

State Fiscal Year 2023 Print Annual Reviews Quarter 4

Count	Category/Medication
1.	Acute Opioid Overdose Reversal Medications
2.	Anti-Emetic Medications
3.	Butalbital Medications
4.	Gout Medications
5.	H.P. Acthar® Gel (Repository Corticotropin Injection)
6.	Heart Failure Medications
7.	Idiopathic Pulmonary Fibrosis (IPF) Medications
8.	Insomnia Medications
9.	Leukotriene Modulators
10.	Muscle Relaxant Medications
11.	Non-Steroidal Anti-Inflammatory Drugs (NSAIDs; Systemic)
12.	Nuedexta® (Dextromethorphan/Quinidine)
13.	Ophthalmic Allergy Medications
14.	Qutenza® (Capsaicin 8% Patch)
15.	Ryplazim® (Plasminogen, Human-tvmh)
16.	Smoking Cessation Products
17.	Sylvant® (Siltuximab)
18.	Topical Antibiotic Products
19.	Topical Antifungal Products

Fiscal Year 2023 = July 1, 2022 – June 30, 2023

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 2023 Annual Review of Acute Opioid Overdose Reversal Medications

Oklahoma Health Care Authority
Fiscal Year 2023 Print Report

Current Prior Authorization Criteria

Acute opioid overdose reversal medications, including naloxone injection, naloxone nasal spray, and Opvee® (nalmefene nasal spray) are currently covered without prior authorization.

Utilization of Acute Opioid Overdose Reversal Medications: Fiscal Year 2023

Comparison of Fiscal Years

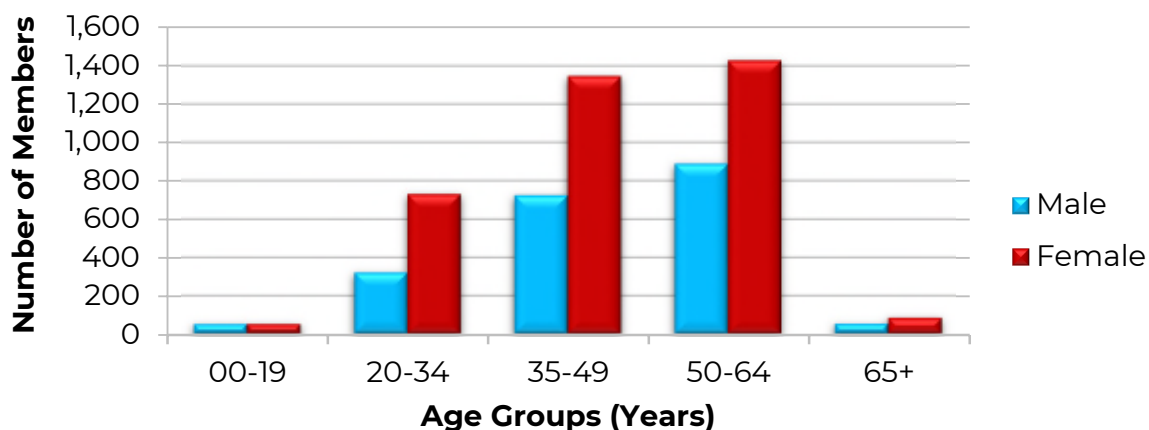
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2022	4,063	4,352	\$510,307.04	\$117.26	\$3.87	8,680	131,924
2023	5,667	6,155	\$545,986.42	\$88.71	\$2.89	12,247	189,155
% Change	39.5%	41.4%	7.0%	-24.3%	-25.3%	41.1%	43.4%
Change	1,604	1,803	\$35,679.38	\$28.55	\$0.98	3,567	57,231

Costs do not reflect rebated prices or net costs.

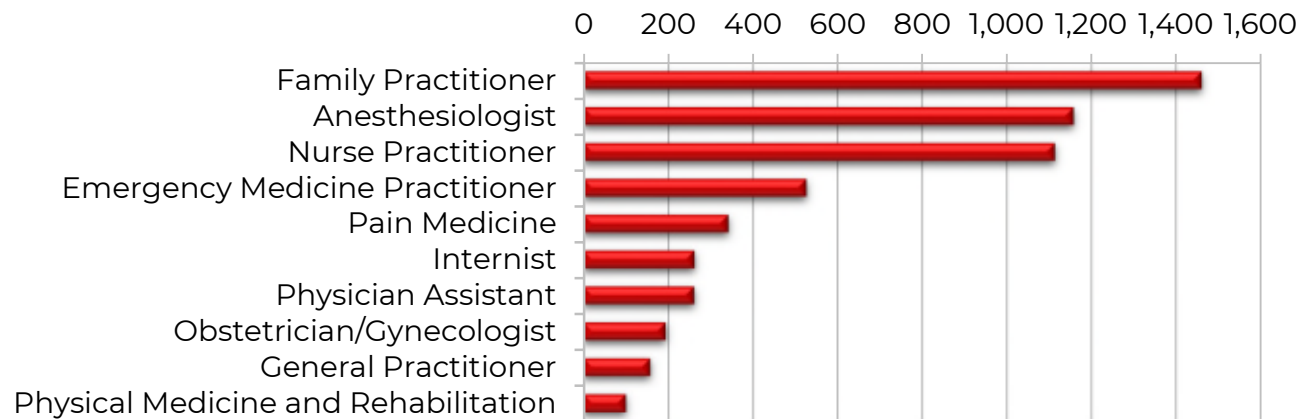
*Total number of unduplicated utilizing members.

Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Demographics of Members Utilizing Acute Opioid Overdose Reversal Medications



Top Prescriber Specialties of Acute Opioid Overdose Reversal Medications by Number of Claims



Prior Authorization of Acute Opioid Overdose Reversal Medications

There were 4 prior authorization requests submitted for acute opioid overdose reversal medications during fiscal year 2023. All 4 prior authorization requests were deemed incomplete, as these medications currently do not require prior authorization.

Market News and Updates^{1,2,3,4,5,6,7,8,9,10,11}

Anticipated Patent Expiration(s):

- Kloxxado[®] (naloxone nasal spray): August 2034
- Narcan[®] (naloxone nasal spray): March 2035
- Opvee[®] (nalmefene nasal spray): July 2038

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

- **March 2023:** The FDA approved brand name Narcan[®] (naloxone nasal spray) for over-the-counter (OTC) use. This OTC product will only be available in a 4mg dose.
- **May 2023:** The FDA approved Opvee[®] (nalmefene nasal spray) for the acute treatment of opioid overdose in adults and pediatric patients 12 years of age and older. Opvee[®] is an opioid receptor antagonist that has been demonstrated to be longer acting than naloxone products in pharmacodynamic studies, with an observed half-life of around 11 hours compared to 2 hours for naloxone. Adverse reactions seen in healthy volunteers were similar to those reported in those taking naloxone including body aches, diarrhea, and nausea.
- **July 2023:** The FDA approved the first generic naloxone nasal spray product for OTC use, which is manufactured by Padagis. The product

will be available as a 4mg nasal spray and will be available for sale in stores and online.

- **July 2023:** The FDA approved RiVive™ (naloxone nasal spray) as an OTC product. RiVive™ is available as a 3mg nasal spray with 2 single-dose applicators. The manufacturer, Harm Reduction Therapeutics, has focused distribution to organizations that focus on harm reduction efforts, including public safety departments and state governments.
- **April 2024:** An OTC generic naloxone nasal spray product manufactured by Amneal Pharmaceuticals was approved by the FDA. The product will be available in a 4mg dose and sold at commercial locations and to government organizations for use in the community.

News:

- **November 2020:** Drug manufacturer Kaleo announced the discontinuation of Evzio® (naloxone auto-injector) from the market following government action on its pricing practices and provider engagement strategies.
- **November 2023:** The FDA accepted a New Drug Application (NDA) for a high-dose naloxone formulation, OX124. Results from the Phase 3 clinical study demonstrated that OX124 provided a faster and better absorbed delivery of naloxone than injected agents. OX124 is formulated as a powder for nasal administration. The Prescription Drug User Fee Act (PDUFA) date is set for July 15, 2024, with potential availability starting in late 2024.

Recommendations

The College of Pharmacy does not recommend any changes to the current acute opioid overdose reversal medications coverage criteria at this time.

Utilization Details of Acute Opioid Overdose Reversal Medications: Fiscal Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/CLAIM	CLAIMS/MEMBER	% COST
NALOXONE HCL SPR 4MG	4,635	4,311	\$394,137.39	\$85.04	1.08	72.19%
NALOXONE SPR 4MG	1,172	1,140	\$109,583.64	\$93.50	1.03	20.07%
NARCAN SPR 4MG	311	304	\$40,214.52	\$129.31	1.02	7.37%
NALOXONE INJ 0.4MG/ML	16	15	\$328.21	\$20.51	1.07	0.06%
NALOXONE INJ 2MG/ML PFS	9	9	\$505.66	\$56.18	1	0.09%
NALOXONE INJ 1MG/ML PFS	6	6	\$430.26	\$71.71	1	0.08%
KLOXXADO SPR 8MG	6	6	\$786.74	\$131.12	1	0.14%
TOTAL	6,155	5,667*	\$545,986.42	\$88.71	1.09	100%

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated utilizing members.

HCL = hydrochloride; INJ = injection; PFS = prefilled syringe; SPR = spray

Fiscal Year 2023 = 07/01/2022 to 06/30/2023

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 06/2024. Last accessed 06/04/2024.

² Evzio® Naloxone Auto-Injectors Discontinued. Mitchell International. Available online at: <https://www.mitchell.com/insights/news-release/pharmacy-benefit-management/evzio-naloxone-auto-injectors-discontinued>. Issued 11/04/2020. Last accessed 06/18/2024.

³ United States Office of Public Affairs. Kaleo Inc. Agrees to Pay \$12.7 Million to Resolve Allegations of False Claims for Anti-Overdose Drug. Available online at: <https://www.justice.gov/opa/pr/kal-o-inc-agrees-pay-127-million-resolve-allegations-false-claims-anti-overdose-drug>. Issued 11/09/2021. Last accessed 06/18/2024.

⁴ U.S. FDA. FDA Approves First Over-the-Counter Naloxone Nasal Spray. Available online at: <https://www.fda.gov/news-events/press-announcements/fda-approves-first-over-counter-naloxone-nasal-spray>. Issued 03/29/2023. Last accessed 06/13/2024.

⁵ Harris E. FDA Approves Nalmefene, a Longer-Lasting Opioid Reversal Nasal Spray. *JAMA* 2023; 329(23): 2012. doi: 10.1001/jama.2023.9608.

⁶ Park B. First Generic Nonprescription Naloxone Nasal Spray Now Available. *Medical Professionals Reference*. Available online at: <https://www.empr.com/home/news/first-generic-nonprescription-naloxone-nasal-spray-now-available/>. Issued 08/09/2023. Last accessed 06/14/2024.

⁷ Harm Reduction Therapeutics, Inc. FDA Approval of RiVive™ is a Critical Milestone in Making Emergency Treatment of Opioid Overdose More Widely Available. Available online at: https://www.harmreductiontherapeutics.org/wp-content/uploads/2023/08/HRT-RiVive-Press-Release-July-28-2023-FINAL_DATED.pdf. Issued 07/28/2023. Last accessed 06/13/2024.

⁸ Orexo. Orexo Announces Positive Results from Pivotal Trial for its Leading Pharmaceutical Pipeline Asset OX124. *PR Newswire*. Available online at: <https://www.prnewswire.com/news-releases/orexo-announces-positive-results-from-pivotal-trial-for-its-leading-pharmaceutical-pipeline-asset-ox124-301425001.html>. Issued 11/16/2021. Last accessed 06/14/2024.

⁹ Orexo. Orexo Submits New Drug Application to FDA for OX124, a High-Dose Rescue Medication for Opioid Overdose. *PR Newswire*. Available online at: <https://www.prnewswire.com/news-releases/orexo-submits-new-drug-application-to-fda-for-ox124-a-high-dose-rescue-medication-for-opioid-overdose-301738186.html>. Issued 02/03/2023. Last accessed 06/14/2024.

¹⁰ U.S. FDA. FDA Approves Second Over-the-Counter Naloxone Nasal Spray Product. Available online at: <https://www.fda.gov/news-events/press-announcements/fda-approves-second-over-counter-naloxone-nasal-spray-product>. Issued 07/28/2023. Last accessed 06/13/2024.

¹¹ Amneal Pharmaceuticals, Inc. Amneal Announces U.S. FDA Approval of Over-the-Counter Naloxone Hydrochloride Nasal Spray for Emergency Treatment of an Opioid Overdose. Available online at: <https://investors.amneal.com/news/press-releases/press-release-details/2024/Amneal-Announces-U.S.-FDA-Approval-of-Over-the-Counter-Naloxone-Hydrochloride-Nasal-Spray-for-Emergency-Treatment-of-an-Opioid-Overdose/default.aspx>. Issued 04/24/2024. Last accessed 06/14/2024.

Fiscal Year 2023 Annual Review of Anti-Emetic Medications

Oklahoma Health Care Authority Fiscal Year 2023 Print Report

Current Prior Authorization Criteria

Akynzeo® (Netupitant/Palonosetron) and Akynzeo® IV (Fosnetupitant/Palonosetron) Approval Criteria:

1. An FDA approved indication for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy; and
2. For Akynzeo® oral capsules, a previously failed trial of oral aprepitant (Emend®) that resulted in an inadequate response, or a patient-specific, clinically significant reason why oral aprepitant cannot be used must be provided; and
3. For Akynzeo® IV, a previously failed trial of intravenous (IV) fosaprepitant (Emend® IV) that resulted in an inadequate response, or a patient-specific, clinically significant reason why IV fosaprepitant cannot be used must be provided; and
4. Akynzeo® IV will require a patient-specific, clinically significant reason why the oral capsule formulation cannot be used; and
5. Approval length will be based on duration of need; and
6. A quantity limit of 1 capsule or vial per chemotherapy cycle will apply; and
7. Akynzeo® oral capsules will not require prior authorization for members with cancer and claims will pay at the point of sale if the member has a reported oncology diagnosis within the past 6 months of claims history.
 - a. Based on the current low net cost, Akynzeo® oral capsules will not require prior authorization for members with cancer; however, Akynzeo® oral capsules will follow the original criteria and require a previously failed trial of oral aprepitant if the net cost increases compared to other available products.

Anzemet® (Dolasetron), Cinvanti® and Emend® (Aprepitant), Emend® IV (Fosaprepitant), and Kytril® and Sancuso® (Granisetron) Approval Criteria:

1. An FDA approved diagnosis; and
2. A recent trial of ondansetron (within the past 6 months) used for at least 3 days or 1 cycle that resulted in an inadequate response is required for authorization in members receiving moderately emetogenic chemotherapy; and

3. No ondansetron trial is required for authorization of Emend® (aprepitant) in members receiving highly emetogenic chemotherapy; and
4. For Emend® (aprepitant) oral suspension, an age restriction of 6 years and younger will apply. Members older than 6 years of age will require a patient-specific, clinically significant reason why the oral capsule formulation cannot be used; and
5. For Cinvanti® [aprepitant intravenous (IV) emulsion], a previously failed trial of IV fosaprepitant (Emend® IV) that resulted in an inadequate response or a patient-specific, clinically significant reason why IV fosaprepitant cannot be used must be provided; and
6. Approval length will be based on duration of need.

Aponvie™ (Aprepitant 32mg/4.4ml Vial) Approval Criteria:

1. An FDA approved diagnosis for the prevention of postoperative nausea and vomiting (PONV); and
2. A patient-specific, clinically significant reason why the member cannot use other cost-effective therapeutic alternatives for the prevention of PONV (e.g., ondansetron) must be provided.

Barhemsys® (Amisulpride) Approval Criteria:

1. An FDA approved indication of 1 of the following:
 - a. Prevention of postoperative nausea and vomiting (PONV), either alone or in combination with an anti-emetic of a different class; or
 - b. Treatment of PONV in members who have received anti-emetic prophylaxis with an agent of a different class or who have not received prophylaxis; and
2. Member must be 18 years of age or older; and
3. Member must not have received a preoperative dopamine-2 (D2) antagonist (e.g., metoclopramide); and
4. A patient-specific, clinically significant reason why the member cannot use other cost-effective therapeutic alternatives for the prevention or treatment of PONV (e.g., ondansetron, dexamethasone) must be provided.

Bonjesta® (Doxylamine/Pyridoxine) and Doxylamine/Pyridoxine (Generic Diclegis®) Approval Criteria:

1. Authorization of Bonjesta® (doxylamine/pyridoxine) or the generic doxylamine/pyridoxine tablets requires a patient-specific, clinically significant reason why brand formulation Diclegis® (doxylamine/pyridoxine) tablets are not appropriate.

Cesamet® (Nabilone) and Marinol® and Syndros® (Dronabinol) Approval Criteria*:

1. An FDA approved diagnosis; and

2. Approval length will be based on duration of need; and
3. For Marinol® (dronabinol) and Cesamet® (nabilone), a quantity limit of 60 capsules per 30 days will apply; and
4. Cesamet® (nabilone) will require a patient-specific, clinically significant reason why dronabinol oral capsules cannot be used; and
5. For Syndros® (dronabinol) oral solution, the quantity approved will be patient-specific depending on patient diagnosis, maximum recommended dosage, and manufacturer packaging; and
6. For Syndros® (dronabinol) oral solution, an age restriction of 6 years and younger will apply. Members older than 6 years of age will require a patient-specific, clinically significant reason why dronabinol oral capsules cannot be used.

Palonosetron 0.25mg/5mL Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use generic Aloxi® (palonosetron 0.25mg/5mL), which is available without a prior authorization, must be provided.

Sustol® (Granisetron Subcutaneous Injection) Approval Criteria:

1. An FDA approved indication for use in the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy (MEC) or anthracycline and cyclophosphamide (AC) combination chemotherapy regimens; and
2. Chemotherapy regimen must be listed on the prior authorization request; and
3. A recent trial of ondansetron (within the past 6 months) used for at least 3 days or 1 cycle that resulted in inadequate response is required for authorization in members receiving MEC; and
4. No ondansetron trial is required for authorization of granisetron in members receiving AC combination chemotherapy regimens; and
5. A patient-specific, clinically significant reason why the member cannot use Kytril® (granisetron hydrochloride injection) must be provided; and
6. A quantity limit of 1 injection per chemotherapy cycle will apply.

Varubi® and Varubi® IV (Rolapitant) Approval Criteria:

1. An FDA approved indication for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy; and
2. For oral Varubi® (rolapitant oral tablets), a previously failed trial of aprepitant (Emend®) that resulted in an inadequate response or a patient-specific, clinically significant reason why aprepitant cannot be used must be provided; and
3. For Varubi® IV [rolapitant intravenous (IV) emulsion], a previously failed trial of IV fosaprepitant (Emend® IV) that resulted in an inadequate

- response or a patient-specific, clinically significant reason why IV fosaprepitant cannot be used must be provided; and
4. Approval length will be based on duration of need; and
 5. A quantity limit of 2 tablets or 2 vials per chemotherapy cycle will apply.

Zuplenz® (Ondansetron) Approval Criteria*:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot take all other available formulations of generic ondansetron must be provided.

*Current prior authorization criteria is only applicable to anti-emetic medications with a current federal drug rebate agreement. All criteria, regardless of coverage, are provided in this report for informational purposes.

Utilization of Anti-Emetic Medications: Fiscal Year 2023

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2022	95,865	136,935	\$2,178,886.93	\$15.91	\$2.10	2,504,391	1,038,499
2023	116,721	168,646	\$2,625,027.03	\$15.57	\$2.03	3,105,061	1,295,099
% Change	21.80%	23.20%	20.50%	-2.10%	-3.30%	24.00%	24.70%
Change	20,856	31,711	\$446,140.10	-\$0.34	-\$0.07	600,670	256,600

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated utilizing members.

Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Comparison of Fiscal Years: Medical Claims

Fiscal Year	*Total Members	*Total Claims	Total Cost	Cost/Claim	Claims/Member
2022	731	3,030	\$310,998.65	\$102.64	4.15
2023	967	4,040	\$438,358.44	\$108.50	4.18
% Change	32.28%	33.33%	40.95%	5.71%	0.72%
Change	236	1,010	\$127,359.79	5.86	0.03

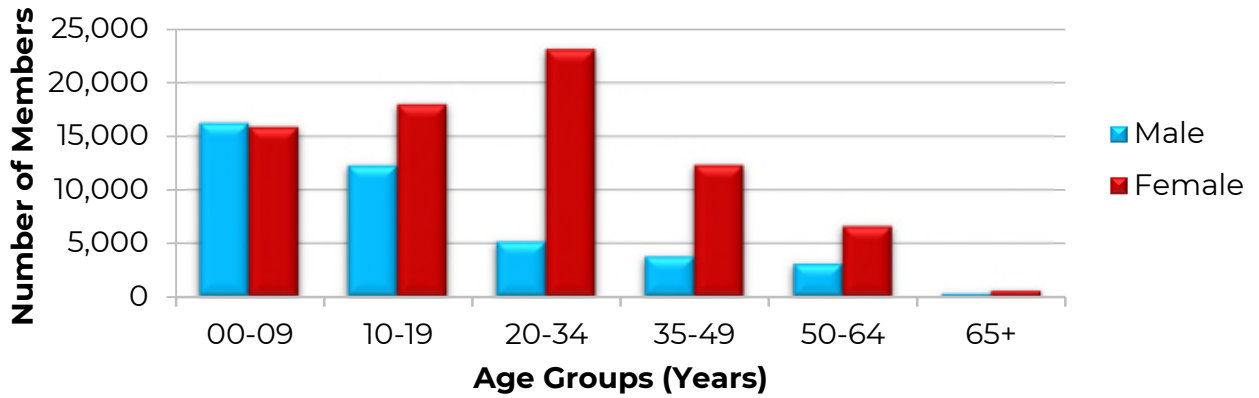
Costs do not reflect rebated prices or net costs.

*Total number of unduplicated utilizing members.

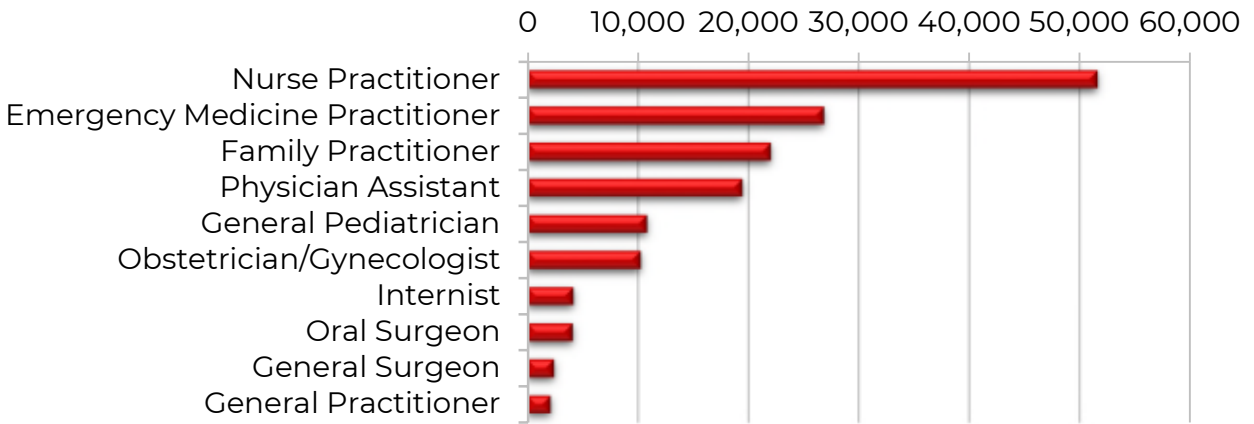
*Total number of unduplicated claims.

Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Demographics of Members Utilizing Anti-Emetic Medications



Top Prescriber Specialties of Anti-Emetic Medications by Number of Claims



Prior Authorization of Anti-Emetic Medications

There were 559 prior authorization requests submitted for anti-emetic medications during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

Status of Petitions



Market News and Updates¹

Anticipated Patent Expiration(s):

- Sustol® [granisetron subcutaneous (sub-Q) injection]: September 2024
- Sancuso® (granisetron transdermal patch): January 2025
- Emend® (aprepitant oral suspension): September 2027
- Syndros® (dronabinol oral solution): August 2028
- Varubi® (rolapitant tablet): October 2029
- Varubi® (rolapitant injectable emulsion): July 2032
- Bonjesta® [doxylamine/pyridoxine extended-release (ER) tablet]: February 2033
- Akynzeo® (netupitant/palonosetron capsule): September 2035
- Aponvie™ (aprepitant injectable emulsion): September 2035
- Cinvanti® [aprepitant intravenous (IV) emulsion]: September 2035
- Akynzeo® IV (fosnetupitant/palonosetron powder and solution): June 2037
- Barhemsys® (amisulpride injection): February 2038

News:

- Zuplenz® (ondansetron) has been discontinued by the manufacturer and no generic equivalents are available.

Recommendations

The College of Pharmacy recommends removing the prior authorization criteria for Zuplenz® (ondansetron) due to product discontinuation (changes shown in red).

Zuplenz® (Ondansetron) Approval Criteria*:

- ~~1.—An FDA-approved diagnosis; and~~
- ~~2.—A patient-specific, clinically significant reason why the member cannot take all other available formulations of generic ondansetron must be provided.~~

Utilization Details of Anti-Emetic Medications: Fiscal Year 2023

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/CLAIM	CLAIMS/MEMBER	% COST
ONDANSETRON PRODUCTS						
ONDANSETRON ODT 4MG	108,813	83,651	\$1,484,223.93	\$13.64	1.3	56.54%
ONDANSETRON TAB 4MG	22,952	16,700	\$264,989.44	\$11.55	1.37	10.09%
ONDANSETRON ODT 8MG	22,121	14,907	\$311,450.41	\$14.08	1.48	11.86%
ONDANSETRON TAB 8MG	7,037	4,507	\$84,333.29	\$11.98	1.56	3.21%
ONDANSETRON SOL 4MG/5ML	6,690	6,051	\$123,183.70	\$18.41	1.11	4.69%
ONDANSETRON INJ 4MG/2ML	54	19	\$1,048.50	\$19.42	2.44	0.04%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/CLAIM	CLAIMS/MEMBER	% COST
ONDANSETRON INJ 40MG/20ML	6	4	\$125.26	\$20.88	2.84	0.00%
SUBTOTAL	167,673	125,839	\$2,269,354.53	\$13.53	1.33	86.45%
DOXYLAMINE/PYRIDOXINE PRODUCTS						
DICLEGIS TAB 10-10MG	423	322	\$133,286.22	\$315.10	1.31	5.08%
BONJESTA TAB 20-20MG	385	260	\$186,884.53	\$485.41	1.48	7.12%
SUBTOTAL	808	582	\$320,170.75	\$396.25	1.39	12.20%
DRONABINOL PRODUCTS						
DRONABINOL CAP 5MG	53	26	\$7,172.81	\$135.37	2.04	0.27%
DRONABINOL CAP 2.5MG	50	28	\$3,365.29	\$67.31	1.79	0.13%
DRONABINOL CAP 10MG	14	3	\$2,903.04	\$207.36	4.67	0.11%
SUBTOTAL	117	57	\$13,441.14	\$114.88	2.05	0.51%
GRANISETRON PRODUCTS						
SANCUSO DIS 3.1MG	22	10	\$17,421.75	\$791.90	2.2	0.66%
GRANISETRON TAB 1MG	16	11	\$784.75	\$49.05	1.45	0.03%
SUBTOTAL	38	21	\$18,206.50	\$479.12	1.81	0.69%
APREPITANT PRODUCTS						
APREPITANT PAK 80MG & 125MG	5	3	\$2,017.40	\$403.48	1.67	0.08%
EMEND SUS 125MG	2	2	\$1,390.14	\$695.07	1	0.05%
APREPITANT CAP 40MG	2	2	\$233.67	\$116.84	1	0.01%
APREPITANT CAP 80MG	1	1	\$212.90	\$212.90	1	0.01%
SUBTOTAL	10	8	\$3,854.11	\$385.41	1.25	0.15%
TOTAL	168,646	116,721*	\$2,625,027.03	\$15.57	1.44	100%

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated utilizing members.

CAP = capsule; DIS = patches; INJ = injection; ODT = orally disintegrating tablet; PAK = pack; SOL = solution, SUS = suspension; TAB = tablet

Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS*	TOTAL MEMBERS*	TOTAL COST	COST/CLAIM	CLAIMS/MEMBER
FOSAPREPITANT INJ (J1453)	1,800	450	\$45,725.42	\$25.40	4
APREPITANT INJ (J0185)	1,655	416	\$373,524.39	\$225.69	3.98
GRANISETRON INJ (J1626)	545	128	\$2,130.15	\$3.91	4.26
FOSNETUPITANT/PALONOSETRON INJ (J1454)	38	12	\$16,852.48	\$443.49	3.17
FOSAPREPITANT INJ (J1456)	2	1	\$126.00	\$63.00	2
TOTAL	4,040	967	\$438,358.44	\$108.50	4.18

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated claims.

*Total number of unduplicated utilizing members.

INJ = injection

Fiscal Year 2023 = 07/01/2022 to 06/30/2023

¹ 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/>. Last revised 05/2024. Last accessed 05/29/2024.

Fiscal Year 2023 Annual Review of Butalbital Medications

Oklahoma Health Care Authority Fiscal Year 2023 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.

Vanadol™ 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 2023

Comparison of Fiscal Years

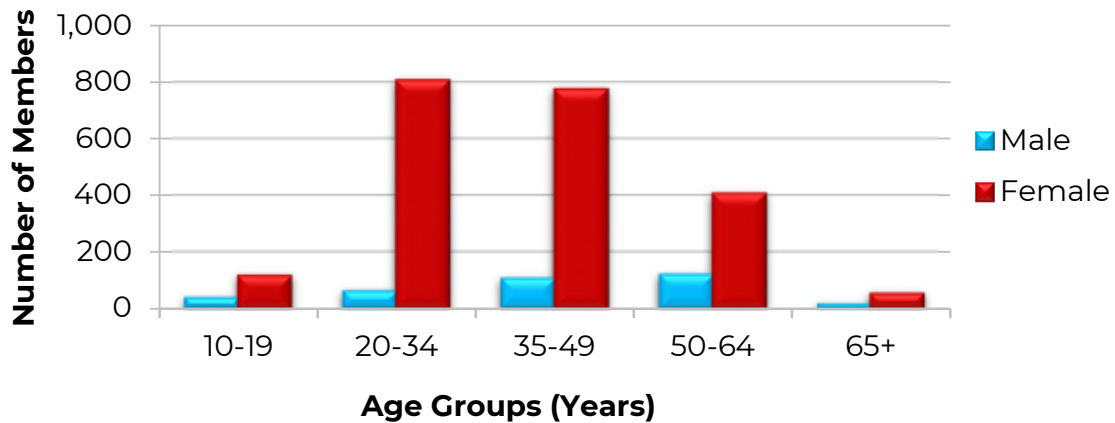
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2022	2,395	6,436	\$151,125.04	\$23.48	\$1.33	315,710	113,943
2023	2,455	6,702	\$150,022.88	\$22.38	\$1.25	327,537	120,039
% Change	2.50%	4.10%	-0.70%	-4.70%	-6.00%	3.70%	5.40%
Change	60	266	-\$1,102.16	-\$1.10	-\$0.08	11,827	6,096

Costs do not reflect rebated prices or net costs.

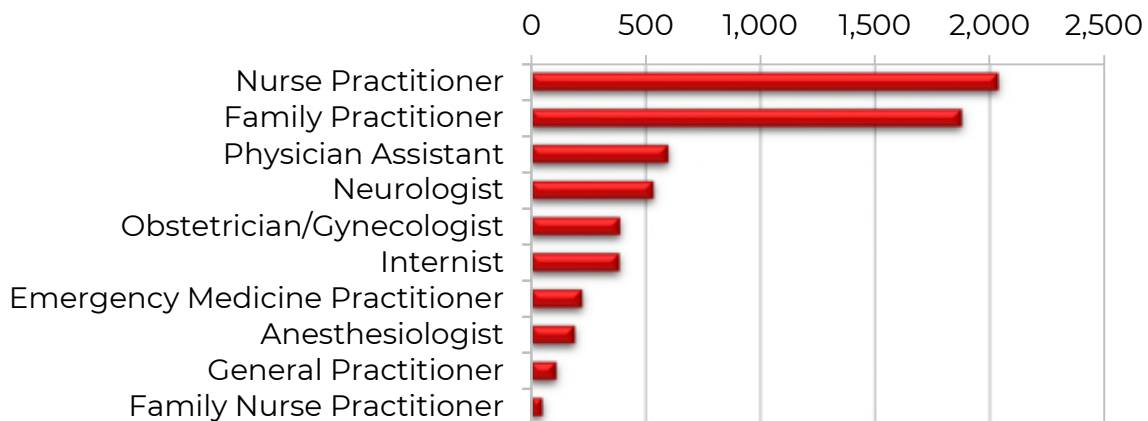
*Total number of unduplicated utilizing members.

Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Demographics of Members Utilizing Butalbital Medications



Top Prescriber Specialties of Butalbital Medications by Number of Claims



Prior Authorization of Butalbital Medications

There were 343 prior authorization requests submitted for butalbital medications during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

Status of Petitions



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 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
BUTALBITAL PRODUCTS						
BUT/APAP/CAF TAB 50/325/40MG	5,762	2,235	\$96,149.70	\$16.69	2.58	64.09%
BUT/ASA/CAF CAP 50/325/40MG	335	118	\$14,732.67	\$43.98	2.84	9.82%
BUT/APAP TAB 50/325MG	56	21	\$3,428.06	\$61.22	2.67	2.29%
BUT/APAP/CAF CAP 50/300/40MG	29	5	\$1,016.89	\$35.07	5.8	0.68%
BUT/APAP/CAF CAP 50/325/40MG	2	2	\$175.63	\$87.82	1	0.12%
SUBTOTAL	6,184	2,381	\$115,502.95	\$18.68	2.6	76.99%
BUTALBITAL/CODEINE PRODUCTS						
BUT/ASA/CAF/COD CAP 50/325/40/30MG	366	98	\$20,766.07	\$56.74	3.73	13.84%
BUT/APAP/CAF/COD CAP 50/300/40/30MG	112	28	\$9,249.60	\$82.59	6.07	6.17%
ASCOMP/COD CAP 50/325/40/30MG	40	9	\$4,504.26	\$112.61	4.44	3.00%
SUBTOTAL	518	135	\$34,519.93	\$66.64	3.84	23.01%
TOTAL	6,702	2,455*	\$150,022.88	\$22.38	2.73	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 2023 = 07/01/2022 to 06/30/2023

Fiscal Year 2023 Annual Review of Gout Medications

Oklahoma Health Care Authority Fiscal Year 2023 Print Report

Current Prior Authorization Criteria

Allopurinol 200mg Tablet Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use 2 allopurinol 100mg tablets in place of allopurinol 200mg must be provided.

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

1. A quantity of 6 tablets/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 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 2023

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2022	2,335	7,966	\$125,463.74	\$15.75	\$0.35	427,794	363,043
2023	3,017	10,115	\$142,511.68	\$14.09	\$0.30	561,297	479,124
% Change	29.20%	27.00%	13.60%	-10.50%	-14.30%	31.20%	32.00%
Change	682	2,149	\$17,047.94	-\$1.66	-\$0.05	133,503	116,081

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated utilizing members.

Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Fiscal Year 2023 Utilization: Medical Claims

Fiscal Year	*Total Members	*Total Claims	Total Cost	Cost/Claim	Claims/Member
2023	4	8	\$203,463.36	\$25,432.92	2

Costs do not reflect rebated prices or net costs.

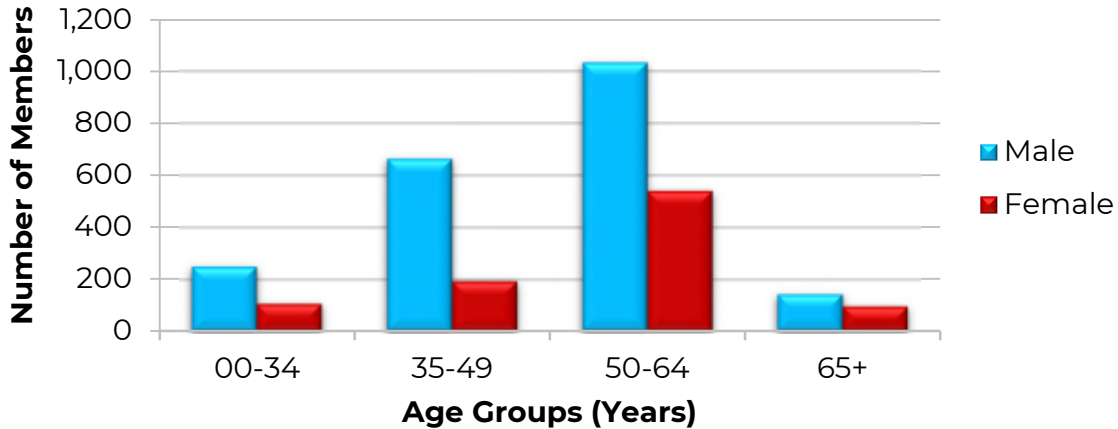
*Total number of unduplicated utilizing members.

*Total number of unduplicated claims.

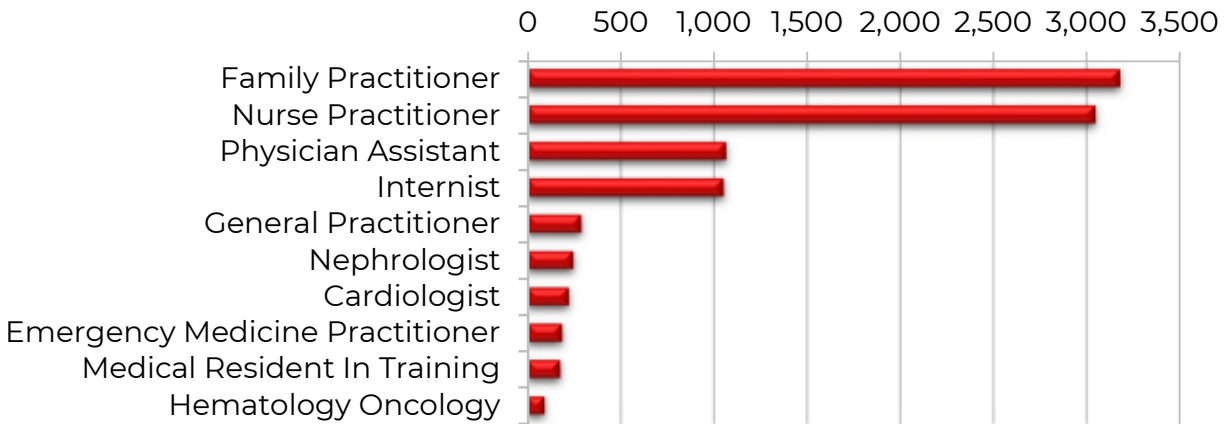
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Please note: There were no SoonerCare paid medical claims for gout medications during fiscal year 2022 to allow for a fiscal year comparison.

Demographics of Members Utilizing Gout Medications



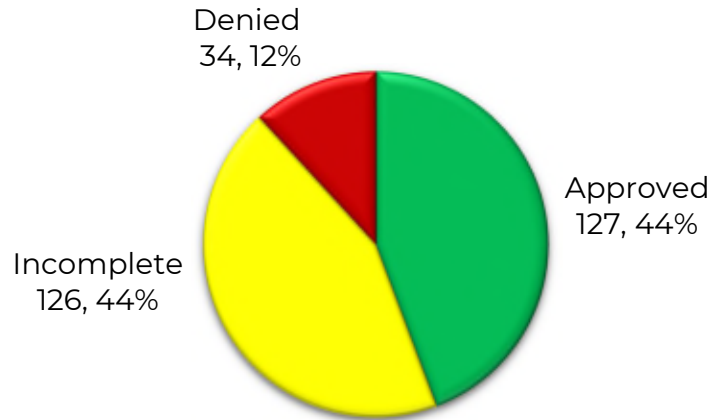
Top Prescriber Specialties of Gout Medications by Number of Claims



Prior Authorization of Gout Medications

There were 287 prior authorization requests submitted for gout medications during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

Status of Petitions



Market News and Updates¹

Anticipated Patent Expiration(s):

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

Recommendations

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

Utilization Details of Gout Medications: Fiscal Year 2023

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ALLOPURINOL PRODUCTS						
ALLOPURINOL TAB 100MG	4,874	1,582	\$54,662.07	\$11.22	3.08	38.36%
ALLOPURINOL TAB 300MG	3,546	1,134	\$48,342.49	\$13.63	3.13	33.92%
SUBTOTAL	8,420	2,716	\$103,004.56	\$12.23	3.1	72.28%
COLCHICINE PRODUCTS						
COLCHICINE TAB 0.6MG	1,157	577	\$14,477.76	\$12.51	2.01	10.16%
COLCHICINE CAP 0.6MG	106	58	\$2,624.81	\$24.76	1.83	1.84%
MITIGARE CAP 0.6MG	3	3	\$79.70	\$26.57	1	0.06%
SUBTOTAL	1,266	638	\$17,182.27	\$13.57	1.98	12.06%
FEBUXOSTAT PRODUCTS						
FEBUXOSTAT TAB 40MG	195	41	\$5,462.03	\$28.01	4.76	3.83%
FEBUXOSTAT TAB 80MG	76	15	\$2,411.71	\$31.73	5.07	1.69%
ULORIC TAB 40MG	12	1	\$3,929.24	\$327.44	12	2.76%
ULORIC TAB 80MG	9	2	\$2,967.96	\$329.77	4.5	2.08%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/CLAIM	CLAIMS/MEMBER	% COST
SUBTOTAL	292	59	\$14,770.94	\$50.59	4.95	10.36%
PROBENECID PRODUCTS						
PROBENECID TAB 500MG	93	21	\$4,847.83	\$52.13	4.43	3.40%
SUBTOTAL	93	21	\$4,847.83	\$52.13	4.43	3.40%
PROBENECID/COLCHICINE COMBINATION PRODUCTS						
PROBEN/COLCH TAB 500/0.5MG	44	13	\$2,706.08	\$61.50	3.38	1.90%
SUBTOTAL	44	13	\$2,706.08	\$61.50	3.38	1.90%
TOTAL	10,115	3,017*	\$142,511.68	\$14.09	3.35	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 2023 = 07/01/2022 to 06/30/2023

Medical Claims

PRODUCT UTILIZED	*TOTAL CLAIMS	*TOTAL MEMBERS	TOTAL COST	COST/CLAIM	CLAIMS/MEMBER	% COST
KRYSTEXXA INJ 1MG J2507	8	4	\$203,463.36	\$25,432.92	2	100%
TOTAL	8	4	\$203,463.36	\$25,432.92	2	100%

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated utilizing members.

*Total number of unduplicated claims.

INJ = injection

Fiscal Year 2023 = 07/01/2022 to 06/30/2023

¹ 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 05/2024. Last accessed 05/17/2024.

Fiscal Year 2023 Annual Review of H.P. Acthar® Gel (Repository Corticotropin Injection)

Oklahoma Health Care Authority
Fiscal Year 2023 Print Report

Current Prior Authorization Criteria

H.P. Acthar® Gel (Repository Corticotropin Injection) Approval Criteria:

1. An FDA approved diagnosis of infantile spasms; and
 - a. Member must be 2 years of age or younger; and
 - b. Must be prescribed by, or in consultation with, a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); or
2. An FDA approved diagnosis of multiple sclerosis (MS); and
 - a. Member is experiencing an acute exacerbation; and
 - b. Must be prescribed by, or in consultation with, a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist) or a prescriber who specializes in MS; and
 - c. Prescriber must rule out pseudo-exacerbation from precipitating factors (e.g., pain, stress, infection, premenstrual syndrome); and
 - d. Symptoms of acute exacerbation last at least 24 hours; and
 - e. Member must be currently stable within the last 30 days on an immunomodulator agent, unless contraindicated; and
 - f. A patient-specific, clinically significant reason why the member cannot use alternative corticosteroid therapy [e.g., intravenous (IV) methylprednisolone, IV dexamethasone, oral prednisone] must be provided; and
 - g. A quantity limit of daily doses of up to 120 units for up to 3 weeks for acute exacerbation will apply; or
3. An FDA approved diagnosis of nephrotic syndrome without uremia of the idiopathic type or that is due to lupus erythematosus to induce a diuresis or a remission of proteinuria; and
 - a. Must be prescribed by, or in consultation with, a nephrologist (or an advanced care practitioner with a supervising physician who is a nephrologist); and
 - b. A patient-specific, clinically significant reason why the member cannot use alternative corticosteroid therapy (e.g., prednisone) must be provided; or
4. An FDA approved diagnosis of the following disorders or diseases: rheumatic; collagen; dermatologic; allergic states; ophthalmic; respiratory; or edematous states; and

- a. A patient-specific, clinically significant reason why the member cannot use alternative corticosteroid therapy must be provided.

Utilization of H.P. Acthar® Gel (Repository Corticotropin Injection): Fiscal Year 2023

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2022	6	8	\$670,479.85	\$83,809.98	\$2,782.07	90	241
2023	12	35	\$2,415,360.01	\$69,010.29	\$2,766.74	325	873
% Change	100.0%	337.5%	260.2%	-17.7%	-0.6%	261.1%	262.2%
Change	6	27	\$1,744,880.16	-\$14,799.69	-\$15.33	235	632

*Total number of unduplicated utilizing members.

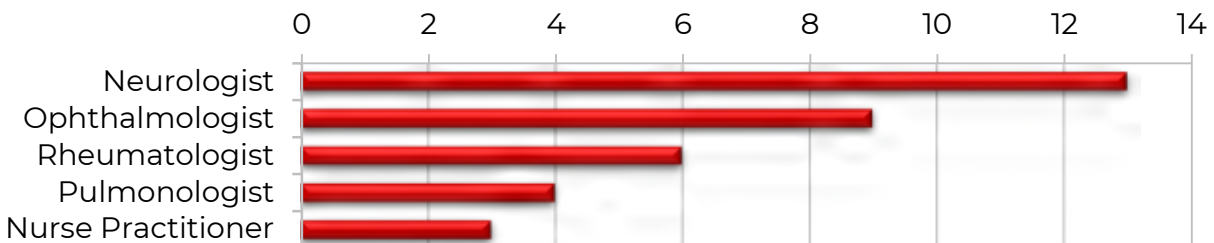
Costs do not reflect rebated prices or net costs.

Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Demographics of Members Utilizing H.P. Acthar® Gel (Repository Corticotropin Injection)

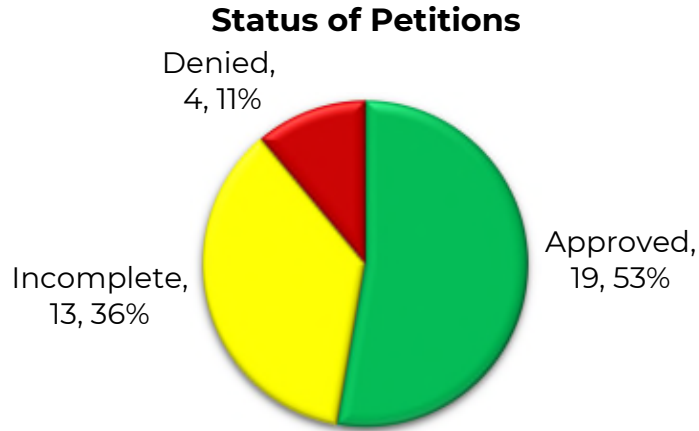
- Due to the limited number of members utilizing H.P. Acthar® Gel during fiscal year 2023, detailed demographic information could not be provided.

Top Prescriber Specialties of H.P. Acthar® Gel (Repository Corticotropin Injection) by Number of Claims



Prior Authorization of H.P. Acthar® Gel (Repository Corticotropin Injection)

There were 36 prior authorization requests submitted for 15 unique members for H.P. Acthar® Gel during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.



Recommendations

The College of Pharmacy does not recommend any changes to the current H.P. Acthar® Gel (repository corticotropin injection) prior authorization criteria at this time.

Utilization Details of H.P. Acthar® Gel (Repository Corticotropin Injection): Fiscal Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/CLAIM	CLAIMS/MEMBER
ACTHAR INJ 80 UNIT	26	7	\$1,830,491.32	\$70,403.51	3.7
CORTROPHIN GEL 80 UNIT	9	5	\$584,868.69	\$64,985.41	1.8
TOTAL	35	12*	\$2,415,360.01	\$69,010.29	2.9

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated utilizing members.

INJ = Injection

Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Fiscal Year 2023 Annual Review of Heart Failure (HF) Medications

Oklahoma Health Care Authority Fiscal Year 2023 Print Report

Current Prior Authorization Criteria

Corlanor® (Ivabradine) Approval Criteria:

1. An FDA approved indication of 1 of the following:
 - a. To reduce the risk of hospitalization for worsening heart failure (HF) in adult members with stable, symptomatic chronic HF with reduced left ventricular ejection fraction (LVEF); or
 - b. For the treatment of stable, symptomatic HF due to dilated cardiomyopathy (DCM) in members 6 months of age and older; and
2. For a diagnosis of worsening HF in adults:
 - a. Prescriber must verify that the member has LVEF $\leq 35\%$; and
 - b. Prescriber must verify that the member is in sinus rhythm with a resting heart rate ≥ 70 beats per minute (bpm); and
 - c. Member must be on maximal/maximally tolerated doses of beta blockers or have a contraindication to beta blockers; and
3. For a diagnosis of DCM in members 6 months of age or older:
 - a. Prescriber must verify that the member has LVEF $\leq 45\%$; and
 - b. Prescriber must verify that the member is in sinus rhythm with a resting heart rate (HR) as follows:
 - i. Age 6 to 12 months, HR ≥ 105 bpm; or
 - ii. Age 1 to 3 years, HR ≥ 95 bpm; or
 - iii. Age 3 to 5 years, HR ≥ 75 bpm; or
 - iv. Age 5 to 18 years, HR ≥ 70 bpm; and
 - c. Prescriber must verify that dose titration will be followed according to package labeling; and
 - d. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
4. Authorization of Corlanor® solution for members >40 kg requires a patient-specific, clinically significant reason why Corlanor® tablets cannot be used; and
5. For Corlanor® tablets, a quantity limit of 60 tablets per 30 days will apply; and
6. For Corlanor® solution, a quantity limit of 112 ampules (4 boxes) per 28 days, or 560mL per 28 days, will apply.

Entresto® (Sacubitril/Valsartan) Approval Criteria:

1. An FDA approved diagnosis of chronic heart failure [New York Heart Association (NYHA) Class II, III, or IV]; and
2. A quantity limit of 60 tablets per 30 days will apply.

Furoscix® (Furosemide On-Body Infusor) Approval Criteria:

1. An FDA approved indication for the treatment of congestion due to fluid overload in members with New York Heart Association (NYHA) Class II-III heart failure; and
2. Member must be 18 years of age or older; and
3. Furoscix® must be prescribed by, or in consultation with, a cardiologist or a provider trained in managing acute decompensated heart failure (ADHF); and
4. Member is currently showing signs of fluid overload; and
5. Member has been stable and refractory to at least 1 of the following loop diuretics, at maximally indicated doses:
 - a. Bumetanide oral tablets; or
 - b. Furosemide oral tablets; or
 - c. Torsemide oral tablets; and
6. Prescriber must verify the member will discontinue oral diuretics during the treatment with Furoscix® and will transition back to oral diuretic maintenance therapy when practical; and
7. Prescriber must verify the member is stable and suitable for at-home treatment with Furoscix®, as determined by:
 - a. Oxygen saturation $\geq 90\%$ on exertion; and
 - b. Respiratory rate < 24 breaths per minute; and
 - c. Resting heart rate < 100 beats per minute; and
 - d. Systolic blood pressure > 100 mmHg; and
8. Member must have an adequate environment for at-home administration and have been trained on the proper use of Furoscix®; and
9. Member must have a creatinine clearance (CrCl) > 30 mL/min or an estimated glomerular filtration rate (eGFR) > 20 mL/min/1.73m² and no evidence of acute renal failure; and
10. Member must not have any contraindications for use of Furoscix® including anuria, hepatic cirrhosis, or ascites; and
11. Member must not have acute pulmonary edema or other conditions that require immediate hospitalization; and
12. Approvals will be issued per incident of fluid overload; and
13. Reauthorization is not permitted. A new prior authorization request must be submitted and the member must meet all initial approval criteria for each incident of fluid overload.

Verquvo® (Vericiguat) Approval Criteria:

1. An FDA approved indication to reduce the risk of cardiovascular death and hospitalization for heart failure (HF) in adults with all of the following:
 - a. Chronic symptomatic HF [New York Heart Association (NYHA) Class II, III, or IV]; and
 - b. Reduced left ventricular ejection fraction (LVEF) <45%; and
 - c. Already receiving guideline-directed medical therapy for HF, as documented in member's pharmacy claims history; and
2. Member has evidence of worsening HF (decompensation) demonstrated by at least 1 of the following:
 - a. Hospitalization for HF within the past 6 months; or
 - b. Received outpatient intravenous (IV) diuretics within the past 3 months; and
3. Member must be 18 years of age or older; and
4. Member must not be taking concomitant soluble guanylate cyclase (sGC) stimulators (e.g., riociguat); and
5. Female members of reproductive potential must not be breastfeeding, must have a negative pregnancy test prior to initiation of therapy, and must agree to use effective contraception during treatment and for 1 month after the final dose of Verquvo®; and
6. Prescriber must agree to titrate to the target maintenance dose according to package labeling, as tolerated by the member; and
7. Initial approvals will be for the duration of 6 months. Compliance will be checked for continued approval every 6 months; and
8. A quantity limit of 30 tablets per 30 days will apply.

Utilization of HF Medications: Fiscal Year 2023

Comparison of Fiscal Years

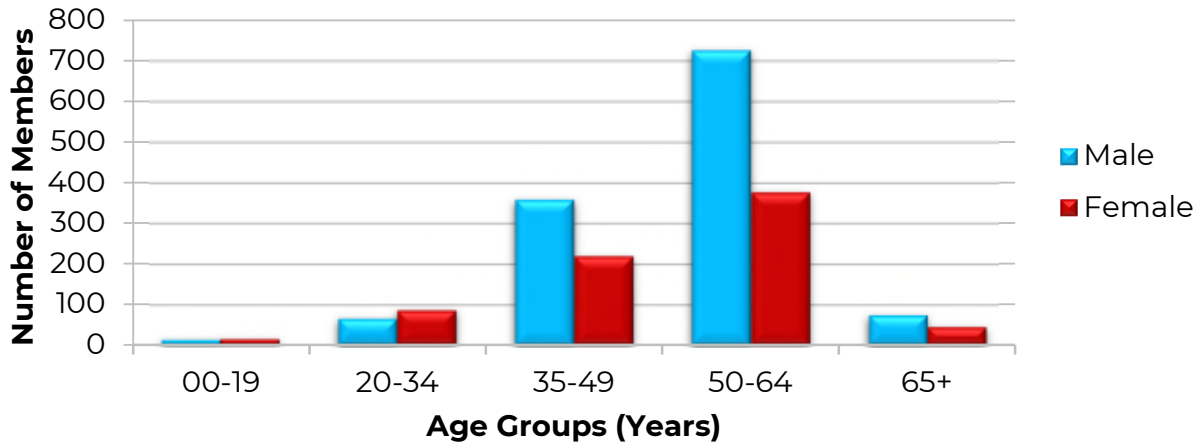
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2022	1,281	5,851	\$3,283,141.67	\$561.12	\$18.66	345,715	175,933
2023	1,971	10,436	\$6,283,561.35	\$602.10	\$19.96	617,839	314,865
% Change	53.90%	78.40%	91.40%	7.30%	7.00%	78.70%	79.00%
Change	690	4,585	\$3,000,419.68	\$40.98	\$1.30	272,124	138,932

Costs do not reflect rebated prices or net costs.

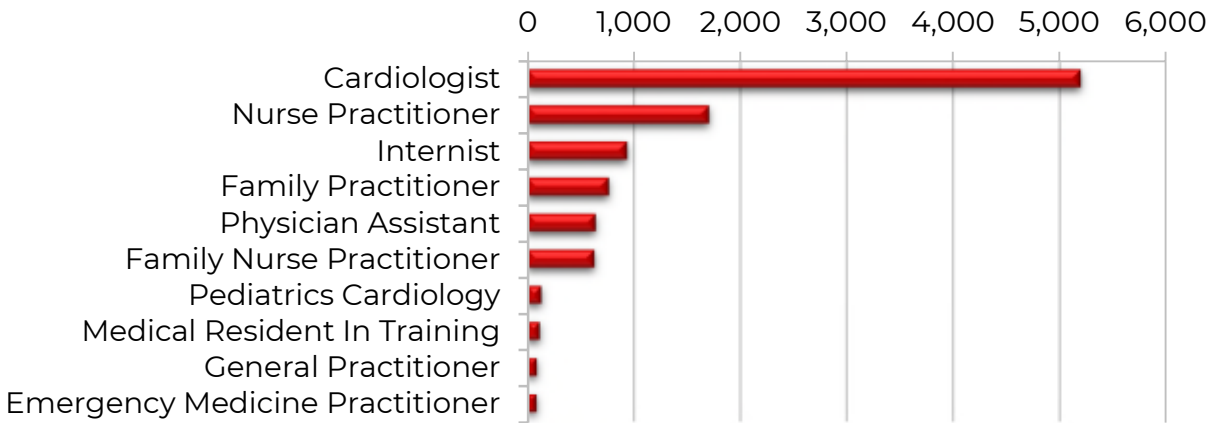
*Total number of unduplicated utilizing members.

Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Demographics of Members Utilizing HF Medications

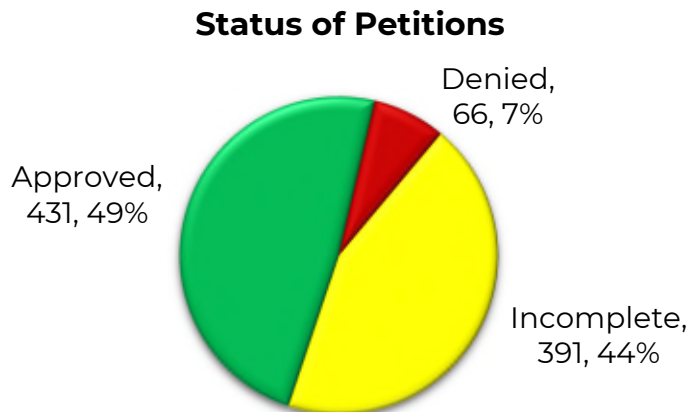


Top Prescriber Specialties of HF Medications by Number of Claims



Prior Authorization of HF Medications

There were 888 prior authorization requests submitted for HF medications during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.



Market News and Updates^{1,2,3,4,5,6,7,8}

Anticipated Patent Expiration(s):

- Corlanor® (ivabradine oral solution): December 2026
- Corlanor® (ivabradine tablet): June 2027
- Verquvo® (vericiguat tablet): November 2032
- Furoscix® (furosemide on-body infusor): April 2034
- Entresto® (sacubitril/valsartan tablet): May 2036

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

- **April 2024:** The FDA approved Entresto® Sprinkle (sacubitril/valsartan), a new oral formulation that will be available as 6mg/6mg and 15mg/16mg film-coated oral pellets within capsules. These oral pellets are to be administered by opening the capsule and sprinkling the full contents onto 1 to 2 teaspoons of soft food. The oral pellets cannot be administered via nasogastric, gastrostomy, or other enteral tubes because they may cause obstruction. The FDA package labeling has been updated to contain the new formulation; however, the product is not yet available on the market. Information from Novartis regarding the anticipated launch is pending.

Pipeline:

- **Revascor® (Rexlemestrocel-L):** Mesoblast is evaluating Revascor® for the treatment of advanced and end-stage heart failure with reduced ejection fraction (HFrEF). Revascor® is a stem cell therapy consisting of 150 million mesenchymal precursor cells (MPCs) that are administered into the myocardium as a single, direct injection. MPCs are believed to release a variety of factors which may lead to cardiac recovery through induction of vascular network formulation, reduction in inflammation, reduction in cardiac scarring and fibrosis, and regeneration of myocardium. In February 2023, results from the Phase 3 DREAM-HF study were published in the *Journal of the American College of Cardiology*. After 1 injection of Revascor®, the study showed improvements in left ventricular ejection fraction (LVEF) and reductions in the risk of myocardial infarction (MI), stroke, and cardiovascular (CV) death in high-risk patients with congestive heart failure (HF). In March 2024, Mesoblast announced they are meeting with the FDA to discuss the data presentation, timing, and expectations for an accelerated approval for Revascor® in end-stage ischemic HFrEF patients with left ventricular assist device (LVAD) implantation.
- **Ziltivekimab (NN6018):** Novo Nordisk is evaluating ziltivekimab for the treatment of HF. Ziltivekimab is a monoclonal antibody which inhibits interleukin-6 (IL-6) and is being studied in patients with HF and inflammation. The Phase 3 HERMES study is currently recruiting patients with a diagnosis of New York Heart Association (NYHA) Class II,

III, or IV HF and LVEF \geq 40%, and patients will be randomized to receive ziltivekimab or placebo once monthly (in addition to standard of care) for up to 4 years. The primary efficacy outcome will be the time to first occurrence of a composite of CV death, HF hospitalization or urgent HF visit, non-fatal MI, or non-fatal stroke. The estimated completion of this study is July 2027.

Recommendations

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

Utilization Details of HF Medications: Fiscal Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/CLAIM	CLAIMS/MEMBER	% COST
SACUBITRIL/VALSARTAN PRODUCTS						
ENTRESTO TAB 24/26MG	5,088	1,202	\$3,028,195.63	\$595.16	4.23	48.19%
ENTRESTO TAB 49/51MG	2,917	681	\$1,770,413.49	\$606.93	4.28	28.18%
ENTRESTO TAB 97/103MG	2,060	385	\$1,255,796.75	\$609.61	5.35	19.99%
SUBTOTAL	10,065	1,921*	\$6,054,405.87	\$601.53	5.24	96.35%
IVABRADINE PRODUCTS						
CORLANOR TAB 5MG	226	58	\$139,348.91	\$616.59	3.9	2.22%
CORLANOR TAB 7.5MG	81	17	\$52,743.90	\$651.16	4.76	0.84%
CORLANOR SOL 5MG/5ML	17	4	\$10,112.81	\$594.87	4.25	0.16%
SUBTOTAL	324	73*	\$202,205.62	\$624.09	4.44	3.22%
VERICIGUAT PRODUCTS						
VERQUVO TAB 2.5MG	15	3	\$7,564.89	\$504.33	5	0.12%
VERQUVO TAB 5MG	19	4	\$11,315.53	\$595.55	4.75	0.18%
VERQUVO TAB 10MG	13	4	\$8,069.44	\$620.73	3.25	0.13%
SUBTOTAL	47	10*	\$26,949.86	\$573.40	4.7	0.43%
TOTAL	10,436	1,971*	\$6,283,561.35	\$602.10	5.29	100%

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated utilizing members.

SOL = solution; TAB = tablet

Fiscal Year 2023 = 07/01/2022 to 06/30/2023

¹ 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 05/2024. Last Accessed 05/24/2024.

² Entresto® Sprinkle (Sacubitril/Valsartan) – New Formulation Approval. *OptumRx*®. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/drug-approvals/drugapproval_entresto_2024-0417.pdf. Issued 04/12/2024. Last accessed 05/29/2024.

³ Entresto® Sprinkle (Sacubitril/Valsartan) Prescribing Information. Novartis. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/207620s025.218591s000lbl.pdf. Last revised 04/2024. Last accessed 05/29/2024.

⁴ Mesoblast Limited. Appendix 4C Quarterly Activity Report for Quarter Ended March 31, 2024. Available online at: <https://investorsmedia.mesoblast.com/static-files/59ef5b66-b6dd-4eb1-be54-78a65a9e4f5d>. Issued 04/29/2024. Last accessed 05/24/2024.

⁵ Mesoblast Limited. DREAM-HF Phase 3 Trial Results for Mesoblast Cell Therapy in Heart Failure Published in Journal of The American College of Cardiology (JACC). Available online at: <https://investorsmedia.mesoblast.com/static-files/a6e8e761-7014-4e99-80d1-0171c226a3a0>. Issued 02/27/2023. Last accessed 05/24/2024.

⁶ Mesoblast Limited. Product Candidates. Available online at: <https://www.mesoblast.com/product-candidates/product-candidates-overview>. Last accessed 05/24/2024.

⁷ Novo Nordisk. R&D Pipeline. Available online at: <https://www.novonordisk.com/science-and-technology/r-d-pipeline.html>. Last accessed 05/24/2024.

⁸ A Research Study to Look at How Ziltivekimab Works Compared to Placebo in People with Heart Failure and Inflammation (HERMES). *ClinicalTrials.gov*. Available online at: <https://clinicaltrials.gov/ct2/show/NCT05636176>. Last revised 06/12/2023. Last accessed 05/24/2024.

Fiscal Year 2023 Annual Review of Idiopathic Pulmonary Fibrosis (IPF) Medications

Oklahoma Health Care Authority
Fiscal Year 2023 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 patient-specific, clinically significant reason why the member cannot use Ofev® (nintedanib) must be provided; and
6. 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 543mg and 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 2023

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2022	24	117	\$1,318,148.94	\$11,266.23	\$375.54	7,470	3,510
2023	29	180	\$2,075,733.29	\$11,531.85	\$386.54	11,481	5,370
% Change	20.8%	53.8%	57.5%	2.4%	2.9%	53.7%	53.0%
Change	5	63	\$757,584.35	\$265.62	\$11.00	4,011	1,860

Costs do not reflect rebated prices or net costs.

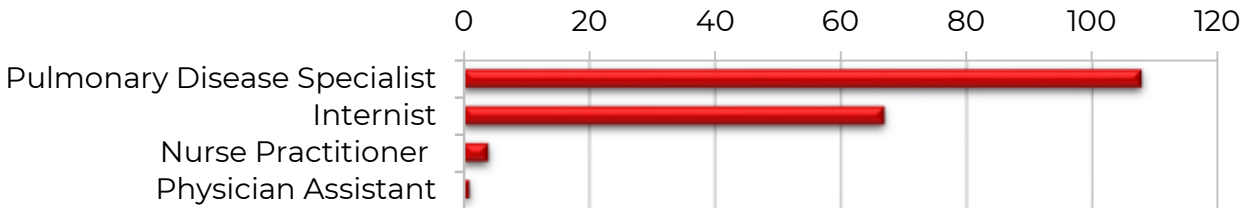
*Total number of unduplicated utilizing members.

Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Demographics of Members Utilizing IPF Medications

- All members utilizing IPF medications during fiscal year 2023 were adults; however, detailed demographic information cannot be provided due to the limited number of members using IPF medications during fiscal year 2023.

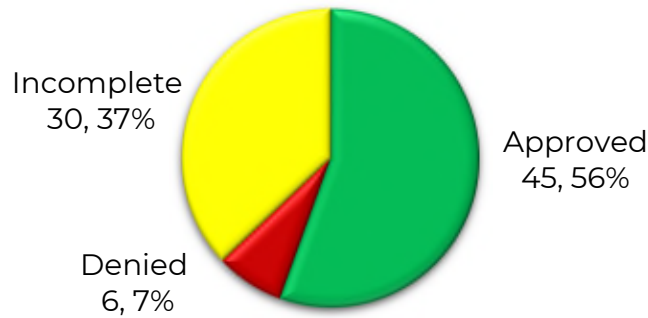
Top Prescriber Specialties of IPF Medications by Number of Claims



Prior Authorization of IPF Medications

There were 81 prior authorization requests submitted for IPF medications during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

Status of Petitions



Market News and Updates^{1,2,3}

Anticipated Patent Expiration(s):

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

Pipeline:

- **Deupirfenidone (LYT-100):** PureTech announced the completion of enrollment in the Phase 2b ELEVATE IPF trial which is a randomized, double-blind, placebo-controlled, dose-finding study evaluating the use of deupirfenidone in patients with IPF. LYT-100 is a deuterated form of pirfenidone with a favorable tolerability profile that has the potential to improve patient persistence with the medication to enable more optimal disease management.

Recommendations

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

Utilization Details of IPF Medications: Fiscal Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
NINTEDANIB PRODUCTS						
OFEV CAP 150MG	123	22	\$1,478,088.01	\$12,016.98	5.59	71.21%
OFEV CAP 100MG	49	12	\$578,542.65	\$11,806.99	4.08	27.87%
SUBTOTAL	172	34	\$2,056,630.66	\$11,957.16	5.06	99.08%
PIRFENIDONE PRODUCTS						
ESBRIET TAB 267MG	7	1	\$11,079.99	\$1,582.86	7	0.53%
ESBRIET CAP 267MG	1	1	\$8,022.64	\$8,022.64	1	0.39%
SUBTOTAL	8	2	\$19,102.63	\$2,387.83	4	0.92%
TOTAL	180	29*	\$2,075,733.29	\$11,531.85	6.21	100%

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated utilizing members.

CAP = capsule; TAB = tablet

Fiscal Year 2023 = 07/01/2022 to 06/30/2023

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 05/2024. Last accessed 05/22/2024.

² PureTech. Programs: LYT-100. Available online at: <https://www.puretechhealth.com/programs/details/lyt-100>. Last accessed 05/22/2024.

³ PureTech. PureTech Announces Completion of Enrollment in Phase 2b ELEVATE IPF Trial of LYT-100 (Deupirfenidone) in Idiopathic Pulmonary Fibrosis. Available online at: <https://news.puretechhealth.com/news-releases/news-release-details/puretech-announces-completion-enrollment-phase-2b-elevate-ipf>. Issued 04/16/2024. Last accessed 06/19/2024.

Fiscal Year 2023 Annual Review of Insomnia Medications

Oklahoma Health Care Authority Fiscal Year 2023 Print Report

Current Prior Authorization Criteria

Insomnia Medications			
Tier-1	Tier-2	Tier-3	Special PA*
estazolam (ProSom®)	zolpidem CR (Ambien® CR)	lemborexant (Dayvigo®)	daridorexant (Quviviq®)
eszopiclone (Lunesta®)		suvorexant (Belsomra®)	doxepin (Silenor®)
flurazepam (Dalmane®)			quazepam (Doral®)
ramelteon (Rozerem®) – Brand Preferred			tasimelteon (Hetlioz®, Hetlioz LQ®)*
temazepam (Restoril®) 15mg and 30mg			temazepam (Restoril®) 7.5mg and 22.5mg
triazolam (Halcion®)			zolpidem 7.5mg capsule
zaleplon (Sonata®)			zolpidem SL tablets (Edluar®)
zolpidem (Ambien®)			zolpidem SL tablets (Intermezzo®)
			zolpidem oral spray (Zolpimist®)

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).

*Medications in the Special PA Tier, including unique dosage formulations, require a special reason for use in place of lower-tiered medications.

*Individual criteria specific to tasimelteon applies.

CR = controlled release; PA = prior authorization; SL = sublingual

- Tier-1 medications are available without a prior authorization for members 19 years of age and older.
- Members 18 years of age or younger will be required to submit a prior authorization for consideration of all insomnia medications.
- All medications have a quantity limit of 30 units per 30 days.

Insomnia Medications Tier-2 Approval Criteria:

1. An FDA approved diagnosis; and

2. Member must have a minimum of a 30-day trial with at least 2 Tier-1 medications and clinical documentation of attempts to correct any primary cause for insomnia; and
3. No concurrent anxiolytic benzodiazepine therapy greater than 3 times daily dosing; and
4. Approvals will be granted for the duration of 6 months.

Insomnia Medications Tier-3 Approval Criteria:

1. An FDA approved diagnosis; and
2. Member must have a minimum of a 30-day trial with at least 2 Tier-1 medications and clinical documentation of attempts to correct any primary cause for insomnia; and
3. Member must have a minimum of a 30-day trial with at least 2 Tier-2 medications; and
 - a. If only 1 Tier-2 medication is available, a minimum of a 30-day trial with 1 Tier-2 medication will be required; and
4. No concurrent anxiolytic benzodiazepine therapy greater than 3 times daily dosing; and
5. Approvals will be granted for the duration of 6 months.

Hetlioz® (Tasimelteon Capsule) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
 - a. Non-24-Hour Sleep-Wake Disorder (Non-24) confirmed by a sleep specialist; or
 - b. Nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) confirmed by a sleep specialist; and
2. Member must be 18 years of age or older for a diagnosis of Non-24 or 16 years of age or older for a diagnosis of SMS; and
3. Member must have a failed trial of appropriately timed doses of melatonin; and
4. Initial approvals will be for the duration of 12 weeks. For continuation, the prescriber must include information regarding improved response/effectiveness of this medication; and
5. A quantity limit of 30 capsules for 30 days will apply.

Hetlioz LQ® (Tasimelteon Oral Suspension) Approval Criteria:

1. An FDA approved diagnosis of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) confirmed by a sleep specialist; and
2. Member must be 3 to 15 years of age; and
3. Member must have a failed trial of appropriately timed doses of melatonin; and
4. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to the Hetlioz LQ™ package labeling; and

- Initial approvals will be for the duration of 12 weeks. For continuation, the prescriber must include information regarding improved response/effectiveness of this medication.

Ramelteon (Generic Rozerem®) Approval Criteria:

- A patient-specific, clinically significant reason why the member cannot use the brand formulation (Rozerem®) must be provided.

Seconal Sodium™ (Secobarbital Sodium Capsule) Approval Criteria:

- An FDA approved indication for 1 of the following:
 - Short-term treatment of insomnia; or
 - As a preanesthetic; and
- A patient-specific, clinically significant reason why the member cannot use other cost-effective therapeutic alternatives must be provided; and
- For the short-term treatment of insomnia, a quantity limit of 1 capsule per day not to exceed 14 capsules per 30 days will apply.

Utilization of Insomnia Medications: Fiscal Year 2023

Comparison of Fiscal Years

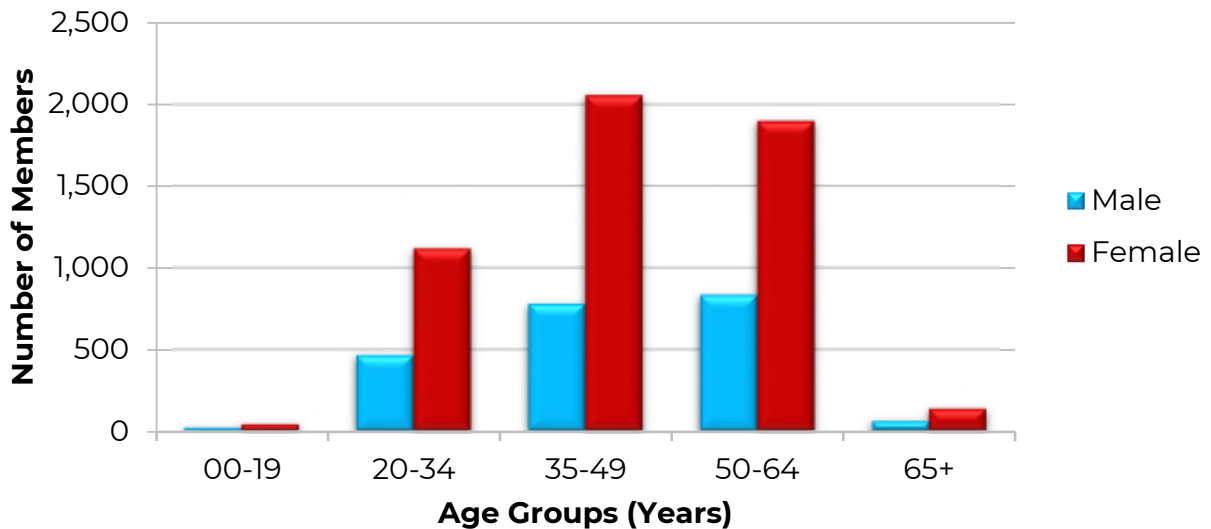
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2022	6,088	29,204	\$1,343,670.18	\$46.01	\$1.58	847,012	848,160
2023	7,377	36,075	\$1,777,047.33	\$49.26	\$1.70	1,045,322	1,046,033
% Change	21.2%	23.5%	32.3%	7.1%	7.6%	23.4%	23.3%
Change	1,289	6,871	\$433,377.15	\$3.25	\$0.12	198,310	197,873

Costs do not reflect rebated prices or net costs.

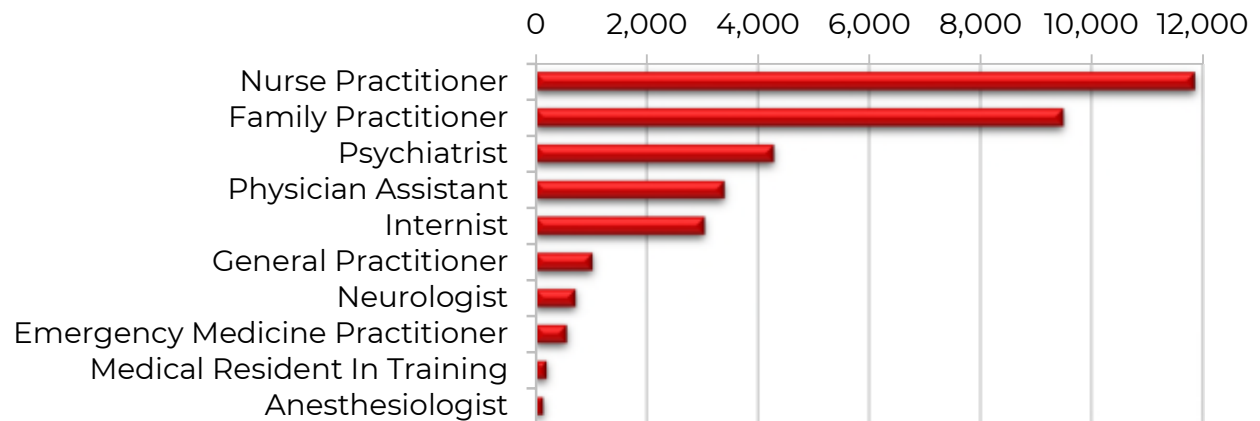
*Total number of unduplicated utilizing members.

Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Demographics of Members Utilizing Insomnia Medications

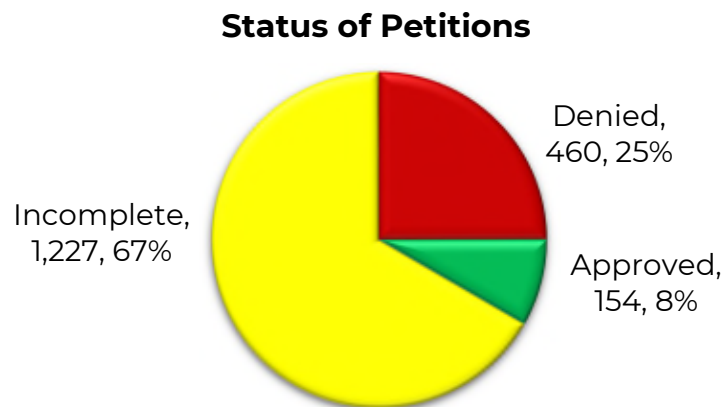


Top Prescriber Specialties of Insomnia Medications by Number of Claims



Prior Authorization of Insomnia Medications

There were 1,841 prior authorization requests submitted for insomnia medications during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.



Market News and Updates^{1,2,3,4,5}

Anticipated Patent Expiration(s):

- Doral® (quazepam tablets): June 2028
- Silenor® (doxepin tablets): September 2030
- Edluar® (zolpidem sublingual tablets): February 2031
- Zolpimist® (zolpidem oral spray): August 2032
- Belsomra® (suvorexant tablets): May 2033
- Quviviq® (daridorexant tablets): December 2034
- Dayvigo® (lemborexant tablets): October 2035
- Hetlioz® (tasimelteon capsules): February 2041
- Hetlioz LQ® (tasimelteon oral suspension): February 2041

Pipeline:

- **Seltorexant:** Seltorexant is a novel orexin receptor type 2 antagonist that is being studied for adjunct treatment of major depressive disorder (MDD) with insomnia symptoms. The Phase 2 clinical trial reported an improvement in the primary outcome, which was the change from baseline in the Montgomery-Åsberg Depression Rating Scale (MADRS) at week 6 compared to placebo. The preliminary results of the Phase 3 clinical trial showed an improvement in the MADRS score by day 43 and improved sleep outcomes. A New Drug Application (NDA) has not yet been submitted for this product.
- **Vornorexant (TS-142):** Vornorexant is a new dual orexin receptor type 1 and 2 antagonist being studied for the treatment of insomnia and sleep apnea. In the Phase 2 clinical trial for the treatment of insomnia, it was reported that there was a significant improvement in the primary endpoint which was the latency to persistent sleep (LPS). Phase 3 clinical trials have been completed but results have not been published at this time.

Recommendations

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

Utilization Details of Insomnia Medications: Fiscal Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/CLAIM	CLAIMS/MEMBER	% COST
TIER-1 PRODUCTS						
ZOLPIDEM TAB 10MG	16,607	3,099	\$168,293.10	\$10.13	5.36	9.47%
ZOLPIDEM TAB 5MG	4,354	1,556	\$43,492.39	\$9.99	2.8	2.45%
ESZOPICLONE TAB 3MG	3,323	799	\$41,964.08	\$12.63	4.16	2.36%
TEMAZEPAM CAP 30MG	2,755	593	\$32,930.65	\$11.95	4.65	1.85%
ROZEREM TAB 8MG	1,859	430	\$668,199.60	\$359.44	4.32	37.60%
TEMAZEPAM CAP 15MG	1,773	605	\$18,053.75	\$10.18	2.93	1.02%
ESZOPICLONE TAB 2MG	1,734	597	\$21,452.72	\$12.37	2.9	1.21%
ESZOPICLONE TAB 1MG	768	378	\$10,603.72	\$13.81	2.03	0.60%
ZALEPLON CAP 10MG	595	231	\$7,921.12	\$13.31	2.58	0.45%
ZALEPLON CAP 5MG	240	184	\$2,461.15	\$10.25	1.3	0.14%
ESTAZOLAM TAB 2MG	39	7	\$1,425.84	\$36.56	5.57	0.08%
ESTAZOLAM TAB 1MG	13	3	\$410.76	\$31.60	4.33	0.02%
RAMELTEON TAB 8MG	6	4	\$250.01	\$41.67	1.5	0.01%
FLURAZEPAM CAP 15MG	2	1	\$43.18	\$21.59	2	0.00%
TIER-1 SUBTOTAL	34,068	8,487	\$1,017,502.07	\$29.87	4.01	57.26%
TIER-2 PRODUCTS						
ZOLPIDEM ER TAB 12.5MG	1,422	240	\$19,009.63	\$13.37	5.93	1.07%
ZOLPIDEM ER TAB 6.25MG	159	44	\$1,945.12	\$12.23	3.61	0.11%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/CLAIM	CLAIMS/MEMBER	% COST
AMBIEN CR TAB 12.5MG	12	1	\$7,294.26	\$17.73	12	0.41%
TIER-2 SUBTOTAL	1,593	285	\$28,249.01	\$17.73	5.59	1.59%
TIER-3 PRODUCTS						
DAYVIGO TAB 10MG	128	27	\$37,307.77	\$291.47	4.74	2.10%
BELSOMRA TAB 20MG	106	22	\$40,962.38	\$386.44	4.82	2.31%
DAYVIGO TAB 5MG	49	15	\$14,872.50	\$303.52	3.27	0.84%
BELSOMRA TAB 10MG	40	13	\$16,277.10	\$406.93	3.08	0.92%
BELSOMRA TAB 15MG	10	4	\$4,026.19	\$402.62	2.5	0.23%
BELSOMRA TAB 5MG	1	1	\$395.22	\$395.22	1	0.02%
TIER-3 SUBTOTAL	334	82	\$113,841.16	\$340.84	4.07	6.41%
SPECIAL PRIOR AUTHORIZATION (PA) PRODUCTS						
HETLIOZ CAP 20MG	23	2	\$545,918.25	\$23,735.58	11.5	30.72%
TEMAZEPAM CAP 7.5MG	19	6	\$837.28	\$44.07	3.17	0.05%
DOXEPIN TAB 6MG	17	4	\$4,158.01	\$244.59	4.25	0.23%
QUVIVIQ TAB 50MG	8	3	\$3,716.87	\$4,464.61	2.67	0.21%
TEMAZEPAM CAP 22.5MG	8	1	\$412.91	\$51.61	8	0.02%
TASIMELTEON CAP 20MG	3	1	\$61,747.11	\$20,582.37	3	3.47%
DOXEPIN TAB 3MG	2	2	\$664.66	\$332.33	1	0.04%
SPECIAL PA SUBTOTAL	80	19	\$617,455.09	\$7,718.19	4.21	34.75%
TOTAL	36,075	7,377*	\$1,777,047.33	\$49.26	4.89	100%

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated utilizing members.

CAP = capsule; CR = controlled-release; ER = extended-release; HCL = hydrochloride; TAB = tablet
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

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 06/2024. Last accessed 06/05/2024.

² Johnson & Johnson. Johnson & Johnson Pivotal Study of Seltorexant Shows Statistically Significant and Clinically Meaningful Improvement in Depressive Symptoms and Sleep Disturbance Outcomes. *PR Newswire*. Available online at: <https://www.prnewswire.com/news-releases/johnson-johnson-pivotal-study-of-seltorexant-shows-statistically-significant-and-clinically-meaningful-improvement-in-depressive-symptoms-and-sleep-disturbance-outcomes-302157980.html>. Issued 05/29/2024. Last accessed 06/10/2024.

³ Savitz A, Wajs E, Zhang Y, et al. Efficacy and Safety of Seltorexant as Adjunctive Therapy in Major Depressive Disorder: A Phase 2b, Randomized, Placebo-Controlled, Adaptive Dose-Finding Study. *Int J Neuropsychopharmacol* 2021; 24:965-976. doi: 10.1093/ijnp/pyab050.

⁴ Meglio M. Phase 3 Study Aims to Confirm Benefit of Dual Orexin-Receptor Antagonist TS-142 in Insomnia. *NeurologyLive*. Available online at: <https://www.neurologylive.com/view/phase-3-aims-confirm-benefit-dual-orexin-receptor-antagonist-ts142-insomnia>. Issued 04/20/2023. Last accessed 06/10/2024.

⁵ Uchiyama M, Kambe D, Imadera Y, et al. Effects of TS-142, a Novel Dual Orexin Receptor Antagonist, on Sleep in Patients with Insomnia: A Randomized, Double-Blind, Placebo-Controlled Phase 2 Study. *Psychopharmacology* 2022; 239:2143-2154. doi: 10.1007/s00213-022-06089-6.

Fiscal Year 2023 Annual Review of Leukotriene Modulators

Oklahoma Health Care Authority Fiscal Year 2023 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® (Zileuton) and 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 beta₂ 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 2023

Comparison of Fiscal Years

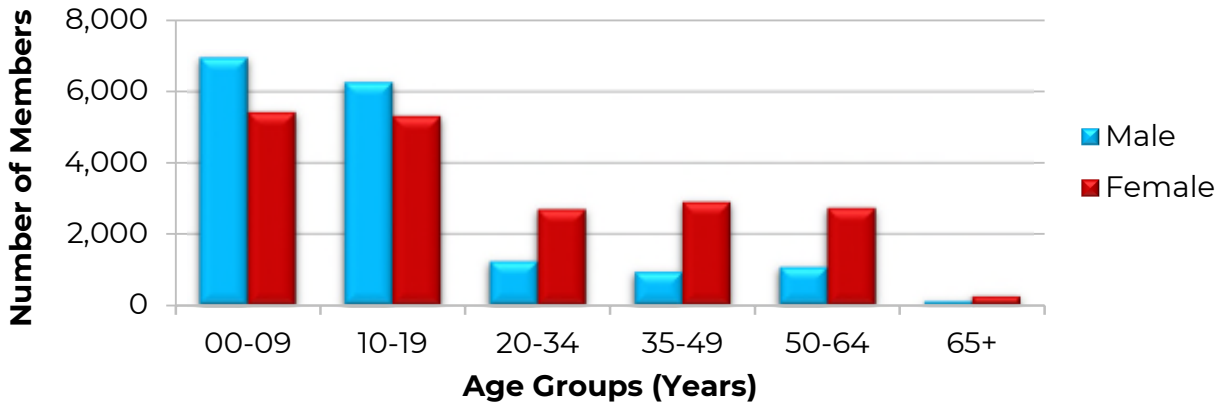
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2022	34,656	104,859	\$1,549,175.04	\$14.77	\$0.35	4,373,252	4,379,641
2023	35,752	103,384	\$1,474,102.54	\$14.26	\$0.31	4,752,755	4,759,527
% Change	3.2%	-1.4%	-4.8%	-3.5%	-11.4%	8.7%	8.7%
Change	1,096	-1,475	-\$75,072.50	-\$0.51	-\$0.04	379,503	379,886

Costs do not reflect rebated prices or net costs.

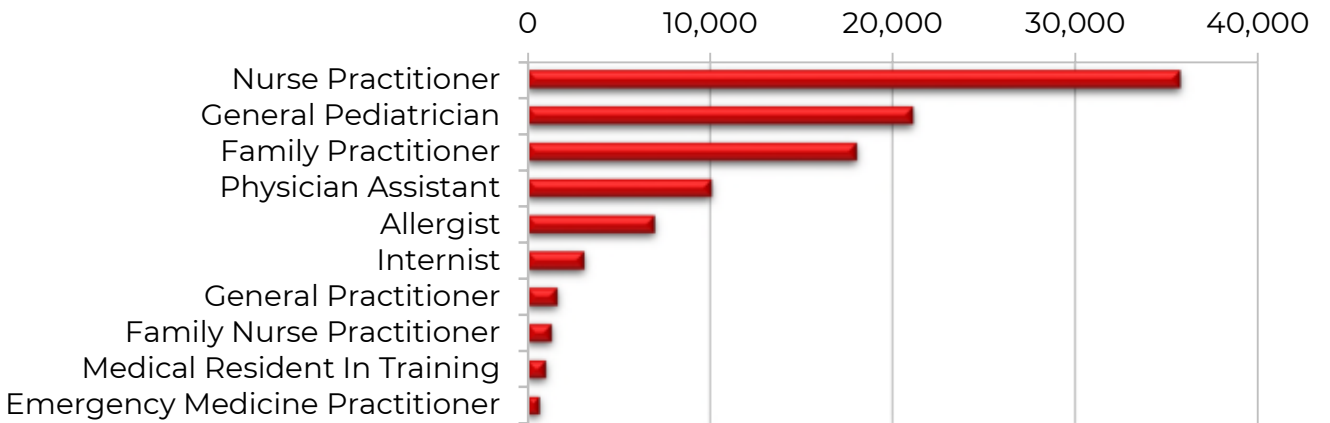
*Total number of unduplicated utilizing members.

Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Demographics of Members Utilizing Leukotriene Modulators



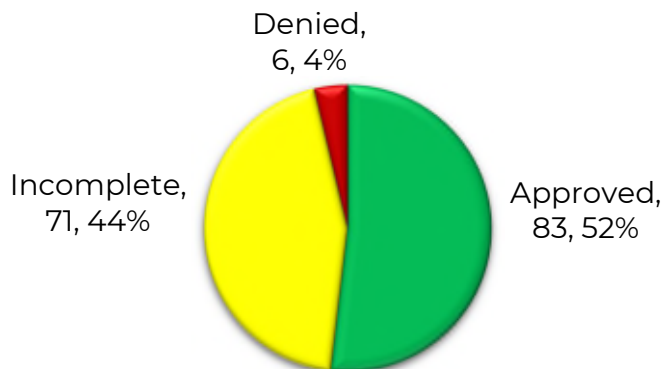
Top Prescriber Specialties of Leukotriene Modulators by Number of Claims



Prior Authorization of Leukotriene Modulators

There were 160 prior authorization requests submitted for leukotriene modulators during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

Status of Petitions



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 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
MONTELUKAST PRODUCTS						
MONTELUKAST TAB 10MG	46,172	17,428	\$596,844.28	\$12.93	2.65	40.49%
MONTELUKAST CHW 5MG	33,537	10,971	\$482,042.68	\$14.37	3.06	32.70%
MONTELUKAST CHW 4MG	22,124	7,676	\$319,063.60	\$14.42	2.88	21.64%
MONTELUKAST GRA 4MG	1,549	745	\$69,148.08	\$44.64	2.08	4.69%
SUBTOTAL	103,382	36,820	\$1,467,098.64	\$14.19	2.81	99.52%
ZILEUTON PRODUCTS						
ZYFLO TAB 600MG	1	1	\$3,770.45	\$3,770.45	1	0.26%
ZILEUTON ER TAB 600MG	1	1	\$3,233.45	\$3,233.45	1	0.22%
SUBTOTAL	2	2	\$7,003.90	\$3,501.95	1	0.48%
TOTAL	103,384	35,752*	\$1,474,102.54	\$14.26	2.89	100%

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated utilizing members.

CHW = chewable; ER = extended release; GRA = granule; TAB = tablet

Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Fiscal Year 2023 Annual Review of Muscle Relaxant Medications

Oklahoma Health Care Authority
Fiscal Year 2023 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 500mg (Parafon Forte®)		baclofen oral granules (Lyvispah®)
cyclobenzaprine (Flexeril®)		baclofen 5mg/5mL oral soln (Ozobax®)
methocarbamol (Robaxin®)		baclofen 25mg/5mL oral susp (Fleqsuvy®)
orphenadrine (Norflex®)		carisoprodol 250mg (Soma®)
tizanidine tabs (Zanaflex®)		carisoprodol 350mg (Soma®)
		carisoprodol/ASA
		carisoprodol/ASA/codeine
		chlorzoxazone 375mg, 750mg (Lorzone®)
		cyclobenzaprine 7.5mg tabs (Fexmid®)
		cyclobenzaprine ER caps (Amrix®)
		orphenadrine/ASA/caffeine tabs (Norgesic®, Norgesic® Forte, Orphengesic® Forte)
		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; susp = suspension; 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 an 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.

Fleqsuvy® 25mg/5mL (Baclofen Oral Suspension), Lyvispah® (Baclofen Oral Granules), and Ozobax® 5mg/5mL (Baclofen Oral Solution) 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. Requests for Fleqsuvy® and Ozobax® will require a patient-specific, clinically significant reason why the member cannot use Lyvispah®; and
3. 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.

Norgesic®, Norgesic® Forte, and Orphengestic® Forte (Orphenadrine/Aspirin/Caffeine) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use all lower-tiered products must be provided.

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 3 months of carisoprodol 350mg per rolling 365 days without prior authorization; and
2. After the member has received the 3 months, 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 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 2023**Comparison of Fiscal Years**

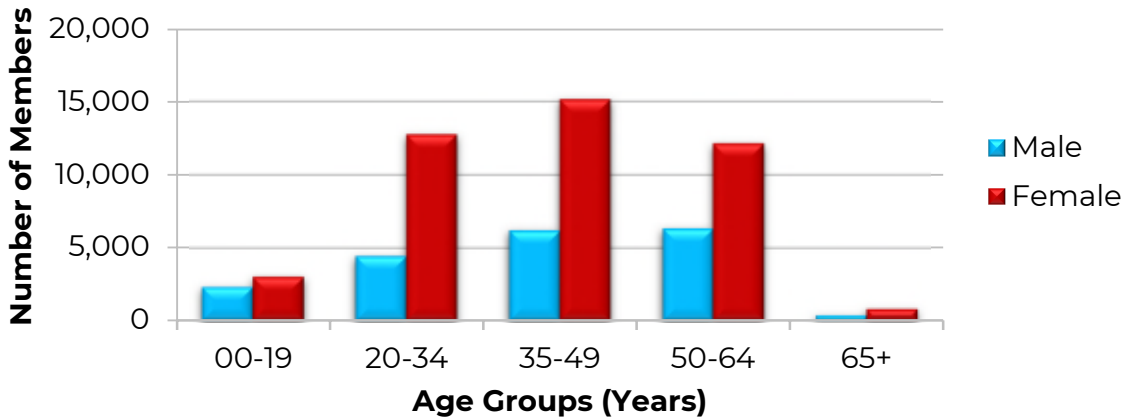
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2022	49,774	135,990	\$1,777,867.37	\$13.07	\$0.54	8,726,119	3,286,843
2023	63,418	171,615	\$2,146,997.28	\$12.51	\$0.52	10,741,958	4,135,020
% Change	27.4%	26.2%	20.8%	-4.3%	-3.7%	23.1%	25.8%
Change	13,644	35,625	\$369,129.91	-\$0.56	-\$0.02	2,015,839	848,177

Costs do not reflect rebated prices or net costs.

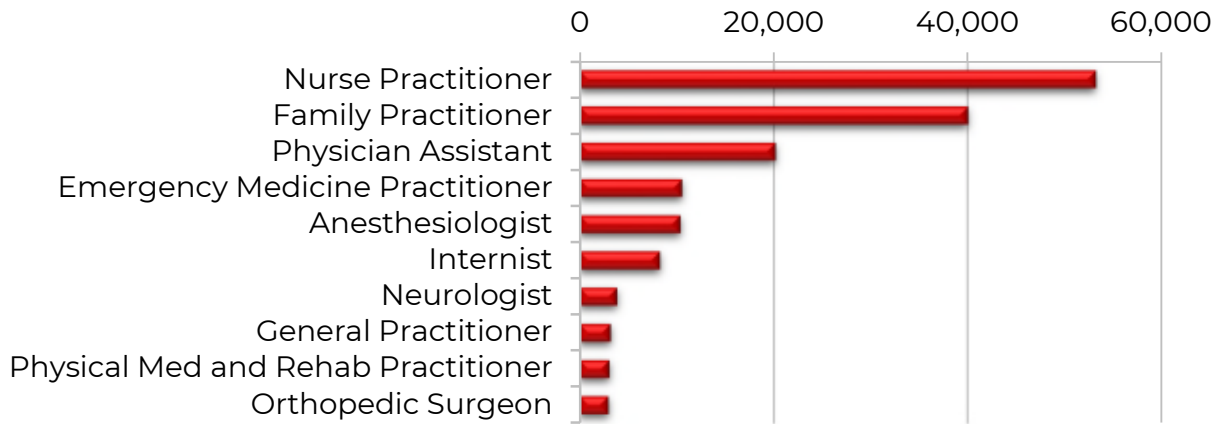
*Total number of unduplicated utilizing members.

Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Demographics of Members Utilizing Muscle Relaxant Medications

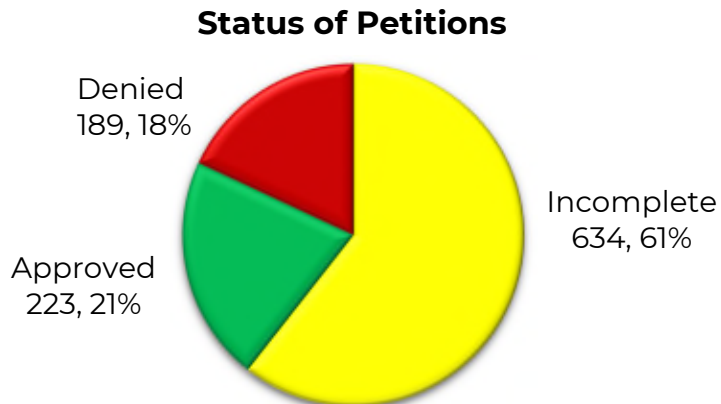


Top Prescriber Specialties of Muscle Relaxant Medications by Number of Claims



Prior Authorization of Muscle Relaxant Medications

There were 1,046 prior authorization requests submitted for muscle relaxant medications during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.



Market News and Updates¹

Anticipated Patent Expiration(s):

- Amrix® [cyclobenzaprine extended-release (ER) capsule]: February 2025
- Skelaxin® (metaxalone tablet): February 2026
- Fleqsuvy® (baclofen 25mg/5mL oral suspension): September 2037
- Ozobax® (baclofen 5mg/5mL oral solution): August 2039
- Lyvispah® (baclofen oral granules): September 2041

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 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 UTILIZATION						
CYCLOBENZAPRINE PRODUCTS						
CYCLOBENZAPRINE TAB 10MG	53,621	24,804	\$553,873.40	\$10.33	2.16	25.80%
CYCLOBENZAPRINE TAB 5MG	15,319	9,314	\$160,185.17	\$10.46	1.64	7.46%
SUBTOTAL	68,940	34,118	\$714,058.57	\$10.36	2.02	33.26%
TIZANIDINE PRODUCTS						
TIZANIDINE TAB 4MG	39,801	13,307	\$479,826.64	\$12.06	2.99	22.35%
TIZANIDINE TAB 2MG	7,039	3,257	\$85,643.24	\$12.17	2.16	3.99%
SUBTOTAL	46,840	16,564	\$565,469.88	\$12.07	2.83	26.34%
BACLOFEN PRODUCTS						
BACLOFEN TAB 10MG	18,421	5,819	\$250,582.59	\$13.60	3.17	11.67%
BACLOFEN TAB 20MG	7,429	1,575	\$126,882.19	\$17.08	4.72	5.91%
BACLOFEN POWDER	368	50	\$5,245.69	\$14.25	7.36	0.24%
LIORESAL INT INJ 40MG/20ML	12	6	\$12,423.74	\$1,035.31	2	0.58%
BACLOFEN INJ 40MG/20ML	12	1	\$10,806.00	\$900.50	12	0.50%
GABLOFEN INJ 40,000MCG/20ML	7	1	\$6,607.87	\$943.98	7	0.31%
SUBTOTAL	26,249	7,452	\$412,548.08	\$15.72	3.52	19.22%
METHOCARBAMOL PRODUCTS						
METHOCARBAMOL TAB 750MG	10,899	5,297	\$137,928.12	\$12.66	2.06	6.42%
METHOCARBAMOL TAB 500MG	10,629	6,295	\$127,521.33	\$12.00	1.69	5.94%
METHOCARBAMOL INJ 100MG/ML	4	2	\$2,612.64	\$653.16	2	0.12%
SUBTOTAL	21,532	11,594	\$268,062.09	\$12.45	1.86	12.49%
ORPHENADRINE PRODUCTS						
ORPHENADRINE TAB 100MG ER	5,779	4,122	\$114,133.86	\$19.75	1.4	5.32%
ORPHENADRINE INJ 30MG/ML	1	1	\$12.79	\$12.79	1	0.00%
SUBTOTAL	5,780	4,123	\$114,146.65	\$19.75	1.4	5.32%
CHLORZOXAZONE PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/CLAIM	CLAIMS/MEMBER	% COST
CHLORZOXAZONE TAB 500MG	958	368	\$24,178.35	\$25.24	2.6	1.13%
SUBTOTAL	958	368	\$24,178.35	\$25.24	2.6	1.13%
TIER-1 SUBTOTAL	170,299	74,219	\$2,098,463.62	\$12.32	2.29	97.74%
TIER-2 UTILIZATION						
METAXALONE PRODUCTS						
METAXALONE TAB 800MG	225	65	\$9,724.05	\$43.22	3.46	0.45%
METAXALONE TAB 400MG	14	6	\$8,439.18	\$602.80	2.33	0.39%
SUBTOTAL	239	71	\$18,163.23	\$76.00	3.37	0.85%
TIER-2 SUBTOTAL	239	71	\$18,163.23	\$76.00	3.37	0.85%
SPECIAL PA UTILIZATION						
CARISOPRODOL PRODUCTS						
CARISOPRODOL TAB 350MG	927	418	\$11,358.01	\$12.25	2.22	0.53%
SUBTOTAL	927	418	\$11,358.01	\$12.25	2.22	0.53%
BACLOFEN PRODUCTS						
BACLOFEN TAB 5MG	98	28	\$3,031.94	\$30.94	3.5	0.14%
BACLOFEN SOL 5MG/5ML	34	10	\$11,072.23	\$325.65	3.4	0.52%
LYVISPAH GRA 5MG	5	1	\$2,384.04	\$476.81	5	0.11%
FLEQSUVY SUS 25MG/5ML	2	1	\$1,342.82	\$671.41	2	0.06%
BACLOFEN SUS 25MG/5ML	1	1	\$737.40	\$737.40	1	0.03%
SUBTOTAL	140	41	\$18,568.43	\$132.63	3.41	0.86%
TIZANIDINE PRODUCTS						
TIZANIDINE CAP 4MG	8	6	\$150.63	\$18.83	1.33	0.01%
SUBTOTAL	8	6	\$150.63	\$18.83	1.33	0.01%
CHLORZOXAZONE PRODUCTS						
CHLORZOXAZONE TAB 750MG	1	1	\$256.41	\$256.41	1	0.01%
SUBTOTAL	1	1	\$256.41	\$256.41	1	0.01%
CYCLOBENZAPRINE PRODUCTS						
CYCLOBENZAPRINE TAB 7.5MG	1	1	\$36.95	\$36.95	1	0.00%
SUBTOTAL	1	1	\$36.95	\$36.95	1	0.00%
SPECIAL PA SUBTOTAL	1,077	467	\$30,370.43	\$28.20	2.31	1.41%
TOTAL	171,615	63,418*	\$2,146,997.28	\$12.51	2.71	100%

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated utilizing members.

CAP = capsule; ER = extended-release; GRA = granules; INJ = injection; INT = intrathecal; PA = prior authorization; SOL = solution; SUS = suspension; TAB = tablet

¹ 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/>. Last revised 04/2024. Last accessed 04/16/2024.

Fiscal Year 2023 Annual Review of Systemic Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)

Oklahoma Health Care Authority
Fiscal Year 2023 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 ODT (Qmiiz 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

*Unique criteria applies

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 2023

Comparison of Fiscal Years

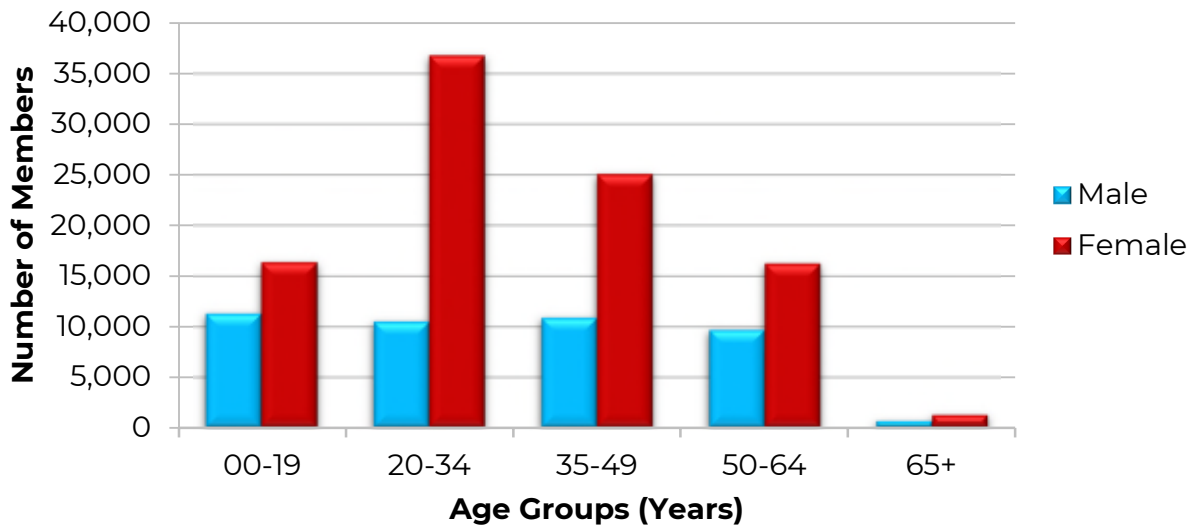
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2022	111,805	214,852	\$3,022,183.13	\$14.07	\$0.61	10,665,788	4,941,208
2023	138,167	271,607	\$3,661,923.58	\$13.48	\$0.58	13,337,922	6,358,493
% Change	23.60%	26.40%	21.20%	-4.20%	-4.90%	25.10%	28.70%
Change	26,362	56,755	\$639,740.45	-\$0.59	-\$0.03	2,672,134	1,417,285

Costs do not reflect rebated prices or net costs.

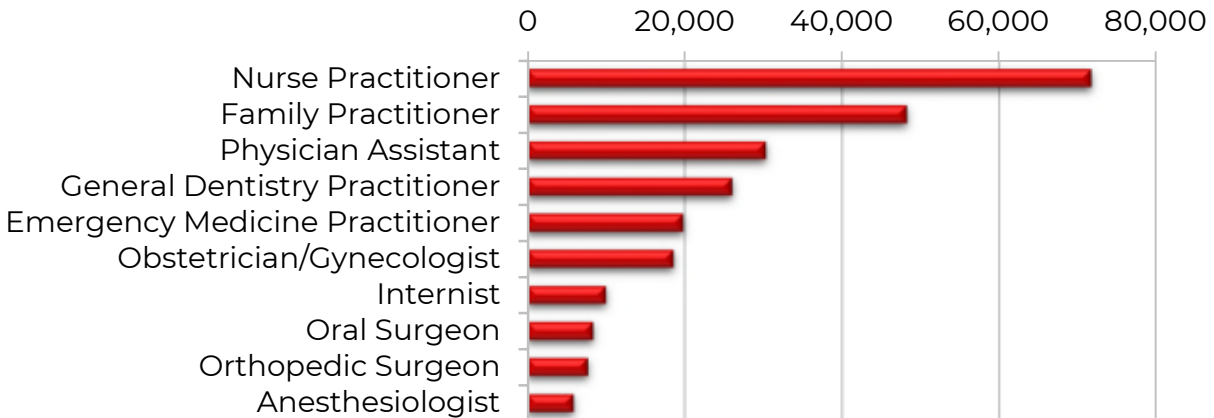
*Total number of unduplicated utilizing members.

Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Demographics of Members Utilizing NSAIDs

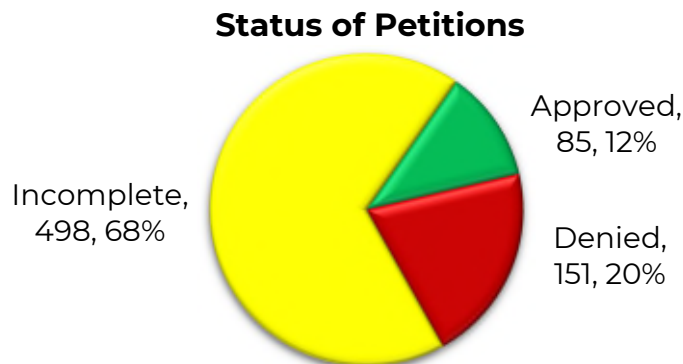


Top Prescriber Specialties of NSAIDs by Number of Claims



Prior Authorization of NSAIDs

There were 734 prior authorization requests submitted for NSAIDs during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.



Market News and Updates¹

Anticipated Patent Expiration(s):

- 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
- Caldolor® (ibuprofen injection): March 2032
- Licart® (diclofenac epolamine topical system): February 2035
- 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 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 PRODUCTS						
IBUPROFEN PRODUCTS						
IBUPROFEN TAB 800MG	87,238	58,154	\$1,025,945.29	\$11.76	1.5	28.02%
IBUPROFEN TAB 600MG	19,760	16,992	\$215,884.95	\$10.93	1.16	5.90%
IBUPROFEN TAB 400MG	2,618	2,088	\$30,438.96	\$11.63	1.25	0.83%
IBU TAB 800MG	843	624	\$11,869.38	\$14.08	1.35	0.32%
IBU TAB 600MG	94	89	\$1,174.25	\$12.49	1.06	0.03%
IBU TAB 400MG	36	20	\$405.89	\$11.27	1.8	0.01%
IBUPROFEN POW	14	14	\$165.58	\$11.83	1	0.00%
SUBTOTAL	110,603	77,981	\$1,285,884.30	\$11.63	1.42	35.11%
MELOXICAM PRODUCTS						
MELOXICAM TAB 15MG	38,277	18,906	\$384,179.05	\$10.04	2.02	10.49%
MELOXICAM TAB 7.5MG	16,827	9,406	\$169,562.42	\$10.08	1.79	4.63%
SUBTOTAL	55,104	28,312	\$553,741.47	\$10.05	1.95	15.12%
NAPROXEN PRODUCTS						
NAPROXEN TAB 500MG	31,979	22,004	\$359,914.53	\$11.25	1.45	9.83%
NAPROXEN TAB 375MG	2,629	1,968	\$31,784.06	\$12.09	1.34	0.87%
NAPROXEN TAB 250MG	1,747	1,157	\$22,421.87	\$12.83	1.51	0.61%
NAPROXEN DR TAB 500MG	538	386	\$64,677.38	\$120.22	1.39	1.77%
EC-NAPROXEN TAB 500MG	498	316	\$58,390.71	\$117.25	1.58	1.59%
NAPROXEN SUS 125MG/5ML	468	272	\$81,582.93	\$174.32	1.72	2.23%
NAPROXEN DR TAB 375MG	105	70	\$2,149.44	\$20.47	1.5	0.06%
EC-NAPROXEN TAB 375MG	9	9	\$207.91	\$23.10	1	0.01%
SUBTOTAL	37,973	26,182	\$621,128.83	\$16.36	1.45	16.96%
DICLOFENAC PRODUCTS						
DICLOFENAC TAB 75MG DR	13,723	6,275	\$190,500.52	\$13.88	2.19	5.20%
DICLOFENAC GEL 1%	10,375	5,852	\$211,122.88	\$20.35	1.77	5.77%
DICLOFENAC TAB 50MG DR	4,204	2,240	\$61,868.34	\$14.72	1.88	1.69%
FLECTOR DIS 1.3%	144	48	\$42,893.39	\$297.87	3	1.17%
SUBTOTAL	28,446	14,415	\$506,385.13	\$17.80	1.97	13.83%
CELECOXIB PRODUCTS						
CELECOXIB CAP 200MG	13,628	5,149	\$204,828.65	\$15.03	2.65	5.59%
CELECOXIB CAP 100MG	5,775	2,330	\$84,347.60	\$14.61	2.48	2.30%
CELECOXIB CAP 50MG	284	125	\$4,248.62	\$14.96	2.27	0.12%
SUBTOTAL	19,687	7,604	\$293,424.87	\$14.90	2.59	8.01%
KETOROLAC PRODUCTS						
KETOROLAC TAB 10MG	9,491	8,462	\$174,137.75	\$18.35	1.12	4.76%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/CLAIM	CLAIMS/MEMBER	% COST
KETOROLAC INJ 60MG/2ML	21	12	\$367.77	\$17.51	1.75	0.01%
KETOROLAC INJ 30MG/ML	15	11	\$178.23	\$11.88	1.36	0.00%
SUBTOTAL	9,527	8,485	\$174,683.75	\$18.34	1.12	4.77%
NABUMETONE PRODUCTS						
NABUMETONE TAB 750MG	2,040	783	\$33,651.60	\$16.50	2.61	0.92%
NABUMETONE TAB 500MG	1,420	567	\$22,948.76	\$16.16	2.5	0.63%
SUBTOTAL	3,460	1,350	\$56,600.36	\$16.36	2.56	1.55%
ETODOLAC PRODUCTS						
ETODOLAC TAB 400MG	2,099	1,294	\$46,044.48	\$21.94	1.62	1.26%
ETODOLAC TAB 500MG	918	567	\$19,453.22	\$21.19	1.62	0.53%
SUBTOTAL	3,017	1,861	\$65,497.70	\$21.71	1.62	1.79%
INDOMETHACIN PRODUCTS						
INDOMETHACIN CAP 50MG	1,092	674	\$14,444.73	\$13.23	1.62	0.39%
INDOMETHACIN CAP 25MG	566	371	\$7,689.07	\$13.58	1.53	0.21%
SUBTOTAL	1,658	1,045	22,133.80	\$13.35	1.59	0.60%
SULINDAC PRODUCTS						
SULINDAC TAB 200MG	316	130	\$6,815.53	\$21.57	2.43	0.19%
SULINDAC TAB 150MG	158	43	\$2,833.01	\$17.93	3.67	0.08%
SUBTOTAL	474	173	\$9,648.54	\$20.36	2.74	0.26%
FLURBIPROFEN PRODUCTS						
FLURBIPROFEN TAB 100MG	113	25	\$3,103.56	\$27.47	4.52	0.08%
SUBTOTAL	113	25	\$3,103.56	\$27.47	4.52	0.08%
TIER-1 SUBTOTAL	270,062	138,037*	\$3,592,232.31	\$13.30	1.96	98.10%
TIER-2 PRODUCTS						
DICLOFENAC PRODUCTS						
DICLOFENAC POT TAB 50MG	420	210	\$9,215.14	\$21.94	2	0.25%
DICLOFENAC TAB 100MG ER	399	164	\$23,035.93	\$57.73	2.43	0.63%
DICLOFENAC TAB 25MG DR	53	17	\$2,467.48	\$46.56	3.12	0.07%
SUBTOTAL	872	391	\$34,718.55	\$39.81	2.23	0.95%
ETODOLAC PRODUCTS						
ETODOLAC CAP 300MG	167	146	\$3,596.22	\$21.53	1.14	0.10%
ETODOLAC CAP 200MG	109	88	\$2,558.30	\$23.47	1.24	0.07%
ETODOLAC ER TAB 400MG	12	5	\$503.88	\$41.99	2.4	0.01%
ETODOLAC ER TAB 500MG	1	1	\$86.88	\$86.88	1	0.00%
ETODOLAC ER TAB 600MG	1	1	\$144.01	\$144.01	1	0.00%
SUBTOTAL	290	241	\$6,889.29	\$23.76	1.2	0.19%
NAPROXEN PRODUCTS						
NAPROXEN SOD TAB 550MG	203	129	\$4,417.46	\$21.76	1.57	0.12%
NAPROXEN SOD TAB 275MG	9	8	\$273.22	\$30.36	1.13	0.01%
SUBTOTAL	212	137	\$4,690.68	\$22.13	1.55	0.13%
DICLOFENAC/MISOPROSTOL PRODUCTS						
DICLO/MISOPR TAB 75/0.2MG	81	24	\$5,989.19	\$73.94	3.38	0.16%
DICLO/MISOPR TAB 50/0.2MG	18	7	\$1,217.88	\$67.66	2.57	0.03%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/CLAIM	CLAIMS/MEMBER	% COST
SUBTOTAL	99	31	\$7,207.07	\$72.80	3.19	0.20%
PIROXICAM PRODUCTS						
PIROXICAM CAP 20MG	32	12	\$854.42	\$26.70	2.67	0.02%
SUBTOTAL	32	12	\$854.42	\$26.70	2.67	0.02%
OXAPROZIN PRODUCTS						
OXAPROZIN TAB 600MG	15	6	\$695.16	\$46.34	2.5	0.02%
SUBTOTAL	15	6	\$695.16	\$46.34	2.5	0.02%
TIER-2 SUBTOTAL	1,520	811*	\$55,055.17	\$36.22	1.87	1.50%
SPECIAL PRIOR AUTHORIZATION (PA) UTILIZATION						
DICLOFENAC PRODUCTS						
CAMBIA POW 50MG	5	2	\$4,302.95	\$860.59	2.5	0.12%
DICLOFENAC SOL 2%	4	1	\$6,498.92	\$1,624.73	4	0.18%
DICLOFENAC POW 50MG	2	2	\$1,203.94	\$601.97	1	0.03%
SUBTOTAL	11	5	\$12,005.81	\$1,091.44	2.2	0.33%
IBUPROFEN/FAMOTIDINE PRODUCTS						
IBU/FAMOT TAB 800/26.6MG	8	1	\$2,499.53	\$312.44	8	0.07%
SUBTOTAL	8	1	\$2,499.53	\$312.44	8	0.07%
INDOMETHACIN PRODUCTS						
INDOMETHACIN CAP 75MG ER	6	2	\$130.76	\$21.79	3	0.00%
SUBTOTAL	6	2	\$130.76	\$21.79	3	0.00%
SPECIAL PA SUBTOTAL	25	7*	\$14,636.10	\$585.44	3.57	0.40%
TOTAL	271,607	138,167*	\$3,661,923.58	\$13.48	1.97	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; IBU/FAMOT = ibuprofen/famotidine; INJ = injection; POT = potassium; POW = powder; SOD = sodium; SOL = solution; SUS = suspension; TAB = tablet

Fiscal Year 2023 = 07/01/2022 to 06/30/2023

¹ 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 05/2024 Last accessed 05/31/2024.

Fiscal Year 2023 Annual Review of Nuedexta® (Dextromethorphan/Quinidine)

**Oklahoma Health Care Authority
Fiscal Year 2023 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 2023

Comparison of Fiscal Years

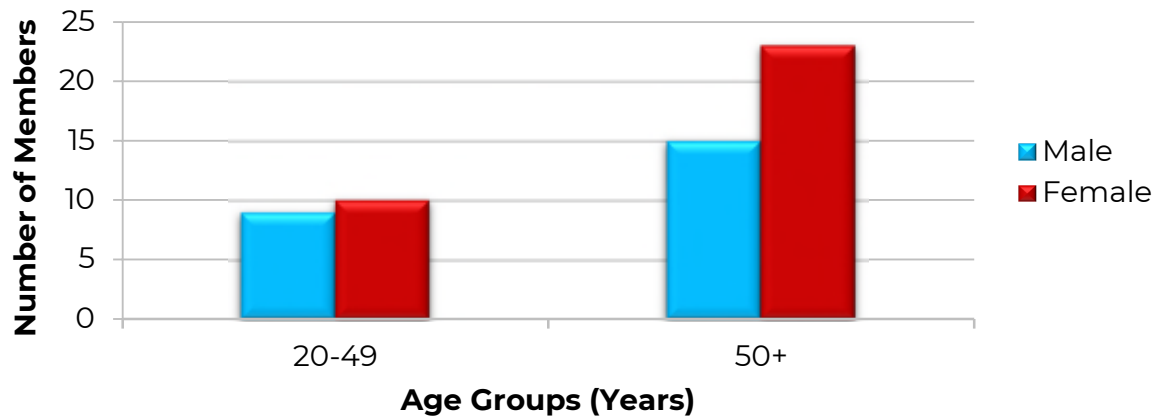
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2022	75	683	\$756,143.98	\$1,107.09	\$41.90	34,451	18,046
2023	57	585	\$678,941.88	\$1,160.58	\$44.72	28,752	15,181
% Change	-24.0%	-14.3%	-10.2%	4.8%	6.7%	-16.5%	-15.9%
Change	-18	-98	-\$77,202.10	\$53.49	\$2.82	-5,699	-2,865

Costs do not reflect rebated prices or net costs.

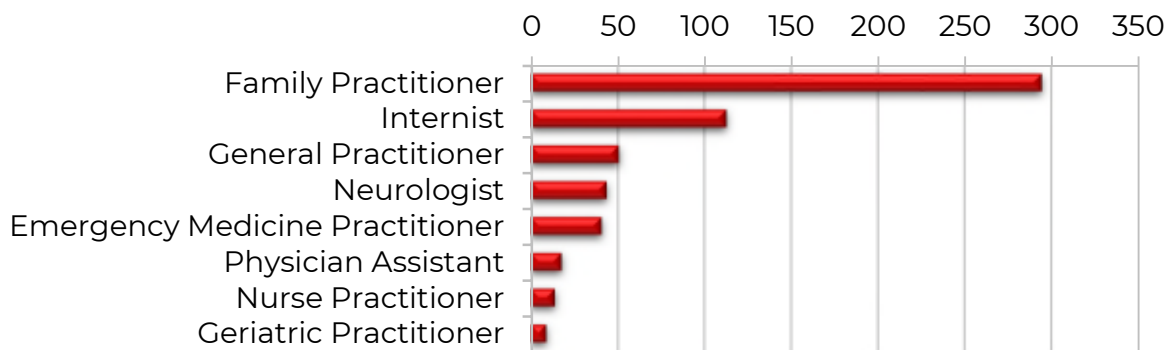
*Total number of unduplicated utilizing members.

Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Demographics of Members Utilizing Nuedexta® (Dextromethorphan/Quinidine)



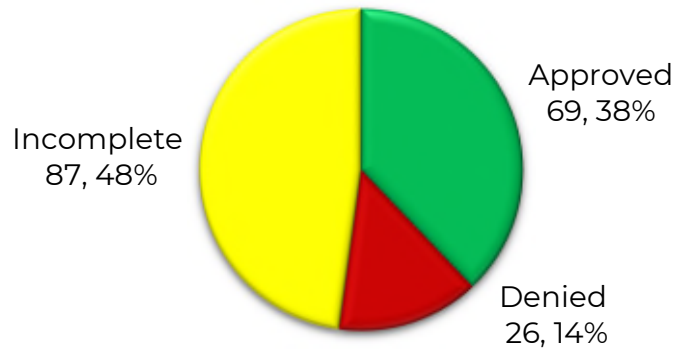
Top Prescriber Specialties of Nuedexta® (Dextromethorphan/Quinidine) by Number of Claims



Prior Authorization of Nuedexta® (Dextromethorphan/Quinidine)

There were 182 prior authorization requests submitted for Nuedexta® (dextromethorphan/quinidine) during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

Status of Petitions



Market News and Updates¹

Anticipated Patent Expiration(s):

- 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 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/CLAIM	CLAIMS/MEMBER
NUEDEXTA CAP 20/10MG	585	57	\$678,941.88	\$1,160.58	10.26
TOTAL	585	57*	\$678,941.88	\$1,160.58	10.26

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated utilizing members.

CAP = capsule

Fiscal Year 2023 = 07/01/2022 to 06/30/2023

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 03/2024. Last accessed 03/27/2024.

Fiscal Year 2023 Annual Review of Ophthalmic Allergy Medications

Oklahoma Health Care Authority
Fiscal Year 2023 Print Report

Current Prior Authorization Criteria

Ophthalmic Allergy Medications		
Tier-1	Tier-2	Tier-3
cromolyn (Crolom [®])	azelastine (Optivar [®])	bepotastine (Bepreve [®])
ketotifen (Alaway [®] , Zaditor [®] OTC)	epinastine (Elestat [®])	cetirizine (Zerviate [®])
	olopatadine 0.1% (Patanol [®] , Pataday [®] Twice Daily Relief OTC)	emedastine (Emadine [®])
	olopatadine 0.7% (Pazeo [®] , Pataday [®] Once Daily Relief Extra Strength OTC)	lodoxamide (Alomide [®])
		loteprednol (Alrex [®])
		nedocromil (Alocril [®])
		olopatadine 0.2% (Pataday [®] , Pataday [®] Once Daily Relief OTC)

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 = over-the-counter

Ophthalmic Allergy Medications Tier-2 Approval Criteria:

1. An FDA approved diagnosis; and
2. Member must have a trial of 1 Tier-1 product for a minimum of 2 weeks in the last 30 days that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or
3. A contraindication to all lower tiered medications.

Ophthalmic Allergy Medications Tier-3 Approval Criteria:

1. An FDA approved diagnosis; and
2. Member must have recent trials of 1 Tier-1 product and all available Tier-2 products for a minimum of 2 weeks each that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or
3. A contraindication to all lower tiered medications.

Verkazia[®] (Cyclosporine 0.1% Ophthalmic Emulsion) Approval Criteria:

1. An FDA approved indication of vernal keratoconjunctivitis (VKC); and
2. Member has had 1 recurrence of VKC in the last year; and

3. Verkazia® must be prescribed by, or in consultation with, an allergist, optometrist, or ophthalmologist (or an advanced care practitioner with a supervising physician who is an allergist, optometrist, or ophthalmologist); and
4. Prescriber must verify that environmental factors (e.g., sun, wind, salt water) have been addressed; and
5. Member must have a trial of a topical mast cell stabilizer, antihistamine, or combination product or a patient-specific, clinically significant reason why those products are not appropriate must be provided; and
6. A patient-specific, clinically significant reason why the member cannot use cyclosporine 0.05% ophthalmic emulsion single-use vials, which are available without a prior authorization, must be provided; and
7. A quantity limit of 120 single-use vials per 30 days will apply.

Utilization of Ophthalmic Allergy Medications: Fiscal Year 2023

Comparison of Fiscal Years

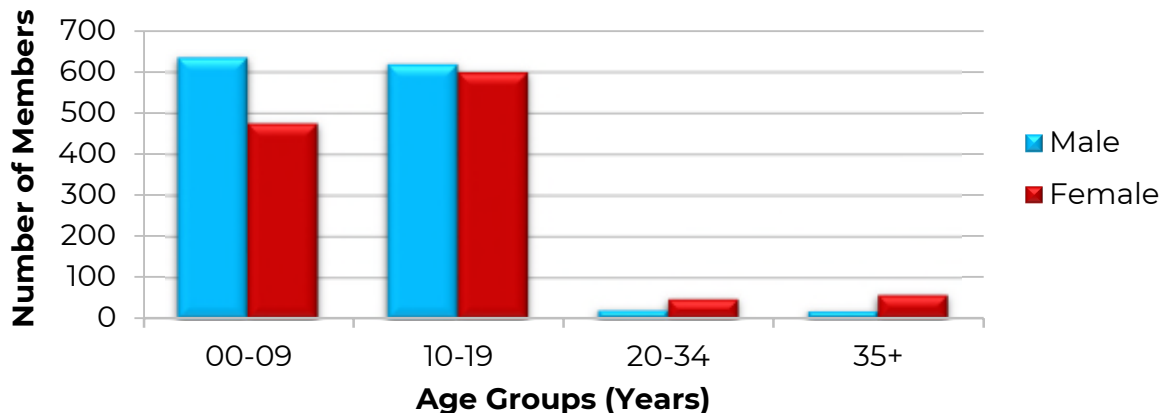
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2022	2,438	3,391	\$53,363.03	\$15.74	\$0.48	21,516	110,081
2023	2,469	3,284	\$51,650.53	\$15.73	\$0.48	20,275	107,852
% Change	1.3%	-3.2%	-3.2%	-0.1%	0.0%	-5.8%	-2.0%
Change	31	-107	-\$1,712.50	-\$0.01	\$0.0	-1,241	-2,229

Costs do not reflect rebated prices or net costs.

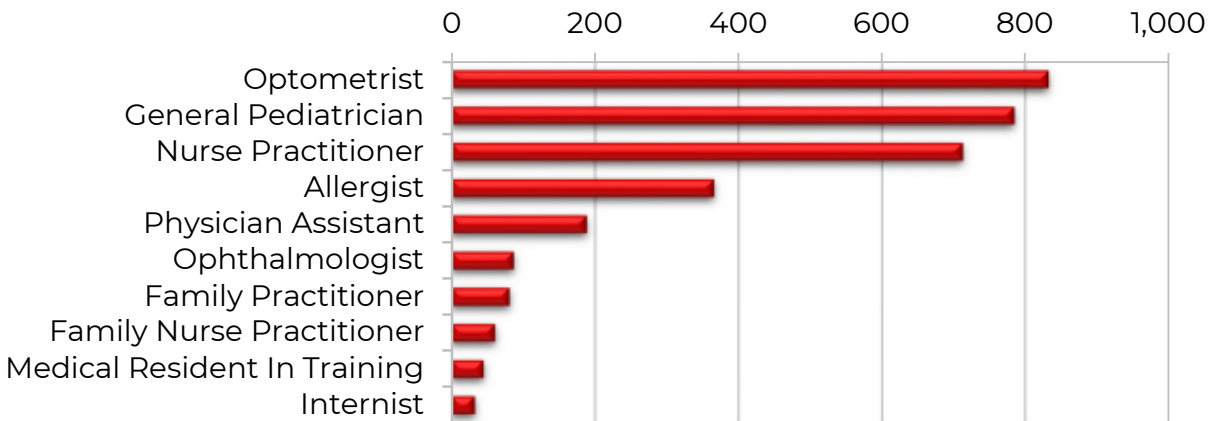
*Total number of unduplicated utilizing members.

Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Demographics of Members Utilizing Ophthalmic Allergy Medications

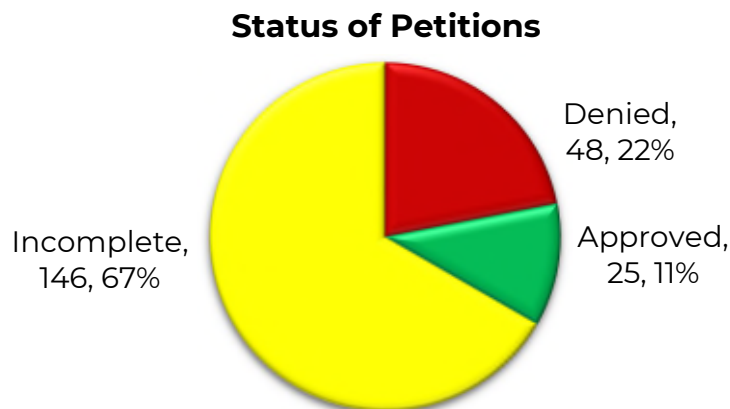


Top Prescriber Specialties of Ophthalmic Allergy Medications by Number of Claims



Prior Authorization of Ophthalmic Allergy Medications

There were 219 prior authorization requests submitted for ophthalmic allergy medications during fiscal year 2023. 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 2023.



Market News and Updates¹

Anticipated Patent Expiration(s):

- Bepreve[®] (bepotastine ophthalmic solution): January 2025
- Verkazia[®] (cyclosporine 0.1% ophthalmic emulsion): June 2029
- Pataday[®] Once Daily Relief (olopatadine 0.7% ophthalmic solution): May 2032
- Zerviate[®] (cetirizine ophthalmic solution): January 2033

Recommendations

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

Utilization Details of Ophthalmic Allergy Medications: Fiscal Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 PRODUCTS						
KETOTIFEN PRODUCTS						
KETOTIFEN FUM DRO 0.035% OP	2,246	1,763	\$34,687.69	\$15.44	1.27	67.16%
ALAWAY DRO 0.035% OP	481	340	\$7,222.11	\$15.01	1.41	13.98%
EYE ITCH RELIEF DRO 0.035% OP	186	174	\$3,073.29	\$16.52	1.07	5.95%
ALAWAY CHILD DRO 0.035% OP	5	5	\$78.93	\$15.79	1	0.15%
SUBTOTAL	2,918	2,282	\$45,062.02	\$15.44	1.28	87.24%
CROMOLYN PRODUCTS						
CROMOLYN SOD SOL 4% OP	303	221	\$4,592.02	\$15.16	1.37	8.89%
SUBTOTAL	303	221	\$4,592.02	\$15.16	1.37	8.89%
TIER-1 SUBTOTAL	3,221	2,503	\$49,654.04	\$15.42	1.29	96.13%
TIER-2 PRODUCTS						
AZELASTINE PRODUCTS						
AZELASTINE DRO 0.05%	25	14	\$388.83	\$15.55	1.79	0.75%
SUBTOTAL	25	14	\$388.83	\$15.55	1.79	0.75%
EPINASTINE PRODUCTS						
EPINASTINE DRO 0.05%	17	3	\$1,161.78	\$68.34	5.67	2.25%
SUBTOTAL	17	3	\$1,161.78	\$68.34	5.67	2.25%
OLOPATADINE PRODUCTS						
OLOPATADINE DRO 0.1%	14	5	\$284.10	\$20.29	2.8	0.55%
PATADAY SOL 0.7%	7	2	\$161.78	\$23.11	3.5	0.31%
SUBTOTAL	21	7	\$445.88	\$21.23	3	0.86%
TIER-2 SUBTOTAL	63	24	\$1,996.49	\$31.69	2.63	3.87%
TOTAL	3,284	2,469*	\$51,650.53	\$15.73	1.33	100%

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated utilizing members.

DRO = drops; FUM = fumarate; OP = ophthalmic; SOD = sodium; SOL = solution

Fiscal Year 2023 = 07/01/2022 to 06/30/2023

¹ 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 06/2024. Last accessed 06/05/2024.

Fiscal Year 2023 Annual Review of Qutenza® (Capsaicin 8% Patch)

Oklahoma Health Care Authority Fiscal Year 2023 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 2023

Fiscal Year 2023 Utilization: Medical Claims

Fiscal Year	*Total Members	*Total Claims	Total Cost	Cost/Claim	Claims/Member
2023	3	6	\$21,817.60	\$3,636.27	2

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated utilizing members.

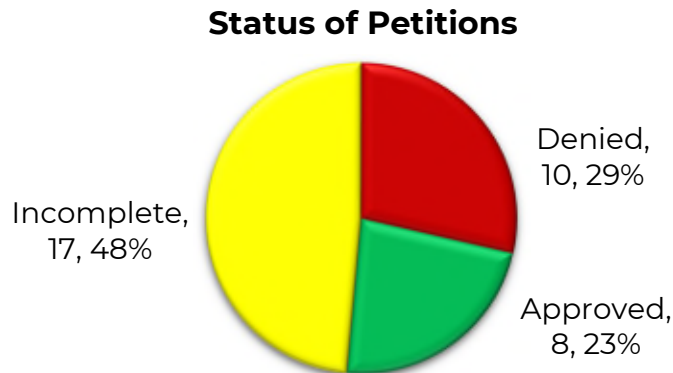
*Total number of unduplicated claims.

Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Please note: There were no paid medical claims for Qutenza® during fiscal year 2022 to allow for a fiscal year comparison.

Prior Authorization of Qutenza® (Capsaicin 8% Patch)

There were 35 prior authorization requests submitted for Qutenza® (capsaicin 8% patch) for 19 unique members during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.



Market News and Updates¹

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.

Utilization Details of Qutenza® (Capsaicin 8% Patch): Fiscal Year 2023

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS*	TOTAL MEMBERS*	TOTAL COST	COST/CLAIM	CLAIMS/MEMBER
J7336 CAPSAICIN 8% PATCH	6	3	\$21,817.60	\$3,636.27	2
TOTAL	6	3	\$21,817.60	\$3,636.27	2

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated claims.

*Total number of unduplicated utilizing members.

Fiscal Year 2023 = 07/01/2022 to 06/30/2023

¹ 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 05/2024. Last accessed 05/31/2024.

Fiscal Year 2023 Annual Review of Ryplazim® (Plasminogen, Human-tvmh)

Oklahoma Health Care Authority
Fiscal Year 2023 Print Report

Current Prior Authorization Criteria

Ryplazim® (Plasminogen, Human-tvmh) Approval Criteria:

1. An FDA approved indication of plasminogen deficiency type 1 (hypoplasminogenemia) as confirmed by at least 2 of the following:
 - a. Genetic testing confirming biallelic mutations in the plasminogen (*PLG*) gene; or
 - b. Plasminogen activity level $\leq 45\%$; or
 - c. Documentation of clinical symptoms and lesions consistent with plasminogen deficiency type 1 (e.g., ligneous conjunctivitis, ligneous gingivitis or gingival overgrowth, vision abnormalities, respiratory distress and/or obstruction, abnormal wound healing); and
2. Ryplazim® must be prescribed by, or in consultation with, a hematologist, pulmonologist, ophthalmologist, geneticist, or other specialist with expertise in the treatment of plasminogen deficiency (or an advanced care practitioner with a supervising physician who is a hematologist, pulmonologist, ophthalmologist, geneticist, or other specialist with expertise in the treatment of plasminogen deficiency); and
3. Prescriber must verify that members at high risk for bleeding and/or confirmed or suspected airway disease will be monitored by a health care provider for 4 hours after receiving the first dose; and
4. Documented vaccination history to hepatitis A and B must be provided or provider must verify member has received the first vaccine dose and is scheduled to receive the second vaccine dose; and
5. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
6. Initial approvals will be for 6 months, after which time the prescriber must document improvement in clinical symptoms, partial or complete lesion resolution, and increased plasminogen activity level; and
7. Subsequent approvals will be for the duration of 1 year and will require documentation from the prescriber that member has not developed new or recurrent lesions while on Ryplazim® and that adequate plasminogen activity trough levels are being maintained

Utilization of Ryplazim® (Plasminogen, Human-tvmh): Fiscal Year 2023

There was no SoonerCare utilization of Ryplazim® (plasminogen, human-tvmh) during fiscal year 2023 (07/01/2022 to 06/30/2023).

Prior Authorization of Ryplazim® (Plasminogen, Human-tvmh)

There were no prior authorization requests submitted for Ryplazim® (plasminogen, human-tvmh) during fiscal year 2023.

Recommendations

The College of Pharmacy does not recommend any changes to the current Ryplazim® (plasminogen, human-tvmh) prior authorization criteria at this time.

Fiscal Year 2023 Annual Review of Smoking Cessation Products

Oklahoma Health Care Authority Fiscal Year 2023 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 2023

Comparison of Fiscal Years

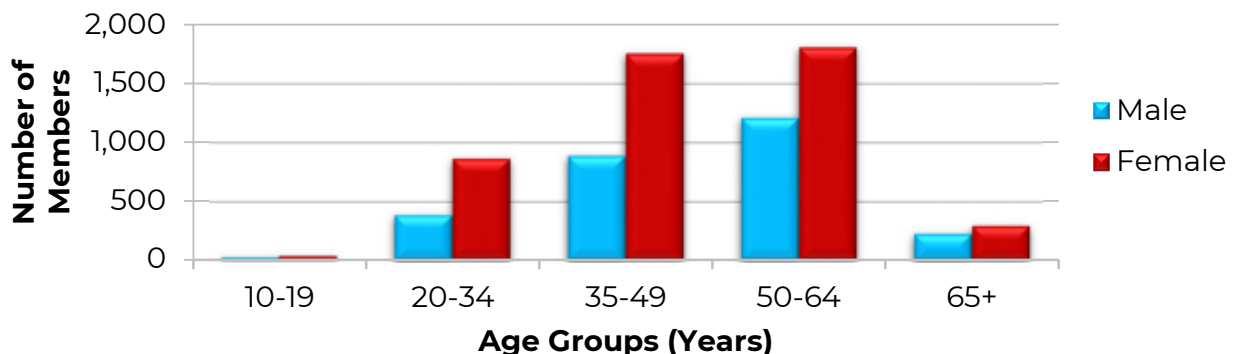
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2022	5,012	9,707	\$1,229,366.67	\$126.65	\$5.43	461,296	226,507
2023	7,480	14,806	\$2,473,886.44	\$167.09	\$6.65	763,592	372,163
% Change	49.20%	52.50%	101.20%	31.90%	22.50%	65.50%	64.30%
Change	2,468	5,099	\$1,244,519.77	\$40.44	\$1.22	302,296	145,656

Costs do not reflect rebated prices or net costs.

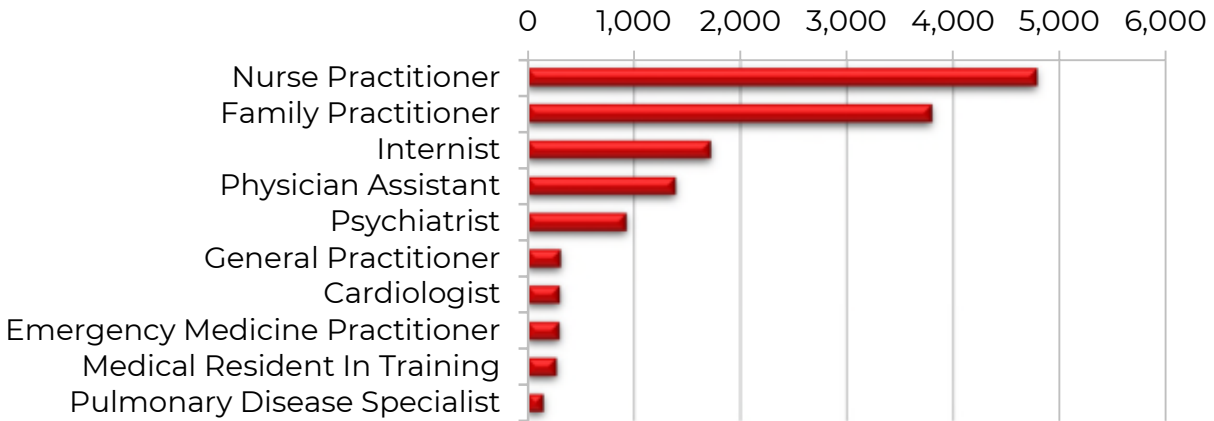
*Total number of unduplicated utilizing members.

Fiscal Year 2022= 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Demographics of Members Utilizing Smoking Cessation Products

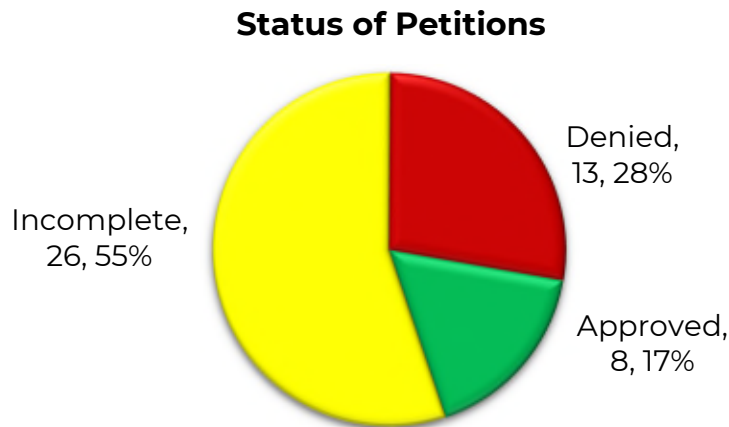


Top Prescriber Specialties of Smoking Cessation Products by Number of Claims



Prior Authorization of Smoking Cessation Products

There were 47 prior authorization requests submitted for smoking cessation products during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.



Market News and Updates^{1,2}

News:

- May 2024:** A study was published in the *American Journal of Preventative Medicine* that looked at the use of varenicline for e-cigarette cessation. The results showed that the varenicline group yielded a numerically higher Week 8 quit rate versus placebo [9/20 (45%) in the varenicline group vs. 6/20 (30%) in the placebo group; relative risk: 1.51; 95% confidence interval: 0.68, 3.37].

Pipeline:

- Cytisinicline:** Cytisinicline is a plant-based alkaloid with a high affinity to nicotinic acetylcholine receptors, which is thought to help treat nicotine addiction. The positive results of 2 Phase 3 studies, ORCA-2 and ORCA-3 were published in 2023; however, the FDA advised the makers of cystininicline they would need long-term exposure data to assess safety beyond 12 weeks. The FDA views smoking cessation products as a chronic, repeat, or intermittent use product considering patients may need re-treatment throughout their lifetime. An open-label study evaluating the long-term safety of cystininicline is underway, and a New Drug Application (NDA) submission to the FDA is expected in 2025.

Recommendations

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

Utilization Details of Smoking Cessation Products: Fiscal Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
NICOTINE REPLACEMENT PRODUCTS						
NICOTINE TD DIS 21MG/24H	3,109	2,189	\$154,153.96	\$49.58	1.42	6.23%
NICOTINE TD DIS 14MG/24H	1,942	1,383	\$93,915.08	\$48.36	1.4	3.80%
NICOTINE TD DIS 7MG/24HR	918	649	\$40,580.64	\$44.21	1.41	1.64%
NICOTINE POL LOZ 4MG MINT	299	118	\$16,548.46	\$55.35	2.53	0.67%
NICOTROL INH 10MG	206	157	\$109,789.45	\$532.96	1.31	4.44%
NICOTINE POL GUM 4MG MINT	151	60	\$7,032.15	\$46.57	2.52	0.28%
NICOTINE POL GUM 4MG	123	58	\$6,332.21	\$51.48	2.12	0.26%
SM NICOTINE DIS 14MG/24H	118	88	\$5,590.86	\$47.38	1.34	0.23%
HM NICOTINE DIS 21MG/24H	118	92	\$5,826.40	\$49.38	1.28	0.24%
NICOTINE LOZ 2MG MINT	97	47	\$4,433.78	\$45.71	2.06	0.18%
NICOTINE POL LOZ 2MG MINT	94	45	\$4,805.89	\$51.13	2.09	0.19%
NICOTINE POL GUM 2MG	92	78	\$3,900.49	\$42.40	1.18	0.16%
NICOTINE POL GUM 2MG CINN	90	48	\$3,662.57	\$40.70	1.88	0.15%
SM NICOTINE DIS 21MG/24H	90	80	\$4,675.52	\$51.95	1.13	0.19%
GNP NICOTINE DIS 21MG/24H	89	55	\$4,496.35	\$50.52	1.62	0.18%
NICOTINE POL GUM 4MG CINN	86	51	\$4,474.51	\$52.03	1.69	0.18%
NICOTINE TD DIS STEP 1	75	55	\$3,721.00	\$49.61	1.36	0.15%
NICOTINE POL GUM 4MG ORIG	66	45	\$3,864.99	\$58.56	1.47	0.16%
NICOTINE LOZ 4MG MINT	60	20	\$4,632.90	\$77.22	3	0.19%
SM NICOTINE DIS 7MG/24HR	52	39	\$2,286.38	\$43.97	1.33	0.09%
HM NICOTINE LOZ 4MG MINT	50	25	\$2,899.33	\$57.99	2	0.12%
NICOTROL NS SPR 10MG/ML	45	22	\$35,841.07	\$796.47	2.05	1.45%
SM NICOTINE LOZ 4MG MINT	43	23	\$2,724.07	\$63.35	1.87	0.11%
NICOTINE POL GUM 2MG MINT	41	31	\$2,574.27	\$62.79	1.32	0.10%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
HM NICOTINE DIS 14MG/24HR	41	37	\$1,836.67	\$44.80	1.11	0.07%
GNP NICOTINE DIS 14MG/24H	38	32	\$1,676.09	\$44.11	1.19	0.07%
SM NICOTINE LOZ 2MG MINT	37	23	\$1,460.45	\$39.47	1.61	0.06%
SM NICOTINE GUM 4MG MINT	28	24	\$1,369.27	\$48.90	1.17	0.06%
GNP NICOTINE LOZ 4MG MINT	27	13	\$1,583.76	\$58.66	2.08	0.06%
HM NICOTINE DIS 7MG/24HR	24	20	\$1,168.44	\$48.69	1.2	0.05%
HM NICOTINE LOZ 2MG MINT	23	15	\$1,026.01	\$44.61	1.53	0.04%
HM NICOTINE GUM 2MG MINT	23	18	\$1,037.27	\$45.10	1.28	0.04%
NICOTINE TD DIS STEP 3	22	20	\$1,089.79	\$49.54	1.1	0.04%
GNP NICOTINE DIS 7MG/24HR	20	12	\$849.52	\$42.48	1.67	0.03%
SM NICOTINE GUM 4MG	16	15	\$885.26	\$55.33	1.07	0.04%
SM NICOTINE GUM 2MG	16	10	\$420.48	\$26.28	1.6	0.02%
HM NICOTINE GUM 4MG FRUIT	15	9	\$680.03	\$45.34	1.67	0.03%
HM NICOTINE GUM 4MG MINT	13	12	\$558.68	\$42.98	1.08	0.02%
GNP NICOTINE LOZ MINI 2MG	13	6	\$867.21	\$66.71	2.17	0.04%
SM NICOTINE LOZ 2MG CINN	13	3	\$2,890.70	\$222.36	4.33	0.12%
NICOTINE POL GUM 2MG ORIG	12	11	\$391.87	\$32.66	1.09	0.02%
NICOTINE POL GUM 2MG FRUIT	12	10	\$477.43	\$39.79	1.2	0.02%
SM NICOTINE LOZ 2MG CHRY	9	6	\$468.77	\$52.09	1.5	0.02%
NICOTINE POL GUM 4MG FRUIT	9	6	\$303.83	\$33.76	1.5	0.01%
SM NICOTINE GUM 2MG MINT	8	8	\$340.85	\$42.61	1	0.01%
HM NICOTINE LOZ 2MG CINN	8	5	\$571.25	\$71.41	1.6	0.02%
NICOTINE LOZ MINI 2MG	7	6	\$383.45	\$54.78	1.17	0.02%
GNP NICOTINE GUM 4MG MINT	7	6	\$245.14	\$35.02	1.17	0.01%
GNP NICOTINE GUM 2MG MINT	6	4	\$214.82	\$35.80	1.5	0.01%
NICOTINE GUM 2MG	6	4	\$146.05	\$24.34	1.5	0.01%
GNP NICOTINE GUM 4MG ORIG	3	1	\$61.60	\$20.53	3	0.00%
SM NICOTINE LOZ 4MG CINN	2	2	\$75.06	\$37.53	1	0.00%
SM NICOTINE LOZ 4MG	2	2	\$278.56	\$139.28	1	0.00%
QC NICOTINE DIS 14MG/24H	1	1	\$32.65	\$32.65	1	0.00%
NICOTINE POL LOZ 2MG MINI	1	1	\$41.27	\$41.27	1	0.00%
GNP NICOTINE LOZ 2MG MINT	1	1	\$80.16	\$80.16	1	0.00%
SUBTOTAL	8,517	4,648*	\$552,274.72	\$64.84	1.83	22.32%
VARENICLINE PRODUCTS						
VARENICLINE TAB 1MG	3,244	1,537	\$1,073,491.54	\$330.92	2.11	43.39%
VARENICLINE PAK 0.5MG & 1MG	2,034	1,768	\$699,689.06	\$344.00	1.15	28.28%
VARENICLINE TAB 0.5MG	522	407	\$125,468.82	\$208.11	1.19	5.07%
CHANTIX TAB 1MG	11	8	\$4,926.45	\$402.68	1.14	0.20%
CHANTIX PAK 1MG	9	5	\$4,139.73	\$431.37	1.22	0.17%
CHANTIX PAK 0.5MG & 1MG	4	4	\$1,838.52	\$433.71	1.01	0.07%
SUBTOTAL	5,824	2,883*	\$1,909,554.12	\$327.88	2.02	77.19%
BUPROPION PRODUCTS						
BUPROPION TAB 150MG SR	465	208	\$12,057.60	\$25.93	1.67	0.49%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	465	208*	\$12,057.60	\$25.93	1.67	0.49%
TOTAL	14,806	7,480*	\$2,473,886.44	\$167.09	1.98	100%

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated utilizing members.

CHRY = cherry; CINN = cinnamon; DIS = patch; GNP = Good Neighbor Pharmacy®; HM = Health Mart®; INH = inhaler; LOZ = lozenge; NS = nasal spray; ORIG = original; PAK = pack; POL = polacrilex; QC = quality choice; SM = Sunmark®; SPR = spray; SR = sustained release; SYS = system; TAB = tablet; TD = transdermal

Fiscal Year 2023 = 07/01/2022 to 06/30/2023

¹ Fucito L, Baldassarri S, Baker N, et al. Varenicline for E-Cigarette Cessation in Adults: A Preliminary Placebo-Controlled Randomized Trial. *Am J Prev Med* 2024; 000(000):1-3. doi: 10.1016/j.amepre.2024.04.007. Online ahead of print.

² Achieve Life Sciences, Inc. Achieve Life Sciences Reaches Agreement with the FDA on Long-Term Cytisinicline Exposure Data Requirements for NDA Submission. Available online at: <https://ir.achievelifesciences.com/news-events/press-releases/detail/189/achieve-life-sciences-reaches-agreement-with-the-fda-on>. Issued 02/29/2024. Last accessed 06/04/2024.

Fiscal Year 2023 Annual Review of Sylvant® (Siltuximab)

Oklahoma Health Care Authority Fiscal Year 2023 Print Report

Current Prior Authorization Criteria

Sylvant® (Siltuximab) Approval Criteria:

1. An FDA approved diagnosis of Multicentric Castleman's Disease (also known as giant lymph node hyperplasia); and
2. Member must be human immunodeficiency virus (HIV) and human herpesvirus-8 (HHV-8) negative; and
3. Member must be 18 years of age or older; and
4. The following FDA approved dosing restrictions will apply:
 - a. 11mg/kg via intravenous (IV) infusion every 3 weeks until treatment failure (defined as disease progression based on increase in symptoms, radiologic progression, or deterioration in performance status); and
5. Sylvant® must be administered in a clinical setting able to provide resuscitation equipment, medications, and trained personnel; and
6. The prescriber must verify that a complete blood count (CBC) will be done prior to each dose for the first 12 months and for an additional 3 doses thereafter; and
7. Approvals will be for the duration of 6 months.

Utilization of Sylvant® (Siltuximab): Fiscal Year 2023

There was no SoonerCare utilization, including pharmacy and medical claims, of Sylvant® (siltuximab) during fiscal year 2023 (07/01/2022 to 06/30/2023).

Prior Authorization of Sylvant® (Siltuximab)

There were no prior authorization requests submitted for Sylvant® (siltuximab) during fiscal year 2023.

Recommendations

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

Fiscal Year 2023 Annual Review of Topical Antibiotic Products

Oklahoma Health Care Authority Fiscal Year 2023 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.

Nuversa® (Metronidazole 1.3% Vaginal Gel) Approval Criteria:

1. An FDA approved diagnosis of bacterial vaginosis in non-pregnant women; and
2. A patient-specific, clinically significant reason why the member cannot use MetroGel-Vaginal® 0.75% (metronidazole 0.75% vaginal gel) or generic metronidazole oral tablets must be provided.

Xaciatto™ (Clindamycin Vaginal Gel) Approval Criteria:

1. An FDA approved diagnosis of bacterial vaginosis; and
2. A patient specific, clinically significant reason why the member cannot use clindamycin 2% vaginal cream, Clindesse® (clindamycin phosphate 2% vaginal cream), and Cleocin® vaginal ovules (clindamycin phosphate 2.5g vaginal suppositories), which are available without a prior authorization, must be provided.

Utilization of Topical Antibiotic Products: Fiscal Year 2023

Comparison of Fiscal Years

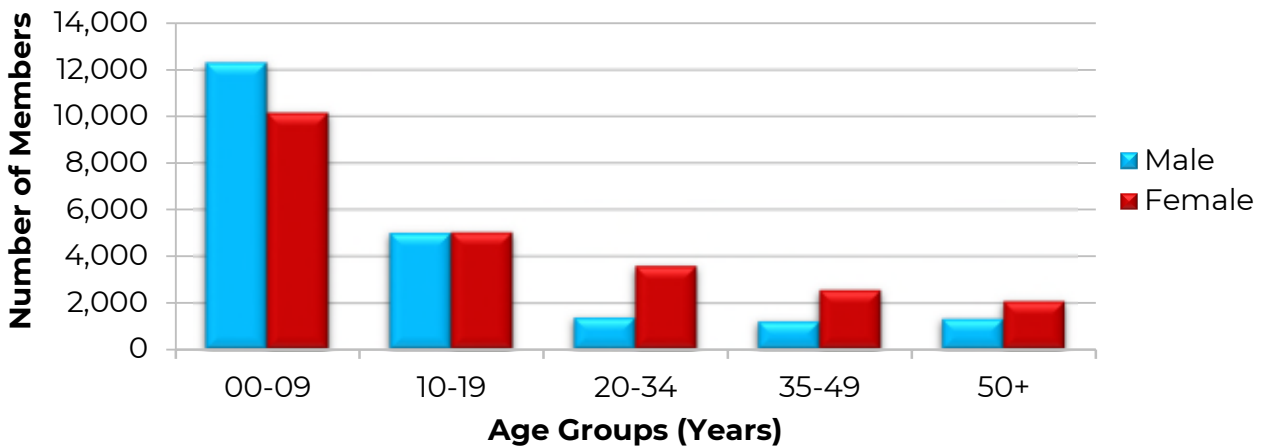
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2022	34,930	41,070	\$674,205.90	\$16.42	\$1.45	1,125,756	464,513
2023	44,419	52,006	\$828,931.40	\$15.94	\$1.37	1,363,006	607,238
% Change	27.2%	26.6%	22.9%	-2.9%	-5.5%	21.1%	30.7%
Change	9,489	10,936	\$154,725.50	-\$0.48	-\$0.08	237,250	142,725

Costs do not reflect rebated prices or net costs.

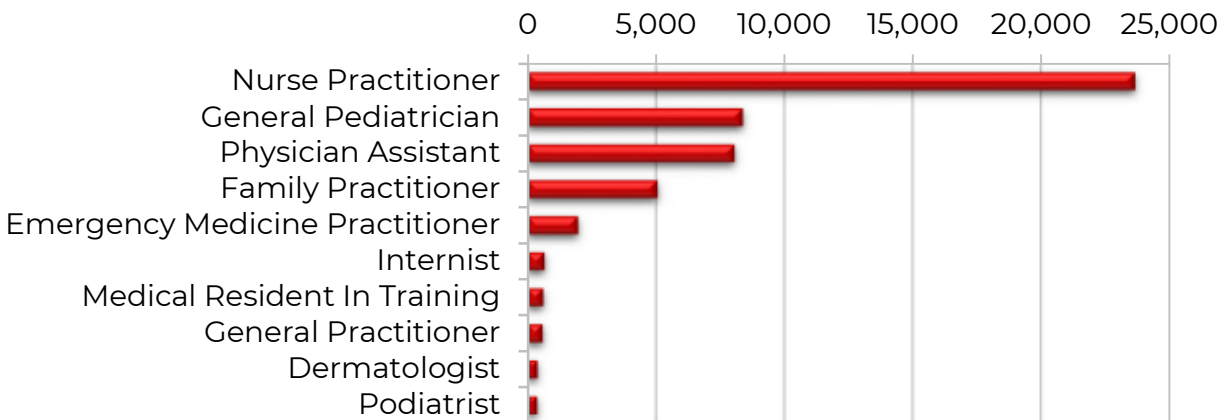
*Total number of unduplicated utilizing members.

Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Demographics of Members Utilizing Topical Antibiotic Products

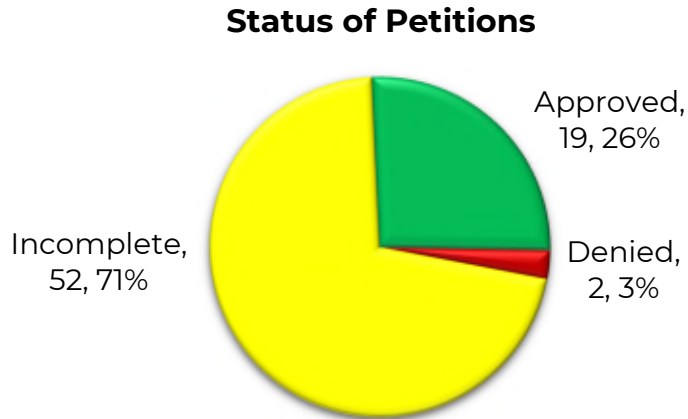


Top Prescriber Specialties of Topical Antibiotic Products by Number of Claims



Prior Authorization of Topical Antibiotic Products

There were 73 prior authorization requests submitted for topical antibiotic products during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.



Market News and Updates¹

Anticipated Patent Expiration(s):

- Altabax[®] (retapamulin 1% ointment): February 2027
- Xepi[®] (ozenoxacin 1% cream): January 2032
- Nuversa[®] (metronidazole 1.3% vaginal gel): June 2032
- Xaciato[™] (clindamycin vaginal gel): September 2036

News:

- Cortisporin[®] (neomycin/polymyxin B sulfates/hydrocortisone 0.5% cream) and Cortisporin[®] (neomycin/polymyxin B sulfates/bacitracin zinc/hydrocortisone 1% ointment) have been discontinued by the manufacturer. No generic equivalents currently exist for either the cream or the ointment formulation.

Recommendations

The College of Pharmacy recommends the following changes to the Topical Antibiotic Products Product Based Prior Authorization (PBPA) category due to product discontinuations (changes shown in red):

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

Utilization Details of Topical Antibiotic Products: Fiscal Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/CLAIM	CLAIMS/MEMBER	% COST
TIER-1 PRODUCTS						
MUPIROCIN OIN 2%	51,389	44,159	\$788,834.62	\$15.35	1.16	95.16%
GENTAMICIN OIN 0.1%	390	207	\$29,174.73	\$74.81	1.88	3.52%
GENTAMICIN CRE 0.1%	215	131	\$9,888.71	\$45.99	1.64	1.19%
TIER-1 SUBTOTAL	51,994	44,497	\$827,898.06	\$15.92	1.17	99.88%
TIER-2 PRODUCTS						
MUPIROCIN CRE 2%	12	10	\$1,033.34	\$86.11	1.2	0.12%
TIER-2 SUBTOTAL	12	10	\$1,033.34	\$86.11	1.2	0.12%
TOTAL	52,006	44,419*	\$828,931.40	\$15.94	1.17	10%

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated utilizing members.

CRE = cream; OIN = ointment

Fiscal Year 2023 = 07/01/2022 to 06/30/2023

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 05/2024. Last accessed 5/28/2024.

Fiscal Year 2023 Annual Review of Topical Antifungal Products

Oklahoma Health Care Authority Fiscal Year 2023 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 (Loprox [®] , Penlac [®])	tavaborole (Kerydin [®])
clotrimazole (OTC)* cream	clotrimazole 1% solution	
clotrimazole/betamethasone cream	clotrimazole/betamethasone lotion	
econazole nitrate 1% 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. Prescription clotrimazole NDCs require prior authorization for members older than 20 years of age. 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 2023

Comparison of Fiscal Years

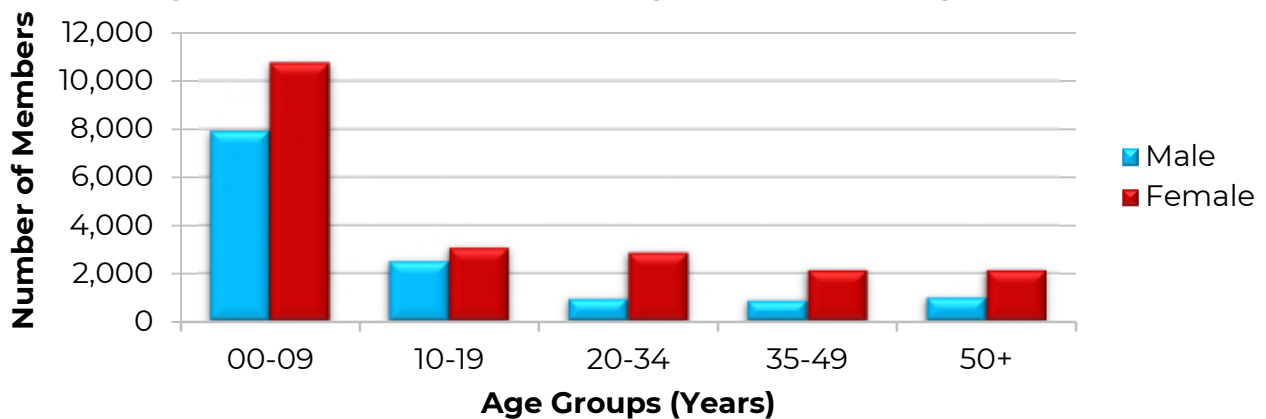
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2022	30,099	43,817	\$851,349.27	\$19.43	\$1.11	1,991,213	770,358
2023	33,927	49,890	\$917,699.68	\$18.39	\$1.01	2,428,907	908,054
% Change	12.70%	13.90%	7.80%	-5.40%	-9.00%	22.00%	17.90%
Change	3,828	6,073	\$66,350.41	-\$1.04	-\$0.10	437,694	137,696

Costs do not reflect rebated prices or net costs.

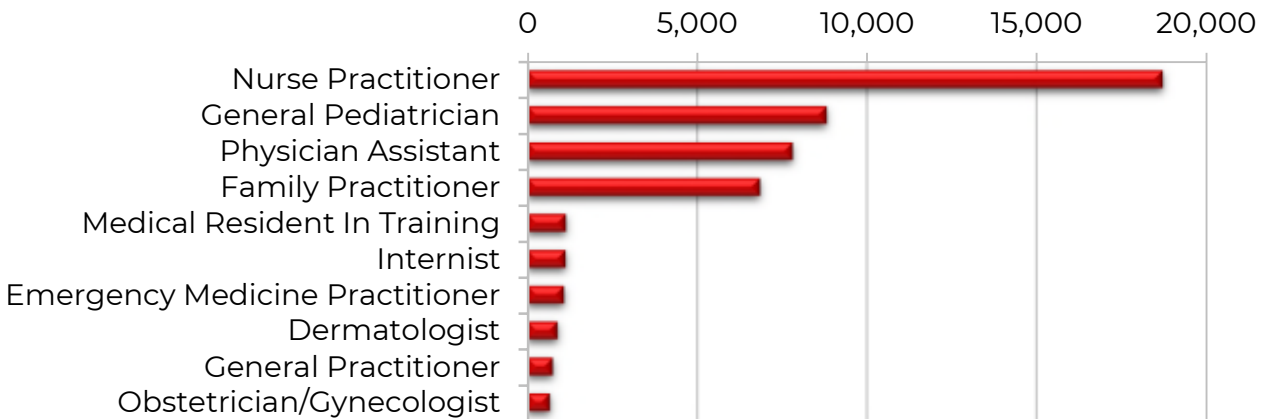
*Total number of unduplicated utilizing members.

Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Demographics of Members Utilizing Topical Antifungal Products

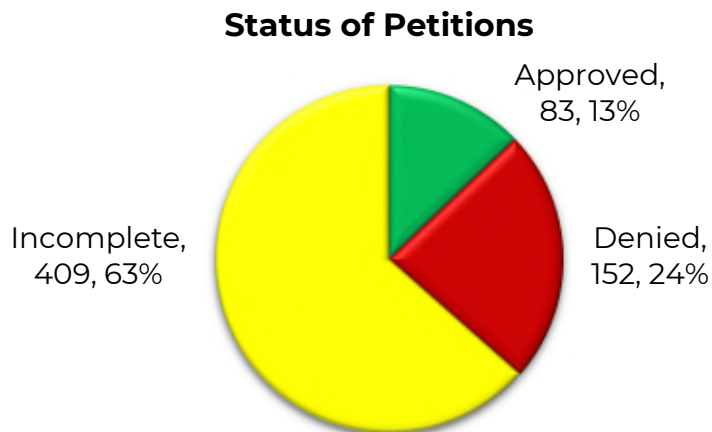


Top Prescriber Specialties of Topical Antifungal Products by Number of Claims



Prior Authorization of Topical Antifungal Products

There were 644 prior authorization requests submitted for topical antifungal products during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.



Market News and Updates¹

Anticipated Patent Expiration(s):

- 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

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 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/CLAIM	CLAIMS/MEMBER	% COST
TIER-1 PRODUCTS						
NYSTATIN PRODUCTS						
NYSTATIN CRE 100000	13,579	10,680	\$228,218.32	\$16.81	1.27	24.87%
NYSTATIN OIN 100000	7,223	5,907	\$131,424.22	\$18.20	1.22	14.32%
NYSTATIN POW 100000	2,964	2,039	\$52,651.82	\$17.76	1.45	5.74%
NYSTOP POW 100000	1,464	1,135	\$25,681.31	\$17.54	1.29	2.80%
NYAMYC POW 100000	869	486	\$16,289.71	\$18.75	1.79	1.78%
SUBTOTAL	26,099	20,247	\$454,265.38	\$17.41	1.29	49.50%
KETOCONAZOLE PRODUCTS						
KETOCONAZOLE SHA 2%	7,599	4,391	\$162,045.86	\$21.32	1.73	17.66%
KETOCONAZOLE CRE 2%	6,363	5,160	\$135,215.40	\$21.25	1.23	14.73%
SUBTOTAL	13,962	9,551	\$297,261.26	\$21.29	1.46	32.39%
CLOTRIMAZOLE PRODUCTS						
CLOTRIMAZOLE CRE 1%	5,421	4,675	\$81,886.90	\$15.11	1.16	8.92%
ANTIFUNGAL CRE 1%	45	40	\$537.36	\$11.94	1.13	0.06%
ATHLETE'S FOOT CRE 1%	20	18	\$244.04	\$12.20	1.11	0.03%
SUBTOTAL	5,486	4,733	\$82,668.30	\$15.07	1.16	9.01%
CLOTRIMAZOLE/BETAMETHASONE PRODUCTS						
CLOTRIM/BETA DIPROP CRE 1-0.05%	2,210	1,747	\$38,319.60	\$17.34	1.27	4.18%
CLOTRIM/BETA CRE 1-0.05%	861	712	\$14,334.41	\$16.65	1.21	1.56%
SUBTOTAL	3,071	2,459	\$52,654.01	\$17.15	1.25	5.74%
CICLOPIROX PRODUCTS						
CICLOPIROX CRE 0.77%	384	283	\$6,684.21	\$17.41	1.36	0.73%
CICLOPIROX SUS 0.77%	35	24	\$1,648.58	\$47.10	1.46	0.18%
SUBTOTAL	419	307	\$8,332.79	\$19.89	1.36	0.91%
TERBINAFINE PRODUCTS						
TERBINAFINE CRE 1%	382	352	\$6,494.80	\$17.00	1.09	0.71%
ATHLETE'S FOOT CRE 1%	34	34	\$669.52	\$19.69	1	0.07%
SUBTOTAL	416	386	\$7,164.32	\$17.22	1.08	0.78%
ECONAZOLE PRODUCTS						
ECONAZOLE CRE 1%	297	229	\$6,245.08	\$21.03	1.3	0.68%
SUBTOTAL	297	229	\$6,245.08	\$21.03	1.3	0.68%
TOLNAFTATE PRODUCTS						
TOLNAFTATE CRE 1%	14	14	\$188.95	\$13.50	1	0.02%
SM ANTIFUNGAL CRE 1%	2	2	\$29.35	\$14.68	1	0.00%
SUBTOTAL	16	16	\$218.30	\$13.64	1	0.02%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 SUBTOTAL	49,766	37,928	\$908,809.44	\$18.26	1.31	99.03%
TIER-2 PRODUCTS						
CICLOPIROX PRODUCTS						
CICLOPIROX SHA 1%	42	19	\$1,878.95	\$44.74	2.21	0.20%
CICLOPIROX SOL 8%	20	13	\$414.36	\$20.72	1.54	0.05%
CICLOPIROX GEL 0.77%	3	3	\$138.41	\$46.14	1	0.02%
SUBTOTAL	65	35	\$2,431.72	\$37.41	1.86	0.26%
NYSTATIN/TRIAMCINOLONE PRODUCTS						
NYSTAT/TRIAM CRE 100000-0.1%	26	16	\$623.77	\$23.99	1.63	0.07%
NYSTAT/TRIAM OIN 100000-0.1%	7	5	\$145.99	\$20.86	1.4	0.02%
SUBTOTAL	33	21	\$769.76	\$23.33	1.57	0.08%
CLOTRIMAZOLE PRODUCTS						
CLOTRIMAZOLE SOL 1%	16	15	\$641.02	\$40.06	1.07	0.07%
SUBTOTAL	16	15	\$641.02	\$40.06	1.07	0.07%
OXICONAZOLE PRODUCTS						
OXICONAZOLE CRE 1%	2	1	\$1,006.40	\$503.20	2	0.11%
SUBTOTAL	2	1	\$1,006.40	\$503.20	2	0.11%
NAFTIFINE PRODUCTS						
NAFTIFINE GEL 1%	1	1	\$320.23	\$320.23	1	0.03%
SUBTOTAL	1	1	\$320.23	\$320.23	1	0.03%
KETOCONAZOLE PRODUCTS						
KETOCONAZOLE FOAM 2%	1	1	\$180.16	\$180.16	1	0.02%
SUBTOTAL	1	1	\$180.16	\$180.16	1	0.02%
CLOTRIMAZOLE/BETAMETHASONE PRODUCTS						
CLOTRIM/BETA DIPROP LOT 1-0.05%	1	1	\$85.20	\$85.20	1	0.01%
SUBTOTAL	1	1	\$85.20	\$85.20	1	0.01%
TIER-2 SUBTOTAL	119	75	\$5,434.49	\$45.67	1.59	0.59%
SPECIAL PA PRODUCTS						
EFINACONAZOLE PRODUCTS						
JUBLIA SOL 10%	5	2	\$3,455.75	\$691.15	2.5	0.38%
SUBTOTAL	5	2	\$3,455.75	\$691.15	2.5	0.38%
SPECIAL PA SUBTOTAL	5	2	\$3,455.75	\$691.15	2.5	0.38%
TOTAL	49,890	33,927*	\$917,699.68	\$18.39	1.47	100%

Costs do not reflect rebated prices or net costs.

*Total number of unduplicated utilizing members.

CLOTRIM/BETA = clotrimazole/betamethasone; CRE = cream; DIPROP = dipropionate; LOT = lotion; NYSTAT/TRIAM = nystatin/triamcinolone; OIN = ointment; PA = prior authorization; POW = powder; SHA = shampoo; SOL = solution; SUS = suspension

Fiscal Year 2023= 07/01/2022 to 06/30/2023

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 05/2024. Last accessed 05/28/2024.