Muscle Specific Kinase (MuSK) Positive

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
RIABNI (rituximab-arrx) – *Medical Billing Only*	RYSTIGGO (rozanolixizumab-noli) *– Medical Billing Only*
RITUXAN (rituximab) – *Medical Billing Only*	
RUXIENCE (rituximab-pvvr) – *Medical Billing Only*	
TRUXIMA (rituximab-abbs) – *Medical Billing Only*	

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), Soliris (eculizumab), 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)

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.

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:
  A. Rituximab
  B. Ultomiris
  C. Vyvgart or Rystiggo

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

Seborrheic Dermatitis

See Antifungals – Topical

See Steroids - Topical

Topical Phosphodiesterase-4 (PDE-4) Inhibitors

CLINICAL PA REQUIRED
ZORYVE (roflumilast) FOAM

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must have had a 4-week trial of concurrent use of a topical antifungal (shampoo or foam) AND a high potency topical corticosteroid (foam, spray or shampoo).

FIRST REVIEW OF MOLLUSCUM CONTAGIOSUM

Molluscum contagiosum is a viral skin infection consisting of skin lesions or Mollusca. This skin infection can be contracted by contact with infected persons and inanimate objects. Symptoms are self-limiting and usually resolve within 6-12 months but can last 4-5 years. Since symptoms are self-limiting, treatment is optional for immunocompetent patients. Treatment is recommended for those who are immunocompromised or who contract the infection by sexual contact.

Population: 6 million Americans (5% of children), primarily pediatrics but can occur in adults as well

Treatment: Lack of clinical guideline or consensus recommendations for treatment

- In office procedures: ablation, cryotherapy, laser
- Off label use of various medications (tretinoin, imiquimod, podophyllotoxin cream, OTC products) have been proven to be efficacious
- FDA approved medications: Ycanth and Zelsuvmi
- If dermatitis is present, the use of short-term topical corticosteroids can prevent spreading

General key notes for treatment options:

- For topical use only
- Both have risk of skin reactions

Ycanth (cantharidin)	
Labeled population	Adults and pediatrics ≥ 2 years old
Mechanism	Vesicant: blistering agent leads to the disappearance of lesion and healing without scarring
Administration	• Delivered by healthcare provider (HCP) with a single use applicator over 2-4 visits every 3 weeks • Not for ophthalmic, mucosal, or oral use
Key Points	• Ocular contact toxicities: corneal necrosis, ocular perforation, deep ocular injuries • Oral contact toxicities: renal failure, blistering/damage to GI tract, coagulopathy, seizures
Cost	$1370-5480; would be billed on medical side
Zelsuvmi (berdazimer)	
Labeled population	Adults and pediatrics ≥ 1 year old
Mechanism	Nitric oxide releasing agent, exact mechanism for treatment of molluscum contagiosum is unknown
Administration	• Applied by patient or caregiver at home once daily to each lesion up to 12 weeks • Not for ophthalmic, intravaginal, or oral use
Key notes	Possible challenges regarding storage and delivery to ensure stability
Cost	Estimated $2740 per treatment course; would be billed on pharmacy side

Based on lowest per unit WAC cost

FDA Approval

Ycanth (cantharidin): July 21, 2023; 505(b) New Drug Application (NDA) pathway Type 5 New Formulation of New Manufacturer, STANDARD

Zelsuvmi (berdazimer): January 5, 2024; 505(b) New Drug Application (NDA) pathway Type 1 New Molecular Entity, STANDARD

Clinical Trials

Zelsuvmi: Approval was based on three B-SIMPLE Phase 3 multicenter, randomized, double-blind, parallel-group, vehicle-controlled trial consisting of a total of 1598 patients. Eligible patients included those ≥ 6 months of age in generally good health with 3-70 lesions. Trials: B-SIMPLE 4 (NCT04535531), B-SIMPLE 2 (NCT03927703), B-SIMPLE 1 (NCT03927716)

Primary Endpoint: Complete clearance at week 12 in B-SIMPLE 4 showed 32.4% Zelsuvmi (n = 144) vs 19.7% vehicle (n = 88) (p <0.001)
**Efficacy was not statistically significant in B-SIMPLE 1 and 2*

Secondary Endpoint: Complete clearance at week 8 in B-SIMPLE 4 showed 19.6% Zelsuvmi (n = 87) vs 11.6% vehicle (n = 88) (p=0.001) and B-SIMPLE 2 showed 13.9% Zelsuvmi (n = 33) vs 5.9% vehicle (n = 7) (p=0.028)

Safety: Main adverse effects were application pain and erythema

**Only included Zelsuvmi clinical trials; Ycanth would be billed on the medical side*

Place in Therapy

Recommended for immunocompromised members or who contract the infection by sexual contact; optional for immunocompetent patients.

Advantages	Disadvantages
• Data supporting use and FDA approval • Zelsuvmi: at home treatment	• High cost • No head-to-head comparisons • Painful treatment that may lead to scarring

Current Utilization

	Quarter 3 2023 – Quarter 1 2024		
Medication	**Rx Count**	**Rx Count**	**% of Rx**
Ycanth	0	0%	$0
Zelsuvmi	0	0%	$0

References:

1. *Zelsuvmi (berdazimer) topical gel. [prescribing information]. Wilmington, Delaware: EPIH SPV, LLC; January 2024.*
2. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Zelsuvmi NDA 217424 approval letter, January 5, 2024. https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/217424Orig1s000ltr.pdf*
3. *Zelsuvmi (berdazimer): New Drug Review. IPD Analytics. Aventura, FL. February 2024. https://www.ipdanalytics.com*
4. *Zelsuvmi. Quick Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. January 17, 2024. https://www.micromedexsolutions.com*
5. *Ycanth* (cantharidin) topical solution. *[prescribing information]. West Chester, PA: Verrica Pharmaceuticals, Inc; July 2023.*
6. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Ycanth NDA 212905 approval letter, July 21, 2023. https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/212905Orig1s000ltr.pdf*
7. *Ycanth. Quick Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. December 8, 2023. https://www.micromedexsolutions.com*
8. *Isaacs SN. Molluscum contagiosum. UpToDate, Hirsch MS, Levy ML, Rosen T (Ed) [Internet]. Waltham, MA: UptoDate; January 10, 2024. Available from: www.uptodate.com*

FIRST REVIEW OF EPIDERMOLYSIS BULLOSA

Epidermolysis bullosa (EB) is a rare genetic disorder which leads to impaired skin structural proteins and fragile skin. Mild friction can cause painful and chronic blisters, erosions, ulcers, and fibrosis; these wounds may take years to heal. Patients can also experience damage to mucosal tissues of the gastrointestinal, respiratory, and urinary tract and develop further complications such as malnutrition, electrolyte abnormalities, anemia, and strictures. The 4 types of EB are classified by their gene mutation and level of blistering: EB simplex (EBS), dystrophic EB (DEB), junctional EB (JEB), and kindler EB (KEB). There are FDA approved wound treatments for DEB and JEB which are the more severe subtypes.

Population: Estimated 1100 patients with DEB and less than 200 patients with JEB in the United States

Treatment: Individualized, multidisciplinary treatment should address wound care, infection control, nutritional needs, and prevention/treatment of complications

- **Wound Treatment:** FDA approved medications are Vyjuvek and Filsuvez; locally acting and not curative
  - Patients with mild disease may not require treatment with these agents

Vyjuvek (beremagene geperpavec-svdt)	
Labeled population	Adults and pediatrics ≥ 6 months old with DEB
Mechanism	Topical gene therapy that delivers copies of the COL7A1 gene, the mutation that causes DEB
Administration	• Applied once weekly to open wounds by HCP • Max specified weekly dosing
Cost (annual)	Up to $1,271,400; billed on medical side
Filsuvez (birch triterpenes)	
Labeled population	Adults and pediatrics ≥ 6 months old with DEB and JEB
Mechanism	Keratinocyte activator that is thought to promote wound healing; exact mechanism for treatment in DEB is unknown
Administration	• Applied by patient or caregiver at home to open partial-thickness wounds at dressing changes until healing occurs • Each tube is for one time use only • Topical use; not for oral, intravaginal, intra-anal, or ophthalmic use
Key notes	• Main adverse reaction is application site reactions • Cannot use with active infection present
Cost (annual)	$583,200 (based on average use of 27 tubes per month in studied patients); billed on pharmacy side

Based on lowest per unit WAC cost; cost will vary based on frequency of administrations and extent of wounds

FDA Approval

Filsuvez (birch triterpenes): December 18, 2023; 505(b) New Drug Application (NDA) pathway Type 1 New Molecular Entity, PRIORITY, Orphan

Clinical Trials

Approval was based on Phase 3 EASE (NCT03068780) double-blind, randomized, vehicle-controlled trial consisting of 223 patients with DEB and JEB. Patients included in the trial were at least 6 months old and had a target wound present for 21 days to 9 months.

Primary Endpoint: First complete closure of target wound within 45 days showed 41.3% Filsuvez vs. 28.9% placebo (p = 0.01)
*Only shown to be efficacious in patients with DEB

Secondary Endpoints: Secondary endpoints were not met except for greater reduction in pain in patients ≥ 4 years of age at day 14 (p=0.022).

Safety: Similar to placebo, mainly application site reactions

Place in Therapy

Patients with DEB requiring wound treatment. The agent was not shown to be efficacious for patients with JEB.

Advantages	Disadvantages
• First FDA approved treatment option for JEB • Second FDA approved treatment option for DEB	• High cost • No evidence showing efficacy in patients with JEB • No head-to-head comparisons or data showing use alongside Vyjuvek • Frequent administrations • Lack of long-term data • Cannot use with active infection • Did not meet secondary endpoints

Current Utilization

	Quarter 2 2023 – Quarter 1 2024		
Vyjuvek	0	0%	$0
Filsuvez	0	0%	$0

References:

1. *Filsuvez (birch triterpenes) topical gel. [prescribing information]. Wahlstedt Germany: Lichtenheldt GmbH; December 2023.*
2. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Filsuvez NDA 215064 approval letter, December 18, 2023. https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/215064Orig1s000correctedltr.pdf*
3. *Filsuvez (birch triterpenes). New Drug Review. IPD Analytics. Aventura, FL. March 2024. https://www.ipdanalytics.com*
4. *Filsuvez. Quick Answers. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. April 15, 2024. https://www.micromedexsolutions.com*
5. *Vyjuvek. Quick Answers. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. August 11, 2023. https://www.micromedexsolutions.com*
6. *Murrell DF. Overview of the management of epidermolysis bullosa. UpToDate, Hand JL, Corona R (Ed) [Internet]. Waltham, MA: UptoDate; January 8, 2024. Available from: www.uptodate.com*

FIRST REVIEW OF METABOLIC DYSFUNCTION–ASSOCIATED STEATOHEPATITIS

Metabolic dysfunction-associated steatohepatitis (MASH) is the most severe form of metabolic dysfunction-associated steatotic liver disease (MASLD); these conditions are associated with hepatic steatosis without heavy alcohol use. MASH can lead to the development of cirrhosis and/or liver cancer.

Population: 1.5-6.5% adults in the United States

Treatment:

- Modifying risk factors including elimination of alcohol use, management of cardiovascular disease risk factors (e.g., hypertension, dyslipidemia, diabetes)
- Patients who are unable to meet weight loss goals and have developed moderate to severe fibrosis may require liver targeted therapy
    - Rezdiffra is the first FDA approved treatment for MASH that is to be used in combination with lifestyle modifications
    - Vitamin E and pioglitazone have been used off-label but there is minimal data to support the use of these agents

MASH and MASLD were formerly known as non-alcoholic steatohepatitis (NASH) and nonalcohol-associated fatty liver disease (NAFLD) respectively.

Rezdiffra (resmetirom)	
Labeled population	Adults, MASH with moderate to severe fibrosis (F2-F3) in conjunction with diet and exercise
Mechanism	Thyroid hormone receptor-beta partial agonist
Administration	Oral, once daily (weight-based dosing)
Key Points	• Cannot be used in patients with decompensated cirrhosis • Warnings/precautions due to the risk of hepatotoxicity and gallbladder adverse effects (cholelithiasis, acute cholecystitis, obstructive pancreatitis) • Drug interactions: CYP2C8 inhibitors and substrates, OAT1B1 and OAT1B3 inhibitors, statins
Cost (annual)	$48,058

Based on lowest per unit WAC cost for a patient weighing 100 kg

FDA Approval

Rezdiffra (resmetirom): March 14, 2024; 505(b) New Drug Application (NDA) pathway Type 1 New Molecular Entity, PRIORITY

Clinical Trials

Approval was based on MAESTRO-NASH (NCT03900429), a Phase 3 randomized, double-blind, placebo-controlled trial consisting of 888 patients with biopsy confirmed MASH. Eligible patients included those with F2 and F3 fibrosis, NAFLD Activity Score (NAS) ≥ 4, and metabolic risk factors. Patients were randomized 1:1:1 to receive Rezdiffra 80 mg, Rezdiffra 100 mg, and placebo daily.

Primary Endpoints:

- Resolution of steatohepatitis without fibrosis worsening: 25.9% Rezdiffra 80 mg, 29.9% Rezdiffra 100 mg, vs 9.7% placebo ($p<0.001$ for Rezdiffra 80 and 100 mg)
- Improvement of fibrosis by ≥1 stage without worsening of steatohepatitis at 12 months: 24.2% Rezdiffra 80 mg, 25.9% Rezdiffra 100 mg, vs 14.2% placebo ($p<0.001$ for Rezdiffra 80 and 100 mg)

Secondary endpoint:
Reduction of LDL-C level at 24 weeks: -13.6% Rezdiffra 80 mg, -16.3% Rezdiffra 100 mg, 0.1% placebo (p=<0.001 for Rezdiffra 80 and 100 mg)

Safety: main adverse effects were gastrointestinal (nausea, vomiting, diarrhea, constipation, abdominal pain), pruritis, and dizziness

Place in Therapy

May be considered for patients that have developed moderate to severe fibrosis

Advantages	Disadvantages
• First FDA approved agent for MASH	• Adverse effects may decrease adherence

Current Utilization

	Quarter 1 2024		
Medication	**Rx Count**	**% of Rx**	**Reimb Amount**
Rezdiffra	0	0%	$0

References:

1. *Rezdiffra (resmetirom) tablets, for oral use. [prescribing information]. West Conshohocken, PA: Madrigal Pharmaceuticals, Inc; March 2024.*
2. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Rezdiffra NDA 217785 approval letter, March 14, 2024. https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/217785Orig1s000ltr.pdf*
3. *Rezdiffra (resmetirom): New Drug Review. IPD Analytics. Aventura, FL. March 2024. https://www.ipdanalytics.com*
4. *Harrison SA, Bedossa P, Guy, CD, Schattenberg JM, Loomba R, et al. A Phase 3, randomized, controlled trial of resmetirom in NASH with liver fibrosis. N Eng J Med. 2024; 390(6):497-509. doi:10.1056/NEJMoa2309000*
5. *Rezdiffra. Quick Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. April 2, 2024. https://www.micromedexsolutions.com*
6. *Chopra S, Lai M. Management of metabolic dysfunction-associated steatotic liver disease (nonalcoholic fatty liver disease) in adults. UpToDate, Lindor K, Robson KM (Ed) [Internet]. Waltham, MA: UptoDate; February 28, 2024. Available from: www.uptodate.com*
7. *Tendler DA. Pathogenesis of metabolic dysfunction-associated steatotic liver disease (nonalcoholic fatty liver disease). UpToDate, Lindor K, Robson KM (Ed) [Internet]. Waltham, MA: UptoDate; August 23, 2022. Available from: www.uptodate.com*

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
DUR BOARD MEETING MARCH 2024

1. Antipsychotics / ND Drugs Covered for Weight Gain (Negating)
Alert Message: The use of antipsychotics has been associated with the development of metabolic disturbances. All patients receiving antipsychotic treatment should have baseline weight and metabolic parameter levels obtained at initiation and regular monitoring of metabolic parameters throughout therapy. Products covered for antipsychotic-induced weight gain can be found in the PDL.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Antipsychotics		Victoza
		Metformin
		Phentermine

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Zeier K, Connell R, Resch W, et al. Recommendations for Lab Monitoring of Atypical Antipsychotics. Current Psychiatry. 2013;12(No. 9):51-54.
Pillinger T, McCutcheon RA, Vano L, et.al., Comparative Effects of 18 Antipsychotics on Metabolic Function in patients with Schizophrenia, Predictors of Metabolic Dysregulation, and Association with Psychopathology: A Systematic Review and Network Meta-Analysis. Lancet Psychiatry. 2020 Jan;7(1):64-77.

2. Antibiotics / Viral Infections / Bacterial Infections
Alert Message: Based on a review of the patient's medical history, the patient has received antibiotic therapy and has a diagnosis of a viral infection but no diagnosis of a bacterial infection. Inappropriate antibiotic use is a contributor to antibiotic resistance, as well as putting the patient at risk for antibiotic-related adverse events.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Oral Antibiotics	Viral Infections	Bacterial Infections

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Centers for Disease Control and Prevention, Core Elements of Outpatient Antibiotic Stewardship (Department of Health and Human Services) last Reviewed 2021. www.cdc.gov/antibiotic-use/core-elements/outpatient.html#print Accessed March 2024.
The Pew Charitable Trusts, "Study Shows That Inappropriate Antibiotic Prescribing for Children Leads to Increased Costs, Complications" (2022), https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2022/05/study-shows-that-inappropriate-antibiotic-prescribing-for-children-leads-to-increased-complications. Accessed March 2024.

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
DUR BOARD MEETING JUNE 2024

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
2ND QUARTER 2024

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

1. Sitagliptin / Overuse _____ _____

Alert Message: Zituvio (sitagliptin) may be over-utilized. The manufacturer's recommended maximum dose is 100 mg once daily.

Drugs/Diseases

Util A	Util B	Util C
Sitagliptin		

Max Dose: 100 mg/day

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Zituvio Prescribing Information, Oct. 2023, Zydus Pharmaceuticals, Inc.

2. Sitagliptin / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Sitagliptin		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Zituvio Prescribing Information, Oct. 2023, Zydus Pharmaceuticals, Inc.

3. Sitagliptin / Moderate Renal Impairment _____ _____

Alert Message: The recommended dose of Zituvio (sitagliptin) in patients with moderate renal impairment (CrCl >/= 30mL/min/1.73m2 to < 45 mL/min/1.73m2) is 50 mg once daily. Patients with more severe renal insufficiency (CrCl < 30 mL/min/1.73m2) or with end-stage renal disease on hemodialysis or peritoneal dialysis should be dosed at 25 mg once daily. Assessment of renal function is recommended prior to initiation of sitagliptin therapy and periodically thereafter.

Drugs/Diseases

Util A	Util B	Util C
Sitagliptin	CKD 3	

Max Dose: 50 mg/day

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Zituvio Prescribing Information, Oct. 2023, Zydus Pharmaceuticals, Inc.

4. Sitagliptin / Moderate Renal Impairment _____ _____

Alert Message: The recommended dose of Zituvio (sitagliptin) in patients with severe renal insufficiency (CrCl < 30mL/min/1.73m2) or with end-stage renal disease on hemodialysis or peritoneal dialysis is 25 mg once daily. In patients with moderate renal impairment (CrCl >/=30 mL/min/1.73m2 to < 45mL/min/1.73m2) sitagliptin should be dosed at 50 mg once daily. Assessment of renal function is recommended prior to initiation of sitagliptin therapy and periodically thereafter.

Drugs/Diseases

Util A	Util B	Util C
Sitagliptin	CKD 4 & 5	
	ESRD	
	Dialysis	

Max Dose: 25 mg/day

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Zituvio Prescribing Information, Oct. 2023, Zydus Pharmaceuticals, Inc.

5. Sitagliptin / Type 1 Diabetes _____ _____

Alert Message: Zituvio (sitagliptin) should not be used in patients with type 1 diabetes mellitus.

Drugs/Diseases

Util A	Util B	Util C
Sitagliptin	Type 1 Diabetes	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Zituvio Prescribing Information, Oct. 2023, Zydus Pharmaceuticals, Inc.

6. Sitagliptin / Insulin & Insulin Secretagogues _____ _____

Alert Message: The concurrent use of Zituvio (sitagliptin) with insulin and insulin secretagogues can increase the risk of hypoglycemia. A lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used in combination with ertugliflozin/sitagliptin.

Drugs/Diseases

Util A	Util B	Util C
Sitagliptin	Insulin	
	Insulin Secretagogues	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Zituvio Prescribing Information, Oct. 2023, Zydus Pharmaceuticals, Inc.

Criteria Recommendations ***Approved Rejected***

7. Sitagliptin / Pregnancy / Pregnancy Negating _____ _____

Alert Message: There are no adequate and well-controlled studies of Zituvio (sitagliptin) in pregnant women. During pregnancy, consider appropriate alternative therapies. Sitagliptin should be used during pregnancy only if clearly needed.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Zituvio Prescribing Information, Oct. 2023, Zydus Pharmaceuticals, Inc.
American Diabetes Association (ADA). 15. Management of Diabetes in Pregnancy. In Standards of Medical Care in Diabetes - 2023. Diabetes Care. 2023;46(Suppl. 1):S254-S266.

8. Sitagliptin / Lactation _____ _____

Alert Message: There is no information regarding the presence of Zituvio (sitagliptin) in human milk, the effects on the breastfed infant, or the effects on milk production. Sitagliptin is present in rat milk and, therefore, possibly present in human milk. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for sitagliptin and any potential adverse effects on the breastfed infant from sitagliptin or the underlying maternal condition.

Drugs/Diseases

Util A	Util B	Util C
Sitagliptin	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Zituvio Prescribing Information, Oct. 2023, Zydus Pharmaceuticals, Inc.

Criteria Recommendations	*Approved*	*Rejected*

9. Sitagliptin / Non-adherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Zituvio (sitagliptin). 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
Sitagliptin		

References:

Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.

Ho PM, Rumsfeld JS, Masoudi FA, et al., Effect of Medication Nonadherence in Diabetes Mellitus. Cardiology Review, April 2007, Vol. 24 No. 4. p.18-22.

Currie CJ, Peyrot M, Morgan CL, et al. The Impact of Treatment Noncompliance on Mortality in People With Type 2 Diabetes. Diabetes Care 35:1279-1284, June 2012.

Butler RJ, Davis TK, Johnson WL, et al. Effects of Nonadherence with Prescription Drugs Among Older Adults. Am J Manag Care. 2011 Feb; 17(2):153-60.

10. Tafamidis / Overuse _____ _____

Alert Message: Vyndamax (tafamidis) may be over-utilized. The recommended dosage of tafamidis is 61 mg once daily.

Drugs/Diseases

Util A	Util B	Util C
Tafamidis		

Max Dose: 61 mg/day

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Vyndaqel and Vyndamax Prescribing Information, Oct. 2023, Pfizer Inc.

Criteria Recommendations	*Approved*	*Rejected*

11. Tafamidis / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Tafamidis		

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Vyndaqel and Vyndamax Prescribing Information, Oct. 2023, Pfizer Inc.

12. Tafamidis / BCRP Substrates _____ _____

Alert Message: Vyndamax (tafamidis) inhibits breast cancer resistant protein (BCRP) in humans. Coadministration of tafamidis and drugs that are BCRP substrates may increase the exposure of the BCRP substrates (e.g., methotrexate, rosuvastatin, and imatinib) and the risk of substrate-related toxicities. Monitor for signs of BCRP substrate-related toxicities and modify the dosage of the substrate if appropriate.

Drugs/Diseases

Util A	Util B		Util C
Tafamidis	Alpelisib	Prazosin	
	Berotralstat	Rosuvastatin	
	Dolutegravir	Talazoparib	
	Glyburide	Tenofovir	
	Methotrexate	Topotecan	
	Pazopanib	Ubrogepant	
	Pibrentasvir	Vemurafenib	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Vyndaqel and Vyndamax Prescribing Information, Oct. 2023, Pfizer Inc.

Criteria Recommendations	*Approved*	*Rejected*

13. Tafamidis / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on findings from animal studies, Vyndamax (tafamidis) may cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Report pregnancies to the Pfizer reporting line at 1-800-438-1985.

Drugs/Diseases

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

Gender: Female

Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Vyndaqel and Vyndamax Prescribing Information, Oct. 2023, Pfizer Inc.

14. Tafamidis / Therapeutic Appropriateness _____ _____

Alert Message: There are no available data on the presence of Vyndamax (tafamidis) in human milk, the effect on the breastfed infant, or the effect on milk production. Tafamidis is present in rat milk. When a drug is present in animal milk, it is likely the drug will be present in human milk. Based on findings from animal studies that suggest the potential for serious adverse reactions in the breastfed infant, advise patients that breastfeeding is not recommended during treatment with tafamidis.

Drugs/Diseases

Util A	Util B	Util C
Tafamidis	Lactation	

Gender: Female

Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Vyndaqel and Vyndamax Prescribing Information, Oct. 2023, Pfizer Inc.

Criteria Recommendations ***Approved Rejected***

15. Tafamidis / Non-adherence _____ _____

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

Util A Util B Util C

Tafamidis

References:

Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Kim J, Combs K, Downs J, Tillman F., Medication Adherence: The Elephant in the Room. US Pharm. 2018;43(1)30-34.

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

16. Levodopa Inhalation / Overuse _____ _____

Alert Message: Inbrija (levodopa inhalation) may be overutilized. The maximum recommended dose of levodopa inhalation per OFF period is 420 mg daily (2 capsules inhaled up to 5 times a day).

Drugs/Diseases

Util A Util B Util C

Levodopa Inhalation

Max Dose:

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

Criteria Recommendations	*Approved*	*Rejected*

17. Levodopa Inhalation / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Inbrija (levodopa inhalation) has not been established in pediatric patients.

Drugs/Diseases

Util A	Util B	Util C
Levodopa Inhalation		

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

18. Levodopa Inhalation / Respiratory Disorders _____ _____

Alert Message: Because of the risk of bronchospasm, use of Inbrija (levodopa inhalation) in patients with asthma, COPD, or another chronic underlying lung disease is not recommended.

Drugs/Diseases

Util A	Util B	Util C
Levodopa Inhalation	Asthma	
	Bronchiectasis	
	Chronic Bronchitis	
	COPD	
	Cystic Fibrosis	
	Emphysema	
	Pulmonary Fibrosis	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

Criteria Recommendations	*Approved*	*Rejected*

19. Tirzepatide / Overuse _____ _____

Alert Message: Zepbound (tirzepatide) may be over-utilized. The maximum recommended dose of tirzepatide is 15 mg injected subcutaneously once weekly.

Drugs/Diseases

Util A	Util B	Util C
Tirzepatide		

Max Dose: 15 mg q weekly

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Zepbound Prescribing Information, Nov. 2023, Eli Lilly and Company.

20. Tirzepatide / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Zepbound (tirzepatide) have not been established in pediatric patients younger than 18 years of age.

Drugs/Diseases

Util A	Util B	Util C
Tirzepatide		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Zepbound Prescribing Information, Nov. 2023, Eli Lilly and Company.

21. Tirzepatide / Therapeutic Appropriateness _____ _____

Alert Message: Zepbound (tirzepatide) is contraindicated in patients with a personal or family history of MTC or patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk of MTC and symptoms of thyroid tumors (e.g., a mass in the neck, dysphagia, dyspnea, persistent hoarseness).

Drugs/Diseases

Util A	Util B	Util C (Include)
Tirzepatide		Medullary Thyroid Carcinoma
		HX of Medullary Thyroid Carcinoma
		Multiple Endocrine Neoplasia Syndrome 2

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Zepbound Prescribing Information, Nov. 2023, Eli Lilly and Company.

Criteria Recommendations	*Approved*	*Rejected*

22. Tirzepatide / Therapeutic Appropriateness _____ _____

Alert Message: Zepbound (tirzepatide) causes a statistically significant increase in thyroid C-cell tumors in rats. It is unknown whether tirzepatide causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC) in humans, as the human relevance of tirzepatide-induced rodent thyroid C-cell tumors has not been determined.

Drugs/Diseases

Util A	Util B	Util C (Include)
Tirzepatide		

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Zepbound Prescribing Information, Nov. 2023, Eli Lilly and Company.

23. Tirzepatide / Pancreatitis _____ _____

Alert Message: Acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, has been observed in patients treated with GLP-1 receptor agonists, including Zepbound (tirzepatide). Tirzepatide has not been studied in patients with a prior history of pancreatitis. It is unknown if patients with a history of pancreatitis are at higher risk for the development of pancreatitis on tirzepatide. After initiation of tirzepatide, observe patients carefully for signs and symptoms of pancreatitis (including persistent severe abdominal pain, sometimes radiating to the back and which may or may not be accompanied by vomiting). If pancreatitis is suspected, discontinue tirzepatide and initiate appropriate management.

Drugs/Diseases

Util A	Util B	Util C
Tirzepatide	Pancreatitis	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Zepbound Prescribing Information, Nov. 2023, Eli Lilly and Company.

24. Tirzepatide / Kidney Injury _____ _____

Alert Message: In patients treated with GLP-1 receptor agonists, including Zepbound (tirzepatide), there have been postmarketing reports of acute kidney injury and worsening of chronic renal failure, which may sometimes require hemodialysis. Some of these events have been reported in patients without known underlying renal disease. A majority of the reported events occurred in patients who had experienced nausea, vomiting, diarrhea, or dehydration. Monitor renal function when initiating or escalating doses of tirzepatide in patients with renal impairment reporting severe gastrointestinal adverse reactions.

Drugs/Diseases

Util A	Util B	Util C
Tirzepatide	Renal Impairment	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Zepbound Prescribing Information, Nov. 2023, Eli Lilly and Company.

Criteria Recommendations	*Approved*	*Rejected*

25. Tirzepatide / Gastroparesis _____ _____

Alert Message: Use of Zepbound (tirzepatide) has been associated with gastrointestinal adverse reactions, sometimes severe. Tirzepatide has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis, and is therefore not recommended in these patients.

Drugs/Diseases

Util A	Util B	Util C
Tirzepatide	Gastroparesis	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Zepbound Prescribing Information, Nov. 2023, Eli Lilly and Company.

26. Tirzepatide / Diabetic Retinopathy _____ _____

Alert Message: Rapid improvement in glucose control has been associated with a temporary worsening of diabetic retinopathy. Zepbound (tirzepatide) has not been studied in patients with non-proliferative diabetic retinopathy requiring acute therapy, proliferative diabetic retinopathy, or diabetic macular edema. Patients with a history of diabetic retinopathy should be monitored for the progression of diabetic retinopathy.

Drugs/Diseases

Util A	Util B	Util C
Tirzepatide	Diabetic Retinopathy	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Zepbound Prescribing Information, Nov. 2023, Eli Lilly and Company.

27. Tirzepatide / Gallbladder Disease _____ _____

Alert Message: Acute events of gallbladder disease, such as cholelithiasis or cholecystitis, have been reported in GLP-1 receptor agonist (including tirzepatide) trials and postmarketing. If cholelithiasis is suspected, gallbladder diagnostic studies and appropriate clinical follow-up are indicated.

Drugs/Diseases

Util A	Util B	Util C
Tirzepatide	Cholelithiasis	
	Biliary Colic	
	Cholecystitis	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Zepbound Prescribing Information, Nov. 2023, Eli Lilly and Company.

28. Tirzepatide / Insulin & Insulin Secretagogues _____ _____

Alert Message: Patients receiving Zepbound (tirzepatide) in combination with an insulin secretagogue (e.g., sulfonylurea) or insulin may have an increased risk of hypoglycemia, including severe hypoglycemia. The risk of hypoglycemia may be lowered by a reduction in the dose of sulfonylurea (or other concomitantly administered insulin secretagogue) or insulin. Inform patients using these concomitant medications of the risk of hypoglycemia and educate them on the signs and symptoms of hypoglycemia.

Drugs/Diseases

Util A	Util B	Util C
Tirzepatide	Insulin	
	Insulin Secretagogues	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Zepbound Prescribing Information, Nov. 2023, Eli Lilly and Company.

29. Tirzepatide / Oral Drugs with NTI _____ _____

Alert Message: Zepbound (tirzepatide) delays gastric emptying, and thereby has the potential to impact the absorption of concomitantly administered oral medications. Caution should be exercised when oral medications are concomitantly administered with tirzepatide. Monitor patients on oral medications dependent on threshold concentrations for efficacy and those with a narrow therapeutic index (e.g., warfarin) when concomitantly administered with tirzepatide.

Drugs/Diseases

Util A	Util B		Util C
Tirzepatide	Carbamazepine	Phenytoin	
	Cyclosporine	Procainamide	
	Digoxin	Tacrolimus	
	Ethosuximide	Theophylline	
	Levothyroxine	Warfarin	
	Lithium		

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Zepbound Prescribing Information, Nov. 2023, Eli Lilly and Company.

30. Tirzepatide / Oral Contraceptives _____ _____

Alert Message: The use of Zepbound (tirzepatide) may reduce the efficacy of oral hormonal contraceptives due to delayed gastric emptying. Advise patients using oral hormonal contraceptives to switch to a non-oral contraceptive method or add a barrier method of contraception for 4 weeks after initiation and 4 weeks after each dose escalation with tirzepatide.

Drugs/Diseases

Util A	Util B	Util C
Tirzepatide	Oral Contraceptives	

Gender: Female

Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Zepbound Prescribing Information, Nov. 2023, Eli Lilly and Company.

Criteria Recommendations	*Approved*	*Rejected*

31. Tirzepatide / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Available data with Zepbound (tirzepatide) in pregnant patients are insufficient to evaluate for a drug-related risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. Advise pregnant patients that weight loss is not recommended during pregnancy and to discontinue tirzepatide when a pregnancy is recognized. Weight loss offers no benefit to a pregnant patient and may cause fetal harm.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Zepbound Prescribing Information, Nov. 2023, Eli Lilly and Company.

32. Tirzepatide / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Tirzepatide	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Zepbound Prescribing Information, Nov. 2023, Eli Lilly and Company.

33. Quizartinib / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Quizartinib		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Vanflyta Prescribing Information, July 2023, Daiichi Sankyo, Inc.

Criteria Recommendations	*Approved*	*Rejected*

34. Quizartinib / Box Warning _____ _____

Alert Message: Vanflyta (quizartinib) use is contraindicated in patients with severe hypokalemia or severe hypomagnesemia.

Drugs/Diseases

Util A	Util B	Util C
Quizartinib	Hypokalemia	
	Hypomagnesemia	

References:

Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Vanflyta Prescribing Information, July 2023, Daiichi Sankyo, Inc.

35. Quizartinib / Box Warning _____ _____

Alert Message: Vanflyta (quizartinib) use is contraindicated in patients with long QT syndrome or with a history of ventricular arrhythmias or torsades de pointes. Quizartinib prolongs the QT interval in a dose- and concentration-dependent manner. Torsades de pointes, ventricular fibrillation, cardiac arrest, and sudden death have occurred in patients treated with quizartinib. Do not initiate treatment with quizartinib or escalate the quizartinib dose if the QT interval corrected by Fridericia's formula (QTcF) is greater than 450 ms.

Drugs/Diseases

Util A	Util B	Util C
Quizartinib	QT Prolongation	
	Torsades de Pointes	
	Ventricular Arrhythmias	

References:

Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Vanflyta Prescribing Information, July 2023, Daiichi Sankyo, Inc.

Criteria Recommendations	*Approved*	*Rejected*

36. Quizartinib / QT prolongation Medications (Box Warning) _____ _____

Alert Message: Vanflyta (quizartinib) prolongs the QT/QTc interval. Coadministration of quizartinib with other drugs that prolong the QT interval may further increase the incidence of QT prolongation. Monitor patients more frequently with ECG if coadministration of quizartinib with drugs known to prolong the QT interval is required.

Drugs/Diseases

Util A	Util B				Util C
Quizartinib	Abiraterone	Efavirenz	Lithium	Rilpivirine	
	Alfuzosin	Eliglustat	Lofexidine	Risperidone	
	Amiodarone	Encorafenib	Loperamide	Ritonavir	Amitriptyline
	Entrectinib	Maprotiline	Romidepsin		
	Amoxapine	Eribulin	Methadone	Sertraline	
	Anagrelide	Erythromycin	Metoclopramide	Siponimod	
	Aripiprazole	Escitalopram	Midostaurin	Solifenacin	
	Arsenic Trioxide	Ezogabine	Mifepristone	Sotalol	
	Artemether/Lum	Famotidine	Mirabegron	Sunitinib	
	Asenapine	Felbamate	Mirtazapine	Tacrolimus	
	Atazanavir	Fingolimod	Moexipril	Tamoxifen	
	Atomoxetine	Flecainide	Moxifloxacin	Telavancin	
	Azithromycin	Fluconazole	Nelfinavir	Tetrabenazine	
	Bedaquiline	Fluoxetine	Nilotinib	Thioridazine	
	Bortezomib	Fluvoxamine	Nortriptyline	Tizanidine	
	Bendamustine	Foscarnet	Ofloxacin	Tolterodine	
	Bosutinib	Galantamine	Ondansetron	Toremifene	
	Buprenorphine	Ganciclovir	Osimertinib	Tramadol	
	Ceritinib	Gemifloxacin	Oxaliplatin	Trazodone	
	Chloroquine	Gilteritinib	Paliperidone	Tranylcypromine	
	Chlorpromazine	Glasdegib	Palonosetron	Trimipramine	
	Cilostazol	Granisetron	Panobinostat	Valbenazine	
	Ciprofloxacin	Haloperidol	Paroxetine	Vandetanib	
	Citalopram	Hydroxychloroquine	Pasireotide	Vemurafenib	
	Clarithromycin	Hydroxyzine	Pazopanib	Venlafaxine	
	Clomipramine	Ibutilide	Pentamidine	Voriconazole	
	Clozapine	Iloperidone	Pimavanserin		
	Crizotinib	Imipramine	Pimozide		
	Dabrafenib	Indapamide	Pitolisant		
	Dasatinib	Isocarboxazid	Phenelzine		
	Desipramine	Itraconazole	Posaconazole		
	Deutetrabenazine	Ivosidenib	Procainamide		
	Diphenhydramine	Ivabradine	Promethazine		
	Disopyramide	Ketoconazole	Propafenone		
	Dofetilide	Lapatinib	Protriptyline		
	Dolasetron	Lefamulin	Quetiapine		
	Donepezil	Lenvatinib	Quinidine		
	Doxepin	Leuprolide	Quinine		
	Dronedarone		Ranolazine		

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Vanflyta Prescribing Information, July 2023, Daiichi Sankyo, Inc.

Criteria Recommendations	*Approved*	*Rejected*

37. Quizartinib / Strong CYP3A4 Inhibitors _____ _____

Alert Message: The coadministration of Vanflyta (quizartinib) with a strong CYP3A4 inhibitor increases quizartinib systemic exposure, which may increase the risk of quizartinib adverse reactions. If concurrent use is warranted, reduce the quizartinib dose according to the official prescribing information.

Drugs/Diseases

Util A	Util B	Util C
Quizartinib	Clarithromycin	Nelfinavir
	Cobicistat	Posaconazole
	Itraconazole	Ritonavir
	Ketoconazole	Voriconazole
	Nefazodone	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Vanflyta Prescribing Information, July 2023, Daiichi Sankyo, Inc.

38. Quizartinib / Moderate & Strong CYP3A4 Inducers _____ _____

Alert Message: The concurrent use of Vanflyta (quizartinib) with strong CYP3A4 inducers should be avoided. Inhibitor decreases quizartinib systemic exposure, which may decrease quizartinib efficacy.

Drugs/Diseases

Util A	Util B	Util C
Quizartinib	Clarithromycin	Nelfinavir
	Cobicistat	Posaconazole
	Itraconazole	Ritonavir
	Ketoconazole	Voriconazole
	Nefazodone	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Vanflyta Prescribing Information, July 2023, Daiichi Sankyo, Inc.

39. Quizartinib / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on findings in animals and its mechanism of action, Vanflyta (quizartinib) can cause fetal harm when administered to a pregnant woman. In animal reproduction studies, administration of quizartinib to pregnant rats during organogenesis at exposures 3 times the maximum recommended human dose (MRHD) of 53 mg/day caused structural abnormalities and alterations to growth. Advise pregnant women of the potential risk to a fetus.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Vanflyta Prescribing Information, July 2023, Daiichi Sankyo, Inc.

40. Quizartinib / Lactation _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Quizartinib	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Vanflyta Prescribing Information, July 2023, Daiichi Sankyo, Inc.

41. Quizartinib / Therapeutic Appropriateness _____ _____

Alert Message: Advise females of reproductive potential to use effective contraception during treatment with Vanflyta (quizartinib) and for 7 months after the last dose. Based on findings in animals and its mechanism of action, quizartinib can cause fetal harm when administered to a pregnant woman.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Quizartinib		Contraceptives

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Vanflyta Prescribing Information, July 2023, Daiichi Sankyo, Inc.

42. Quizartinib / Therapeutic Appropriateness _____ _____

Alert Message: Based on genotoxicity findings, advise male patients with female partners of reproductive potential to use effective contraception during treatment with Vanflyta (quizartinib) and for 4 months after the last dose.

Drugs/Diseases
Util A Util B Util C
Quizartinib

Gender: Male

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Vanflyta Prescribing Information, July 2023, Daiichi Sankyo, Inc.

43. Ofatumumab / Overuse _____ _____

Alert Message: Kesimpta (ofatumumab) may be over-utilized. The recommended maintenance dose for ofatumumab is one 20 mg subcutaneous injection once a month.

Drugs/Diseases
Util A Util B Util C
Ofatumumab

Max Dose: 20 mg/month

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Kesimpta Prescribing Information, Jan. 2024, Novartis Pharmaceuticals Corporation.

44. Ofatumumab / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases
Util A Util B Util C
Ofatumumab

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Kesimpta Prescribing Information, Jan. 2024, Novartis Pharmaceuticals Corporation.

45. Ofatumumab / Active Hepatitis B _____ _____

Alert Message: Kesimpta (ofatumumab) is contraindicated in patients with active hepatitis B. There were no reports of HBV reactivation in patients with MS treated with ofatumumab. However, HBV reactivation, in some cases resulting in fulminant hepatitis, hepatic failure, and death, has occurred in patients being treated with ofatumumab for chronic lymphocytic leukemia (CLL) (at higher intravenous doses than the recommended dose in MS but for a shorter duration of treatment) and in patients treated with other anti-CD20 antibodies.

Drugs/Diseases

Util A	Util B	Util C
Ofatumumab	Hepatitis B	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Kesimpta Prescribing Information, Jan. 2024, Novartis Pharmaceuticals Corporation.

46. Ofatumumab / Infections _____ _____

Alert Message: Serious, including life-threatening or fatal, bacterial, fungal, and new or reactivated viral infections have been observed during and following completion of treatment with anti-CD20 B-cell depleting therapies, including Kesimpta (ofatumumab). Delay ofatumumab administration in patients with an active infection until the infection is resolved. Vaccination with live-attenuated or live vaccines is not recommended during treatment and after discontinuation until B-cell repletion.

Drugs/Diseases

Util A	Util B	Util C
Ofatumumab	Serious Infection	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Kesimpta Prescribing Information, Jan. 2024, Novartis Pharmaceuticals Corporation.

47. Ofatumumab / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on animal data, Kesimpta (ofatumumab) can cause fetal harm due to B-cell lymphopenia and reduce antibody response in offspring exposed to ofatumumab in utero. Transient peripheral B-cell depletion and lymphocytopenia have been reported in infants born to mothers exposed to other anti-CD20 B-cell depleting antibodies during pregnancy. Advise females of reproductive potential to use effective contraception while receiving ofatumumab and for at least 6 months after the last dose.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Kesimpta Prescribing Information, Jan. 2024, Novartis Pharmaceuticals Corporation.

Criteria Recommendations	*Approved*	*Rejected*

48. Ofatumumab / Lactation _____ _____

Alert Message: There are no data on the presence of Kesimpta (ofatumumab) in human milk, the effects on the breastfed infant, or the effects of the drug on milk production. Human IgG is excreted in human milk, and the potential for absorption of ofatumumab to lead to B-cell depletion in the infant is unknown. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ofatumumab and any potential adverse effects on the breastfed infant from ofatumumab or the underlying maternal condition.

Drugs/Diseases

Util A	Util B	Util C
Ofatumumab	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Kesimpta Prescribing Information, Jan. 2024, Novartis Pharmaceuticals Corporation.

49. Ofatumumab / Adverse Fetal Effects _____ _____

Alert Message: Females of childbearing potential should use effective contraception while receiving Kesimpta (ofatumumab) and for 6 months after the last treatment of ofatumumab.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Ofatumumab		Contraceptives

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Kesimpta Prescribing Information, Jan. 2024, Novartis Pharmaceuticals Corporation.

50. Ofatumumab / Non-adherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Kesimpta (ofatumumab). 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
Ofatumumab		

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
McKay KA, Tremlett H, Patten SB, et al. Determinants of Non-Adherence to Disease-Modifying Therapies in Multiple Sclerosis: A Cross-Canada Prospective Study. Mult Scler. 2016;23(4):588-596.

Higuera L, Carlin CS, Anderson S. Adherence to Disease-Modifying Therapies for Multiple Sclerosis. J Manag Care Spec Pharm. 2016;22(12):1394-1401.

51. Omaveloxolone / Overuse _____ _____

Alert Message: Skyclarys (omaveloxolone) may be over-utilized. The recommended dosage of omaveloxolone is 150 mg (3 capsules) once daily.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Omaveloxolone		Hepatic Impairment

Max Dose: 150 mg/day

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Skyclarys Prescribing Information, Jan. 2024, Reata Pharmaceuticals, Inc.

52. Omaveloxolone / Overuse – Moderate Hepatic Impairment _____ _____

Alert Message: Skyclarys (omaveloxolone) may be over-utilized. The recommended dosage of omaveloxolone in patients with moderate hepatic impairment is 100 mg once daily, with close monitoring for adverse reactions. If adverse reactions emerge, consider lowering the dose to 50 mg once daily.

Drugs/Diseases

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

Max Dose: 100 mg/day

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Skyclarys Prescribing Information, Jan. 2024, Reata Pharmaceuticals, Inc.

53. Omaveloxolone / Severe Hepatic Impairment _____ _____

Alert Message: Skyclarys (omaveloxolone) use should be avoided in patients with severe hepatic impairment. In clinical studies, subjects with severe hepatic impairment (Child-Pugh Class C) receiving omaveloxolone had significantly reduced clearance.

Drugs/Diseases

Util A	Util B	Util C (Include)
Omaveloxolone		Cirrhosis
		Hepatic Failure

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Skyclarys Prescribing Information, Jan. 2024, Reata Pharmaceuticals, Inc.

54. Omaveloxolone / Hypercholesterolemia _____ _____

Alert Message: Treatment with Skyclarys (omaveloxolone) can cause changes in cholesterol. In a clinical study (Study 1), 29% of patients treated with omaveloxolone reported elevated cholesterol above ULN at one or more time points. Mean increases were observed within 2 weeks of initiation of omaveloxolone and returned to baseline within 4 weeks of discontinuing treatment. A total of 16% of patients treated with omaveloxolone had an increase in low-density lipoprotein cholesterol (LDL-C) from baseline, compared to 8% of patients who received placebo. The mean increase in LDL-C for all omaveloxolone-treated patients was 23.5 mg/dL at 48 weeks. A total of 6% of patients treated with omaveloxolone had decreases in high-density lipoprotein cholesterol (HDL-C) from baseline compared to 4% of patients who received placebo. Assess lipid parameters prior to initiation of omaveloxolone and monitor periodically during treatment. Manage lipid abnormalities according to clinical guidelines.

Drugs/Diseases

Util A	Util B	Util C
Omaveloxolone	Hypercholesterolemia	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Skyclarys Prescribing Information, Jan. 2024, Reata Pharmaceuticals, Inc.

55. Omaveloxolone / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Skyclarys (omaveloxolone) have not been established in pediatric patients less than 16 years of age.

Drugs/Diseases

Util A	Util B	Util C
Omaveloxolone		

Age Range: 0 – 15 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Skyclarys Prescribing Information, Jan. 2024, Reata Pharmaceuticals, Inc.

56. Omaveloxolone / Hormonal Contraceptives _____ _____

Alert Message: Skyclarys (omaveloxolone) is a weak CYP3A4 inducer. Concomitant use with omaveloxolone may reduce the efficacy of hormonal contraceptives. Advise patients to avoid concomitant use with combined hormonal contraceptives (e.g., pill, patch, ring), implants, and progestin-only pills. Counsel females using hormonal contraceptives to use an alternative contraceptive method (e.g., non-hormonal intrauterine system) or additional non-hormonal contraceptive (e.g., condoms) during concomitant use and for 28 days after discontinuation of omaveloxolone.

Drugs/Diseases

Util A	Util B	Util C
Omaveloxolone	Hormonal Contraceptives	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Skyclarys Prescribing Information, Jan. 2024, Reata Pharmaceuticals, Inc.

57. Omaveloxolone / Strong or Moderate CYP3A4 Inhibitors _____ _____

Alert Message: Skyclarys (omaveloxolone) is a CYP3A4 substrate. Concomitant use of omaveloxolone with moderate or strong CYP3A4 inhibitors is expected to result in clinically significant increased exposure to omaveloxolone, which may increase the risk of adverse reactions. Avoid concomitant use of omaveloxolone with moderate or strong CYP3A4 inhibitors. If use cannot be avoided, reduce the dose of omaveloxolone to 100 mg once daily and monitor for adverse reactions. If adverse reactions emerge, reduce the dose to 50 mg once daily.

Drugs/Diseases

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

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Skyclarys Prescribing Information, Jan. 2024, Reata Pharmaceuticals, Inc.

58. Omaveloxolone / Strong or Moderate CYP3A4 Inducers _____ _____

Alert Message: Skyclarys (omaveloxolone) is a CYP3A4 substrate. Concomitant use of omaveloxolone with moderate or strong CYP3A4 inducers may significantly decrease omaveloxolone exposure, which may reduce the effectiveness of omaveloxolone. Avoid concomitant use of omaveloxolone with moderate or strong CYP3A4 inducers.

Drugs/Diseases

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

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Skyclarys Prescribing Information, Jan. 2024, Reata Pharmaceuticals, Inc.

Criteria Recommendations	*Approved*	*Rejected*

59. Omaveloxolone / Pregnancy / Pregnancy Negating _____ _____

Alert Message: There are no adequate data on the developmental risks associated with the use of Skyclarys (omaveloxolone) in pregnant women. In animal studies, administration of omaveloxolone during pregnancy or throughout pregnancy and lactation produced evidence of developmental toxicity (embryofetal mortality and growth impairment, and mortality, growth impairment, and neurobehavioral deficits in offspring) at plasma exposures similar to or less than exposures in humans.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Skyclarys Prescribing Information, Jan. 2024, Reata Pharmaceuticals, Inc.

60. Omaveloxolone / Lactation _____ _____

Alert Message: There are no data on the presence of Skyclarys (omaveloxolone) or its metabolites in human milk. The effects on milk production and the breastfed infant are unknown. Omaveloxolone was excreted in the milk of lactating rats following oral administration. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for omaveloxolone and any potential adverse effects on the breastfed infant from omaveloxolone or the underlying maternal condition.

Drugs/Diseases

Util A	Util B	Util C
Omaveloxolone	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Skyclarys Prescribing Information, Jan. 2024, Reata Pharmaceuticals, Inc.

61. Omaveloxolone / Non-adherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Skyclarys (omaveloxolone). 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
Omaveloxolone		

References:

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

Marcum ZA, Sevick MA, Handler SM. Medication Nonadherence: A Diagnosable and Treatable Medical Condition. JAMA. 2013;309(20):2105-2106. doi:10.1001/jama.2013.4638.

Kim J, Combs K, Downs J, Tillman F., Medication Adherence: The Elephant in the Room. US Pharm. 2018;43(1)30-34.

62. Reslizumab / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Cinqair (reslizumab) in pediatric patients less than 18 years of age have not been established.

Drugs/Diseases

Util A	Util B	Util C
Reslizumab		

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

63. Reslizumab / Pregnancy / Pregnancy Negating _____ _____

Alert Message: The data on pregnancy exposure to Cinqair (reslizumab) from the clinical trials are insufficient to inform on drug associated risk. Monoclonal antibodies, such as reslizumab, are transported across the placenta in a linear fashion as pregnancy progresses; therefore, potential effects on a fetus are likely to be greater during the second and third trimester of pregnancy. Reslizumab has a long half-life. This should be taken into consideration.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

Criteria Recommendations	*Approved*	*Rejected*

64. Reslizumab / Lactation _____ _____

Alert Message: It is not known whether Cinqair (reslizumab) is present in human milk, and the effects of reslizumab on the breast fed infant and on milk production are not known. However, human IgG is known to be present in human milk. Reslizumab was present in the milk of lactating mice following dosing during pregnancy. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for reslizumab and any potential adverse effects on the breast-fed child from reslizumab or the underlying maternal condition.

Drugs/Diseases

Util A	Util B	Util C
Reslizumab	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

65. Reslizumab / Helminth Infection _____ _____

Alert Message: Eosinophils may be involved in the immunological response to some helminth infections. It is unknown if Cinqair (reslizumab) will influence the immune response against parasitic infections. Treat patients with pre-existing helminth infections before initiating reslizumab. If patients become infected while receiving treatment with reslizumab and do not respond to anti-helminth treatment, discontinue treatment with reslizumab until infection resolves.

Drugs/Diseases

Util A	Util B	Util C
Reslizumab	Helminth Infection	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.