State Fiscal Year 2021 Print Annual Reviews Quarter 4

Count	Category/Medication
1.	Benzodiazepine Medications
2.	Bowel Preparation Medications
3.	Butalbital Medications
4.	Gout Medications
5.	Idiopathic Pulmonary Fibrosis (IPF) Medications
6.	Leukotriene Modulators
7.	Mozobil® (Plerixafor)
8.	Muscle Relaxant Medications
9.	Naloxone Medications
10.	Non-Steroidal Anti-Inflammatory Drugs (NSAIDs; systemic)
11.	Nuedexta® (Dextromethorphan/Quinidine)
12.	Otic Anti-Infective Medications
13.	Phosphate Binders
14.	Prenatal Vitamins
15.	Pulmonary Hypertension Medications
16.	Qutenza® (Capsaicin 8% Patch)
17.	Ravicti® (Glycerol Phenylbutyrate)
18.	Smoking Cessation Products
19.	Topical Antibiotic Products
20.	Topical Antifungal Products
21.	Vasomotor Symptom Medications
22.	Vesicular Monoamine Transporter 2 (VMAT2) Inhibitor Medications

Fiscal Year 2021 = July 1, 2020 – June 30, 2021

NOTE: An analysis of the atypical [Aged, Blind, and Disabled (ABD)] patient subgroup of the Oklahoma Medicaid population has been performed pertaining to all recommendations included in this DUR Board print annual review packet to ensure fair and knowledgeable deliberation of the potential impact of the recommendations on this patient population.

Fiscal Year 2021 Annual Review of Benzodiazepine Medications

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

Benzodiazepine Medications Approval Criteria for Members 19 Years of Age and Older:

1. Currently there is no prior authorization required; however, quantity limits are set at a maximum of 3 units per day for most products (except alprazolam 2mg, which is set at 2 units per day); and
2. Approval for dosing >3 times daily requires a chronic physical diagnosis; for these diagnoses, the maximum allowed dosing would be 4 times daily (no anxiolytic benzodiazepine therapy >3 times daily dosing if member also concurrently taking an insomnia medication); and
    a. Member may receive >3 units per day if the following criteria exist:
        i. The number of units per day is >3, but is less than the maximum daily dose for the product (or for a total daily dosing of 3 times daily); or
        ii. The member has a chronic diagnosis and a clinical reason for excessive units has been provided; and
3. Current members will be given 2 months to taper dosing to no more than 3 doses daily.

Benzodiazepine Medications Approval Criteria for Members Younger than 19 Years of Age:

1. Member must have a chronic behavioral health-related diagnosis or a chronic physical diagnosis; and
2. Approval criteria for a chronic behavior health-related diagnosis:
    a. No concurrent stimulant ADHD medications; and
    b. Maximum dosing of 3 times daily will apply; or
3. Approval criteria for a chronic physical diagnosis:
    a. Maximum dosing of 3 times daily will apply if a hypnotic medication is being used concurrently; or
    b. Maximum dosing of 4 times daily will apply if no hypnotic medication is being used concurrently; and
4. Exceptions can be granted for administration prior to procedures; and
5. Members 12 years of age or younger will have the same criteria as above, and the prescription must be originally written by a psychiatrist or neurologist.

Niravam™ (Alprazolam Orally Disintegrating Tablet) Approval Criteria:

1. An FDA approved diagnosis; and
2. A diagnosis indicating that the member has a condition that prevents him/her from swallowing tablets; and
3. The physician's signature is required for approval; and
4. Dosing regimens that involve splitting of tablets will not be covered.

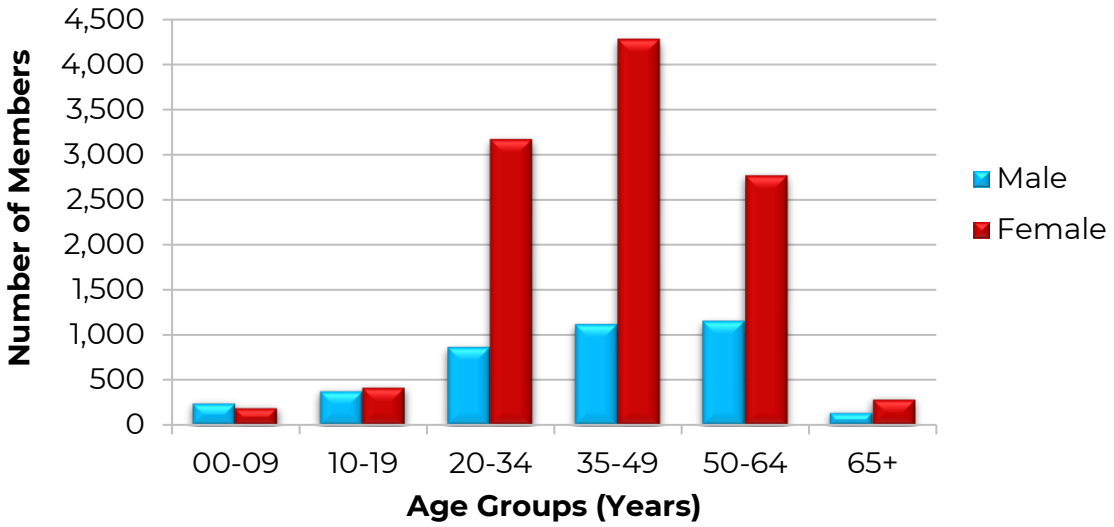
Utilization of Benzodiazepine Medications: Fiscal Year 2021

Comparison of Fiscal Years

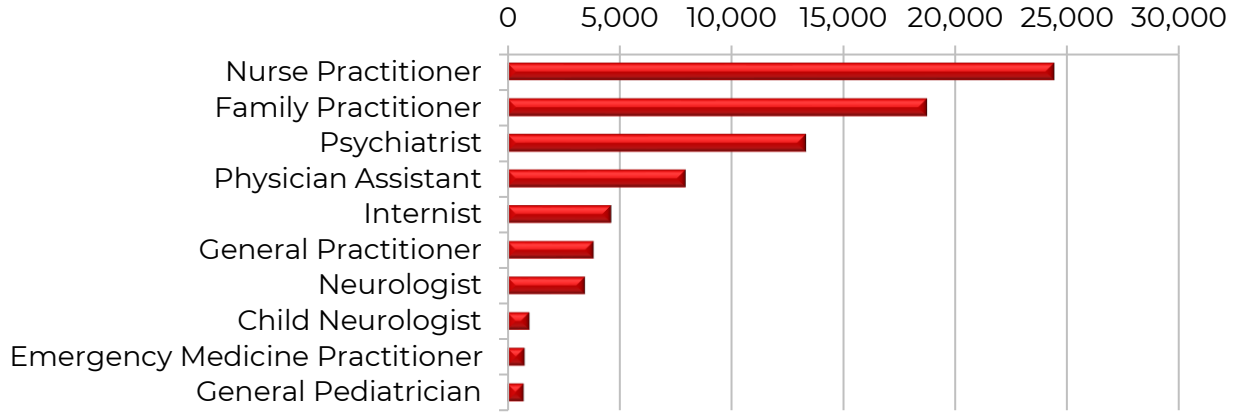
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	15,009	82,301	$1,003,062.37	$12.19	$0.45	4,882,425	2,239,479
2021	14,972	82,759	$1,010,243.06	$12.21	$0.45	4,907,664	2,253,042
% Change	**-0.2%**	**0.6%**	**0.7%**	**0.2%**	**0.0%**	**0.5%**	**0.6%**
Change	**-37**	**458**	**$7,180.69**	**$0.02**	**$0.00**	**25,239**	**13,563**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Demographics of Members Utilizing Benzodiazepine Medications



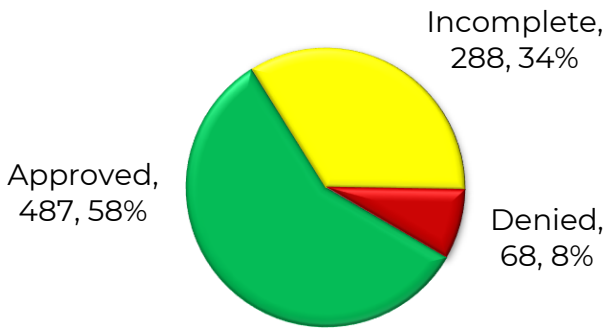
Top Prescriber Specialties of Benzodiazepine Medications by Number of Claims



Prior Authorization of Benzodiazepine Medications

There were 843 prior authorization requests submitted for benzodiazepine medications during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.

Status of Petitions



Recommendations

The College of Pharmacy does not recommend any changes to the current benzodiazepine medications prior authorization criteria at this time.

Utilization Details of Benzodiazepine Medications: Fiscal Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ALPRAZOLAM PRODUCTS						
ALPRAZOLAM TAB 1MG	18,539	2,810	$198,181.28	$10.69	6.6	19.62%
ALPRAZOLAM TAB 0.5MG	8,691	2,012	$91,246.01	$10.50	4.32	9.03%
ALPRAZOLAM TAB 2MG	6,524	924	$80,637.36	$12.36	7.06	7.98%
ALPRAZOLAM TAB 0.25MG	2,487	760	$25,284.57	$10.17	3.27	2.50%
ALPRAZOLAM TAB 2MG ER	166	38	$3,190.96	$19.22	4.37	0.32%
ALPRAZOLAM TAB 1MG ER	108	33	$1,672.72	$15.49	3.27	0.17%
ALPRAZOLAM TAB 2MG XR	87	13	$1,699.96	$19.54	6.69	0.17%
ALPRAZOLAM TAB 0.5MG ER	72	17	$1,038.36	$14.42	4.24	0.10%
ALPRAZOLAM TAB 1MG XR	70	20	$1,029.38	$14.71	3.5	0.10%
ALPRAZOLAM TAB 3MG ER	35	9	$757.79	$21.65	3.89	0.08%
ALPRAZOLAM TAB 3MG XR	24	2	$525.64	$21.90	12	0.05%
ALPRAZOLAM TAB 0.5MG XR	13	8	$187.10	$14.39	1.63	0.02%
SUBTOTAL	**36,816**	**6,646**	**$405,451.13**	**$11.01**	**5.54**	**40.14%**
CLONAZEPAM PRODUCTS						
CLONAZEPAM TAB 1MG	11,663	2,102	$128,032.18	$10.98	5.55	12.67%
CLONAZEPAM TAB 0.5MG	10,498	2,454	$107,635.71	$10.25	4.28	10.65%
CLONAZEPAM TAB 2MG	2,733	453	$30,103.21	$11.01	6.03	2.98%
CLONAZEPAM ODT 0.25MG	1,153	380	$40,940.36	$35.51	3.03	4.05%
CLONAZEPAM ODT 0.5MG	628	219	$23,126.49	$36.83	2.87	2.29%
CLONAZEPAM ODT 0.125MG	612	216	$21,741.40	$35.53	2.83	2.15%
CLONAZEPAM ODT 1MG	341	125	$12,808.19	$37.56	2.73	1.27%
CLONAZEPAM ODT 2MG	61	21	$1,795.18	$29.43	2.9	0.18%
KLONOPIN TAB 2MG	2	1	$498.86	$249.43	2	0.05%
SUBTOTAL	**27,691**	**5,971**	**$366,681.58**	**$13.24**	**4.64**	**36.29%**
DIAZEPAM PRODUCTS						
DIAZEPAM TAB 10MG	4,206	1,088	$42,853.07	$10.19	3.87	4.24%
DIAZEPAM TAB 5MG	4,140	1,372	$41,623.33	$10.05	3.02	4.12%
DIAZEPAM TAB 2MG	907	333	$9,195.38	$10.14	2.72	0.91%
DIAZEPAM SOL 5MG/5ML	240	48	$8,849.28	$36.87	5	0.88%
DIAZEPAM CON 5MG/ML	25	10	$1,182.77	$47.31	2.5	0.12%
DIAZEPAM INJ 5MG/ML	12	1	$2,495.28	$207.94	12	0.25%
SUBTOTAL	**9,530**	**2,852**	**$106,199.11**	**$11.14**	**3.34**	**10.52%**
LORAZEPAM PRODUCTS						
LORAZEPAM TAB 1MG	3,914	1,126	$43,903.87	$11.22	3.48	4.35%
LORAZEPAM TAB 0.5MG	2,982	940	$32,115.34	$10.77	3.17	3.18%
LORAZEPAM TAB 2MG	975	256	$11,253.25	$11.54	3.81	1.11%
LORAZEPAM CON 2MG/ML	94	44	$3,064.20	$32.60	2.14	0.30%
LORAZEPAM INJ 2MG/ML	24	7	$843.04	$35.13	3.43	0.08%
SUBTOTAL	**7,989**	**2,373**	**$91,179.70**	**$11.41**	**3.37**	**9.02%**
CLORAZEPATE PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
CLORAZ DIPOT TAB 3.75MG	141	17	$11,190.57	$79.37	8.29	1.11%
CLORAZ DIPOT TAB 7.5MG	133	18	$12,608.90	$94.80	7.39	1.25%
CLORAZ DIPOT TAB 15MG	74	11	$9,367.64	$126.59	6.73	0.93%
SUBTOTAL	**348**	**46**	**$33,167.11**	**$95.31**	**7.57**	**3.29%**
CHLORDIAZEPOXIDE PRODUCTS						
CHLORDIAZEP CAP 25MG	183	94	$2,243.16	$12.26	1.95	0.22%
CHLORDIAZEP CAP 10MG	112	51	$1,452.77	$12.97	2.2	0.14%
CHLORDIAZEP CAP 5MG	26	16	$350.32	$13.47	1.63	0.03%
SUBTOTAL	**321**	**161**	**$4,046.25**	**$12.61**	**1.99**	**0.39%**
OXAZEPAM PRODUCTS						
OXAZEPAM CAP 10MG	28	8	$1,375.15	$49.11	3.5	0.14%
OXAZEPAM CAP 15MG	19	2	$821.11	$43.22	9.5	0.08%
OXAZEPAM CAP 30MG	17	4	$1,321.92	$77.76	4.25	0.13%
SUBTOTAL	**64**	**14**	**$3,518.18**	**$54.97**	**4.57**	**0.35%**
TOTAL	**82,759**	**14,972***	**$1,010,243.06**	**$12.21**	**5.53**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; CHLORDIAZEP = chlordiazepoxide; CLORAZ DIPOT = clorazepate dipotassium;
CON = concentrate; ER = extended-release; INJ = injection; ODT = orally disintegrating tablet;
SOL = solution; TAB = tablet; XR = extended-release
Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Fiscal Year 2021 Annual Review of Bowel Preparation Medications

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

Clenpiq®, ColPrep™ Kit, OsmoPrep®, Plenvu®, Prepopik®, and SUPREP® Approval Criteria:

1. An FDA approved indication for use in cleansing of the colon as a preparation for colonoscopy; and
2. A patient-specific, clinically significant reason other than convenience why the member cannot use other bowel preparation medications available without prior authorization must be provided; and
3. If the member requires a low volume polyethylene glycol electrolyte lavage solution, Moviprep® is available without prior authorization. Other medications currently available without prior authorization include: Colyte®, Gavilyte®, Golytely®, and Trilyte®.

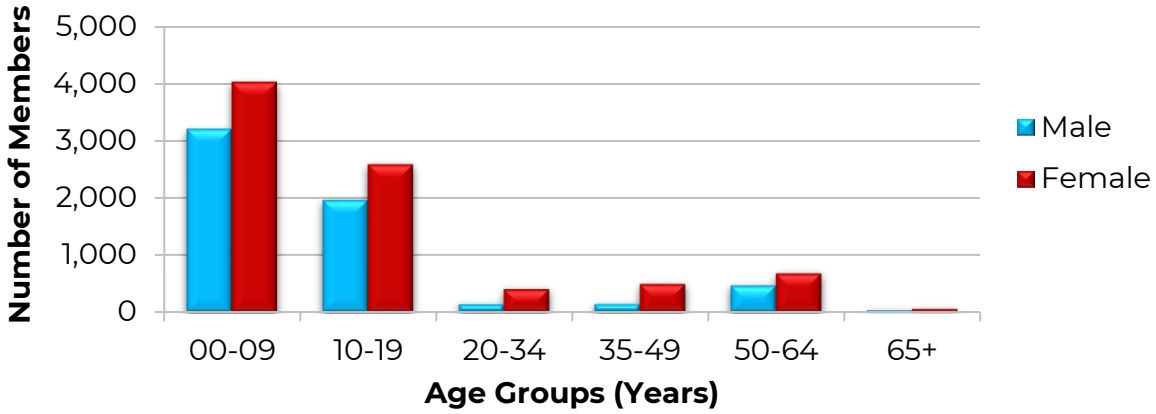
Utilization of Bowel Preparation Medications: Fiscal Year 2021

Comparison of Fiscal Years

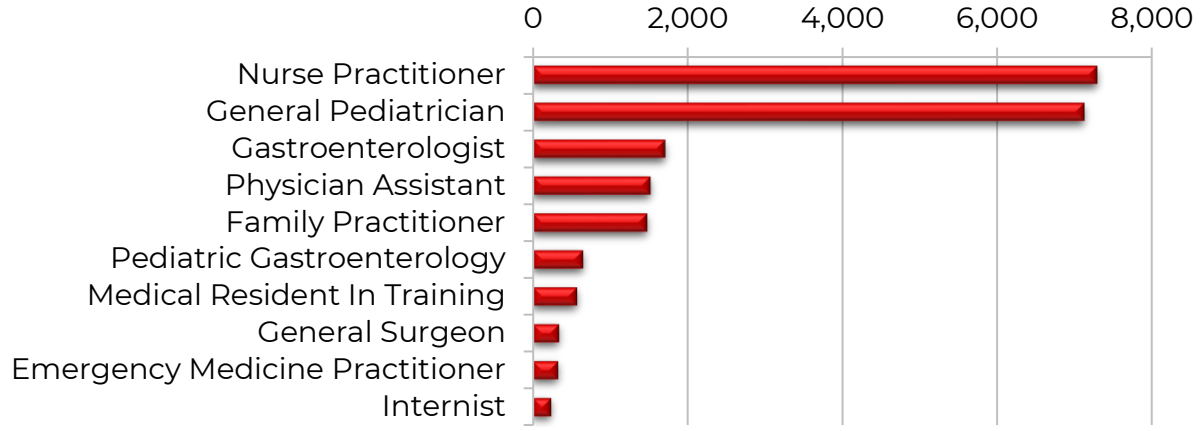
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	14,089	22,514	$435,892.22	$19.36	$0.76	18,245,759	570,512
2021	14,235	22,225	$432,654.01	$19.47	$0.76	17,791,647	570,951
% Change	**1.0%**	**-1.30%**	**-0.70%**	**-0.60%**	**0%**	**-2.50%**	**0.10%**
Change	**146**	**-289**	**-$3,238.21**	**-$0.11**	**$0.00**	**-454,112**	**439**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Demographics of Members Utilizing Bowel Preparation Medications



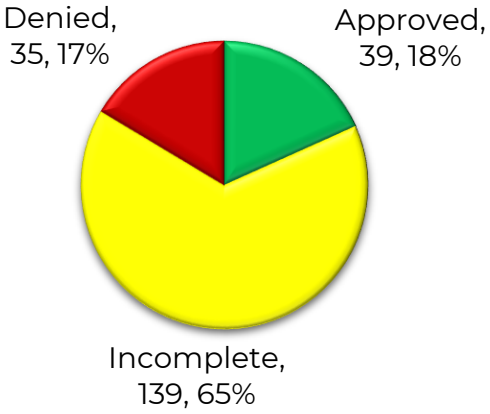
Top Prescriber Specialties of Bowel Preparation Medications by Number of Claims



Prior Authorization of Bowel Preparation Medications

There were 213 prior authorization requests submitted for bowel preparation medications during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[1]

- SUPREP® (sodium sulfate/potassium sulfate/magnesium sulfate): March 2023
- OsmoPrep® (sodium phosphate dibasic/sodium phosphate monobasic): June 2028

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 06/2022. Last accessed 06/27/2022.

- Prepopik® (sodium picosulfate/magnesium oxide/anhydrous citric acid): October 2028
- Plenvu® [polyethylene glycol (PEG) 3350/sodium ascorbate/sodium sulfate/ascorbic acid/sodium chloride/potassium chloride]: September 2033
- Clenpiq® (sodium picosulfate/magnesium oxide/anhydrous citric acid): June 2034
- Sutab® (sodium sulfate/magnesium sulfate/potassium chloride): August 2037

New U.S. Food and Drug Administration (FDA) Approvals:

- **November 2020:** The FDA approved Sutab® (sodium sulfate/ magnesium sulfate/potassium chloride oral tablets) for cleansing of the colon as a preparation for colonoscopy in adults. The approval is supported by 2 randomized, single-blind, active-controlled, multi-center trials in adult patients evaluating successful colon cleansing with Sutab® versus PEG. In the 2 trials, successful colon cleansing was achieved in 92% vs. 89% [99% confidence interval (CI): -3.2, 9.3] and 92% vs. 88% (99% CI: -4.5, 10.7) of patients receiving Sutab®, demonstrating non-inferiority of Sutab® relative to the active comparator product.[2]

Recommendations

The College of Pharmacy does not recommend any changes to the current bowel preparation medications prior authorization criteria at this time.

[2] U.S. FDA. New Drug Application (NDA) Approval of Sutab®. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/213135Orig1s000ltr.pdf. Issued 11/10/2020. Last accessed 06/28/2022.

Utilization Details of Bowel Preparation Medications: Fiscal Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
PEG-3350 POW	16,439	10,087	$275,097.61	$16.73	1.63	63.58%
HM CLEARLAX POW	826	505	$14,407.22	$17.44	1.64	3.33%
PEG-3350 PAK	750	540	$33,585.97	$44.78	1.39	7.76%
PEG-3350/KCL/NACL/NABI SOL	676	643	$11,315.21	$16.74	1.05	2.62%
CLEARLAX POW	629	374	$11,747.96	$18.68	1.68	2.72%
PEG-3350/KCL/NABI/NASUL SOL	592	561	$11,564.50	$19.53	1.06	2.67%
GAVILYTE-G SOL	590	557	$11,481.40	$19.46	1.06	2.65%
GNP CLEARLAX POW	496	381	$9,084.84	$18.32	1.3	2.10%
PEG-3350 POW	415	280	$7,882.08	$18.99	1.48	1.82%
GAVILYTE-C SOL	237	225	$3,978.30	$16.79	1.05	0.92%
PEG-3350/KCL/NACL/NASUL/NAAS/ASAC	196	191	$17,975.64	$91.71	1.03	4.15%
MOVIPREP SOL	144	139	$16,971.70	$117.86	1.04	3.92%
PEG-3350 POW PAK	93	55	$3,902.07	$41.96	1.69	0.90%
GAVILYTE-N SOL FLAV PK	73	72	$1,000.68	$13.71	1.01	0.23%
HEALTHYLAX POW	19	7	$791.63	$41.66	2.71	0.18%
TRILYTE SOL	14	14	$212.10	$15.15	1	0.05%
PEG-3350/KCL/NABI/NASUL SOL	10	9	$180.95	$18.10	1.11	0.04%
SUPREP BOWEL PREP SOL	8	8	$876.59	$109.57	1	0.20%
NATURA-LAX	5	5	$83.77	$16.75	1	0.02%
SM CLEARLAX POW	4	4	$51.43	$12.86	1	0.01%
GNP CLEARLAX PAK	3	2	$89.81	$29.94	1.5	0.02%
GOLYTELY SOL	2	2	$43.94	$21.97	1	0.01%
PLENVU SOL	1	1	$125.64	$125.64	1	0.03%
CLENPIQ SOL	1	1	$158.34	$158.34	1	0.04%
GLYCOLAX POW 3350	1	1	$19.62	$19.62	1	0.00%
GOLYTELY SOL	1	1	$25.01	$25.01	1	0.01%
TOTAL	**22,225**	**14,235***	**$432,654.01**	**$19.47**	**1.56**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
ASAC = ascorbic acid; FLAV PK = flavor pack; KCL = potassium chloride; NAAS = sodium ascorbate; NABI = sodium bicarbonate; NACL = sodium chloride; NASUL = sodium sulfate; PAK = packet; PEG = polyethylene glycol; POLYETH GLYC = polyethylene glycol; POT = potassium; POW = powder; PREP = preparation; SOL = solution
Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Fiscal Year 2021 Annual Review of Butalbital Medications

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

Esgic® Capsule (Butalbital/Acetaminophen/Caffeine 50mg/325mg/40mg) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use Fioricet® tablets (butalbital/acetaminophen/caffeine 50mg/325mg/40mg) must be provided.

Fioricet® with Codeine (Butalbital/Acetaminophen/Caffeine/Codeine 50mg/300mg/40mg/30mg) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot take the 325mg acetaminophen formulation (butalbital/ acetaminophen/caffeine/codeine 50mg/325mg/40mg/30mg), which is available generically, must be provided.

Miscellaneous Butalbital Medications Approval Criteria:

1. An FDA approved indication for the treatment of tension-type headache; and
2. Member must be 12 years of age or older; and
3. Failure within the previous 60 days of the following:
    a. All available formulations of butalbital/acetaminophen medications that do not require prior authorization (medications available without prior authorization contain butalbital/acetaminophen/ caffeine in the standard 50mg/325mg/40mg dose); and
    b. At least 2 nonsteroidal anti-inflammatory drugs (NSAIDs), unless contraindicated.

Vanatol™ LQ (Butalbital/Acetaminophen/Caffeine Oral Solution) Approval Criteria:

1. An FDA approved indication for the treatment of the symptom complex of tension (or muscle contraction) headache; and
2. A patient-specific, clinically significant reason why a liquid formulation is needed in place of the generic tablets, even when the tablets are crushed, must be provided; and
3. Members with other solid dosage formulations in pharmacy claims history will not generally be approved.

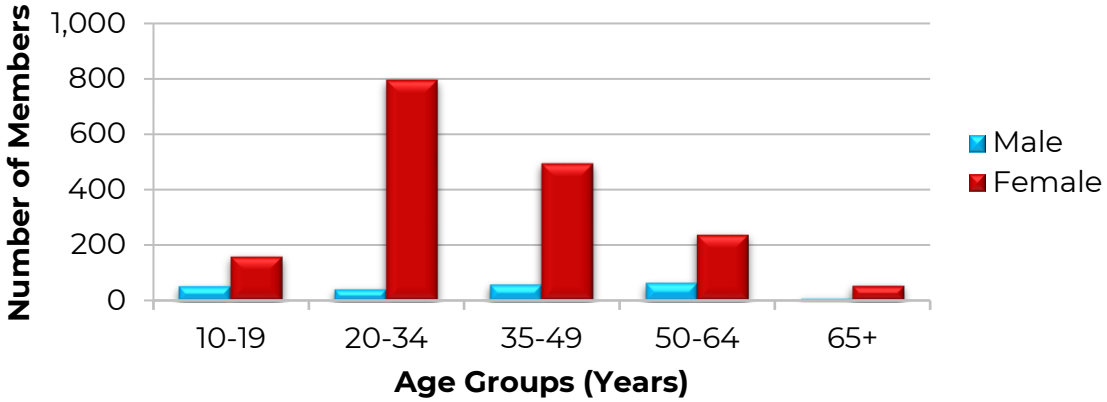
Utilization of Butalbital Medications: Fiscal Year 2021

Comparison of Fiscal Years

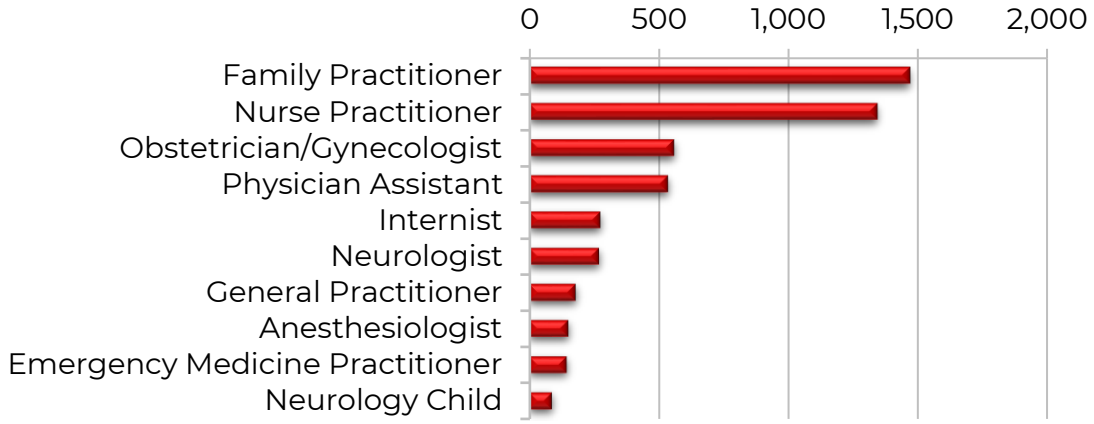
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	2,310	6,180	$155,925.43	$25.23	$1.54	292,875	101,424
2021	1,948	5,383	$126,201.79	$23.44	$1.37	263,124	92,049
% Change	**-15.70%**	**-12.90%**	**-19.10%**	**-7.10%**	**-11.00%**	**-10.20%**	**-9.20%**
Change	**-362**	**-797**	**-$29,723.64**	**-$1.79**	**-$0.17**	**-29,751**	**-9,375**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Demographics of Members Utilizing Butalbital Medications

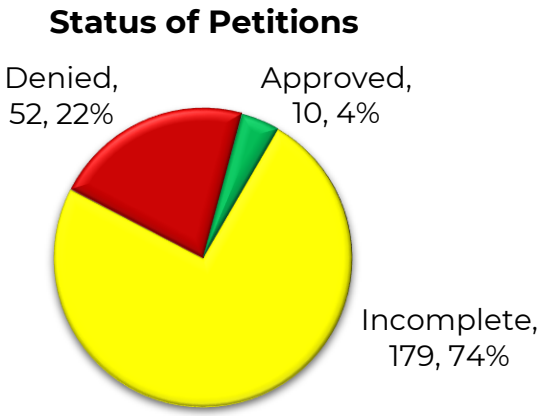


Top Prescriber Specialties of Butalbital Medications by Number of Claims



Prior Authorization of Butalbital Medications

There were 241 prior authorization requests submitted for butalbital medications during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.



Recommendations

The College of Pharmacy does not recommend any changes to the current butalbital medications prior authorization criteria at this time.

Utilization Details of Butalbital Medications: Fiscal Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
BUTALBITAL PRODUCTS						
BUT/APAP/CAF TAB 50/325/40MG	4,589	1,755	$85,420.53	$18.61	2.61	67.69%
BUT/ASA/CAF CAP 50/325/40MG	355	121	$14,121.41	$39.78	2.93	11.19%
BUT/APAP TAB 50/325MG	42	17	$2,365.20	$56.31	2.47	1.87%
BUT/APAP/CAF CAP 50/300/40MG	13	2	$502.20	$38.63	6.5	0.40%
BUT/APAP/CAF CAP 50/325/40MG	7	1	$2,062.00	$294.57	7	1.63%
SUBTOTAL	**5,006**	**1,896**	**$104,471.34**	**$20.87**	**2.64**	**82.78%**
BUTALBITAL/CODEINE PRODUCTS						
BUT/APAP/CAF/COD CAP 50/325/40/30MG	262	85	$13,284.00	$50.70	3.08	10.53%
BUT/ASA/CAF/COD CAP 50/325/40/30MG	66	21	$4,706.10	$71.30	3.14	3.73%
ASCOMP/COD CAP 50/325/40/30MG	49	13	$3,740.35	$76.33	3.77	2.96%
SUBTOTAL	**377**	**119**	**$21,730.45**	**$57.64**	**3.17**	**17.22%**
TOTAL	**5,383**	**1,948***	**$126,201.79**	**$23.44**	**2.76**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
APAP = acetaminophen; ASA = aspirin; BUT = butalbital; CAF = caffeine; CAP = capsule; COD = codeine; TAB = tablet
Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Fiscal Year 2021 Annual Review of Gout Medications

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

Colcrys® (Colchicine Tablet), Gloperba® (Colchicine Oral Solution), and Mitigare® (Colchicine Capsule) Approval Criteria:

1. A quantity of 6 tablets or capsules for a 3-day supply is available without prior authorization for the treatment of acute gouty attacks; and
2. Member must have failure of allopurinol after 6 months of treatment defined by persistent gouty attacks with serum urate levels >6.0mg/dL; and
3. A patient-specific, clinically significant reason why colchicine/ probenecid would not be a viable option for the member must be provided; and
4. For authorization of Gloperba®, a patient-specific, clinically significant reason why the member cannot use colchicine tablets or capsules must be provided; and
5. A quantity limit of 60 tablets or capsules per 30 days or 300mL per 30 days will apply for gout; and
6. Members with the diagnosis of Familial Mediterranean Fever verified by genetic testing will be approved for up to 2.4mg per day.

Krystexxa® (Pegloticase) Approval Criteria:

1. An FDA approved diagnosis of gout; and
2. Member must have symptomatic gout confirmed by at least 1 of the following:
   a. ≥3 gout flares in the previous 18 months; or
   b. ≥1 gout tophus; or
   c. Gouty arthritis; and
3. Member must have failure of the following urate-lowering therapies titrated to the maximum tolerable dose for at least 3 months:
   a. Allopurinol; and
   b. Febuxostat; and
   c. Probenecid; and
4. Pegloticase must be administered in a health care setting by a health care provider prepared to manage anaphylaxis; and
5. Prescriber must attest that the member will be pre-medicated with antihistamines and corticosteroids to reduce the risk of anaphylaxis; and

6. Prescriber must document that the member does not have glucose-6-phosphate dehydrogenase (G6PD) deficiency prior to starting pegloticase; and
7. Member must continue oral urate-lowering agents prior to starting pegloticase; and
8. Member must receive gout flare prophylaxis with nonsteroidal anti-inflammatory drug(s) (NSAIDs) or colchicine at least 1 week before initiation of pegloticase therapy and continue for at least 6 months unless medically contraindicated or member is unable to tolerate therapy; and
9. Approvals will be for the duration of 6 months. Reauthorizations may be granted if the prescriber documents the member is responding well to treatment, and the member has not exceeded >4 consecutive weeks without therapy.

Uloric® (Febuxostat) Approval Criteria:

1. Member must have failure of allopurinol defined by persistent gouty attacks with serum urate levels >6.5mg/dL; and
2. A patient-specific, clinically significant reason why allopurinol is not a viable option for the member must be provided; and
3. A quantity limit of 30 tablets per 30 days will apply.

Utilization of Gout Medications: Fiscal Year 2021

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	1,322	5,602	$138,726.04	$24.76	$0.61	276,293	228,570
2021	1,361	5,601	$104,268.52	$18.62	$0.43	287,361	241,280
% Change	**3.0%**	**0.0%**	**-24.8%**	**-24.8%**	**-29.5%**	**4.0%**	**5.6%**
Change	**39**	**-1**	**-$34,457.52**	**-$6.14**	**-$0.18**	**11,068**	**12,710**

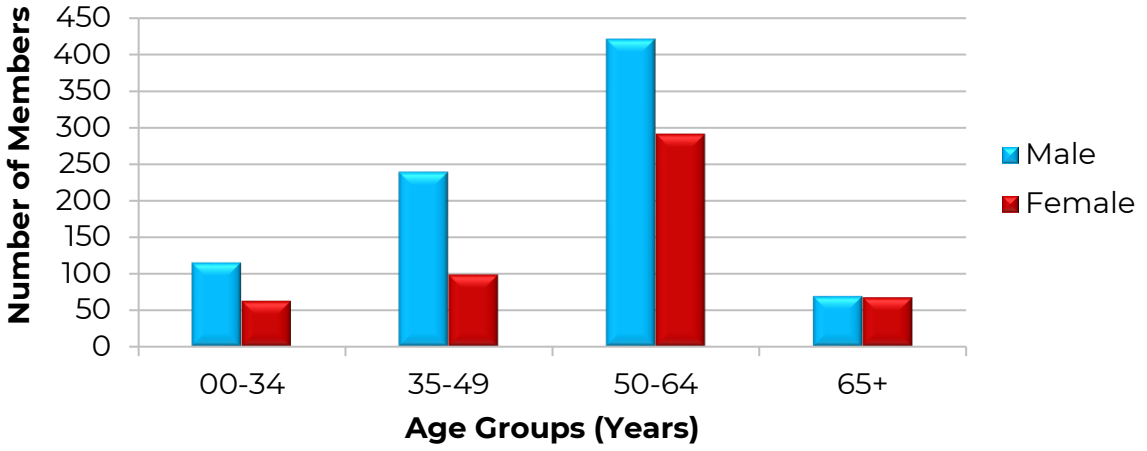
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Fiscal Year 2021 Utilization: Medical Claims

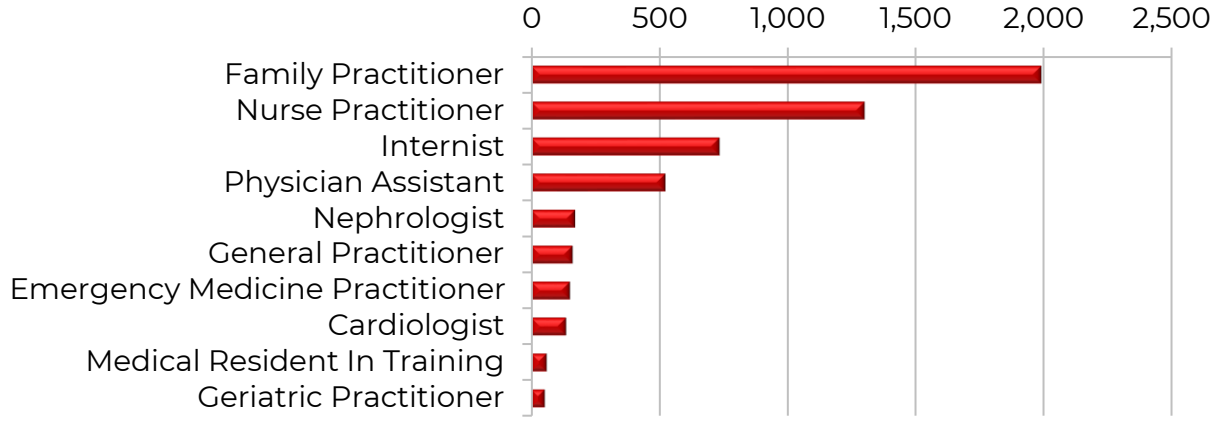
Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2021	3	46	$182,275.87	$3,962.52	15.33

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Demographics of Members Utilizing Gout Medications: Pharmacy Claims

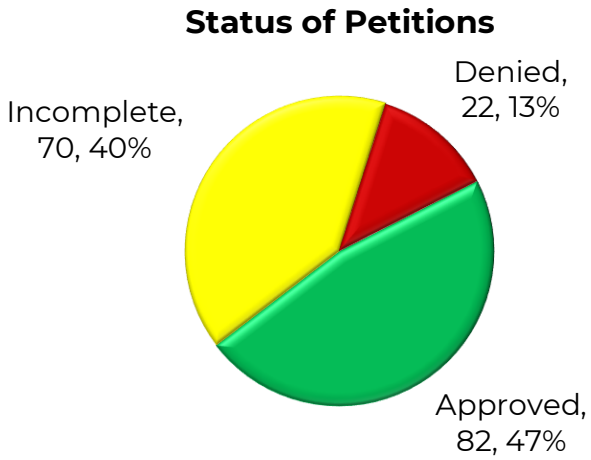


Top Prescriber Specialties of Gout Medications by Number of Claims: Pharmacy Claims



Prior Authorization of Gout Medications

There were 174 prior authorization requests submitted for gout medications during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.



Market News and Updates

Anticipated Patent Expiration(s):[3]

- Colcrys® (colchicine tablet): February 2029
- Uloric® (febuxostat tablet): September 2031
- Mitigare® (colchicine capsule): August 2033
- Gloperba® (colchicine oral solution): December 2037

Pipeline:

- **SEL-212:** The DISSOLVE 1 trial, 1 of 2 Phase 3, double-blind, placebo-controlled trials evaluating SEL-212 for the treatment of chronic refractory gout, has completed enrollment. SEL-212 consists of pegadricase that is co-administered with ImmTOR™, which is designed to mitigate the formation of anti-drug antibodies. SEL-212 will potentially be a new, once-monthly treatment option and is being studied at 2 doses of ImmTOR™ (0.1mg/kg and 0.15mg/kg) and 1 dose of pegadricase (0.2mg/kg) in both trials. The primary endpoint in both Phase 3 trials is serum uric acid levels at 6 months.[4]

Recommendations

The College of Pharmacy does not recommend any changes to the current gout medications prior authorization criteria at this time.

---

[3] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 05/2022. Last accessed 05/05/2022.

[4] Selecta Biosciences. Selecta Biosciences and Sobi Announce Completion of Enrollment in DISSOLVE Phase 3 Study Evaluating SEL-212 for Chronic Refractory Gout. Available online at: https://ir.selectabio.com/news-releases/news-release-details/selecta-biosciences-and-sobi-announce-completion-enrollment. Issued 12/01/2021. Last accessed 05/18/2022.

Utilization Details of Gout Medications: Fiscal Year 2021

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
ALLOPURINOL PRODUCTS						
ALLOPURINOL TAB 100MG	2,480	680	$31,878.31	$0.27	$13.63	30.57%
ALLOPURINOL TAB 300MG	2,124	562	$30,880.58	$0.28	$14.54	29.62%
SUBTOTAL	**4,604**	**1,242**	**$62,758.89**	**$0.28**	**$13.63**	**60.19%**
COLCHICINE PRODUCTS						
COLCHICINE TAB 0.6MG	553	195	$12,712.23	$2.93	$22.99	12.19%
COLCHICINE CAP 0.6MG	100	37	$3,108.63	$7.83	$31.09	2.98%
SUBTOTAL	**653**	**232**	**$15,820.86**	**$3.34**	**$24.23**	**15.17%**
FEBUXOSTAT PRODUCTS						
FEBUXOSTAT TAB 40MG	135	20	$7,405.79	$1.93	$54.86	7.10%
FEBUXOSTAT TAB 80MG	101	13	$6,518.85	$2.15	$64.54	6.25%
ULORIC TAB 40MG	14	3	$4,599.29	$10.95	$328.52	4.41%
ULORIC TAB 80MG	11	1	$3,561.45	$10.79	$323.77	3.42%
SUBTOTAL	**261**	**37**	**$22,085.38**	**$2.90**	**$84.62**	**21.18%**
PROBENECID PRODUCTS						
PROBENECID TAB 500MG	42	11	$1,577.50	$1.02	$37.56	1.51%
SUBTOTAL	**42**	**11**	**$1,577.50**	**$1.02**	**$37.56**	**1.51%**
PROBENECID/COLCHICINE PRODUCTS						
PROBEN/COLCH TAB 500-0.5MG	41	13	$2,025.89	$1.49	$49.41	1.94%
SUBTOTAL	**41**	**13**	**$2,025.89**	**$1.49**	**$49.41**	**1.94%**
TOTAL	**5,601**	**1,361***	**$104,268.52**	**$0.43**	**$18.62**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; COLCH = colchicine; PROBEN = probenecid; TAB = tablet
Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
PEGLOTICASE PRODUCTS					
KRYSTEXXA 1MG (J2507)	46	3	$182,275.87	15.33	$3,962.52
TOTAL	**46⁺**	**3***	**$182,275.87**	**15.33**	**$3,962.52**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
⁺Total number of unduplicated claims.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Fiscal Year 2021 Annual Review of Idiopathic Pulmonary Fibrosis (IPF) Medications

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

Esbriet® (Pirfenidone) Approval Criteria:

1. An FDA approved diagnosis of idiopathic pulmonary fibrosis (IPF); and
2. Member must be 18 years of age or older; and
3. Prescriber must verify liver function tests (LFTs) (e.g., ALT, AST, bilirubin) will be monitored prior to the initiation of Esbriet®, monthly for the first 6 months of treatment, and every 3 months thereafter and as clinically indicated; and
4. Medication must be prescribed by, or in consultation with, a pulmonologist or pulmonary specialist (or an advanced care practitioner with a supervising physician who is a pulmonologist or pulmonary specialist); and
5. A quantity limit of 270 capsules or tablets per 30 days will apply for the 267mg strength capsules and tablets, and a quantity limit of 90 tablets per 30 days will apply for the 801mg strength tablets.

Ofev® (Nintedanib) Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. Treatment of idiopathic pulmonary fibrosis (IPF); or
   b. Treatment of chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype; or
   c. To slow the rate of decline in pulmonary function in members with systemic sclerosis-associated interstitial lung disease (SSc-ILD); and
2. Member must be 18 years of age or older; and
3. Prescriber must verify liver function tests (LFTs) (e.g., ALT, AST, bilirubin) will be monitored prior to initiation of Ofev® treatment, at regular intervals during the first 3 months of treatment, and periodically thereafter or as clinically indicated; and
4. Female members must not be pregnant and must have a negative pregnancy test immediately prior to therapy initiation. Female members of reproductive potential must be willing to use effective contraception while on therapy and for at least 3 months after therapy completion; and
5. Medication must be prescribed by, or in consultation with, a pulmonologist or pulmonary specialist (or an advanced care practitioner with a supervising physician who is a pulmonologist or pulmonary specialist); and

6. A quantity limit of 60 capsules per 30 days will apply.

Utilization of IPF Medications: Fiscal Year 2021

Comparison of Fiscal Years

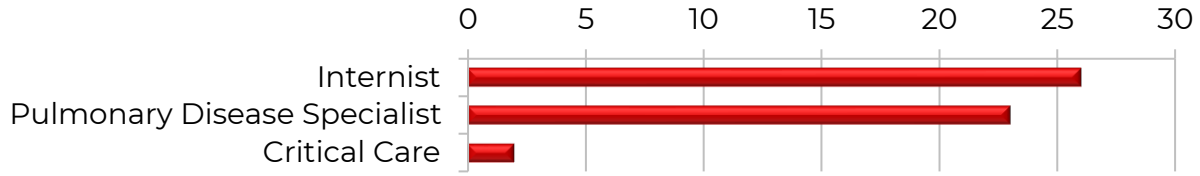
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	8	45	$390,086.57	$8,668.59	$276.66	5,547	1,410
2021	8	51	$501,215.09	$9,827.75	$327.59	4,500	1,530
% Change	**0.00%**	**13.3%**	**28.5%**	**13.4%**	**18.4%**	**-18.9%**	**8.5%**
Change	**0**	**6**	**$111,128.52**	**$1,159.16**	**$50.93**	**-1,047**	**120**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Demographics of Members Utilizing IPF Medications

- All members utilizing IPF medications during fiscal year 2021 were adults; however, detailed demographic information cannot be provided due to the limited number of members using IPF medications during fiscal year 2021.

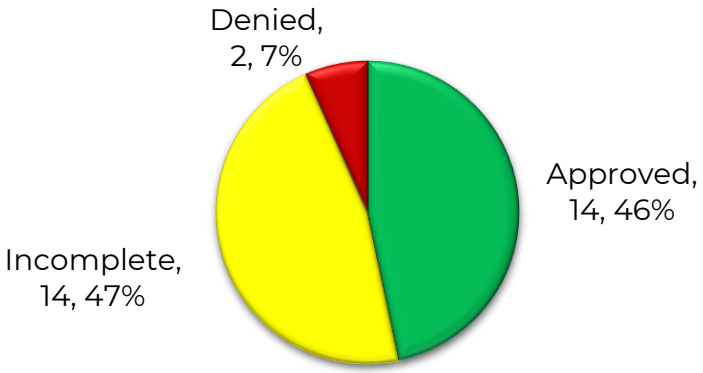
Top Prescriber Specialties of IPF Medications by Number of Claims



Prior Authorization of IPF Medications

There were 30 prior authorization requests submitted for IPF medications during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[5]

- Ofev® (nintedanib): June 2029
- Esbriet® (pirfenidone): March 2037

Pipeline:

- **Pamrevlumab:** Pamrevlumab is a first-in-class antibody developed by FibroGen to inhibit the activity of connective tissue growth factor (CTGF), a common factor in fibrotic and proliferative disorders characterized by persistent and excessive scarring that can lead to organ dysfunction and failure. FibroGen announced that ZEPHYRUS-1, the first of 2 Phase 3 trials, has completed enrollment. The ZEPHYRUS-2 trial is still currently enrolling. The 2 trials will be randomized, double-blind, placebo-controlled trials to evaluate the safety and efficacy of pamrevlumab in patients with IPF. The primary endpoint of both trials will be the change from baseline in forced vital capacity (FVC). Data from ZEPHRYUS-1 is anticipated in mid-2023.[6,7]
- **PRM-151:** PRM-151 is recombinant human pentraxin-2 (rhPTX-2), a novel antifibrotic agent with activity on monocyte differentiation, being studied for the treatment of IPF as monotherapy or as add-on therapy to nintedanib or pirfenidone. The current Phase 3 trial will evaluate the efficacy, safety, and pharmacokinetics (PK) of PRM-151 compared with placebo in patients with IPF. The trial will include patients on stable doses of nintedanib or pirfenidone and those not currently receiving either therapy. The primary endpoint will be an absolute change from baseline in FVC at week 52.[6,3]

Recommendations

The College of Pharmacy does not recommend any changes to the current IPF medications prior authorization criteria at this time.

---

[5] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 05/2022. Last accessed 05/20/2022.

[6] Pulmonary Fibrosis Foundation. Drug Development Pipeline – PF and IPF. Available online at: https://www.pulmonaryfibrosis.org/patients-caregivers/medical-and-support-resources/clinical-trials-education-center/pipeline. Last revised 01/2022. Last accessed 05/20/2022.

[7] FibroGen. FibroGen Announces Completion of Patient Enrollment in ZEPHYRUS-1, a Phase 3 Clinical Study of Pamrevlumab in Idiopathic Pulmonary Fibrosis. Available online at: https://fibrogen.gcs-web.com/news-releases/news-release-details/fibrogen-announces-completion-patient-enrollment-zephyrus-1. Issued 04/20/2022. Last accessed 05/20/2022.

Utilization Details of IPF Medications: Fiscal Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
NINTEDANIB PRODUCTS						
OFEV CAP 150MG	27	6	$292,097.36	$10,818.42	4.5	58.28%
OFEV CAP 100MG	12	1	$129,048.63	$10,754.05	12	25.75%
SUBTOTAL	**39**	**7**	**$421,145.99**	**$10,798.62**	**5.57**	**84.03%**
PIRFENIDONE PRODUCTS						
ESBRIET TAB 267MG	12	1	$80,069.10	$6,672.43	12	15.97%
SUBTOTAL	**12**	**1**	**$80,069.10**	**$6,672.43**	**12**	**15.97%**
TOTAL	**51**	**8***	**$501,215.09**	**$9,827.75**	**6.38**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; TAB = tablet
Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Fiscal Year 2021 Annual Review of Leukotriene Modulators

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

Singulair® (Montelukast) Approval Criteria:

1. Montelukast tablets and chewable tablets are available without prior authorization.
2. A prior authorization is required for the granule formulation of montelukast:
    a. Use of the granule formulation requires a patient-specific, clinically significant reason why the member cannot use montelukast tablets or chewable tablets.

Zyflo CR® (Zileuton) Approval Criteria:

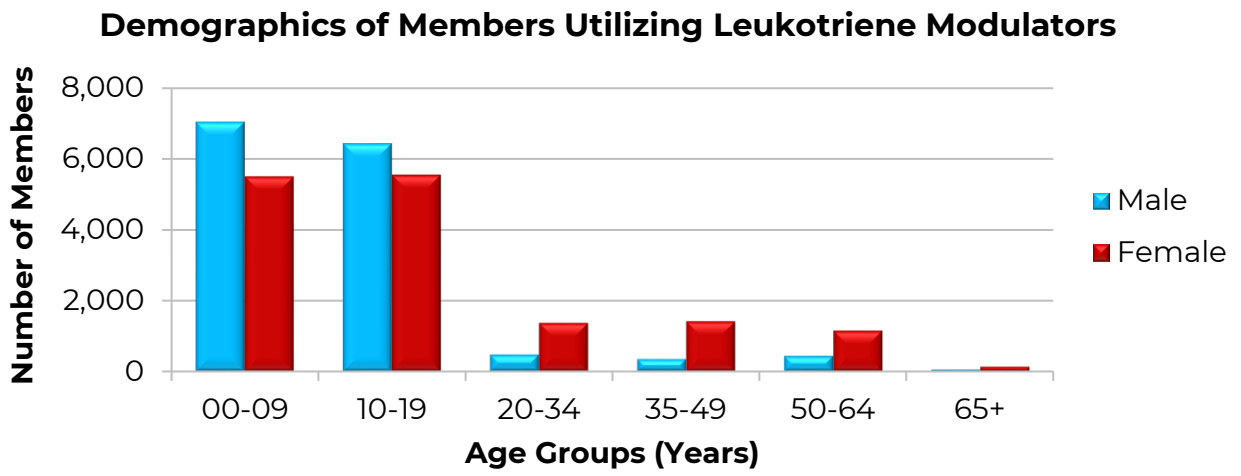
1. An FDA approved diagnosis of mild or moderate persistent asthma; and
2. Member must be 12 years of age or older; and
3. Member must meet the following trial requirements:
    a. A trial of an inhaled corticosteroid (ICS) and ICS/long-acting beta$_2$ agonist (LABA) therapy within the previous 6 months and the reason for trial failure must be provided; and
    b. A recent trial with at least 1 other available leukotriene modifier that did not yield adequate response.

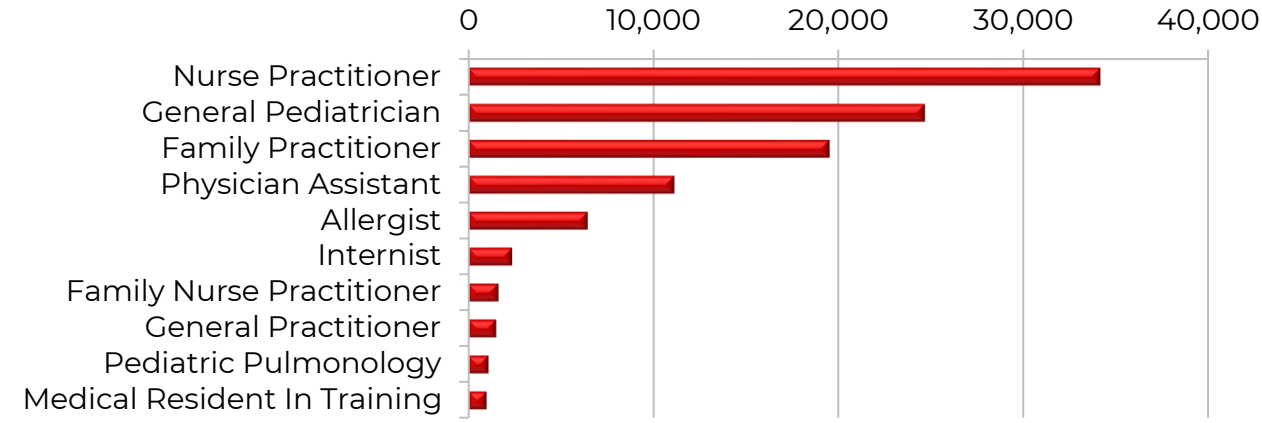
Utilization of Leukotriene Modulators: Fiscal Year 2021

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	37,563	140,818	$2,081,770.89	$14.78	$0.48	4,293,895	4,301,285
2021	29,843	106,969	$1,531,190.54	$14.31	$0.42	3,643,502	3,648,363
% Change	**-20.6%**	**-24.0%**	**-26.4%**	**-3.2%**	**-12.5%**	**-15.1%**	**-15.2%**
Change	**-7,720**	**-33,849**	**-$550,580.35**	**-$0.47**	**-$0.06**	**-650,393**	**-652,922**

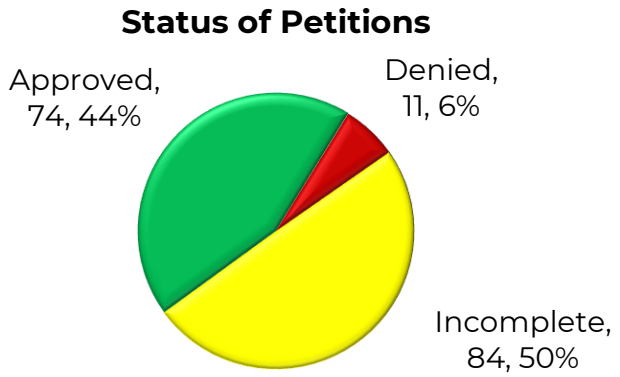
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021





Prior Authorization of Leukotriene Modulators

There were 169 prior authorization requests submitted for leukotriene modulators during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.



Recommendations

The College of Pharmacy does not recommend any changes to the current leukotriene modulators prior authorization criteria at this time.

Utilization Details of Leukotriene Modulators: Fiscal Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
MONTELUKAST PRODUCTS						
MONTELUKAST TAB 10MG	42,645	11,283	$495,982.54	$11.63	3.78	32.39%
MONTELUKAST CHW 5MG	37,994	11,108	$555,296.27	$14.62	3.42	36.27%
MONTELUKAST CHW 4MG	24,375	7,718	$364,000.56	$14.93	3.16	23.77%
MONTELUKAST GRA 4MG	1,951	891	$114,952.33	$58.92	2.19	7.51%
SINGULAIR CHW 5MG	4	1	$958.84	$239.71	4	0.06%
TOTAL	**106,969**	**29,843***	**$1,531,190.54**	**$14.31**	**3.58**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CHW = chewable; GRA = granule; TAB = tablet
Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Fiscal Year 2021 Annual Review of Mozobil® (Plerixafor)

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

Mozobil® (Plerixafor) Approval Criteria:

1. An FDA approved indication for use in combination with a granulocyte-colony stimulating factor (G-CSF) to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in members with non-Hodgkin's lymphoma (NHL) or multiple myeloma (MM); and
2. Member must have an oncology diagnosis of NHL or MM. This medication is not covered for the diagnosis of leukemia; and
3. Mozobil® must be prescribed by an oncologist; and
4. Member must be 18 years of age or older; and
5. Mozobil® must be used in combination with the G-CSF filgrastim; and
6. The following dosing restrictions will apply (current body weight in kilograms is required):
    a. Recommended dose is 0.24mg/kg (maximum dose is 40mg/day) administered 11 hours prior to apheresis for up to 4 consecutive days; or
    b. For members with renal impairment (creatinine clearance ≤50mL/min), the recommended dose is 0.16mg/kg (maximum dose is 27mg/day); and
7. Approvals will be for the duration of 2 months.

Utilization of Mozobil® (Plerixafor): Fiscal Year 2021

Fiscal Year 2021 Utilization: Medical Claims

Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2020	2	3	$33,383.04	$11,127.68	1.5
2021	3	4	$10,654.40	$2,663.60	1.33
% Change	**50%**	**33.33%**	**-68.08%**	**-73.06%**	**-11.33%**
Change	**1**	**1**	**-$22,728.64**	**-$8,464.08**	**-0.17**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Demographics of Members Utilizing Mozobil® (Plerixafor)

- Due to the limited number of members utilizing Mozobil® (plerixafor), detailed demographic information could not be provided.

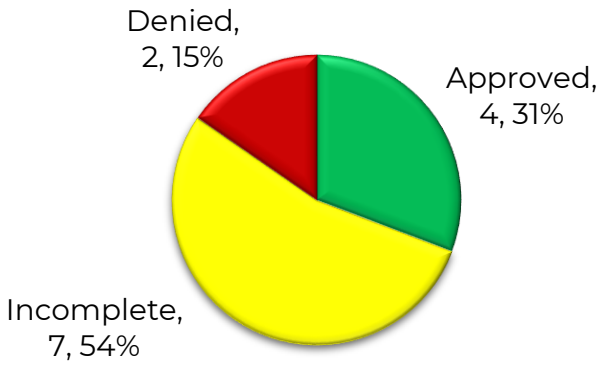
Top Prescriber Specialties of Mozobil® (Plerixafor) by Number of Claims

- The only prescriber specialty listed on approved prior authorization requests for Mozobil® (plerixafor) during fiscal year 2021 was hematologist oncologist.

Prior Authorization of Mozobil® (Plerixafor)

There were 13 prior authorization requests submitted for Mozobil® (plerixafor) during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.

Status of Petitions



Recommendations

The College of Pharmacy does not recommend any changes to the current Mozobil® (plerixafor) prior authorization criteria at this time.

Utilization Details of Mozobil® (Plerixafor): Fiscal Year 2021

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
MOZOBIL J2562	4	3	$10,654.40	$2,663.60	1.33
TOTAL	**4⁺**	**3***	**$10,654.40**	**$2,663.60**	**1.33**

Costs do not reflect rebated prices or net costs.
⁺Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Fiscal Year 2021 Annual Review of Muscle Relaxant Medications

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

Muscle Relaxant Medications*		
Tier-1	**Tier-2**	**Special PA**
baclofen 10mg, 20mg (Lioresal®)	metaxalone (Skelaxin®)	baclofen 5mg (Lioresal®)
chlorzoxazone (Parafon Forte®)		baclofen 5mg/5mL oral soln (Ozobax®)
cyclobenzaprine (Flexeril®)		carisoprodol 250mg (Soma®)
methocarbamol (Robaxin®)		carisoprodol 350mg (Soma®)
orphenadrine (Norflex®)		carisoprodol/ASA
tizanidine tabs (Zanaflex®)		carisoprodol/ASA/codeine
		chlorzoxazone tabs (Lorzone®)
		cyclobenzaprine 7.5mg tabs (Fexmid®)
		cyclobenzaprine ER caps (Amrix®)
		tizanidine caps (Zanaflex®)

* Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
ASA = aspirin; caps = capsules; ER = extended-release; PA = prior authorization; soln = solution; tabs = tablets

Muscle Relaxant Medications Tier-2 Approval Criteria:

1. Member must have failure with at least 2 Tier-1 medications within the past 90 days defined as no beneficial response after at least 2 weeks of use during which time the drug has been titrated to the recommended dose; and
2. Approvals will be for the duration of 3 months, except for members with chronic diseases such as multiple sclerosis, cerebral palsy, muscular dystrophy, paralysis, or other chronic musculoskeletal diagnosis confirmed with diagnostic results, in which case authorizations will be for the duration of 1 year; and
3. For repeat authorizations, there must be documentation of a failed withdrawal attempt within the past 3 months defined as increase in pain and debilitating symptoms when medication was discontinued.

Amrix® [Cyclobenzaprine Extended-Release (ER) Capsule] and Fexmid® (Cyclobenzaprine 7.5mg Tablet) Approval Criteria:

1. Authorization requires clinical documentation of inability to take other generically available forms of cyclobenzaprine tablets; and
2. The following quantity limits apply:
    a. Amrix® 15mg and 30mg ER capsules: 30 capsules per 30 days; or
    b. Fexmid® 7.5mg tablets: 90 tablets per 30 days.

Baclofen 5mg Tablets Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use other appropriate Tier-1 products, including splitting a baclofen 10mg tablet to achieve a 5mg dose, must be provided.

Baclofen 5mg/5mL Oral Solution (Generic Ozobax®) Approval Criteria:

1. An FDA approved diagnosis of spasticity resulting from multiple sclerosis (relief of flexor spasms and concomitant pain, clonus, and muscular rigidity) or spinal cord injuries/diseases; and
2. Members older than 10 years of age require a patient-specific, clinically significant reason why the member cannot use baclofen oral tablets, even when tablets are crushed.

Lorzone® (Chlorzoxazone) Approval Criteria:

1. Generic chlorzoxazone 500mg tablets must be tried prior to consideration of Lorzone®; and
2. A patient-specific, clinically significant reason why the member cannot use generic chlorzoxazone 500mg tablets must be provided; and
3. The following quantity limits apply:
    a. Lorzone® 375mg tablets: 120 tablets per 30 days; or
    b. Lorzone® 750mg tablets: 120 tablets per 30 days.

Soma® (Carisoprodol 250mg) Approval Criteria:

1. Authorization requires detailed documentation regarding member's inability to use other skeletal muscle relaxants including carisoprodol 350mg, and patient-specific reason(s) why member cannot be drowsy for even a short time period must be provided. Member must not have other sedating medications in current claims history; and
2. For a diagnosis of acute musculoskeletal pain, the approval will be for the duration of 14 days per 365-day period. Conditions requiring chronic use will not be approved.

Soma® (Carisoprodol 350mg) or Soma® (Carisoprodol 350mg) Combination Product(s) Approval Criteria:

1. Members may receive 90 days of carisoprodol 350mg per rolling 365 days without prior authorization; and

2. After the member has received the 90 days' supply, an additional approval for 1 month may be granted to allow titration or change to a Tier-1 muscle relaxant. This additional 1-month approval will be granted 1 time only. Further authorizations will not be granted; or
3. Clinical exceptions may be made for members with 1 of the following diagnoses and approvals will be granted for the duration of 1 year: multiple sclerosis, cerebral palsy, muscular dystrophy, paralysis, or cancer pain; and
4. A quantity limit of 120 tablets per 30 days will apply for carisoprodol and carisoprodol combination products.

Zanaflex® (Tizanidine Capsule) Approval Criteria:

1. Tizanidine tablets must be tried prior to consideration of tizanidine capsules; and
2. The capsule formulation may be considered for approval only if there is supporting information as to why the member cannot take the tablets.

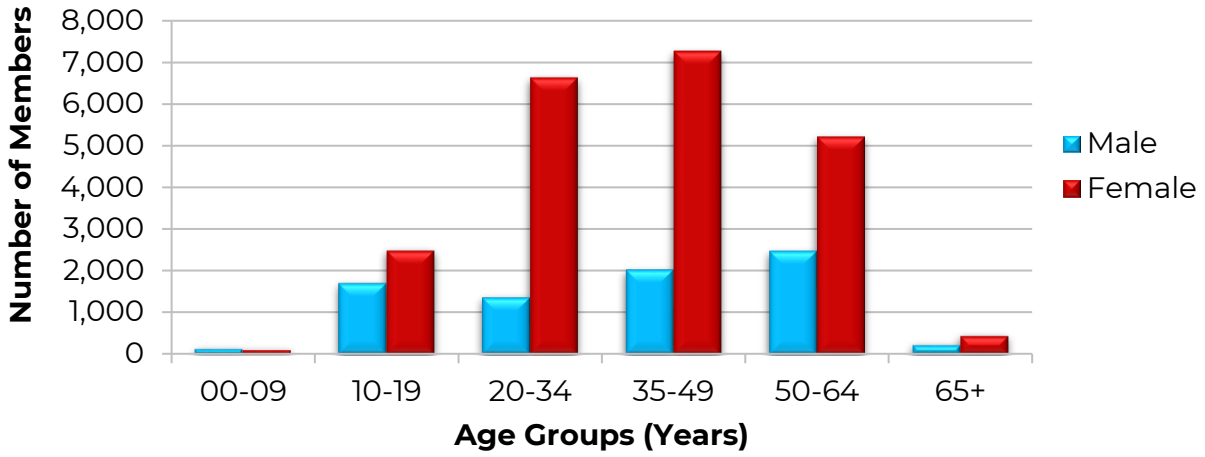
Utilization of Muscle Relaxant Medications: Fiscal Year 2021

Comparison of Fiscal Years

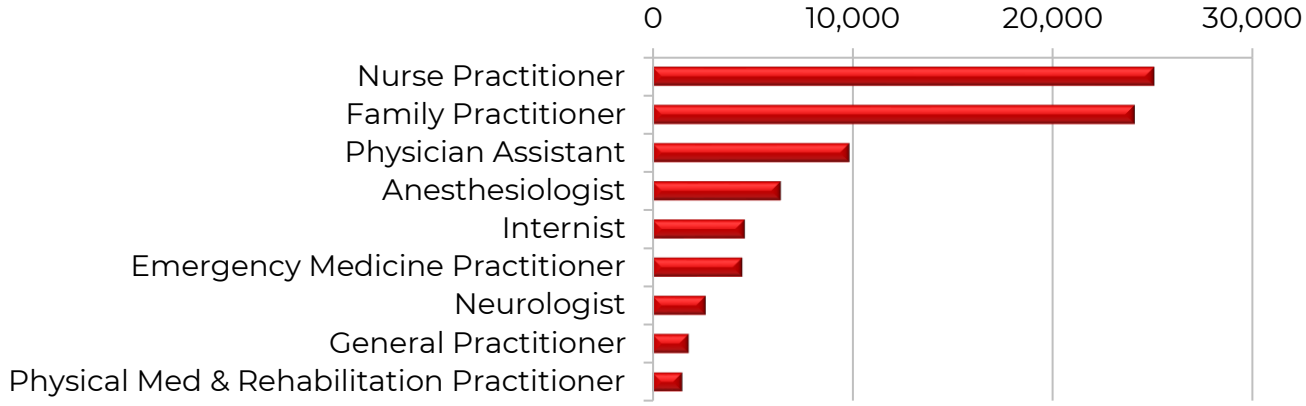
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	27,551	85,998	$1,220,538.11	$14.19	$0.56	5,796,873	2,161,380
2021	29,982	91,472	$1,215,594.62	$13.29	$0.53	6,040,738	2,278,491
% Change	**8.8%**	**6.4%**	**-0.4%**	**-6.3%**	**-5.4%**	**4.2%**	**5.4%**
Change	**2,431**	**5,474**	**-$4,943.49**	**-$0.90**	**-$0.03**	**243,865**	**117,111**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Demographics of Members Utilizing Muscle Relaxant Medications



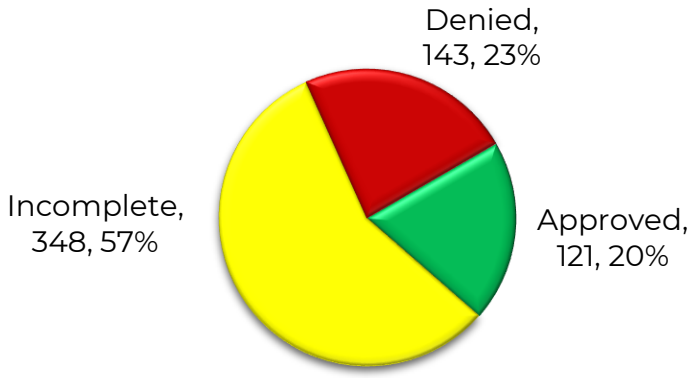
Top Prescriber Specialties of Muscle Relaxant Medications by Number of Claims



Prior Authorization of Muscle Relaxant Medications

There were 612 prior authorization requests submitted for muscle relaxant medications during fiscal year 2021. Computer edits are in place to detect lower tiered medications in a member's recent claims history and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions for fiscal year 2021.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[8]

- Amrix® [cyclobenzaprine extended-release (ER) capsule]: February 2025
- Skelaxin® (metaxalone tablet): February 2026

[8] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 06/2022. Last accessed 06/16/2022.

Recommendations

The College of Pharmacy does not recommend any changes to the muscle relaxant medications Product Based Prior Authorization (PBPA) category at this time.

Utilization Details of Muscle Relaxant Medications: Fiscal Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 UTILIZATION						
CYCLOBENZAPRINE PRODUCTS						
CYCLOBENZAPRINE TAB 10MG	28,109	12,133	$284,742.29	$10.13	2.32	23.42%
CYCLOBENZAPRINE TAB 5MG	7,347	4,245	$77,487.54	$10.55	1.73	6.37%
SUBTOTAL	**35,456**	**16,378**	**$362,229.83**	**$10.22**	**2.16**	**29.79%**
TIZANIDINE PRODUCTS						
TIZANIDINE TAB 4MG	22,692	6,807	$277,059.61	$12.21	3.33	22.79%
TIZANIDINE TAB 2MG	3,290	1,381	$44,354.36	$13.48	2.38	3.65%
SUBTOTAL	**25,982**	**8,188**	**$321,413.97**	**$12.37**	**3.17**	**26.44%**
BACLOFEN PRODUCTS						
BACLOFEN TAB 10MG	12,570	3,352	$188,912.16	$15.03	3.75	15.54%
BACLOFEN TAB 20MG	5,488	1,042	$116,195.65	$21.17	5.27	9.56%
LIORESAL INT INJ 40MG/20ML	12	2	$19,953.36	$1,662.78	6	1.64%
SUBTOTAL	**18,070**	**4,396**	**$325,061.17**	**$17.99**	**4.11**	**26.74%**
METHOCARBAMOL PRODUCTS						
METHOCARBAMOL TAB 750MG	4,322	1,878	$64,334.66	$14.89	2.3	5.29%
METHOCARBAMOL TAB 500MG	3,947	2,187	$54,047.70	$13.69	1.8	4.45%
METHOCARBAMOL INJ 1000MG	1	1	$907.41	$907.41	1	0.07%
SUBTOTAL	**8,270**	**4,066**	**$119,289.77**	**$14.42**	**2.03**	**9.81%**
ORPHENADRINE PRODUCTS						
ORPHENADRINE TAB 100MG ER	1,972	1,391	$40,976.24	$20.78	1.42	3.37%
SUBTOTAL	**1,972**	**1,391**	**$40,976.24**	**$20.78**	**1.42**	**3.37%**
CHLORZOXAZONE PRODUCTS						
CHLORZOXAZONE TAB 500MG	805	243	$19,395.57	$24.09	3.31	1.60%
SUBTOTAL	**805**	**243**	**$19,395.57**	**$24.09**	**3.31**	**1.60%**
TIER-1 SUBTOTAL	**90,555**	**34,662**	**$1,188,366.55**	**$13.12**	**2.61**	**97.75%**
TIER-2 UTILIZATION						
METAXALONE PRODUCTS						
METAXALONE TAB 800MG	201	63	$11,855.15	$58.98	3.19	0.98%
METAXALONE TAB 400MG	10	3	$3,045.02	$304.50	3.33	0.25%
SUBTOTAL	**211**	**66**	**$14,900.17**	**$70.62**	**3.20**	**1.23%**
TIER-2 SUBTOTAL	**211**	**66**	**$14,900.17**	**$70.62**	**3.20**	**1.23%**
SPECIAL PA UTILIZATION						
CARISOPRODOL PRODUCTS						
CARISOPRODOL TAB 350MG	637	306	$8,008.42	$12.57	2.08	0.66%
SUBTOTAL	**637**	**306**	**$8,008.42**	**$12.57**	**2.08**	**0.66%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
BACLOFEN PRODUCTS						
BACLOFEN TAB 5MG	67	18	$4,254.27	$63.50	3.72	0.35%
SUBTOTAL	**67**	**18**	**$4,254.27**	**$63.50**	**3.72**	**0.35%**
TIZANIDINE PRODUCTS						
TIZANIDINE CAP 2MG	2	1	$65.21	$32.61	2	0.01%
SUBTOTAL	**2**	**1**	**$65.21**	**$32.61**	**2**	**0.01%**
SPECIAL PA SUBTOTAL	**706**	**325**	**$12,327.90**	**$17.46**	**2.17**	**1.02%**
TOTAL	**91,472**	**29,982***	**$1,215,594.62**	**$13.29**	**3.05**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; ER = extended-release; INJ = injection; INT = intrathecal; PA = prior authorization; TAB = tablet
Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Fiscal Year 2021 Annual Review of Naloxone Medications

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

Naloxone injection and nasal spray are currently covered without prior authorization.

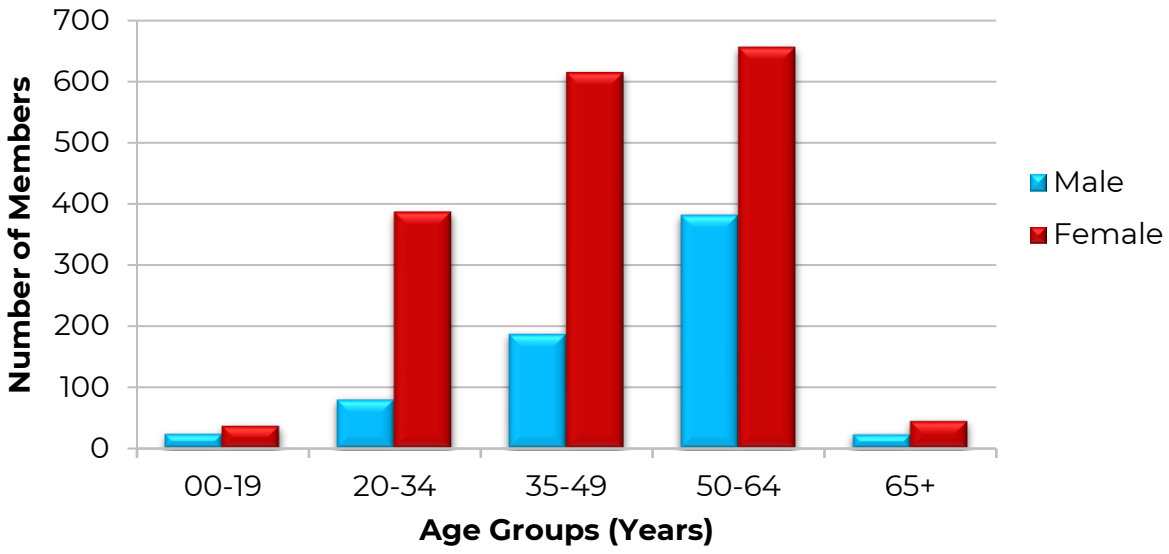
Utilization of Naloxone Medications: Fiscal Year 2021

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	1,925	2,008	$260,359.68	$129.66	$4.27	4,026	60,998
2021	2,436	2,615	$339,108.83	$129.68	$4.28	5,237	79,264
% Change	**26.5%**	**30.2%**	**30.2%**	**0.0%**	**0.2%**	**30.1%**	**29.9%**
Change	**511**	**607**	**$78,749.15**	**$0.02**	**$0.01**	**1,211**	**18,266**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Demographics of Members Utilizing Naloxone Medications



Top Prescriber Specialties of Naloxone Medications by Number of Claims

Prior Authorization of Naloxone Medications

There were 5 prior authorization requests submitted for naloxone medications during fiscal year 2021. All 5 prior authorization requests were deemed incomplete, as naloxone medications currently do not require prior authorization.

Market News and Updates

Anticipated Patent Expiration(s):[9]

- Kloxxado™ (naloxone nasal spray): August 2034
- Evzio® (naloxone auto-injector): March 2035
- Narcan® (naloxone nasal spray): March 2035

New U.S. Food and Drug Administration (FDA) Approval(s):

- **April 2021:** The FDA approved Kloxxado™, an 8mg naloxone nasal spray, to treat opioid overdose. Kloxxado™ delivers 8mg of naloxone into the nasal cavity, which is a higher dose compared to the previously FDA approved 2mg and 4mg naloxone nasal spray products (Narcan®). The recommended dosing of Kloxxado™ is to administer a single spray intranasally into 1 nostril; additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.[10,11]

---

[9] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 06/2022. Last accessed 06/01/2022.

[10] U.S. FDA. FDA Approves Higher Dosage of Naloxone Nasal Spray to Treat Opioid Overdose. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-higher-dosage-naloxone-nasal-spray-treat-opioid-overdose. Issued 04/30/2021. Last accessed 06/01/2022.

[11] Kloxxado™ (Naloxone Nasal Spray) Prescribing Information. Hikma Pharmaceuticals. Available online at: https://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=ebf0f833-c1c0-487c-8f29-01fa8c61b6cb&version=1. Last revised 04/2021. Last accessed 06/01/2022.

Recommendations

The College of Pharmacy does not recommend any changes to the current naloxone medications coverage criteria at this time.

Utilization Details of Naloxone Medications: Fiscal Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
NARCAN 4MG/0.1ML SPR	2,602	2,427	$338,287.39	$130.01	1.07	99.76%
NALOXONE INJ 1MG/ML PFS	8	7	$515.86	$64.48	1.14	0.15%
NALOXONE INJ 0.4MG/ML	2	2	$59.02	$29.51	1	0.02%
NALOXONE INJ 0.4MG/ML CART	2	2	$203.80	$101.90	1	0.06%
NALOXONE INJ 2MG/2ML PFS	1	1	$42.76	$42.76	1	0.01%
TOTAL	**2,615**	**2,436***	**$339,108.83**	**$129.68**	**1.07**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CART = cartridge; INJ = injection; PFS = prefilled syringe; SPR = spray
Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Fiscal Year 2021 Annual Review of Systemic Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)		
Tier-1	**Tier-2**	**Special PA**
celecoxib (Celebrex®) 50mg, 100mg, & 200mg caps	diclofenac ER (Voltaren® XR)	celecoxib (Celebrex®) 400mg caps
diclofenac epolamine (Flector® Patch) – **Brand Preferred**	diclofenac potassium (Cataflam®)	diclofenac (Zorvolex®)
diclofenac sodium (Voltaren®) 50mg & 75mg tabs	diclofenac sodium/ misoprostol (Arthrotec®)	diclofenac epolamine (Licart™) topical system
diclofenac sodium 1% (Voltaren® Gel)	diclofenac sodium (Voltaren®) 25mg tabs	diclofenac potassium (Cambia®) powder pack
etodolac (Lodine®) 400mg & 500mg tabs	etodolac (Lodine®) 200mg & 300mg caps	diclofenac potassium (Lofena™) tabs
flurbiprofen (Ansaid®)	etodolac ER (Lodine® XL)	diclofenac potassium (Zipsor®) caps
ibuprofen (Motrin®)	naproxen sodium (Anaprox®) 275mg & 550mg tabs	diclofenac sodium (Dyloject™) inj
meloxicam (Mobic®)	oxaprozin (Daypro®)	diclofenac sodium (Pennsaid®) topical drops
nabumetone (Relafen®)	piroxicam (Feldene®)	fenoprofen (Nalfon®)
naproxen* (Naprosyn®)	tolmetin (Tolectin®)	ibuprofen (Caldolor®) inj
naproxen EC (Naprosyn®)		ibuprofen/famotidine (Duexis®)
sulindac (Clinoril®)		indomethacin (Indocin®) susp & ER caps
		indomethacin (Tivorbex®)
		ketoprofen (Orudis®) caps
		ketoprofen ER (Oruvail®)
		ketorolac tromethamine (Sprix®) nasal spray
		meclofenamate (Meclomen®)
		mefenamic acid (Ponstel®)
		meloxicam (Anjeso®) inj
		meloxicam (Vivlodex®) caps

Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)		
Tier-1	**Tier-2**	**Special PA**
		meloxicam (Qmiiz ODT™) ODT
		nabumetone 1,000mg (Relafen DS®)
		naproxen sodium ER (Naprelan®)
		naproxen/esomeprazole (Vimovo®)

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), or Wholesale Acquisition Costs (WAC) if NADAC unavailable.
*Naproxen oral suspension is available without prior authorization for members 12 years of age and younger. Members older than 12 years of age require a reason why a special formulation product is needed in place of the regular tablet formulation.
caps = capsules; ER = extended-release; EC = enteric-coated; inj = injection; ODT = orally disintegrating tablet; PA = prior authorization; susp = suspension; tabs = tablets

NSAIDs Tier-2 Approval Criteria:

1. Previous use of at least 2 Tier-1 NSAID products (from different product lines) plus a proton pump inhibitor (PPI) within the last 120 days.

NSAIDs Special Prior Authorization (PA) Approval Criteria:

1. A unique indication for which a Tier-1 or Tier-2 product is not appropriate; or
2. Previous use of at least 2 Tier-1 NSAID products (from different product lines); and
3. A patient-specific, clinically significant reason why a special formulation is needed over a Tier-1 product must be provided; and
4. Additionally, use of Tivorbex® (indomethacin) will require a patient-specific, clinically significant reason why the member cannot use all other available generic indomethacin products; and
5. Additionally, use of Celebrex® (celecoxib) 400mg capsules will require a diagnosis of Familial Adenomatous Polyposis (FAP) and a patient-specific, clinically significant reason why the member cannot use 2 celecoxib 200mg capsules to achieve a 400mg dose.

Anjeso® (Meloxicam Injection) Approval Criteria:

1. An FDA approved diagnosis of management of moderate-to-severe pain, alone or in combination with non-NSAID analgesics; and
2. Member must be 18 years of age or older; and
3. Member must be well hydrated before Anjeso® administration to reduce the risk of renal toxicity; and
4. Anjeso® should be used for the shortest duration consistent with individual patient treatment goals; and

5. A patient-specific, clinically significant reason the member cannot use oral meloxicam tablets or other Tier-1 NSAID products must be provided; and
6. A quantity limit of 3 vials per 3 days will apply; and
7. For consideration of a longer duration of use, a patient-specific, clinically significant reason why the member cannot transition to an oral Tier-1 NSAID product must be provided, along with the anticipated duration of treatment.

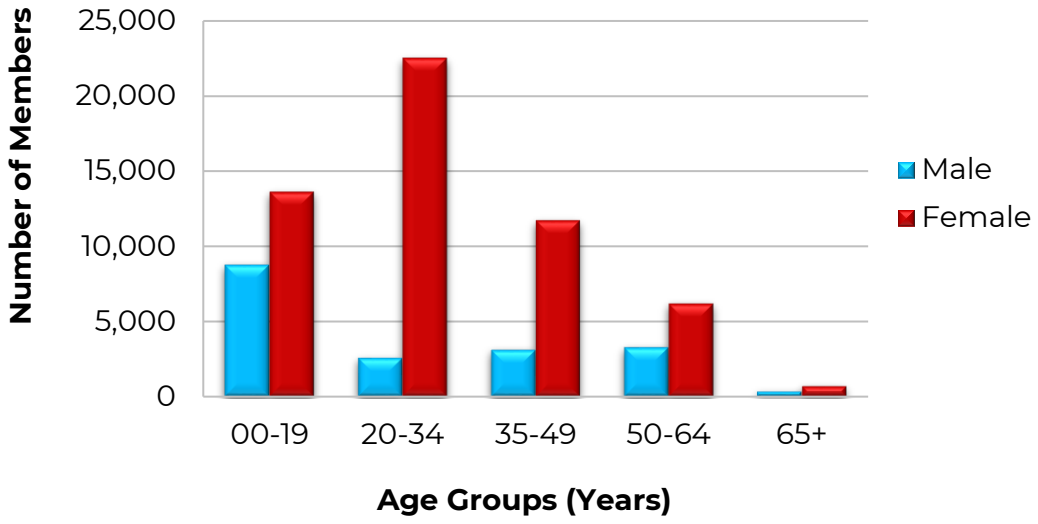
Utilization of NSAIDs: Fiscal Year 2021

Comparison of Fiscal Years

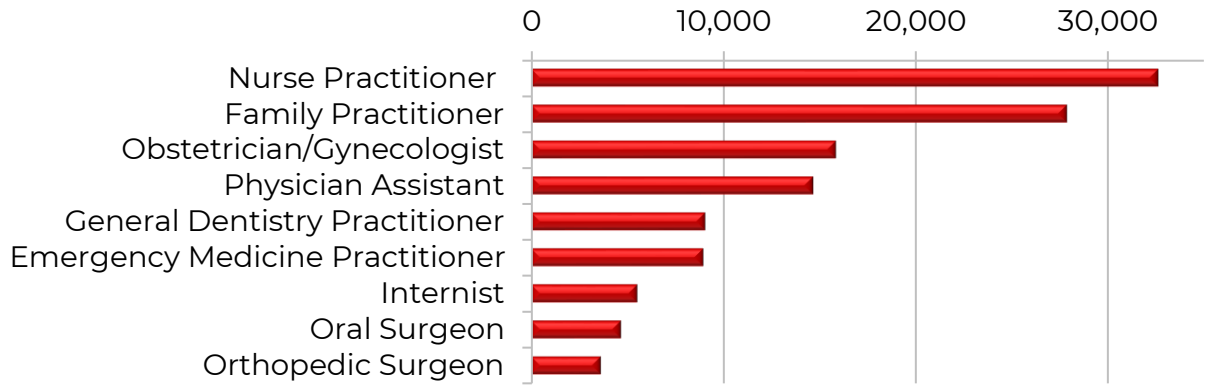
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	68,449	132,163	$2,002,975.18	$15.16	$0.67	6,797,156	3,003,035
2021	72,707	140,628	$2,112,913.10	$15.02	$0.66	7,273,833	3,199,278
% Change	**6.2%**	**6.4%**	**5.5%**	**-0.9%**	**-1.5%**	**7.0%**	**6.5%**
Change	**4,258**	**8,465**	**$109,937.92**	**-$0.14**	**-$0.01**	**476,677**	**196,243**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Demographics of Members Utilizing NSAIDs



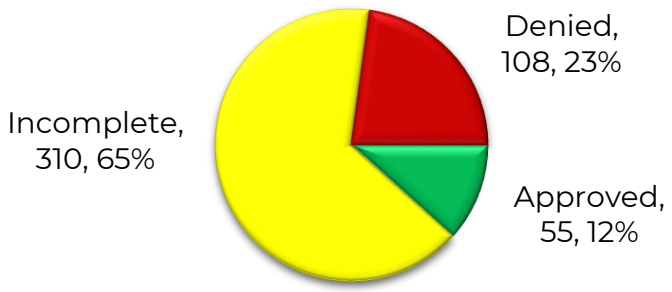
Top Prescriber Specialties of NSAIDs by Number of Claims



Prior Authorization of NSAIDs

There were 473 prior authorization requests submitted for NSAIDs during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[12]

- Cambia® (diclofenac potassium powder packs): June 2026
- Duexis® (ibuprofen/famotidine tablets): July 2026
- Dyloject™ (diclofenac sodium injection): March 2027
- Zipsor® (diclofenac potassium capsules): February 2029
- Tivorbex® (indomethacin capsules): April 2030
- Zorvolex® (diclofenac capsules): April 2030
- Pennsaid® (diclofenac sodium 2% topical drops): August 2030
- Qmiiz™ ODT (meloxicam orally disintegrating tablets): August 2030

[12] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 06/2022. Last accessed 06/02/2022.

- Caldolor® (ibuprofen injection): September 2030
- Vimovo® (naproxen/esomeprazole tablets): October 2031
- Vivlodex® (meloxicam capsules): March 2035
- Anjeso® (meloxicam injection): March 2039

Recommendations

The College of Pharmacy does not recommend any changes to the NSAIDs Product Based Prior Authorization (PBPA) category at this time.

Utilization Details of NSAIDs: Fiscal Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
IBUPROFEN PRODUCTS						
IBUPROFEN TAB 800MG	46,964	31,173	$600,238.09	$12.78	1.51	28.41%
IBUPROFEN TAB 600MG	12,597	10,691	$142,887.02	$11.34	1.18	6.76%
IBUPROFEN TAB 400MG	2,334	1,721	$27,508.88	$11.79	1.36	1.30%
IBU TAB 800MG	831	611	$11,726.21	$14.11	1.36	0.55%
IBU TAB 600MG	100	92	$1,297.63	$12.98	1.09	0.06%
IBU TAB 400MG	35	34	$429.61	$12.27	1.03	0.02%
SUBTOTAL	**62,861**	**44,322**	**$784,087.44**	**$12.47**	**1.42**	**37.10%**
MELOXICAM PRODUCTS						
MELOXICAM TAB 15MG	16,406	7,579	$149,148.17	$9.09	2.16	7.06%
MELOXICAM TAB 7.5MG	8,403	4,513	$80,734.24	$9.61	1.86	3.82%
SUBTOTAL	**24,809**	**12,092**	**$229,882.41**	**$9.27**	**2.05**	**10.88%**
NAPROXEN PRODUCTS						
NAPROXEN TAB 500MG	17,548	11,450	$210,238.83	$11.98	1.53	9.95%
NAPROXEN TAB 375MG	1,932	1,335	$24,489.72	$12.68	1.45	1.16%
NAPROXEN TAB 250MG	1,550	1,009	$20,309.64	$13.10	1.54	0.96%
NAPROXEN SUS 125MG/5ML	427	225	$118,328.89	$277.12	1.9	5.60%
NAPROXEN DR TAB 500MG	299	230	$14,896.08	$49.82	1.3	0.71%
EC-NAPROXEN TAB 500MG	219	155	$11,333.92	$51.75	1.41	0.54%
NAPROXEN SOD TAB 550MG	111	63	$3,243.91	$29.22	1.76	0.15%
NAPROXEN DR TAB 375MG	88	51	$1,648.69	$18.74	1.73	0.08%
NAPROXEN SOD TAB 275MG	9	6	$188.36	$20.93	1.5	0.01%
EC-NAPROXEN TAB 375MG	8	5	$135.91	$16.99	1.6	0.01%
SUBTOTAL	**22,191**	**14,529**	**$404,813.95**	**$18.24**	**1.53**	**19.17%**
DICLOFENAC PRODUCTS						
DICLOFENAC GEL 1%	6,700	3,560	$189,136.03	$28.23	1.88	8.95%
DICLOFENAC TAB 75MG DR	5,932	2,717	$82,049.34	$13.83	2.18	3.88%
DICLOFENAC TAB 50MG DR	1,980	961	$31,778.20	$16.05	2.06	1.50%
DICLOFENAC TAB 100MG ER	262	119	$18,908.27	$72.17	2.2	0.89%
DICLOFENAC POT TAB 50MG	182	99	$7,415.43	$40.74	1.84	0.35%
FLECTOR DIS 1.3%	114	45	$37,931.41	$332.73	2.53	1.80%
DICLOFENAC TAB 25MG DR	12	8	$671.94	$56.00	1.5	0.03%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
DICLOFENAC DIS 1.3%	2	1	$303.58	$151.79	2	0.01%
SUBTOTAL	**15,184**	**7,510**	**$368,194.20**	**$24.25**	**2.02**	**17.41%**
CELECOXIB PRODUCTS						
CELECOXIB CAP 200MG	4,739	1,927	$80,157.98	$16.91	2.46	3.79%
CELECOXIB CAP 100MG	1,947	744	$31,020.27	$15.93	2.62	1.47%
CELECOXIB CAP 50MG	36	28	$630.22	$17.51	1.29	0.03%
SUBTOTAL	**6,722**	**2,699**	**$111,808.47**	**$16.63**	**2.49**	**5.29%**
KETOROLAC PRODUCTS						
KETOROLAC TAB 10MG	3,814	3,269	$86,535.69	$22.69	1.17	4.10%
KETOROLAC INJ 60MG/2ML	36	11	$558.80	$15.52	3.27	0.03%
KETOROLAC INJ 30MG/ML	13	9	$149.58	$11.51	1.44	0.01%
SUBTOTAL	**3,863**	**3,289**	**$87,244.07**	**$22.58**	**1.17**	**4.14%**
NABUMETONE PRODUCTS						
NABUMETONE TAB 750MG	1,240	424	$22,190.80	$17.90	2.92	1.05%
NABUMETONE TAB 500MG	905	377	$14,486.21	$16.01	2.4	0.69%
SUBTOTAL	**2,145**	**801**	**$36,677.01**	**$17.10**	**2.68**	**1.74%**
ETODOLAC PRODUCTS						
ETODOLAC TAB 400MG	1,088	688	$28,099.66	$25.83	1.58	1.33%
ETODOLAC TAB 500MG	440	198	$13,639.48	$31.00	2.22	0.65%
ETODOLAC CAP 300MG	61	46	$2,248.46	$36.86	1.33	0.11%
ETODOLAC CAP 200MG	35	22	$1,288.05	$36.80	1.59	0.06%
ETODOLAC ER TAB 400MG	11	7	$852.01	$77.46	1.57	0.04%
ETODOLAC ER TAB 500MG	10	3	$563.38	$56.34	3.33	0.03%
ETODOLAC ER TAB 600MG	10	2	$1,621.37	$162.14	5	0.08%
SUBTOTAL	**1,655**	**966**	**$48,312.41**	**$29.19**	**1.71**	**2.30%**
INDOMETHACIN PRODUCTS						
INDOMETHACIN CAP 50MG	443	291	$6,254.99	$14.12	1.52	0.30%
INDOMETHACIN CAP 25MG	334	208	$4,952.68	$14.83	1.61	0.23%
INDOCIN SUS 25MG/5ML	8	1	$4,284.30	$535.54	8	0.20%
SUBTOTAL	**785**	**500**	**$15,491.97**	**$19.73**	**1.57**	**0.73%**
SULINDAC PRODUCTS						
SULINDAC TAB 150MG	159	49	$2,742.98	$17.25	3.24	0.13%
SULINDAC TAB 200MG	112	48	$2,260.87	$20.19	2.33	0.11%
SUBTOTAL	**271**	**97**	**$5,003.85**	**$18.46**	**2.79**	**0.24%**
DICLOFENAC/MISOPROSTOL PRODUCTS						
DICLO/MISOPR TAB 50-0.2MG	38	6	$4,177.94	$109.95	6.33	0.20%
DICLO/MISOPR TAB 75-0.2MG	17	4	$1,839.96	$108.23	4.25	0.09%
SUBTOTAL	**55**	**10**	**$6,017.90**	**$109.42**	**5.50**	**0.29%**
FLURBIPROFEN PRODUCTS						
FLURBIPROFEN TAB 100MG	40	12	$1,262.51	$31.56	3.33	0.06%
SUBTOTAL	**40**	**12**	**$1,262.51**	**$31.56**	**3.33**	**0.06%**
PIROXICAM PRODUCTS						
PIROXICAM CAP 20MG	20	7	$510.35	$25.52	2.86	0.02%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
PIROXICAM CAP 10MG	3	2	$47.48	$15.83	1.5	0.00%
SUBTOTAL	**23**	**9**	**$557.83**	**$24.25**	**2.56**	**0.02%**
OXAPROZIN PRODUCTS						
OXAPROZIN TAB 600MG	15	4	$838.17	$55.88	3.75	0.04%
SUBTOTAL	**15**	**4**	**$838.17**	**$55.88**	**3.75**	**0.04%**
IBUPROFEN/FAMOTIDINE PRODUCTS						
DUEXIS TAB 800-26.6MG	5	1	$12,448.05	$2,489.61	5	0.59%
SUBTOTAL	**5**	**1**	**$12,448.05**	**$2,489.61**	**5**	**0.59%**
FENOPROFEN PRODUCTS						
FENOPROFEN TAB 600MG	4	1	$272.86	$68.22	4	0.01%
SUBTOTAL	**4**	**1**	**$272.86**	**$68.22**	**4**	**0.01%**
TOTAL	**140,628**	**72,707***	**$2,112,913.10**	**$15.02**	**1.93**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; DICLO/MISOPR = diclofenac/misoprostol; DIS = patch; DR = delayed-release; EC = enteric-coated; ER = extended-release; INJ = injection; POT = potassium; SOL = solution; SUS = suspension; TAB = tablet
Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Fiscal Year 2021 Annual Review of Nuedexta® (Dextromethorphan/Quinidine)

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

Nuedexta® (Dextromethorphan/Quinidine) Approval Criteria:

1. An FDA approved diagnosis of pseudobulbar affect (PBA) secondary to a neurological condition [e.g., amyotrophic lateral sclerosis (ALS), multiple sclerosis (MS), Parkinson's disease, stroke, traumatic brain injury]; and
2. Documentation of the neurological condition must be submitted; and
3. Member must be 18 years of age or older; and
4. Nuedexta® must be prescribed by, or in consultation with, a neurologist or psychiatrist (or an advanced care practitioner with a supervising physician who is a neurologist or psychiatrist); and
5. Member must not have any contraindications to therapy [e.g., concomitant use with quinidine, quinine, or mefloquine; history of quinidine, quinine, or mefloquine-induced thrombocytopenia, hepatitis, or other hypersensitivity reactions; known hypersensitivity to dextromethorphan; use with a monoamine oxidase inhibitor (MAOI) or within 14 days of stopping an MAOI; prolonged QT interval, congenital long QT syndrome, history suggestive of torsades de pointes, or heart failure; complete atrioventricular (AV) block without implanted pacemaker, or at high risk of complete AV block; currently taking other drugs that both prolong QT interval and are metabolized by CYP2D6 (e.g., thioridazine, pimozide)]; and
6. Prescriber must document baseline number of PBA laughing or crying episodes per day; and
7. A quantity limit of 60 capsules per 30 days will apply; and
8. Initial approvals will be for the duration of 12 weeks. Reauthorizations may be granted if the prescriber documents the member is responding well to treatment as indicated by a reduction in the number of PBA episodes of laughing or crying per day compared to baseline. Current users must meet the revised approval criteria when reapplying for prior authorization continuation.

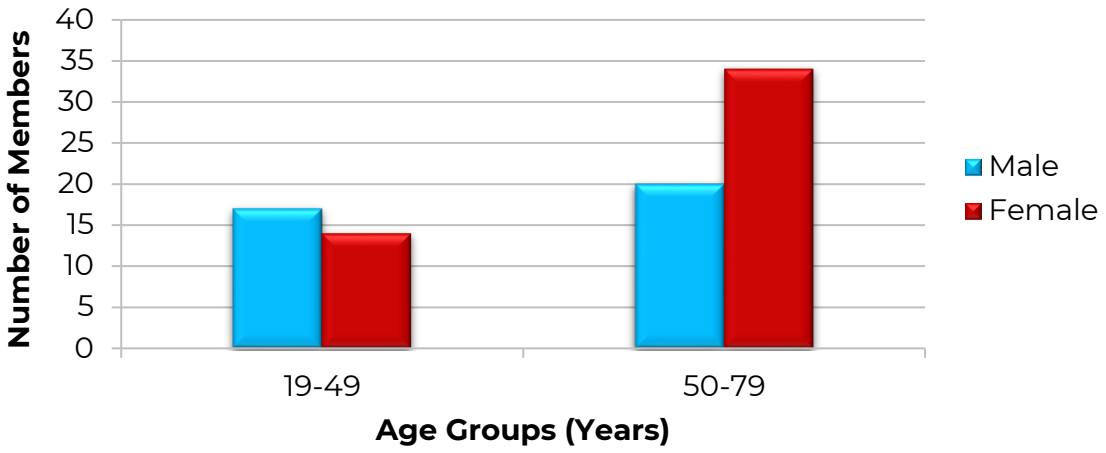
Utilization of Nuedexta® (Dextromethorphan/Quinidine): Fiscal Year 2021

Comparison of Fiscal Years

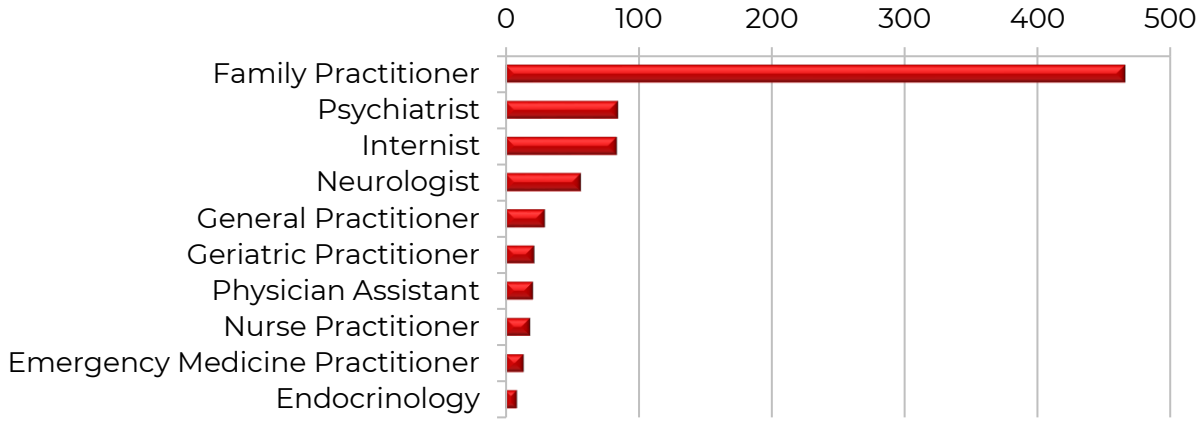
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	112	953	$991,419.23	$1,040.31	$37.00	51,278	26,796
2021	85	807	$885,640.07	$1,097.45	$39.57	43,362	22,382
% Change	**-24.1%**	**-15.3%**	**-10.7%**	**5.5%**	**6.9%**	**-15.4%**	**-16.5%**
Change	**-27**	**-146**	**-$105,779.16**	**$57.14**	**$2.57**	**-7,916**	**-4,414**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Demographics of Members Utilizing Nuedexta® (Dextromethorphan/Quinidine)

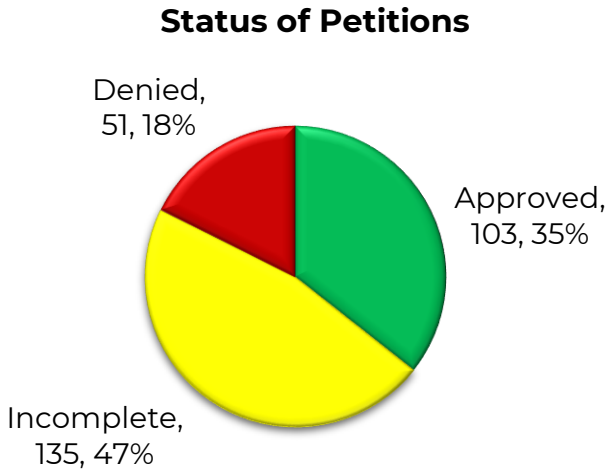


Top Prescriber Specialties of Nuedexta® (Dextromethorphan/Quinidine) by Number of Claims



Prior Authorization of Nuedexta® (Dextromethorphan/Quinidine)

There were 289 prior authorization requests submitted for Nuedexta® (dextromethorphan/quinidine) during fiscal year 2021. The following chart shows the status of the submitted petitions for year 2021.



Market News and Updates

Anticipated Patent Expiration(s):[13]

- Nuedexta® (dextromethorphan/quinidine): August 2026

Recommendations

The College of Pharmacy does not recommend any changes to the current Nuedexta® (dextromethorphan/quinidine) prior authorization criteria at this time.

Utilization Details of Nuedexta® (Dextromethorphan/Quinidine): Fiscal Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
NUEDEXTA CAP 20-10MG	807	85	$885,640.07	$1,097.45	9.49
TOTAL	**807**	**85**	**$885,640.07**	**$1,097.45**	**9.49**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule
Fiscal Year 2021 = 07/01/2020 to 06/30/2021

[13] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 05/2022. Last accessed 05/25/2022.

Fiscal Year 2021 Annual Review of Otic Anti-Infective Medications

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

Otic Anti-Infective Medications		
Tier-1	**Tier-2**	**Special PA**
acetic acid (Acetasol®, VoSol®)	ciprofloxacin 0.2% (Cetraxal®)	acetic acid/HC (Acetasol® HC, VoSol® HC)
ciprofloxacin/dexamethasone (Ciprodex®)	ciprofloxacin/fluocinolone (Otovel®)	ciprofloxacin 6% (Otiprio®)
ciprofloxacin/HC (Cipro® HC)	finafloxacin (Xtoro™)	
neomycin/colistin/HC/ thonzonium (Coly-Mycin® S)	neomycin/polymyxin B/HC (Cortisporin®, Pediotic®)	
	ofloxacin (Floxin® Otic)	

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
HC = hydrocortisone; PA = prior authorization

Otic Anti-Infective Medications Tier-2 Approval Criteria:

1. Member must have an adequate 14-day trial of at least 2 Tier-1 medications; or
2. Approval may be granted if there is a unique FDA approved indication not covered by Tier-1 medications or infection by an organism not known to be covered by any of the Tier-1 medications.

Acetasol® HC and VoSol® HC (Acetic Acid/Hydrocortisone Otic Solution) Approval Criteria:

1. Diagnosis of acute otitis externa; and
2. Member must have recent trials (within the last 6 months) with all other commonly used topical otic anti-infective medications that have failed to resolve infection; or
3. Allergy to all available products and failure of acetic acid alone.

Otiprio® (Ciprofloxacin 6% Otic Suspension) Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. For the treatment of bilateral otitis media with effusion in members undergoing tympanostomy tube placement; or
   b. For the treatment of acute otitis externa due to *Pseudomonas aeruginosa (P. aeruginosa)* or *Staphylococcus aureus (S. aureus)*; and
2. Member must be 6 months of age or older; and
3. Otiprio® must be administered by a health care professional; and

4. A patient-specific, clinically significant reason why appropriate lower tiered otic anti-infective medications cannot be used must be provided; and
5. A quantity limit of 1 vial per treatment course will apply.

Utilization of Otic Anti-Infective Medications: Fiscal Year 2021

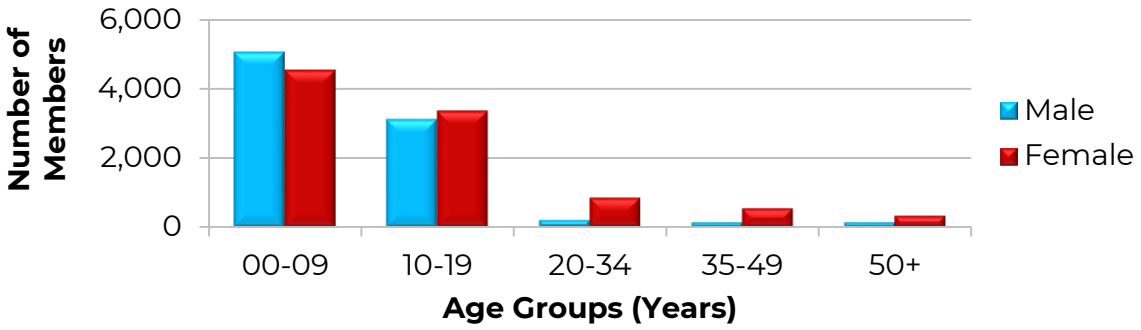
Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	21,829	26,435	$6,161,353.31	$233.08	$21.09	200,980	292,133
2021	18,341	21,821	$4,264,409.23	$195.43	$18.28	166,667	233,337
% Change	**-16.00%**	**-17.50%**	**-30.80%**	**-16.20%**	**-13.30%**	**-17.10%**	**-20.10%**
Change	**-3,488**	**-4,614**	**-$1,896,944.08**	**-$37.65**	**-$2.81**	**-34,313**	**-58,796**

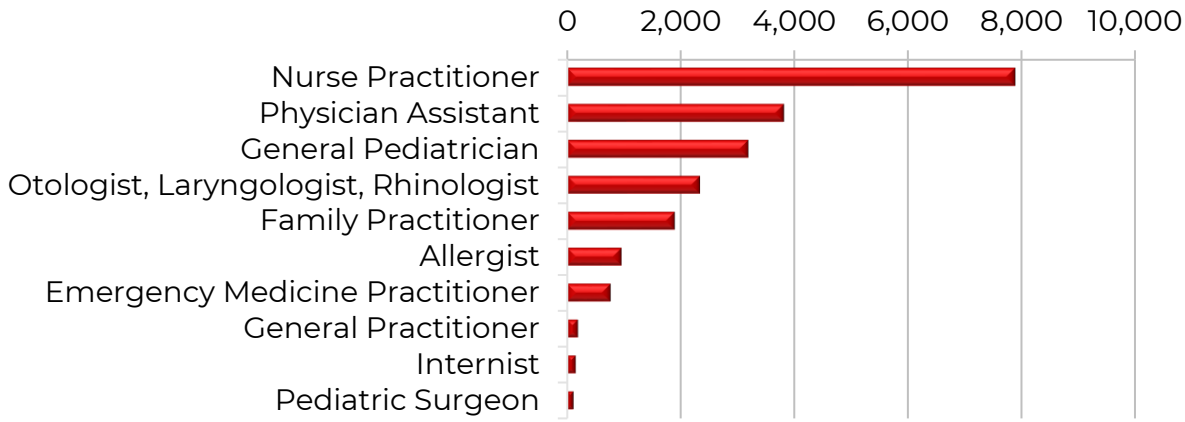
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

- Please note: Some Tier-1 products participate in supplemental rebates; therefore, costs shown do not reflect net costs.

Demographics of Members Utilizing Otic Anti-Infective Medications

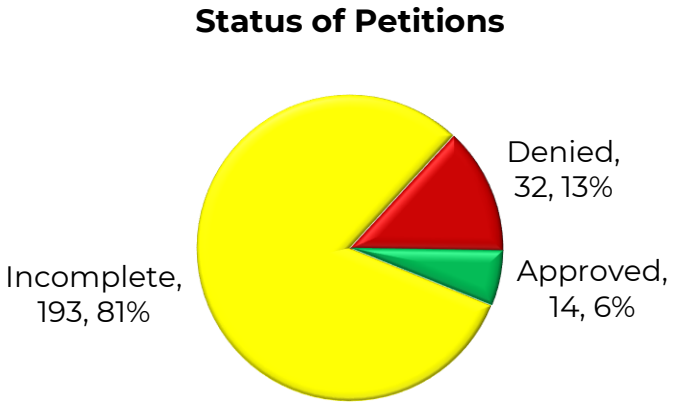


Top Prescriber Specialties of Otic Anti-Infective Medications by Number of Claims



Prior Authorization of Otic Anti-Infective Medications

There were 239 prior authorization requests submitted for otic anti-infective medications during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.



Market News and Updates

Anticipated Patent Expiration(s):[14]

- Ciprodex® (ciprofloxacin/dexamethasone): June 2025
- Otovel® (ciprofloxacin/fluocinolone): March 2030
- Xtoro™ (finafloxacin): November 2033
- Otiprio® (ciprofloxacin): July 2035

Recommendations

The College of Pharmacy does not recommend any changes to the otic anti-infective medications Product Based Prior Authorization (PBPA) category at this time.

[14] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 05/2022. Last Accessed 05/27/2022.

Utilization Details of Otic Anti-Infective Medications: Fiscal Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 PRODUCTS						
CIPRO/DEXA SUS 0.3-0.1%	12,950	11,147	$2,156,928.47	$166.56	1.16	50.58%
CIPRODEX SUS 0.3-0.1%	8,162	7,693	$1,977,794.54	$242.32	1.06	46.38%
CIPRO HC SUS OTIC 0.2-1%	289	280	$87,737.66	$303.59	1.03	2.06%
ACETIC ACID SOL 2% OTIC	260	247	$6,771.45	$26.04	1.05	0.16%
CORTISPORIN SUS -TC 0.33-0.3-1-0.05%	150	131	$34,684.95	$231.23	1.15	0.81%
SUBTOTAL	**21,811**	**18,339**	**$4,263,917.07**	**$195.49**	**1.19**	**99.99%**
TIER-2 PRODUCTS						
NEO/POLY/HC SUS 1% OTIC	5	4	$326.54	$65.31	1.25	0.01%
OFLOXACIN DRO 0.3% OTIC	4	4	$97.48	$24.37	1	0.00%
NEO/POLY/HC SOL 1% OTIC	1	1	$68.14	$68.14	1	0.00%
SUBTOTAL	**10**	**9**	**$492.16**	**$49.22**	**1.25**	**0.01%**
TOTAL	**21,821**	**18,341***	**$4,264,409.23**	**$195.43**	**1.19**	**100%**

Please note: Tier-1 products may participate in supplemental rebates; therefore, costs shown do not reflect net costs.
*Total number of unduplicated utilizing members.
CIPRO/DEXA = ciprofloxacin/dexamethasone; DRO = drops; HC = hydrocortisone; NEO = neomycin; POLY = polymyxin; SOL = solution; SUS = suspension
Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Fiscal Year 2021 Annual Review of Phosphate Binders

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

Generic calcium acetate containing products, Fosrenol® (lanthanum carbonate 500mg and 750mg chewable tablet), PhosLo® (calcium acetate gel capsule), Phoslyra® (calcium acetate oral solution), Renagel® (sevelamer hydrochloride tablet), and Renvela® (sevelamer carbonate tablet and packet for suspension) are currently available without prior authorization.

Auryxia® (Ferric Citrate) Approval Criteria:

1. An FDA approved diagnosis of hyperphosphatemia in members with chronic kidney disease (CKD) on dialysis; and
    a. Documented trials of inadequate response to at least 2 of the phosphate binders available without prior authorization or a patient-specific, clinically significant reason why the member cannot use a phosphate binder available without prior authorization must be provided; or
2. An FDA approved diagnosis of iron deficiency anemia (IDA) in members with CKD not on dialysis; and
    a. Documented lab results verifying IDA; and
    b. Documented intolerance or inadequate response to prior treatment with oral iron; and
3. A quantity limit of 12 tablets per day will apply based on the maximum recommended dose.

Fosrenol® (Lanthanum Carbonate) 1,000mg Chewable Tablets, 750mg Oral Powder, and 1,000mg Oral Powder Approval Criteria:

1. An FDA approved diagnosis of hyperphosphatemia in members with end stage renal disease (ESRD); and
2. Documented trials of inadequate response to at least 2 of the phosphate binders available without prior authorization or a patient-specific, clinically significant reason why the member cannot use a phosphate binder available without prior authorization must be provided; and
3. For the approval of Fosrenol® oral powder, a patient-specific, clinically significant reason why a special formulation is needed over a phosphate binder available without prior authorization, such as brand Fosrenol® 500mg or 750mg chewable tablets which can be crushed, must be provided; and
4. For the approval of Fosrenol® 1,000mg chewable tablets, a patient-specific, clinically significant reason why the member cannot use a

phosphate binder available without a prior authorization, such as brand Fosrenol® 500mg or 750mg chewable tablets, must be provided; and
5. Fosrenol® 500mg or 750mg chewable tablets are brand preferred. Authorization of the generic formulation requires a patient-specific, clinically significant reason why the member cannot use the brand formulation.

Velphoro® (Sucroferric Oxyhydroxide) Approval Criteria:

1. An FDA approved diagnosis of hyperphosphatemia in members with chronic kidney disease (CKD) on dialysis; and
2. Documented trials of inadequate response to at least 2 of the phosphate binders available without prior authorization or a patient-specific, clinically significant reason why the member cannot use a phosphate binder available without prior authorization must be provided.

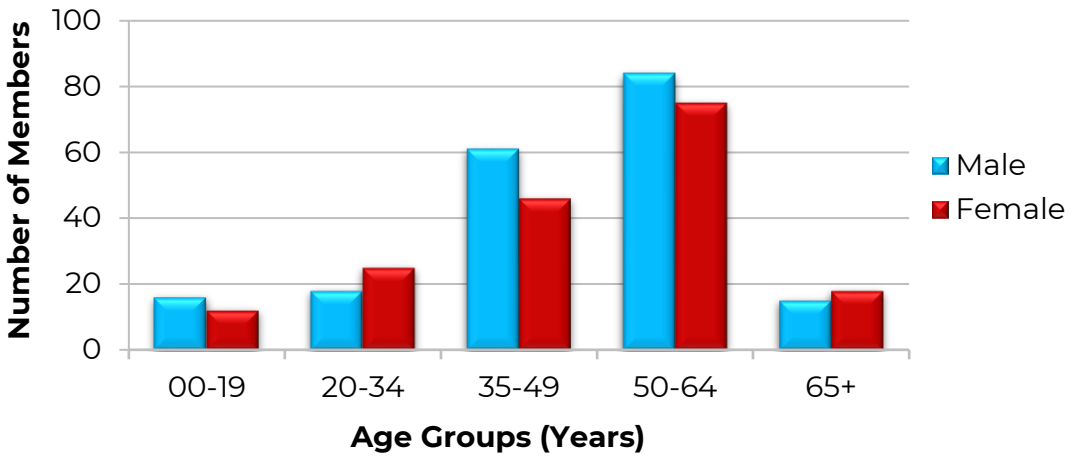
Utilization of Phosphate Binders: Fiscal Year 2021

Comparison of Fiscal Years

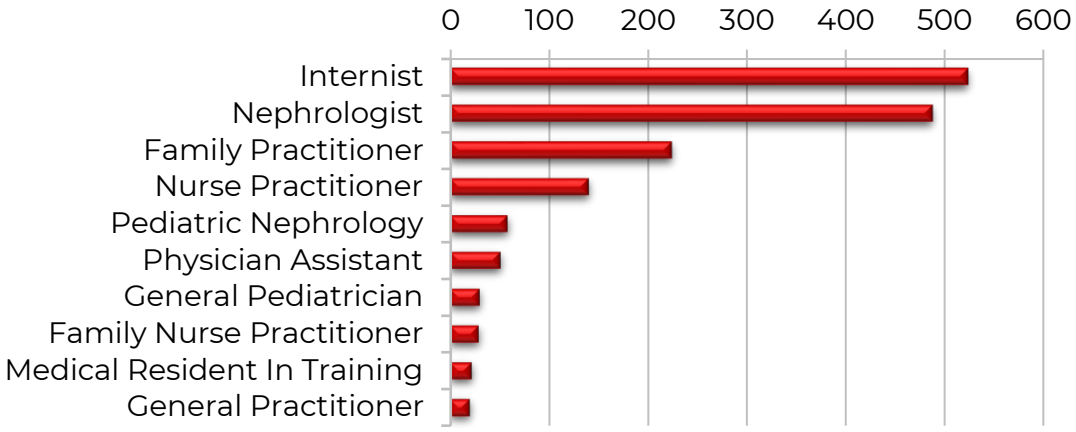
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	379	1,523	$539,808.64	$354.44	$12.18	311,248	44,325
2021	370	1,664	$655,288.28	$393.80	$13.45	354,798	48,718
% Change	**-2.40%**	**9.30%**	**21.40%**	**11.10%**	**10.40%**	**14.00%**	**9.90%**
Change	**-9**	**141**	**$115,479.64**	**$39.36**	**$1.27**	**43,550**	**4,393**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Demographics of Members Utilizing Phosphate Binders



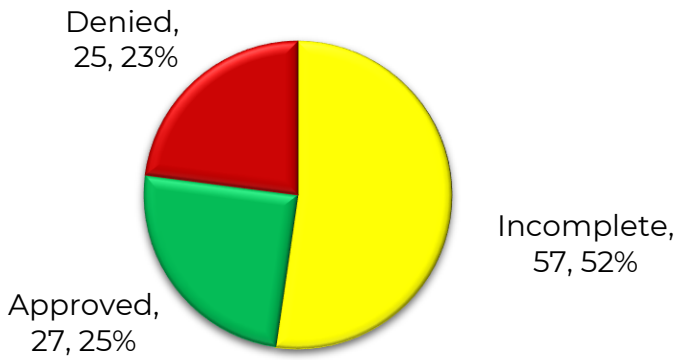
Top Prescriber Specialties of Phosphate Binders by Number of Claims



Prior Authorization of Phosphate Binders

There were 109 prior authorization requests submitted for phosphate binders during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[15]

- Fosrenol® (lanthanum carbonate): August 2024
- Renvela® (sevelamer carbonate tablet): October 2025
- Phoslyra® (calcium acetate): February 2030
- Auryxia® (ferric citrate): July 2030
- Renvela® (sevelamer carbonate packet for suspension): December 2030
- Velphoro® (sucroferric oxyhydroxide): May 2035

[15] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 06/2022. Last accessed 06/01/2022.

Pipeline:

- **Xphozah® (Tenapanor):** In April 2022, Ardelyx announced that the U.S. Food and Drug Administration (FDA) has provided an interim response to Ardelyx's second level of appeal of the Complete Response Letter (CRL) received on July 28, 2021, for Xphozah® (tenapanor). The FDA noted that additional input from the cardiovascular and renal drug advisory committee, including expert clinicians, would be valuable in further considering the clinical meaningfulness of the phosphate lowering effect observed in the Phase 3 clinical study for Xphozah®. The FDA intends to direct the division of cardiology and nephrology to bring the Xphozah® New Drug Application (NDA) to the cardiovascular and renal drugs advisory committee and to provide a response to Ardelyx's appeal. Ardelyx is seeking approval for Xphozah® for the control of serum phosphorus in adult patients with chronic kidney disease (CKD) on dialysis. Xphozah® is an investigational first-in-class phosphate absorption inhibitor (PAI). Tenapanor, a minimally absorbed inhibitor of gastrointestinal sodium/hydrogen exchanger 3 (NHE3), acts via a non-phosphate-binding mechanism, reducing paracellular phosphate transport in the intestine, the primary pathway of phosphate absorption. The studied dosing is (1) 30mg oral tablet twice daily. The most common side effect of tenapanor in clinical studies was diarrhea. Ardelyx markets another tenapanor product, Ibsrela®, which is currently FDA approved for the treatment of irritable bowel syndrome with constipation (IBS-C) in adults.[16,17]
- **PT20:** PT20 is an iron-based phosphate binder for the treatment of hyperphosphatemia in patients with hemodialysis-dependent CKD. Results were recently published from a Phase 2b double-blind, parallel-group, placebo-controlled, dose-ranging trial evaluating the efficacy and safety of 28 days of oral PT20 treatment. Among the 153 patients, 129 completed treatment. PT20 treatment for 28 days resulted in a statistically significant and dose-dependent reduction in serum phosphate concentration. The most common PT20 treatment-related adverse events were diarrhea and discolored feces. There were no serious adverse events reported.[18]

---

[16] Ardelyx, Inc. Ardelyx Announces FDA Plan to Convene Advisory Committee for Xphozah® (Tenapanor). *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/ardelyx-announces-fda-plan-to-convene-advisory-committee-for-xphozah-tenapanor-301531585.html. Issued 04/25/2022. Last accessed 06/01/2022.

[17] Ibsrela® (Tenapanor) Prescribing Information. Ardelyx, Inc. Available online at: https://ardelyx.com/wp-content/uploads/2021/11/IBSRELA-Prescribing-Information-1.pdf. Last revised 04/2022. Last accessed 06/01/2022.

[18] Sampson M, Faria N, Powell JJ. Efficacy and Safety of PT20, an Iron-Based Phosphate Binder, for the Treatment of Hyperphosphataemia: A Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging, Phase IIb Study in Patients with Haemodialysis-Dependent Chronic Kidney Disease. *Nephrol Dial Transplant* 2020; doi: 10.1093/ndt/gfaa116.

Recommendations

The College of Pharmacy does not recommend any changes to the current phosphate binders prior authorization criteria at this time.

Utilization Details of Phosphate Binders: Fiscal Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
SEVELAMER CARBONATE PRODUCTS					
SEVELAMER CARB TAB 800MG	804	206	$67,904.14	3.9	$84.46
SEVELAMER POW 0.8GM	66	15	$60,532.42	4.4	$917.16
SEVELAMER POW 2.4GM	33	9	$58,741.01	3.67	$1,780.03
RENVELA TAB 800MG	3	1	$7,719.58	3	$2,573.19
SUBTOTAL	**906**	**231**	**$194,897.15**	**3.92**	**$215.12**
CALCIUM ACETATE PRODUCTS					
CALCIUM ACETATE CAP 667MG	512	155	$22,170.96	3.3	$43.30
CALCIUM ACETATE TAB 667MG	22	13	$1,599.14	1.69	$72.69
PHOSLYRA SOL 667MG/5ML	4	1	$1,244.40	4	$311.10
SUBTOTAL	**538**	**169**	**$25,014.50**	**3.18**	**$46.50**
SUCROFERRIC OXYHYDROXIDE PRODUCTS					
VELPHORO CHW 500MG	113	22	$283,030.54	5.14	$2,504.70
SUBTOTAL	**113**	**22**	**$283,030.54**	**5.14**	**$2,504.70**
LANTHANUM CARBONATE PRODUCTS					
FOSRENOL CHW 750MG	23	9	$36,961.98	2.56	$1,607.04
FOSRENOL CHW 500MG	16	5	$28,219.66	3.2	$1,763.73
LANTHANUM CHW 500MG	9	1	$16,132.73	9	$1,792.53
LANTHANUM CHW 1,000MG	6	2	$7,263.76	3	$1,210.63
LANTHANUM CHW 750MG	2	1	$1,668.82	2	$834.41
FOSRENOL POW 750MG	2	2	$6,503.04	1	$3,251.52
SUBTOTAL	**58**	**20**	**$96,749.99**	**2.9**	**$1,668.10**
FERRIC CITRATE PRODUCTS					
AURYXIA TAB 210MG	25	7	$33,457.03	3.57	$1,338.28
SUBTOTAL	**25**	**7**	**$33,457.03**	**3.57**	**$1,338.28**
SEVELAMER HYDROCHLORIDE PRODUCTS					
SEVELAMER HCL TAB 800MG	24	14	$22,139.07	1.71	$922.46
SUBTOTAL	**24**	**14**	**$22,139.07**	**1.71**	**$922.46**
TOTAL	**1,664**	**370***	**$655,288.28**	**4.5**	**$393.80**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; CARB = carbonate; CHW = chewable; HCL = hydrochloride; POW = powder; SOL = solution; TAB = tablet
Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Fiscal Year 2021 Annual Review of Prenatal Vitamins

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

Prenatal Vitamins Approval Criteria:

- Most brand formulation prenatal vitamins require prior authorization for SoonerCare members. Preferred products do not require prior authorization. Products that are not listed on the preferred product list are non-preferred and require prior authorization.
- Updated versions of the preferred products list can be downloaded from the Oklahoma Health Care Authority (OHCA) website: https://oklahoma.gov/ohca/providers/types/pharmacy/pharmacy.html.
- The SoonerCare prenatal vitamins category is modified throughout the fiscal year and adjusted for price fluctuations and supplemental rebate participation.

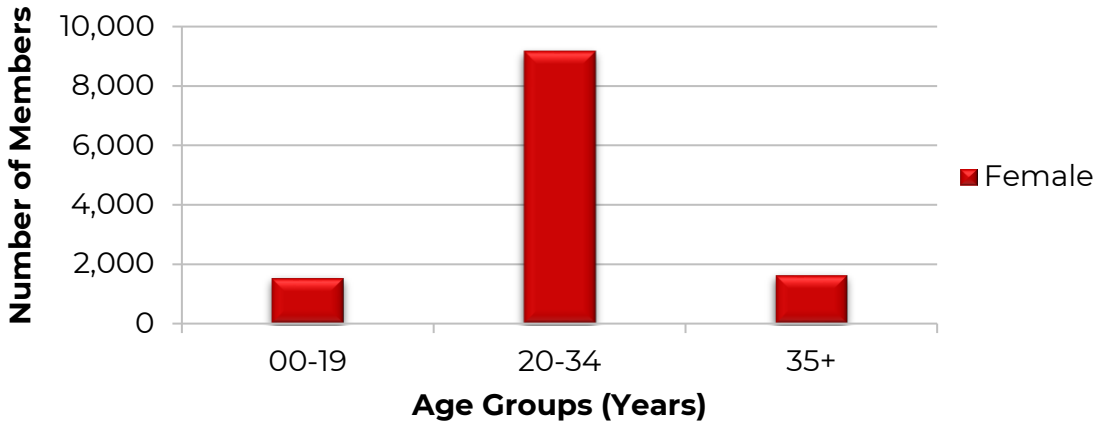
Utilization of Prenatal Vitamins: Fiscal Year 2021

Comparison of Fiscal Years

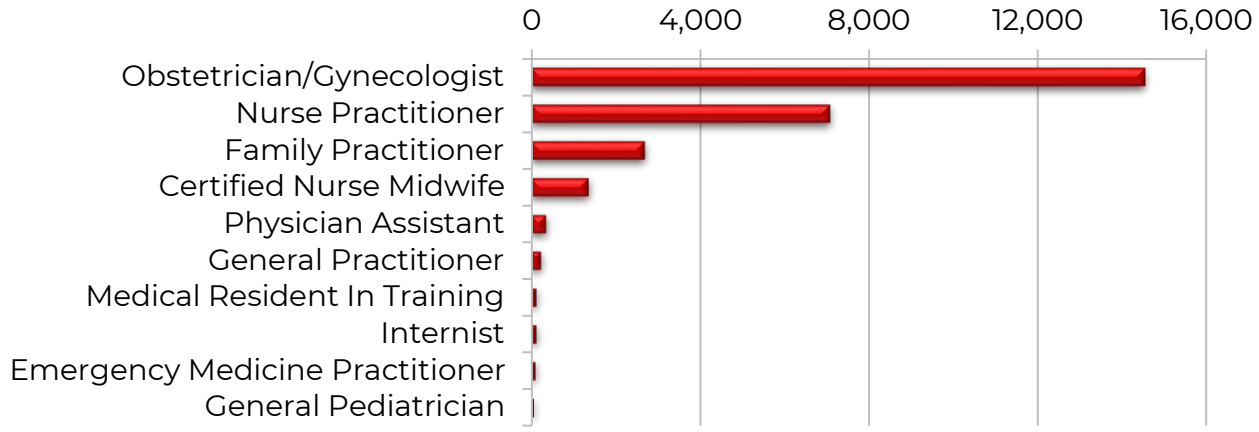
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	13,742	30,250	$3,003,849.11	$99.30	$2.32	1,596,575	1,293,087
2021	12,306	26,952	$2,869,840.31	$106.48	$2.45	1,453,970	1,171,816
% Change	**-10.40%**	**-10.90%**	**-4.50%**	**7.20%**	**5.60%**	**-8.90%**	**-9.40%**
Change	**-1,436**	**-3,298**	**-$134,008.80**	**$7.18**	**$0.13**	**-142,605**	**-121,271**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Demographics of Members Utilizing Prenatal Vitamins

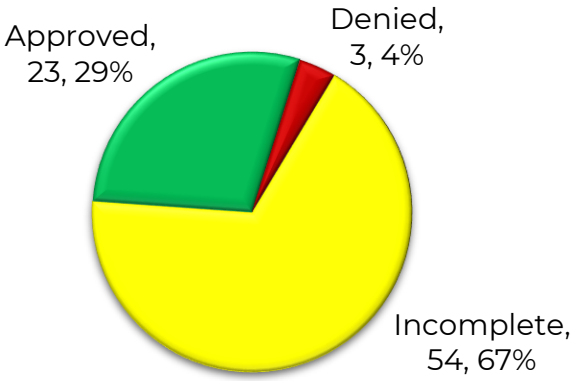


Top Prescriber Specialties of Prenatal Vitamins by Number of Claims



Prior Authorization of Prenatal Vitamins

There were 80 prior authorization requests submitted for prenatal vitamins during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.



Recommendations

The College of Pharmacy does not recommend any changes to the current prenatal vitamins prior authorization criteria at this time.

Utilization Details of Prenatal Vitamins: Fiscal Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
VITAFOL CAP ULTRA	7,557	3,200	$1,214,496.72	$160.71	2.36	42.32%
VITAFOL CHW GUMMIES	3,836	1,766	$487,855.40	$127.18	2.17	17.00%
PRENATAL TAB 27-1MG	2,391	1,523	$39,413.29	$16.48	1.57	1.37%
CITRANATAL CAP HARMONY	2,329	1,056	$393,886.19	$169.12	2.21	13.73%
FOLIVANE-OB CAP	1,540	966	$61,801.44	$40.13	1.59	2.15%
CONCEPT DHA CAP	1,276	813	$43,608.15	$34.18	1.57	1.52%
TARON-C DHA CAP	1,211	675	$39,771.76	$32.84	1.79	1.39%
CITRANATAL MIS 90 DHA	918	427	$103,707.71	$112.97	2.15	3.61%
VIRT-C DHA CAP	742	475	$24,569.72	$33.11	1.56	0.86%
CONCEPT OB CAP	660	448	$30,407.38	$46.07	1.47	1.06%
SE-NATAL 19 TAB	472	246	$12,267.90	$25.99	1.92	0.43%
VITAFOL-NANO TAB	458	224	$76,828.49	$167.75	2.04	2.68%
PRENATAL VIT TAB LOW IRON	424	264	$5,785.54	$13.65	1.61	0.20%
CITRANATAL MIS B-CALM	397	245	$45,830.65	$115.44	1.62	1.60%
CITRANATAL PAK DHA	360	185	$43,478.92	$120.77	1.95	1.52%
M-NATAL PLUS TAB	337	245	$5,426.82	$16.10	1.38	0.19%
CITRANATAL PAK ASSURE	308	122	$38,501.07	$125.00	2.52	1.34%
VITAFOL-OB TAB 65-1MG	268	159	$55,393.28	$206.69	1.69	1.93%
CITRANATAL TAB BLOOM	248	137	$47,831.79	$192.87	1.81	1.67%
VITAFOL-ONE CAP	196	98	$33,656.73	$171.72	2	1.17%
PROVIDA OB CAP	168	114	$8,823.17	$52.52	1.47	0.31%
VITAFOL-OB PAK +DHA	156	83	$20,625.00	$132.21	1.88	0.72%
SE-NATAL 19 CHW	131	78	$4,056.37	$30.96	1.68	0.14%
NIVA-PLUS TAB	120	66	$3,400.86	$28.34	1.82	0.12%
WESTAB PLUS TAB 27-1MG	105	98	$1,765.69	$16.82	1.07	0.06%
VITAFOL FE+ CAP	78	44	$14,749.98	$189.10	1.77	0.51%
COMPLETE NAT PAK DHA	61	38	$1,399.08	$22.94	1.61	0.05%
TRINATAL RX TAB 1	51	18	$911.32	$17.87	2.83	0.03%
CITRANATAL TAB RX	45	25	$5,989.79	$133.11	1.8	0.20%
COMPLETENATE CHW	30	23	$1,119.80	$37.33	1.3	0.04%
TRICARE TAB PRENATAL	24	17	$614.10	$25.59	1.41	0.02%
OB COMPLETE TAB	21	10	$616.32	$29.35	2.1	0.02%
VOL-PLUS TAB	20	17	$545.89	$27.29	1.18	0.02%
ELITE-OB TAB	10	6	$304.92	$30.49	1.67	0.01%
SELECT-OB+ PAK DHA	2	2	$210.66	$105.33	1	0.01%
VITAFOL FE+ CAP	1	1	$135.16	$135.16	1	0.00%
VIRT-PN PLUS CAP	1	1	$53.25	$53.25	1	0.00%
TOTAL	**26,952**	**12,306***	**$2,869,840.31**	**$106.48**	**2.19**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; CHW = chewable; DHA = omega-3 fatty acid; FE = iron; PNV = prenatal vitamin; TAB = tablet; VIT = vitamin
Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Fiscal Year 2021 Annual Review of Pulmonary Hypertension Medications

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

Adcirca® (Tadalafil) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension; and
2. Medical supervision by a pulmonary specialist or cardiologist; and
3. A patient-specific, clinically significant reason why the member cannot use generic sildenafil oral tablets must be provided; or
4. A clinical exception for use as initial combination therapy with Letairis® (ambrisentan) applies; and
5. A quantity limit of 60 tablets per 30 days will apply.

Adempas® (Riociguat) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension or chronic thromboembolic pulmonary hypertension (CTEPH); and
    a. Members with a diagnosis of pulmonary arterial hypertension must have previous failed trials of at least 1 medication in each of the following categories:
        i. Adcirca® (tadalafil) or Revatio® (sildenafil); and
        ii. Letairis® (ambrisentan) or Tracleer® (bosentan); and
    b. Members with a diagnosis of CTEPH must currently be on anticoagulation therapy; and
2. Medical supervision by a pulmonary specialist or cardiologist; and
3. Member must not be on any concurrent phosphodiesterase (PDE) inhibitor therapy; and
4. Member must not have a diagnosis of pulmonary hypertension associated with idiopathic interstitial pneumonias (PH-IIP); and
5. Female members and all health care professionals (prescribers and dispensing pharmacies) must be enrolled in the Adempas® REMS program; and
6. A quantity limit of 90 tablets per 30 days will apply.

Opsumit® (Macitentan) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension; and
2. Member must have previous failed trials of at least 1 medication in each of the following categories:
    a. Adcirca® (tadalafil) or Revatio® (sildenafil); and
    b. Letairis® (ambrisentan) or Tracleer® (bosentan); and
3. Medical supervision by a pulmonary specialist or cardiologist; and

4. Female members and all health care professionals (prescribers and dispensing pharmacies) must be enrolled in the Opsumit® REMS program; and
5. A quantity limit of 30 tablets per 30 days will apply.

Orenitram® (Treprostinil) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension; and
2. Member must have previous failed trials of at least 1 medication in each of the following categories:
   a. Adcirca® (tadalafil) or Revatio® (sildenafil); and
   b. Letairis® (ambrisentan) or Tracleer® (bosentan); and
3. Medical supervision by a pulmonary specialist or cardiologist; and
4. A quantity limit of 90 tablets per 30 days will apply.

Revatio® (Sildenafil Tablets) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension; and
2. Medical supervision by a pulmonary specialist or cardiologist; and
3. A quantity limit of 90 tablets per 30 days will apply.

Revatio® (Sildenafil Suspension) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension; and
2. Medical supervision by a pulmonary specialist or cardiologist; and
3. An age restriction will apply. The oral suspension formulation may be approvable for members 6 years of age and younger. Members 7 years of age and older must have a patient-specific, clinically significant reason why the member is not able to use the oral tablet formulation; and
4. A quantity limit of 224mL (2 bottles) per 30 days will apply.

Uptravi® (Selexipag) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension; and
2. Member must be 18 years of age or older; and
3. Member must have previous failed trials of at least 1 medication in each of the following categories (alone or in combination):
   a. Adcirca® (tadalafil), Adempas® (riociguat), or Revatio® (sildenafil); and
   b. Letairis® (ambrisentan) or Tracleer® (bosentan); and
   c. Orenitram® (treprostinil); and
4. Medical supervision by a pulmonary specialist and/or cardiologist; and
5. A quantity limit of 2 tablets daily will apply for all strengths with an upper dose limit of 1,600mcg twice daily.

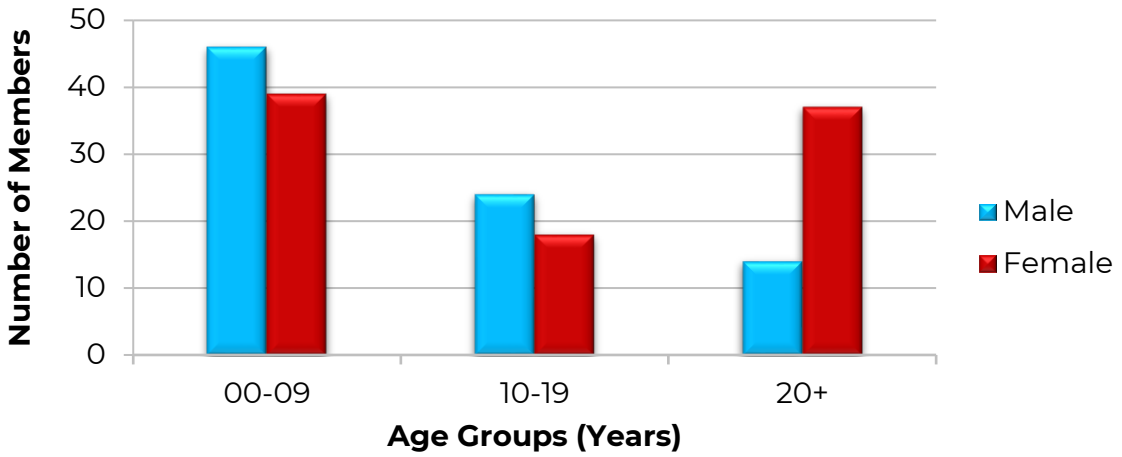
Utilization of Pulmonary Hypertension Medications: Fiscal Year 2021

Comparison of Fiscal Years

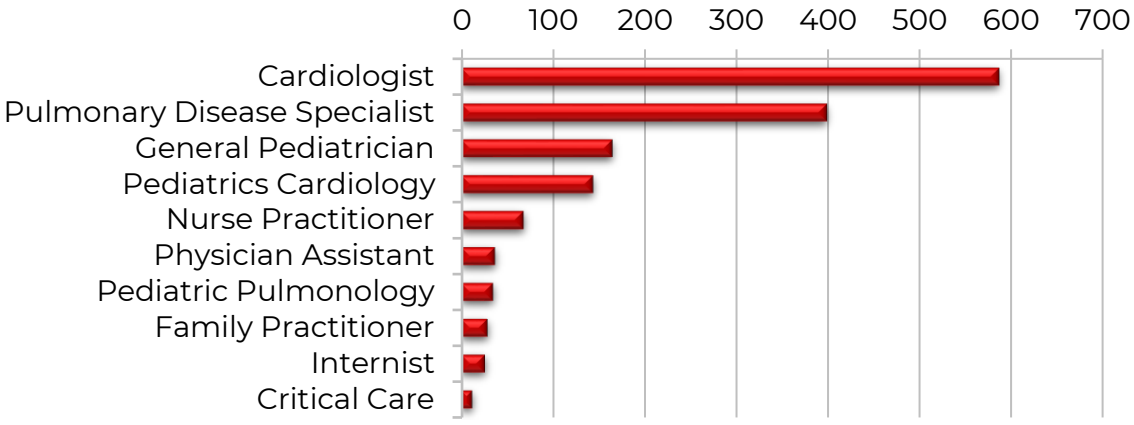
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	182	1,538	$8,243,847.08	$5,360.11	$175.56	112,754	46,958
2021	178	1,516	$7,386,679.16	$4,872.48	$157.07	114,819	47,029
% Change	**-2.20%**	**-1.40%**	**-10.40%**	**-9.10%**	**-10.50%**	**1.80%**	**0.20%**
Change	**-4**	**-22**	**-$857,167.92**	**-$487.63**	**-$18.49**	**2,065**	**71**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Demographics of Members Utilizing Pulmonary Hypertension Medications



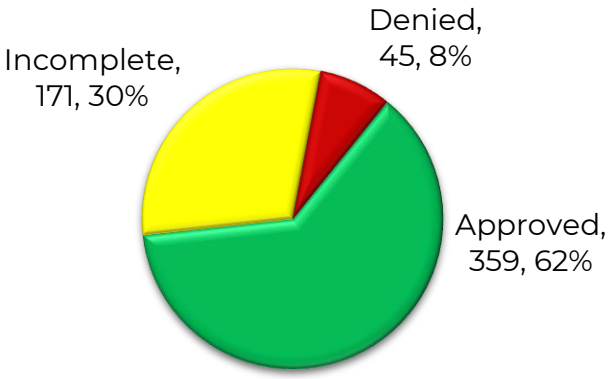
Top Prescriber Specialties of Pulmonary Hypertension Medications by Number of Claims



Prior Authorization of Pulmonary Hypertension Medications

There were 575 prior authorization requests submitted for pulmonary hypertension medications during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[19]

- Opsumit® (macitentan): April 2029
- Orenitram® (treprostinil): August 2031
- Letairis® (ambrisentan): October 2031
- Adempas® (riociguat): February 2034
- Uptravi® (selexipag): December 2036

New U.S. Food and Drug Administration (FDA) Approval(s):

- **July 2021:** The FDA approved a new intravenous (IV) formulation of Uptravi® (selexipag) for the treatment of pulmonary arterial hypertension in adult patients with World Health Organization (WHO) functional class II-III who are temporarily unable to take oral therapy. Approval of the IV formulation will potentially allow patients who are stable on Uptravi® therapy to avoid the need for treatment interruption or therapy changes when they are temporarily unable to take oral medications.[20]

[19] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 06/2022. Last accessed 06/17/2022.
[20] Janssen Pharmaceutical Companies. Uptravi® (Selexipag) Receives FDA Approval for Intravenous Use in Adult Patients with Pulmonary Arterial Hypertension (PAH). *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/uptravi-selexipag-receives-fda-approval-for-intravenous-use-in-adult-patients-with-pulmonary-arterial-hypertension-pah-301345104.html. Issued 07/30/2021. Last accessed 06/27/2022.

Recommendations

The College of Pharmacy does not recommend any changes to the current pulmonary hypertension medications prior authorization criteria at this time.

Utilization Details of Pulmonary Hypertension Medications: Fiscal Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
PHOSPHODIESTERASE-5 (PDE-5) INHIBITORS						
SILDENAFIL TAB 20MG	321	54	$5,713.39	$17.80	5.94	0.08%
TADALAFIL TAB 20MG	302	46	$12,244.45	$40.54	6.57	0.17%
SILDENAFIL SUS 10MG/ML	275	56	$625,865.46	$2,275.87	4.91	8.47%
ALYQ TAB 20MG+	17	2	$0.00	$0.00	8.5	0.00%
REVATIO SUS 10MG/ML	8	3	$79,121.90	$9,890.24	2.67	1.07%
SUBTOTAL	**923**	**161**	**$722,945.20**	**$783.26**	**6.15**	**9.79%**
ENDOTHELIN RECEPTOR ANTAGONISTS (ERA)						
TRACLEER TAB 32MG	117	21	$825,146.35	$7,052.53	5.57	11.16%
LETAIRIS TAB 10MG	112	17	$1,152,822.21	$10,293.06	6.59	15.61%
OPSUMIT TAB 10MG	66	10	$646,270.16	$9,791.97	6.6	8.75%
BOSENTAN TAB 62.5MG	56	5	$58,429.02	$1,043.38	11.2	0.79%
LETAIRIS TAB 5MG	17	6	$282,203.53	$16,600.21	2.83	3.82%
BOSENTAN TAB 125MG	14	2	$103,659.04	$7,404.22	7	1.40%
SUBTOTAL	**382**	**61**	**$3,068,530.31**	**$8,032.80**	**6.7**	**41.53%**
PROSTACYCLIN VASODILATORS						
TYVASO REFILL SOL 0.6MG/ML	24	5	$434,881.37	$18,120.06	4.8	5.89%
ORENITRAM TAB 1MG	21	6	$492,516.92	$23,453.19	3.5	6.67%
ORENITRAM TAB 5MG	21	5	$562,089.74	$26,766.18	4.2	7.61%
REMODULIN INJ 1MG/ML	15	1	$18,954.97	$1,263.66	15	0.26%
TREPROSTINIL INJ 5MG/ML	13	3	$200,649.23	$15,434.56	4.33	2.72%
UPTRAVI TAB 1400MCG	12	1	$224,764.16	$18,730.35	12	3.04%
UPTRAVI TAB 800MCG	11	1	$205,563.85	$18,687.62	11	2.78%
UPTRAVI TAB 1000MCG	10	1	$184,351.85	$18,435.19	10	3.19%
REMODULIN INJ 10MG/ML	10	3	$235,526.50	$23,552.65	3.33	2.50%
UPTRAVI TAB 1600MCG	9	3	$164,546.37	$18,282.93	3	2.23%
UPTRAVI TAB 400MCG	8	1	$149,553.08	$18,694.14	8	2.02%
ORENITRAM TAB 0.25MG	6	3	$15,662.91	$2,610.49	2	0.21%
UPTRAVI TAB 200MCG	5	3	$110,546.05	$22,109.21	1.67	1.50%
REMODULIN INJ 2.5MG/ML	4	1	$50,479.39	$12,619.85	4	0.68%
ORENITRAM TAB 0.125MG	4	3	$4,176.63	$1,044.16	1.33	0.06%
TYVASO START SOL 0.6MG/ML	3	3	$60,638.47	$20,212.82	1	0.82%
UPTRAVI TAB 200MCG/800MCG	3	3	$83,977.49	$27,992.50	1	1.14%
REMODULIN INJ 5MG/ML	3	1	$86,005.43	$28,668.48	3	1.16%
SUBTOTAL	**182**	**47**	**$3,284,884.41**	**$18,048.82**	**6.5**	**44.48%**
SOLUBLE GUANYLATE CYCLASE (sGC) STIMULATORS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ADEMPAS TAB 2.5MG	26	3	$290,933.76	$11,189.76	8.67	3.94%
ADEMPAS TAB 2MG	2	1	$8,416.00	$4,208.00	2	0.11%
ADEMPAS TAB 1.5MG	1	1	$10,969.48	$10,969.48	1	0.15%
SUBTOTAL	**29**	**5**	**$310,319.24**	**$10,700.66**	**7.25**	**4.20%**
TOTAL	**1,516**	**178***	**$7,386,679.16**	**$4,872.48**	**8.25**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
⁺Claims for Alyq™ in FY21 consist of claims for 2 members for which SoonerCare was not the primary payer; therefore, the reimbursed amount is not a true reflection of the cost of the medication for SoonerCare.
INJ = injection; SUS = suspension; TAB = tablet
Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Fiscal Year 2021 Annual Review of Qutenza® (Capsaicin 8% Patch)

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

Qutenza® (Capsaicin 8% Patch) Approval Criteria:

1. An FDA approved diagnosis of postherpetic neuralgia or diabetic peripheral neuropathy of the feet; and
2. Documented treatment attempts at recommended dosing or contraindication(s) to at least 1 agent from each of the following drug classes:
    a. For postherpetic neuralgia:
        i. Tricyclic antidepressants; and
        ii. Anticonvulsants; and
        iii. Topical lidocaine; or
    b. For diabetic peripheral neuropathy of the feet:
        i. Duloxetine or tricyclic antidepressants; and
        ii. Anticonvulsants; and
        iii. Topical lidocaine; and
3. Qutenza® must be administered by a health care provider; and
4. For a diagnosis of diabetic peripheral neuropathy of the feet, the prescriber must verify that they will examine the member's feet to detect skin lesions related to underlying neuropathy or vascular insufficiency prior to application of Qutenza®; and
5. Initial approvals will be for 1 treatment (for the duration of 90 days). For continuation, the prescriber must include information regarding improved response/effectiveness of this medication; and
6. A quantity limit of no more than 4 patches per treatment every 90 days will apply.

Utilization of Qutenza® (Capsaicin 8% Patch): Fiscal Year 2021

There was no SoonerCare utilization of Qutenza® (capsaicin 8% patch) during fiscal year 2021.

Prior Authorization of Qutenza® (Capsaicin 8% Patch)

There were 2 prior authorization requests submitted for Qutenza® (capsaicin 8% patch) for 1 unique member during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.

Status of Petitions

Market News and Updates[21]

Anticipated Patent Expiration(s):

- Qutenza® (capsaicin 8% patch): March 2030

Recommendations

The College of Pharmacy does not recommend any changes to the current Qutenza® (capsaicin 8% patch) prior authorization criteria at this time.

[21] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 05/2022. Last accessed 05/23/2022.

Fiscal Year 2020 Annual Review of Ravicti® (Glycerol Phenylbutyrate)

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

Ravicti® (Glycerol Phenylbutyrate) Approval Criteria:

1. An FDA approved diagnosis of urea cycle disorder (UCD); and
2. Active management with a protein restricted diet; and
3. A patient-specific, clinically significant reason why member cannot use Buphenyl® (sodium phenylbutyrate) must be provided.

Utilization of Ravicti® (Glycerol Phenylbutyrate): Fiscal Year 2021

Comparison of Fiscal Years

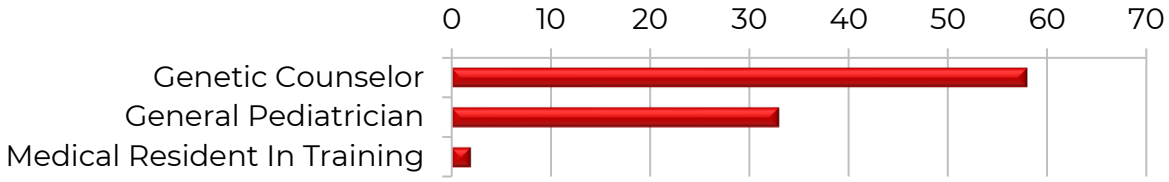
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	9	88	$2,456,664.28	$27,916.64	$914.96	12,525	2,685
2021	9	93	$2,352,593.13	$25,296.70	$881.78	11,450	2,668
% Change	**0%**	**5.70%**	**-4.20%**	**-9.40%**	**-3.60%**	**-8.60%**	**-0.60%**
Change	**0**	**5**	**$104,071.15**	**$2,619.94**	**-$33.18**	**-1,075**	**-17**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Demographics of Members Utilizing Ravicti® (Glycerol Phenylbutyrate)

- There were 9 unique pediatric members utilizing Ravicti® (glycerol phenylbutyrate) during fiscal year 2021; however, due to the limited number of members utilizing Ravicti® (glycerol phenylbutyrate), detailed demographic information could not be provided.

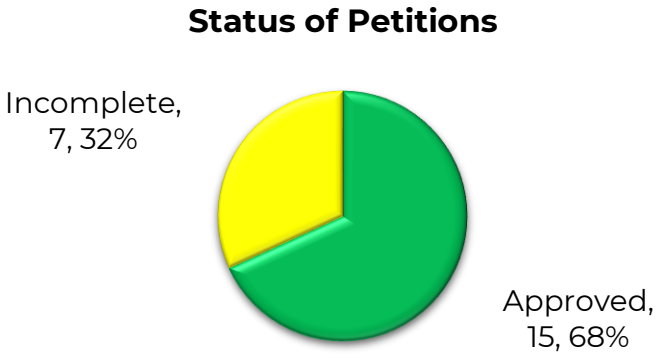
Top Prescriber Specialties of Ravicti® (Glycerol Phenylbutyrate) by Number of Claims



- Upon further research, all members utilizing Ravicti® (glycerol phenylbutyrate) during fiscal year 2021 were originally prescribed this medication by physicians specializing in medical or clinical genetics.

Prior Authorization of Ravicti® (Glycerol Phenylbutyrate)

There were 22 prior authorization requests submitted for 8 unique members for Ravicti® (glycerol phenylbutyrate) during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.



Market News and Updates

Anticipated Patent Expiration(s):[22]

- Ravicti® (glycerol phenylbutyrate): March 2032

Pipeline:

- **ACER-001:** Acer Therapeutics is developing ACER-001 for the treatment of urea cycle disorders (UCD). ACER-001 is a fully taste-masked, immediate release formulation of sodium phenylbutyrate developed using a microencapsulation process which was designed with the goal of improving patient compliance. Acer recently conducted a bioequivalence study comparing the pharmacokinetics of ACER-001 and found similar relative bioavailability to Buphenyl® (sodium phenylbutyrate) under fed conditions. The U.S. Food and Drug Administration (FDA) has accepted Acer's New Drug Application (NDA) under the Section 505(b)(2) regulatory pathway for ACER-001 for the treatment of UCD.[23]

Recommendations

The College of Pharmacy does not recommend any changes to the current Ravicti® (glycerol phenylbutyrate) prior authorization criteria at this time.

---

[22] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 06/2022. Last Accessed 06/14/2022.

[23] Acer Therapeutics, Inc. Acer Pipeline: ACER-001 for UCD. Available online at: https://www.acertx.com/rare-disease-research/acer-001-for-urea-cycle-disorders-ucds/. Last accessed 06/17/2022.

Utilization Details of Ravicti® (Glycerol Phenylbutyrate): Fiscal Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
RAVICTI LIQ 1.1GM/ML	93	9	$2,352,593.13	$25,296.70	10.33	100%
TOTAL	**93**	**9***	**$2,352,593.13**	**$25,296.70**	**10.33**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
LIQ = liquid
Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Fiscal Year 2021 Annual Review of Smoking Cessation Products

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

Smoking Cessation Products Coverage Criteria:

1. All nicotine replacement products (patches, gum, lozenges, and inhalers), Zyban® (bupropion), and Chantix® (varenicline) do not require prior authorization.
2. Chantix® (varenicline) may be used for up to 180 days per calendar year. Varenicline is not covered for members younger than 16 years of age.
3. Nicotine replacement patches have a quantity limit of 30 patches per 30 days.
4. Smoking cessation products do not count against the 6 prescription limit per month.
5. Smoking cessation products are available without a co-pay.

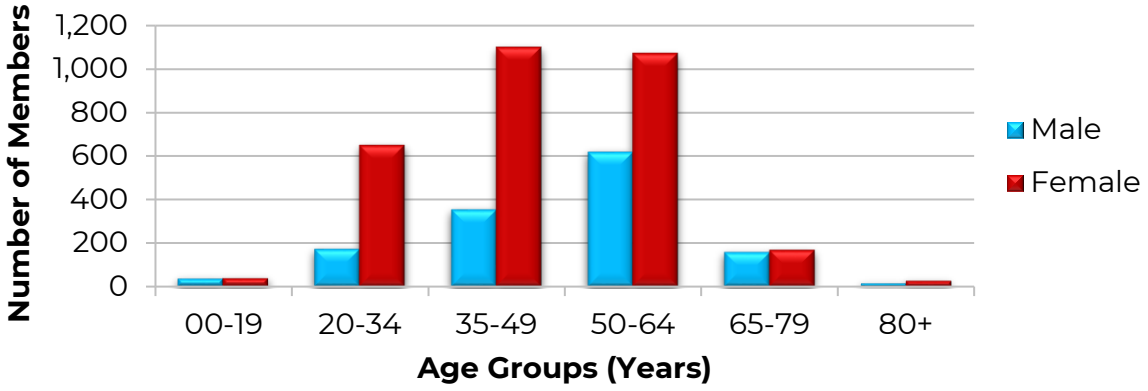
Utilization of Smoking Cessation Products: Fiscal Year 2021

Comparison of Fiscal Years

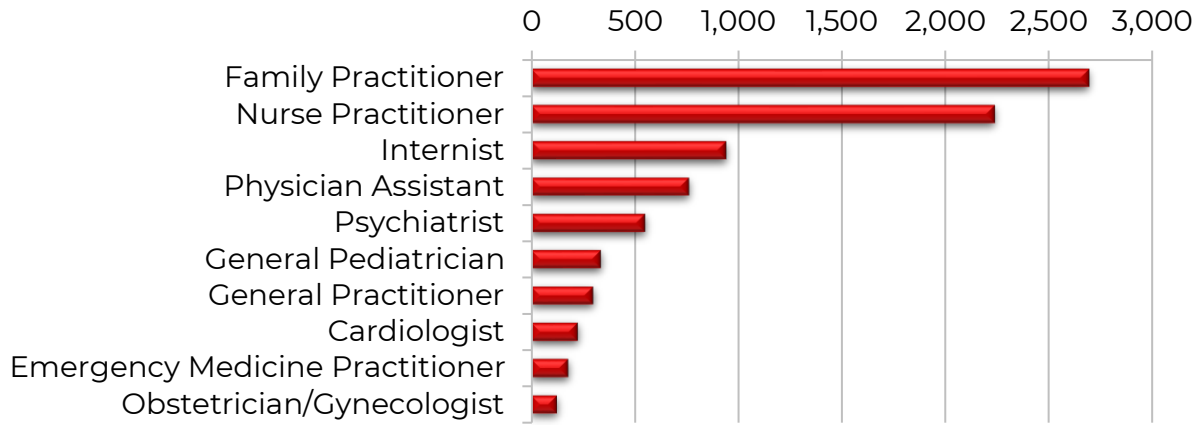
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	4,958	10,492	$2,337,875.93	$222.82	$9.10	519,470	256,858
2021	4,403	8,942	$2,069,747.30	$231.46	$9.33	460,397	221,879
% Change	**-11.20%**	**-14.80%**	**-11.50%**	**3.90%**	**2.50%**	**-11.40%**	**-13.60%**
Change	**-555**	**-1,550**	**-$268,128.63**	**$8.64**	**$0.23**	**-59,073**	**-34,979**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Demographics of Members Utilizing Smoking Cessation Products



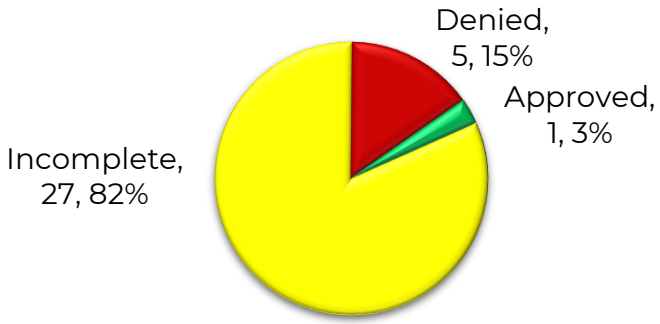
Top Prescriber Specialties of Smoking Cessation Products by Number of Claims



Prior Authorization of Smoking Cessation Products

There were 33 prior authorization requests submitted for smoking cessation products during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.

Status of Petitions



Market News and Updates

News:

- **July 2021:** Pfizer voluntarily recalled 2 lots of Chantix® 0.5mg tablets, 2 lots of Chantix® 1mg tablets, and 8 lots of Chantix® kit (0.5mg/1mg tablets) due to the presence of a nitrosamine, N-nitroso-varenicline, above the Pfizer established acceptable daily intake level. Long-term ingestion of N-nitroso-varenicline may be associated with a theoretical potential increased cancer risk in humans.[24]

[24] U.S. Food and Drug Administration (FDA). Recalls, Market Withdrawals, & Safety Alerts. Pfizer Issues a Voluntary Nationwide Recall for Twelve Lots of Chantix® (Varenicline) Tablets Due to N-Nitroso Varenicline Content. Available online at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/pfizer-issues-voluntary-nationwide-recall-twelve-lots-chantixr-varenicline-tablets-due-n-nitroso. Issued 07/19/2021. Last accessed 06/17/2022.

- **August 2021:** The U.S. Food and Drug Administration (FDA) approved the Abbreviated New Drug Application (ANDA) for the first generic version of Chantix® (varenicline), developed by Par Pharmaceutical. The generic is available in doses of 0.5mg and 1mg.[25]
- **September 2021:** Pfizer expanded its voluntary recall to include all lots of Chantix® 0.5mg and 1mg tablets due to the presence of unacceptable N-nitroso-varenicline levels. To lessen the impact to patients from a drug shortage due to this recall, FDA will allow certain manufacturers distributing varenicline tablets containing N-nitroso-varenicline above FDA's acceptable intake limit of 37ng per day, but below the interim acceptable intake limit of 185ng per day until the impurity can be eliminated or reduced to acceptable levels. The FDA temporarily exercised regulatory flexibility and discretion with respect to Apotex's distribution of Health Canada-approved apo-varenicline tablets in the United States containing N-nitroso-varenicline up to the FDA's interim acceptable intake limit in order to help maintain adequate varenicline supply.[26]
- **September 2021:** Endo International announced that one of its operating companies, Par Pharmaceutical, has begun shipping the generic version of Pfizer's Chantix® (varenicline), 0.5mg and 1mg tablets, following final approval from the FDA for its ANDA.[27]
- **May 2022:** The FDA's current assessment shows manufacturers can adequately supply the market with varenicline at or below the acceptable intake limit of N-nitroso-varenicline of 37ng per day. Any newly manufactured varenicline for the United States market should have levels of the N-nitroso-varenicline impurity at or below that limit.[28]

Recommendations

The College of Pharmacy does not recommend any changes to the current smoking cessation products prior authorization criteria at this time.

---

[25] Myshko D. FDA Approves Generic of Chantix, Pfizer's Smoking Cessation Drug. *Formulary Watch*. Available online at: https://www.formularywatch.com/view/fda-approves-generic-of-chantix-pfizer-s-smoking-cessation-drug. Issued 08/13/2021. Last accessed 06/17/2022.

[26] U.S. FDA. Drug Safety and Availability. FDA Updates and Press Announcements on Nitrosamine in Varenicline (Chantix®). Available online at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-nitrosamine-varenicline-chantix. Issued 09/17/2021. Last accessed 06/17/2022.

[27] Endo International. Endo Launches First and Only Generic Version of Chantix® (Varenicline) Tablets in the United States. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/endo-launches-first-and-only-generic-version-of-chantix-varenicline-tablets-in-the-united-states-301382946.html. Issued 09/22/2021. Last accessed 06/17/2022.

[28] U.S. FDA. Drug Safety and Availability. FDA Updates and Press Announcements on Nitrosamine in Varenicline (Chantix). Available online at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-nitrosamine-varenicline-chantix. Issued 05/05/2022. Last accessed 06/17/2022.

Utilization Details of Smoking Cessation Products: Fiscal Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
VARENICLINE PRODUCTS						
CHANTIX PAK 0.5MG & 1MG	1,858	1,621	$815,657.13	$439.00	1.15	39.41%
CHANTIX PAK 1MG	1,140	607	$499,990.72	$438.59	1.88	24.16%
CHANTIX TAB 1MG	975	483	$425,949.44	$436.87	2.02	20.58%
CHANTIX TAB 0.5MG	85	60	$33,774.21	$397.34	1.42	1.60%
SUBTOTAL	**4,058**	**2,771**	**$1,775,371.50**	**$437.50**	**1.46**	**85.75%**
NICOTINE REPLACEMENT PRODUCTS						
NICOTINE TD DIS 21MG/24H	1,708	1,162	$85,076.55	$49.81	1.47	4.11%
NICOTINE TD DIS 14MG/24H	1,010	714	$49,193.66	$48.71	1.41	2.38%
NICOTINE TD DIS 7MG/24HR	495	314	$21,879.67	$44.20	1.58	1.06%
NICOTINE POL LOZ 4MG MINT	218	60	$10,122.84	$46.44	3.63	0.49%
NICOTINE POL GUM 4MG	118	40	$4,902.15	$41.54	2.95	0.24%
NICOTINE POL GUM 4MG MINT	111	34	$5,116.38	$46.09	3.26	0.25%
NICOTINE POL GUM 4MG ORIG	109	41	$4,536.02	$41.61	2.66	0.22%
NICOTROL INH	95	72	$41,663.20	$438.56	1.32	2.01%
HM NICOTINE DIS 14MG/24H	67	35	$3,147.42	$46.98	1.91	0.15%
SM NICOTINE DIS 21MG/24H	58	48	$2,908.01	$50.14	1.21	0.14%
NICOTINE POL GUM 2MG	57	43	$2,133.94	$37.44	1.33	0.10%
NICOTINE POL LOZ 2MG MINT	56	31	$3,152.60	$56.30	1.81	0.15%
HM NICOTINE DIS 21MG/24H	50	31	$2,395.16	$47.90	1.61	0.12%
SM NICOTINE DIS 14MG/24H	41	40	$2,072.81	$50.56	1.03	0.10%
NICOTINE POL GUM 2MG MINT	39	19	$2,849.25	$73.06	2.05	0.14%
NICOTROL NS SPR 10MG/ML	39	12	$27,095.53	$694.76	3.25	1.31%
SM NICOTINE GUM 4MG MINT	35	14	$1,372.04	$39.20	2.5	0.07%
NICOTINE TD DIS STEP 1	33	17	$1,791.05	$54.27	1.94	0.09%
GNP NICOTINE DIS 21MG/24H	30	22	$1,454.76	$48.49	1.36	0.07%
NICOTINE POL GUM 2MG CINN	30	15	$1,032.20	$34.41	2	0.05%
HM NICOTINE LOZ 2MG MINT	29	7	$1,045.72	$36.06	4.14	0.05%
SM NICOTINE DIS 7MG/24HR	29	28	$1,279.01	$44.10	1.04	0.06%
SM NICOTINE LOZ 2MG MINT	27	14	$1,149.01	$42.56	1.93	0.06%
SM NICOTINE LOZ 4MG MINT	26	7	$1,138.66	$43.79	3.71	0.06%
NICOTINE LOZ 2MG MINT	24	10	$1,855.84	$77.33	2.4	0.09%
HM NICOTINE LOZ 4MG MINT	23	14	$1,352.70	$58.81	1.64	0.07%
HM NICOTINE GUM 2MG MINT	22	5	$782.98	$35.59	4.4	0.04%
NICOTINE POL GUM 2MG ORIG	19	14	$581.35	$30.60	1.36	0.03%
HM NICOTINE DIS 7MG/24HR	15	14	$633.46	$42.23	1.07	0.03%
SM NICOTINE GUM 4MG	14	4	$2,061.04	$147.22	3.5	0.10%
GNP NICOTINE DIS 14MG/24H	10	8	$473.35	$47.34	1.25	0.02%
NICOTINE LOZ 4MG MINT	9	5	$421.08	$46.79	1.8	0.02%
GNP NICOTINE GUM 4MG MINT	7	6	$195.19	$27.88	1.17	0.01%
HM NICOTINE GUM 4MG MINT	5	5	$385.09	$77.02	1	0.02%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
GNP NICOTINE LOZ MINI 2MG	5	2	$236.83	$47.37	2.5	0.01%
SM NICOTINE GUM 2MG MINT	4	4	$187.97	$46.99	1	0.01%
NICOTINE POL GUM 2MG FRUIT	3	3	$168.96	$56.32	1	0.01%
GNP NICOTINE GUM 4MG ORIG	3	3	$112.39	$37.46	1	0.01%
NICOTINE POL GUM 4MG CINN	3	2	$145.48	$48.49	1.5	0.01%
GNP NICOTINE DIS 7MG/24HR	3	3	$148.53	$49.51	1	0.01%
GNP NICOTINE LOZ 4MG MINT	3	3	$288.72	$96.24	1	0.01%
GNP NICOTINE GUM 2MG MINT	2	2	$164.99	$82.50	1	0.01%
SM NICOTINE GUM 2MG	2	2	$54.91	$27.46	1	0.00%
NICOTINE POL LOZ 4MG CHRY	1	1	$40.57	$40.57	1	0.00%
SM NICOTINE LOZ 4MG	1	1	$36.55	$36.55	1	0.00%
SM NICOTINE LOZ 2MG CHRY	1	1	$37.72	$37.72	1	0.00%
NICOTINE GUM 2MG	1	1	$21.75	$21.75	1	0.00%
NICOTINE TD DIS STEP 3	1	1	$67.21	$67.21	1	0.00%
SUBTOTAL	**4,691**	**2,934**	**$288,962.30**	**$61.60**	**1.6**	**13.99%**
BUPROPION PRODUCTS						
BUPROPION TAB 150MG	193	86	$5,413.50	$28.05	2.24	0.26%
SUBTOTAL	**193**	**86**	**$5,413.50**	**$28.05**	**2.24**	**0.26%**
TOTAL	**8,942**	**4,403***	**$2,069,747.30**	**$231.46**	**2.03**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CHRY = cherry; CINN = cinnamon; DIS = patch; INH = inhaler; LOZ = lozenge; NS = nasal spray; ORIG = original; SPR = spray; TAB = tablet
Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Fiscal Year 2021 Annual Review of Topical Antibiotic Products

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

Topical Antibiotic Products*	
Tier-1	**Tier-2**
gentamicin 0.1% cream (Garamycin®)	mupirocin 2% cream (Bactroban®)
gentamicin 0.1% ointment (Garamycin®)	mupirocin 2% kit (Centany®)
gentamicin powder	mupirocin 2% nasal ointment (Bactroban®)
mupirocin 2% ointment (Bactroban®)	ozenoxacin 1% cream (Xepi®)
neomycin/polymyxin B sulfates/ bacitracin zinc/HC 1% ointment (Cortisporin®)	retapamulin ointment 2% (Altabax®)
neomycin/polymyxin B sulfates/HC 0.5% cream (Cortisporin®)	

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
HC = hydrocortisone

Topical Antibiotic Products Tier-2 Approval Criteria:

1. A documented 5-day trial of a Tier-1 product within the last 30 days; or
2. Clinical exceptions apply for adverse effects with all Tier-1 products or for a unique indication not covered by Tier-1 products; and
3. Approvals will be for the duration of 10 days.

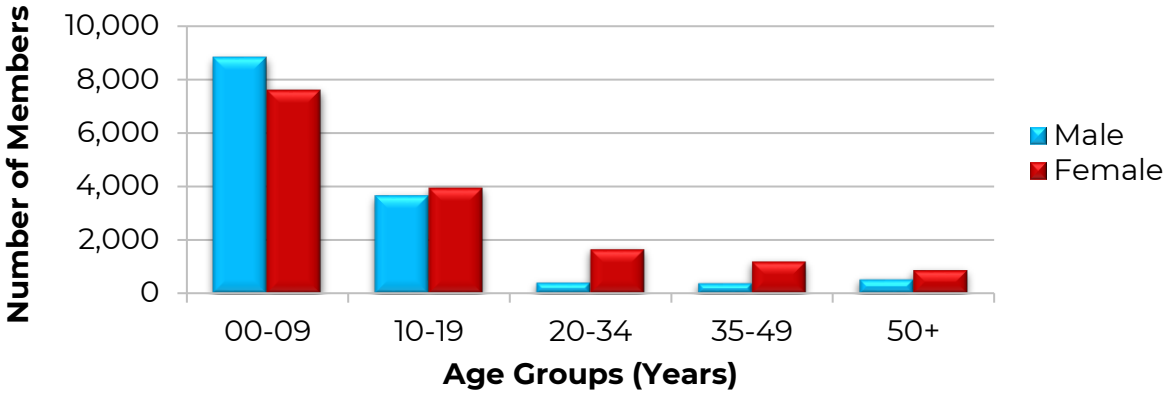
Utilization of Topical Antibiotic Products: Fiscal Year 2021

Comparison of Fiscal Years

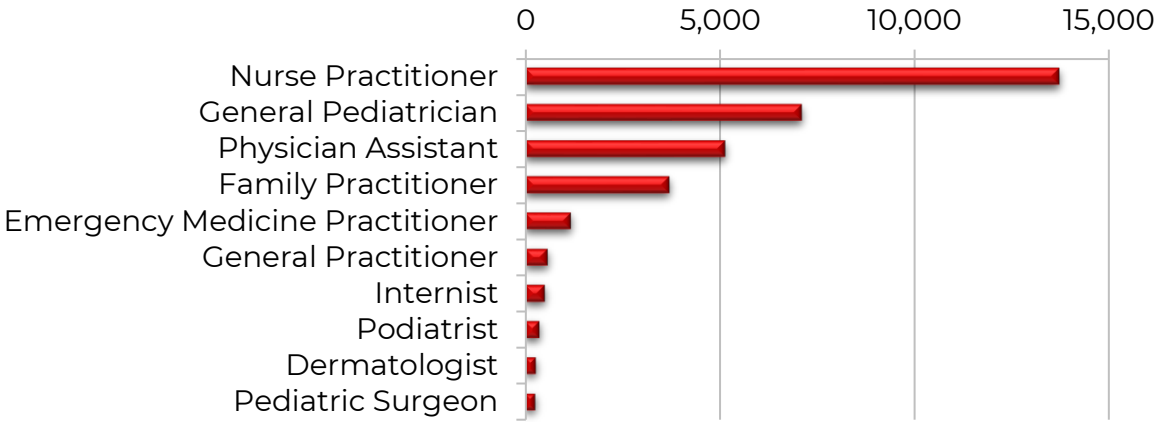
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	32,320	38,238	$626,655.03	$16.39	$1.54	967,063	406,947
2021	29,035	34,493	$560,118.38	$16.24	$1.46	938,238	383,231
% Change	**-10.20%**	**-9.80%**	**-10.60%**	**-0.90%**	**-5.20%**	**-3.00%**	**-5.80%**
Change	**-3,285**	**-3,745**	**-$66,536.65**	**-$0.15**	**-$0.08**	**-28,825**	**-23,716**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Demographics of Members Utilizing Topical Antibiotic Products



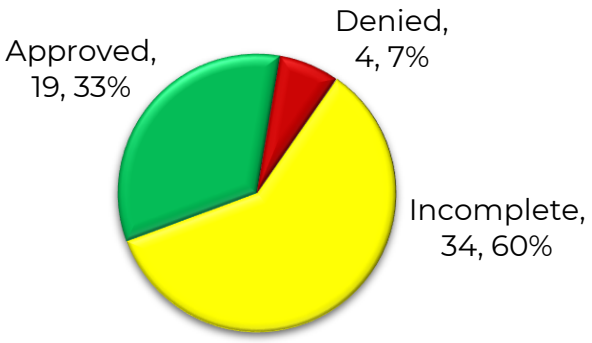
Top Prescriber Specialties of Topical Antibiotic Products by Number of Claims



Prior Authorization of Topical Antibiotic Products

There were 57 prior authorization requests submitted for topical antibiotic products during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[29]

- Altabax® (retapamulin 1% ointment): February 2027
- Xepi® (ozenoxacin 1% cream): January 2032

Recommendations

The College of Pharmacy does not recommend any changes to the topical antibiotic products Product Based Prior Authorization (PBPA) category at this time.

Utilization Details of Topical Antibiotic Products: Fiscal Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
TIER-1 PRODUCTS					
MUPIROCIN OIN 2%	34,069	28,868	$531,658.43	1.18	$15.61
GENTAMICIN OIN 0.1%	268	129	$16,939.82	2.08	$63.21
GENTAMICIN CRE 0.1%	149	72	$10,419.26	2.07	$69.93
TIER-1 SUBTOTAL	**34,486**	**29,069**	**$559,017.51**	**1.19**	**$16.21**
TIER-2 PRODUCTS					
MUPIROCIN CRE 2%	5	4	$1,068.21	1.25	$213.64
CENTANY OIN 2%	2	2	$32.66	1	$16.33
TIER-2 SUBTOTAL	**7**	**6**	**$1,100.87**	**1.17**	**$157.27**
TOTAL	**34,493**	**29,035***	**$560,118.38**	**1.19**	**$16.24**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CRE = cream; OIN = ointment
Fiscal Year 2021 = 07/01/2020 to 06/30/2021

[29] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 06/2022. Last accessed 06/16/2022.

Fiscal Year 2021 Annual Review of Topical Antifungal Products

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

Topical Antifungal Products		
Tier-1	**Tier-2**	**Special PA**
ciclopirox cream, suspension	butenafine (Mentax®)	efinaconazole (Jublia®)
clotrimazole (Rx) cream	ciclopirox solution, shampoo, gel (Penlac® and Loprox®)	tavaborole (Kerydin®)
clotrimazole (OTC)* cream	clotrimazole solution	
clotrimazole/betamethasone cream	clotrimazole/betamethasone lotion	
econazole cream	ketoconazole foam (Extina®)	
ketoconazole cream, shampoo	ketoconazole gel (Xolegel®)	
nystatin cream, ointment, powder	luliconazole cream (Luzu®)	
terbinafine (OTC)* cream	miconazole/zinc oxide/white petrolatum (Vusion®)	
tolnaftate (OTC)* cream	naftifine (Naftin®)	
	nystatin/triamcinolone cream, ointment	
	oxiconazole (Oxistat®)	
	salicylic acid (Bensal HP®)	
	sertaconazole nitrate (Ertaczo®)	
	sulconazole (Exelderm®)	

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*OTC antifungal medications are covered for pediatric members 0 to 20 years of age without prior authorization; OTC antifungal medications require a prescription to be covered at the pharmacy.
OTC = over-the-counter; PA = prior authorization; Rx = prescription

Topical Antifungal Products Tier-2 Approval Criteria:

1. Documented, recent trials with at least 2 Tier-1 topical antifungal products for at least 90 days each; and
2. When the same medication is available in Tier-1, a patient-specific, clinically significant reason must be provided for using a special dosage formulation of that medication in Tier-2 (e.g., foams, shampoos, spray, kit); and
3. Authorization of combination products nystatin/triamcinolone or clotrimazole/betamethasone lotion requires a patient-specific, clinically

significant reason why the member cannot use the individual components separately, or in the case of clotrimazole/betamethasone lotion, why the Tier-1 cream cannot be used; and

4. For treatment of onychomycosis, a trial of oral antifungals (6 weeks for fingernails and 12 weeks for toenails) will be required for consideration of approval of Penlac® (ciclopirox solution).

Jublia® (Efinaconazole) and Kerydin® (Tavaborole) Approval Criteria:

1. An FDA approved diagnosis of onychomycosis of the toenails due to *Trichophyton rubrum* or *Trichophyton mentagrophytes*; and
2. Member must have a documented trial of oral antifungals (12 weeks for toenails); and
3. A patient-specific, clinically significant reason why the member cannot use Penlac® (ciclopirox solution) must be provided; and
4. A clinically significant reason why the member requires treatment for onychomycosis must be provided (cosmetic reasons will not be approved).

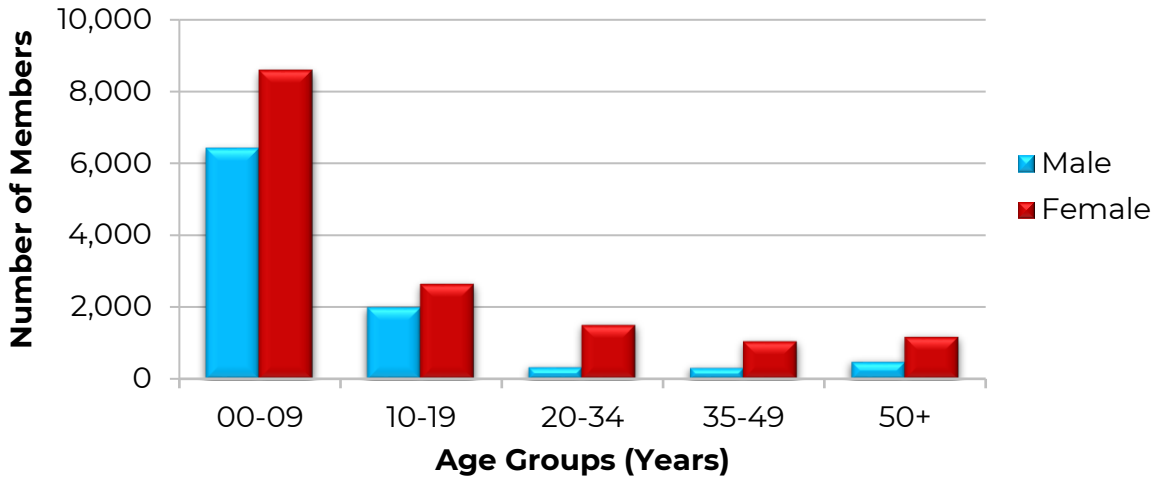
Utilization of Topical Antifungal Products: Fiscal Year 2021

Comparison of Fiscal Years

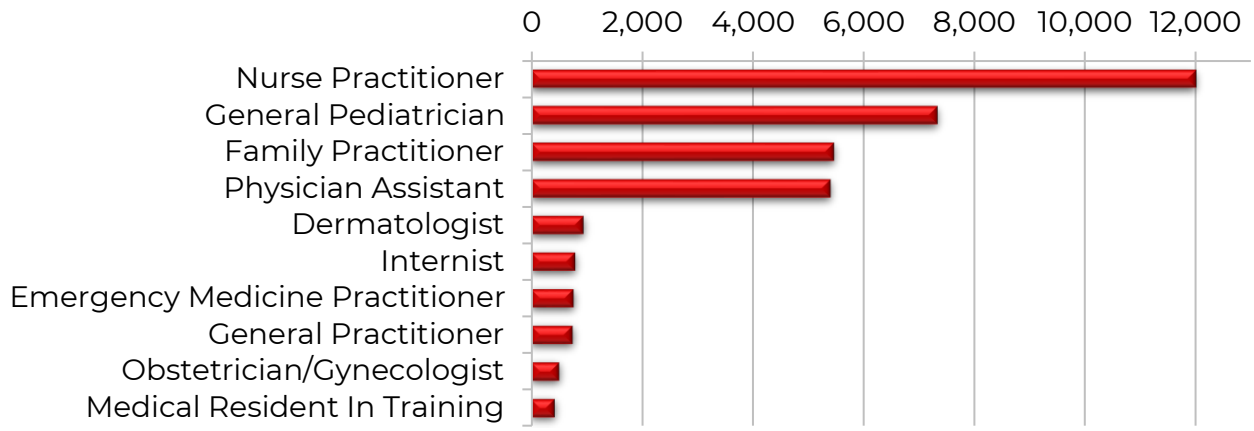
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	26,573	38,328	$802,430.65	$20.94	$1.31	1,613,343	612,650
2021	24,416	35,572	$696,227.32	$19.57	$1.17	1,561,129	596,118
% Change	**-8.10%**	**-7.20%**	**-13.20%**	**-6.50%**	**-10.70%**	**-3.20%**	**-2.70%**
Change	**-2,157**	**-2,756**	**-$106,203.33**	**-$1.37**	**-$0.14**	**-52,214**	**-16,532**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Demographics of Members Utilizing Topical Antifungal Products



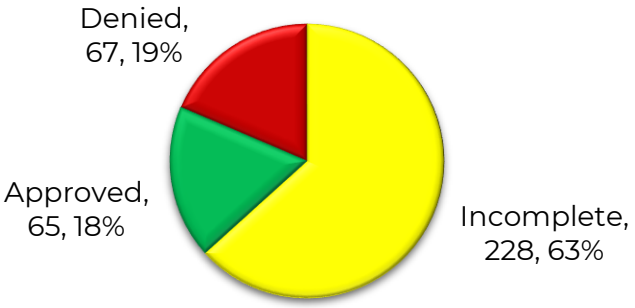
Top Prescriber Specialties of Topical Antifungal Products by Number of Claims



Prior Authorization of Topical Antifungal Products

There were 360 prior authorization requests submitted for topical antifungal products during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[30]

- Vusion® (miconazole/zinc oxide/white petrolatum ointment): March 2028
- Naftin® (naftifine 2% gel): January 2033
- Luzu® (luliconazole cream): April 2034
- Jublia® (efinaconazole solution): April 2035

[30] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 06/2022. Last accessed 06/27/2022.

Recommendations

The College of Pharmacy does not recommend any changes to the topical antifungal products Product Based Prior Authorization (PBPA) category at this time.

Utilization Details of Topical Antifungal Products: Fiscal Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 PRODUCTS						
NYSTATIN PRODUCTS						
NYSTATIN CRE 100000	10,117	7,868	$165,995.30	$16.41	1.29	23.84%
NYSTATIN OIN 100000	5,101	4,108	$97,104.79	$19.04	1.24	13.95%
NYSTOP POW 100000	1,838	1,248	$35,698.46	$19.42	1.47	5.13%
NYSTATIN POW 100000	993	599	$20,735.56	$20.88	1.66	2.98%
NYAMYC POW 100000	657	292	$12,910.83	$19.65	2.25	1.85%
SUBTOTAL	**18,706**	**14,115**	**$332,444.94**	**$17.77**	**1.33**	**47.75%**
KETOCONAZOLE PRODUCTS						
KETOCONAZOLE SHA 2%	4,670	2,734	$88,874.57	$19.03	1.71	12.77%
KETOCONAZOLE CRE 2%	4,252	3,447	$134,497.08	$31.63	1.23	19.32%
SUBTOTAL	**8,922**	**6,181**	**$223,371.65**	**$25.04**	**1.44**	**32.08%**
CLOTRIMAZOLE PRODUCTS						
CLOTRIMAZOLE CRE 1%	4,960	4,176	$80,352.30	$16.20	1.19	11.54%
ANTIFUNGAL CRE 1%	19	17	$223.87	$11.78	1.12	0.03%
ATHLETE'S FOOT CRE 1%	9	8	$116.84	$12.98	1.13	0.02%
SUBTOTAL	**4,988**	**4,201**	**$80,693.01**	**$16.18**	**1.19**	**11.59%**
CLOTRIMAZOLE/BETAMETHASONE PRODUCTS						
CLOTRIM/BETA DIPROP CRE 1-0.05%	1,460	1,178	$27,122.55	$18.58	1.24	3.90%
CLOTRIM/BETA CRE 1-0.05%	469	359	$9,114.36	$19.43	1.31	1.31%
SUBTOTAL	**1,929**	**1,537**	**$36,236.91**	**$18.79**	**1.26**	**5.20%**
TERBINAFINE PRODUCTS						
TERBINAFINE CRE 1%	375	341	$6,391.78	$17.04	1.1	0.92%
ATHLETE'S FOOT CRE 1%	31	30	$626.29	$20.20	1.03	0.09%
SUBTOTAL	**406**	**371**	**$7,018.07**	**$17.29**	**1.09**	**1.01%**
CICLOPIROX PRODUCTS						
CICLOPIROX CRE 0.77%	253	201	$4,627.41	$18.29	1.26	0.66%
CICLOPIROX SUS 0.77%	18	8	$788.65	$43.81	2.25	0.11%
SUBTOTAL	**271**	**209**	**$5,416.06**	**$19.99**	**1.3**	**0.78%**
ECONAZOLE PRODUCTS						
ECONAZOLE CRE 1%	245	187	$5,814.23	$23.73	1.31	0.84%
SUBTOTAL	**245**	**187**	**$5,814.23**	**$23.73**	**1.31**	**0.84%**
TOLNAFTATE PRODUCTS						
TOLNAFTATE CRE 1%	8	8	$100.13	$12.52	1	0.01%
ANTIFUNGAL CRE 1%	3	3	$31.03	$10.34	1	0.00%
SM ANTIFUNGAL CRE 1%	2	2	$27.61	$13.81	1	0.00%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**13**	**13**	**$158.77**	**$12.21**	**1**	**0.02%**
TIER-1 SUBTOTAL	**35,480**	**26,814**	**$691,153.64**	**$19.48**	**1.32**	**99.27%**
TIER-2 PRODUCTS						
CICLOPIROX PRODUCTS						
CICLOPIROX SOL 8%	18	6	$371.78	$20.65	3	0.05%
CICLOPIROX SHA 1%	12	6	$595.74	$49.65	2	0.09%
CICLOPIROX GEL 0.77%	5	2	$379.22	$75.84	2.5	0.05%
SUBTOTAL	**35**	**14**	**$1,346.74**	**$38.48**	**2.5**	**0.19%**
NYSTATIN/TRIAMCINOLONE PRODUCTS						
NYSTAT/TRIAM CRE 100000-1%	21	17	$637.05	$30.34	1.24	0.09%
NYSTAT/TRIAM OIN 100000-1%	7	3	$175.65	$25.09	2.33	0.03%
SUBTOTAL	**28**	**20**	**$812.70**	**$29.03**	**1.4**	**0.12%**
CLOTRIMAZOLE PRODUCTS						
CLOTRIMAZOLE SOL 1%	26	24	$1,314.85	$50.57	1.08	0.19%
SUBTOTAL	**26**	**24**	**$1,314.85**	**$50.57**	**1.08**	**0.19%**
NAFTIFINE PRODUCTS						
NAFTIFINE GEL 1%	1	1	$385.52	$385.52	1	0.06%
SUBTOTAL	**1**	**1**	**$385.52**	**$385.52**	**1**	**0.06%**
TIER-2 SUBTOTAL	**90**	**59**	**$3,859.81**	**$42.89**	**1.53**	**0.55%**
SPECIAL PA PRODUCTS						
EFINACONAZOLE PRODUCTS						
JUBLIA SOL 10%	2	1	$1,213.87	$606.94	2	0.17%
SUBTOTAL	**2**	**1**	**$1,213.87**	**$606.94**	**2**	**0.17%**
SPECIAL PA SUBTOTAL	**2**	**1**	**$1,213.87**	**$606.94**	**2**	**0.17%**
TOTAL	**35,572**	**24,416***	**$696,227.32**	**$19.57**	**1.46**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CLOTRIM/BETA = clotrimazole/betamethasone; CRE = cream; DIPROP = dipropionate; NYSTAT/TRIAM = nystatin/triamcinolone; OIN = ointment; PA = prior authorization; POW = powder; SHA = shampoo; SOL = solution; SUS = suspension
Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Fiscal Year 2021 Annual Review of Vasomotor Symptom Medications

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

Bijuva® (Estradiol/Progesterone Capsule) Approval Criteria:

1. An FDA approved indication for the treatment of moderate-to-severe vasomotor symptoms due to menopause in women with an intact uterus; and
2. A patient-specific, clinically significant reason why the member cannot use all other available estrogen/progestin products indicated for vasomotor symptoms of menopause must be provided; and
3. A quantity limit of 30 capsules (1 pack) per 30 days will apply.

Brisdelle® (Paroxetine Mesylate 7.5mg) Approval Criteria:

1. An FDA approved indication for the treatment of moderate-to-severe vasomotor symptoms associated with menopause; and
2. Approvals for Brisdelle® will not be granted for psychiatric indications; and
3. Members must not have any of the contraindications for use of Brisdelle®; and
4. Two previous trials with either a selective serotonin reuptake inhibitor (SSRI) or a selective serotonin norepinephrine reuptake inhibitor (SNRI) or both, or a patient-specific, clinically significant reason why a SSRI or SNRI is not appropriate for the member must be provided; and
5. Authorization requires a patient-specific, clinically significant reason why paroxetine 10mg is not appropriate for the member; and
6. A quantity limit of 30 capsules per 30 days will apply.

Duavee® (Conjugated Estrogens/Bazedoxifene) Approval Criteria:

1. An FDA approved indication for the treatment of moderate-to-severe vasomotor symptoms associated with menopause or for prevention of postmenopausal osteoporosis; and
2. Member must be a female with an intact uterus; and
3. For the treatment of moderate-to-severe vasomotor symptoms associated with menopause:
    a. Member must have at least 7 moderate-to-severe hot flushes per day or at least 50 per week prior to treatment; and
4. For the prevention of postmenopausal osteoporosis:
    a. A trial of Fosamax® (alendronate), Actonel® (risedronate), Boniva® (ibandronate), or Reclast® (zoledronic acid) used compliantly for at

least 6 months concomitantly with calcium and vitamin D, that failed to prevent fracture or improve bone mineral density (BMD) scores; or

b. Contraindication to, hypersensitivity to, or intolerable adverse effects with all bisphosphonates indicated for prevention of postmenopausal osteoporosis; and

5. Member must not have any of the contraindications for use of Duavee®; and
6. Members older than 65 years of age will generally not be approved without supporting information; and
7. Approvals will be for the duration of 6 months to ensure the need for continued therapy is reassessed periodically and the medication is being used for the shortest duration possible; and
8. A quantity limit of 30 tablets per 30 days will apply.

Elestrin® (Estradiol 0.06% Gel) Approval Criteria:

1. An FDA approved indication for the treatment of moderate-to-severe vasomotor symptoms due to menopause; and
2. Member must not have any contraindications for use of Elestrin®; and
3. A patient-specific, clinically significant reason why other topical estradiol formulations (e.g., Divigel®) are not appropriate for the member must be provided; and
4. Members older than 65 years of age will generally not be approved without supporting information; and
5. Approvals will be for the duration of 6 months to ensure the need for continued therapy is reassessed periodically and the medication is being used for the shortest duration possible; and
6. A quantity limit of 52 grams per 30 days will apply.

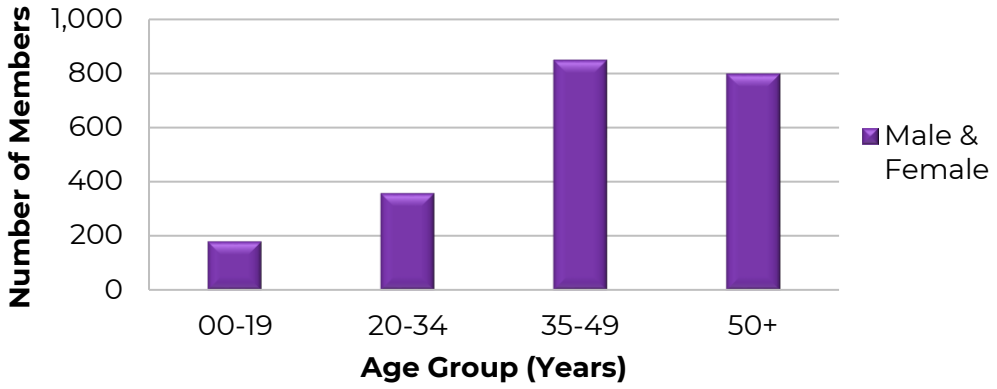
Utilization of Vasomotor Symptom Medications: Fiscal Year 2021

Comparison of Fiscal Years

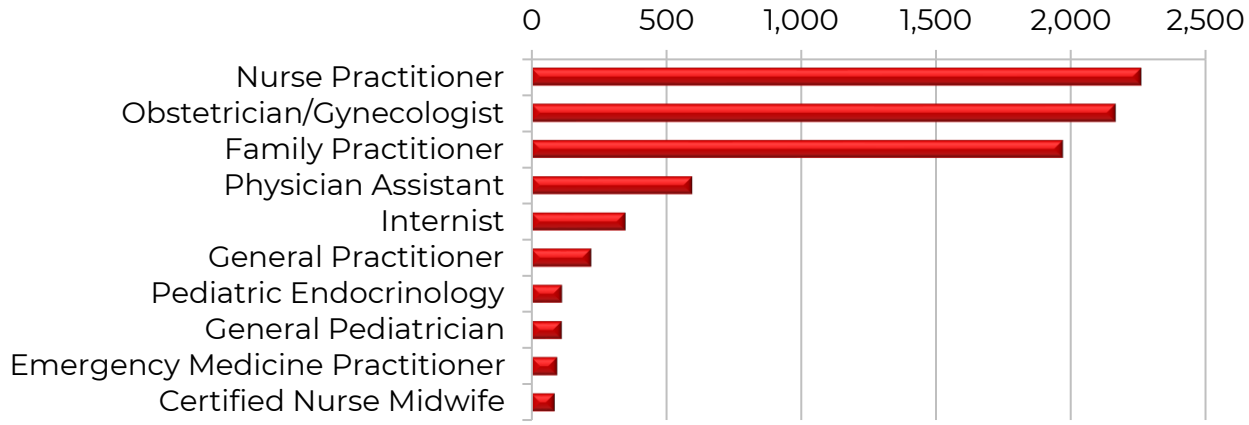
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	1,977	7,504	$712,408.24	$94.94	$2.10	310,791	338,907
2021	2,180	8,240	$734,757.09	$89.17	$2.00	340,762	368,054
% Change	**10.3%**	**9.8%**	**3.1%**	**-6.1%**	**-4.8%**	**9.6%**	**8.6%**
Change	**203**	**736**	**$22,348.85**	**-$5.77**	**-$0.10**	**29,971**	**29,147**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Demographics of Members Utilizing Vasomotor Symptom Medications



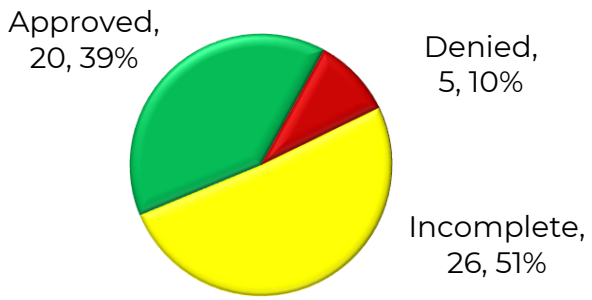
Top Prescriber Specialties of Vasomotor Symptom Medications by Number of Claims



Prior Authorization of Vasomotor Symptom Medications

There were 51 prior authorization requests submitted for vasomotor symptom medications during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[31]

- Evamist® (estradiol transdermal spray): July 2022
- Duavee® (conjugated estrogens/bazedoxifene tablet): March 2027
- Brisdelle® (paroxetine capsule): April 2029
- Minivelle® (estradiol transdermal system): July 2030
- Angeliq® (drospirenone/estradiol tablet): October 2031
- Bijuva® (estradiol/progesterone capsule): November 2032

Pipeline:

- **Elinzanetant:** Bayer started a Phase 3 trial for elinzanetant, a non-hormonal, dual neurokinin-1,3 receptor antagonist for the treatment of vasomotor symptoms during menopause. The transition into Phase 3 trials was based on positive results from 2 Phase 2 trials, RELENT-1 and SWITCH-1. RELENT-1 was a Phase 1b/2a trial investigating the safety, pharmacokinetics, and preliminary efficacy of elinzanetant. SWITCH-1 was a Phase 2b trial, which investigated the efficacy and safety of 4 different doses of elinzanetant compared to placebo in patients with vasomotor symptoms.[32]
- **Fezolinetant:** Astellas is currently investigating fezolinetant, an oral, non-hormonal compound for the treatment of moderate-to-severe vasomotor symptoms associated with menopause. Fezolinetant is a selective neurokinin-3 (NK3) receptor antagonist. Astellas has announced positive results from the Phase 3 SKYLIGHT 1 and SKYLIGHT 2 trials. Both trials met all 4 co-primary endpoints showing statistically significant reduction from baseline in the frequency and severity of moderate-to-severe vasomotor symptoms to week 4 and week 12 for women who received fezolinetant 30mg and 45mg once daily versus placebo. Detailed results will be submitted for publication and for consideration at upcoming medical meetings following the 52-week analyses.[33]

---

[31] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 05/2022. Last accessed 05/23/2022.

[32] Bayer Inc. Bayer Starts Phase III Clinical Development Program OASIS with Elinzanetant. Available online at: https://www.bayer.com/en/ca/bayer-starts-phase-iii-clinical-development-program-oasis-with-elinzanetant. Issued 10/07/2021. Last accessed 05/23/2022.

[33] Astellas Pharma, Inc. Astellas Announces Positive Topline Results from Two Phase 3 Pivotal Global Trials of Fezolinetant for the Nonhormonal Treatment of Vasomotor Symptoms in Postmenopausal Women. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/astellas-announces-positive-topline-results-from-two-phase-3-pivotal-global-trials-of-fezolinetant-for-the-nonhormonal-treatment-of-vasomotor-symptoms-in-postmenopausal-women-301231420.html. Issued 02/19/2021. Last accessed 05/23/2022.

Recommendations

The College of Pharmacy does not recommend any changes to the current vasomotor symptom medications prior authorization criteria at this time.

Utilization Details of Vasomotor Symptom Medications: Fiscal Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ORAL ESTROGEN PRODUCTS						
ESTRADIOL TAB 1MG	2,000	684	$26,150.00	$13.08	2.92	3.56%
ESTRADIOL TAB 2MG	1,783	481	$28,083.81	$15.75	3.71	3.82%
ESTRADIOL TAB 0.5MG	814	281	$10,507.91	$12.91	2.9	1.43%
PREMARIN TAB 0.625MG	497	125	$151,528.98	$304.89	3.98	20.62%
PREMARIN TAB 1.25MG	444	130	$146,244.37	$329.38	3.42	19.90%
PREMARIN TAB 0.3MG	214	62	$61,941.87	$289.45	3.45	8.43%
PREMARIN TAB 0.9MG	91	25	$24,196.07	$265.89	3.64	3.29%
PREMARIN TAB 0.45MG	50	18	$14,669.47	$293.39	2.78	2.00%
MENEST TAB 0.625MG	8	3	$1,871.20	$233.90	2.67	0.25%
MENEST TAB 0.3MG	1	1	$64.09	$64.09	1	0.01%
SUBTOTAL	**5,902**	**1,810**	**$465,257.77**	**$78.83**	**3.26**	**63.31%**
TOPICAL ESTROGEN PRODUCTS						
ESTRADIOL DIS 0.1MG	247	69	$14,034.03	$56.82	3.58	1.91%
ESTRADIOL DIS 0.1MG	245	56	$16,087.67	$65.66	4.38	2.19%
ESTRADIOL DIS 0.05MG	134	41	$7,266.71	$54.23	3.27	0.99%
ESTRADIOL DIS 0.025MG	134	41	$7,632.26	$56.96	3.27	1.04%
DOTTI DIS 0.1MG	125	36	$8,412.84	$67.30	3.47	1.14%
ESTRADIOL DIS 0.05MG	88	29	$5,634.48	$64.03	3.03	0.77%
ESTRADIOL DIS 0.025MG	65	21	$4,406.98	$67.80	3.1	0.60%
ESTRADIOL DIS 0.0375MG	61	14	$3,271.19	$53.63	4.36	0.45%
ESTRADIOL DIS 0.075MG	59	15	$3,368.53	$57.09	3.93	0.46%
ESTRADIOL DIS 0.0375MG	59	22	$3,868.02	$65.56	2.68	0.53%
DOTTI DIS 0.0375MG	48	13	$3,151.25	$65.65	3.69	0.43%
DIVIGEL GEL 1MG/GM	46	10	$6,793.86	$147.69	4.6	0.92%
DOTTI DIS 0.05MG	45	15	$2,716.05	$60.36	3	0.37%
ESTRADIOL DIS 0.075MG	40	13	$2,802.65	$70.07	3.08	0.38%
DOTTI DIS 0.025MG	34	12	$2,253.63	$66.28	2.83	0.31%
DOTTI DIS 0.075MG	31	10	$2,216.31	$71.49	3.1	0.30%
ESTRADIOL DIS 0.06MG	23	7	$1,123.60	$48.85	3.29	0.15%
DIVIGEL GEL 0.5MG	20	9	$2,465.74	$123.29	2.22	0.34%
DIVIGEL GEL 0.25MG	19	6	$2,785.01	$146.58	3.17	0.38%
EVAMIST SPR 1.53MG	12	3	$1,567.22	$130.60	4	0.21%
DIVIGEL GEL 1.25MG	2	1	$239.44	$119.72	2	0.03%
LYLLANA DIS 0.025MG	2	1	$130.68	$65.34	2	0.02%
DIVIGEL GEL 0.75MG	1	1	$156.33	$156.33	1	0.02%
SUBTOTAL	**1,540**	**445**	**$102,384.48**	**$66.48**	**3.46**	**13.94%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ORAL ESTROGEN/PROGESTIN PRODUCTS						
PREMPRO TAB 0.3-1.5MG	129	30	$31,387.48	$243.31	4.3	4.27%
PREMPRO TAB 0.625-2.5MG	125	29	$36,414.05	$291.31	4.31	4.96%
PREMPRO TAB 0.45-1.5MG	79	18	$19,786.54	$250.46	4.39	2.69%
ESTRA/NORETH TAB 1-0.5MG	56	24	$3,125.09	$55.81	2.33	0.43%
ESTRA/NORETH TAB 0.5-0.1MG	42	8	$2,603.45	$61.99	5.25	0.35%
PREMPRO TAB 0.625-5MG	36	9	$13,163.27	$365.65	4	1.79%
NORETH/ETHIN TAB 0.5-2.5MCG	11	2	$510.47	$46.41	5.5	0.07%
NORETH/ETHIN TAB 1MG-5MCG	8	3	$652.66	$81.58	2.67	0.09%
MIMVEY TAB 1-0.5MG	7	5	$716.56	$102.37	1.4	0.10%
BIJUVA CAP 1-100MG	6	1	$1,316.28	$219.38	6	0.18%
FYAVOLV TAB 1-5	5	2	$331.29	$66.26	2.5	0.05%
ANGELIQ TAB 0.25-0.5	4	3	$2,263.72	$565.93	1.33	0.31%
ANGELIQ TAB 0.5-1MG	3	2	$957.09	$319.03	1.5	0.13%
FYAVOLV TAB 0.5-2.5	1	1	$45.15	$45.15	1	0.01%
JINTELI TAB 1MG-5MCG	1	1	$100.93	$100.93	1	0.01%
PREMPHASE TAB 0.625-5MG	1	1	$588.06	$588.06	1	0.08%
SUBTOTAL	**514**	**139**	**$113,962.09**	**$221.72**	**3.70**	**15.52%**
INJECTABLE ESTROGEN PRODUCTS						
DEPO-ESTRADIOL INJ 5MG/ML	129	64	$16,855.02	$130.66	2.02	2.29%
ESTRADIOL VAL INJ 20MG/ML	29	12	$3,234.65	$111.54	2.42	0.44%
DELESTROGEN INJ 40MG/ML	5	4	$1,588.60	$317.72	1.25	0.22%
DELESTROGEN INJ 10MG/ML	1	1	$140.14	$140.14	1	0.02%
ESTRADIOL VAL INJ 200MG/5ML	1	1	$160.88	$160.88	1	0.02%
ESTRADIOL VAL INJ 40MG/ML	1	1	$171.55	$171.55	1	0.02%
SUBTOTAL	**166**	**83**	**$22,150.84**	**$133.44**	**2**	**3.01**
TOPICAL ESTROGEN/PROGESTIN PRODUCTS						
COMBIPATCH DIS 0.05-0.14MG/DAY	47	13	$10,073.30	$214.33	3.62	1.37%
CLIMARA PRO DIS 0.045-0.015MG/DAY	37	15	$8,173.61	$220.91	2.47	1.11%
COMBIPATCH DIS 0.05-0.25MG/DAY	17	6	$3,638.74	$214.04	2.83	0.50%
SUBTOTAL	**101**	**34**	**$21,885.65**	**$216.69**	**2.97**	**2.98%**
VAGINAL ESTROGEN PRODUCTS						
FEMRING MIS 0.1MG/24H	12	5	$6,725.10	$560.43	2.4	0.92%
FEMRING MIS 0.05MG/24H	4	2	$2,209.52	$552.38	2	0.30%
SUBTOTAL	**16**	**7**	**$8,934.62**	**$558.41**	**2.29**	**1.22%**
ORAL ESTROGEN/SERM PRODUCTS						
DUAVEE TAB 0.45-20MG	1	1	$181.64	$181.64	1	0.02%
SUBTOTAL	**1**	**1**	**$181.64**	**$181.64**	**1**	**0.02%**
TOTAL	**8,240**	**2,180**	**$734,757.09**	**$89.17**	**3.78**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
DIS = patch; ESTRA/NORETH = estradiol/norethindrone; INJ = injection; MIS = insert;
NORETH/ETHIN = norethindrone/ethinyl estradiol; SERM = selective estrogen receptor modulator;
SPR = spray; TAB = tablet; VAL = valerate
Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Fiscal Year 2021 Annual Review of Vesicular Monoamine Transporter 2 (VMAT2) Inhibitor Medications

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

Austedo® (Deutetrabenazine) Approval Criteria [Huntington's Disease Diagnosis]:

1. An FDA approved diagnosis of chorea associated with Huntington's disease; and
2. Austedo® must be prescribed by a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
3. A previous trial of Xenazine® (tetrabenazine) or a patient-specific, clinically significant reason why the member cannot use Xenazine® (tetrabenazine) must be provided; and
4. Member must not be actively suicidal or have uncontrolled depression and prescriber must verify member will be monitored for depression prior to starting Austedo® therapy and throughout treatment; and
5. Member must not have hepatic impairment; and
6. Member must not be taking monoamine oxidase inhibitors (MAOIs) or have taken an MAOI within the last 14 days; and
7. Member must not be taking reserpine or have taken reserpine within the last 20 days; and
8. Member must not use another vesicular monoamine transporter 2 (VMAT2) inhibitor (e.g., tetrabenazine, valbenazine) concurrently with Austedo®; and
9. For members requiring doses of Austedo® above 24mg per day, who are using Austedo® concomitantly with other medications that are known to prolong the QTc interval [antipsychotic medications (e.g., chlorpromazine, haloperidol, thioridazine, ziprasidone), antibiotics (e.g., moxifloxacin), Class 1A (e.g., quinidine, procainamide) and Class III (e.g., amiodarone, sotalol) antiarrhythmic medications, or any other medications known to prolong the QTc interval], the prescriber must agree to assess the QTc interval before and after increasing the dose of Austedo® or other medications that are known to prolong the QTc interval; and
10. The member must not have congenital long QT syndrome or a history of cardiac arrhythmias; and
11. The daily dose of Austedo® must not exceed 36mg per day if the member is taking strong CYP2D6 inhibitors (e.g., paroxetine, fluoxetine,

quinidine, bupropion) or if they are a known poor CYP2D6 metabolizer; and
12. Approvals will be for the duration of 6 months at which time the prescriber must document that the signs and symptoms of chorea have decreased and the member is not showing worsening signs of depression.

Austedo® (Deutetrabenazine) Approval Criteria [Tardive Dyskinesia Diagnosis]:

1. An FDA approved diagnosis of tardive dyskinesia meeting the following DSM-5 criteria:
    a. Involuntary athetoid or choreiform movements; and
    b. History of treatment with a dopamine receptor blocking agent (DRBA); and
    c. Symptom duration lasting longer than 4 to 8 weeks; and
2. Member must be 18 years of age or older; and
3. Austedo® must be prescribed by a neurologist or psychiatrist (or an advanced care practitioner with a supervising physician who is a neurologist or psychiatrist); and
4. Member must not be actively suicidal or have uncontrolled depression and prescriber must verify member will be monitored for depression prior to starting Austedo® therapy and throughout treatment; and
5. Member must not have hepatic impairment; and
6. Member must not be taking monoamine oxidase inhibitors (MAOIs) or have taken an MAOI within the last 14 days; and
7. Member must not be taking reserpine or have taken reserpine within the last 20 days; and
8. Member must not use another vesicular monoamine transporter 2 (VMAT2) inhibitor (e.g., tetrabenazine, valbenazine) concurrently with Austedo®; and
9. For members requiring doses of Austedo® above 24mg per day, who are using Austedo® concomitantly with other medications that are known to prolong the QTc interval [antipsychotic medications (e.g., chlorpromazine, haloperidol, thioridazine, ziprasidone), antibiotics (e.g., moxifloxacin), Class 1A (e.g., quinidine, procainamide) and Class III (e.g., amiodarone, sotalol) antiarrhythmic medications, or any other medications known to prolong the QTc interval], the prescriber must agree to assess the QTc interval before and after increasing the dose of Austedo® or other medications that are known to prolong the QTc interval; and
10. The member must not have congenital long QT syndrome or a history of cardiac arrhythmias; and
11. The daily dose of Austedo® must not exceed 36mg per day if the member is taking strong CYP2D6 inhibitors (e.g., paroxetine, fluoxetine,

quinidine, bupropion) or if they are a known poor CYP2D6 metabolizer; and
12. Female members must not be pregnant or breastfeeding; and
13. Prescriber must document a baseline evaluation using the Abnormal Involuntary Movement Scale (AIMS); and
14. Approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment as indicated by an improvement from baseline in the AIMS total score (a negative change in score indicates improvement) or documentation of a positive clinical response to therapy.

Ingrezza® (Valbenazine) Approval Criteria:

1. An FDA approved diagnosis of tardive dyskinesia meeting the following DSM-5 criteria:
    a. Involuntary athetoid or choreiform movements; and
    b. History of treatment with a dopamine receptor blocking agent (DRBA); and
    c. Symptom duration lasting longer than 4 to 8 weeks; and
2. Member must be 18 years of age or older; and
3. Ingrezza® must be prescribed by a neurologist or psychiatrist (or an advanced care practitioner with a supervising physician who is a neurologist or psychiatrist); and
4. The daily dose of Ingrezza® must not exceed 40mg per day if the member is taking strong CYP2D6 inhibitors (e.g., paroxetine, fluoxetine, quinidine); and
5. The daily dose of Ingrezza® must not exceed 40mg per day if the member is taking strong CYP3A4 inhibitors (e.g., itraconazole, ketoconazole, clarithromycin); and
6. Member must not be taking strong CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort); and
7. Member must not be taking monoamine oxidase inhibitors (MAOIs); and
8. Member must not be taking other vesicular monoamine transporter 2 (VMAT2) inhibitors (e.g., tetrabenazine, deutetrabenazine); and
9. The daily dose of Ingrezza® must not exceed 40mg per day for members with moderate or severe hepatic impairment (Child-Pugh score 7 to 15); and
10. The member must not have congenital long QT syndrome or a history of arrhythmias associated with a prolonged QT interval; and
11. Female members must not be pregnant or breastfeeding; and
12. Prescriber must agree to monitor digoxin concentration when co-administering Ingrezza® with digoxin; and
13. Prescriber must document a baseline evaluation using the Abnormal Involuntary Movement Scale (AIMS); and

14. A quantity limit of 1 capsule per day will apply; and
15. Approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment as indicated by an improvement from baseline in the AIMS total score (a negative change in score indicates improvement) or documentation of a positive clinical response to therapy.

Xenazine® (Tetrabenazine) Approval Criteria:

1. Diagnosis of 1 of the following:
    a. Chorea associated with Huntington's disease; or
    b. Tardive dyskinesia; or
    c. Tourette syndrome; and
2. Xenazine® must be prescribed by a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
3. Member must not be actively suicidal or have uncontrolled depression and prescriber must verify member will be monitored for depression prior to starting Xenazine® therapy and throughout treatment; and
4. Member must not have hepatic impairment; and
5. Member must not be taking monoamine oxidase inhibitors (MAOIs) or have taken an MAOI within the last 14 days; and
6. Member must not be taking reserpine or have taken reserpine within the last 20 days; and
7. Member must not use another vesicular monoamine transporter 2 (VMAT2) inhibitor (e.g., deutetrabenazine, valbenazine) concurrently with Xenazine®; and
8. Member must not be taking medications that are known to prolong the QTc interval concomitantly with Xenazine® [antipsychotic medications (e.g., chlorpromazine, haloperidol, thioridazine, ziprasidone), antibiotics (e.g., moxifloxacin), Class 1A (e.g., quinidine, procainamide) and Class III (e.g., amiodarone, sotalol) antiarrhythmic medications, or any other medications known to prolong the QTc interval]; and
9. Patients who require doses of tetrabenazine greater than 50mg per day must be tested and genotyped to determine if they are poor metabolizers (PMs), intermediate metabolizers (IMs), or extensive metabolizers (EMs) by their ability to express the drug metabolizing enzyme, CYP2D6. The following dose limits will apply based on patient metabolizer status:
    a. Extensive and Intermediate CYP2D6 Metabolizers: 100mg divided daily; or
    b. Poor CYP2D6 Metabolizers: 50mg divided daily; and
10. The daily dose of Xenazine® must not exceed 50mg per day if the member is taking strong CYP2D6 inhibitors (e.g., paroxetine, fluoxetine, quinidine, bupropion); and

11. Approvals will be for the duration of 6 months at which time the prescriber must document that the signs and symptoms of chorea, tardive dyskinesia, or Tourette syndrome have decreased, and the member is not showing worsening signs of depression.

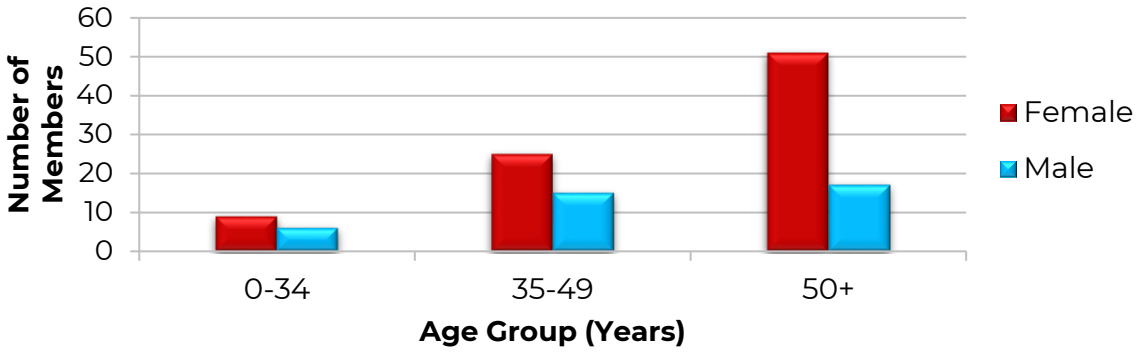
Utilization of VMAT2 Inhibitor Medications: Fiscal Year 2021

Comparison of Fiscal Years: Pharmacy Claims

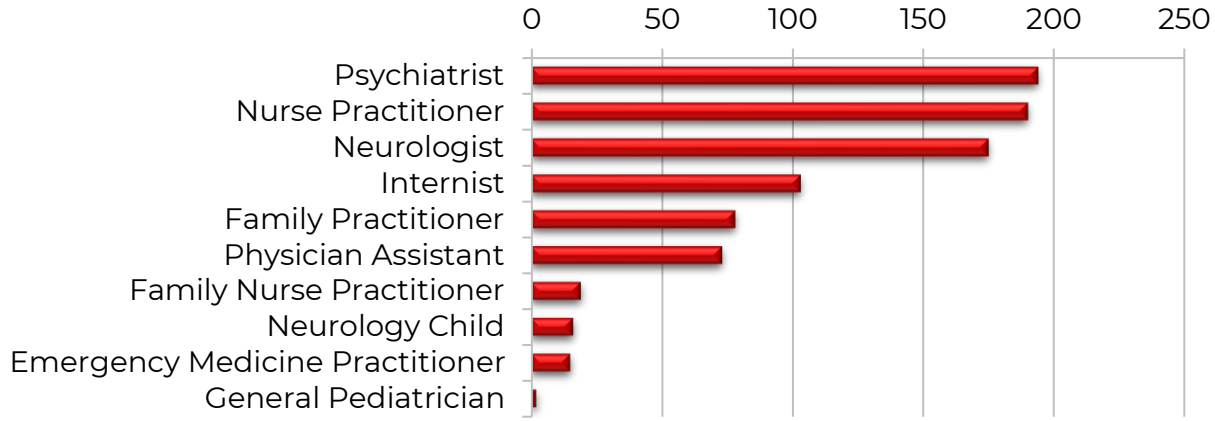
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	126	794	$5,044,769.01	$6,353.61	$215.53	36,256	23,406
2021	123	865	$5,936,007.35	$6,862.44	$230.04	43,670	25,804
% Change	**-2.40%**	**8.90%**	**17.70%**	**8.00%**	**6.70%**	**20.40%**	**10.20%**
Change	**-3**	**71**	**$891,238.34**	**$508.83**	**$14.51**	**7,414**	**2,398**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Demographics of Members Utilizing VMAT2 Inhibitor Medications



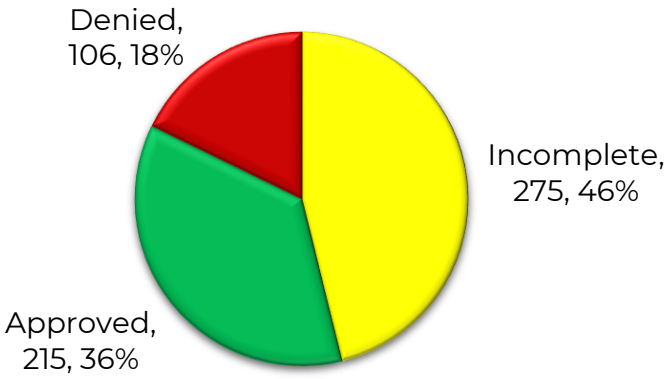
Top Prescriber Specialties of VMAT2 Inhibitor Medications by Number of Claims



Prior Authorization of VMAT2 Inhibitor Medications

There were 596 prior authorization requests submitted for VMAT2 inhibitor medications during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[34]

- Austedo® (deutetrabenazine): September 2038
- Ingrezza® (valbenazine): August 2039

News:

- **November 2021:** New pooled analysis from the KINECT clinical trial program and long-term extension trials found that long-term use of Ingrezza® (valbenazine) led to substantial and clinically meaningful improvements in patients 65 years of age and older with tardive dyskinesia (TD), some of the first TD-specific VMAT2 inhibitor data for this age group.[35]

Recommendations

The College of Pharmacy does not recommend any changes to the current VMAT2 inhibitor medications prior authorization criteria at this time.

---

[34] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 06/2022. Last accessed 06/27/2022.

[35] Neurocrine Biosciences, Inc. Neurocrine Biosciences Presents New Ingrezza® (Valbenazine) Data at Psych Congress 2021. *BioSpace.* Available online at: https://www.biospace.com/article/releases/neurocrine-biosciences-presents-new-ingrezza-valbenazine-data-at-psych-congress-2021/. Issued 11/01/2021. Last accessed 06/27/2022.

Utilization Details of VMAT2 Inhibitor Medications: Fiscal Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
VALBENAZINE PRODUCTS					
INGREZZA CAP 80MG	271	48	$1,871,006.01	$230.56	$6,904.08
INGREZZA CAP 40MG	170	36	$1,058,268.56	$210.52	$6,225.11
INGREZZA CAP 40-80MG	3	3	$21,155.73	$251.85	$7,051.91
SUBTOTAL	**444**	**87**	**$2,950,430.30**	**$223.08**	**$6,645.11**
DEUTETRABENAZINE PRODUCTS					
AUSTEDO TAB 12MG	202	32	$1,447,546.37	$243.53	$7,166.07
AUSTEDO TAB 9MG	97	16	$523,666.98	$175.14	$5,398.63
AUSTEDO TAB 6MG	56	17	$209,090.32	$126.19	$3,733.76
SUBTOTAL	**355**	**65**	**$2,180,303.67**	**$205.86**	**$6,141.70**
TETRABENAZINE PRODUCTS					
XENAZINE TAB 25MG	24	3	$612,596.98	$850.83	$25,524.87
TETRABENAZINE TAB 25MG	16	2	$25,287.77	$52.68	$1,580.49
XENAZINE TAB 12.5MG	13	1	$159,263.64	$408.37	$12,251.05
TETRABENAZINE TAB 12.5MG	13	3	$8,124.99	$20.47	$625.00
SUBTOTAL	**66**	**9**	**$805,273.38**	**$405.27**	**$12,201.11**
TOTAL	**865**	**123***	**$5,936,007.35**	**$230.04**	**$6,862.44**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; TAB = tablet
Fiscal Year 2021 = 07/01/2020 to 06/30/2021