State Fiscal Year 2022 Print Annual Reviews
Quarter 4

Count	Category/Medication
1.	Anti-Emetic Medications
2.	Antiviral Medications
3.	Brineura® (Cerliponase Alfa)
4.	Butalbital Medications
5.	Gout Medications
6.	H.P. Acthar® Gel (Repository Corticotropin Injection)
7.	Heart Failure Medications
8.	Idiopathic Pulmonary Fibrosis (IPF) Medications
9.	Kanuma® (Sebelipase Alfa)
10.	Leukotriene Modulators
11.	Mepsevii® (Vestronidase Alfa-vjbk)
12.	Nasal Allergy Medications
13.	Non-Steroidal Anti-Inflammatory Drugs (NSAIDs; Systemic)
14.	Nuedexta® (Dextromethorphan/Quinidine)
15.	Ophthalmic Allergy Medications
16.	Phenylketonuria Medications
17.	Phosphate Binders
18.	Qutenza® (Capsaicin 8% Patch)
19.	Smoking Cessation Products
20.	Sylvant® (Siltuximab)
21.	Topical Antibiotic Products
22.	Topical Antifungal Products
23.	Vasomotor Symptom Medications

Fiscal Year 2022 = July 1, 2021 – June 30, 2022

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 2022 Annual Review of Anti-Emetic Medications

Oklahoma Health Care Authority
Fiscal Year 2022 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.

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

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.

Doxylamine/Pyridoxine (Generic Diclegis®) Approval Criteria:

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

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.

Utilization of Anti-Emetic Medications: Fiscal Year 2022

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	54,630	80,528	$1,365,494.47	$16.96	$2.18	1,514,366	627,246
2022	95,868	136,939	$2,178,950.66	$15.91	$2.10	2,504,467	1,038,526
% Change	**75.5%**	**70.1%**	**59.6%**	**-6.2%**	**-3.7%**	**65.40%**	**65.60%**
Change	**41,238**	**56,411**	**$813,456.19**	**-$1.05**	**-$0.08**	**990,101**	**411,280**

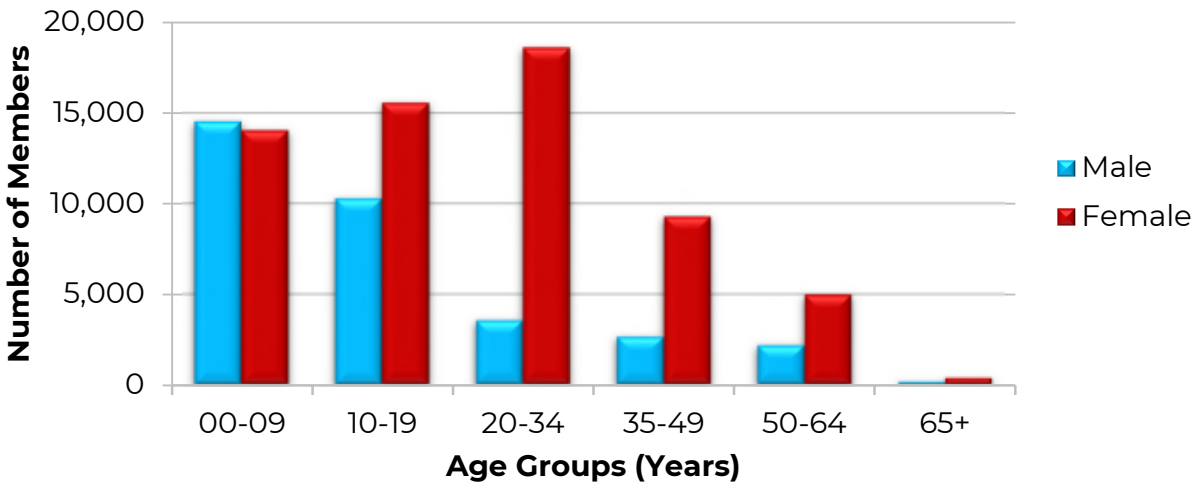
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021; Fiscal Year 2022 = 07/01/2021 to 06/30/2022

Fiscal Year 2022 Utilization: Medical Claims

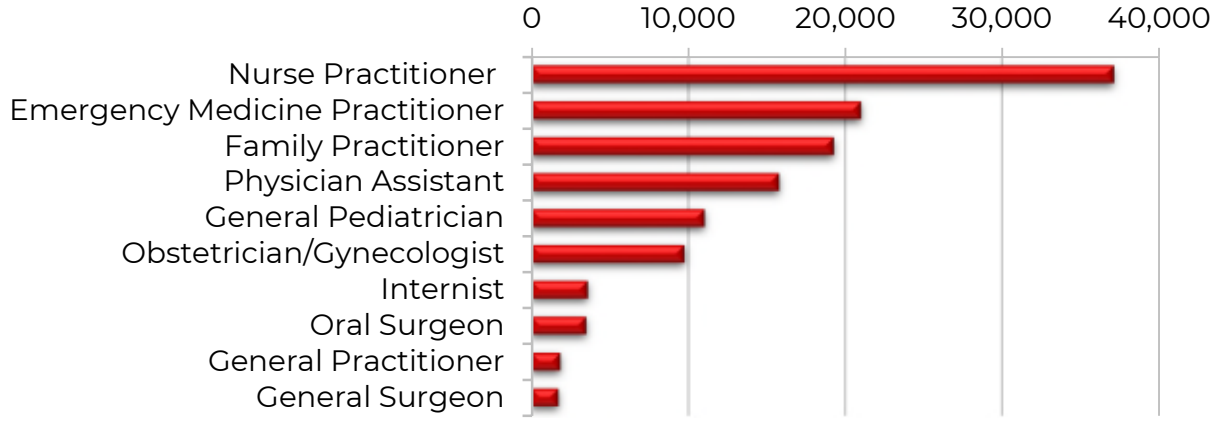
Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2022	745	3,047	$311,212.04	$102.14	4.09

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

Demographics of Members Utilizing Anti-Emetic Medications



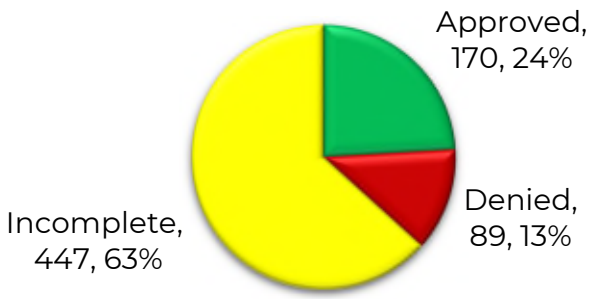
Top Prescriber Specialties of Anti-Emetic Medications by Number of Claims



Prior Authorization of Anti-Emetic Medications

There were 706 prior authorization requests submitted for anti-emetic medications during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions



Market News and Updates[1]

Anticipated Patent Expiration(s):

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

Recommendations

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

Utilization Details of Anti-Emetic Medications: Fiscal Year 2022

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ONDANSETRON PRODUCTS						
ONDANSETRON ODT 4MG	83,683	65,802	$1,180,120.08	$14.10	1.27	54.16%
ONDANSETRON TAB 4MG	22,383	16,097	$264,950.11	$11.84	1.39	12.16%
ONDANSETRON ODT 8MG	17,855	12,244	$268,087.77	$15.01	1.46	12.30%
ONDANSETRON SOL 4MG/5ML	6,404	5,739	$124,851.62	$19.50	1.12	5.73%
ONDANSETRON TAB 8MG	5,761	3,592	$70,592.56	$12.25	1.6	3.24%
ONDANSETRON INJ 4MG/2ML	30	16	$785.12	$26.17	1.88	0.04%
ONDANSETRON INJ 40MG/20ML	17	8	$461.23	$27.13	2.13	0.02%
SUBTOTAL	**136,133**	**103,498**	**$1,909,848.49**	**$14.03**	**1.32**	**87.65%**
DOXYLAMINE/PYRIDOXINE PRODUCTS						
DICLEGIS TAB 10-10MG	458	312	$148,049.76	$323.25	1.47	6.79%
BONJESTA TAB 20-20MG	164	124	$75,370.07	$459.57	1.32	3.46%
SUBTOTAL	**622**	**436**	**$223,419.83**	**$359.20**	**1.43**	**10.25%**
DRONABINOL PRODUCTS						
DRONABINOL CAP 2.5MG	45	22	$3,653.39	$81.19	2.05	0.17%
DRONABINOL CAP 5MG	44	21	$6,075.89	$138.09	2.1	0.28%
DRONABINOL CAP 10MG	21	4	$4,982.42	$237.26	5.25	0.23%
SUBTOTAL	**110**	**47**	**$14,711.70**	**$133.74**	**2.34**	**0.68%**
GRANISETRON PRODUCTS						
GRANISETRON TAB 1MG	22	9	$1,109.81	$50.45	2.44	0.05%
SANCUSO DIS 3.1MG	19	9	$16,663.40	$877.02	2.11	0.76%
SUBTOTAL	**41**	**18**	**$17,773.21**	**$433.49**	**2.28**	**0.82%**
APREPITANT PRODUCTS						
APREPITANT PAK 80MG & 125MG	20	5	$8,944.89	$447.24	4	0.41%
APREPITANT CAP 80MG	10	3	$1,928.40	$192.84	3.33	0.09%
APREPITANT CAP 40MG	1	1	$1,669.31	$1,669.31	1	0.08%
SUBTOTAL	**31**	**9**	**$12,542.60**	**$404.60**	**3.44**	**0.58%**
NETUPITANT/PALONOSETRON PRODUCTS						
AKYNZEO CAP 300-0.5MG	2	1	$654.83	$327.42	2	0.03%
SUBTOTAL	**2**	**1**	**$654.83**	**$327.42**	**2**	**0.03%**
TOTAL	**136,939**	**95,868***	**$2,178,950.66**	**$15.91**	**1.43**	**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, TAB = tablet
Fiscal Year 2022 = 07/01/2021 to 06/30/2022

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS[+]	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
FOSAPREPITANT INJ (J1453)	1,384	364	$48,169.40	$34.80	3.8
APREPITANT INJ (J0185)	1,147	283	$250,853.62	$218.70	4.05
GRANISETRON INJ (J1626)	480	104	$2,355.63	$4.91	4.62
FOSNETUPITANT/PALONOSETRON INJ (J1454)	19	5	$9,619.70	$506.30	3.8
APREPITANT CAP (J8501)	17	15	$213.69	$12.57	1.13
TOTAL	**3,047**	**745**	**$311,212.04**	**$102.14**	**4.09**

Costs do not reflect rebated prices or net costs.
[+]Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
CAP = capsule; INJ = injection
Fiscal Year 2022 = 07/01/2021 to 06/30/2022

[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 06/2023. Last accessed 06/05/2023.

Fiscal Year 2022 Annual Review of Antiviral Medications

Oklahoma Health Care Authority
Fiscal Year 2022 Print Report

Current Prior Authorization Criteria

Acyclovir 5% Cream (Generic Zovirax®) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use the brand formulation must be provided.

Denavir® (Penciclovir Cream), Sitavig® (Acyclovir Buccal Tablets), and Xerese® (Acyclovir/Hydrocortisone Cream) Approval Criteria:

1. An FDA approved diagnosis of recurrent herpes labialis (cold sores); and
2. A patient-specific, clinically significant reason why the member cannot use oral acyclovir, famciclovir, or valacyclovir tablets must be provided; and
3. A patient-specific, clinically significant reason why the member cannot use acyclovir cream must be provided.

Livtencity® (Maribavir) Approval Criteria:

1. An FDA approved diagnosis of post-transplant cytomegalovirus (CMV) infection and disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir, or foscarnet in adults and pediatric members (12 years of age and older weighing ≥35kg); and
2. A previously failed trial at least 14 days in duration with ganciclovir, valganciclovir, cidofovir, or foscarnet; and
3. Prescriber must verify the member does not have CMV disease involving the central nervous system including the retina (CMV retinitis); and
4. Prescriber must verify member will not receive concurrent treatment with ganciclovir and/or valganciclovir while taking Livtencity®; and
5. Prescriber must verify the member will be monitored for virologic failure during and after treatment with Livtencity®; and
6. Livtencity® must be prescribed by an oncology, hematology, infectious disease, or transplant specialist (or an advanced care practitioner with a supervising physician who is an oncology, hematology, infectious disease, or transplant specialist); and
7. Prescriber must verify Livtencity® will not be used concomitantly with strong inducers of CYP3A4 (e.g., rifampin, rifabutin, St. John's wort) except carbamazepine, phenobarbital, or phenytoin. Use of carbamazepine, phenobarbital, or phenytoin concomitantly with

Livtencity® will require dose adjustment according to package labeling; and
8. Prescriber must agree to monitor drug concentrations of immunosuppressant drugs that are CYP3A4 and/or P-glycoprotein (P-gp) substrates (e.g., tacrolimus, cyclosporine, sirolimus, everolimus) throughout treatment with Livtencity® and adjust the dose of immunosuppressant drug(s) as needed; and
9. Approvals will be for a maximum duration of 8 weeks, and a quantity limit of 112 tablets per 28 days will apply.

Prevymis® (Letermovir Tablets and Injection) Approval Criteria:

1. An FDA approved indication of prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients [R+] of an allogenic hematopoietic stem cell transplant (HSCT); and
2. Member must be CMV R+; and
3. Member must have received a HSCT within the last 28 days; and
4. Members taking concomitant cyclosporine will only be approved for the 240mg dose; and
5. Members must not be taking the following medications:
    a. Pimozide; or
    b. Ergot alkaloids (e.g., ergotamine, dihydroergotamine); or
    c. Rifampin; or
    d. Atorvastatin, lovastatin, pitavastatin, simvastatin, or repaglinide when co-administered with cyclosporine; and
6. Prevymis® must be prescribed by an oncology, hematology, infectious disease, or transplant specialist (or an advanced care practitioner with a supervising physician who is an oncology, hematology, infectious disease, or transplant specialist); and
7. Prescriber must verify the member will be monitored for CMV reactivation while on therapy; and
8. Approvals will be for the duration of 100 days post-transplant; and
    a. For Prevymis® vials, authorization will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation; and
    b. Approval length for vial formulation will be based on duration of need; and
9. A quantity limit of one tablet or vial per day will apply.

Zovirax® (Acyclovir Ointment) Approval Criteria:

1. An FDA approved indication of management of initial genital herpes or in limited non-life-threatening mucocutaneous herpes simplex virus (HSV) infections in immunocompromised patients; and
2. A patient-specific, clinically significant reason why the member cannot use oral acyclovir, famciclovir, or valacyclovir tablets must be provided.

Zovirax® (Acyclovir Suspension) Approval Criteria:

1. An age restriction of 7 years and younger will apply. Members older than 7 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.

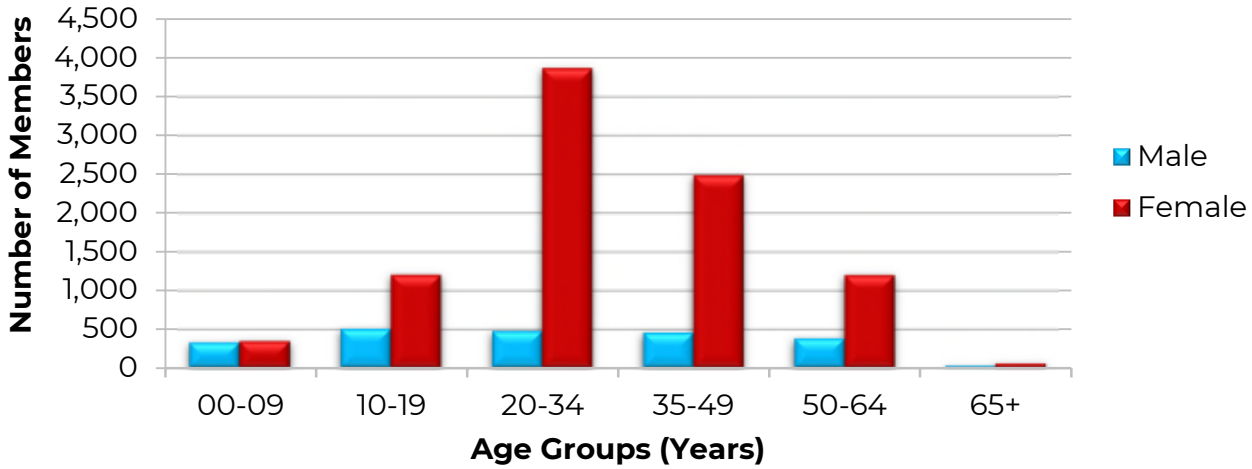
Utilization of Antiviral Medications: Fiscal Year 2022

Comparison of Fiscal Years

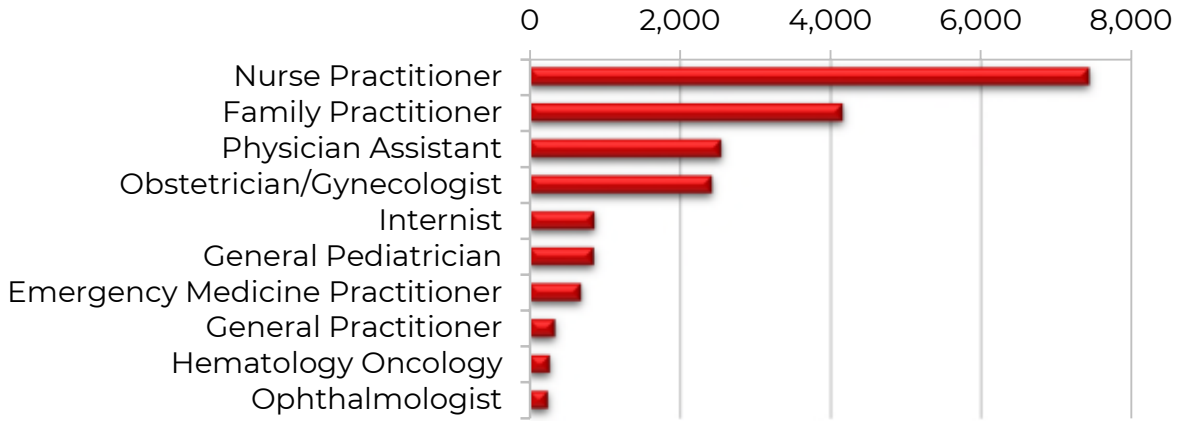
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	7,367	14,044	$593,914.92	$42.29	$1.97	629,007	301,515
2022	11,321	21,242	$661,319.28	$31.13	$1.40	922,297	471,201
% Change	**53.70%**	**51.30%**	**11.30%**	**-26.40%**	**-28.90%**	**46.60%**	**56.30%**
Change	**3,954**	**7,198**	**$67,404.36**	**-$11.16**	**-$0.57**	**293,290**	**169,686**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021; Fiscal Year 2022 = 07/01/2021 to 06/30/2022

Demographics of Members Utilizing Antiviral Medications



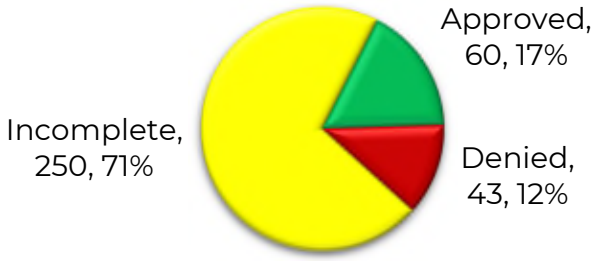
Top Prescriber Specialties of Antiviral Medications by Number of Claims



Prior Authorization of Antiviral Medications

There were 353 prior authorization requests submitted for antiviral medications during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions



Market News and Updates[1,2,3]

Anticipated Patent Expiration(s):

- Prevymis® (letermovir oral tablet): May 2024
- Livtencity® (maribavir tablet): November 2026
- Sitavig® (acyclovir buccal tablet): June 2030
- Prevymis® (letermovir injection): February 2033

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

- **August 2022:** The FDA approved a supplemental New Drug Application (sNDA) for Xofluza® (baloxavir marboxil) expanding the age range to 5 years of age or older for the treatment of acute uncomplicated influenza in patients who have been symptomatic for 48 hours or for the prevention of influenza in those following exposure.

Pipeline:

- **Posoleucel (Viralym-M):** Posoleucel is designed to restore T cell immunity in patients during times of severe immune compromise, such as after hematopoietic cell transplantation (HCT), which may help reduce or prevent virus-associated morbidity and mortality. Posoleucel works by targeting 6 viral pathogens including adenovirus, BK virus, cytomegalovirus (CMV), Epstein-Barr virus (EBV), herpesvirus 6, and John Cunningham (JC) virus (JCV). Posoleucel is currently in Phase 3 trials and has been granted Orphan Drug designation and 3 Regenerative Medicine Advanced Therapy (RMAT) designations from the FDA.

Recommendations

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

Utilization Details of Antiviral Medications: Fiscal Year 2022

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
VALACYCLOVIR PRODUCTS						
VALACYCLOVIR TAB 1GM	6,430	4,202	$156,121.32	$24.28	1.53	23.61%
VALACYCLOVIR TAB 500MG	5,073	2,466	$111,708.65	$22.02	2.06	16.89%
SUBTOTAL	**11,503**	**6,668**	**$267,829.97**	**$23.28**	**1.73**	**40.50%**
ACYCLOVIR PRODUCTS						
ACYCLOVIR TAB 400MG	5,418	2,766	$78,142.83	$14.42	1.96	11.82%
ACYCLOVIR TAB 800MG	2,043	1,396	$32,113.18	$15.72	1.46	4.86%
ACYCLOVIR CAP 200MG	835	503	$12,152.09	$14.55	1.66	1.84%
ACYCLOVIR SUS 200MG/5ML	765	567	$46,368.41	$60.61	1.35	7.01%
ZOVIRAX CRE 5%	221	153	$53,222.40	$240.83	1.44	8.05%
ACYCLOVIR CRE 5%	5	5	$1,537.96	$307.59	1	0.23%
SUBTOTAL	**9,287**	**5,390**	**$223,536.87**	**$24.07**	**1.72**	**33.81%**
FAMCICLOVIR PRODUCTS						
FAMCICLOVIR TAB 500MG	257	175	$8,094.67	$31.50	1.47	1.22%
FAMCICLOVIR TAB 250MG	130	47	$4,207.39	$32.36	2.77	0.64%
FAMCICLOVIR TAB 125MG	17	4	$293.59	$17.27	4.25	0.04%
SUBTOTAL	**404**	**226**	**$12,595.65**	**$31.18**	**1.79**	**1.90%**
LETERMOVIR PRODUCTS						
PREVYMIS TAB 480MG	24	11	$154,675.49	$6,444.81	2.18	23.39%
SUBTOTAL	**24**	**11**	**$154,675.49**	**$6,444.81**	**2.18**	**23.39%**
RIBAVIRIN PRODUCTS						
RIBAVIRIN TAB 200MG	18	7	$1,743.52	$96.86	2.57	0.26%
RIBAVIRIN CAP 200MG	6	4	$937.78	$156.30	1.5	0.14%
SUBTOTAL	**24**	**11**	**$2,681.30**	**$111.72**	**2.18**	**0.40%**
TOTAL	**21,242**	**11,321***	**$661,319.28**	**$31.13**	**1.88**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; CRE = cream; SUS = suspension; TAB = tablet
Fiscal Year 2022 = 07/01/2021 to 06/30/2022

[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 05/2023. Last accessed 05/22/2023.
[2] Roche Ltd. Roche announces U.S. FDA approval of Xofluza® to Treat Influenza in Children Aged Five Years and Older. *Globe Newswire*. Available online at: https://www.globenewswire.com/news-release/2022/08/12/2497294/0/en/Roche-announces-U-S-FDA-approval-of-Xofluza-to-treat-influenza-in-children-aged-five-years-and-older.html. Issued 08/12/2022. Last accessed 05/22/2023.
[3] Allovir. Posoleucel (Viralym-M, ALVR105): A Multi-Virus Specific T Cell Therapy (VST) Targeting Six Devastating Viruses. Available online at: https://www.allovir.com/products/alvr105. Last accessed 05/22/2023.

Fiscal Year 2022 Annual Review of Brineura® (Cerliponase Alfa)

Oklahoma Health Care Authority
Fiscal Year 2022 Print Report

Current Prior Authorization Criteria

Brineura® (Cerliponase Alfa) Approval Criteria:

1. An FDA approved diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2) also known as tripeptidyl peptidase-1 (TPP-1) deficiency; and
2. Member must have confirmed TPP-1 enzymatic deficiency via enzyme assay, confirmed by molecular analysis; and
3. Member must be 3 years of age or older; and
4. Brineura® must be prescribed by a specialist with expertise in the treatment of CLN2 (or an advanced care practitioner with a supervising physician who is a specialist with expertise in treating CLN2); and
5. Brineura® must be administered in a health care facility by a prescriber who is knowledgeable in intraventricular administration; and
6. Member must not have ventriculoperitoneal shunts or acute intraventricular access device-related complications; and
7. Member must not have documented generalized status epilepticus within 4 weeks of initiating treatment; and
8. Prescriber must verify member's blood pressure and heart rate will be monitored prior to each infusion, during infusion, and post-infusion; and
9. Prescriber must be willing to perform regular 12-lead electrocardiogram (ECG) evaluation at baseline and at least every 6 months and verify that they are acceptable to the prescriber; and
10. A baseline assessment must be performed to assess the Motor plus Language CLN2 score; and
11. Initial authorizations will be for the duration of 6 months, at which time compliance will be required for continued approval. After 12 months of utilization, the prescriber must verify the member is responding to the medication as demonstrated by ≤2 point decline in Motor plus Language CLN2 score from baseline; and
12. Approval quantity will be based on package labeling and FDA approved dosing regimen.

Utilization of Brineura® (Cerliponase Alfa): Fiscal Year 2022

There was no SoonerCare pharmacy utilization of Brineura® (cerliponase alfa) during fiscal year 2022 (07/01/2021 to 06/30/2022).

Comparison of Fiscal Years: Medical Claims

Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Total Units
2021	1	8	$14,400	$1,800	2,400
2022	1	12	$21,600	$1,800	3,600
% Change	**0%**	**50.00%**	**50.00%**	**0%**	**50.00%**
Change	**0**	**4**	**$7,200**	**$0.00**	**1,200**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021; Fiscal Year 2022 = 07/01/2021 to 06/30/2022

Demographics of Members Utilizing Brineura® (Cerliponase Alfa)

- Due to the limited number of members utilizing Brineura® (cerliponase alfa) during fiscal year 2022, detailed demographic information could not be provided.

Prior Authorization of Brineura® (Cerliponase Alfa)

There were no prior authorization requests submitted for Brineura® (cerliponase alfa) during fiscal year 2022.

Market News and Updates[1,2]

Pipeline:

- **RGX-181:** Late infantile neuronal ceroid lipofuscinosis type 2 (CLN2) is a rare genetic disorder caused by a mutation in the gene that makes tripeptidyl peptidase-1 (TPP-1). RGX-181 is a novel, investigational, one-time gene therapy uses the adeno-associated virus 9 (AAV9) vector to deliver the TPP-1 gene directly into the central nervous system for patients with CLN2. Investigators in Brazil have dosed the first child with CLN2 with RGX-181 in a single-patient, investigator-initiated study, and as of December 2022, the patient was tolerating the treatment well and had no drug-related side effects. Following the single-patient study, REGENXBIO announced a program to outline their progress and development plans for RGX-181, including initiating a Phase 1/2 clinical study of RGX-181 in 2023.

Recommendations

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

Utilization Details of Brineura® (Cerliponase Alfa): Fiscal Year 2022

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
CERLIPONASE ALFA INJ J0567	12	1	$21,600	$1,800	12
TOTAL	**12**	**1**	**$21,600**	**$1,800**	**12**

Costs do not reflect rebated prices or net costs.
+Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
INJ = injection
Fiscal Year 2022 = 07/01/2021 to 06/30/2022

[1] REGENXBIO, Inc. REGENXBIO Reports Updates on Advancement of Program for CLN2 Disease. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/regenxbio-reports-update-on-advancement-of-programs-for-cln2-disease-301707881.html. Issued 12/21/2022. Last accessed 06/15/2023.
[2] REGENXBIO, Inc. Therapeutic Programs: RGX-181. Available online at: https://www.regenxbio.com/therapeutic-programs/rgx-181/. Last accessed 06/15/2023.

Fiscal Year 2022 Annual Review of Butalbital Medications

Oklahoma Health Care Authority
Fiscal Year 2022 Print Report

Current Prior Authorization Criteria

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

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

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

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

Miscellaneous Butalbital Medications Approval Criteria:

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

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

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

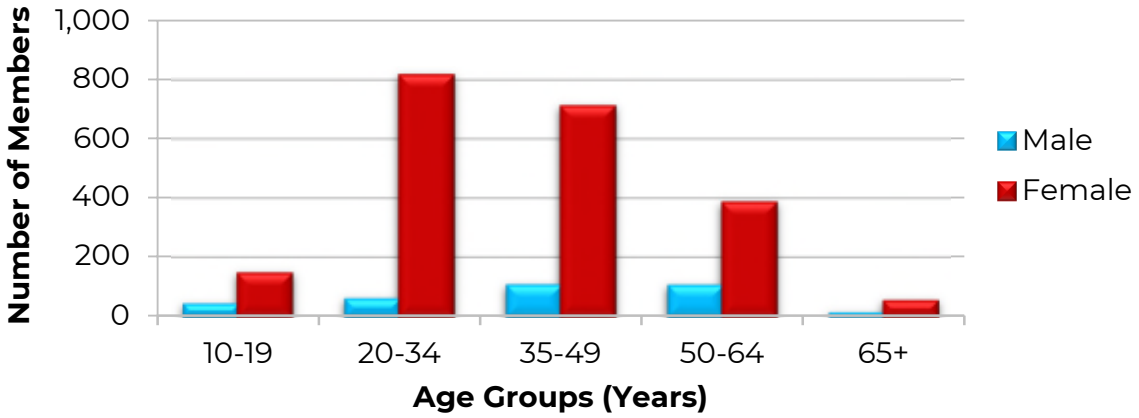
Utilization of Butalbital Medications: Fiscal Year 2022

Comparison of Fiscal Years

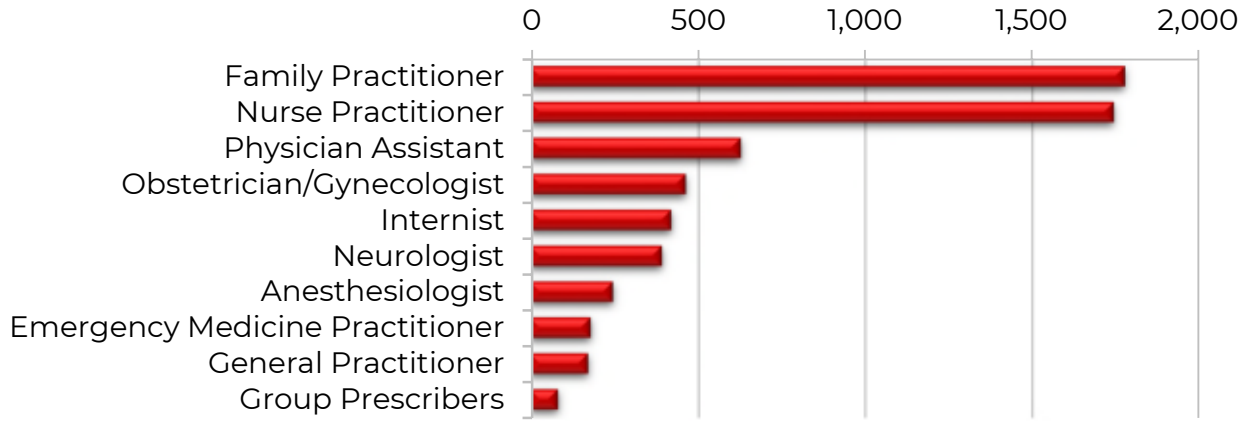
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	1,948	5,383	$126,201.79	$23.44	$1.37	263,124	92,049
2022	2,395	6,436	$151,125.04	$23.48	$1.33	315,710	113,943
% Change	**22.9%**	**19.6%**	**19.7%**	**0.2%**	**-2.9%**	**20.0%**	**23.8%**
Change	**447**	**1,053**	**$24,923.25**	**$0.04**	**-$0.04**	**52,586**	**21,894**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021; Fiscal Year 2022 = 07/01/2021 to 06/30/2022

Demographics of Members Utilizing Butalbital Medications

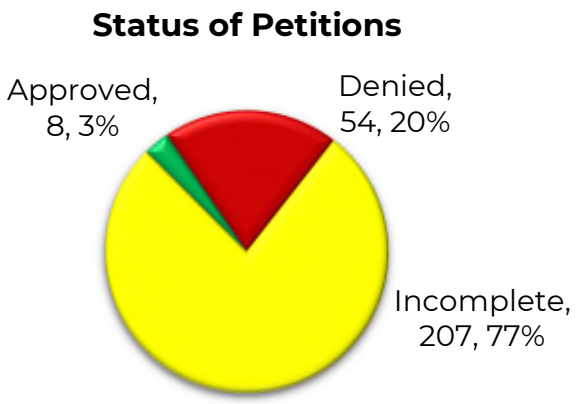


Top Prescriber Specialties of Butalbital Medications by Number of Claims



Prior Authorization of Butalbital Medications

There were 269 prior authorization requests submitted for butalbital medications during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.



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 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
BUTALBITAL PRODUCTS						
BUT/APAP/CAF TAB 50/325/40MG	5,554	2,159	$100,067.88	$18.02	2.57	66.22%
BUT/ASA/CAF CAP 50/325/40MG	343	112	$18,672.14	$54.44	3.06	12.36%
BUT/APAP TAB 50/325MG	47	20	$2,646.55	$56.31	2.35	1.75%
BUT/APAP/CAF CAP 50/300/40MG	24	4	$868.93	$36.21	6	0.57%
BUT/APAP/CAF CAP 50/325/40MG	1	1	$15.72	$15.72	1	0.01%
SUBTOTAL	**5,969**	**2,296**	**$122,271.22**	**$20.48**	**2.60**	**80.91%**
BUTALBITAL/CODEINE PRODUCTS						
BUT/APAP/CAF/COD CAP 50/325/40/30MG	307	98	$15,134.94	$49.30	3.13	10.01%
BUT/ASA/CAF/COD CAP 50/325/40/30MG	102	29	$7,973.06	$78.17	3.52	5.28%
ASCOMP/COD CAP 50/325/40/30MG	57	22	$5,606.78	$98.36	2.59	3.71%
BUT/APAP/CAF/COD CAP 50/300/40/30MG	1	1	$139.04	$139.04	1	0.09%
SUBTOTAL	**467**	**150**	**$28,853.82**	**$61.79**	**3.11**	**19.08%**
TOTAL	**6,436**	**2,395***	**$151,125.04**	**$23.48**	**2.69**	**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 2022 = 07/01/2021 to 06/30/2022

Fiscal Year 2022 Annual Review of Gout Medications

Oklahoma Health Care Authority
Fiscal Year 2022 Print Report

Current Prior Authorization Criteria

Colcrys® (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 2022

Comparison of Fiscal Years: Pharmacy Claims

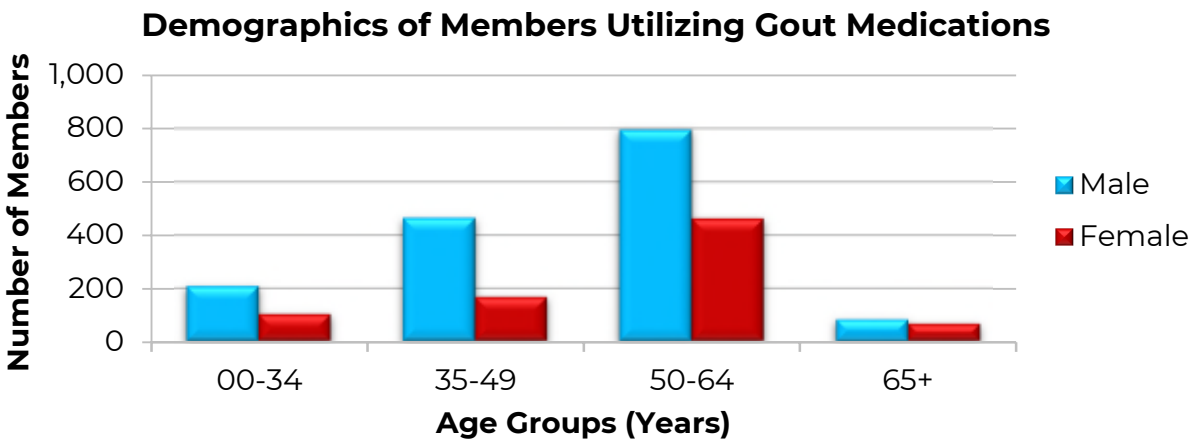
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	1,361	5,601	$104,268.52	$18.62	$0.43	287,361	241,280
2022	2,335	7,966	$125,463.74	$15.75	$0.35	427,794	363,043
% Change	**71.60%**	**42.20%**	**20.30%**	**-15.40%**	**-18.60%**	**48.90%**	**50.50%**
Change	**974**	**2,365**	**$21,195.22**	**-$2.87**	**-$0.08**	**140,433**	**121,763**

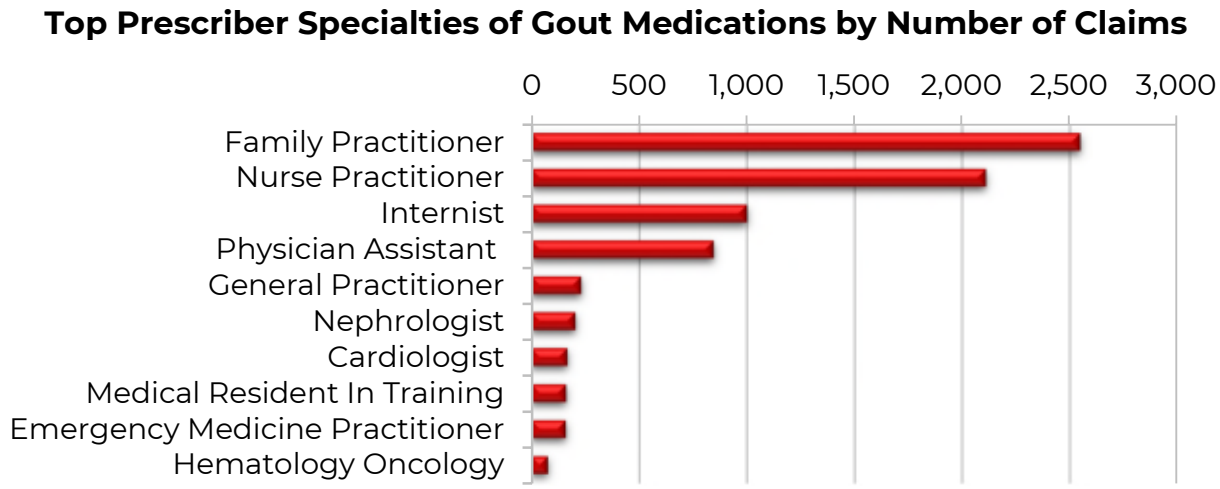
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021; Fiscal Year 2022 = 07/01/2021 to 06/30/2022

Comparison of Fiscal Years: Medical Claims

Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2021	3	46	$182,275.87	$3,962.52	15.33
2022	0	0	$0.00	$0.00	0
% Change	**-100.0%**	**-100.0%**	**-100.0%**	**-100.0%**	**-100.0%**
Change	**-3**	**-46**	**-$182,275.87**	**-$3,962.52**	**-15.33**

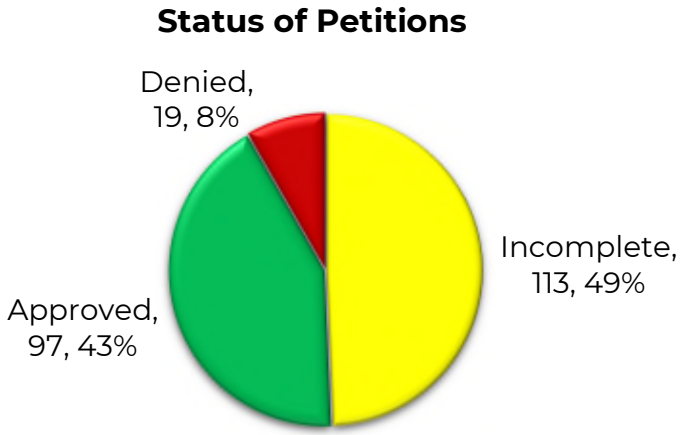
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021; Fiscal Year 2022 = 07/01/2021 to 06/30/2022





Prior Authorization of Gout Medications

There were 229 prior authorization requests submitted for gout medications during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.



Market News and Updates[1,2]

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

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

- **July 2022:** The FDA approved a supplemental Biologics License Application (sBLA) to expand the label for Krystexxa® (pegloticase) to be co-administered with methotrexate for patients with uncontrolled gout. The co-administration with methotrexate is used to help prevent the development of anti-drug antibodies and allow more patients to achieve a complete response with Krystexxa®.

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 2022

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ALLOPURINOL PRODUCTS						
ALLOPURINOL TAB 100MG	3,793	1,203	$46,897.80	$12.36	3.15	37.38%
ALLOPURINOL TAB 300MG	2,772	901	$39,635.22	$14.30	3.08	31.59%
SUBTOTAL	**6,565**	**2,104**	**$86,533.02**	**$13.18**	**3.12**	**68.97%**
COLCHICINE PRODUCTS						
COLCHICINE TAB 0.6MG	905	398	$13,270.66	$14.66	2.27	10.58%
COLCHICINE CAP 0.6MG	106	62	$3,406.09	$32.13	1.71	2.71%
MITIGARE CAP 0.6MG	4	3	$162.38	$40.60	1.33	0.13%
SUBTOTAL	**1,015**	**463**	**$16,839.13**	**$16.59**	**2.19**	**13.42%**
FEBUXOSTAT PRODUCTS						
FEBUXOSTAT TAB 40MG	150	35	$5,167.66	$34.45	4.29	4.12%
FEBUXOSTAT TAB 80MG	97	17	$3,669.48	$37.83	5.71	2.92%
ULORIC TAB 40MG	12	2	$3,920.10	$326.68	6	3.12%
ULORIC TAB 80MG	10	1	$3,273.90	$327.39	10	2.61%
SUBTOTAL	**269**	**55**	**$16,031.14**	**$59.60**	**4.89**	**12.77%**
PROBENECID PRODUCTS						
PROBENECID TAB 500MG	66	22	$3,276.92	$49.65	3	2.61%
SUBTOTAL	**66**	**22**	**$3,276.92**	**$49.65**	**3**	**2.61%**
PROBENECID/COLCHICINE COMBINATION PRODUCTS						
PROBEN/COLCH TAB 500/0.5MG	51	15	$2,783.53	$54.58	3.4	2.22%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**51**	**15**	**$2,783.53**	**$54.58**	**3.4**	**2.22%**
TOTAL	**7,966**	**2,335***	**$125,463.74**	**$15.75**	**3.41**	**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 2022 = 07/01/2021 to 06/30/2022

[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 05/2023. Last accessed 06/05/2023.
[2] Horizon Therapeutics. FDA Approves Krystexxa® (Pegloticase) Injection Co-Administered with Methotrexate, Expanding the Labeling to Help More People with Uncontrolled Gout Achieve a Complete Response to Therapy. Available online at: https://ir.horizontherapeutics.com/news-releases/news-release-details/fda-approves-krystexxar-pegloticase-injection-co-administered. Issued 07/08/2022. Last accessed 06/05/2023.

Fiscal Year 2022 Annual Review of H.P. Acthar® Gel (Repository Corticotropin Injection)

Oklahoma Health Care Authority
Fiscal Year 2022 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 2022

Comparison of Fiscal Years: Pharmacy Claims

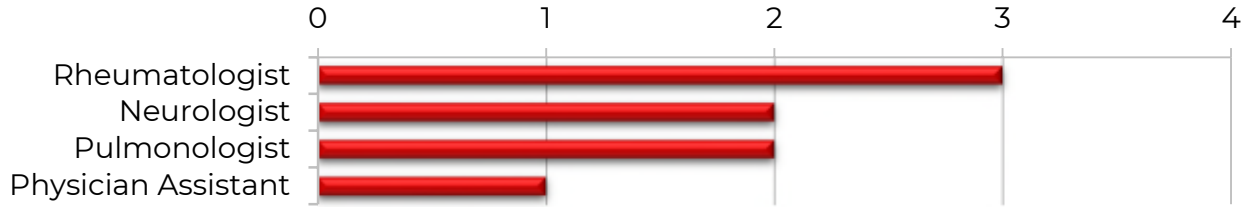
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	1	4	$159,501.64	$39,875.41	$7,975.08	20	20
2022	6	8	$670,479.85	$83,809.98	$2,782.07	90	241
% Change	**500.0%**	**100.0%**	**320.4%**	**110.2%**	**-65.1%**	**350.0%**	**1,105.0%**
Change	**5**	**4**	**$510,978.21**	**$43,934.57**	**-$5,193.01**	**70**	**221**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021; Fiscal Year 2022 = 07/01/2021 to 06/30/2022

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 2022, detailed demographic information could not be provided.

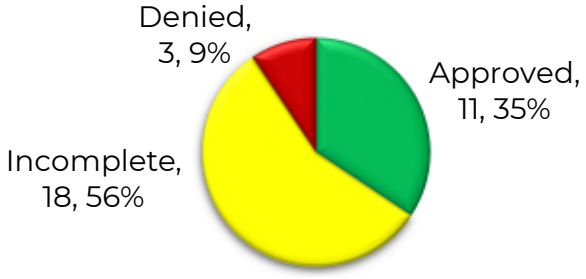
Top Prescriber Specialties of H.P. Acthar® Gel (Repository Corticotropin Injection) by Number of Claims



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

There were 32 prior authorization requests submitted for 10 unique members for H.P. Acthar® Gel during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions



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 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
ACTHAR INJ 80 UNIT	7	5	$606,770.44	$86,681.49	1.4
CORTROPHIN GEL 80 UNIT	1	1	$63,709.41	$63,709.41	1
TOTAL	**8**	**6***	**$670,479.85**	**$83,809.98**	**1.33**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
INJ = Injection
Fiscal Year 2022 = 07/01/2021 to 06/30/2022

Fiscal Year 2022 Annual Review of Heart Failure (HF) Medications

Oklahoma Health Care Authority
Fiscal Year 2022 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 ≤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 ≤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 >40kg 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.

Verquvo® (Vericiguat) Approval Criteria:

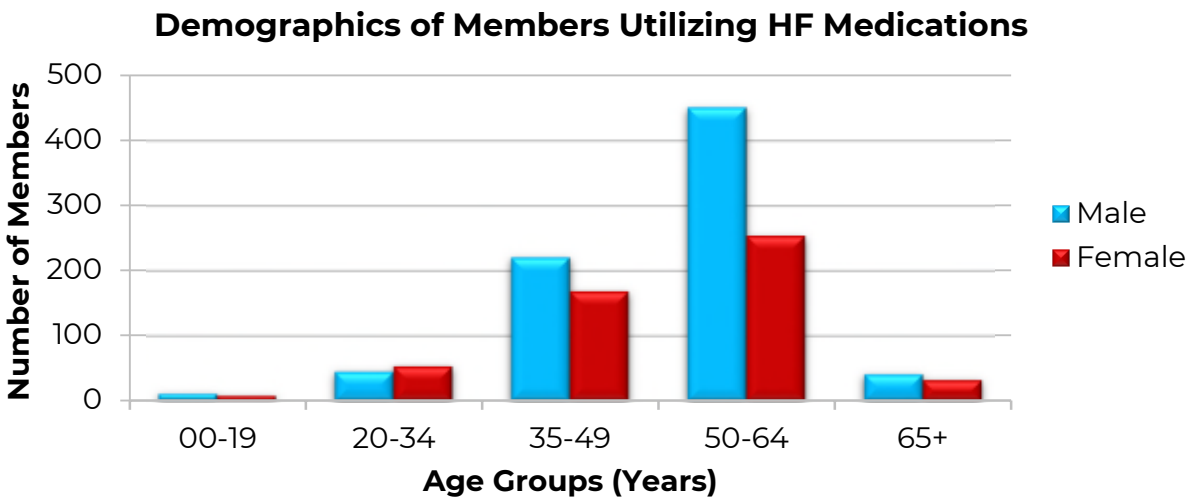
1. An FDA approved indication to reduce the risk of cardiovascular death and hospitalization for heart failure (HF) in adults with all of the following:
   a. Chronic symptomatic HF [New York Heart Association (NYHA) Class II, III, or IV]; and
   b. Reduced left ventricular ejection fraction (LVEF) <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.

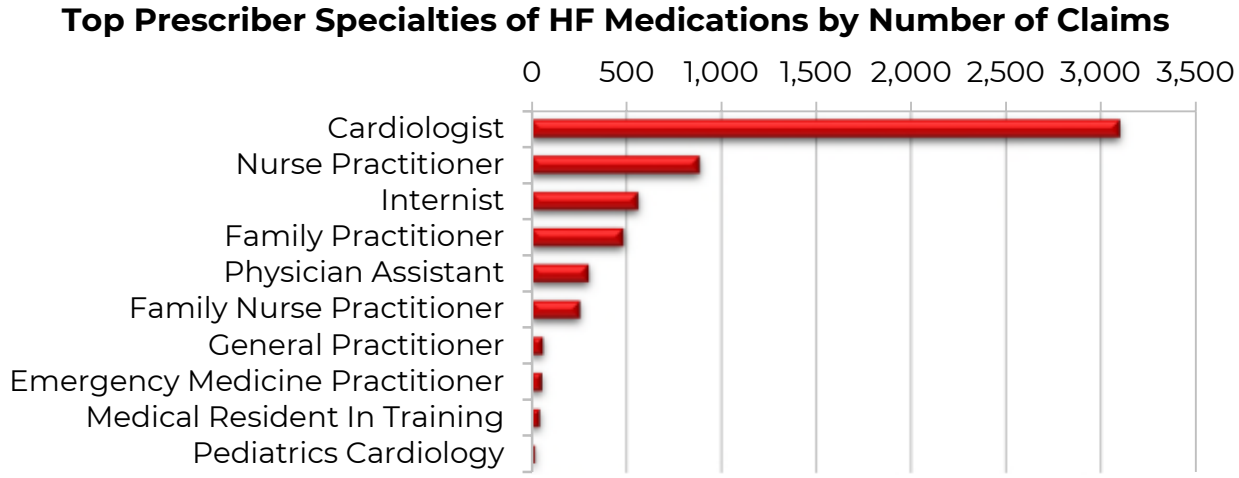
Utilization of HF Medications: Fiscal Year 2022

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	600	3,150	$1,678,760.22	$532.94	$17.67	186,329	94,982
2022	1,281	5,851	$3,283,141.67	$561.12	$18.66	345,715	175,933
% Change	**113.50%**	**85.70%**	**95.60%**	**5.30%**	**5.60%**	**85.50%**	**85.20%**
Change	**681**	**2,701**	**$1,604,381.45**	**$28.18**	**$0.99**	**159,386**	**80,951**

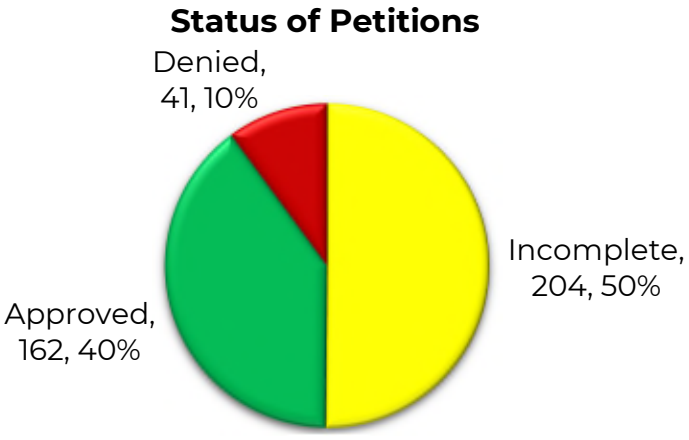
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021; Fiscal Year 2022 = 07/01/2021 to 06/30/2022





Prior Authorization of HF Medications

There were 407 prior authorization requests submitted for HF medications during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.



Market News and Updates[1,2,3,4,5,6,7,8,9]

Anticipated Patent Expiration(s):

- Corlanor® (ivabradine oral solution): December 2026
- Corlanor® (ivabradine tablet): June 2027
- Verquvo® (vericiguat tablet): November 2032
- Entresto® (sacubitril/valsartan tablet): May 2036

News:

- **April 2023:** The American College of Cardiology (ACC) published the *2023 ACC Expert Consensus Decision Pathway on Management of Heart Failure with Preserved Ejection Fraction* (HFpEF). Based on data showing reductions in the risk of hospitalization for HF and cardiovascular (CV) death across all ejection fraction subgroups, the ACC states sodium-glucose cotransporter-2 (SGLT-2) inhibitors should be initiated in all individuals with HFpEF, unless contraindicated. Additional medications with evidence for use in HFpEF include aldosterone antagonists, angiotensin receptor-neprilysin inhibitors (ARNIs), and angiotensin receptor blockers (ARBs).

Pipeline:

- **Omecamtiv Mecarbil:** Cytokinetics is evaluating omecamtiv mecarbil for the treatment of HF with reduced ejection fraction (HFrEF). Omecamtiv mecarbil is a novel, selective, oral cardiac myosin activator that binds to cardiac myosin heads and helps recruit additional myosin heads to interact with actin during systole, augmenting the impaired contractility associated with HFrEF. In February 2023, the U.S. Food and Drug Administration (FDA) issued a Complete Response Letter (CRL) for omecamtiv mecarbil. Cytokinetics intends to meet with the FDA to discuss the CRL but has no plans to conduct additional clinical studies for omecamtiv mecarbil.
- **Revascor® (Rexlemestrocel-L):** Mesoblast is evaluating Revascor® for the treatment of advanced and end-stage chronic HF (CHF). Revascor® is a stem cell therapy consisting of 150 million mesenchymal precursor cells (MPCs) that are administered into the heart muscle by 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 heart muscle. 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 CV death in high-risk patients with CHF. Mesoblast plans to meet with the

FDA to discuss the potential pathway to marketing approval for Revascor®.

- **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 ≥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.

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 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SACUBITRIL/VALSARTAN PRODUCTS						
ENTRESTO TAB 24/26MG	2,732	790	$1,509,395.88	$552.49	3.46	45.97%
ENTRESTO TAB 49/51MG	1,715	438	$974,051.33	$567.96	3.92	29.67%
ENTRESTO TAB 97/103MG	1,201	253	$689,997.50	$574.52	4.75	21.02%
SUBTOTAL	**5,648**	**1,254***	**$3,173,444.71**	**$561.87**	**4.5**	**96.66%**
IVABRADINE PRODUCTS						
CORLANOR TAB 5MG	132	33	$68,220.56	$516.82	4	2.08%
CORLANOR TAB 7.5MG	44	12	$27,692.78	$629.38	3.67	0.84%
CORLANOR SOL 5MG/5ML	17	5	$7,686.58	$452.15	3.4	0.23%
SUBTOTAL	**193**	**45***	**$103,599.92**	**$536.79**	**4.29**	**3.16%**
VERICIGUAT PRODUCTS						
VERQUVO TAB 2.5MG	7	3	$4,238.81	$605.54	2.33	0.13%
VERQUVO TAB 10MG	3	1	$1,858.23	$619.41	3	0.06%
SUBTOTAL	**10**	**4***	**$6,097.04**	**$609.70**	**2.5**	**0.19%**
TOTAL	**5,851**	**1,281***	**$3,283,141.67**	**$561.12**	**4.57**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
SOL = solution; TAB = tablet
Fiscal Year 2022 = 07/01/2021 to 06/30/2022

[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 06/2023. Last Accessed 06/01/2023.
[2] Kittleson M, Panjrath G, Amancherla K, et al. 2023 ACC Expert Consensus Decision Pathway on Management of Heart Failure with Preserved Ejection Fraction. *J Am Coll Cardiol* 2023; 81(18):1835–1878. doi: 10.1016/j.jacc.2023.03.393.
[3] Cytokinetics, Inc. Pipeline: Omecamtiv Mecarbil. Available online at: https://cytokinetics.com/omecamtiv-mecarbil/. Last accessed 06/16/2023.
[4] Cytokinetics, Inc. Cytokinetics Receives Complete Response Letter from FDA for New Drug Application for Omecamtiv Mecarbil. Available online at: https://ir.cytokinetics.com/news-releases/news-release-details/cytokinetics-receives-complete-response-letter-fda-new-drug. Issued 02/28/2023. Last accessed 06/16/2023.
[5] Mesoblast Limited. Product Candidates. Available online at: https://www.mesoblast.com/product-candidates/product-candidates-overview. Last accessed 06/16/2023.
[6] Mesoblast Limited. Cardiovascular Diseases: Chronic Heart Failure. Available online at: https://www.mesoblast.com/product-candidates/cardiovascular-diseases/congestive-heart-failure. Last accessed 06/16/2023.
[7] 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 02/28/2023. Last accessed 06/16/2023.
[8] Novo Nordisk. R&D Pipeline. Available online at: https://www.novonordisk.com/science-and-technology/r-d-pipeline.html. Last accessed 06/16/2023.
[9] 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 06/19/2023.

Fiscal Year 2022 Annual Review of Idiopathic Pulmonary Fibrosis (IPF) Medications

Oklahoma Health Care Authority
Fiscal Year 2022 Print Report

Current Prior Authorization Criteria

Esbriet® (Pirfenidone) Approval Criteria:

1. An FDA approved diagnosis of idiopathic pulmonary fibrosis (IPF); and
2. Member must be 18 years of age or older; and
3. Prescriber must verify liver function tests (LFTs) (e.g., ALT, AST, bilirubin) will be monitored prior to the initiation of Esbriet®, monthly for the first 6 months of treatment, and every 3 months thereafter and as clinically indicated; and
4. Medication must be prescribed by, or in consultation with, a pulmonologist or pulmonary specialist (or an advanced care practitioner with a supervising physician who is a pulmonologist or pulmonary specialist); and
5. A quantity limit of 270 capsules or tablets per 30 days will apply for the 267mg strength capsules and tablets, and a quantity limit of 90 tablets per 30 days will apply for the 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 2022

Comparison of Fiscal Years

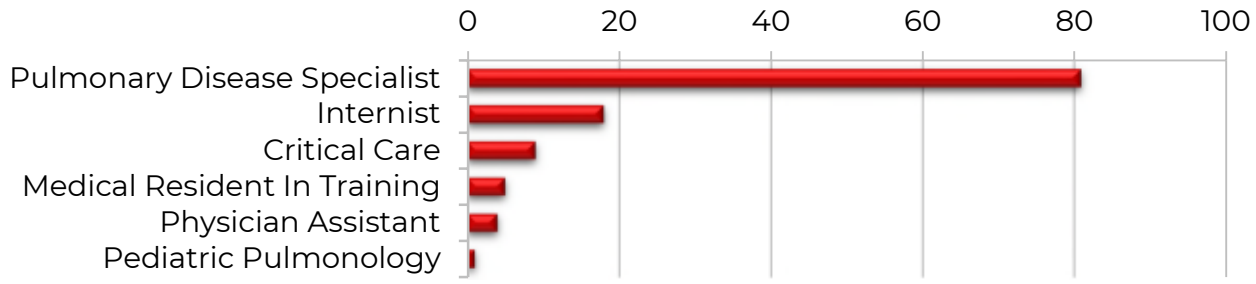
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	8	51	$501,215.09	$9,827.75	$327.59	4,500	1,530
2022	24	118	$1,329,718.49	$11,268.80	$375.63	7,530	3,540
% Change	**200%**	**131.4%**	**165.3%**	**14.7%**	**14.7%**	**67.3%**	**131.4%**
Change	**16**	**67**	**$828,503.40**	**$1,441.05**	**$48.04**	**3,030**	**2,010**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021; Fiscal Year 2022 = 07/01/2021 to 06/30/2022

Demographics of Members Utilizing IPF Medications

- All members utilizing IPF medications during fiscal year 2022 were adults; however, detailed demographic information cannot be provided due to the limited number of members using IPF medications during fiscal year 2022.

Top Prescriber Specialties of IPF Medications by Number of Claims



Prior Authorization of IPF Medications

There were 78 prior authorization requests submitted for IPF medications during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions

Market News and Updates[1,2,3]

Anticipated Patent Expiration(s):

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

News:

- **January 2023:** Multiple manufacturers have launched AB-rated generic Esbriet® (pirfenidone) capsules. Esbriet® is also available in a tablet formulation with the same indication.

Pipeline:

- **Pamrevlumab:** Fibrogen's connective tissue growth factor (CTGF), pamrevlumab, is currently in Phase 3 trials for the treatment of IPF.

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 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
NINTEDANIB PRODUCTS						
OFEV CAP 150MG	90	18	$1,022,303.32	$11,358.93	5	76.88%
OFEV CAP 100MG	25	6	$283,415.73	$11,336.63	4.17	21.31%
SUBTOTAL	**115**	**24**	**$1,305,719.05**	**$11,354.08**	**4.79**	**98.19%**
PIRFENIDONE PRODUCTS						
ESBRIET TAB 267MG	2	1	$13,542.10	$6,771.05	2	1.02%
ESBRIET CAP 267MG	1	1	$10,457.34	$10,457.34	1	0.79%
SUBTOTAL	**3**	**2**	**$23,999.44**	**$7,999.81**	**1.5**	**1.81%**
TOTAL	**118**	**24***	**$1,329,718.49**	**$11,268.80**	**4.92**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; TAB = tablet
Fiscal Year 2022 = 07/01/2021 to 06/30/2022

[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 04/2023. Last accessed 05/22/2023.
[2] OptumRx. Esbriet® (Pirfenidone) – First-Time Generic. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/new-generics/newgeneric_esbriet_2023-0118.pdf. Last accessed 05/22/2023.
[3] Fibrogen. Pamrevlumab Trials. Available online at: https://www.fibrogen.com/pamrevlumab-trials. Last accessed 05/22/2023.

Fiscal Year 2022 Annual Review of Kanuma® (Sebelipase Alfa)

Oklahoma Health Care Authority
Fiscal Year 2022 Print Report

Current Prior Authorization Criteria

Kanuma® (Sebelipase Alfa) Approval Criteria:

1. An FDA approved diagnosis of lysosomal acid lipase (LAL) deficiency; and
2. Kanuma® (sebelipase alfa) must be administered in a health care setting by a health care professional prepared to manage anaphylaxis; and
3. 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.

Utilization of Kanuma® (Sebelipase Alfa): Fiscal Year 2022

There was no SoonerCare utilization of Kanuma® (sebelipase alfa) during fiscal year 2022 (07/01/2021 to 06/30/2022).

Prior Authorization of Kanuma® (Sebelipase Alfa)

There were no prior authorization requests submitted for Kanuma® (sebelipase alfa) during fiscal year 2022.

Recommendations

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

Fiscal Year 2022 Annual Review of Leukotriene Modulators

Oklahoma Health Care Authority
Fiscal Year 2022 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:

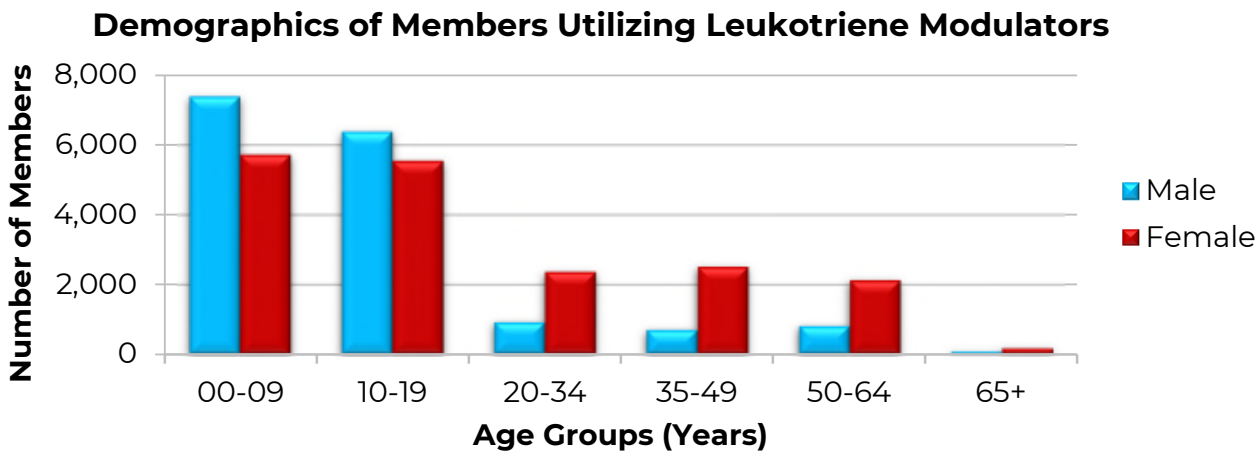
1. An FDA approved diagnosis of mild or moderate persistent asthma; and
2. Member must be 12 years of age or older; and
3. Member must meet the following trial requirements:
    a. A trial of an inhaled corticosteroid (ICS) and ICS/long-acting beta$_2$ agonist (LABA) therapy within the previous 6 months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

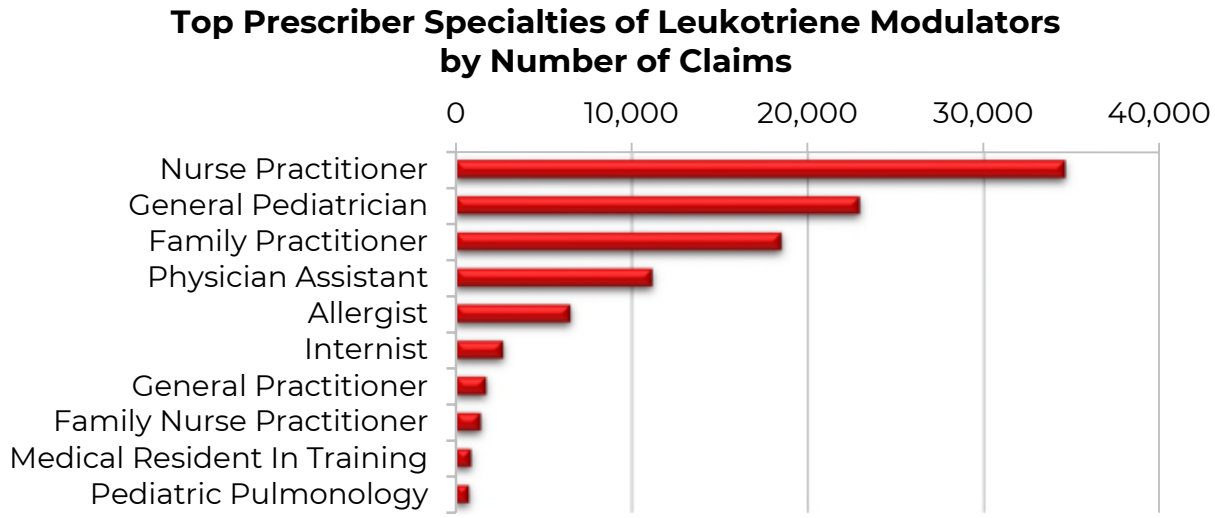
Utilization of Leukotriene Modulators: Fiscal Year 2022

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	29,843	106,969	$1,531,190.54	$14.31	$0.42	3,643,502	3,648,363
2022	34,655	104,857	$1,549,147.87	$14.77	$0.35	4,373,192	4,379,581
% Change	**16.1%**	**-2.0%**	**1.2%**	**3.2%**	**-16.7%**	**20.0%**	**20.0%**
Change	**4,812**	**-2,112**	**$17,957.33**	**$0.46**	**-$0.07**	**729,690**	**731,218**

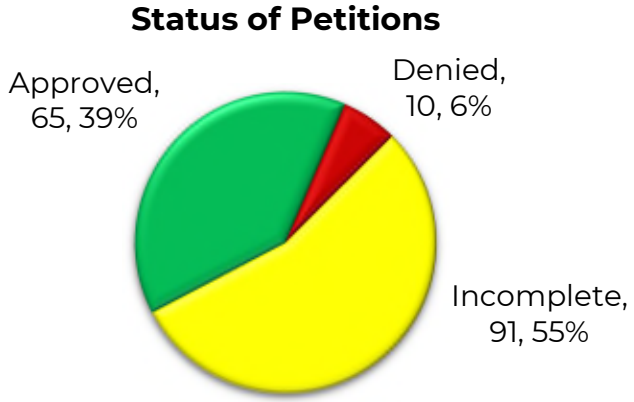
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021; Fiscal Year 2022 = 07/01/2021 to 06/30/2022





Prior Authorization of Leukotriene Modulators

There were 166 prior authorization requests submitted for leukotriene modulators during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.



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 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
MONTELUKAST PRODUCTS						
MONTELUKAST TAB 10MG	43,706	15,525	$567,992.57	$13.00	2.82	36.66%
MONTELUKAST CHW 5MG	35,211	11,161	$514,998.59	$14.63	3.15	33.24%
MONTELUKAST CHW 4MG	23,992	8,212	$360,241.64	$15.02	2.92	23.25%
MONTELUKAST GRA 4MG	1,948	896	$105,915.07	$54.37	2.17	6.84%
TOTAL	**104,857**	**34,655***	**$1,549,147.87**	**$14.77**	**3.02**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CHW = chewable; GRA = granule; TAB = tablet
Fiscal Year 2022 = 07/01/2021 to 06/30/2022

Fiscal Year 2022 Annual Review of Mepsevii® (Vestronidase Alfa-vjbk)

Oklahoma Health Care Authority
Fiscal Year 2022 Print Report

Current Prior Authorization Criteria

Mepsevii® (Vestronidase Alfa-vjbk) Approval Criteria:

1. An FDA approved diagnosis of Sly syndrome (mucopolysaccharidosis VII; MPS VII) confirmed by:
   a. Enzyme analysis demonstrating a deficiency of beta-glucuronidase activity; or
   b. Genetic testing to confirm diagnosis of MPS VII; and
2. Mepsevii® must be administered by a health care professional prepared to manage anaphylaxis; and
3. Initial approvals will be for the duration of 12 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment; 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 package labeling.

Utilization of Mepsevii® (Vestronidase Alfa-vjbk): Fiscal Year 2022

There was no SoonerCare utilization of Mepsevii® (vestronidase alfa-vjbk) during fiscal year 2022 (07/01/2021 to 06/30/2022).

Prior Authorization of Mepsevii® (Vestronidase Alfa-vjbk)

There were no prior authorization requests submitted for Mepsevii® (vestronidase alfa-vjbk) during fiscal year 2022.

Recommendations

The College of Pharmacy does not recommend any changes to the current Mepsevii® (vestronidase alfa-vjbk) prior authorization criteria at this time.

Fiscal Year 2022 Annual Review of Nasal Allergy Medications

Oklahoma Health Care Authority
Fiscal Year 2022 Print Report

Current Prior Authorization Criteria

Nasal Allergy Medications		
Tier-1	**Tier-2**	**Tier-3**
azelastine (Astelin®)	azelastine (Astepro®)	azelastine/fluticasone (Dymista®)
beclomethasone (Beconase® AQ)	mometasone (Nasonex®)	beclomethasone (Qnasl® 80mcg, 40mcg)
fluticasone (Flonase®)		ciclesonide (Omnaris®, Zetonna®)
		flunisolide (Nasalide®, Nasarel®)
		fluticasone (Veramyst®)
		fluticasone (Xhance®)*
		olopatadine (Patanase®)
		olopatadine/mometasone (Ryaltris™)

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).
*Xhance®: Unique criteria applies.

Nasal Allergy Medications Tier-2 Approval Criteria:

1. Member must have failure with all Tier-1 medications defined as no beneficial response after at least 3 weeks use at the maximum recommended dose; or
2. Documented adverse effect or contraindication to all Tier-1 medications; and
3. For members 2 to 4 years of age, the age-appropriate, lower-tiered generic medications must be tried prior to the approval of higher-tiered medications; and
4. Approvals will be for the duration of 3 months, except for members with chronic diseases such as asthma or chronic obstructive pulmonary disease (COPD), in which case authorizations will be for the duration of 1 year.

Nasal Allergy Medications Tier-3 Approval Criteria:

1. All Tier-2 criteria must be met; and

2. Member must have failure with all available Tier-2 medications defined as no beneficial response after at least 3 weeks use at the maximum recommended dose; or
3. Documented adverse effect or contraindication to all Tier-2 medications; and
4. For members 2 to 4 years of age, the age-appropriate, lower-tiered generic medications must be tried prior to the approval of higher-tiered medications; and
5. Approvals will be for the duration of 3 months, except for members with chronic diseases such as asthma or COPD, in which case authorizations will be for the duration of 1 year.

Sinuva® (Mometasone Furoate Sinus Implant) Approval Criteria:

1. An FDA approved indication of nasal polyps in adults 18 years of age and older who have had ethmoid sinus surgery; and
2. Date of ethmoid sinus surgery must be provided; and
3. Sinuva® must be prescribed and implanted by a physician specializing in otolaryngology; and
4. Failure of intranasal corticosteroids after at least a 3-month trial at the maximum recommended dose in combination with a 14-day trial of oral corticosteroids within the last 6 months (if not contraindicated); and
5. Prescriber must confirm the member has recurrent nasal obstruction/ congestion symptoms and recurrent bilateral sinusitis or chronic sinusitis due to nasal polyps; and
6. A quantity limit of 2 implants per member will apply.

Xhance® (Fluticasone Propionate Nasal Spray) Approval Criteria:

1. An FDA approved diagnosis of nasal polyps; and
2. A patient-specific, clinically significant reason why the member cannot use intranasal fluticasone, budesonide, mometasone, and/or other cost-effective therapeutic equivalent medication(s) must be provided; and
3. Current Tier structure rules will also apply.

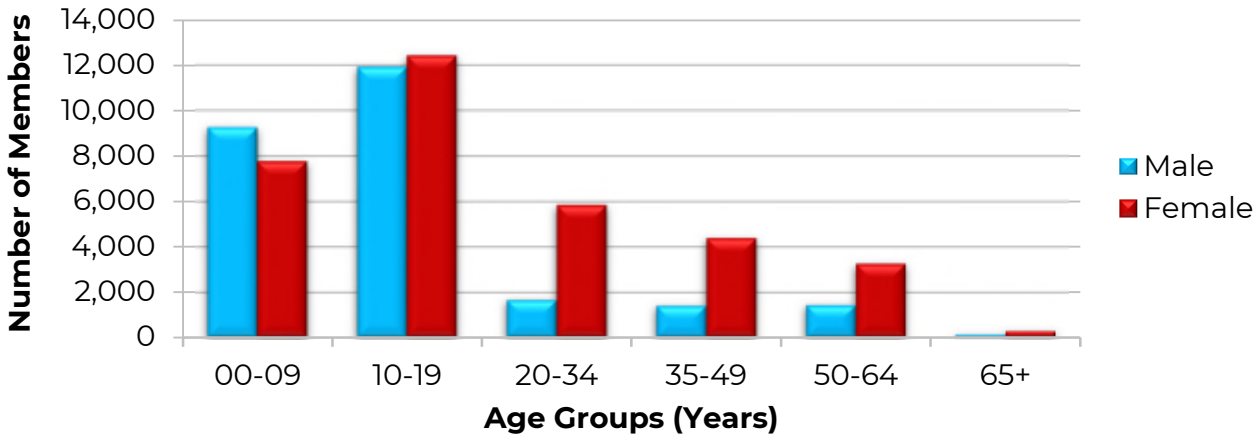
Utilization of Nasal Allergy Medications: Fiscal Year 2022

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	43,061	85,674	$1,688,630.60	$19.71	$0.51	1,387,668	3,319,542
2022	59,595	107,072	$2,083,351.94	$19.46	$0.50	1,734,215	4,172,818
% Change	**38.40%**	**25.00%**	**23.40%**	**-1.30%**	**-2.00%**	**25.00%**	**25.70%**
Change	**16,534**	**21,398**	**$394,721.34**	**-$0.25**	**-$0.01**	**346,547**	**853,276**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021; Fiscal Year 2022 = 07/01/2021 to 06/30/2022

Demographics of Members Utilizing Nasal Allergy Medications

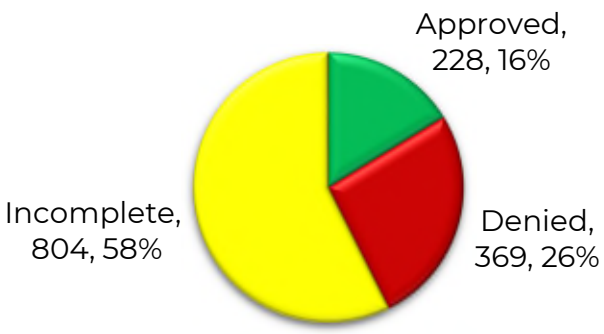


Top Prescriber Specialties of Nasal Allergy Medications by Number of Claims

Prior Authorization of Nasal Allergy Medications

There were 1,401 prior authorization requests submitted for nasal allergy medications during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions



Market News and Updates[1]

Anticipated Patent Expiration(s):

- Patanase® (olopatadine): August 2023
- Dymista® (azelastine/fluticasone): August 2026
- Omnaris® (ciclesonide): February 2028
- Zetonna® (ciclesonide): February 2028
- Astepro® (azelastine): June 2028
- Qnasl® (beclomethasone): October 2031
- Ryaltris™ (olopatadine/mometasone): September 2034
- Sinuva® (mometasone furoate): November 2034
- Xhance® (fluticasone): February 2036

Recommendations

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

Utilization Details of Nasal Allergy Medications: Fiscal Year 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 PRODUCTS						
FLUTICASONE SPR 50MCG	104,877	58,978	$1,594,905.17	$15.21	1.78	76.55%
BECONASE AQ SUS 0.042%	1,488	725	$437,729.51	$294.17	2.05	21.01%
AZELASTINE SPR 0.1%	504	275	$9,441.65	$18.73	1.83	0.45%
SUBTOTAL	**106,869**	**59,563***	**$2,042,076.33**	**$19.11**	**1.79**	**98.02%**
TIER-2 PRODUCTS						
MOMETASONE SPR 50MCG	25	9	$1,257.94	$50.32	2.78	0.06%
AZELASTINE SPR 0.15%	17	3	$367.02	$21.59	5.67	0.02%
SUBTOTAL	**42**	**12***	**$1,624.96**	**$38.69**	**3.5**	**0.08%**
TIER-3 PRODUCTS						
QNASL AER 80MCG	64	14	$16,998.60	$256.60	4.57	0.82%
AZEL/FLUTIC SPR 137/50MCG	58	10	$7,129.78	$112.93	5.8	0.34%
XHANCE 93MCG	20	6	$11,486.59	$574.33	3.33	0.55%
QNASL CHILD SPR 40MCG	14	3	$3,769.02	$269.22	4.67	0.18%
OLOPATADINE SPR 0.6%	5	2	$266.66	$53.33	2.5	0.01%
SUBTOTAL	**161**	**34***	**$39,650.65**	**$246.28**	**4.74**	**1.90%**
TOTAL	**107,072**	**59,595***	**$2,083,351.94**	**$19.46**	**1.8**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
AER = aerosol; AQ = aqueous; AZEL/FLUTIC = azelastine/fluticasone; SPR = spray; SUS = suspension

[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 06/2023. Last accessed 06/02/2023.

Fiscal Year 2022 Annual Review of Systemic Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)

Oklahoma Health Care Authority
Fiscal Year 2022 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), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Naproxen oral suspension is available without prior authorization for members 12 years of age and younger. Members older than 12 years of age require a reason why a special formulation product is needed in place of the regular tablet formulation.
caps = capsules; ER = extended-release; EC = enteric-coated; inj = injection; ODT = orally disintegrating tablet; PA = prior authorization; susp = suspension; tabs = tablets

NSAIDs Tier-2 Approval Criteria:

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

NSAIDs Special Prior Authorization (PA) Approval Criteria:

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

Anjeso® (Meloxicam Injection) Approval Criteria:

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

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

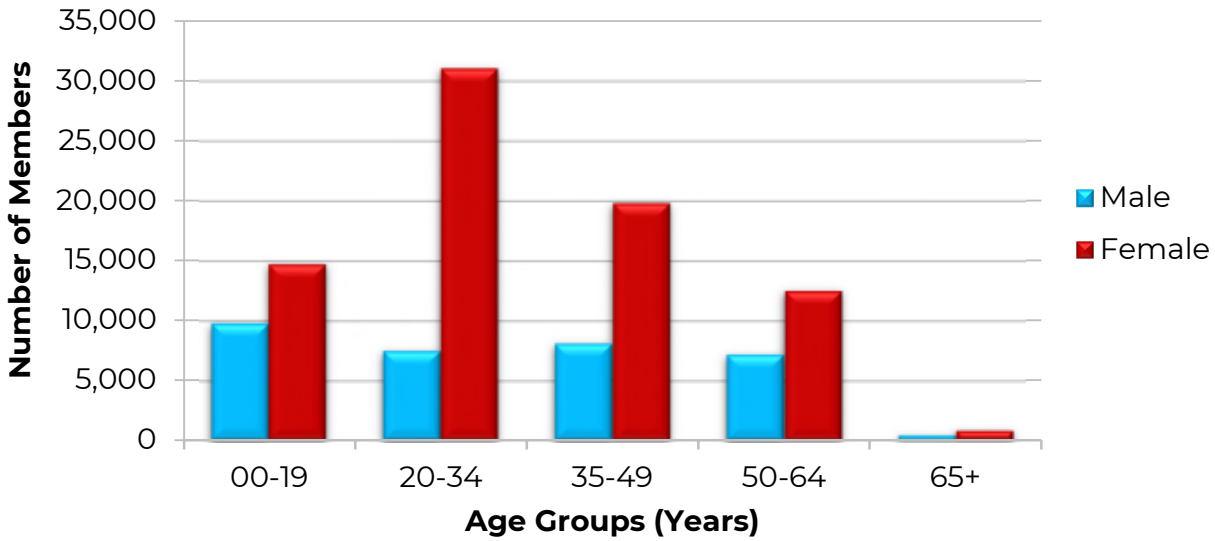
Utilization of NSAIDs: Fiscal Year 2022

Comparison of Fiscal Years

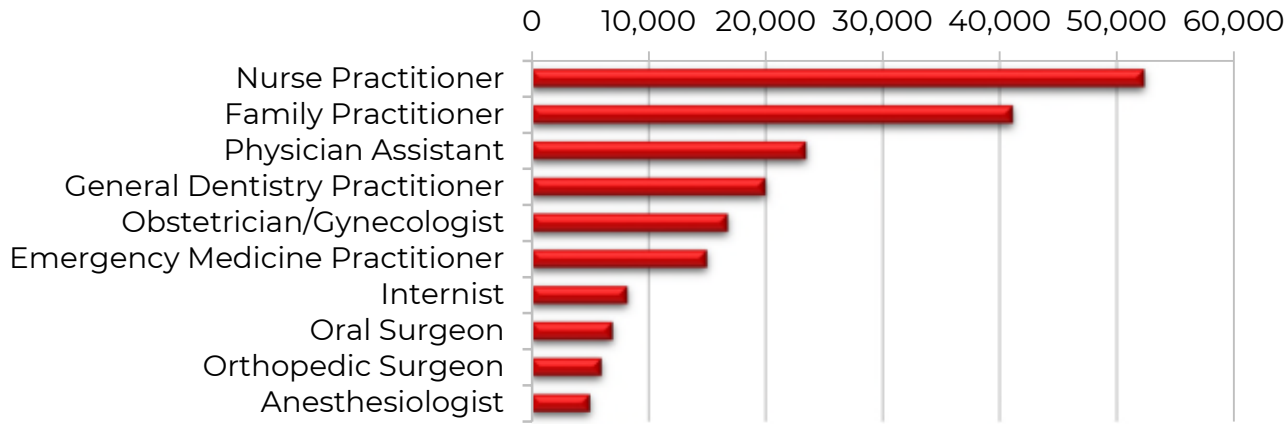
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	72,713	140,642	$2,113,264.30	$15.03	$0.66	7,276,465	3,199,500
2022	111,805	214,853	$3,022,195.15	$14.07	$0.61	10,665,818	4,941,238
% Change	**53.80%**	**52.80%**	**43.00%**	**-6.40%**	**-7.60%**	**46.60%**	**54.40%**
Change	**39,092**	**74,211**	**$908,930.85**	**-$0.96**	**-$0.05**	**3,389,353**	**1,741,738**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021; Fiscal Year 2022 = 07/01/2021 to 06/30/2022

Demographics of Members Utilizing NSAIDs



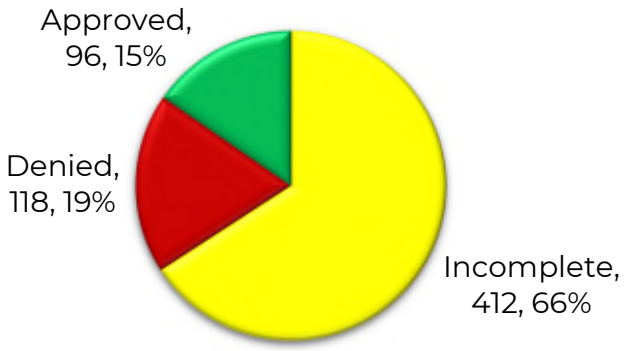
Top Prescriber Specialties of NSAIDs by Number of Claims



Prior Authorization of NSAIDs

There were 626 prior authorization requests submitted for NSAIDs during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions



Market News and Updates[1]

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
- Vimovo® (naproxen/esomeprazole tablets): October 2031

- Caldolor® (ibuprofen injection): March 2032
- 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 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 PRODUCTS						
IBUPROFEN PRODUCTS						
IBUPROFEN TAB 800MG	71,771	47,796	$861,965.87	$12.01	1.5	28.52%
IBUPROFEN TAB 600MG	16,116	13,747	$177,456.68	$11.01	1.17	5.87%
IBUPROFEN TAB 400MG	2,323	1,807	$27,175.49	$11.70	1.29	0.90%
IBU TAB 800MG	857	581	$12,259.87	$14.31	1.48	0.41%
IBU TAB 600MG	169	146	$2,150.39	$12.72	1.16	0.07%
IBU TAB 400MG	23	19	$307.77	$13.38	1.21	0.01%
IBUPROFEN POW	11	9	$123.86	$11.26	1.22	0.00%
SUBTOTAL	**91,270**	**64,105**	**$1,081,439.93**	**$11.85**	**1.42**	**35.78%**
MELOXICAM PRODUCTS						
MELOXICAM TAB 15MG	28,967	14,507	$257,875.14	$8.90	2	8.53%
MELOXICAM TAB 7.5MG	13,484	7,802	$127,504.86	$9.46	1.73	4.22%
SUBTOTAL	**42,451**	**22,309**	**$385,380.00**	**$9.08**	**1.9**	**12.75%**
NAPROXEN PRODUCTS						
NAPROXEN TAB 500MG	25,780	17,688	$298,265.26	$11.57	1.46	9.87%
NAPROXEN TAB 375MG	2,350	1,756	$28,769.04	$12.24	1.34	0.95%
NAPROXEN TAB 250MG	1,605	1,030	$21,069.65	$13.13	1.56	0.70%
NAPROXEN SUS 125MG/5ML	517	276	$138,799.24	$268.47	1.87	4.59%
NAPROXEN DR TAB 500MG	478	387	$48,808.62	$102.11	1.24	1.62%
EC-NAPROXEN TAB 500MG	416	292	$42,253.52	$101.57	1.42	1.40%
NAPROXEN DR TAB 375MG	92	51	$1,980.81	$21.53	1.8	0.07%
EC-NAPROXEN TAB 375MG	5	5	$104.66	$20.93	1	0.00%
SUBTOTAL	**31,243**	**21,485**	**$580,050.80**	**$18.57**	**1.45**	**19.19%**
DICLOFENAC PRODUCTS						
DICLOFENAC TAB 75MG DR	10,479	5,076	$145,317.51	$13.87	2.06	4.81%
DICLOFENAC GEL 1%	8,554	4,880	$187,674.96	$21.94	1.75	6.21%
DICLOFENAC TAB 50MG DR	3,270	1,738	$50,256.54	$15.37	1.88	1.66%
FLECTOR DIS 1.3%	147	58	$40,979.78	$278.77	2.53	1.36%
SUBTOTAL	**22,450**	**11,752**	**$424,228.79**	**$18.90**	**1.91**	**14.04%**
CELECOXIB PRODUCTS						
CELECOXIB CAP 200MG	9,482	3,904	$155,577.73	$16.41	2.43	5.15%
CELECOXIB CAP 100MG	3,612	1,541	$54,369.63	$15.05	2.34	1.80%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
CELECOXIB CAP 50MG	98	61	$1,650.59	$16.84	1.61	0.05%
SUBTOTAL	**13,192**	**5,506**	**$211,597.95**	**$16.04**	**2.4**	**7.00%**
KETOROLAC PRODUCTS						
KETOROLAC TAB 10MG	6,405	5,689	$127,763.50	$19.95	1.13	4.23%
KETOROLAC INJ 60MG/2ML	35	12	$645.48	$18.44	2.92	0.02%
KETOROLAC INJ 30MG/ML	16	13	$207.36	$12.96	1.23	0.01%
SUBTOTAL	**6,456**	**5,714**	**$128,616.34**	**$19.92**	**1.13**	**4.26%**
NABUMETONE PRODUCTS						
NABUMETONE TAB 750MG	1,576	626	$27,554.23	$17.48	2.52	0.91%
NABUMETONE TAB 500MG	1,056	475	$17,612.25	$16.68	2.22	0.58%
SUBTOTAL	**2,632**	**1,101**	**$45,166.48**	**$17.16**	**2.39**	**1.49%**
ETODOLAC PRODUCTS						
ETODOLAC TAB 400MG	1,550	950	$37,237.69	$24.02	1.63	1.23%
ETODOLAC TAB 500MG	616	336	$15,323.06	$24.88	1.83	0.51%
SUBTOTAL	**2,166**	**1,286**	**$52,560.75**	**$24.27**	**1.68**	**1.74%**
INDOMETHACIN PRODUCTS						
INDOMETHACIN CAP 50MG	833	510	$12,145.45	$14.58	1.63	0.40%
INDOMETHACIN CAP 25MG	483	313	$7,204.87	$14.92	1.54	0.24%
SUBTOTAL	**1,316**	**823**	**$19,350.32**	**$14.70**	**1.6**	**0.64%**
SULINDAC PRODUCTS						
SULINDAC TAB 200MG	256	127	$5,836.15	$22.80	2.02	0.19%
SULINDAC TAB 150MG	192	51	$3,451.08	$17.97	3.76	0.11%
SUBTOTAL	**448**	**178**	**$9,287.23**	**$20.73**	**2.52**	**0.31%**
FLURBIPROFEN PRODUCTS						
FLURBIPROFEN TAB 100MG	100	42	$3,087.29	$30.87	2.38	0.10%
SUBTOTAL	**100**	**42**	**$3,087.29**	**$30.87**	**2.38**	**0.10%**
TIER-1 SUBTOTAL	**213,724**	**111,670***	**$2,940,765.88**	**$13.76**	**1.91**	**97.31%**
TIER-2 PRODUCTS						
DICLOFENAC PRODUCTS						
DICLOFENAC TAB 100MG ER	379	158	$23,341.48	$61.59	2.4	0.77%
DICLOFENAC POT TAB 50MG	236	140	$7,515.43	$31.85	1.69	0.25%
DICLOFENAC TAB 25MG DR	37	13	$1,632.26	$44.12	2.85	0.05%
SUBTOTAL	**652**	**311**	**$32,489.17**	**$49.83**	**2.1**	**1.08%**
NAPROXEN PRODUCTS						
NAPROXEN SOD TAB 550MG	164	104	$4,134.12	$25.21	1.58	0.14%
NAPROXEN SOD TAB 275MG	8	8	$229.66	$28.71	1	0.01%
SUBTOTAL	**172**	**112**	**$4,363.78**	**$25.37**	**1.54**	**0.14%**
ETODOLAC PRODUCTS						
ETODOLAC CAP 300MG	102	87	$2,625.37	$25.74	1.17	0.09%
ETODOLAC CAP 200MG	41	23	$1,338.45	$32.65	1.78	0.04%
ETODOLAC ER TAB 400MG	10	5	$560.76	$56.08	2	0.02%
ETODOLAC ER TAB 500MG	9	2	$839.42	$93.27	4.5	0.03%
ETODOLAC ER TAB 600MG	8	1	$510.12	$63.77	8	0.02%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**170**	**118**	**$5,874.12**	**$34.55**	**1.44**	**0.19%**
DICLOFENAC/MISOPROSTOL PRODUCTS						
DICLO/MISOPR TAB 75-0.2MG	30	12	$2,851.65	$95.06	2.5	0.09%
DICLO/MISOPR TAB 50-0.2MG	25	7	$2,774.49	$110.98	3.57	0.09%
SUBTOTAL	**55**	**19**	**$5,626.14**	**$102.29**	**2.89**	**0.19%**
PIROXICAM PRODUCTS						
PIROXICAM CAP 20MG	35	9	$897.25	$25.64	3.89	0.03%
PIROXICAM CAP 10MG	1	1	$22.03	$22.03	1	0.00%
SUBTOTAL	**36**	**10**	**$919.28**	**$25.54**	**3.6**	**0.03%**
OXAPROZIN PRODUCTS						
OXAPROZIN TAB 600MG	11	2	$601.82	$54.71	5.5	0.02%
SUBTOTAL	**11**	**2**	**$601.82**	**$54.71**	**5.5**	**0.02%**
TIER-2 SUBTOTAL	**1,096**	**571***	**$49,874.31**	**$45.51**	**1.92**	**1.65%**
SPECIAL PRIOR AUTHORIZATION (PA) UTILIZATION						
INDOMETHACIN PRODUCTS						
INDOCIN SUS 25MG/5ML	10	1	$13,124.80	$1,312.48	10	0.43%
INDOMETHACIN CAP 75MG ER	9	3	$204.97	$22.77	3	0.01%
SUBTOTAL	**19**	**4**	**$13,329.77**	**$701.57**	**4.75**	**0.44%**
IBUPROFEN/FAMOTIDINE PRODUCTS						
DUEXIS TAB 800-26.6MG	7	1	$15,287.73	$2,183.96	7	0.51%
IBU/FAMOT TAB 800-26.6MG	1	1	$330.04	$330.04	1	0.01%
SUBTOTAL	**8**	**2**	**$15,617.77**	**$1,952.22**	**4**	**0.52%**
MEFENAMIC ACID PRODUCTS						
MEFENAMIC ACID CAP 250MG	4	3	$117.87	$29.47	1.33	0.00%
SUBTOTAL	**4**	**3**	**$117.87**	**$29.47**	**1.33**	**0.00%**
DICLOFENAC PRODUCTS						
CAMBIA POW 50MG	1	1	$861.32	$861.32	1	0.03%
DICLOFENAC SOL 2%	1	1	$1,628.23	$1,628.23	1	0.05%
SUBTOTAL	**2**	**2**	**$2,489.55**	**$1,244.78**	**1**	**0.08%**
SPECIAL PA SUBTOTAL	**33**	**10***	**$31,554.96**	**$956.21**	**3.3**	**1.04%**
TOTAL	**214,853**	**111,805***	**$3,022,195.15**	**$14.07**	**1.92**	**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 2022 = 07/01/2021 to 06/30/2022

[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 06/2023 Last accessed 06/01/2023.

Fiscal Year 2022 Annual Review of Nuedexta® (Dextromethorphan/Quinidine)

Oklahoma Health Care Authority
Fiscal Year 2022 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.

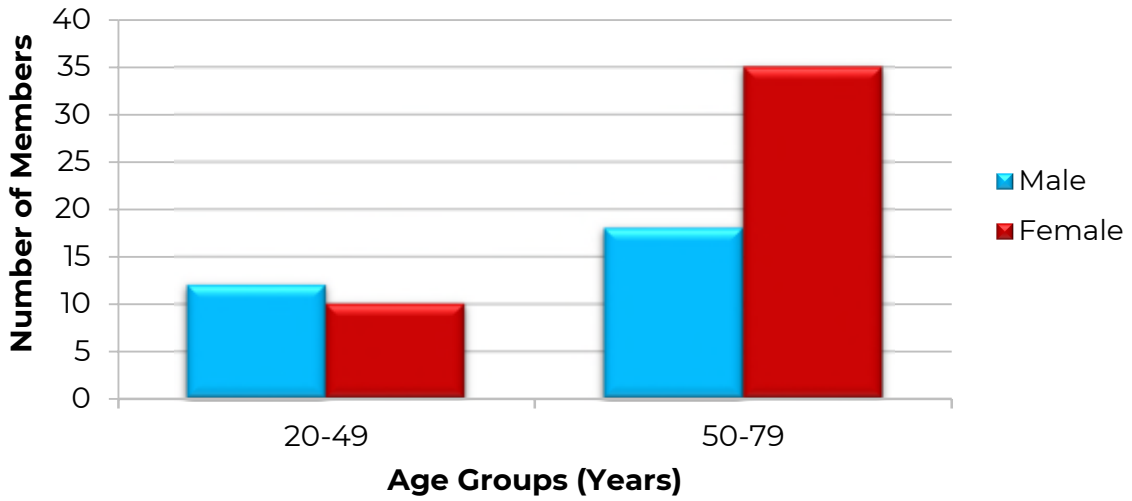
Utilization of Nuedexta® (Dextromethorphan/Quinidine): Fiscal Year 2022

Comparison of Fiscal Years

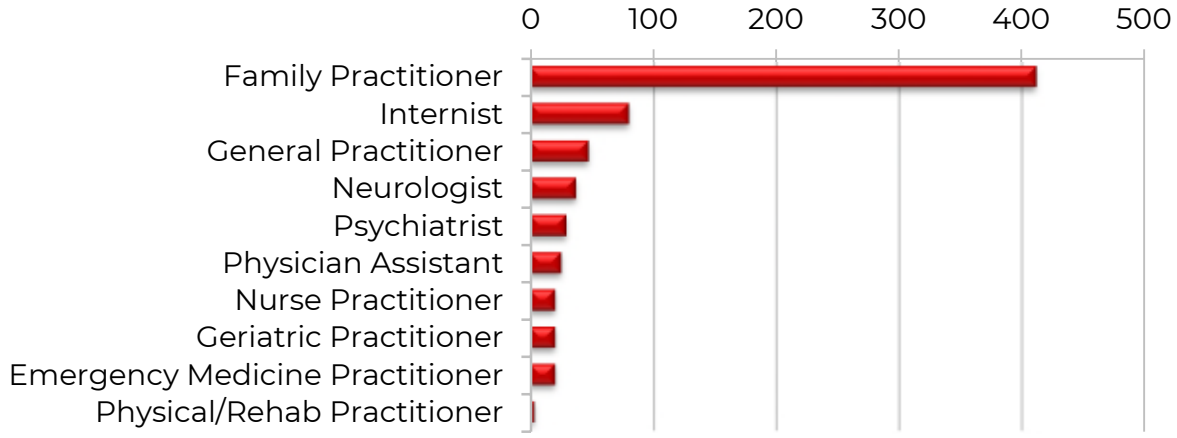
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	85	807	$885,640.07	$1,097.45	$39.57	43,362	22,382
2022	75	683	$756,143.98	$1,107.09	$41.90	34,451	18,046
% Change	**-11.8%**	**-15.4%**	**-14.6%**	**0.9%**	**5.9%**	**-20.6%**	**-19.4%**
Change	**-10**	**-124**	**-$129,496.09**	**$9.64**	**$2.33**	**-8,911**	**-4,336**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021; Fiscal Year 2022 = 07/01/2021 to 06/30/2022

Demographics of Members Utilizing Nuedexta® (Dextromethorphan/Quinidine)



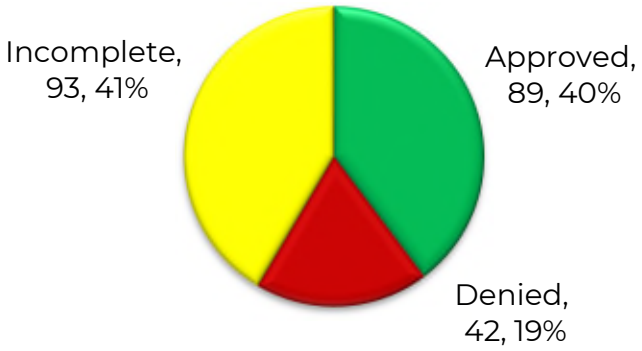
Top Prescriber Specialties of Nuedexta® (Dextromethorphan/Quinidine) by Number of Claims



Prior Authorization of Nuedexta® (Dextromethorphan/Quinidine)

There were 224 prior authorization requests submitted for Nuedexta® (dextromethorphan/quinidine) during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions



Market News and Updates[1]

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 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
NUEDEXTA CAP 20/10MG	683	75	$756,143.98	$1,107.09	9.11
TOTAL	**683**	**75***	**$756,143.98**	**$1,107.09**	**9.11**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule
Fiscal Year 2022 = 07/01/2021 to 06/30/2022

[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 06/2023. Last accessed 06/05/2023.

Fiscal Year 2022 Annual Review of Ophthalmic Allergy Medications

Oklahoma Health Care Authority
Fiscal Year 2022 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.

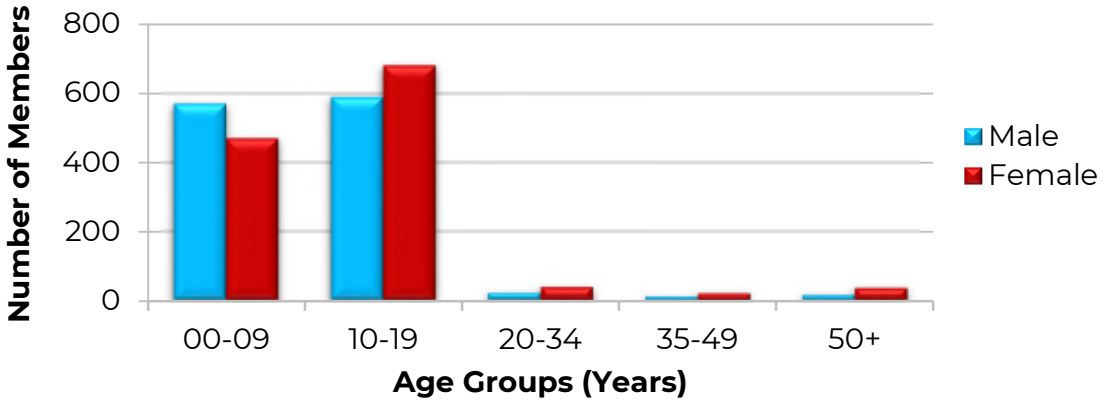
Utilization of Ophthalmic Allergy Medications: Fiscal Year 2022

Comparison of Fiscal Years

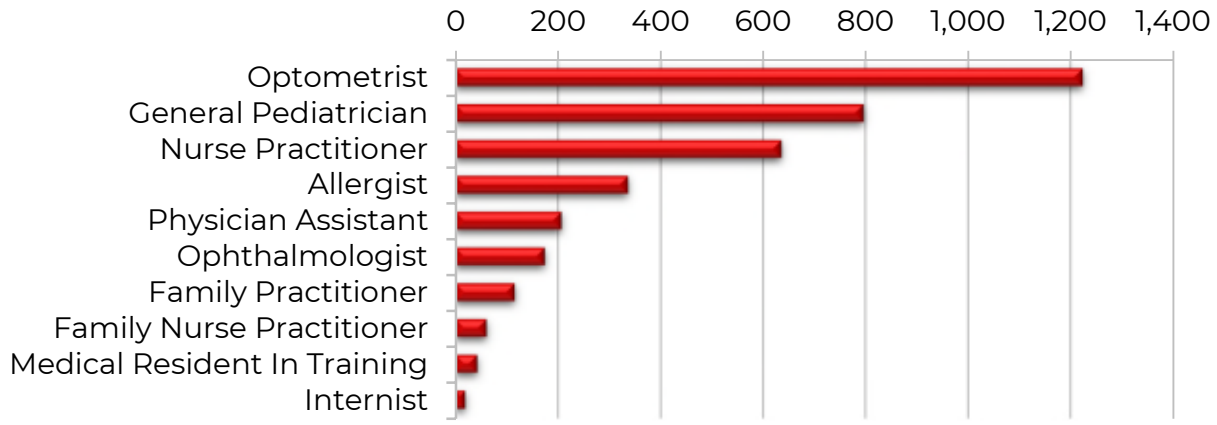
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	2,409	3,585	$60,596.37	$16.90	$0.52	22,737	116,559
2022	2,437	3,390	$53,345.38	$15.74	$0.48	21,511	110,051
% Change	**1.2%**	**-5.4%**	**-12.0%**	**-6.9%**	**-7.7%**	**-5.4%**	**-5.6%**
Change	**28**	**-195**	**-$7,250.99**	**-$1.16**	**-$0.04**	**-1,226**	**-6,508**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021; Fiscal Year 2022 = 07/01/2021 to 06/30/2022

Demographics of Members Utilizing Ophthalmic Allergy Medications



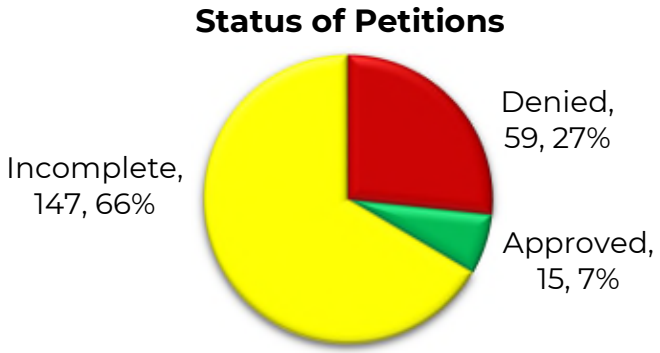
Top Prescriber Specialties of Ophthalmic Allergy Medications by Number of Claims



Prior Authorization of Ophthalmic Allergy Medications

There were 221 prior authorization requests submitted for ophthalmic allergy medications during fiscal year 2022. 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 2022.



Market News and Updates[1,2,3,4]

Anticipated Patent Expiration(s):

- Bepreve® (bepotastine): January 2025
- Pataday® Once Daily Relief (olopatadine 0.7%): May 2032
- Zerviate® (cetirizine): January 2033

Pipeline:

- **Reproxalap:** Reproxalap is a novel, small-molecule reactive aldehyde species (RASP) inhibitor. RASP is elevated in ocular and systemic inflammatory diseases. Reproxalap is being evaluated in Phase 3 studies for the treatment of allergic conjunctivitis and dry eye disease (DED). In February 2023, Aldeyra Therapeutics announced the U.S. Food and Drug Administration (FDA) has accepted a New Drug Application (NDA) for reproxalap for the treatment of the signs and symptoms of DED. In the Phase 3 Tranquility-2 clinical study for the treatment of DED, reproxalap was statistically superior in the 2 primary endpoints, Schirmer test (P=0.0001) and ≥10mm Schirmer test responder proportions (P<0.0001) after a single day of dosing. The Schirmer test is a measure of ocular tear production. The assigned Prescription Drug User Fee Act (PDUFA) date is November 23, 2023. Phase 3 studies of reproxalap for the treatment of allergic conjunctivitis are ongoing.

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 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 PRODUCTS						
KETOTIFEN PRODUCTS						
KETOTIFEN FUM DRO 0.025% OP	2,248	1,732	$35,119.19	$15.62	1.3	65.83%
KETOTIFEN FUM DRO 0.025%	71	51	$1,148.23	$16.17	1.39	2.15%
ALAWAY DRO 0.025% OP	639	390	$9,058.80	$14.18	1.64	16.98%
EYE ITCH RELIEF DRO 0.025% OP	35	31	$602.17	$17.20	1.13	1.13%
ALAWAY CHILD DRO 0.025% OP	30	30	$425.01	$14.17	1	0.80%
SUBTOTAL	**3,023**	**2,234**	**$46,353.40**	**$15.33**	**1.35**	**86.89%**
CROMOLYN PRODUCTS						
CROMOLYN SOD SOL 4% OP	281	207	$4,632.16	$16.48	1.36	8.68%
SUBTOTAL	**281**	**207**	**$4,632.16**	**$16.48**	**1.36**	**8.68%**
TIER-1 SUBTOTAL	**3,304**	**2,441**	**$50,985.56**	**$15.43**	**1.35**	**95.57%**
TIER-2 PRODUCTS						
OLOPATADINE PRODUCTS						
OLOPATADINE DRO 0.1%	55	16	$1,225.15	$22.28	3.44	2.30%
PATADAY SOL 0.7%	1	1	$15.03	$15.03	1	0.03%
SUBTOTAL	**56**	**17**	**$1,240.18**	**$22.15**	**3.29**	**2.33%**
EPINASTINE PRODUCTS						
EPINASTINE DRO 0.05%	16	4	$877.46	$54.84	4	1.64%
SUBTOTAL	**16**	**4**	**$877.46**	**$54.84**	**4**	**1.64%**
AZELASTINE PRODUCTS						
AZELASTINE DRO 0.05%	14	7	$242.18	$17.30	2	0.45%
SUBTOTAL	**14**	**7**	**$242.18**	**$17.30**	**2**	**0.45%**
TIER-2 SUBTOTAL	**86**	**28**	**$2,359.82**	**$27.44**	**3.07**	**4.42%**
TOTAL	**3,390**	**2,437***	**$53,345.38**	**$15.74**	**1.39**	**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 2022 = 07/01/2021 to 06/30/2022

[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 06/2023. Last accessed 06/09/2023.
[2] Eyewire. FDA Accepts NDA for Aldeyra's Reproxalap for the Treatment of Dry Eye Disease. Available online at: https://eyewire.news/news/fda-accepts-nda-for-aldeyras-reproxalap-for-the-treatment-of-dry-eye-disease?c4src=article:infinite-scroll. Issued 02/07/2023. Last accessed 06/09/2023.
[3] Aldeyra Therapeutics, Inc. Aldeyra Pipeline. Available online at: https://www.aldeyra.com/pipeline-disease-areas/. Last accessed 06/09/2023.
[4] Aldeyra Therapeutics, Inc. Aldeyra Therapeutics Achieves Primary Endpoint in Phase 3 TRANQUILITY-2 Trial in Dry Eye Disease and Intends to Submit New Drug Application for Symptoms and Three Sign Endpoints of Dry Eye Disease. Available online at: https://ir.aldeyra.com/news-releases/news-release-details/aldeyra-therapeutics-achieves-primary-endpoint-phase-3. Issued 06/08/2022. Last accessed 06/09/2023.

Fiscal Year 2022 Annual Review of Phenylketonuria Medications

Oklahoma Health Care Authority
Fiscal Year 2022 Print Report

Current Prior Authorization Criteria

Kuvan® (Sapropterin) Approval Criteria:

1. An FDA approved diagnosis of phenylketonuria; and
2. Documentation of active management with a phenylalanine restricted diet; and
3. Member must not have 2 null mutations in *trans*; and
4. Baseline phenylalanine concentration must be documented on the prior authorization request and must be drawn within the last 30 days; and
5. Concomitant use with Palynziq® (pegvaliase-pqpz) will not be approved; and
6. Initial approvals will be for the duration of 30 days. After which time, the prescriber must verify that the member responded to treatment as defined by laboratory documentation of ≥30% decrease in blood phenylalanine levels from baseline.
    a. If the member was initiated at 10mg/kg/day dose, then a subsequent trial of 20mg/kg/day for a duration of 30 days can be approved, after which time the prescriber must verify the member responded to treatment as defined by laboratory documentation of ≥30% decrease in blood phenylalanine levels from baseline; or
    b. If the member was initiated at 20mg/kg/day dose, then no additional approvals will be granted after a trial period of 30 days if the member did not respond to treatment as defined by laboratory documentation of ≥30% decrease in blood phenylalanine levels from baseline; and
7. Subsequent approvals will be for the duration of 1 year; and
8. Reauthorization will require the following:
    a. Documentation of active management with a phenylalanine restricted diet; and
    b. Verification from the prescriber of continued response to therapy.

Palynziq® (Pegvaliase-pqpz) Approval Criteria:

1. An FDA approved indication to reduce blood phenylalanine concentrations in members with phenylketonuria who have uncontrolled blood phenylalanine concentrations >600µmol/L on existing management; and

2. Documentation of active management with a phenylalanine restricted diet; and
3. Baseline phenylalanine concentration must be documented on the prior authorization request and must be drawn within the last 30 days; and
4. Documentation the member's average blood phenylalanine concentration over the last 6 months is >600µmol/L on existing management; and
5. Concomitant use with Kuvan® (sapropterin) will not be approved; and
6. Prescriber, pharmacy, and member must be enrolled in the Palynziq® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
7. Initial dose must be administered under the supervision of a health care provider equipped to manage anaphylaxis and observe the member for at least 60 minutes following injection; and
8. Member must be prescribed auto-injectable epinephrine and be counseled on its appropriate use; and
9. Initial approvals will be for the duration of 33 weeks to allow for initial titration and for 24 weeks of maintenance treatment with 20mg once daily dosing. Members should then be assessed for a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration ≤600µmol/L.
    a. If member has not achieved a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration ≤600µmol/L, approvals may be granted for the 40mg once daily dosing for a duration of 16 weeks; or
    b. If member has achieved a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration ≤600µmol/L, subsequent approvals will be for the duration of 1 year; and
10. Members who do not achieve at least a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration ≤600µmol/L after 16 weeks of continuous treatment with the maximum dosage of 40mg once daily will not be approved for subsequent approvals; and
11. Subsequent approvals will be for the duration of 1 year; and
12. Reauthorization will require the following:
    a. Documentation of active management with a phenylalanine restricted diet; and
    b. Verification from the prescriber of continued response to therapy.

Utilization of Phenylketonuria Medications: Fiscal Year 2022

Comparison of Fiscal Years

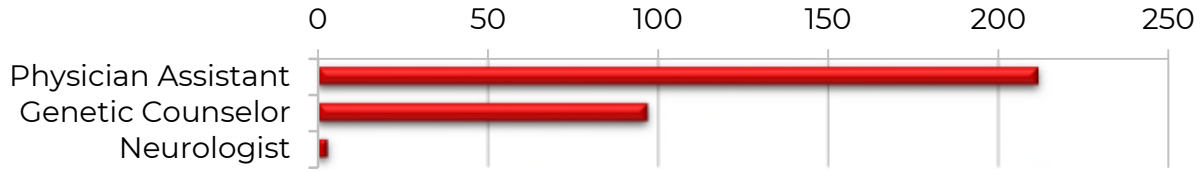
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	29	283	$2,815,183.08	$9,947.64	$333.12	56,535	8,451
2022	33	312	$3,176,293.30	$10,180.43	$340.84	63,921	9,319
% Change	**13.80%**	**10.20%**	**12.80%**	**2.30%**	**2.30%**	**13.10%**	**10.30%**
Change	**4**	**29**	**$361,110.22**	**$232.79**	**$7.72**	**7,386**	**868**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021; Fiscal Year 2022 = 07/01/2021 to 06/30/2022

Demographics of Members Utilizing Phenylketonuria Medications

- Due to the limited number of members utilizing phenylketonuria medications during fiscal year 2022, detailed demographic information could not be provided.

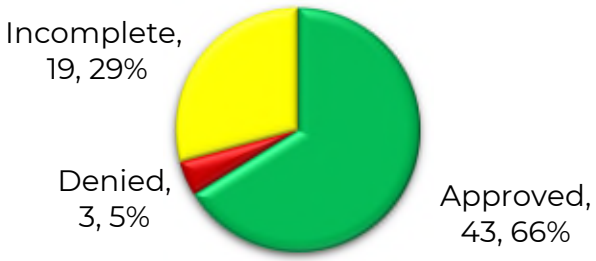
Top Prescriber Specialties of Phenylketonuria Medications by Number of Claims



Prior Authorization of Phenylketonuria Medications

There were 65 prior authorization requests submitted for phenylketonuria medications during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions



Market News and Updates[1,2]

Anticipated Patent Expiration(s):

- Kuvan® tablets (sapropterin): May 2026

- Kuvan® powder (sapropterin): May 2033

Pipeline:

- **Sepiapterin:** Sepiapterin is an oral formulation of synthetic sepiapterin. Sepiapterin is a precursor to intracellular tetrahydrobiopterin, which is an enzyme cofactor used in the degradation of phenylalanine. In May 2023, the results from the APHENITY, Phase 3 clinical trial were announced. Participants in the APHENITY trial were randomized to receive sepiapterin or placebo for 6 weeks with the primary endpoint being a reduction in blood phenylalanine levels. The APHENITY trial achieved its primary endpoint with a statistically significant (P<0.0001) reduction of 63% in mean blood phenylalanine levels.

Recommendations

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

Utilization Details of Phenylketonuria Medications: Fiscal Year 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
SAPROPTERIN PRODUCTS						
KUVAN TAB 100MG	139	16	$2,231,785.99	$535.20	$16,056.01	70.26%
KUVAN POW 100MG	93	11	$298,725.69	$107.07	$3,212.10	9.40%
KUVAN POW 500MG	48	6	$384,839.68	$267.25	$8,017.49	12.12%
SAPROPTERIN POW 100MG	12	1	$22,693.24	$63.04	$1,891.10	0.71%
SAPROPTERIN POW 500MG	1	1	$19,351.41	$645.05	$19,351.41	0.61%
SUBTOTAL	**293**	**35**	**$2,957,396.01**	**$336.45**	**$10,093.50**	**93.11%**
PEGVALIASE-PQPZ PRODUCTS						
PALYNZIQ INJ 10MG/0.5ML	15	3	$182,773.65	$421.14	$12,184.91	5.75%
PALYNZIQ INJ 2.5MG/0.5ML	2	2	$3,329.82	$95.14	$1,664.91	0.10%
PALYNZIQ INJ 20MG/ML	2	2	$32,793.82	$546.56	$16,396.91	1.03%
SUBTOTAL	**19**	**7**	**$218,897.29**	**$413.79**	**$11,520.91**	**6.89%**
TOTAL	**312**	**33***	**$3,176,293.30**	**$340.84**	**$10,180.43**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
INJ = injection; POW = powder; TAB = tablet
Fiscal Year 2022 = 07/01/2021 to 06/30/2022

[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 06/2023. Last accessed 06/09/2023.
[2] PTC Therapeutics, Inc. PTC Therapeutics Announces APHENITY Trial Achieved Primary Endpoint with Sepiapterin in PKU Patients. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/ptc-therapeutics-announces-aphenity-trial-achieved-primary-endpoint-with-sepiapterin-in-pku-patients-301827138.html. Issued 05/17/2023. Last accessed 06/09/2023.

Fiscal Year 2022 Annual Review of Phosphate Binders

Oklahoma Health Care Authority
Fiscal Year 2022 Print Report

Current Prior Authorization Criteria

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

Auryxia® (Ferric Citrate) Approval Criteria:

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

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

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

4. For the approval of Fosrenol® 1,000mg chewable tablets, a patient-specific, clinically significant reason why the member cannot use a phosphate binder available without a prior authorization, such as brand Fosrenol® 500mg or 750mg chewable tablets, must be provided; and
5. Fosrenol® 500mg or 750mg chewable tablets are brand preferred. Authorization of the generic formulation requires a patient-specific, clinically significant reason why the member cannot use the brand formulation.

Velphoro® (Sucroferric Oxyhydroxide) Approval Criteria:

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

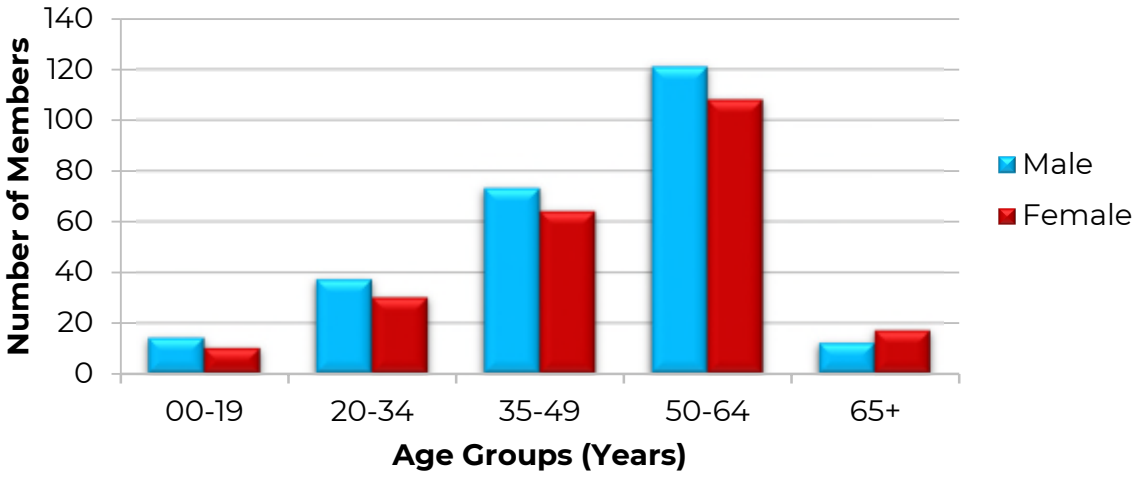
Utilization of Phosphate Binders: Fiscal Year 2022

Comparison of Fiscal Years

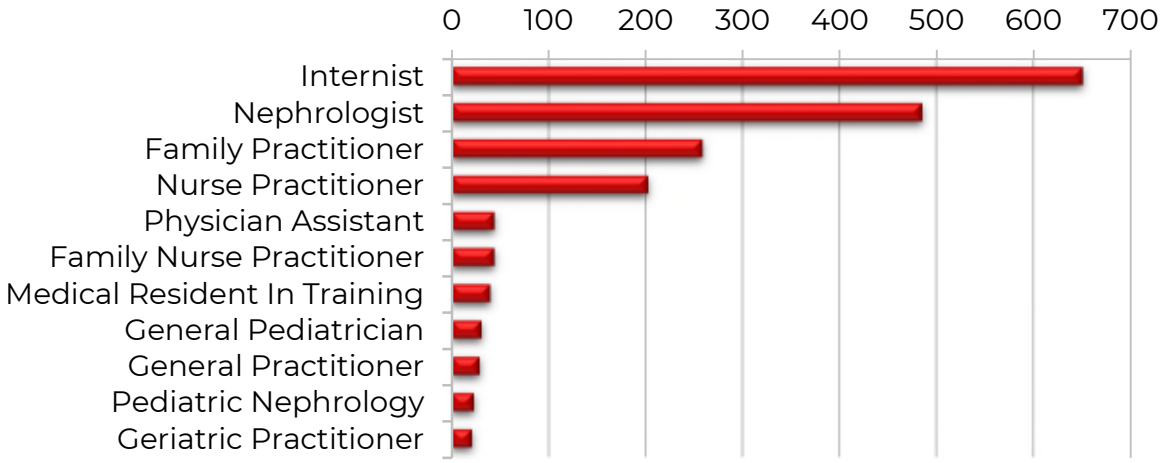
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	370	1,662	$653,557.31	$393.24	$13.43	354,078	48,658
2022	486	1,873	$725,620.14	$387.41	$13.34	366,422	54,380
% Change	**31.4%**	**12.7%**	**11.0%**	**-1.5%**	**-0.7%**	**3.5%**	**11.8%**
Change	**116**	**211**	**$72,062.83**	**-$5.83**	**-$0.09**	**12,344**	**5,722**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021; Fiscal Year 2022 = 07/01/2021 to 06/30/2022

Demographics of Members Utilizing Phosphate Binders



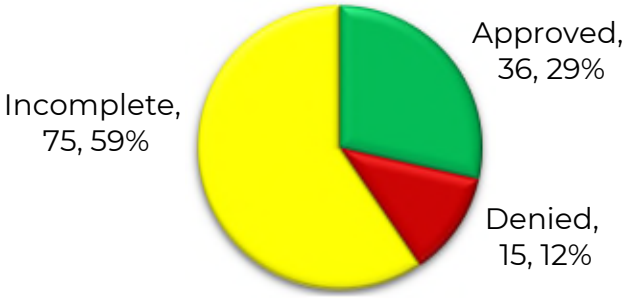
Top Prescriber Specialties of Phosphate Binders by Number of Claims



Prior Authorization of Phosphate Binders

There were 126 prior authorization requests submitted for phosphate binders during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions



Market News and Updates[1,2,3,4]

Anticipated Patent Expiration(s):

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

Pipeline:

- **Xphozah® (Tenapanor):** In December 2022, Ardelyx announced that the U.S. Food and Drug Administration (FDA) has granted their appeal to the Complete Response Letter (CRL) they previously received for the

New Drug Application (NDA) for Xphozah®. In May 2023, Ardelyx announced the FDA has accepted its new NDA submission with a 6-month review period. Xphozah® is being evaluated for the control of serum phosphate in adult patients with chronic kidney disease on dialysis who have had an inadequate response or intolerance to a phosphate binder therapy. The Prescription Drug User Fee Act (PDUFA) target date is October 17, 2023. If approved by the FDA, Ardelyx plans to make Xphozah® commercially available in the fourth quarter of 2023. Ardelyx markets another tenapanor product, Ibsrela®, which is FDA approved for the treatment of irritable bowel syndrome with constipation (IBS-C) in adults.

Recommendations

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

Utilization Details of Phosphate Binders: Fiscal Year 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
SEVELAMER CARBONATE PRODUCTS					
SEVELAMER CARB TAB 800MG	938	284	$64,354.38	3.3	$68.61
SEVELAMER POW 0.8GM	43	15	$23,299.11	2.87	$541.84
SEVELAMER POW 2.4GM	35	12	$31,058.59	2.92	$887.39
SUBTOTAL	**1,016**	**311**	**$118,712.08**	**3.27**	**$116.84**
CALCIUM ACETATE PRODUCTS					
CALCIUM ACETATE CAP 667MG	531	183	$31,031.76	2.9	$58.44
CALCIUM ACETATE TAB 667MG	35	19	$1,959.49	1.84	$55.99
PHOSLYRA SOL 667MG/5ML	13	3	$1,920.28	4.33	$147.71
SUBTOTAL	**579**	**205**	**$34,911.53**	**2.82**	**$60.30**
SUCROFERRIC OXYHYDROXIDE PRODUCTS					
VELPHORO CHW 500MG	127	24	$331,219.52	5.29	$2,608.03
SUBTOTAL	**127**	**24**	**$331,219.52**	**5.29**	**$2,608.03**
LANTHANUM CARBONATE PRODUCTS					
FOSRENOL CHW 750MG	48	7	$75,714.76	6.86	$1,577.39
FOSRENOL CHW 500MG	37	9	$72,707.65	4.11	$1,965.07
LANTHANUM CHW 500MG	12	2	$28,687.53	6	$2,390.63
FOSRENOL POW 750MG	3	2	$9,752.81	1.5	$3,250.94
LANTHANUM CHW 750MG	2	1	$1,668.82	2	$834.41
SUBTOTAL	**102**	**21**	**$188,531.57**	**4.86**	**$1,848.35**
SEVELAMER HYDROCHLORIDE PRODUCTS					
SEVELAMER HCL TAB 800MG	27	15	$23,754.59	1.8	$879.80
SUBTOTAL	**27**	**15**	**$23,754.59**	**1.8**	**$879.80**
FERRIC CITRATE PRODUCTS					
AURYXIA TAB 210MG	22	7	$28,490.85	3.14	$1,295.04

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
SUBTOTAL	**22**	**7**	**$28,490.85**	**3.14**	**$1,295.04**
TOTAL	**1,873**	**486***	**$725,620.14**	**3.85**	**$387.41**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; CARB = carbonate; CHW = chewable; HCL = hydrochloride; POW = powder; SOL = solution; TAB = tablet
Fiscal Year 2022 = 07/01/2021 to 06/30/2022

[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 06/2023. Last accessed 06/01/2023.
[2] Ardelyx, Inc. FDA Grants Appeal for Ardelyx's Xphozah® (Tenapanor). *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/fda-grants-appeal-for-ardelyxs-xphozah-tenapanor-301710866.html. Issued 12/29/2022. Last accessed 06/01/2023.
[3] Ardelyx, Inc. Ardelyx Announces FDA Acceptance and Six-Month Review for Resubmission of its New Drug Application of Xphozah® (Tenapanor). Available online at: https://ir.ardelyx.com/news-releases/news-release-details/ardelyx-announces-fda-acceptance-and-six-month-review. Issued 05/17/2023. Last accessed 06/07/2023.
[4] Ibsrela® (Tenapanor) Prescribing Information. Ardelyx, Inc. Available online at: https://ardelyx.com/wp-content/uploads/2021/11/IBSRELA-Prescribing-Information-1.pdf. Last revised 04/2022. Last accessed 06/01/2023.

Fiscal Year 2022 Annual Review of Qutenza® (Capsaicin 8% Patch)

Oklahoma Health Care Authority
Fiscal Year 2022 Print Report

Current Prior Authorization Criteria

Qutenza® (Capsaicin 8% Patch) Approval Criteria:

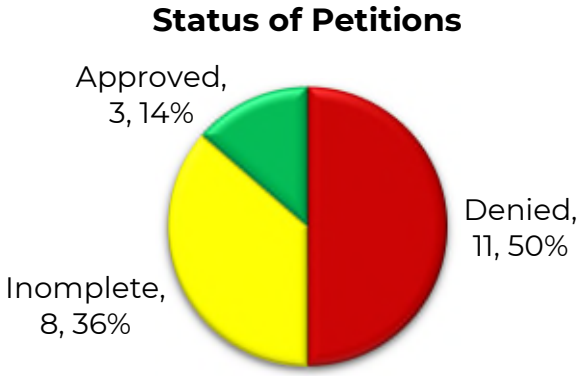
1. An FDA approved diagnosis of postherpetic neuralgia or diabetic peripheral neuropathy of the feet; and
2. Documented treatment attempts at recommended dosing or contraindication(s) to at least 1 agent from each of the following drug classes:
    a. For postherpetic neuralgia:
        i. Tricyclic 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 2022

There was no SoonerCare utilization of Qutenza® (capsaicin 8% patch) during fiscal year 2022 (07/01/2021 to 06/30/2022).

Prior Authorization of Qutenza® (Capsaicin 8% Patch)

There were 22 prior authorization requests submitted for Qutenza® (capsaicin 8% patch) for 13 unique members during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.



Market News and Updates[1]

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.

[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 06/2023. Last accessed 06/01/2023.

Fiscal Year 2022 Annual Review of Smoking Cessation Products

Oklahoma Health Care Authority
Fiscal Year 2022 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.

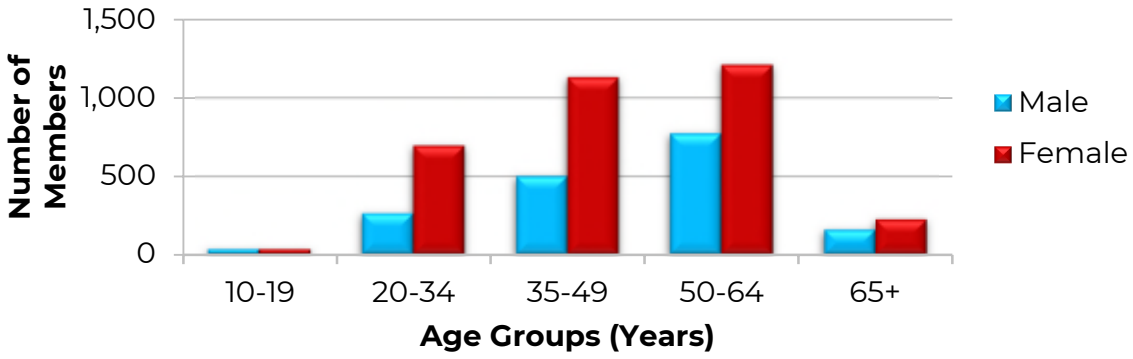
Utilization of Smoking Cessation Products: Fiscal Year 2022

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	4,403	8,942	$2,069,747.30	$231.46	$9.33	460,397	221,879
2022	5,010	9,704	$1,229,212.18	$126.67	$5.43	461,226	226,737
% Change	**13.80%**	**8.50%**	**-40.60%**	**-45.30%**	**-41.80%**	**0.2%**	**2.10%**
Change	**607**	**762**	**-$840,535.12**	**-$104.79**	**-$3.90**	**829**	**4,558**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2021= 07/01/2020 to 06/30/2021; Fiscal Year 2022 = 07/01/2021 to 06/30/2022

Demographics of Members Utilizing Smoking Cessation Products

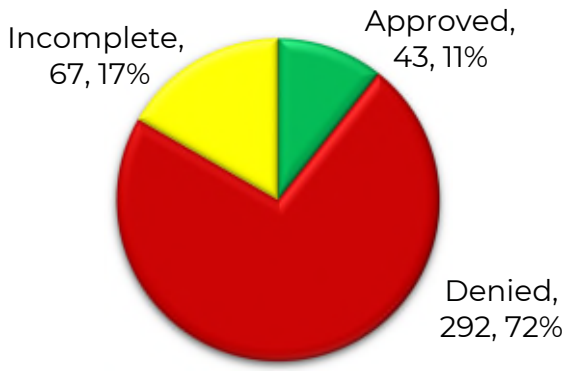


Top Prescriber Specialties of Smoking Cessation Products by Number of Claims

Prior Authorization of Smoking Cessation Products

There were 402 prior authorization requests submitted for smoking cessation products during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions



Market News and Updates[1,2]

News:

- **February 2023:** A study published in the *Journal of the American Medical Association (JAMA) Network Open*, looked at the association of the Chantix® (varenicline tartrate) recall with United States prescribing of varenicline and other medications used for nicotine dependence. In 2021, Pfizer voluntarily stopped production of Chantix® and eventually recalled all lots of Chantix® due to elevated levels of nitrosamine. This recall created a shortage of effective treatment options for nicotine dependence. To help alleviate the shortage, the U.S. Food and Drug Administration (FDA) allowed the United States distribution of the

Canadian generic Apo-varenicline, and the FDA approved the first generic varenicline in September 2021. The study looked at pharmacy claims from January 1, 2021 to June 30, 2022 using a national pharmacy benefit database. The search included patients with commercial insurance and a prescription for a medication to treat nicotine dependence. The study showed a 74.7% absolute reduction (P<0.001) in varenicline use by September 2021 when compared to the pre-washout period. In October 2021, there was a significant increase in varenicline use; however, by June 2022, the use of varenicline was still lower than in June 2021. There was no significant change in the use of sustained-release bupropion or nicotine replacement therapy (NRT) throughout the study period. The authors noted that the continued decrease in pharmacy claims through June 2022 was not due to a lack of drug being available, but more likely a lack of clinician and patient awareness regarding availability of varenicline after the recall and the concern over nitrosamine levels.

Pipeline:

- **Cytisinicline:** In May 2023, the results of the Phase 3 ORCA-3 trial of cystisinicline for smoking cessation were announced. Cytisinicline is a plant-based alkaloid with a high affinity to nicotinic acetylcholine receptors, which is thought to help treat nicotine addiction. The trial met both its primary and secondary endpoints for both the 6- and 12-week cystisinicline treatment durations. Both groups demonstrated statically significant smoking cessation when compared to placebo.

Recommendations

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

Utilization Details of Smoking Cessation Products: Fiscal Year 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
VARENICLINE PRODUCTS						
VARENICLINE TAB 1MG	1,427	816	$491,041.21	$344.11	1.75	39.95%
VARENICLINE TAB 0.5MG	481	403	$100,103.22	$208.11	1.19	8.14%
CHANTIX PAK 0.5MG & 1MG	124	123	$53,780.21	$433.71	1.01	4.38%
CHANTIX PAK 1MG	93	76	$40,116.96	$431.37	1.22	3.26%
VARENICLINE TAB 0.5MG & 1MG	82	82	$30,502.80	$371.99	1	2.48%
CHANTIX TAB 1MG	73	64	$29,395.30	$402.68	1.14	2.39%
APO-VARENICLINE TAB 1MG	52	31	$21,377.96	$411.11	1.68	1.74%
CHANTIX TAB 0.5MG	29	26	$9,735.43	$335.70	1.12	0.79%
APO-VARENICLINE TAB 0.5MG	3	3	$1,570.28	$523.43	1	0.13%
SUBTOTAL	**2,364**	**1,258***	**$777,623.37**	**$328.94**	**1.88**	**63.26%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
NICOTINE REPLACEMENT PRODUCTS						
NICOTINE TD DIS 21MG/24H	2,585	1,796	$129,807.30	$50.22	1.44	10.56%
NICOTINE TD DIS 14MG/24H	1,583	1,066	$77,095.86	$48.70	1.48	6.27%
NICOTINE TD DIS 7MG/24HR	670	470	$30,752.03	$45.90	1.43	2.50%
NICOTINE POL LOZ 4MG MINT	337	101	$14,546.35	$43.16	3.34	1.18%
NICOTROL INH 10MG	165	127	$78,019.01	$472.84	1.3	6.35%
NICOTINE POL GUM 4MG	143	65	$5,499.03	$38.45	2.2	0.45%
GNP NICOTINE DIS 21MG/24H	115	87	$5,752.27	$50.02	1.32	0.47%
SM NICOTINE DIS 21MG/24H	114	101	$6,003.98	$52.67	1.13	0.49%
NICOTINE POL GUM 4MG ORIG	104	52	$4,909.43	$47.21	2	0.40%
HM NICOTINE DIS 21MG/24H	97	79	$4,906.03	$50.58	1.23	0.40%
NICOTINE POL GUM 4MG MINT	95	33	$3,850.41	$40.53	2.88	0.31%
NICOTINE POL LOZ 2MG MINT	70	24	$3,255.97	$46.54	2.92	0.26%
SM NICOTINE DIS 14MG/24H	67	60	$3,368.11	$50.27	1.12	0.27%
HM NICOTINE DIS 14MG/24H	66	59	$3,417.73	$51.78	1.12	0.28%
NICOTINE POL GUM 2MG	58	44	$2,262.16	$39.00	1.32	0.18%
NICOTINE POL GUM 2MG CINN	52	30	$2,223.97	$42.77	1.73	0.18%
NICOTINE TD DIS STEP 1	49	32	$2,554.54	$52.13	1.53	0.21%
NICOTINE LOZ 4MG MINT	46	24	$2,957.19	$64.29	1.92	0.24%
SM NICOTINE LOZ 4MG MINT	43	18	$2,537.53	$59.01	2.39	0.21%
SM NICOTINE DIS 7MG/24HR	41	37	$1,807.37	$44.08	1.11	0.15%
NICOTINE LOZ 2MG MINT	39	23	$2,321.67	$59.53	1.7	0.19%
NICOTINE POL GUM 2MG MINT	37	22	$2,627.32	$71.01	1.68	0.21%
GNP NICOTINE DIS 14MG/24H	30	24	$1,437.58	$47.92	1.25	0.12%
HM NICOTINE LOZ 2MG MINT	28	9	$1,113.74	$39.78	3.11	0.09%
NICOTROL NS SPR 10MG/ML	27	10	$33,229.61	$1,230.73	2.7	2.70%
HM NICOTINE LOZ 4MG MINT	25	11	$2,292.38	$91.70	2.27	0.19%
SM NICOTINE GUM 2MG MINT	22	12	$786.48	$35.75	1.83	0.06%
GNP NICOTINE LOZ 4MG MINT	21	9	$1,034.88	$49.28	2.33	0.08%
SM NICOTINE GUM 4MG MINT	20	20	$1,008.28	$50.41	1	0.08%
HM NICOTINE GUM 4MG MINT	17	13	$762.04	$44.83	1.31	0.06%
NICOTINE TD DIS STEP 3	14	8	$718.30	$51.31	1.75	0.06%
NICOTINE POL GUM 2MG ORIG	14	12	$457.22	$32.66	1.17	0.06%
HM NICOTINE DIS 7MG/24HR	14	13	$602.26	$43.02	1.08	0.04%
SM NICOTINE GUM 4MG	14	14	$716.02	$51.14	1	0.05%
HM NICOTINE GUM 2MG MINT	12	9	$459.38	$38.28	1.33	0.04%
NICOTINE POL GUM 4MG CINN	12	8	$413.79	$34.48	1.5	0.03%
SM NICOTINE LOZ 2MG CINN	11	1	$1,178.09	$107.10	11	0.10%
SM NICOTINE GUM 2MG	10	6	$326.96	$32.70	1.67	0.03%
GNP NICOTINE GUM 4MG MINT	9	6	$301.84	$33.54	1.5	0.02%
GNP NICOTINE LOZ MINI 2MG	9	8	$606.19	$67.35	1.13	0.05%
GNP NICOTINE DIS 7MG/24HR	8	7	$402.67	$50.33	1.14	0.02%
GNP NICOTINE GUM 2MG MINT	8	7	$258.39	$32.30	1.14	0.03%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SM NICOTINE LOZ 2MG CHRY	6	5	$277.89	$46.32	1.2	0.02%
NICOTINE POL GUM 2MG FRUIT	5	5	$326.22	$65.24	1	0.03%
NICOTINE POL GUM 4MG FRUIT	4	4	$97.32	$24.33	1	0.01%
SM NICOTINE LOZ 2MG MINT	4	4	$137.62	$34.41	1	0.01%
SM NICOTINE LOZ 4MG CINN	3	3	$181.52	$60.51	1	0.01%
HM NICOTINE GUM 2MG	3	3	$145.25	$48.42	1	0.01%
NICOTINE SYS KIT TD	2	2	$150.75	$75.38	1	0.03%
NICOTINE LOZ MINI 2MG	2	2	$364.91	$182.46	1	0.01%
GNP NICOTINE GUM 4MG ORIG	1	1	$34.64	$34.64	1	0.00%
HM NICOTINE GUM 4MG FRUIT	1	1	$36.89	$36.89	1	0.00%
NICOTINE GUM 4MG	1	1	$15.40	$15.40	1	0.00%
NICOTINE GUM 2MG	1	1	$21.73	$21.73	1	0.00%
GNP NICOTINE GUM 2MG ORIG	1	1	$24.05	$24.05	1	0.00%
SUBTOTAL	**6,935**	**3,669***	**$440,395.55**	**$63.50**	**1.89**	**35.83%**
BUPROPION PRODUCTS						
BUPROPION TAB 150MG SR	405	208	$11,193.26	$27.64	1.95	0.91%
SUBTOTAL	**405**	**208***	**$11,193.26**	**$27.64**	**1.95**	**0.91%**
TOTAL	**9,704**	**5,010***	**$1,229,212.18**	**$126.67**	**1.94**	**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; POL = polacrilex; NS = nasal spray; ORIG = original; SM = Sunmark®; SPR = spray; SR = sustained release; SYS = system; TAB = tablet; TD = transdermal
Fiscal Year 2022 = 07/01/2021 to 06/30/2022

[1] Lang A, Patel U, Fitzpatrick J, et al. Association of the Chantix Recall with US Prescribing of Varenicline and Other Medications for Nicotine Dependence. *JAMA Netw Open* 2023; 6(2):e2254655. doi:10.1001/jamanetworkopen.2022.54655.
[2] Achieve Life Sciences, Inc. Achieve Life Sciences Reports Statistically Significant Smoking Cessation Benefit for Cytisinicline in Second, Confirmatory Phase 3 Clinical Trial. *GlobeNewswire*. Available online at: https://www.globenewswire.com/news-release/2023/05/23/2674061/0/en/Achieve-Life-Sciences-Reports-Statistically-Significant-Smoking-Cessation-Benefit-for-Cytisinicline-in-Second-Confirmatory-Phase-3-Clinical-Trial.html. Issued 05/03/2023. Last accessed 06/09/2023.

Fiscal Year 2022 Annual Review of Sylvant® (Siltuximab)

Oklahoma Health Care Authority
Fiscal Year 2022 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 2022

There was no SoonerCare utilization, including pharmacy and medical claims, of Sylvant® (siltuximab) during fiscal year 2022 (07/01/2021 to 06/30/2022).

Prior Authorization of Sylvant® (Siltuximab)

There were no prior authorization requests submitted for Sylvant® (siltuximab) during fiscal year 2022.

Market News and Updates[1]

Pipeline:

- **Sirolimus:** A Phase 2, single-arm, open-label, multi-center study of sirolimus in previously treated idiopathic Multicentric Castleman's Disease (iMCD) is currently being conducted. The study is evaluating the use of sirolimus for iMCD patients who are either unable to tolerate interleukin-6 (IL-6) blockade therapy (siltuximab or tocilizumab), or who fail, relapse, or are refractory to such treatment. The estimated study enrollment is 24 male or female adults 18 to 80 years of age. Patients

will receive daily oral sirolimus (loading dose of 5mg/m^2 on day 1 and 2.5mg/m^2/day starting on day 2) for 12 months. The primary outcome measure is the proportion of patients achieving a positive clinical benefit response after 12 months. The study is estimated to be completed in December 2023.

Recommendations

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

[1] Sirolimus in Previously Treated Idiopathic Multicentric Castleman Disease. *Clinicaltrials.gov*. Available online at: https://clinicaltrials.gov/ct2/show/study/NCT03933904. Last revised 01/09/2023. Last accessed 06/16/2023.

Fiscal Year 2022 Annual Review of Topical Antibiotic Products

Oklahoma Health Care Authority
Fiscal Year 2022 Print Report

Current Prior Authorization Criteria

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

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

Topical Antibiotic Products Tier-2 Approval Criteria:

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

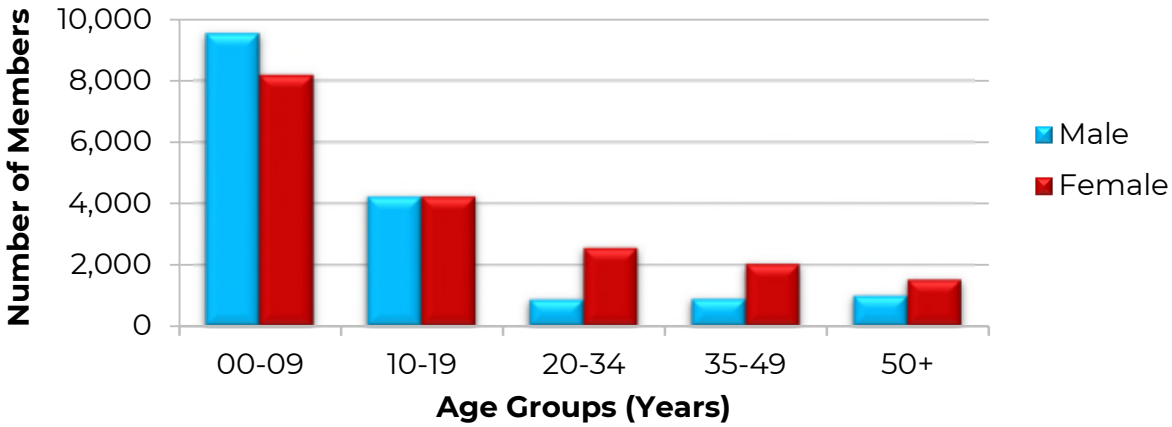
Utilization of Topical Antibiotic Products: Fiscal Year 2022

Comparison of Fiscal Years

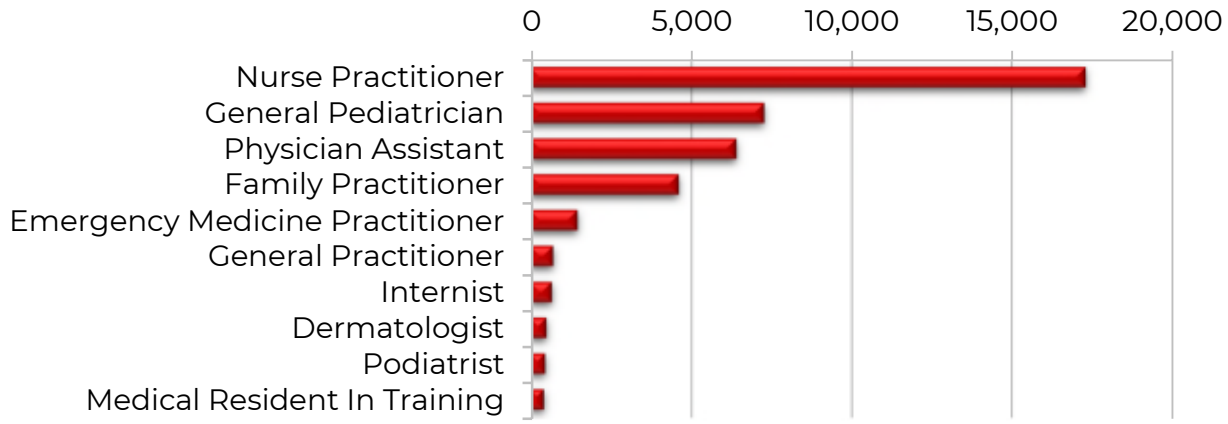
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	29,072	34,546	$562,037.72	$16.27	$1.46	944,265	384,459
2022	34,930	41,070	$674,205.90	$16.42	$1.45	1,125,756	464,513
% Change	**20.1%**	**18.9%**	**20.0%**	**0.9%**	**-0.7%**	**19.2%**	**20.8%**
Change	**5,858**	**6,524**	**$112,168.18**	**$0.15**	**-$0.01**	**181,491**	**80,054**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021; Fiscal Year 2022 = 07/01/2021 to 06/30/2022

Demographics of Members Utilizing Topical Antibiotic Products



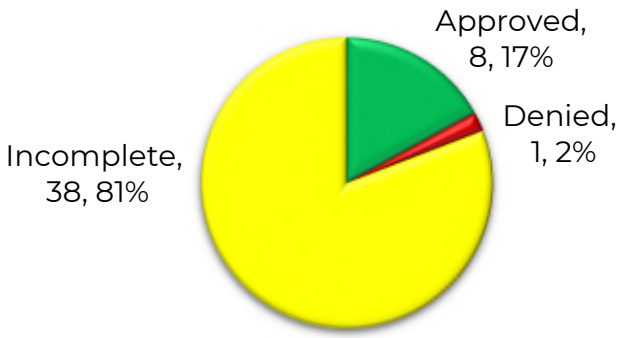
Top Prescriber Specialties of Topical Antibiotic Products by Number of Claims



Prior Authorization of Topical Antibiotic Products

There were 47 prior authorization requests submitted for topical antibiotic products during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions



Market News and Updates[1]

Anticipated Patent Expiration(s):

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

Recommendations

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

Utilization Details of Topical Antibiotic Products: Fiscal Year 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
TIER-1 PRODUCTS					
MUPIROCIN OIN 2%	40,464	34,667	$630,152.79	1.17	$15.57
GENTAMICIN OIN 0.1%	415	224	$32,494.82	1.85	$78.30
GENTAMICIN CRE 0.1%	172	107	$8,615.74	1.61	$50.09
TIER-1 SUBTOTAL	**41,051**	**34,998**	**$671,263.35**	**1.17**	**$16.35**
TIER-2 PRODUCTS					
MUPIROCIN CRE 2%	18	12	$2,925.79	1.5	$162.54
CENTANY OIN 2%	1	1	$16.76	1	$16.76
TIER-2 SUBTOTAL	**19**	**13**	**$2,942.55**	**1.46**	**$154.87**
TOTAL	**41,070**	**34,930***	**$674,205.90**	**1.18**	**$16.42**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CRE = cream; OIN = ointment
Fiscal Year 2022 = 07/01/2021 to 06/30/2022

[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 06/2023. Last accessed 06/05/2023.

Fiscal Year 2022 Annual Review of Topical Antifungal Products

Oklahoma Health Care Authority
Fiscal Year 2022 Print Report

Current Prior Authorization Criteria

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

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

Topical Antifungal Products Tier-2 Approval Criteria:

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

3. Authorization of combination products nystatin/triamcinolone or clotrimazole/betamethasone lotion requires a patient-specific, clinically significant reason why the member cannot use the individual components separately, or in the case of clotrimazole/betamethasone lotion, why the Tier-1 cream cannot be used; and
4. For treatment of onychomycosis, a trial of oral antifungals (6 weeks for fingernails and 12 weeks for toenails) will be required for consideration of approval of Penlac® (ciclopirox solution).

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

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

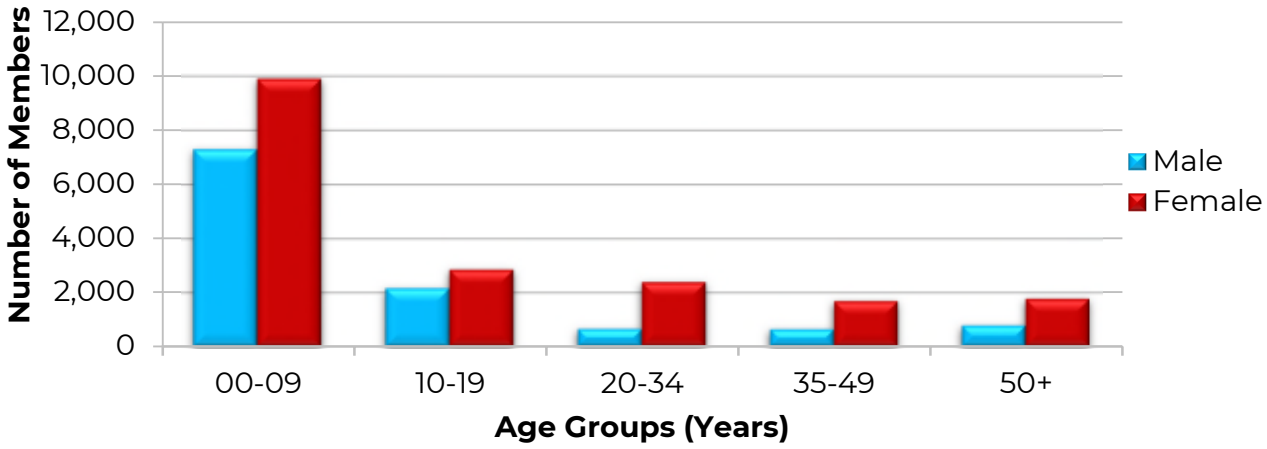
Utilization of Topical Antifungal Products: Fiscal Year 2022

Comparison of Fiscal Years

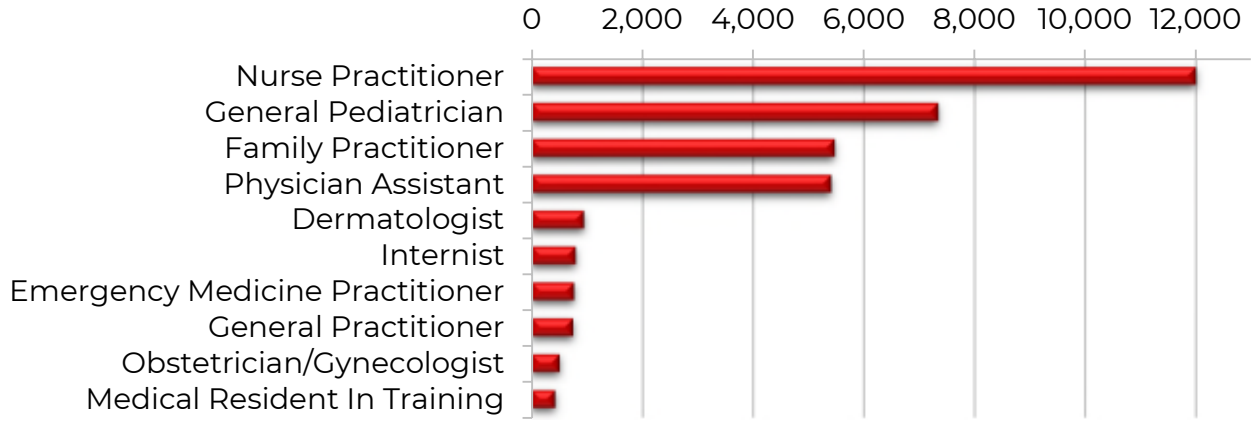
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	24,546	35,799	$700,118.34	$19.56	$1.17	1,578,639	600,903
2022	30,099	43,817	$851,360.21	$19.43	$1.11	1,991,242	770,368
% Change	**22.6%**	**22.4%**	**21.6%**	**-0.7%**	**-5.1%**	**26.1%**	**28.2%**
Change	**5,553**	**8,018**	**$151,241.87**	**-$0.13**	**-$0.06**	**412,603**	**169,465**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021; Fiscal Year 2022 = 07/01/2021 to 06/30/2022

Demographics of Members Utilizing Topical Antifungal Products



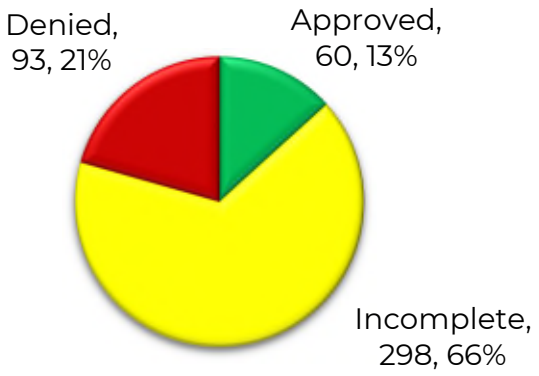
Top Prescriber Specialties of Topical Antifungal Products by Number of Claims



Prior Authorization of Topical Antifungal Products

There were 451 prior authorization requests submitted for topical antifungal products during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions



Market News and Updates[1]

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 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 PRODUCTS						
NYSTATIN PRODUCTS						
NYSTATIN CRE 100000	12,193	9,495	$204,927.86	$16.81	1.28	24.07%
NYSTATIN OIN 100000	6,285	5,131	$121,344.03	$19.31	1.22	14.25%
NYSTOP POW 100000	2,227	1,632	$39,498.88	$17.74	1.36	4.64%
NYSTATIN POW 100000	1,274	787	$26,704.25	$20.96	1.62	3.14%
NYAMYC POW 100000	734	328	$14,149.45	$19.28	2.24	1.66%
NYSTATIN OIN 100000	55	50	$924.74	$16.81	1.1	0.11%
SUBTOTAL	**22,768**	**17,423**	**$407,549.21**	**$17.90**	**1.31**	**47.87%**
KETOCONAZOLE PRODUCTS						
KETOCONAZOLE SHA 2%	6,153	3,565	$134,490.76	$21.86	1.73	15.80%
KETOCONAZOLE CRE 2%	5,446	4,470	$147,494.35	$27.08	1.22	17.32%
SUBTOTAL	**11,599**	**8,035**	**$281,985.11**	**$24.31**	**1.44**	**33.12%**
CLOTRIMAZOLE PRODUCTS						
CLOTRIMAZOLE CRE 1%	5,693	4,847	$89,254.76	$15.68	1.17	10.48%
ANTIFUNGAL CRE 1%	43	36	$516.53	$12.01	1.19	0.06%
ATHLETE'S FOOT CRE 1%	14	12	$158.00	$11.29	1.17	0.02%
SUBTOTAL	**5,750**	**4,895**	**$89,929.29**	**$15.64**	**1.17**	**10.56%**
CLOTRIMAZOLE/BETAMETHASONE PRODUCTS						
CLOTRIM/BETA DIPROP CRE 1-0.05%	1,849	1,447	$32,191.54	$17.41	1.28	3.78%
CLOTRIM/BETA CRE 1-0.05%	645	526	$11,687.63	$18.12	1.23	1.37%
SUBTOTAL	**2,494**	**1,973**	**$43,879.17**	**$17.59**	**1.26**	**5.15%**
TERBINAFINE PRODUCTS						
TERBINAFINE CRE 1%	382	357	$6,599.56	$17.28	1.07	0.78%
ATHLETE'S FOOT CRE 1%	38	38	$727.48	$19.14	1	0.09%
SUBTOTAL	**420**	**395**	**$7,327.04**	**$17.45**	**1.06**	**0.87%**
CICLOPIROX PRODUCTS						
CICLOPIROX CRE 0.77%	351	262	$6,676.72	$19.02	1.34	0.78%
CICLOPIROX SUS 0.77%	29	23	$1,489.34	$51.36	1.26	0.17%
SUBTOTAL	**380**	**285**	**$8,166.06**	**$21.49**	**1.33**	**0.95%**
ECONAZOLE PRODUCTS						
ECONAZOLE CRE 1%	298	246	$6,665.92	$22.37	1.21	0.78%
SUBTOTAL	**298**	**246**	**$6,665.92**	**$22.37**	**1.21**	**0.78%**
TOLNAFTATE PRODUCTS						
TOLNAFTATE CRE 1%	4	4	$58.42	$14.61	1	0.01%
SM ANTIFUNGAL CRE 1%	3	3	$42.64	$14.21	1	0.01%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ANTIFUNGAL CRE 1%	1	1	$14.32	$14.32	1	0.00%
SUBTOTAL	**8**	**8**	**$115.38**	**$14.42**	**1**	**0.02%**
TIER-1 SUBTOTAL	**43,717**	**33,260**	**$845,617.18**	**$19.34**	**1.31**	**99.33%**
TIER-2 PRODUCTS						
CICLOPIROX PRODUCTS						
CICLOPIROX SHA 1%	30	10	$2,189.28	$72.98	3	0.26%
CICLOPIROX SOL 8%	9	8	$202.94	$22.55	1.13	0.02%
CICLOPIROX GEL 0.77%	2	1	$155.56	$77.78	2	0.02%
SUBTOTAL	**41**	**19**	**$2,547.78**	**$62.14**	**2.16**	**0.30%**
NYSTATIN/TRIAMCINOLONE PRODUCTS						
NYSTAT/TRIAM CRE 100000-1%	24	13	$632.79	$26.37	1.85	0.07%
NYSTAT/TRIAM OIN 100000-1%	6	6	$159.68	$26.61	1	0.02%
SUBTOTAL	**30**	**19**	**$792.47**	**$26.42**	**1.58**	**0.09%**
CLOTRIMAZOLE PRODUCTS						
CLOTRIMAZOLE SOL 1%	23	22	$995.42	$43.28	1.05	0.12%
SUBTOTAL	**23**	**22**	**$995.42**	**$43.28**	**1.05**	**0.12%**
OXICONAZOLE PRODUCTS						
OXICONAZOLE CRE 1%	2	1	$553.90	$276.95	2	0.07%
SUBTOTAL	**2**	**1**	**$553.90**	**$276.95**	**2**	**0.07%**
CLOTRIMAZOLE/BETAMETHASONE PRODUCTS						
CLOTRIM/BETA DIPROP LOT 1-0.05%	2	2	$188.90	$94.45	1	0.02%
SUBTOTAL	**2**	**2**	**$188.90**	**$94.45**	**1**	**0.02%**
NAFTIFINE PRODUCTS						
NAFTIFINE GEL 1%	1	1	$385.52	$385.52	1	0.06%
SUBTOTAL	**1**	**1**	**$385.52**	**$385.52**	**1**	**0.06%**
KETOCONAZOLE PRODUCTS						
KETOCONAZOLE FOAM 2%	1	1	$340.33	$340.33	1	0.04%
SUBTOTAL	**1**	**1**	**$340.33**	**$340.33**	**1**	**0.04%**
TIER-2 SUBTOTAL	**100**	**65**	**$5,743.03**	**$57.43**	**1.54**	**0.67%**
TOTAL	**43,817**	**30,099***	**$851,360.21**	**$19.43**	**1.46**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CLOTRIM/BETA = clotrimazole/betamethasone; CRE = cream; DIPROP = dipropionate; LOT = lotion; NYSTAT/TRIAM = nystatin/triamcinolone; OIN = ointment; PA = prior authorization; POW = powder; SHA = shampoo; SOL = solution; SUS = suspension
Fiscal Year 2022= 07/01/2021 to 06/30/2022

[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 06/2023. Last accessed 06/06/2023.

Fiscal Year 2022 Annual Review of Vasomotor Symptom Medications

Oklahoma Health Care Authority
Fiscal Year 2022 Print Report

Current Prior Authorization Criteria

Bijuva® (Estradiol/Progesterone Capsule) Approval Criteria:

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

Brisdelle® (Paroxetine Mesylate 7.5mg) Approval Criteria:

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

Duavee® (Conjugated Estrogens/Bazedoxifene) Approval Criteria:

1. An FDA approved indication for the treatment of moderate-to-severe vasomotor symptoms associated with menopause or for prevention of postmenopausal osteoporosis; and
2. Member must be a female with an intact uterus; and
3. For the treatment of moderate-to-severe vasomotor symptoms associated with menopause:
    a. Member must have at least 7 moderate-to-severe hot flushes per day or at least 50 per week prior to treatment; and
4. For the prevention of postmenopausal osteoporosis:

a. A trial of Fosamax® (alendronate), Actonel® (risedronate), Boniva® (ibandronate), or Reclast® (zoledronic acid) used compliantly for at least 6 months concomitantly with calcium and vitamin D, that failed to prevent fracture or improve bone mineral density (BMD) scores; or
b. Contraindication to, hypersensitivity to, or intolerable adverse effects with all bisphosphonates indicated for prevention of postmenopausal osteoporosis; and

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

Elestrin® (Estradiol 0.06% Gel) Approval Criteria:

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

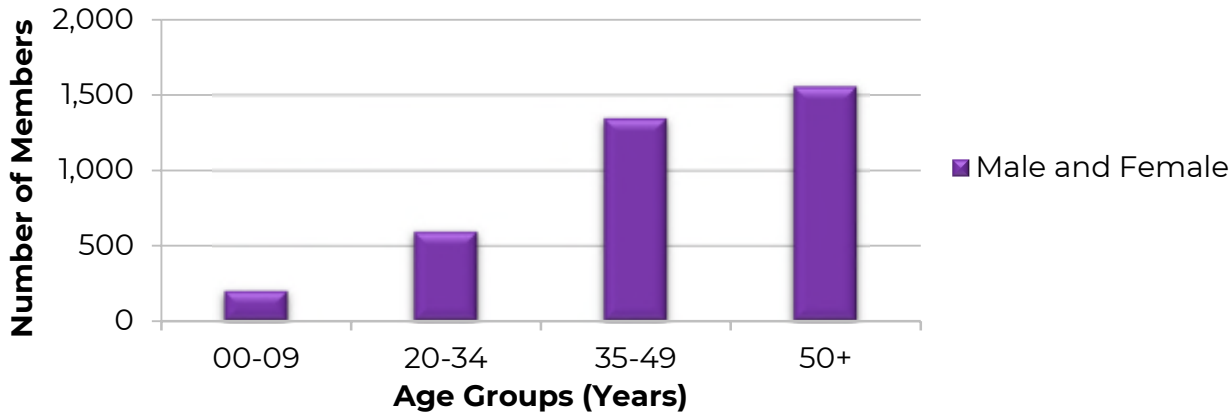
Utilization of Vasomotor Symptom Medications: Fiscal Year 2022

Comparison of Fiscal Years

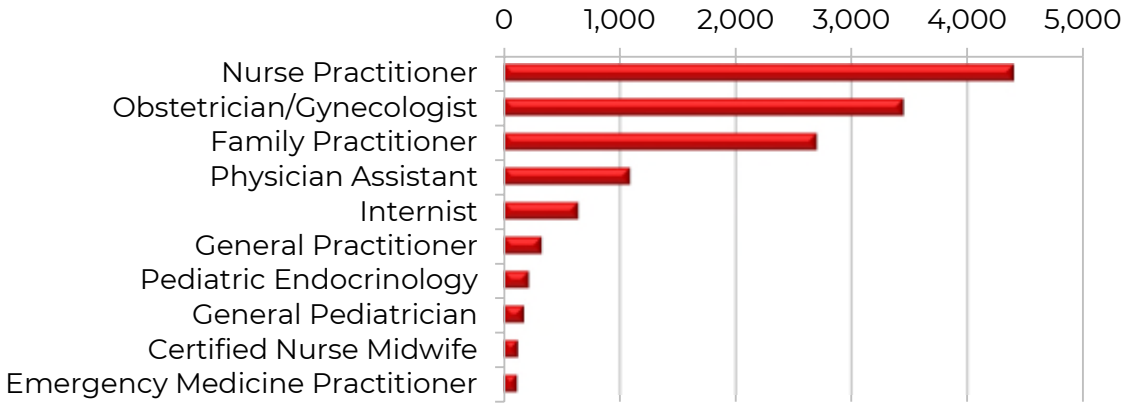
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	2,180	8,240	$734,757.09	$89.17	$2.00	340,762	368,054
2022	3,684	13,719	$1,047,685.87	$76.37	$1.70	596,503	617,533
% Change	**69.0%**	**66.5%**	**42.6%**	**-14.4%**	**-15.0%**	**75.0%**	**67.8%**
Change	**1,504**	**5,479**	**$312,928.78**	**-$12.80**	**-$0.30**	**255,741**	**249,479**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021; Fiscal Year 2022 = 07/01/2021 to 06/30/2022

Demographics of Members Utilizing Vasomotor Symptom Medications



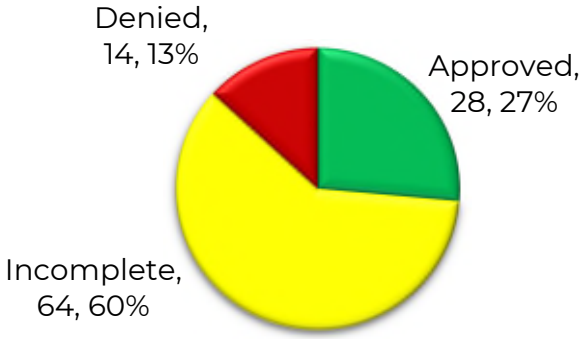
Top Prescriber Specialties of Vasomotor Symptom Medications by Number of Claims



Prior Authorization of Vasomotor Symptom Medications

There were 106 prior authorization requests submitted for vasomotor symptom medications during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions



Market News and Updates[1,2,3]

Anticipated Patent Expiration(s):

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

Pipeline:

- **Elinzanetant:** Bayer is studying elinzanetant, a non-hormonal, dual neurokinin-1,3 receptor antagonist, for the treatment of vasomotor symptoms during menopause. The transition into Phase 3 trials was based on positive results from 2 Phase 2 trials, RELENT-1 and SWITCH-1. The OASIS Phase 3 clinical development program was initiated in August 2021 to evaluate the safety and efficacy of elinzanetant. In October 2022, Bayer announced they are expanding the Phase 3 program by initiating OASIS 4. OASIS 4 is a Phase 3 trial in patients with breast cancer and women at a high risk for breast cancer with vasomotor symptoms caused by endocrine therapy.

Recommendations

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

Utilization Details of Vasomotor Symptom Medications: Fiscal Year 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ORAL ESTROGEN PRODUCTS						
ESTRADIOL TAB 1MG	3,496	1,203	$43,121.79	$12.33	2.91	4.12%
ESTRADIOL TAB 2MG	3,269	913	$54,664.17	$16.72	3.58	5.22%
ESTRADIOL TAB 0.5MG	1,373	493	$17,985.56	$13.10	2.78	1.72%
PREMARIN TAB 0.625MG	500	133	$158,694.39	$317.39	3.76	15.15%
PREMARIN TAB 1.25MG	471	130	$161,121.06	$342.08	3.62	15.38%
PREMARIN TAB 0.3MG	243	81	$72,040.51	$296.46	3	6.88%
PREMARIN TAB 0.9MG	90	23	$23,387.28	$259.86	3.91	2.23%
PREMARIN TAB 0.45MG	48	17	$14,969.12	$311.86	2.82	1.43%
MENEST TAB 0.3MG	11	3	$1,080.57	$98.23	3.67	0.10%
MENEST TAB 1.25MG	8	1	$1,812.35	$226.54	8	0.17%
MENEST TAB 0.625MG	6	4	$1,438.72	$239.79	1.5	0.14%
SUBTOTAL	**9,515**	**3,001**	**$550,315.52**	**$57.84**	**3.17**	**52.53%**
TOPICAL ESTROGEN PRODUCTS						
ESTRADIOL DIS 0.1MG	421	110	$28,862.97	$68.56	3.83	2.75%
ESTRADIOL DIS 0.1MG	389	118	$21,393.16	$55.00	3.3	2.04%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
DOTTI DIS 0.1MG	281	65	$19,296.42	$68.67	4.32	1.84%
ESTRADIOL DIS 0.05MG	242	77	$16,177.54	$66.85	3.14	1.54%
ESTRADIOL DIS 0.025MG	199	53	$11,592.51	$58.25	3.75	1.11%
ESTRADIOL DIS 0.05MG	184	60	$9,803.78	$53.28	3.07	0.94%
ESTRADIOL DIS 0.0375MG	146	45	$10,002.36	$68.51	3.24	0.95%
ESTRADIOL DIS 0.025MG	128	37	$8,776.01	$68.56	3.46	0.84%
DOTTI DIS 0.0375MG	124	34	$8,059.06	$64.99	3.65	0.77%
DOTTI DIS 0.05MG	104	34	$6,379.57	$61.34	3.06	0.61%
ESTRADIOL DIS 0.0375MG	95	21	$5,897.91	$62.08	4.52	0.56%
DOTTI DIS 0.075MG	78	20	$5,395.42	$69.17	3.9	0.51%
ESTRADIOL DIS 0.075MG	76	29	$5,224.51	$68.74	2.62	0.50%
ESTRADIOL DIS 0.075MG	75	18	$4,035.82	$53.81	4.17	0.39%
DIVIGEL GEL 1MG/GM	46	17	$7,272.28	$158.09	2.71	0.69%
DIVIGEL GEL 0.5MG	44	15	$6,902.68	$156.88	2.93	0.66%
DOTTI DIS 0.025MG	44	13	$3,000.08	$68.18	3.38	0.29%
DIVIGEL GEL 0.75MG	34	6	$5,321.94	$156.53	5.67	0.51%
DIVIGEL GEL 0.25MG	33	9	$5,203.31	$157.68	3.67	0.50%
ESTRADIOL DIS 0.06MG	30	8	$1,415.83	$47.19	3.75	0.14%
EVAMIST SPR 1.53MG	23	7	$3,431.84	$149.21	3.29	0.33%
LYLLANA DIS 0.1MG	15	3	$1,019.06	$67.94	5	0.10%
LYLLANA DIS 0.05MG	13	4	$868.42	$66.80	3.25	0.08%
DIVIGEL GEL 1.25MG	10	4	$1,406.25	$140.63	2.5	0.13%
CLIMARA DIS 0.1MG	4	1	$590.36	$147.59	4	0.06%
VIVELLE-DOT DIS 0.1MG	4	2	$230.72	$57.68	2	0.02%
LYLLANA DIS 0.025MG	3	2	$208.53	$69.51	1.5	0.02%
LYLLANA DIS 0.0375MG	2	2	$134.84	$67.42	1	0.01%
CLIMARA DIS 0.025MG	1	1	$60.65	$60.65	1	0.01%
SUBTOTAL	**2,848**	**815**	**$197,963.83**	**$69.51**	**3.49**	**18.90%**
ORAL ESTROGEN/PROGESTIN PRODUCTS						
PREMPRO TAB 0.3-1.5MG	226	61	$70,041.15	$309.92	3.7	6.69%
PREMPRO TAB 0.625-2.5MG	169	36	$54,799.89	$324.26	4.69	5.23%
PREMPRO TAB 0.45-1.5MG	78	26	$23,518.73	$301.52	3	2.24%
ESTRA/NORETH TAB 1-0.5MG	71	28	$3,718.77	$52.38	2.54	0.35%
ESTRA/NORETH TAB 0.5-0.1MG	59	19	$3,546.55	$60.11	3.11	0.34%
PREMPRO TAB 0.625-5MG	42	12	$17,681.28	$420.98	3.5	1.69%
NORETH/ETHIN TAB 0.5MG-2.5MCG	34	9	$2,491.00	$73.26	3.78	0.24%
MIMVEY TAB 1-0.5MG	28	12	$2,562.77	$91.53	2.33	0.24%
NORETH/ETHIN TAB 1MG-5MCG	24	8	$1,303.04	$54.29	3	0.12%
ANGELIQ TAB 0.25-0.5MG	13	7	$5,515.34	$424.26	1.86	0.53%
FYAVOLV TAB 0.5MG-2.5MCG	11	4	$1,262.61	$114.78	2.75	0.12%
BIJUVA CAP 1-100MG	9	1	$2,043.80	$227.09	9	0.20%
ANGELIQ TAB 0.5-1MG	5	4	$2,469.30	$493.86	1.25	0.24%
JINTELI TAB 1MG-5MCG	4	2	$343.21	$85.80	2	0.03%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
AMABELZ TAB 0.5-0.1MG	3	1	$96.23	$32.08	3	0.01%
SUBTOTAL	**776**	**230**	**$191,393.67**	**$246.64**	**3.37**	**18.27%**
INJECTABLE ESTROGEN PRODUCTS						
DEPO-ESTRADIOL INJ 5MG/ML	199	106	$27,873.56	$140.07	1.88	2.66%
ESTRADIOL VAL INJ 20MG/ML	134	62	$15,767.47	$117.67	2.16	1.50%
DELESTROGEN INJ 20MG/ML	17	9	$2,254.56	$132.62	1.89	0.22%
ESTRADIOL VIAL INJ 40MG/ML	12	9	$2,108.40	$175.70	1.33	0.20%
DELESTROGEN INJ 40MG/ML	4	4	$1,211.92	$302.98	1	0.12%
SUBTOTAL	**366**	**190**	**$49,215.91**	**$134.47**	**1.93**	**4.70%**
TOPICAL ESTROGEN/PROGESTIN PRODUCTS						
CLIMARA PRO DIS 0.045-0.015MG/DAY	79	23	$18,349.54	$232.27	3.43	1.75%
COMBIPATCH DIS 0.05-0.014MG/DAY	63	26	$13,543.35	$214.97	2.42	1.29%
COMBIPATCH DIS 0.05-0.025MG/DAY	45	10	$10,239.55	$227.55	4.5	0.98%
SUBTOTAL	**187**	**59**	**$42,132.44**	**$225.31**	**3.17**	**4.02%**
VAGINAL ESTROGEN PRODUCTS						
FEMRING MIS 0.1MG/24H	17	8	$10,764.70	$633.22	2.13	1.03%
FEMRING MIS 0.05MG/24H	10	5	$5,899.80	$589.98	2	0.56%
SUBTOTAL	**27**	**13**	**$16,664.50**	**$617.20**	**2.08**	**1.59%**
TOTAL	**13,719**	**3,684***	**$1,047,685.87**	**$76.37**	**3.72**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
DIS = patch; ESTRA/NORETH = estradiol/norethindrone; INJ = injection; MIS = insert; NORETH/ETHIN = norethindrone/ethinyl estradiol; SPR = spray; TAB = tablet; VAL = valerate
Fiscal Year 2022 = 07/01/2021 to 06/30/2022

[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 06/2023. Last accessed 06/16/2023.
[2] Bayer Inc. Bayer Starts Phase III Clinical Development Program OASIS with Elinzanetant. Available online at: https://www.bayer.com/media/en-us/bayer-starts-phase-iii-clinical-development-program-oasis-with-elinzanetant/. Issued 08/31/2021. Last accessed 06/16/2023.
[3] Bayer Inc. Bayer Expands Development Program for Elinzanetant with Phase III Study in Breast Cancer Patients with Vasomotor Symptoms Caused by Endocrine Therapy. Available online at: https://www.bayer.com/media/en-us/bayer-expands-development-program-for-elinzanetant-with-phase-iii-study-in-breast-cancer-patients-with-vasomotor-symptoms-caused-by-endocrine-therapy/. Issued 10/17/2022. Last accessed 06/16/2023.