North Dakota Medicaid
Drug Utilization Review Board Meeting
September 4, 2024
Conference Room 210/212

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Be Legendary.

Meeting Notice

North Dakota Medicaid Drug Use Review Board

Wednesday, September 4, 2024
1:00 p.m. – 4:00 p.m. CT

In-Person Information

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

Virtual Information

Join by computer: Click here to join the meeting
Join by phone: 701-328-0950, conference ID # 506 213 519

Agenda

- Call to Order
- Roll Call
- Review and Approval of Minutes
- Reports from Department
    - Administrative Report
    - Financial Report: Top Drugs
    - Retrospective DUR Report
    - Clinical Report:
        - Prior Authorization Update
        - Criteria updates: asthma/COPD, chronic kidney disease, Duchenne muscular dystrophy, growth hormone, heart failure, hereditary angioedema, hypertrophic cardiomyopathy, lipid-lowering treatment, plaque psoriasis, medications over $3000, dry eye disease
- Unfinished Business
- New Business
    - Second Review of Molluscum Contagiosum (Ycanth and Zelsuvmi)
    - Second Review of Epidermolysis Bullosa (Filsuvez)
    - Second Review of Metabolic Dysfunction–Associated Steatohepatitis (Rezdiffra)
    - First Review of Attention-Deficit Hyperactivity Disorder Stimulants
    - Review of retrospective DUR criteria recommendations
- Announcements: Next Meeting (December 4, 2024)
- Adjourn

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

Date Posted: January 18, 2024
Date Revised: August 6, 2024 (agenda/meeting details added)

Meeting Minutes
North Dakota Medicaid Drug Use Review (DUR) Board
Meeting Date: June 5th, 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 1:03 pm CST with T. Schmidt 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, Jennifer Iverson, Laura Kroetsch, Kevin Martian, Tanya Schmidt, Amy Werremeyer
Absent: Kristen Peterson, Josh Askvig
Quorum Present: Yes

Board Members Non-Voting:
Absent: Kathleen Traylor

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

Approval of Meeting Minutes:
Motion: Moved by A. Werremeyer to approve the minutes of the March 6th, 2024 meeting, motion was seconded by K. Datz. **Motion carried.**
The minutes of the March 6th, 2024 meeting were approved as distributed.

Reports:
*Administrative Report***:** by A. Murphy
A. Murphy shared with the Board reports reviewing drug utilization in the following: antidepressants in pediatric females, attention-deficit hyperactivity disorder in adult females, biologics, contraceptives, cystic fibrosis, and opioid analgesics prescribed by dentists. This information can be found in the handout.

Financial Report: Budget provided by A. Murphy
A. Murphy shared with the Board trends of post rebate spend since 2020 and the financial effects from AMP cap removal. This information can be found in the handout.

Financial Report: Top Drugs provided by C. Stauter
C. Stauter 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: food allergy, reduction of major adverse cardiovascular events (MACE), pulmonary hypertension, and

tardive dyskinesia. The presented information can be found in the handout. Testimony was provided by Jeremy Whalen from Genentech on Xolair, Mary Claire Wohletz from Merck on Winrevair, and Jasmine Inman from Teva on Austedo.

Special Orders:
Elections
T. Schmidt nominated to serve as Presiding Officer. Moved by T. Schmidt, motion was seconded by A. Honeyman. **Motion carried.**
K. Martian nominated to serve as Vice-Presiding Officer. Moved by K. Datz, motion was seconded by A. Honeyman. **Motion carried.**

Unfinished business:
Criteria Updates provided by C. Stauter
C. Stauter presented criteria updates with emphasis on hyperkalemia. The presented material can be found in the handout.

New business:
Second Reviews presented by C. Stauter
C. Stauter presented group prior authorization criteria for acid blockers, paroxysmal nocturnal hemoglobinuria, Duchenne muscular dystrophy, primary hyperoxaluria type 1, myasthenia gravis, and seborrheic dermatitis. The presented material can be found in the handout. Testimony was provided by Kristin Duffey from Novartis on Fabhalta and Colleen Stoyas from UCB on Zilbrysq.
Motion: Moved by K. Martin to place acid blockers on prior authorization, motion was seconded by A. Werremeyer. **Motion carried.**
Motion: Moved by K. Datz to place paroxysmal nocturnal hemoglobinuria on prior authorization, motion was seconded by K. Martian. **Motion carried.**
Motion: Moved by K. Datz to place Duchenne muscular dystrophy on prior authorization, motion was seconded by A. Honeyman. **Motion carried.**
Motion: Moved by K. Martian to place primary hyperoxaluria type 1 on prior authorization, motion was seconded by K. Datz. **Motion carried.**
Motion: Moved by K. Datz to place myasthenia gravis on prior authorization, motion was seconded by A. Dahl. **Motion carried.**
Motion: Moved by K. Martian to place seborrheic dermatitis on prior authorization, motion was seconded by K. Datz. **Motion carried.**

First Reviews presented by C. Stauter
C. Stauter presented an overview of molloscum cantagiosum, epidermolysis bullosa, and metabolic dysfunction-associated steatohepatitis. The presented material can be found in the handout. Testimony was provided by Tara McKinley from Madrigal on Rezdiffra.
Motion: Moved by K. Datz to draft prior authorization for molloscum cantagiosum, motion was seconded by A. Honeyman. **Motion carried.**
Motion: Moved by K. Martian to draft prior authorization for epidermolysis bullosa, motion was seconded by K. Datz. **Motion carried.**
Motion: Moved by K. Martian to draft prior authorization for metabolic dysfunction-associated steatohepatitis, motion was seconded by K. Datz. **Motion carried.**

Retrospective Drug Utilization Review (RDUR) Criteria Recommendations:
RDUR criteria recommendations were reviewed. The presented material can be found in the handout.

Motion: Moved by K. Datz to approve the RDUR criteria, motion was seconded by K. Martian. **Motion carried.**

Announcements:
Next meeting is September 4th, 2024.

Adjournment:
Meeting adjourned by T. Schmidt at 2:56 pm CST.

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

Administrative Report

Biosimilars:

2024 Plan for Biosimilars:

Adalimumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab-adaz	ABRILADA (adalimumab-afzb)
adalimumab-adbm – labeler 00597	adalimumab-aacf
CYLTEZO (adalimumab-abdm)	adalimumab-aaty
HUMIRA (adalimumab)	adalimumab-adbm – labeler 82009
SIMLANDI (adalimumab-ryvk)	adalimumab-fkjp
YUSIMRY (adalimumab-aqvh)	adalimumab-ryvk
	AMJEVITA (adalimumab-atto)
	HADLIMA (adalimumab-bwwd)
	HULIO (adalimumab-fkjp)
	HYRIMOZ (adalimumab-adaz)
	IDACIO (adalimumab-aacf)
	YUFLYMA (adalimumab-aaty)

Infliximab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – *Medical Billing Only*	INFLECTRA (infliximab-dyyb) – *Medical Billing Only*
RENFLEXIS (infliximab-abda) – *Medical Billing Only*	infliximab – *Medical Billing Only*
	REMICADE (infliximab) – *Medical Billing Only*

2025 Plan for Biosimilars:

Adalimumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab-adaz	ABRILADA (adalimumab-afzb)
adalimumab-adbm – labeler 00597	adalimumab-aacf
CYLTEZO (adalimumab-abdm)	adalimumab-aaty
HUMIRA (adalimumab)	adalimumab-adbm – labeler 82009
SIMLANDI (adalimumab-ryvk)	adalimumab-fkjp
YUSIMRY (adalimumab-aqvh)	adalimumab-ryvk
	AMJEVITA (adalimumab-atto)
	HADLIMA (adalimumab-bwwd)
	HULIO (adalimumab-fkjp)
	HYRIMOZ (adalimumab-adaz)
	IDACIO (adalimumab-aacf)
	YUFLYMA (adalimumab-aaty)

Bevacizumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
MVASI (bevacizumab – awwb)	ALYMSYS (bevacizumab – maly)

ZIRABEV (bevacizumab – bvzr)	AVASTIN (bevacizumab)
	VEGZELMA (bevacizumab – acdc)

Infliximab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – *Medical Billing Only*	infliximab – *Medical Billing Only*
INFLECTRA (infliximab-dyyb) – *Medical Billing Only*	RENFLEXIS (infliximab-abda) – *Medical Billing Only*
	REMICADE (infliximab) – *Medical Billing Only*

Rituximab

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

Tocilizumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TYENNE (tocilizumab-aazg) AUTOINJECTOR, SYRINGE	ACTEMRA (tocilizumab) ACTPEN, SYRINGE
TYENNE (tocilizumab-aazg) VIAL – *Medical Billing Only*	ACTEMRA (tocilizumab) VIAL – *Medical Billing Only*
	TOFIDENCE (tocilizumab-aazg) VIAL – *Medical Billing Only*

Trastuzumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KANJINTI (trastuzuamb – anns) – *Medical Billing Only*	HERZUMA (trastuzumab – pkrb) – *Medical Billing Only*
TRAZIMERA (trastuzumab – qyyp) – *Medical Billing Only*	HERCEPTIN (trastuzumab) – *Medical Billing Only*
	OGIVRI (trastuzumab – dkst) – *Medical Billing Only*
	ONTRUZANT (trastuzumab – dttb) – *Medical Billing Only*

Filgrastim

Medical Billing

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
GRANIX (TBO-filgrastim) – *Medical Billing Only*	NEUPOGEN (filgrastim) – *Medical Billing Only*
NIVESTYM (filgrastim-aafi) – *Medical Billing Only*	RELEUKO (filgrastim-ayow) – *Medical Billing Only*
ZARXIO (filgrastim-sndz) – *Medical Billing Only*	

Pharmacy Billing

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NEUPOGEN (filgrastim)	GRANIX (TBO-filgrastim)
RELEUKO (filgrastim-ayow)	NIVESTYM (filgrastim-aafi)
	ZARXIO (filgrastim-sndz)

Pegfilgrastim

Medical Billing

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NEULASTA (pegfilgrastim) *– Medical Billing Only*	FULPHILA (pegfilgrastrim-jmdb) *– Medical Billing Only*
NEULASTA ONPRO (pegfilgrastim) *– Medical Billing Only*	FYLNETRA (pegfilgrastim -pbbk) *– Medical Billing Only*
NYVEPRIA (pegfilgrastrim–apgf) *– Medical Billing Only*	STIMUFEND (pegfilgrastim-fpgk) *– Medical Billing Only*
UDENYCA ONBODY (pegfligrastim-cbqv) *– Medical Billing Only*	UDENYCA (pegfligrastim-cbqv) *– Medical Billing Only*
	ZIEXTENZO (pegfilgrastim-bmez) *– Medical Billing Only*

Pharmacy Billing

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FULPHILA (pegfilgrastrim-jmdb)	NEULASTA (pegfilgrastim)
FYLNETRA (pegfilgrastim -pbbk)	NYVEPRIA (pegfilgrastrim–apgf)
NEULASTA ONPRO (pegfilgrastim)	STIMUFEND (pegfilgrastim-fpgk)
UDENYCA ONBODY (pegfligrastim-cbqv)	UDENYCA (pegfligrastim-cbqv)
	ZIEXTENZO (pegfilgrastim-bmez)

Sargramostim

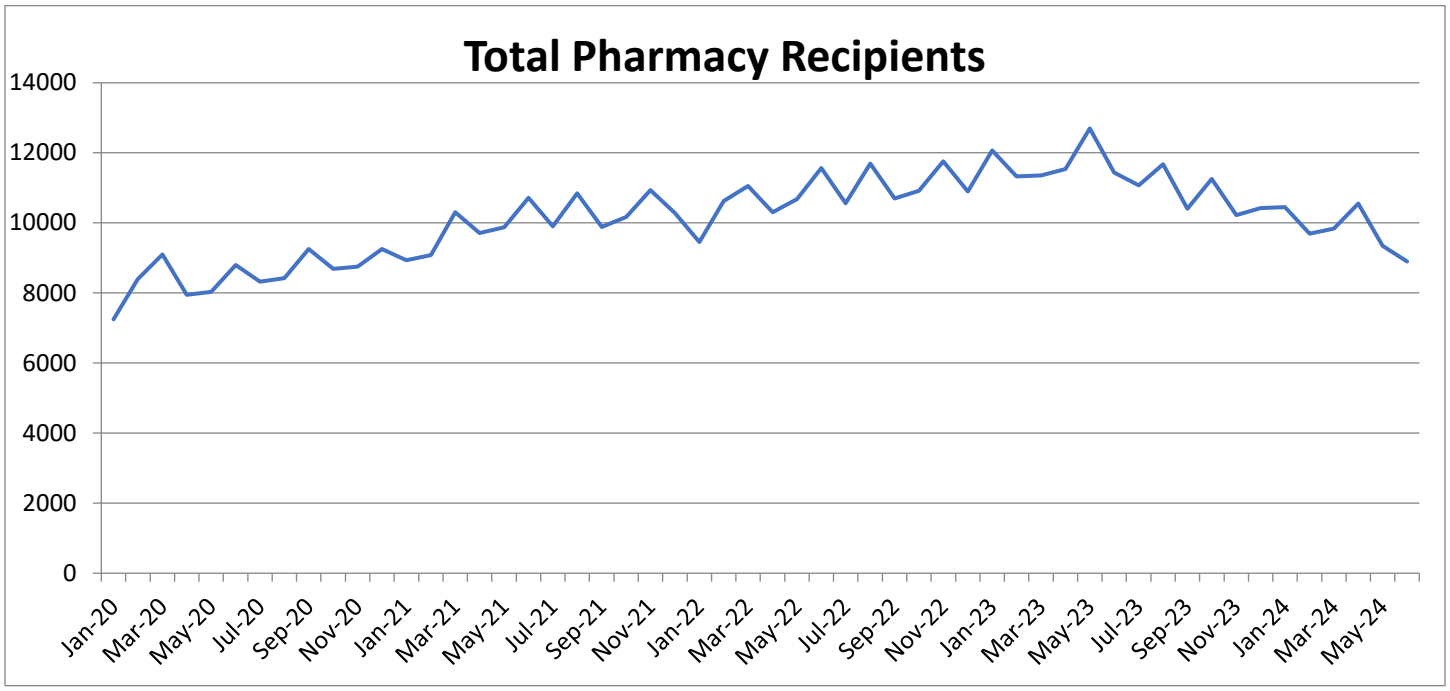
PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
LEUKINE (sargramostim)	
LEUKINE (sargramostim) *– Medical Billing Only*	

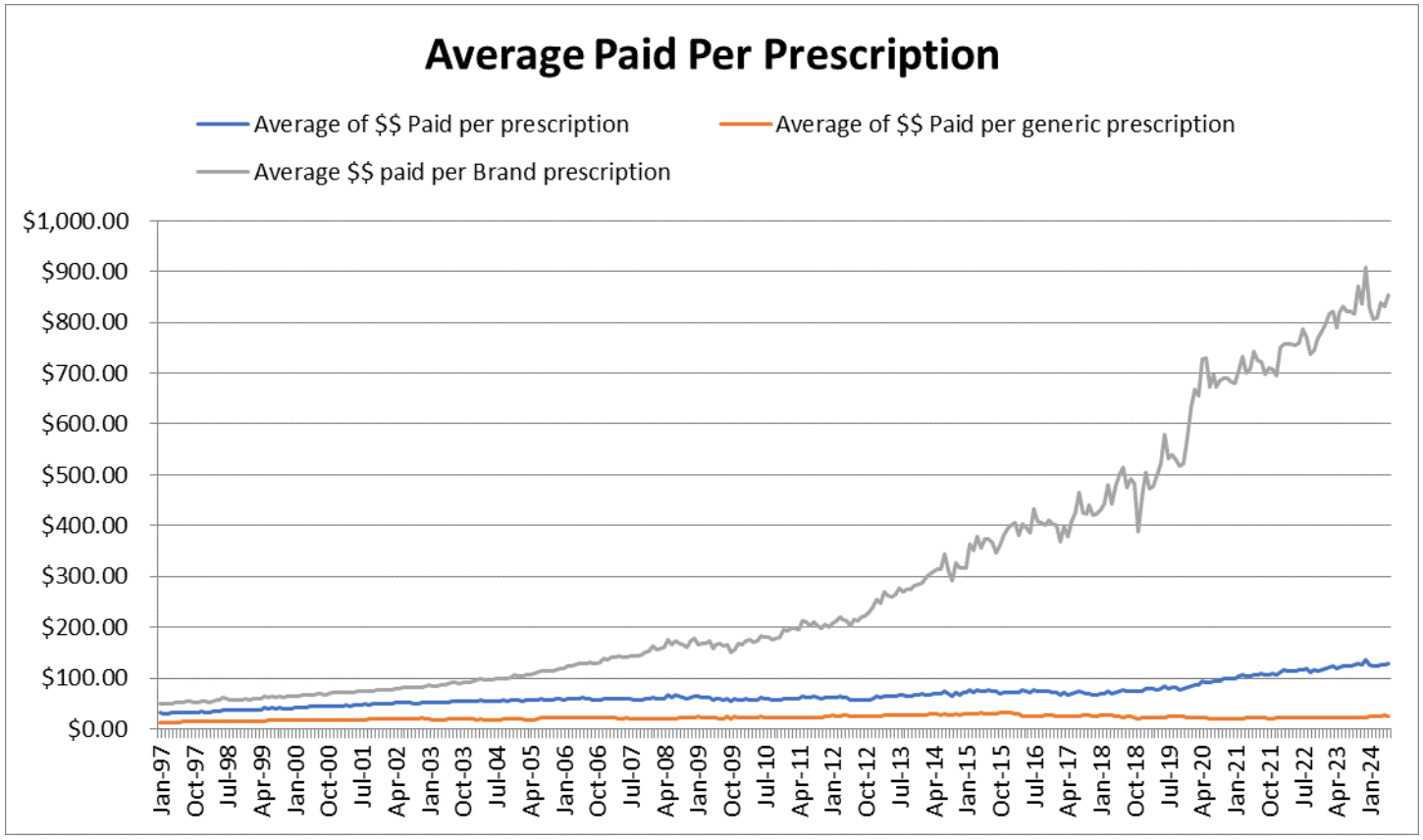
Eflapegrastim-xnst

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ROLVEDON (eflapegrastim-xnst)
	ROLVEDON (eflapegrastim-xnst) *– Medical Billing Only*

Hepatitis C Update	
Quarter	**Members Treated**
QTR 1 2023	34
QTR 2 2023	28
QTR 3 2023	29
QTR 4 2023	47
QTR 1 2024	41
QTR 2 2024	43

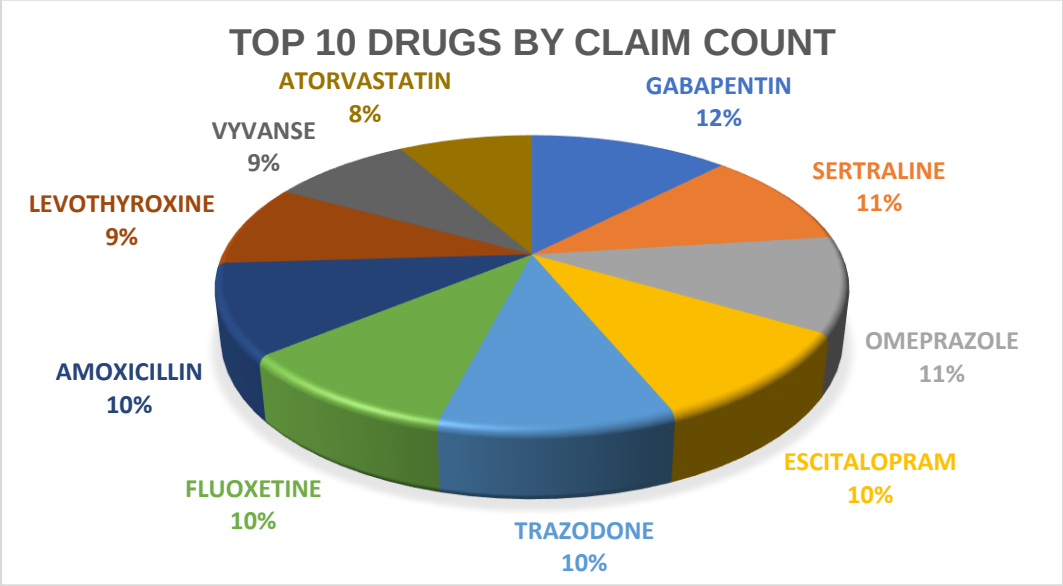
Financial Report





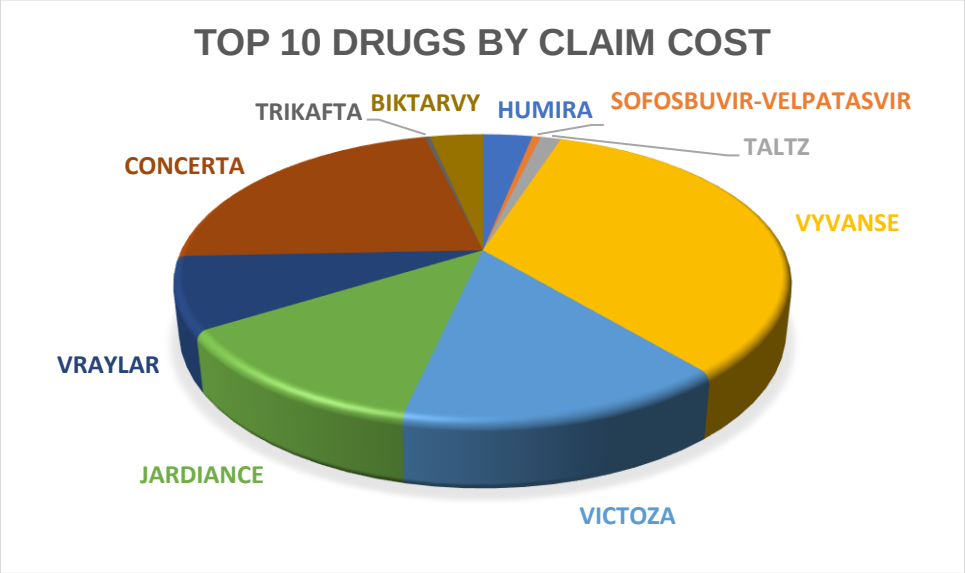
Top 25 Drugs Based on Number of Claims from 04/01/2024 – 06/30/2024

Drug	Claims	Claims Cost	Patients	Cost / Claim	% Claims	Dif.
1. GABAPENTIN	4,053	$59,734.86	1,781	$14.74	1.8%	NC
2. SERTRALINE	3,513	$47,744.65	1,972	$13.59	1.5%	↑2
3. OMEPRAZOLE	3,456	$46,054.06	1,881	$13.33	1.5%	NC
4. ESCITALOPRAM	3,385	$45,436.37	1,929	$13.42	1.5%	↑3
5. TRAZODONE	3,374	$45,299.86	1,780	$13.43	1.5%	↑1
6. FLUOXETINE	3,297	$43,987.95	1,813	$13.34	1.4%	↓1
7. AMOXICILLIN	3,295	$50,569.62	3,130	$15.35	1.4%	↓5
8. LEVOTHYROXINE	2,963	$42,112.61	1,568	$14.21	1.3%	↑1
9. VYVANSE	2,848	$832,301.64	1,224	$292.24	1.2%	↓1
10. ATORVASTATIN	2,729	$38,135.69	1,613	$13.97	1.2%	NC
11. VENTOLIN HFA	2,623	$169,239.72	2,596	$64.52	1.1%	↑2
12. BUPROPION XL	2,619	$42,909.59	1,420	$16.38	1.1%	NC
13. LISINOPRIL	2,595	$33,480.54	1,600	$12.90	1.1%	↓2
14. CLONIDINE	2,548	$31,252.27	1,270	$12.27	1.1%	NC
15. HYDROXYZINE	2,364	$35,601.28	1,458	$15.06	1.0%	↑5
16. PREDNISONE	2,348	$27,109.49	1,887	$11.55	1.0%	↑1
17. AMOXICILLIN-CLAV	2,344	$40,755.77	2,194	$17.39	1.0%	↓1
18. HYDROCODONE-APAP	2,252	$33,432.99	1,455	$14.85	1.0%	↑5
19. LAMOTRIGINE	2,231	$31,016.96	932	$13.90	1.0%	↓1
20. DULOXETINE	2,201	$36,432.73	1,204	$16.55	1.0%	↓1
21. PANTOPRAZOLE	2,180	$30,326.24	1,227	$13.91	0.9%	↓6
22. ARIPIPRAZOLE	2,176	$32,931.90	1,074	$15.13	0.9%	NC
23. BUSPIRONE	2,073	$30,769.54	1,102	$14.84	0.9%	↑3
24. CYCLOBENZAPRINE	2,061	$24,553.78	1,297	$11.91	0.9%	NC
25. CLONAZEPAM	1,994	$26,415.61	855	$13.25	0.9%	↑3
Total Claims						**231,545**



Top 25 Drugs Based on Total Claims Cost from 04/01/2024 – 06/30/2024

Drug	Claims	Claims Cost	Patients	Cost / Patient	% Cost	Dif.
1. HUMIRA	264	$2,117,356.79	120	$17,644.64	6.7%	NC
2. SOFOS-VELPATASVIR	44	$938,637.88	43	$21,828.79	2.9%	↑1
3. TALTZ	109	$903,260.65	53	$17,042.65	2.8%	↑1
4. VYVANSE	2,848	$832,301.64	1,224	$ 679.99	2.6%	↓2
5. VICTOZA	1224	$827,915.83	699	$ 1,184.42	2.6%	↓2
6. JARDIANCE	1,060	$788,073.57	587	$ 1,342.54	2.5%	↓1
7. VRAYLAR	690	$735,100.93	281	$ 2,616.02	2.3%	NC
8. CONCERTA	1,844	$666,901.77	808	$ 825.37	2.1%	↓2
9. TRIKAFTA	28	$622,563.28	11	$56,596.66	2.0%	NC
10. BIKTARVY	282	$617,828.19	142	$4,350.90	1.9%	↓2
11. INVEGA SUSTENNA	192	$528,568.90	84	$6,292.49	1.7%	↓1
12. DUPIXENT	147	$528,235.35	69	$7,655.58	1.7%	NC
13. NORDITROPIN	82	$487,655.96	35	$13,933.03	1.5%	↓2
14. ELIQUIS	640	$391,199.66	327	$1,196.33	1.2%	NC
15. STELARA	16	$390,069.62	12	$32,505.80	1.2%	↑2
16. ADDERALL XR	1,904	$350,515.04	861	$407.10	1.1%	↓1
17. ENBREL	51	$350,081.11	22	$15,912.78	1.1%	↓4
18. INGREZZA	40	$302,686.87	16	$18,917.93	1.0%	↓2
19. SUBLOCADE	143	$286,292.42	70	$4,089.89	0.9%	NC
20. ABILIFY MAINTENA	99	$258,923.34	43	$6,021.47	0.8%	NC
21. DAYBUE	6	$235,979.28	3	$78,659.76	0.7%	↑18
22. TREMFYA	17	$231,125.93	9	$25,680.66	0.7%	↑40
23. INVEGA TRINZA	24	$205,691.85	23	$8,943.12	0.6%	↓1
24. SKYRIZI	10	$203,519.53	9	$22,613.28	0.6%	↓6
25. FARXIGA	314	$185,255.66	169	$1,096.19	0.6%	↓2
Total Claims Cost						**$31,842,570.20**



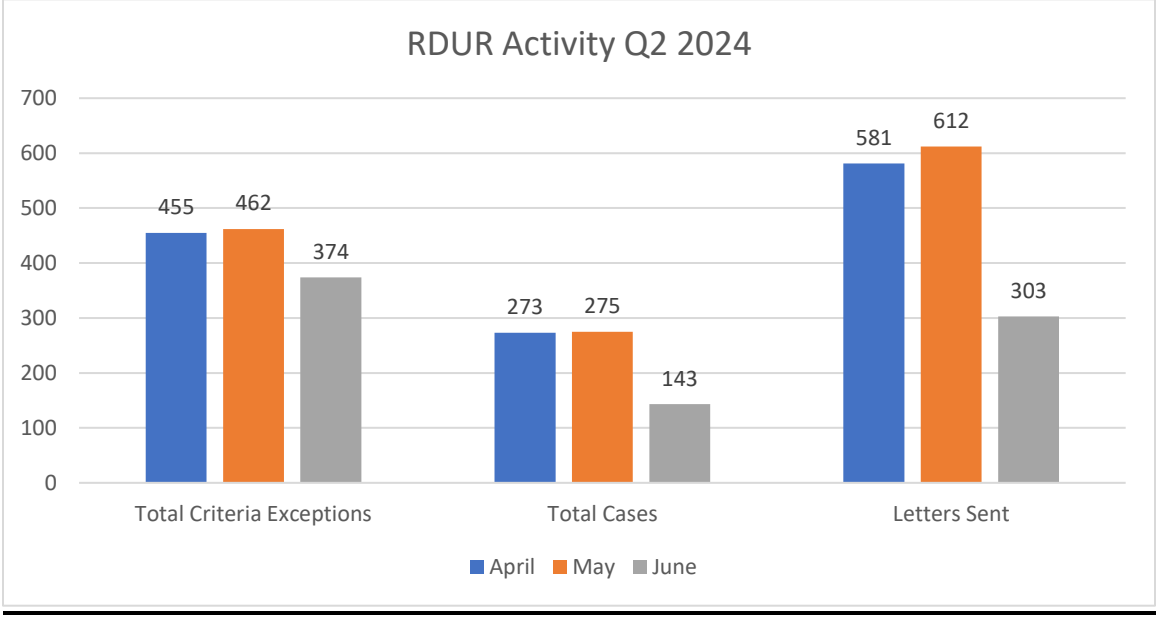
Top 15 Therapeutic Classes Based on Number of Claims from 04/01/2024 – 06/30/2024

Therapeutic Class Description	Claims	Claims Cost	Patients	Cost/Claim	% Claims	Dif.
1. ANTIDEPRESSANTS	24,816	$591,266.06	10,500	$23.83	10.7%	NC
2. ANTIPSYCHOTIC AGENTS	9,099	$2,500,799.63	3,645	$274.84	3.9%	NC
3. AMPHETAMINES	6,382	$1,248,191.69	2,704	$195.58	2.8%	↑3
4. RESP AND CNS STIMULANTS	6,210	$923,310.50	2,488	$148.68	2.7%	↑1
5. GABA ANTICONVULSANTS	6,199	$124,102.76	2,604	$20.02	2.7%	↑2
6. PROTON-PUMP INHIBITORS	5,981	$126,905.92	3,259	$21.22	2.6%	↓2
7. ADRENALS	5,931	$557,401.34	4,021	$93.98	2.6%	↑1
8. PENICILLIN ANTIBIOTICS	5,893	$95,376.68	5,293	$16.18	2.5%	↓5
9. OPIOID AGONISTS	5,662	$102,353.39	2,963	$18.08	2.4%	NC
10. NSAIDS	5,275	$75,779.63	3,599	$14.37	2.3%	NC
11. ANTICONVULSANTS	5,147	$277,034.90	2,044	$53.82	2.2%	NC
12. STATINS	4,891	$70,924.96	2,879	$14.50	2.1%	NC
13. CENTRAL ALPHA-AGONISTS	4,843	$69,593.07	2,206	$14.37	2.1%	NC
14. BETA BLOCKING AGENTS	3,936	$67,911.59	2,232	$17.25	1.7%	NC
15. BETA AGONISTS	3,731	$216,398.28	3,385	$58.00	1.6%	NC

Top 15 Therapeutic Classes Based on Claims Cost from 04/01/2024 – 06/30/2024

Therapeutic Class Description	Claims	Claims Cost	Patients	Cost/Patient	% Cost	Dif.
1. TNF INHIBITORS	338	$2,617,807.48	146	$17,930.19	8.2%	NC
2. ANTIPSYCHOTIC AGENTS	9,099	$2,500,799.63	3,645	$686.09	7.9%	NC
3. INTERLEUKIN AGENTS	152	$1,475,976.72	64	$23,062.14	4.6%	NC
4. AMPHETAMINES	6,382	$1,248,191.69	2,704	$461.61	3.9%	NC
5. ANTINEOPLASTIC AGENTS	511	$1,211,016.00	222	$5,455.03	3.8%	↑1
6. ANTIRETROVIRALS	710	$1,153,012.39	297	$3,882.20	3.6%	↓1
7. SGLT2 INHIBITORS	1,450	$1,017,827.46	792	$1,285.14	3.2%	↑1
8. HCV ANTIVIRALS	45	$1,010,780.17	44	$22,972.28	3.2%	↑2
9. INCRETIN MIMETICS	1,401	$991,937.44	698	$1,421.11	3.1%	↓2
10. RESP AND CNS STIMULANTS	6,210	$923,310.50	2,488	$371.11	2.9%	↓1
11. CFTR CORRECTORS	28	$622,563.28	11	$56,596.66	2.0%	NC
12. ANTIDEPRESSANTS	24,816	$591,266.06	10,500	$56.31	1.9%	↑2
13. INSULINS	2,884	$568,377.78	1,237	$459.48	1.8%	↓1
14. ADRENALS	5,931	$557,401.34	4,021	$138.62	1.8%	↑1
15. PITUITARY	336	$545,590.98	146	$3,736.92	1.7%	↓2

RDUR Report: Q2 2024



April Cases by Type of Criteria		
Criteria Description	**# of Cases**	**% of Cases**
Drug-Disease Interaction	267	97.8%
Underuse	5	1.8%
Therapeutic Appropriateness	1	0.4%

May Cases by Type of Criteria		
Criteria Description	**# of Cases**	**% of Cases**
Drug-Disease Interaction	273	99.3%
Therapeutic Appropriateness	2	0.7%

June Cases by Type of Criteria		
Criteria Description	**# of Cases**	**% of Cases**
Drug-Disease Interaction	125	87.4%
Therapeutic Appropriateness	18	12.6%

Clinical Report

Prior Authorization Updates

September-24	PA Status	Class
Acthar	PA	Medications Over $3000 Criteria
Cimzia	PA	Cytokine Modulators
ciprofloxacin/dexamethasone	PA	ophthalmic anti-infectives
Dexlansoprazole	PA	PPIs
Freshkote	PA	Dry Eye Syndrome
Invokamet	PA	Diabetes
Invokana	PA	Diabetes
Katerzia	PA	non-preferred dosage form
Libervant	PA	non-preferred dosage form
Myhibbin	PA	non-preferred dosage form
Ohtuvayre	PA	Agents Used to Treat COPD
pimecrolimus	PA	Eczema/Atopic Dermatitis
pitavastatin	PA	Lipid-Lowering Therapy
Sentia	PA	Dry Eye Syndrome
tolvaptan	PA	Heart Failure/CKD
Vafseo	PA	Chronic Kidney Disease
verapamil ER PM	PA	non-preferred dosage form
Vetiva	PA	Dry Eye Syndrome
Vigafyde	PA	non-preferred dosage form
Lotronex	remove PA	Irritable Bowel Syndrome
tazarotene cream	remove PA	Acne

Summary of Changes

Ohtuvayre criteria added. ICS/LABA criteria modified to include step 1 and step 2 criteria.

Asthma/COPD

Therapeutic Duplication

- One medication from each class is allowed at time.
  - One inhaled steroid
  - Long-acting anticholinergic
  - Leukotriene pathway inhibitor
  - One short-acting beta agonist
  - One long-acting beta agonist

Electronic Concurrent Medication Required

- Roflumilast: A total of 90 days of an inhaled short or long-acting anticholinergic must be paid within 115 days prior to roflumilast's date of service.
  - According to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines, roflumilast is a recommended add-on therapy to members experiencing exacerbations while on antimuscarinic therapy.

Albuterol / Levalbuterol Rescue Inhalers

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED STEP 1 AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
VENTOLIN (albuterol) HFA *– Brand Required*	levalbuterol HFA	albuterol HFA
	PROAIR RESPICLICK (albuterol)	PROVENTIL (albuterol) HFA
		XOPENEX (levalbuterol) HFA

According to the GINA guidelines:

- A low dose ICS should be taken whenever SABA taken for step 1 control of asthma.
- Dispensing ≥ 3 SABA canisters/year is associated with higher risk of emergency department presentations.
- Dispensing ≥ 12 SABA canisters/year is associated with higher risk of death.

Electronic Step Therapy Required

- Levalbuterol HFA:
  A. PA Not Required Criteria: A 30-day supply of albuterol HFA has been paid within 180 days prior to levalbuterol HFA's date of service.
  B. PA Required Criteria: The member must have failed a 30-day trial of albuterol HFA, as evidenced by paid claims or pharmacy printouts.

Electronic Concurrent Medications Required

- ProAir Respiclick: A total of 30 days of steroid inhaler must be paid within 40 days prior to ProAir Respiclick's date of service.
  A. The quantity limit for Ventolin HFA is set to 2 canisters per 6 months (2 puffs per day). If more is needed, member must switch to ProAir Respiclick HFA and be on a steroid inhaler to control asthma.

If the following conditions apply, please call for an override by calling provider relations at 1-800-755-2604:
- If primary insurance will only pay for ProAir Respiclick and member is well-controlled without steroid inhaler (i.e., uses less than 2 canisters per 6 months).

Therapeutic Duplication

- Short acting beta agonist nebulizers and inhalers are not payable together.

A. Inhalers and Nebulizers work equally well whether used at home, in school, or otherwise outside of the home. If member receives multiple forms of rescue medication, the risk of unidentified uncontrolled asthma and rescue inhaler dependence is increased.

If the following conditions apply, please call for an override by calling provider relations at 1-800-755-2604:
- Maximally treated members with end-stage COPD will be allowed an ongoing override (compliance with inhaled steroid, long-acting beta agonist, long-acting muscarinic antagonist, and Daliresp)
- Members with cystic fibrosis will be allowed an ongoing override.
- Acutely ill children will be allowed a one-time override.

References:

1. Albuterol Overuse: A Marker of Psychological Distress? Joe K. Gerald, Tara F. Carr, Christine Y. Wei, Janet T. Holbrook, Lynn B. Gerald. J Allergy Clin Immunol Pract. 2015 Nov-Dec; 3(6): 957–962. Published online 2015 Sep 1. Doi: 10.1016/j.jaip.2015.06.021. PMCID: PMC4641773
2. Global Initiative for Asthma. Global strategy for asthma management and prevention. 2019 GINA Main Report. Available from: www.ginasthma.org. (Accessed February 5, 2020)
3. National Asthma Education and Prevention Program, Third Expert Panel on the Diagnosis and Management of Asthma. Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma. Bethesda (MD): National Health, Lung, and Blood Institute (US); 2007 Aug. Available from: https://www.ncbi.nlm.nih.gov/books/NBK7232
4. High-Dose Albuterol by Metered-Dose Inhaler Plus a Spacer Device Versus Nebulization in Preschool Children With Recurrent Wheezing: A Double-Blind, Randomized Equivalence Trial Dominique Ploin, François R. Chapuis, Didier Stamm, Jacques Robert, Louis David, Pierre G. Chatelain, Guy Dutau and Daniel Floret Pediatrics. August 2000, 106 (2) 311-317; DOI: https://doi.org/10.1542/peds.106.2.311

Anticholinergics/Beta Agonists Combinations – Short Acting

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
albuterol/ipratropium	DUONEB (albuterol/ipratropium)
COMBIVENT RESPIMAT (albuterol/ipratropium)	

Anticholinergics/Beta Agonists Combinations – Long Acting

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED STEP 1 AGENTS (PA REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
ANORO ELLIPTA (umeclidinium/vilanterol)	BEVESPI AEROSPHERE (glycopyrrolate/formoterol)	DUAKLIR PRESSAIR (aclidinium/formoterol)
STIOLTO RESPIMAT (tiotropium/olodaterol)		

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

Non-Preferred Step 1 Agents
- The member must have failed a 30-day trial of 2 preferred agents, as evidenced by paid claims or pharmacy printouts

Non-Preferred Step 2 Agents:

- The member must have failed a 30-day trial of Bevespi Aerosphere and 2 preferred agents, as evidenced by paid claims or pharmacy printouts
- Clinical justification must be provided explaining why the member is unable to use the preferred products (subject to clinical review).

Anticholinergics – Long-Acting

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED STEP 1 AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
INCRUSE ELLIPTA (umeclidinium)	SPIRIVA RESPIMAT 1.25 MCG (tiotropium)	LONHALA MAGNAIR (glycopyrrolate)
SPIRIVA HANDIHALER (tiotropium)		tiotropium handihaler
SPIRIVA RESPIMAT 2.5 MCG (tiotropium)		TUDORZA PRESSAIR (aclidinium)
		YUPELRI (revefenacin)

Electronic Concurrent Medications Required

- Spiriva Respimat 1.25 mg: A total of 30 days of a long-acting beta agonist (ICS should be used with LABA as combination or single ingredient inhalers) must be paid within 40 days prior to the Spiriva Respimat 1.25 mg date of service.

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.
  - Spiriva Respimat 1.25 mg is indicated for asthma.
  - Spiriva Respimat 2.5 mg is indicated for COPD.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of at least 2 preferred long-acting anticholinergic agents of unique ingredients (in combination or alone), as evidenced by paid claims or pharmacy printouts.
- Lonhala Magnair (glycopyrrolate) only:
  - The member must have failed a 30-day trial of Yupelri, as evidenced by paid claims or pharmacy printouts.

Therapeutic Duplication

- Anticholinergic medications are not covered with acetylcholinesterase inhibitors.
  A. The effects of an anticholinergic (blocks the effect of acetylcholine) and acetylcholinesterase inhibitors (prevents breakdown of acetylcholine) oppose each other, and the therapeutic effect of both products is diminished.

Beta Agonists – Long-Acting

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
arformoterol	BROVANA (arformoterol)
formoterol	PERFOROMIST (formoterol)
SEREVENT DISKUS (salmeterol)	
STRIVERDI RESPIMAT (olodaterol)	

Biologics

Anti-IL-5 biologics

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CINQAIR (reslizumab) – *Medical Billing Only*	NUCALA (mepolizumab) SYRINGE, AUTOINJECTOR
FASENRA (benralizumab)	NUCALA (mepolizumab) VIAL – *Medical Billing Only*

Anti-IL-4/13 biologics

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

Eosinophil-directed biologics

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

Thymic Stromal Lymphopoietin (TSLP) blocker

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TEZSPIRE (tezepelumab-ekko) PENS	
TEZSPIRE (tezepelumab-ekko) VIAL and SYRINGES – *Medical Billing Only*	

Prior Authorization Criteria

Prior Authorization Form – Asthma

Initial Criteria – Approval Duration: 3 months

- The requested medication must be prescribed by, or in consult with, an allergist/immunologist or pulmonologist
- The member must have had at least one exacerbation requiring use of oral corticosteroids in the previous year despite continued compliant use of a high dose inhaled steroid in combination with a long-acting beta agonist (LABA) and long-acting muscarinic antagonist (LAMA) as evidenced by paid claims or pharmacy printouts

Anti-IL-5 biologics:

- The member has eosinophilic phenotype with eosinophil count ≥ 150 cells/mcL within the past 90 days
- Nucala: The member must have failed a 3-month trial of a preferred Anti-IL-5 biologic, as evidenced by paid claims or pharmacy printouts

Eosinophil-directed biologics:

- The member has a serum total IgE level, measured before the start of treatment, of ≥ 30 IU/mL and ≤ 700 IU/mL in members age ≥ 12 years or ≥ 30 IU/mL and ≤ 1300 IU/mL in members ages 6 to < 12 years.
- The member has had a positive skin test or in vitro reactivity to a perennial aeroallergen

Renewal Criteria – Approval Duration: 12 months

- The member must have achieved a significant reduction in asthma exacerbations and utilization of rescue medications since treatment initiation since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review).

Corticosteroids – Inhaled

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ARNUITY ELLIPTA (fluticasone)	ALVESCO (ciclesonide)

ASMANEX (mometasone) TWISTHALER	ASMANEX HFA (mometasone)
budesonide suspension	fluticasone HFA
PULMICORT FLEXHALER (budesonide)	fluticasone diskus
	PULMICORT RESPULES (budesonide)
	QVAR REDIHALER (beclomethasone)

GINA and EPR-3 Guidelines – SMART:

- For steps 3-5, ICS-formoterol is preferred for use as an as needed and regular daily treatment
- Please consider SMART therapy instead of single agent inhaled corticosteroid.
  - Both Symbicort and Dulera are available as HFA products

Quantity Limits to accommodate SMART therapy:

- 2 Symbicort or Dulera inhalers per 30-day supply not to exceed a total of 9 inhalers per 365 days without prior approval.

References:

1. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2023. Updated July 2023. Available from: www.ginasthma.org
2. Cloutier, Michelle M., et al. "2020 focused updates to the asthma management guidelines: a report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group." *Journal of Allergy and Clinical Immunology* 146.6 (2020): 1217-1270. Available at: https://www.epa.gov/sites/default/files/2021-05/documents/_sites_default_files_publications_asthmamanagementguidelinesreport-2-4-21.pdf

Electronic Age Verification:

- Fluticasone HFA does not require PA for ages 4 and under

Electronic Duration Verification:

- Budesonide Suspension 1 mg/2 mL is payable for 30 days every 75 days. For diluted nasal rinses or oral use, please use 0.5 mg/2 mL instead of 1 mg/2 mL for doses 1 mg per day or higher.
  - Guidelines recommend that once control is achieved, dose should be titrated down to minimum dose required to maintain control. For doses 1.5 mg per day or lower, please use 0.5 mg/2 mL strength.

Prior Authorization

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of each preferred inhaler of a unique active ingredient, as evidenced by paid claims or pharmacy printouts.
- *Asmanex HFA and QVAR Redihaler Only:*
  - Preferred agent trials may be bypassed if member meets one of the following criteria:
    - Member is unable to achieve inspiratory flow rate of 40 L/min.
    - Member is unable to achieve inspiratory flow rate of 60 L/min and has previously had adrenal insufficiency with fluticasone.
    - Permanent disability preventing use of a dry powder inhaler
- *fluticasone HFA only:*
  - Preferred agent trials may be bypassed if member meets one of the following criteria:
    - Member is unable to achieve inspiratory flow rate of 40 L/min.
    - Permanent disability preventing use of a dry powder inhaler

References:

1. Sannarangappa V, Jalleh R. Inhaled corticosteroids and secondary adrenal insufficiency. Open Respir Med J. 2014 Jan 31;8:93-100. doi: 10.2174/1874306401408010093. PMID: 25674179; PMCID: PMC4319207.
2. Saag KG, Furst DE, Barnes PJ . Major side effects of inhaled glucocorticoids In: *UpToDate*, Post TW (Ed), UpToDate, Waltham, MA, 2023

Corticosteroid/Long-Acting Beta Agonist (LABA) Combination Inhalers

Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED STEP 1 AGENTS (PA REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
ADVAIR DISKUS (fluticasone/salmeterol) *– Brand Required*	BREO ELLIPTA (fluticasone/vilanterol) *– Brand Required*	budesonide/formoterol
ADVAIR HFA (fluticasone/salmeterol) *– Brand Required*		fluticasone/salmeterol
AIRDUO RESPICLICK (fluticasone/salmeterol) *– Brand Required*		fluticasone/vilanterol
DULERA (mometasone/formoterol)		SYMBICORT (budesonide/formoterol) *– Brand Required*
		WIXELA INHUB (fluticasone/salmeterol)

GINA Guidelines – SMART:

- For mild asthma, ICS-formoterol is the preferred reliever medication for as needed symptom relief
- For steps 3-5, ICS-formoterol is preferred for use as an as needed and regular daily treatment
  Quantity Limits to accommodate SMART therapy:
  - 2 Symbicort or Dulera inhalers per 30-day supply not to exceed a total of 9 inhalers per 182 days without prior approval.

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

Non-Preferred Step 1 Agents:

- The member must have failed a 30-day trial of each preferred agent of a unique ingredient, as evidenced by paid claims or pharmacy printouts.
- For COPD diagnosis only: The member must currently be taking a long acting antimuscarinic agent.

Non-Preferred Step 2 Agents:

- The member must have failed a 30-day trial of each preferred and non-preferred step 1 agent of a unique ingredient, as evidenced by paid claims or pharmacy printouts.
- For COPD diagnosis only: The member must currently be taking a long acting antimuscarinic agent.

Corticosteroid/Anticholinergics/Long-Acting Beta Agonists Combinations

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

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have blood eosinophil of ≥ 100
- The member must have experienced an exacerbation while adherent to a 60-day trial of fluticasone inhaler + umeclidinium + vilanterol which have the same active ingredients as Trelegy Ellipta, as evidenced by paid claims or pharmacy printouts. Clinical justification must also be provided why Trelegy Ellipta is expected to improve outcomes versus using fluticasone inhaler + umeclidinium + vilanterol combination therapy (subject to clinical review).
    - available combination products to achieve this are fluticasone + Anoro Ellipta (umedclidium/vilanterol) and Breo Ellipta (fluticasone/vilanterol) + Incluse Ellipta (umeclidinium)
- The member must have experienced an exacerbation while adherent to a 60-day trial of triple therapy (Steroid/Long-Acting Beta Agonist/Long-Acting Anticholinergic) that has at least one ingredient different from fluticasone inhaler + umeclidinium + vilanterol combination therapy, as evidenced by paid claims or pharmacy printouts.

Non-Preferred Agents Criteria:

- The member must have failed a 30-day trial of the preferred product, as evidenced by paid claims or pharmacy printouts:

Phosphodiesterase-3 (PDE3) and Phosphodiesterase-4 (PDE4) Inhibitor

PREFERRED AGENTS (CLINICAL PA REQUIRED)
OHTUVAYRE (ensifentrine)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must meet one of the following criteria:
    - The member has a blood eosinophil of ≥ 100 and has experienced an exacerbation while adherent to a 60-day trial of a triple combination regimen consisting of an inhaled steroid, long-acting beta agonist, and long-acting anticholinergic.
    - The member has a blood eosinophil of < 100 and has experienced an exacerbation while adherent to a 60-day trial of a dual combination regimen consisting of a long-acting beta agonist and long-acting anticholinergic.
    - The member has experienced an exacerbation while adherent to a 60-day trial of a long-acting anticholinergic and has a contraindication or intolerance to a long-acting beta agonist (subject to clinical review)
    - The member has experienced an exacerbation while adherent to a 60-day trial of a long-acting beta agonist and has a contraindication or intolerance to a long-acting anticholinergic (subject to clinical review)

Summary of Changes

Kerendia Criteria Updated: Kerendia criteria updated to specify UACR and albuminuria labs must be collected while on ACE or ARB therapy based on KDIGO clinical practice guidelines and renewal criteria was updated to allow for stabilization of eGFR based on clinical trial primary endpoint.

Tovlaptan criteria added.

Chronic Kidney Disease

Therapeutic Duplication

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

Dual endothelin angiotensin receptor antagonist

CLINICAL PA REQUIRED
FILSPARI (sparsentan)

Kappa-opioid agonist

CLINICAL PA REQUIRED
KORSUVA (difelikefalin) – *Medical Billing Only*

Non-steroidal selective mineralocorticoid receptor antagonist (MRA)

CLINICAL PA REQUIRED
KERENDIA (finerenone)

Renin-Angiotensin-Aldosterone System (RAAS) Inhibitors

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

SGLT-1/SGLT-2 Inhibitor

CLINICAL PA REQUIRED
INPEFA (sotagliflozin)

SGLT-2 Inhibitor

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

Sodium/Hydrogen Exchanger 3 (NHE3)

CLINICAL PA REQUIRED
XPHOZAH (tenapanor)

Systemic Corticosteroids

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

Vasopressin V2-receptor (V2R) Antagonist

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

Electronic Duration Verification:

- Tarpeyo is payable for 9 months every 3 years.
- tolvaptan is payable for 30 days every year.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

Inpefa Only:

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

Kerendia Only

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

Korsuva Only

- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.
- The member must have failed a 90-day trial of pregabalin or gabapentin, as evidenced by paid claims or pharmacy printouts.

Filspari and Tarpeyo Only

- The member must have eGFR ≥ 30.
- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.
- The member must be experiencing proteinuria > 1 gram/day or UPCR ≥ 1.5 g/g (documentation must be attached) despite 3-month trials with good compliance of the following at the target or maximally tolerated dose, as evidenced by paid claims or pharmacy printouts:
  - ACE inhibitor or an ARB
  - A SGLT-2 inhibitor
  - prednisone or methylprednisolone

Tolvaptan Only

- The requested medication must be prescribed by, or in consult with, a nephrologist.
- The member does not have liver disease.
- The member has eGFR ≥ 25
- The prescriber has provided clinical justification that the member is at high risk of kidney progression such as one of the following (subject to clinical review):
  - Autosomal dominant polycystic kidney disease mayo classes 1C, 1D, or 1E
  - Kidney length > 16.5 cm (by ultrasound, MRI, or CT scan)
  - An annual eGFR decline of at least 5 mL/min/1.73 m2 in one year
  - An annual eGFR decline of at least 2.5 mL/min/1.73 m2 per year over a period of five years
  - A greater than 5 % increase in total kidney volume per year on at least three repeated measurements (via MRI or CT (computed tomography), each at least 6 months apart

Xphozah Only

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

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

- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.
- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including the following scores and symptoms:
  - *Filspari and Tarpeyo Only*: proteinuria <1 gram/day or UPCR < 1.5 g/g or reduction of 30% from baseline
  - *Kerendia Only*: The member has experienced a stabilization in eGFR or one of the following:
    - albuminuria <1 gram/day or reduction of 30% from baseline
    - UACR < 1.5 g/g or reduction of 30% from baseline

References:

1. Stevens, Paul E., et al. "KDIGO 2024 Clinical practice guideline for the evaluation and management of chronic kidney disease." Kidney international 105.4 (2024): S117-S314.
2. de Boer, Ian H., et al. “Diabetes management in chronic kidney disease: a consensus report by the American Diabetes Association (ADA) and Kidney Disease: Improving Global Outcomes (KDIGO).” *Diabetes care* 45.12 (2022): 3075-3090.

Summary of Changes

Added criteria for new drug Duvyzet. Study 1; NCT02851797 included male patients 6 years of age and older with a confirmed diagnosis of DMD who were ambulatory and on a stable dosage of corticosteroids.

Duchenne Muscular Dystrophy

Corticosteroids

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

Prior Authorization Criteria

Prior Authorization Form – Duchenne Muscular Dystrophy

Initial Criteria – Approval Duration: 6 months

(approval may be granted for tapering if all initial criteria are not met)

- 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 physician who specializes in the treatment of Duchenne Muscular Dystrophy (DMD) and/or neuromuscular disorders
- 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):
    i. Stable cardiac function LVEF > 40% by echo
    ii. Scoliosis not requiring surgery
    iii. Stable respiratory function – FVC predicted > 50%, not requiring ventilatory assistance
    iv. 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):
    i. Stable cardiac function LVEF > 40% by ECHO
    ii. Scoliosis not requiring surgery
    iii. Stable respiratory function – FVC predicted > 50%, not requiring ventilatory assistance
    iv. 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

Histone Deacetylase Inhibitor

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

Prior Authorization Criteria

Prior Authorization Form – Duchenne Muscular Dystrophy

Initial Criteria – Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a physician who specializes in the treatment of Duchenne Muscular Dystrophy (DMD) and/or neuromuscular disorders.
- The member must be assigned male at birth.
- The diagnosis must be confirmed by the documented presence of abnormal dystrophin or a confirmed mutation of the dystrophin gene.
- 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.)
- Weight and calculated dose must be provided consistent with approved FDA dose.
- The provider must submit baseline motor milestone score results from at least ONE the following assessments:
    - North Star Ambulatory Assessment (NSAA)
    - 4-stair claim (4SC)
- The member is on a stable dose of corticosteroids for the past 3 months, as evidenced by paid claims and pharmacy print outs.

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.)
- 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:
    - North Star Ambulatory Assessment (NSAA)
    - 4-stair claim (4SC)

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 physician who specializes in the treatment of Duchenne Muscular Dystrophy (DMD) and/or neuromuscular disorders
- 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

Summary of Changes

Changes for Prader – Willi Syndrome due to the following warning:

Somatropin is contraindicated in patients with Prader-Willi syndrome who are severely obese, have a history of upper airway obstruction or sleep apnea, or have severe respiratory impairment. There have been reports of sudden death when somatropin was used in such patients

- GH will not be covered until the BMI is less than 120% of the 95th percentile.
- If member has obesity 95th percentile or greater but below 120% of the 95th percentile, rule out of comorbidities and to meet with dietician every 3 months is required.
- If member does not have obesity 95th percentile or greater, the initial and renewal requests will fall under the 12-month approval period with no additional criteria.

Growth Hormone

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NORDITROPIN FLEXPRO (somatropin)	GENOTROPIN (somatropin)
NUTROPIN AQ (somatropin)	GENOTROPIN MINIQUICK (somatropin)
	HUMATROPE (somatropin)
	NGENLA (somatrogon-ghla)
	OMNITROPE (somatropin)
	SAIZEN (somatropin)
	SKYTROFA (lonapegsomatropin-tcgd)
	SOGROYA (somapacitan-beco)
	ZOMACTON (somatropin)

Prior Authorization Criteria

Prior Authorization Form – Growth Hormone

Initial Criteria – Approval Duration: 12 months (except 6 months if criteria met in Prader-Willi Syndrome)

- Member must have one of the following covered diagnoses (listed below):
  - Multiple pituitary hormone deficiencies caused by a known hypothalamic-pituitary disease or its treatment (brain surgery and/or radiation)
  - Turner's syndrome

- SHOX syndrome
- Noonan syndrome
- Chronic renal insufficiency
- Prader–Willi syndrome
- Endogenous growth hormone deficiency

- The requested medication must be prescribed by, or in consult annually with, an endocrinologist or nephrologist.
- The member must not have active malignancy.
- The member must not have epiphyseal closure and must still be growing, unless one of the below exceptions is present:
  - The member has a diagnosis of Prader-Willi syndrome.
  - The member has a diagnosis of endogenous growth hormone deficiency and is experiencing hypoglycemic episodes without growth hormone and growth hormone is needed to maintain proper blood glucose.

Chronic Renal Insufficiency

- The member must not have received a renal transplant.
- The member must consult with a dietitian annually to maintain a nutritious diet.

Endogenous Growth Hormone Deficiency

- ONE of below criteria must be met:
  - The member has multiple pituitary hormone deficiencies caused by a known hypothalamic-pituitary disease or its treatment (brain surgery and/or radiation) and must have an IGF-1 or IGFBP-3 level of less than SDS -1.3.
  - The member has had GH stimulation testing by at least two different stimuli (e.g., insulin, levodopa, L-arginine, propranolol, clonidine, or glucagon) with a maximum peak of < 10 ng/mL after stimulation no more than 6 months apart.

Prader-Willi Syndrome (PWS)

See covered medications for weight loss

- The member must not have severe obesity (class 2) defined as ≥ 120% of the 95th percentile for age and gender
- If the member has obesity ≥ 95th percentile and < 120% of the 95th percentile for age and gender, all the following must be met (*6-month approval criteria*):
  - The prescriber must attest that member will meet with a dietician every 3 months
  - The member must have had a sleep study to rule out sleep apnea
  - The member must not have non-alcoholic fatty liver disease
  - The member must not have an A1c > 5.7%

Non-Preferred Agent Criteria:

- The member must have failed a 30-day trial of 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 preferred agents (subject to clinical review).

Renewal Criteria – Approval Duration: 12 months (6 months if criteria below for PWS is met)

- The member must have been compliant with growth hormone (last 6 fills must have been on time).

Prader-Willi Syndrome

- If the member has obesity ≥ 95th percentile and < 120% of the 95th percentile for age and gender, initial criteria must be met in addition to the following *(6-month approval criteria)*:
  - The member must have met with a dietician at least 2 times in the past 6 months

Summary of Changes

Tolvaptan and Entresto Sprinkle were added to prior authorization with criteria.

Heart Failure

First Line Agents

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

Second Line Agents

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

Non-Solid Dosage Forms

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

Electronic Diagnosis Verification

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

Electronic Duration Verification:

- tolvaptan is payable every year.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Corlanor Only:
  - The requested medication must be prescribed by, or in consult with, a cardiologist.
  - The member must have a resting HR ≥ 70 beats per minute on maximally tolerated or target beta blocker dose in sinus rhythm.
- Entresto Sprinkle
  - See Non-Solid Dosage Form criteria
  - The member has a diagnosis of heart failure with left ventricular ejection fraction of ≤ 45 %
  - The member has failed a 3 month trial of enalapril, as evidenced by paid claims or pharmacy printouts.
- Inpefa Only:

- The requested medication must be prescribed by, or in consult with, a cardiologist or nephrologist.
- The member is receiving concurrent Entresto, a beta-blocker, a SGLT-2 Inhibitor, and a mineralocorticoid receptor antagonist.
- The member has been admitted to the hospital, a heart failure unit, infusion center, or emergency department for worsening heart failure within the past 3 months.
- Clinical justification must be provided explaining why the member is unable to use Farxiga and Jardiance (subject to clinical review)

- Tolvaptan Only:
  - The requested medication must be prescribed by, or in consult with, a cardiologist or nephrologist.
  - The member is experiencing sodium levels less than 125 mEq/L despite a 30-day trial of an ACE inhibitor or ARB.
  - The member does not have liver disease.
- Verquvo Only:
  - The requested medication must be prescribed by, or in consult with, a cardiologist.
  - The member must have left ventricular ejection fraction (LVEF) < 45% at initiation.
  - The member must have had a hospitalization or need for IV diuretics within the past 3 months
  - The member is receiving concurrent Entresto, a beta-blocker, a SGLT-2 Inhibitor, and a mineralocorticoid receptor antagonist.

Summary of Changes

Berinert moved non-preferred but allowed bypass for members who are pregnant, breastfeeding, or under 18 years old upon request due to more evidence in these populations.

Prophylaxis criteria added for situations likely to require prophylaxis. Renewal criteria added inline with clinical trial endpoints.

Hereditary Angioedema (HAE)

Acute Attack

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
icatibant	BERINERT (plasma derived C1 Esterase Inhibitor)
	BERINERT (plasma derived C1 Esterase Inhibitor) – *Medical Billing Only*
	FIRAZYR (icatibant)
	KALBITOR (ecallantide) – *Medical Billing Only*
	RUCONEST (recombinant C1 Esterase Inhibitor)
	RUCONEST (recombinant C1 Esterase Inhibitor) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

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

Non-Preferred Agent Criteria:

- The member must have a contraindication to or failed a trial of all preferred agents, as evidenced by paid claims or pharmacy printouts.

A. Berinert Only: The preferred agent trial may be bypassed for members who are pregnant, breastfeeding, or under 18 years old upon request.

B. Ruconest Only: The member must have a contraindication to or failed a trial of Berinert, as evidenced by paid claims or pharmacy printouts.

Prophylaxis

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HAEGARDA (plasma derived C1 Esterase Inhibitor)	CINRYZE (plasma derived C1 Esterase Inhibitor)
TAKHZYRO (lanadelumab-flyo)	ORLADEYO (berotrlastat)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, an allergist/immunologist or rheumatologist.
- The member's weight and dose are provided.
- One of the following must be met (A, B, or C):
  - A. The member has had at least 1 moderate to severe acute attack in the past 3 months (e.g., airway swelling, facial swelling, severe abdominal pain)
  - B. The member is using short-term prophylaxis for one of the following:
    - a procedure related to pregnancy
    - oral cavity or invasive procedures
    - stressful life event at high risk for precipitating HAE attack (clinical justification subject to clinical review)
  - C. Estrogen treatment is required, and member is at high risk for estrogen-precipitated HAE attack (clinical justification subject to clinical review)

Non-Preferred Agent Criteria:

- The member must have a contraindication to or failed a 3-month trial of all preferred agents with the same indication for use (prophylaxis or acute treatment), as evidenced by paid claims or pharmacy printouts.

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by at least a 50% reduction in the number of HAE attacks.

Quantity Override Request

- Takhyzro: The number of attacks in the last 6 months must be included if the requested dosing frequency is every 2 weeks (must be more than 0).

References

1. Busse, Paula J., et al. "US HAEA medical advisory board 2020 guidelines for the management of hereditary angioedema." *The Journal of Allergy and Clinical Immunology: In Practice* 9.1 (2021): 132-150.

Summary of Changes

Camzyos criteria was updated to reflect parameters used in the Explorer-HCM and VALOR-HCM trials

Hypertrophic Cardiomyopathy

CLINICAL PA REQUIRED
CAMZYOS (mavacamten)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a cardiologist.
- The member must have all of the following:
  - left ventricular ejection fraction (LVEF) ≥ 55%
  - NYHA class II or III
  - Resting oxygen saturation of ≥ 90%
  - Valsava left ventricular outflow tract (LVOT) gradient ≥ 50 mmHg at rest or with provocation.
- The member must have persistent symptoms despite maximally tolerated therapy with each of the following:
  - Non-dihydropyridine calcium channel blocker
  - beta blocker

Renewal Criteria – Approval Duration: 12 months

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

References

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

Summary of Changes

Non-Preferred Criteria added for Atorvaliq. Pitavastatin moved to non-preferred, criteria added.

Lipid-Lowering Agents

ACL (ATP Citrate Lyase) Inhibitors

PREFERRED AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NEXLETOL (bempedioc acid)	
NEXLIZET (bempedoic acid and ezetimibe)	

Electronic Step Therapy Required

- Nexletol or Nexlizet:
  - PA Not Required Criteria: A total of 90-day supply of rosuvastatin or atorvastatin has been paid within 120 days prior to Nexletol or Nexlizet’s date of service.
  - PA Required Criteria: The member must have failed a 90-day trial of rosuvastatin or atorvastatin, as evidenced by paid claims or pharmacy printouts.

Cholesterol Absorption Inhibitor – 2-Azetidinone

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

Eicosapentaenoic acid (ESA) Ethyl Ester

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
VASCEPA (icosapent ethyl) – *Brand Required*	icosapent ethyl

Fenofibrate

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
fenofibrate, micronized 43 mg, 67 mg, 134 mg, 200mg	ANTARA (fenofibrate, micronized)
fenofibrate, nanocrystallized	fenofibrate capsules 50 mg, 150 mg
fenofibrate tablets 54 mg, 160 mg	fenofibrate, micronized 90 mg, 130 mg
fenofibric acid DR 45 mg, 135 mg	fenofibrate tablets 40 mg, 120 mg
	fenofibric acid 105 mg
	FENOGLIDE (fenofibrate)
	LIPOFEN (fenofibrate)
	TRICOR (fenofibrate, nanocrystalized)
	TRIGLIDE (fenofibrate)
	TRILIPIX (fenofibric acid)

Prior Authorization Criteria

- See Preferred Dosage Form criteria

MTP (Microsomal Triglyceride Transfer Protein) Inhibitor

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

Prior Authorization Criteria

Initial Criteria – Approval Duration: 3 months

- Clinical justification must be provided explaining why the member is unable to use all other products to lower their cholesterol (subject to clinical review)

PCSK9 (Proprotien Convertase Subtilisin/Kexin Type 9) Inhibitors

PREFERRED AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
PRALUENT PEN (alirocumab)	
REPATHA PUSHTRONEX (evolocumab)	
REPATHA SURECLICK (evolocumab)	
REPATHA SYRINGE (evolocumab)	

Underutilization

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

Electronic Step Therapy Required

- Praluent and Repatha:

- PA Not Required Criteria: A total of 90-day supply of rosuvastatin or atorvastatin has been paid within 120 days prior to Praluent and Repatha's date of service.
- PA Required Criteria: The member must have failed a 90-day trial of rosuvastatin or atorvastatin, as evidenced by paid claims or pharmacy printouts.

Statins (HMG-CoA (3-hydroxy-3-methylglutaryl-CoA Reductase Inhibitors))

Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
atorvastatin	ALTROPREV (lovastatin)
CADUET (amlodipine/atorvastatin) – *Brand Required*	amlodipine/atorvastatin
ezetimibe/simvastatin	CRESTOR (rosuvastatin)
fluvastatin	fluvastatin ER
lovastatin	LESCOL XL (fluvastatin ER)
pravastatin	LIPITOR (atorvastatin)
rosuvastatin	LIVALO (pitavastatin)
simvastatin	pitavastatin
	PRAVACHOL (pravastatin)
	VYTORIN (ezetimibe/simvastatin)
	ZOCOR (simvastatin)
	ZYPITAMAG (pitavastatin)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Pitavastatin Only –
  - One of the following criteria must be met:
    - The member is receiving treatment with anti-retroviral therapy for HIV
    - The member is receiving treatment with a strong CYP3A4 inhibitor and is experiencing muscle toxicity despite 90-day trials with fluvastatin, rosuvastatin, and pravastatin.
- All other agents: See Preferred Dosage Form criteria

Non-Solid Dosage Forms

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EZALLOR SPRINKLE (rosuvastatin)	ATORVALIQ (atorvastatin) SOLUTION

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- See Non-Solid Dosage Form criteria

Non-Preferred Agent Criteria

- The member has an LDL-C level greater than 100 mg/dL despite a 90-day trial with Ezallor Sprinkle.

Renewal Criteria – Approval Duration: 12 months

- The member has an LDL-C level less than 100 mg/dL or has achieved a 40% reduction.

Angiopoietin-like 3 (ANGPTL3) Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	EVKEEZA (evinacumab-dgnb) – *Medical Billing Only*

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 cardiologist, endocrinologist, or lipid specialist.
- Documentation of one of the following must be provided:
  - Genetic testing confirming two mutant alleles at the low-density lipoprotein receptor (LDLR), apolipoprotein B (apo B), proprotein convertase subtilisin kexin type 9 (PCSK9) or low-density lipoprotein receptor adaptor protein 1 (LDLRAP1) gene locus
  - Untreated total cholesterol of > 500 mg/dL with one of the following:
    - Cutaneous or tendon xanthoma before age 10 years
    - Evidence of total cholesterol > 250 in both parents
  - Low-density lipoprotein cholesterol (LDL-C) level greater than 100 mg/dL after a 90-day trial of each of the following, as evidenced by paid claims or pharmacy printouts or clinical justification as to why a treatment is unable to be used (subject to clinical review):
    - PCSK9 inhibitor and ezetimibe combined with rosuvastatin ≥20 mg or atorvastatin ≥ 40 mg
    - Nexlizet and ezetimibe combined with rosuvastatin ≥20 mg or atorvastatin ≥ 40 mg

Renewal Criteria – Approval Duration: 12 months

- The member has an LDL-C level less than 100 mg/dL or has achieved a 40% reduction.

siRNA (small interfering RNA) therapy

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	LEQVIO (inclisiran) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must have failed a 90-day trial of both of the following, as evidenced by paid claims or pharmacy printouts:
  - Praluent combined with rosuvastatin ≥20 mg or atorvastatin ≥ 40 mg
  - Nexlizet combined with rosuvastatin ≥20 mg or atorvastatin ≥ 40 mg

Renewal Criteria – Approval Duration: 12 months

- The member has an LDL-C level less than 100 mg/dL or has achieved a 40% reduction.
- The member must currently be receiving a maximally tolerated statin (HMG-CoA reductase inhibitor) agent, as evidenced by paid claims or pharmacy printouts.

Summary of Changes

Vtama criteria added

Plaque Psoriasis

Biologics

Interleukin (IL)-12/IL-23 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	STELARA (ustekinumab)
	WEZLANA (ustekinumab-auub)

Interleukin (IL)-17A Inhibitor

PREFERRED AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TALTZ (ixekizumab)	COSENTYX (secukinumab)
	COSENTYX (secukinumab) – *Medical Billing Only*

Interleukin (IL)-17A and IL-17F inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	BIMZELX (bimekizumab-bkzx)

Interleukin (IL)-17 Receptor Inhibitor

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

Interleukin (IL)-23p19 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ILUMYA (tildrakizumab-asmn) – *Medical Billing Only*
	SKYRIZI (risankizumab-rzaa)
	TREMFYA (guselkumab)

TNF Inhibitors

Adalimumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab-adaz	ABRILADA (adalimumab-afzb)
adalimumab-adbm – labeler 00597	adalimumab-aacf
CYLTEZO (adalimumab-abdm)	adalimumab-aaty
HUMIRA (adalimumab)	adalimumab-adbm – labeler 82009
SIMLANDI (adalimumab-ryvk)	adalimumab-fkjp
YUSIMRY (adalimumab-aqvh)	adalimumab-ryvk
	AMJEVITA (adalimumab-atto)
	HADLIMA (adalimumab-bwwd)
	HULIO (adalimumab-fkjp)
	HYRIMOZ (adalimumab-adaz)
	IDACIO (adalimumab-aacf)

	YUFLYMA (adalimumab-aaty)

Infliximab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – *Medical Billing Only*	INFLECTRA (infliximab-dyyb) – *Medical Billing Only*
RENFLEXIS (infliximab-abda) – *Medical Billing Only*	infliximab – *Medical Billing Only*
	REMICADE (infliximab) – *Medical Billing Only*

Other TNF

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ENBREL (etanercept)	CIMZIA (certolizumab) SYRINGE
	CIMZIA (certolizumab) VIAL – *Medical Billing Only*

Electronic Diagnosis Verification

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

Electronic Step Therapy Required

- Taltz:
  - PA Not Required Criteria: A total of 84-day supply of a TNF Inhibitor has been paid within 120 days prior to Taltz's date of service.
  - PA Required Criteria: The member must have failed a 3-month trial of a TNF inhibitor, as evidenced by paid claims or pharmacy printouts.

Prior Authorization

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 3-month trial of a TNF inhibitor (adalimumab, certolizumab pegol or infliximab) and an Interleukin (IL)-17A Inhibitor, as evidenced by paid claims or pharmacy printouts.
- Remicade, infliximab, and Inflectra Only: See Preferred Dosage Form criteria.
- Stelara, Tremfya, and Wezlana Only: The member must have failed a 3-month trial of an TNF inhibitor (adalimumab, certolizumab pegol or infliximab), an Interleukin (IL)-17A Inhibitor, and Siliq, as evidenced by paid claims or pharmacy printouts.
- Medical billing only agents: Clinical justification must be provided why a self-administered agent cannot be used (subject to clinical review).

Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
acitretin 10 mg, 25 mg	acitretin 17.5 mg
cyclosporine	OTEZLA (apremilast) 20 MG
methotrexate	SOTYKTU (deucravacitinib)
OTEZLA (apremilast) 30 MG	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Acitretin 17.5 mg Only: See Preferred Dosage Form criteria

- Otezla 20 mg Only: The member must have failed a 3-month trial of adalimumab, as evidenced by paid claims or pharmacy printouts.
- Sotyktu Only: The member must have failed a trial of each of the following, as evidenced by paid claims or pharmacy printouts:
    - 30-day trial of Otezla
    - 3-month trial of an TNF inhibitor (adalimumab, certolizumab pegol or infliximab)

Topical

Foams, Gel, Solution, Suspension

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
calcipotriene solution	calcipotriene/betamethasone suspension
calcipotriene foam	SORILUX (calcipotriene) FOAM
ENSTILAR (calcipotriene/betamethasone) FOAM	tazarotene gel
TACLONEX (calcipotriene/betamethasone) SUSPENSION – *Brand Required*	

Cream, Lotion

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
calcipotriene cream	DUOBRII (halobetasol/tazarotene) LOTION
	tazarotene cream
	VTAMA (tapinarof) 1% CREAM
	ZORYVE (roflumilast) 0.3% CREAM

Ointment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
calcipotriene ointment	calcitriol ointment
calcipotriene/betamethasone ointment	

Electronic Diagnosis Verification

- Zoryve: 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 each preferred agent of a unique active ingredient(s) within same route/dosage form category, as evidenced by paid claims or pharmacy printouts.
- Zoryve Only:
    - The member has had a 30-day trial of each of the following, as evidenced by paid claims or pharmacy printouts.
        - calcipotriene/betamethasone
        - halobetasol/tazarotene combination
- Vtama Only:
    - The member has had a 30-day trial of each of the following, as evidenced by paid claims or pharmacy printouts.
        - calcipotriene/betamethasone
        - halobetasol/tazarotene combination
    - The member has had a 2-month trial of Zoryve, as evidenced by paid claims or pharmacy printouts.

Summary of Changes

Added criteria to follow recommendations in available guidelines or expert consensus.

Medications that cost over $3000/month

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- Both of the following must be met:
  - The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).
  - The medication must be used as recommended in available guidelines or expert consensus statements, including medication trials that are recommended prior to use of requested medication.
- The requested medication must be prescribed by, or in consult with, a specialist in the member's treated diagnosis.
- As applicable, documentation must be attached to confirm serum marker or pathogenic gene variants amenable to treatment.
- Documentation of the baseline labs, signs or symptoms that can be utilized for comparison to show member has experienced clinical benefit upon renewal has been submitted with request.

Summary of Changes

Criteria and PA added to high cost lubricants; persistent symptoms category was added and split into step 1 and step 2 agents.

Dry Eye Syndrome

Initial Management – Eye Lubricants

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ARTIFICIAL TEARS (dextran/hypromellose/glycerin)	FRESHKOTE (polyvinyl alcohol/povidone)
ARTIFICIAL TEARS (polyvinyl alcohol/povidone)	SENTIA (propylene glycol)
BION TEARS EYE DROPS (dextran 70/hypromellose)	VENTIVA (propylene glycol)
carboxymethylcellulose	VENTIVA (carboxymethylcellulose)
DRY EYE RELIEF (peg 400/Hypromellose/glycerin)	
GENTEAL TEARS (dextran/hypromellose/glycerin)	
GENTEAL TEARS (dextran 70/hypromellose)	
GENTEAL TEARS (hypromellose)	
LUBRICANT EYE DROPS (carboxymethylcellulose)	
LUBRICANT EYE DROPS (propylene glycol/peg 400)	
REFRESH (carboxymethylcellulose)	
REFRESH (polyvinyl alcohol/povidone)	
REFRESH (carboxymethylcellulose/glycerin)	
REFRESH (carboxymethylcellulose/glycerin/poly80)	
SYSTANE (hypromellose)	
SYSTANE (propylene glycol)	
SYSTANE (propylene glycol/peg 400)	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 1-month trial of each preferred agent of a unique ingredient, as evidenced by paid claims or pharmacy printouts.
- See Preferred Dosage Form Criteria

Persistent Symptoms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED STEP 1 AGENTS (PA REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
RESTASIS (cyclosporine) DROPPERETTE – *Brand Required*	TYRVAYA (varenicline) NASAL SPRAY	CEQUA (cyclosporine)
XIIDRA (lifitegrast)		cyclosporine dropperette
		MIEBO (perfluorohexyloctane)
		RESTASIS MULTIDOSE (cyclosporine)
		VEVYE 0.1% EYE DROP (cyclosporine)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

Non-Preferred Step 1 Agents

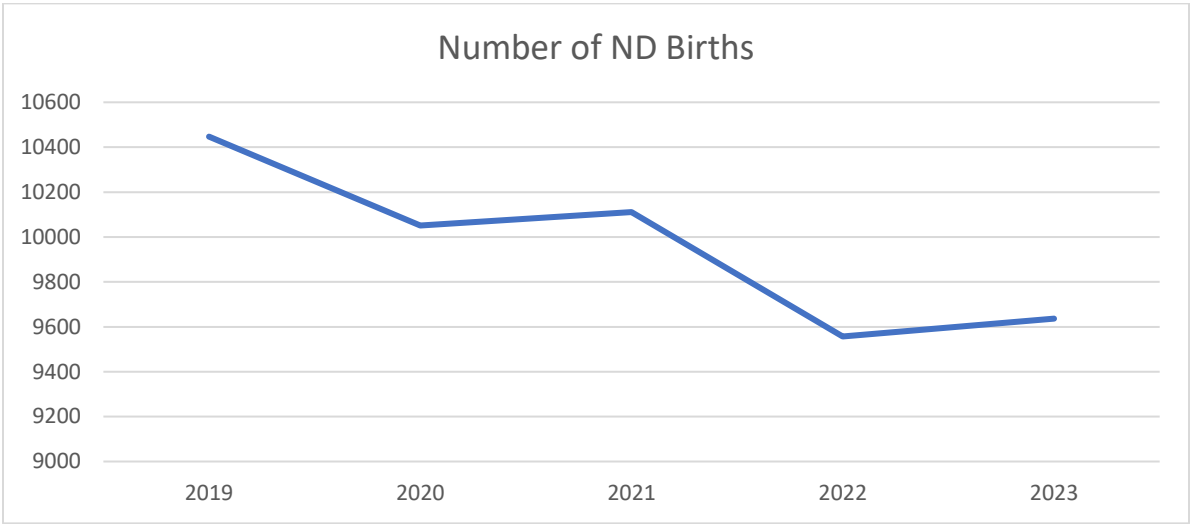
- The requested medication must be prescribed by, or in consult with, an ophthalmologist.
- The member must have failed a 6-month trial of Restasis (cyclosporine) and a 2-month trial of Xiidra (lifitegrast)t, as evidenced by paid claims or pharmacy printouts.

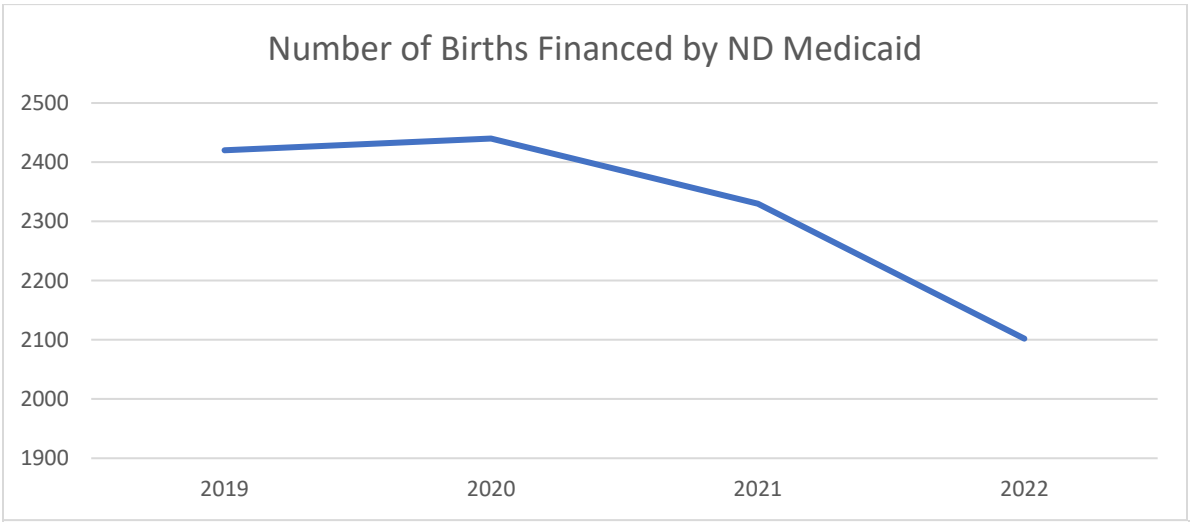
Non-Preferred Step 2 Agents:

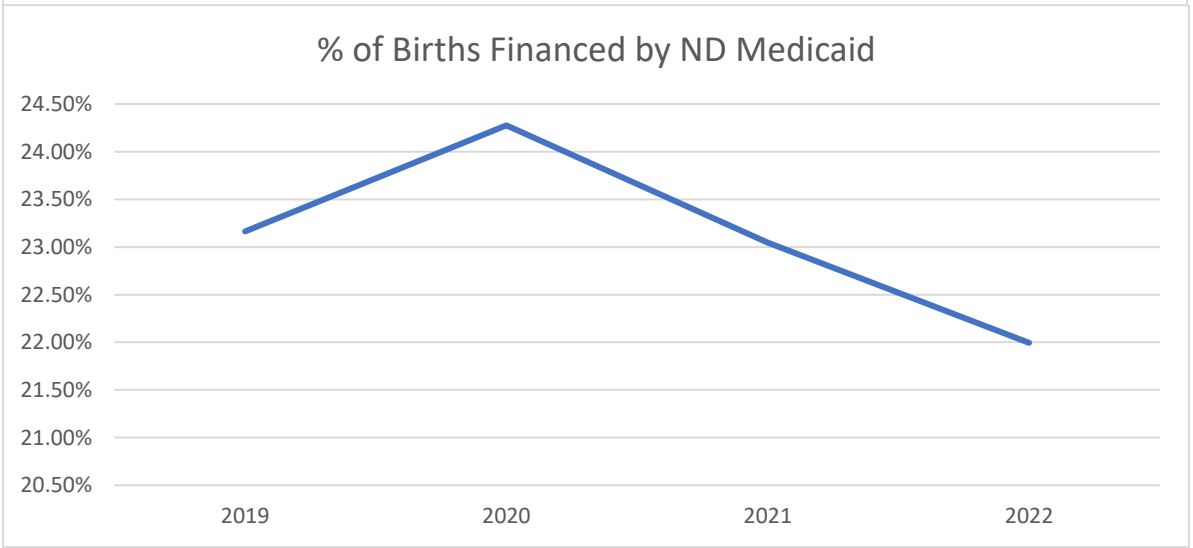
- The requested medication must be prescribed by, or in consult with, an ophthalmologist.
- The member must have failed a 6-month trial of Restasis (cyclosporine) and a 2-month trial of Xiidra (lifitegrast), and a 1-month trial of Tyrvaya (varenicline) as evidenced by paid claims or pharmacy printouts.
- Cyclosporine products: See Preferred Dosage Form criteria

Unfinished Business

Birth Rates:





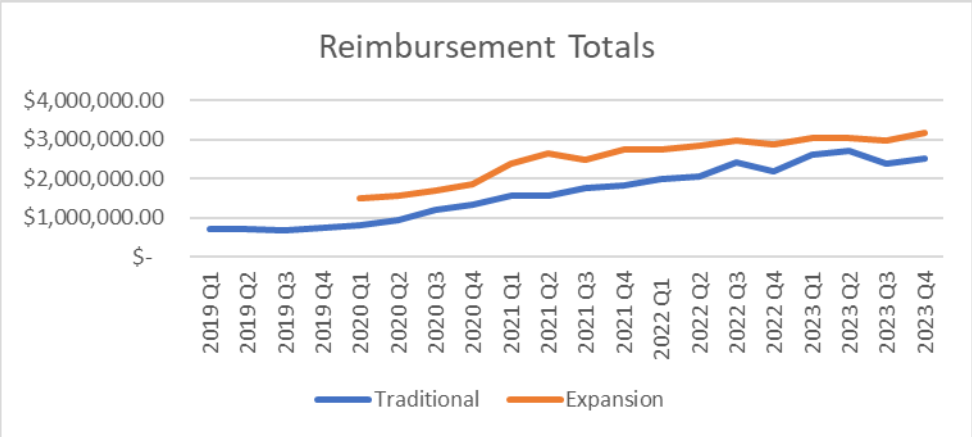


Alternative RDUR Communication Tools:
- Provider and pharmacy online response form
- Investigation of faxing letters

Dentist Prescribed Opioids
- Future targeted mailing

Biologics Breakout Cost
Identified 7 areas of substantial cytokine modulator competition:
- Calculated cost per day by quantity and day supply.
- Broken out by indication, age, and place of administration.

Added additional steps for agents that are much more expensive than competitors and for clinical justification on use of physician administered drugs instead of pharmacy administered drugs. Available evidence was weighed in addition to cost.



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**

New Business:

Second Reviews

Molluscum Contagiosum

PREFERRED AGENTS (CLINICAL PA REQUIRED)
ZELSUVMI (berdazimer) GEL
YCANTH (cantharidin) SOLUTION – *Medical Billing Only*

Initial Criteria - Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a dermatologist or pediatrician.
- One of the following must be present (1 or 2):
  - The member is immunocompromised.
  - The member is immunocompetent but experiences severe bleeding, intense itching, recurring infection, or severe pain for greater than 6 months.

Epidermolysis Bullosa

PREFERRED AGENTS (CLINICAL PA REQUIRED)
FILSUVEZ (birch triterpenes)
VYJUVEK (beremagene geperpavec-svdt) – *Medical Billing Only*

Initial Criteria - Approval Duration: 12 months

- The member has dystrophic epidermolysis bullosa.
- The requested medication must be prescribed by, or in consult with, a dermatologist or wound care specialist.
- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).
- As applicable, documentation must be attached to confirm serum marker or pathogenic gene variants amenable to treatment.
- Documentation of the baseline symptoms (e.g., extensive skin blistering, number and size of wounds) that can be utilized for comparison to show member has experienced clinical benefit upon renewal has been submitted with request.

Metabolic Dysfunction-Associated Steatohepatitis (MASH)

PREFERRED AGENTS (CLINICAL PA REQUIRED)
REZDIFFRA (resmetirom)

Initial Criteria - Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a gastroenterologist or hepatologist.
- The member has moderate to severe fibrosis (F2 or F3) as determined by one of the following (1-5):
  1. Biopsy
  2. Vibration-controlled transient elastography (VCTE; e.g. Fibroscan)
  3. Enhanced Liver Fibrosis (ELF)
  4. Magnetic Resonance Imaging Proton Density Fat Fraction (MRI-PDFF).
  5. Magnetic resonance elastography (MRE)
- If the member has a history of alcohol use, one of the following must be met (1, 2 or 3):
  1. The member has a carbohydrate-deficient transferrin (CDT) level < 3% within the past 3 months.

2. The member has a phosphatidylethanol (PEth) level < 20 ng/mL.
3. The member has submitted two negative alcohol tests with the most recent alcohol test within the past 3 months.

- The member must not have a concomitant terminal diagnosis where life expectancy is less than 1 year.

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced stabilization or improvement of fibrosis and steatohepatitis, as determined by one of the following (1-4):
  1. Biopsy
  2. Vibration-controlled transient elastography (VCTE; e.g. Fibroscan)
  3. Enhanced Liver Fibrosis (ELF)
  4. Magnetic Resonance Imaging Proton Density Fat Fraction (MRI-PDFF)
  5. Magnetic resonance elastography (MRE)

FIRST REVIEW OF ATTENTION-DEFICIT HYPERACTIVITY DISORDER (ADHD)

ADHD is a common neurodevelopmental disorder that leads to impairment of occupational, academic, and social functioning. Symptoms consist of inattention, impulsivity, restlessness, and emotional dysregulation.[1]

Population:

- 2.6% adults globally and 4.4% 18–44-year-olds in US[1]
- 9-15% school-age children[2]

Treatment:

- Preschool-Aged Children (4-5 years of age):
  - First line: behavioral therapy
  - Second line: methylphenidate
- School-Aged Children (6-11 years of age):
  - First line: behavioral therapy and/or methylphenidate
  - Second line: Vyvanse
  - Third line: dextroamphetamine and/or amphetamine OR atomoxetine or guanfacine
- Adolescents (12-18 years of age):
  - First line: long-acting stimulants with less abuse potential (Daytrana, Concerta, Vyvanse) and behavior therapy
  - Second line: atomoxetine > guanfacine > clonidine
- Adults:
  - First line: stimulants and behavior therapy

General key notes for treatment options:

- Mechanism of action: block reuptake of norepinephrine and dopamine
- Effects are seen immediately; medication trials can be accomplished in 3-7 days
- Alternative dosage forms/administration methods* can make easier to swallow and minimize risk of abuse
- Adverse effects: increase heart rate/blood pressure, vascular problems (priapism, Raynaud's), psychosis, mania, lower seizure threshold, decreased appetite, serotonin syndrome[1]
- Boxed warnings due to the risk of abuse and dependence

Amphetamine					
Drug	**Generic**	**Formulation**	**Time to Peak**	**DOA**	**Cost/month ($)**
Adderall	Yes	IR tablet	3 hours	4 hours	• Generic: 15.15 • Brand: 321.69
Adderall XR*	Yes	ER capsule, beaded delivery system (IR:DR of 50:50)	7 hours	10 hours	• Generic: 6.95 • Brand: 213.69
Adzenys XR ODT	No	ER orally disintegrating tablet, contains IR:DR of 50:50	5 hours	10-12 hours	502.18
Dexedrine Spansule **FDA approved for pediatrics*	Yes	SR capsule, initial dose released immediately, remainder released gradually	8 hours	10 hours	• Generic: 43.74 • Brand: 703.24
Dyanavel XR	No	ER tablet and oral suspension; IR and ER components, ER component coated in pH independent polymer	4 hours	12-13 hours	236.00
Evekeo **FDA approved for pediatrics*	No	IR tablet	3 hours	4-6 hours	239.26
Mydayis	Yes	ER capsule, triple-bead delivery system of one IR and two DR types	7-10 hours	~16 hours	• Generic: 22.37 • Brand: 338.82
Procentra **FDA approved for pediatrics*	Yes	Oral solution	3 hours	4-6 hours	• Generic: 45.60 • Brand: 50.74
Vyvanse*	Yes	Capsule and chewable tablet, prodrug	1-3.5 hours	10 hours	• Generic: 55.20 • Brand: 387.78
Xelstrym	No	Transdermal system, worn 9 hours	9 hours	9 hours	486.16
Zenzedi **FDA approved for pediatrics*	Yes	IR tablet	3 hours	4-6 hours	• Generic: 12.89 • Brand: 303.23
Methylphenidate					
Drug	**Generic**	**Formulation**	**Time to Peak**	**DOA**	**Cost/month ($)**
Aptensio XR*	Yes	Capsule with multilayered beads (IR:CR of 40:60)	First: 2 hours Second: 8 hours	~16 hours	• Generic: 51.59 • Brand: 250.12
Azstarys	No	Capsule, prodrug	2 hours	5-12 hours	418.58
Concerta	Yes	Osmotic-release oral system (OROS), tri-layer core with an IR overcoat	6-10 hours	~12 hours	• Generic: 21.60 • Brand: 386.96
Cotempla XR-ODT **FDA approved for pediatrics*	No	ER orally disintegrating tablet (IR:ER of 25:75)	5 hours	4 hours	513.24
Daytrana **FDA approved for pediatrics*	Yes	Adhesive-based matrix transdermal patch	8 hours	12 hours	180.57
Focalin	Yes	IR tablet	1 hour	4 hours	• Generic: 12 • Brand: 40.66
Focalin XR*	Yes	Isomer product dexmethylphenidate, beaded delivery system (IR:ER of 50:50)	First: 1.5 hours Second: 6.5	9-12 hours	• Generic: 39 Brand: 147.53
Jornay PM	Yes	ER capsule, bead delivery system with two film coatings surrounding drug core	14 hours	11-12 hours	455.89
Metadate CD	Yes	ER capsule, bead delivery system (IR:ER of 30:70)	First: 1.5 hours Second: 4.5 hours	6-8 hours	• Generic: 42.60 • Brand: 599
Methylin	Yes	IR solution, chewable tablet, and tablet	1-2 hours	3-5 hours	• Generic: 126.60 • Brand: 357.55
QuilliChew ER	No	ER chewable tablet (IR:ER of 30:70)	5 hours	~12 hours	372.77
Quillivant XR	No	ER suspension (IR: ER of 20:80)	2-4 hours	~6 hours	677.86
Relexxii	Yes	ER tablet, OROS delivery system, bilayer core with IR drug overcoat	First: 1.5 hours Second: 5.5	8 hours	• Generic: 21.60 • Brand: 355.23
Ritalin	Yes	IR tablet	1-2 hours	3-5 hours	• Generic: 7.20 • Brand: 71.26
Ritalin LA*	Yes	SODAS encapsulated biphasic release beads (IR:DR of 50:50)	First: 1.5-3 hours Second: 4.5 – 6.5 hours	6-8 hours	• Generic: 46.50 • Brand: 378.62

Based on lowest per unit WAC cost

Current Utilization

	Quarter 1 2023			Quarter 2 2023		
Medication	**Rx Count**	**% of Rx**	**Reimb Amount**	**Rx Count**	**% of Rx**	**Reimb Amount**
amphetamine	5	0.0%	$1,331.97	7	0.1%	$3,155.10
dexmethylphenidate HCl	899	6.1%	$69,154.88	863	6.3%	$36,597.46
dextroamphetamine sulfate	108	0.7%	$5,288.36	95	0.7%	$3,954.53
dextroamphetamine/amphetamine	4044	27.5%	$487,458.49	3889	28.2%	$489,401.47
lisdexamfetamine dimesylate	4031	27.4%	$1,078,473.03	3713	26.9%	$1,034,676.39
methylphenidate	21	0.1%	$8,341.34	14	0.1%	$4,171.73
methylphenidate HCl	5598	38.1%	$1,034,289.93	5213	37.8%	$986,288.55
serdexmethylphen/dexmethylphen	3	0.0%	$1,156.67	2	0.0%	$767.46
TOTALS	14709		$2,685,494.67	13796		$2,559,012.69
	Quarter 3 2023			**Quarter 4 2023**		
Medication	**Rx Count**	**% of Rx**	**Reimb Amount**	**Rx Count**	**% of Rx**	**Reimb Amount**
amphetamine	3	0.0%	$1,604.08	6	0.0%	$2,743.59
dexmethylphenidate HCl	804	6.4%	$37,119.07	819	6.5%	$37,523.60
dextroamphetamine sulfate	83	0.7%	$3,820.08	89	0.7%	$3,748.33
dextroamphetamine/amphetamine	3617	28.9%	$450,342.40	3561	28.1%	$450,687.19
lisdexamfetamine dimesylate	3167	25.3%	$831,425.36	3154	24.9%	$855,919.07
methylphenidate	16	0.1%	$5,782.31	28	0.2%	$7,004.34
methylphenidate HCl	4817	38.5%	$936,317.20	5032	39.6%	$977,748.96
serdexmethylphen/dexmethylphen	1	0.0%	$141.17	3	0.0%	$307.35
TOTALS	12508		$2,266,551.67	12692		$2,335,682.43

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39. *Methylin oral solution [prescribing information]. Florham Park, NJ: Shionogi Inc; July 2021.*
40. *Methylin. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. https://www.micromedexsolutions.com*
41. *Metadate CD (methylphenidate) [prescribing information]. Philadelphia, PA: Lannett Company Inc; June 2021.*
42. *Metadate CD. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. https://www.micromedexsolutions.com*
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44. *Concerta. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. https://www.micromedexsolutions.com*
45. *Ritalin LA (methylphenidate) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals; June 2021.*
46. *Ritalin/Ritalin SR (methylphenidate) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; June 2021.*
47. *Quillivant XR (methylphenidate) [prescribing information]. Monmouth Junction, NJ: Tris Pharma Inc; June 2021.*
48. *Quillivant XR. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. https://www.micromedexsolutions.com*
49. *Jornay PM (methylphenidate) [prescribing information]. Cherry Hill, NJ: Ironshore Pharmaceuticals Inc; June 2021.*
50. *Jornay PM. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. https://www.micromedexsolutions.com*
51. *Daytrana (methylphenidate) [prescribing information]. Miami, FL: Noven Therapeutics LLC; June 2021.*
52. *Daytrana. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. https://www.micromedexsolutions.com*
53. *Aptensio XR (methylphenidate) extended-release capsules [prescribing information]. Greenville, NC: Patheon; June 2021.*
54. *Aptensio XR. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. https://www.micromedexsolutions.com*
55. *QuilliChew ER (methylphenidate) extended-release chewable tablets [prescribing information]. Monmouth Junction, NJ: Tris Pharma Inc; June 2021.*
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60. *Azstarys. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. https://www.micromedexsolutions.com*
61. *Focalin (dexmethylphenidate hydrochloride) tablets [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals; January 2012.*
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63. *Focalin. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. https://www.micromedexsolutions.com*
64. *Relexxii (methylphenidate hydrochloride) extended-release tablets [prescribing information]. Alpharetta, GA: Vertical Pharmaceuticals; June 2022.*
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NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
DUR BOARD MEETING SEPTEMBER 2024

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
3RD QUARTER 2024

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

1. Zuranolone / Overuse _____ _____

Alert Message:Zurzuvae (zuranolone) may be over-utilized.The recommended dosage of zuranolone is 50 mg once daily in the evening for 14 days.If the patient experiences CNS depressant effects within the 14-day period, consider reducing the dosage to 40 mg once daily in the evening within the 14-day period.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Zuranolone		CKD 3 & 4
		Cirrhosis
		Hepatic Failure

Max Dose: 50 mg/day

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Zurzuvae Prescribing Information, Aug. 2024, Sage Therapeutics, Inc.

2. Zuranolone / Overuse – Severe Hepatic Impairment _____ _____

Alert Message:Zurzuvae (zuranolone) may be over-utilized.The recommended dosage of zuranolone in patients with severe hepatic impairment (Child-Pugh C) is 30 mg once daily in the evening for 14 days.No dosage adjustment is required in patients with mild (Child-Pugh A) or moderate (Child-Pugh B) hepatic impairment.

Drugs/Diseases

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

Max Dose: 30 mg/day

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Zurzuvae Prescribing Information, Aug. 2024, Sage Therapeutics, Inc.

3. Zuranolone / Overuse – Severe Hepatic Impairment _____ _____

Alert Message:Zurzuvae (zuranolone) may be over-utilized.The recommended dosage of zuranolone in patients with moderate or severe renal impairment (eGFR 15 to 59 mL/min/1.73m2) is 30 mg once daily in the evening for 14 days.No dosage adjustment is required in patients with mild (eGFR 60 to 89 mL/min/1.73m2) renal impairment.Zuranolone has not been studied in patients with an eGFR of < 15 mL/min/1.73m2 or patients requiring dialysis.

Drugs/Diseases

Util A	Util B	Util C (Include)
Zuranolone		CKD 3
		CKD 4

Max Dose: 30 mg/day

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Zurzuvae Prescribing Information, Aug. 2024, Sage Therapeutics, Inc.

Criteria Recommendations	*Approved*	*Rejected*

4. Zuranolone / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Zuranolone		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Zurzuvae Prescribing Information, Aug. 2024, Sage Therapeutics, Inc.

5. Zuranolone / Therapeutic Appropriateness _____ _____

Alert Message:The safety and effectiveness of Zurzuvae (zuranolone) use beyond 14 days in a single treatment course have not been established.

Drugs/Diseases

Util A	Util B	Util C
Zuranolone		

Duration: > 14 days

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Zurzuvae Prescribing Information, Aug. 2024, Sage Therapeutics, Inc.

6. Zuranolone / Therapeutic Appropriateness _____ _____

Alert Message:The safety and effectiveness of Zurzuvae (zuranolone) in geriatric patients have not been established.

Drugs/Diseases

Util A	Util B	Util C
Zuranolone		

Age Range: ≥ 65 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Zurzuvae Prescribing Information, Aug. 2024, Sage Therapeutics, Inc.

7. Zuranolone / CNS Depression _____ _____

Alert Message:Zurzuvae (zuranolone) can cause CNS depressant effects such as somnolence and confusion.If patients develop CNS depressant effects, consider dosage reduction or discontinuation of zuranolone.

Drugs/Diseases

Util A	Util B	Util C
Zuranolone	Confusion	
	Gait Disturbances	
	Somnolence	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Zurzuvae Prescribing Information, Aug. 2024, Sage Therapeutics, Inc.

Criteria Recommendations	*Approved*	*Rejected*

8. Zuranolone / CNS Depressant _____ _____

Alert Message:Caution should be used when Zurzuvae (zuranolone) is administered in combination with other CNS drugs or alcohol due to additive pharmacological effects.If use with another CNS depressant is unavoidable, consider zuranolone dosage reduction.

Drugs/Diseases

Util A	Util B	Util C
Zuranolone	CNS Depressants	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Zurzuvae Prescribing Information, Aug. 2024, Sage Therapeutics, Inc.

9. Zuranolone / Strong CYP3A4 Inhibitors _____ _____

Alert Message:The concurrent use ofZurzuvae (zuranolone) with a strong CYP3A4 inhibitor will result in increased zuranolone exposure and may increase the risk of zuranolone-associated adverse reactions.Reduce the zuranolone dosage to 30 mg orally once daily in the evening for 14 days when used concomitantly with a strong CYP3A4 inhibitor.

Drugs/Diseases

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

Max Dose: 30 mg/day

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Zurzuvae Prescribing Information, Aug. 2024, Sage Therapeutics, Inc.

10. Zuranolone / CYP3A4 Inducers _____ _____

Alert Message:The concurrent use ofZurzuvae (zuranolone) with CYP3A4 inducers should be avoided.Zuranolone is a CYP3A4 substrate, and concomitant use with a CYP3A4 inducer will decrease zuranolone exposure which may reduce zuranolone efficacy.

Drugs/Diseases

Util A	Util B	Util C
Zuranolone	Apalutamide	
	Carbamazepine	
	Enzalutamide	
	Mitotane	
	Phenobarbital	
	Phenytoin	
	Primidone	
	Rifampin	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Zurzuvae Prescribing Information, Aug. 2024, Sage Therapeutics, Inc.

Criteria Recommendations	*Approved*	*Rejected*

11. Zuranolone / Pregnancy / Pregnancy Negating _____ _____

Alert Message:Based on findings from animal studies, Zurzuvae (zuranolone) may cause fetal harm.Advise pregnant women of the potential risk to a fetus.Available data on zuranolone use in pregnant women from the clinical development program are insufficient to evaluate for a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Zurzuvae Prescribing Information, Aug. 2024, Sage Therapeutics, Inc.

12. Zuranolone / Lactation _____ _____

Alert Message:Available data from a clinical lactation study in 14 women indicate that Zurzuvae (zuranolone) is present in low levels in human milk. There are no data on the effects of zuranolone on a breastfed infant and limited data on the effects on milk production.The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for zuranolone and any potential adverse effects on the breastfed child from zuranolone or the underlying maternal condition.

Drugs/Diseases

Util A	Util B	Util C
Zuranolone	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Zurzuvae Prescribing Information, Aug. 2024, Sage Therapeutics, Inc.

13. Zuranolone / Reproductive Potential _____ _____

Alert Message:Advise female patients of reproductive potential to use effective contraception during treatment with Zurzuvae (zuranolone) and for one week after the final dose.Based on animal studies, zuranolone may cause embryo-fetal harm when administered to a pregnant woman.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Zuranolone		Contraceptives

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Zurzuvae Prescribing Information, Aug. 2024, Sage Therapeutics, Inc.

Criteria Recommendations	*Approved*	*Rejected*

14. Macitentan/Tadalafil / Overuse _____ _____

Alert Message:Opsynvi (macitentan/tadalafil) may be over-utilized.The maximum recommended dose of macitentan/tadalafil is one 10 mg/40 mg tablet once daily.

Drugs/Diseases

Util A	Util B	Util C
Macitentan/Tadalafil		

Max Dose: 10mg/40 mg per day

References:
Opsynvi Prescribing Information, March 2024, Janssen.
Clinical Pharmacology, 2024 Elsevier/Gold Standard.

15. Macitentan/Tadalafil / Therapeutic Appropriateness _____ _____

Alert Message:The safety and efficacy of Opsynvi (macitentan/tadalafil) in children have not been established.

Drugs/Diseases

Util A	Util B	Util C
Macitentan/Tadalafil		

Age Range: 0 – 17 yoa

References:
Opsynvi Prescribing Information, March 2024, Janssen.
Clinical Pharmacology, 2024 Elsevier/Gold Standard.

16. Macitentan/Tadalafil / Hepatic _____ _____

Alert Message:The macitentan component of Opsynvi (macitentan/tadalafil) is an endothelin receptor antagonist (ERA), and other ERAs have been shown to cause elevated hepatic enzymes, hepatotoxicity, and liver failure.Obtain liver enzyme tests prior to initiation of macitentan/tadalafil and repeat during treatment as clinically indicated.If clinically relevant aminotransferase elevations occur, or if elevations are accompanied by an increase in bilirubin > 2 x ULN, or by clinical symptoms of hepatotoxicity, discontinue macitentan/tadalafil.Do not initiate macitentan/tadalafil in patients with elevated aminotransferases (> 3 x upper limit of normal [ULN]) at baseline.

Drugs/Diseases

Util A	Util B	Util C
Macitentan/Tadalafil	Elevated Liver Transaminase Levels	

References:
Opsynvi Prescribing Information, March 2024, Janssen.
Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Criteria Recommendations	*Approved*	*Rejected*

17. Macitentan/Tadalafil / Severe Hepatic Impairment _____ _____

Alert Message:The macitentan component of Opsynvi (macitentan/tadalafil) is an endothelin receptor antagonist (ERA), and other ERAs have been shown to cause elevated hepatic enzymes, hepatotoxicity, and liver failure.Patients with severe hepatic cirrhosis (Child-Pugh Class C) have not been studied, and, therefore, avoid the use of macitentan/tadalafil in these patients.

Drugs/Diseases

Util A	Util B	Util C
Macitentan/Tadalafil	Cirrhosis	

References:
Opsynvi Prescribing Information, March 2024, Janssen.
Clinical Pharmacology, 2024 Elsevier/Gold Standard.

18. Macitentan/Tadalafil / Pulmonary Edema _____ _____

Alert Message:The macitentan component of Opsynvi (macitentan/tadalafil) is a pulmonary vasodilator and may significantly worsen the cardiovascular status of patients with pulmonary veno-occlusive disease (PVOD).Should signs of pulmonary edema occur, the possibility of PVOD should be considered and, if confirmed, discontinue treatment with macitentan/tadalafil.

Util A	Util B	Util C
Macitentan/Tadalafil	Pulmonary Edema	

References:
Opsynvi Prescribing Information, March 2024, Janssen.
Clinical Pharmacology, 2024 Elsevier/Gold Standard.

19. Macitentan/Tadalafil / Dual CYP3A4 & 2C9 Inhibitors _____ _____

Alert Message:Avoid concomitant use of Opsynvi (macitentan/tadalafil) with moderate dual inhibitors of CYP3A4 and CYP2C9 (such as fluconazole and amiodarone).Concomitant use of moderate dual inhibitors of CYP3A4 and CYP2C9 such as fluconazole is predicted to increase macitentan exposure approximately 4-fold.

Drugs/Diseases

Util A	Util B	Util C
Macitentan/Tadalafil	Amiodarone Fluconazole	

References:
Opsynvi Prescribing Information, March 2024, Janssen.
Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Criteria Recommendations	*Approved*	*Rejected*

20. Macitentan/Tadalafil / Strong CYP3A4 Inducers _____ _____

Alert Message:The use of Opsynvi (macitentan/tadalafil) with strong CYP3A4 inducers should be avoided.Concurrent use of macitentan/tadalafil with strong inducers of CYP3A4 significantly reduces macitentan exposure.

Drugs/Diseases

Util A	Util B	Util C
Macitentan/Tadalafil	Apalutamide	
	Carbamazepine	
	Enzalutamide	
	Mitotane	
	Phenobarbital	
	Phenytoin	
	Primidone	
	Rifampin	

References:
Opsynvi Prescribing Information, March 2024, Janssen.
Clinical Pharmacology, 2024 Elsevier/Gold Standard.

21. Macitentan/Tadalafil / Strong CYP3A4 Inhibitors _____ _____

Alert Message:Avoid concomitant use of Opsynvi (macitentan/tadalafil) with strong CYP3A4 inhibitors such as ritonavir, ketoconazole and itraconazole.Concomitant use with a strong CYP3A4 inhibitor increases exposure to both macitentan and tadalafil.Use other PAH treatment options when strong CYP3A4 inhibitors are needed.

Drugs/Diseases

Util A	Util B		Util C
Macitentan/Tadalafil	Clarithromycin	Nelfinavir	
	Cobicistat	Posaconazole	
	Itraconazole	Ritonavir	
	Ketoconazole	Voriconazole	
	Nefazodone		

References:
Opsynvi Prescribing Information, March 2024, Janssen.
Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Criteria Recommendations	*Approved*	*Rejected*

22. Macitentan/Tadalafil / Alpha-1 Adrenergic Blockers _____ _____

Alert Message:Caution should be exercised when Opsynvi (macitentan/tadalafil) is co-administered with an alpha-1 adrenergic blocker.Tadalafil and alpha-adrenergic blocking agents are both vasodilators with blood-pressure-lowering effects.In patients who are taking alpha-1 blockers, concomitant administration of tadalafil may lead to symptomatic hypotension.

Drugs/Diseases

Util A	Util B	Util C
Macitentan/Tadalafil	Alfuzosin	
	Doxazosin	
	Prazosin	
	Silodosin	
	Tamsulosin	
	Terazosin	

References:
Opsynvi Prescribing Information, March 2024, Janssen.
Clinical Pharmacology, 2024 Elsevier/Gold Standard.

23. Macitentan/Tadalafil / Pregnancy / Pregnancy Negating (Box Warning) _____ _____

Alert Message:Opsynvi (macitentan/tadalafil) may cause fetal harm when administered to a pregnant woman.The use of macitentan/tadalafil is contraindicated in females who are pregnant.The macitentan component of the combination product was consistently shown to have teratogenic effects when administered to animals.If macitentan/tadalafil is used during pregnancy, advise the patient of the potential risk to a fetus.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Macitentan/Tadalafil	Pregnancy	Abortion
	Delivery	
	Miscarriage	

Gender: Female
Age Range: 11 – 50 yoa

References:
Opsynvi Prescribing Information, March 2024, Janssen.
Clinical Pharmacology, 2024 Elsevier/Gold Standard.

24. Macitentan/Tadalafil / Lactation (Box Warning) _____ _____

Alert Message:Because of the potential for serious adverse reactions in breastfed infants from Opsynvi (macitentan/tadalafil), advise women not to breastfeed during treatment with macitentan/tadalafil.There are no data on the presence of tadalafil, macitentan, and/or their metabolites in human milk, the effects on the breastfed infant, or the effect on milk production. Tadalafil and/or its metabolites are present in the milk of lactating rats.When a drug is present in animal milk, it is likely that the drug will be present in human milk.

Drugs/Diseases

Util A	Util B	Util C
Macitentan/Tadalafil	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Opsynvi Prescribing Information, March 2024, Janssen.
Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Criteria Recommendations	*Approved*	*Rejected*

25. Macitentan/Tadalafil / Contraceptives (Negating) _____ _____

Alert Message:In females of reproductive potential, exclude pregnancy prior to initiation of Opsynvi (macitentan/tadalafil) therapy, ensure the use of acceptable contraceptive methods and obtain monthly pregnancy tests.Macitentan/tadalafil may cause fetal harm when administered during pregnancy and is contraindicated for use in females who are pregnant.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Macitentan/Tadalafil		Contraceptives

Gender: Female
Age Range: 11 – 50 yoa

References:
Opsynvi Prescribing Information, March 2024, Janssen.
Clinical Pharmacology, 2024 Elsevier/Gold Standard.

26.Macitentan/Tadalafil / Non-adherence _____ _____

Alert Message:Based on refill history, your patient may be under-utilizing Opsynvi (macitentan/tadalafil).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
Macitentan/Tadalafil		

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Roebuck MC, Liberman JN, Gemmill-Toyama M, Brennan TA. Medication Adherence Leads to Lower Health Care Use and Costs Despite Increased Spending. Health Affairs No. 1 (2011):91-99.
Dean BB, Saundankar V, Stafkey-Mailey D, Anguiano RH, Nelsen AC, Gordon K, Classi P. Medication Adherence and Healthcare Costs Among Patients with Pulmonary Arterial Hypertension Treated with Oral Prostacyclins: A Retrospective Cohort Study. Drugs Real World Outcomes. 2020 Sep;7(3):229-239. doi: 10.1007/s40801-020-00183-x. Erratum in: Drugs Real World Outcomes. 2020 Jun 5;: PMID: 32144746; PMCID: PMC7392967.
Ho PM, Bryson CL, Rumsfeld JS. Medication Adherence: Its Importance in Cardiovascular Outcomes. Circulation. 2009 Jun 16;119(23):3028-3035.

27. Mepolizumab / Therapeutic Appropriateness - CRSwNP _____ _____

Alert Message:The safety and effectiveness of Nucala (mepolizumab) in patients less than 18 years of age with chronic rhinosinusitis with nasal polyps (CRSwNP) have not been established.

Drugs/Diseases

Util A	Util B	Util C (Include)
Mepolizumab		Nasal Polyps

Age Range: 0 – 17 yoa

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

Criteria Recommendations	*Approved*	*Rejected*

28. Mepolizumab / Therapeutic Appropriateness - HES _____ _____

Alert Message:The safety and effectiveness of Nucala (mepolizumab) in pediatric patients less than 12 years of age with hypereosinophilic syndrome (HES) have not been established.

Drugs/Diseases

Util A	Util B	Util C(Include)
Mepolizumab		Hypereosinophilic Syndrome

Age Range: 0 – 11 yoa

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

29.Mepolizumab / Overutilization -HES _____ _____

Alert Message:The manufacturer's recommended dose of Nucala (mepolizumab) for hypereosinophilic syndrome (HES) is 300 mg administered once every 4 weeks by subcutaneous injection.

Drugs/Diseases

Util A	Util B	Util C (Include)
Mepolizumab		Hypereosinophilic Syndrome

Max Dose: 3 injections/4 weeks

Age Range:≥ 12 yoa

References:

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

30. Elagolix/Estradiol/Norethindrone / Overuse _____ _____

Alert Message:Oriahnn (elagolix/estradiol/norethindrone) may be over-utilized. The recommended dosage of elagolix/estradiol/norethindrone is one capsule in the morning and one capsule in the evening.The use of elagolix/estradiol/norethindrone should be limited to 24 months due to the risk of continued bone loss, which may not be reversible.

Drugs/Diseases

Util A	Util B	Util C
Elagolix/Estradiol/Norethindrone		

Max Dose: 2 caps/day

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

31. Elagolix/Estradiol/Norethindrone / Therapeutic Appropriateness _____ _____

Alert Message:The safety and effectiveness of Oriahnn (elagolix/estradiol/norethindrone) in pediatric patients have not been established.

Util A	Util B	Util C
Elagolix/Estradiol/Norethindrone		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

32. Elagolix/Estradiol/Norethindrone / Thrombotic Disorders _____ _____

Alert Message:Oriahnn (elagolix/estradiol/norethindrone) is contraindicated in women with a current or a history of thrombotic or thromboembolic disorders and in women at increased risk for these events. In general, the risk is greatest among women over 35 years of age who smoke and women with uncontrolled hypertension, dyslipidemia, vascular disease, or obesity.

Drugs/Diseases

Util A	Util B	Util C
Elagolix/Estradiol/Norethindrone	Deep Vein Thrombosis	
	Dyslipidemia	
	Migraine with Aura	
	Myocardial Infarction	
	Obesity	
	Pulmonary Embolism	
	Stroke	
	Vascular Disease	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

33. Elagolix/Estradiol/Norethindrone / Pregnancy / Pregnancy Negating _____ _____

Alert Message:Oriahnn (elagolix/estradiol/norethindrone) is contraindicated in women who are pregnant.Exposure to elagolix/estradiol/norethindrone in early pregnancy may increase the risk of early pregnancy loss.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Elagolix/Estradiol/Norethindrone	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

Criteria Recommendations	*Approved*	*Rejected*

33. Elagolix/Estradiol/Norethindrone / Pregnancy / Pregnancy Negating _____ _____

Alert Message:Oriahnn (elagolix/estradiol/norethindrone) is contraindicated in women who are pregnant.Exposure to elagolix/estradiol/norethindrone in early pregnancy may increase the risk of early pregnancy loss.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Elagolix/Estradiol/Norethindrone	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

34. Elagolix/Estradiol/Norethindrone / Osteoporosis _____ _____

Alert Message:Oriahnn (elagolix/estradiol/norethindrone) is contraindicated in women with known osteoporosis because of the risk of further bone loss.Elagolix/estradiol/norethindrone may cause a decrease in bone mineral density (BMD) in some patients.BMD loss is greater with increasing duration of use and may not be completely reversible after stopping treatment.

Drugs/Diseases

Util A	Util B	Util C (Include)
Elagolix/Estradiol/Norethindrone		Osteoporosis

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

35. Elagolix/Estradiol/Norethindrone / Hormonally-Sensitive Malignancies _____ _____

Alert Message:Oriahnn (elagolix/estradiol/norethindrone) is contraindicated in women with breast cancer, a history of breast cancer or other hormonally-sensitive malignancies, and who are at increased risk for hormonally-sensitive malignancies.

Drugs/Diseases

Util A	Util B	Util C (Include)
Elagolix/Estradiol/Norethindrone		Breast Cancer
		Endometrial Cancer
		Ovarian Cancer
		Uterine Cancer

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

Criteria Recommendations	*Approved*	*Rejected*

36. Elagolix/Estradiol/Norethindrone / Hepatic Impairment _____ _____

Alert Message:Oriahnn (elagolix/estradiol/norethindrone) is contraindicated in women with known hepatic impairment or disease.Instruct patients to promptly seek medical attention if they develop symptoms or signs that may reflect liver injury, such as jaundice.

Util A	Util B	Util C
Elagolix/Estradiol/Norethindrone	Cirrhosis	
	Chronic Hepatitis	
	Fibrosis of Liver	
	Inflammatory Liver Disease	
	Jaundice	
	Hepatic Failure	
	Hepatic Impairment	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

37. Elagolix/Estradiol/Norethindrone / OATP1B1 Inhibitors _____ _____

Alert Message:Oriahnn (elagolix/estradiol/norethindrone) is contraindicated in women taking inhibitors of organic anion transporting polypeptide (OATP)1B1 that are known or expected to significantly increase elagolix plasma concentration.

Drugs/Diseases

Util A	Util B		Util C
Elagolix/Estradiol/Norethindrone	Asciminib	Enasidenib	
	Cobicistat	Fostemsavir	
	Cyclosporine	Gemfibrozil	
	Darolutamide	Glecaprevir	
	Eltrombopag	Velpatasvir	
	Clarithromycin	Encorafenib	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

38. Elagolix/Estradiol/Norethindrone / Suicidal Ideation& Depression _____ _____

Alert Message:In clinical trials Oriahnn (elagolix/estradiol/norethindrone)-treated women had a higher incidence of depression, depressed mood, and tearfulness compared to placebo-treated women.Suicidal ideation and behavior, including a completed suicide, occurred in women treated with lower doses of elagolix in clinical trials conducted for a different indication. Promptly evaluate patients with psychiatric symptoms to determine whether the risks of continued therapy outweigh the benefits.

Drugs/Diseases

Util A	Util B	Util C
Elagolix/Estradiol/Norethindrone	Anxiety	
	Depression	
	Mood Disorders	
	Suicidal Ideation	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

39. Elagolix/Estradiol/Norethindrone / Gallbladder Disease _____ _____

Alert Message:Oriahnn (elagolix/estradiol/norethindrone) may increase the risk of gallbladder disease.For women, with a history of cholestatic jaundice associated with past estrogen use or when pregnant, assess the risk-benefit of continuing therapy.Discontinue elagolix/estradiol/norethindrone if jaundice occurs.

Drugs/Diseases

Util A	Util B	Util C (Include)
Elagolix/Estradiol/Norethindrone		Diseases of Gallbladder

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

40. Elagolix/Estradiol/Norethindrone / Digoxin _____ _____

Alert Message:Concurrent use of Oriahnn (elagolix/estradiol/norethindrone) with digoxin may result in increased digoxin concentrations.Increase monitoring of digoxin concentrations and potential signs and symptoms of digoxin toxicity.Digoxin is a P-gp substrate, and the elagolix component of the combination product is a P-gp efflux transport inhibitor.Digoxin dosage adjustment may be required.

Drugs/Diseases

Util A	Util B	Util C
Elagolix/Estradiol/Norethindrone	Digoxin	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

41. Elagolix/Estradiol/Norethindrone / Rosuvastatin _____ _____

Alert Message:Concurrent use of Oriahnn (elagolix/estradiol/norethindrone) with a rosuvastatin-containing product may result in decreased rosuvastatin exposure and loss of therapeutic effect.Monitor the patient for rosuvastatin efficacy.Dosage adjustment of rosuvastatin may be necessary during elagolix/estradiol/norethindrone therapy.

Drugs/Diseases

Util A	Util B	Util C
Elagolix/Estradiol/Norethindrone	Rosuvastatin	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

42. Elagolix/Estradiol/Norethindrone / Midazolam _____ _____

Alert Message:Concurrent use of Oriahnn (elagolix/estradiol/norethindrone) with midazolam may result in decreased midazolam exposure. Monitor the patient for altered response to midazolam therapy.Consider increasing the dose of midazolam by no more than 2-fold and individualize midazolam therapy based on the patient’s response.

Drugs/Diseases

Util A	Util B	Util C
Elagolix/Estradiol/Norethindrone	Midazolam	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

Criteria Recommendations	*Approved*	*Rejected*

43. Elagolix/Estradiol/Norethindrone / Strong CYP3A4 Inducers _____ _____

Alert Message: Concomitant use of Oriahnn (elagolix/estradiol/norethindrone) with a strong CYP3A inducer is not recommended.Elagolix, estradiol, and norethindrone are CYP3A4 substrates, and concurrent use with a CYP3A4 inducer may decrease plasma concentrations of all substrates and efficacy.

Drugs/Diseases

Util A	Util B	Util C
Elagolix/Estradiol/Norethindrone	Apalutamide	
	Carbamazepine	
	Enzalutamide	
	Mitotane	
	Phenobarbital	
	Phenytoin	
	Primidone	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

44. Elagolix/Estradiol/Norethindrone / Strong CYP3A4 Inhibitors _____ _____

Alert Message:Concomitant use of Oriahnn (elagolix/estradiol/norethindrone) with strong CYP3A inhibitors is not recommended.Elagolix, estradiol, and norethindrone are CYP3A4 substrates, and concurrent use with a strong CYP3A4 inhibitor may increase plasma concentrations of all substrates, increasing the risk of adverse reactions.

Drugs/Diseases

Util A	Util B		Util C
Elagolix/Estradiol/Norethindrone	Clarithromycin	Nelfinavir	
	Cobicistat	Posaconazole	
	Itraconazole	Ritonavir	
	Ketoconazole	Voriconazole	
	Nefazodone		

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

45. Elagolix/Estradiol/Norethindrone / Rifampin _____ _____

Alert Message:Concomitant use of Oriahnn (elagolix/estradiol/norethindrone) with rifampin is not recommended.The concurrent use of rifampin with an elagolix-containing agent may result in increased elagolix plasma concentrations, increasing the risk of adverse reactions.

Drugs/Diseases

Util A	Util B	Util C
Elagolix/Estradiol/Norethindrone	Rifampin	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

Criteria Recommendations	*Approved*	*Rejected*

46. Elagolix/Estradiol/Norethindrone / Lactation _____ _____

Alert Message:The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Oriahnn (elagolix/estradiol/norethindrone) and any potential adverse effects on the breastfed child from elagolix/estradiol/norethindrone or the underlying maternal condition.There is no information on the presence of elagolix or its metabolites in human milk, the effects on the breastfed child, or the effects on milk production. Estrogen administration to nursing women has been shown to decrease the quantity and quality of breast milk.Detectable amounts of estrogen and progestin have been identified in the breast milk of women receiving estrogen and progestin combinations.

Drugs/Diseases

Util A	Util B	Util C
Elagolix/Estradiol/Norethindrone	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

47. Oteseconazole / Therapeutic Appropriateness _____ _____

Alert Message:The safety and effectiveness of Vivjoa (oteseconazole) have not been established in pre-menarchal pediatric females.

Drugs/Diseases

Util A	Util B	Util C
Oteseconazole		

Age Range: 0 – 10 yoa

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

48. Oteseconazole / Therapeutic Appropriateness _____ _____

Alert Message:Vivjoa (oteseconazole) use is contraindicated in females of reproductive potential and pregnant or lactating women.Based on animal studies, oteseconazole may cause fetal harm.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Oteseconazole		Hysterectomy
		Postmenopausal
		Salpingo-oophorectomy
		Tubal Ligation
		Pregnancy
		Lactation

Age Range: 11– 50 yoa
Gender: Female

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Vivjoa Prescribing Information, April 2024, Mycovia Pharmaceuticals, Inc.

Criteria Recommendations	*Approved*	*Rejected*

49. Oteseconazole / Pregnancy / Pregnancy Negating _____ _____

Alert Message:Vivjoa (oteseconazole) use is contraindicated in pregnant women.Based on animal studies, oteseconazole may cause fetal harm.Ocular abnormalities were observed in a pre- and postnatal animal study in the offspring of rats administered oteseconazole.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Vivjoa Prescribing Information, April 2024, Mycovia Pharmaceuticals, Inc.

50. Oteseconazole / Lactation _____ _____

Alert Message:Vivjoa (oteseconazole) use is contraindicated in lactating women.Ocular abnormalities were observed in the offspring of pregnant rats dosed at 7.5 mg/kg/day during organogenesis through lactation in pre- and postnatal developmental studies.

Drugs/Diseases

Util A	Util B	Util C
Oteseconazole	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Vivjoa Prescribing Information, April 2024, Mycovia Pharmaceuticals, Inc.

51. Oteseconazole / BRCP Substrates _____ _____

Alert Message:Vivjoa (oteseconazole) is a BCRP inhibitor.Concomitant use of oteseconazole with a BCRP substrate may increase the exposure of the BCRP substrate, which may increase the risk of adverse reactions associated with the substrate.Use the lowest possible starting dose of the BCRP substrate or consider reducing the dose of the substrate drug and monitor for adverse reactions.

Drugs/Diseases

Util A	Util B	Util C
Oteseconazole	Atorvastatin	
	Alpelisib	
	Dolutegravir	
	Pazopanib	
	Rosuvastatin	
	Sulfasalazine	
	Talazoparib	
	Tenofovir ala	
	Tenofovir dis	
	Topotecan	
	Ubrogepant	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Vivjoa Prescribing Information, April 2024, Mycovia Pharmaceuticals, Inc.

52. Vonoprazan / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Voquezna Prescribing Information, November 2023, Phantom Pharmaceuticals.

53. Vonoprazan / Rilpivirine-Containing Drugs _____ _____

Alert Message:Concurrent use of Voquezna (vonoprazan) with rilpivirine-containing products is contraindicated.Vonoprazan reduces intragastric acidity, which may alter the absorption of rilpivirine, leading to changes in safety and/or effectiveness.The inhibitory effect of vonoprazan on acid secretion increases with repeated daily dosing.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan	Rilpivirine	
	Rilpivirine/Cabotegravir	
	Rilpivirine/Dolutegravir	
	Rilpivirine/Emtricitabine/Tenofovir ala	
	Rilpivirine/Emtricitabine/Tenofovir dis	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Voquezna Prescribing Information, November 2023, Phantom Pharmaceuticals.

54. Vonoprazan / Atazanavir-Containing Drugs _____ _____

Alert Message:Concurrent use of Voquezna (vonoprazan) with an atazanavir-containing product should be avoided.Vonoprazan reduces intragastric acidity, which may alter the absorption of atazanavir, leading to changes in safety and/or effectiveness.The inhibitory effect of vonoprazan on acid secretion increases with repeated daily dosing.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan	Atazanavir	
	Atazanavir Cobicistat	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Voquezna Prescribing Information, November 2023, Phantom Pharmaceuticals.

55. Vonoprazan / Nelfinavir _____ _____

Alert Message:Concurrent use of Voquezna (vonoprazan) with nelfinavir should be avoided. Vonoprazan reduces intragastric acidity, which may alter the absorption of nelfinavir, leading to changes in safety and/or effectiveness.The inhibitory effect of vonoprazan on acid secretion increases with repeated daily dosing.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan	Nelfinavir	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Voquezna Prescribing Information, November 2023, Phantom Pharmaceuticals.

56. Vonoprazan / Strong or Moderate CYP3A4 Inducers _____ _____

Alert Message:Voquezna (vonoprazan) is a CYP3A substrate.Concomitant use of vonoprazan with strong or moderate CYP3A inducers may decrease vonoprazan exposure, which may reduce the effectiveness of the vonoprazan.The concurrent use of vonoprazan with strong or moderate CYP3A inducers should be avoided.

Drugs/Diseases

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

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Voquezna Prescribing Information, November 2023, Phantom Pharmaceuticals.

57. Vonoprazan / CYP3A4 Substrates w/ NTI _____ _____

Alert Message:Voquezna (vonoprazan) is a weak CYP3A inhibitor.Concurrent use of vonoprazan with CYP3A substrates where minimal concentration changes may lead to serious toxicities should be done with caution.Frequent monitoring of substrate concentrations and/or adverse reactions related to the substrate drugs is recommended when used with vonoprazan.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan	Cyclosporine	
	Sirolimus	
	Tacrolimus	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Voquezna Prescribing Information, November 2023, Phantom Pharmaceuticals.

58. Vonoprazan / Clopidogrel _____ _____

Alert Message:Voquezna (vonoprazan) is a CYP2C19 inhibitor.Concurrent use of vonoprazan with clopidogrel, a CYP2C19 substrate, may result in reduced clopidogrel efficacy.Vonoprazan may reduce plasma concentrations of the active metabolite of clopidogrel and may cause a reduction in platelet inhibition.Carefully monitor the efficacy of clopidogrel and consider alternative anti-platelet therapy.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan	Clopidogrel	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Voquezna Prescribing Information, November 2023, Phantom Pharmaceuticals.

59. Vonoprazan / Citalopram _____ _____

Alert Message:Voquezna (vonoprazan) is a CYP2C19 inhibitor.Concurrent use of vonoprazan with citalopram, a CYP2C19 substrate, may result in increased citalopram exposure, increasing the risk for citalopram adverse reactions.The dose of citalopram should be limited to 20 mg/day when co-administered with vonoprazan.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan	Citalopram	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Voquezna Prescribing Information, November 2023, Phantom Pharmaceuticals.

60. Vonoprazan / Cilostazol _____ _____

Alert Message:Voquezna (vonoprazan) is a CYP2C19 inhibitor.Concurrent use of vonoprazan with cilostazol, a CYP2C19 substrate, may result in increased cilostazol exposure, increasing the risk for cilostazol-related adverse reactions.The dose of cilostazol should be limited to 50 mg twice daily when co-administered with vonoprazan.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan	Cilostazol	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Voquezna Prescribing Information, November 2023, Phantom Pharmaceuticals.

61. Vonoprazan / Severe Renal Impairment / Erosive Esophagitis _____ _____

Alert Message:The Voquezna (vonoprazan) dose should not exceed 10 mg once daily for the healing of erosive esophagitis in patients with severe renal impairment (eGFR less than 30 mL/minute).In pharmacokinetic studies, patients with severe renal impairment had increased systemic exposure (2.4 times greater) to vonoprazan compared to subjects with normal renal function.

Drugs/Diseases

Util A	Util B	Util C (Include)
Vonoprazan	CKD Stage 4	Erosive Esophagitis
	CKD Stage 5	
	ESRD	

Max Dose: 10 mg/day

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Voquezna Prescribing Information, November 2023, Phantom Pharmaceuticals.

62. Vonoprazan / Severe Renal Impairment / H. pylori _____ _____

Alert Message:The use of Voquezna (vonoprazan) is not recommended for the treatment of Helicobacter pylori in patients with severe renal impairment (eGFR less than 30 mL/minute). In pharmacokinetic studies, patients with severe renal impairment had increased systemic exposure (2.4 times greater) to vonoprazan compared to subjects with normal renal function.

Drugs/Diseases

Util A	Util B	Util C (Include)
Vonoprazan 20 mg	CKD Stage 4	H. Pylori
	CKD Stage 5	
	ESRD	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Voquezna Prescribing Information, November 2023, Phantom Pharmaceuticals.

63. Vonoprazan / Moderate to Severe Hepatic Impairment / H. pylori _____ _____

Alert Message:The use of Voquezna (vonoprazan) for the treatment of Helicobacter pylori infection in patients with moderate to severe hepatic impairment (Child-Pugh Class B or C) is not recommended.In pharmacokinetic studies, patients with moderate and severe hepatic impairment exhibited increased systemic exposure to vonoprazan (2.4 and 2.6 times greater, respectively) as compared to subjects with normal hepatic function.

Drugs/Diseases

Util A	Util B	Util C (Include)
Vonoprazan	Cirrhosis	H. Pylori
	Hepatic Failure	
	Toxic Liver	
	Fatty Liver	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Voquezna Prescribing Information, November 2023, Phantom Pharmaceuticals.

64. Vonoprazan / Pregnancy / Pregnancy Negating _____ _____

Alert Message:There are no adequate and well-controlled studies of Voquezna (vonoprazan) in pregnant women to evaluate for drug-associated risks of major birth defects, miscarriage, or other adverse maternal or fetal outcomes.Avoid the use of vonoprazan during pregnancy unless other treatments are not clinically appropriate.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Voquezna Prescribing Information, November 2023, Phantom Pharmaceuticals.

65. Vonoprazan / Lactation _____ _____

Alert Message:There are no data regarding the presence of Voquezna (vonoprazan) in human milk, the effects on the breastfed infant, or the effects on milk production.Vonoprazan and its metabolites are present in rat milk.Liver injury occurred in offspring from pregnant and lactating rats administered oral vonoprazan.When a drug is present in animal milk, it is likely that the drug will be present in human milk.Because of the potential risk of adverse liver effects shown in animal studies with vonoprazan, a woman should pump and discard human milk for the duration of vonoprazan therapy and for 2 days after therapy ends and feed her infant stored human milk (collected prior to therapy) or formula.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Voquezna Prescribing Information, November 2023, Phantom Pharmaceuticals.

66. Fezolinetant / Overuse _____ _____

Alert Message:Veozah (fezolinetant) may be over-utilized.The recommended daily dose of fezolinetant is one 45 mg tablet once daily.

Drugs/Diseases

Util A	Util B	Util C
Fezolinetant		

Max Dose: 45 mg/day

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Veozah Prescribing Information, May 2023, Astellas Pharma US, Inc.

67. Fezolinetant / Therapeutic Appropriateness _____ _____

Alert Message:The efficacy and safety of Veozah (fezolinetant) in individuals less than 18 years of age have not been established.

Drugs/Diseases

Util A	Util B	Util C
Fezolinetant		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Veozah Prescribing Information, May 2023, Astellas Pharma US, Inc.

Criteria Recommendations	*Approved*	*Rejected*

68. Fezolinetant / Therapeutic Appropriateness _____ _____

Alert Message:Veozah (fezolinetant) is contraindicated in women with cirrhosis. Fezolinetant has not been studied in this patient population.In pharmacokinetics studies, patients with Child-Pugh Class A or B hepatic impairment receiving fezolinetant experienced increased fezolinetant exposure compared to patients with normal hepatic function.Perform baseline bloodwork to evaluate for hepatic function and injury prior to fezolinetant initiation.Do not start fezolinetant if the concentration of ALT or AST is equal to or exceeds two times the ULN or if the total bilirubin is elevated (for example, equal to or exceeds two times the ULN) for the evaluating laboratory.

Drugs/Diseases

Util A	Util B	Util C
Fezolinetant	Cirrhosis	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Veozah Prescribing Information, May 2023, Astellas Pharma US, Inc.

69. Fezolinetant / Severe Renal Impairment & ESRD _____ _____

Alert Message:Veozah (fezolinetant) is contraindicated in women with severe renal impairment (eGFR 15 to < 30 mL/min/1.73m2) or end-stage renal disease (eGFR < 15 mL/min/1.73m2). In pharmacokinetics studies, following oral administration of fezolinetant 30 mg, the AUC of the major metabolite increased by approximately 75% and 380% in patients with moderate and severe renal impairment, respectively.

Drugs/Diseases

Util A	Util B	Util C
Fezolinetant	CKD Stage 4	
	CKD Stage 5	
	ESRD	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Veozah Prescribing Information, May 2023, Astellas Pharma US, Inc.

70. Fezolinetant / CYP1A2 Inhibitors _____ _____

Alert Message:Coadministration of Veozah (fezolinetant) with a CYP1A2 inhibitor is contraindicated.Fezolinetant is a substrate of CYP1A2.Concomitant use of fezolinetant with drugs that are weak, moderate, or strong CYP1A2 inhibitors significantly increases the plasma Cmax and AUC of fezolinetant.

Drugs/Diseases

Util A	Util B		Util C
Fezolinetant	Acyclovir	Methoxsalen	
	Allopurinol	Mexiletine	
	Amiodarone	Obeticholic Acid	
	Cannabidiol	Osilodrostat	
	Capmatinib	Pacritinib	
	Cimetidine	Peginterferon Alfa-2b	
	Ciprofloxacin	Ritlecitinib	
	Deferasirox	Rucaparib	
	Disulfiram	Ticlopidine	
	Enasidenib	Verapamil	
	Fluvoxamine	Vemurafenib	
	Givosiran	Viloxazine	
	Leniolisib	Zileuton	
	Meropenem		

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Veozah Prescribing Information, May 2023, Astellas Pharma US, Inc.

71. Fezolinetant / Pregnancy / Pregnancy Negating _____ _____

Alert Message:There are no data on Veozah (fezolinetant) use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes.Fezolinetant is indicated for the treatment of moderate to severe vasomotor symptoms due to menopause.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Fezolinetant	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.
Veozah Prescribing Information, May 2023, Astellas Pharma US, Inc.

Criteria Recommendations	*Approved*	*Rejected*

72. Fezolinetant / Lactation _____ _____

Alert Message:There are no data on the presence of fezolinetant in human milk, the effects on the breastfed child, or the effects on milk production. It is not known if fezolinetant is present in human milk.Fezolinetant is indicated for the treatment of moderate to severe vasomotor symptoms due to menopause.

Drugs/Diseases

Util A	Util B	Util C
Fezolinetant	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Veozah Prescribing Information, May 2023, Astellas Pharma US, Inc.

73. Fezolinetant / Non-adherence _____ _____

Alert Message:Based on refill history, your patient may be under-utilizing Veozah (fezolinetant). 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
Fezolinetant		

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.

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74. Loxapine Inhalation / Therapeutic Appropriateness _____ _____

Alert Message:The use of Adasuve (loxapine inhalation) is contraindicated in patients with a current diagnosis of asthma, COPD, or other lung diseases associated with bronchospasm.

Drugs/Diseases

Util A	Util B	Util C
Loxapine Inhalation	Asthma	
	COPD	
	Chronic Bronchitis	
	Emphysema	

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

75. Loxapine Inhalation / Drugs to Treat Airway Disease _____ _____

Alert Message:The use of Adasuve (loxapine inhalation) is contraindicated in patients with current use of medications to treat airway disease, such as asthma or COPD.Loxapine inhalation can cause bronchospasm that has the potential to lead to respiratory distress and respiratory arrest.

Drugs/Diseases

Util A	Util B		Util C
Loxapine Inhalation	Albuterol	Terbutaline	Montelukast
	Aclidinium	Theophylline	Zafirlukast
	Arformoterol	Tiotropium	Zileuton
	Formoterol	Umeclidinium	Roflumilast
	Glycopyrrolate	Vilanterol	Beclomethasone
	Indacaterol	Benralizumab	Budesonide
	Ipratropium	Dupilumab	Ciclesonide
	Levalbuterol	Mepolizumab	Fluticasone
	Olodaterol	Omalizumab	Mometasone
	Revefenacin	Reslizumab	Cromolyn
	Salmeterol	Tezepelumab	

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

76. Apremilast / Overuse _____ _____

Alert Message:Otezla (apremilast) may be over-utilized.The recommended maintenance dose of apremilast (after the 5-day titration schedule) for the treatment of moderate to severe plaque psoriasis in pediatric patients 6 years of age and older and weighing at least 50 kg is 30 mg twice a day.The recommended maintenance dose in pediatric patients weighing 20 kg to less than 50 kg is 20 mg twice daily.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Apremilast		CKD Stage 4 & 5

Max Dose: 60 mg/day
Age Range: 6 – 17 yoa

References:
Otezla Prescribing Information, April 2024, Amgen Inc.

77. Apremilast / Overuse - Severe Renal Impairment _____ _____

Alert Message:Otezla (apremilast) may be over-utilized.The recommended maintenance dose of apremilast (after the 5-day titration schedule) for the treatment of moderate to severe plaque psoriasis in pediatric patients 6 years of age and older and weighing at least 50 kg with severe renal impairment is 30 mg once daily.The recommended maintenance dose in pediatric patients weighing 20 kg to less than 50 kg is 20 mg once daily.

Drugs/Diseases

Util A	Util B	Util C (Include)
Apremilast		CKD Stage 4 & 5

Max Dose: 30 mg/day
Age Range: 6 – 17 yoa

References:
Otezla Prescribing Information, April 2024, Amgen Inc.

Criteria Recommendations	*Approved*	*Rejected*

78. Apremilast / Therapeutic Appropriateness _____ _____

Alert Message:The safety and effectiveness of Otezla (apremilast) have not been established in pediatric patients below the age of 6 years or weighing less than 20 kg with moderate to severe plaque psoriasis.

Drugs/Diseases

Util A	Util B	Util C (Include)
Apremilast		Plaque Psoriasis

Age Range: 0 – 5 yoa

References:
Otezla Prescribing Information, April 2024, Amgen Inc.

79. Apremilast / Therapeutic Appropriateness _____ _____

Alert Message:The safety and effectiveness of Otezla (apremilast) have not been established in pediatric patients with psoriatic arthritis or oral ulcers associated with Behcet's Disease.

Drugs/Diseases

Util A	Util B	Util C (Include)
Apremilast		Psoriatic Arthritis
		Behcet's Disease

Age Range: 0 – 17 yoa

References:
Otezla Prescribing Information, April 2024, Amgen Inc.