State Fiscal Year 2023 Print Annual Reviews
Quarter 2

Count	Category/Medication
1.	$Alpha_1$-Proteinase Inhibitors
2.	Antihistamine Medications (Systemic)
3.	Bowel Preparation Medications
4.	Corticosteroid Special Formulations
5.	Crohn's Disease (CD) and Ulcerative Colitis (UC) Medications
6.	Crysvita® (Burosumab-twza)
7.	Fibromyalgia Medications
8.	Givlaari® (Givosiran) and Scenesse® (Afamelanotide)
9.	Gonadotropin-Releasing Hormone (GnRH) Medications
10.	Iron Chelating Agents
11.	Luxturna® (Voretigene Neparvovec-rzyl)
12.	Mycapssa® (Octreotide) and Signifor® LAR (Pasireotide)
13.	Northera® (Droxidopa)
14.	Pancreatic Enzymes
15.	Pediculicide Medications
16.	Xiaflex® (Collagenase Clostridium Histolyticum)
17.	Zokinvy® (Lonafarnib)

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

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

Fiscal Year 2023 Annual Review of Alpha$_1$-Proteinase Inhibitors

Oklahoma Health Care Authority
Fiscal Year 2023 Print Report

Current Prior Authorization Criteria

Aralast® NP, Glassia®, and Zemaira® [Alpha$_1$-Proteinase Inhibitor (Human)] Approval Criteria:

1. An FDA approved indication for augmentation and maintenance therapy of members 18 years of age or older with severe hereditary deficiency of alpha$_1$-antitrypsin (AAT) with clinical evidence of emphysema; and
2. Diagnosis confirmed by all of the following:
   a. Genetic confirmation of PiZZ, PiZ(null) or Pi(null, null) phenotype alpha$_1$-antitrypsin deficiency (AATD) or other alleles determined to increase risk of AATD; and
   b. Serum levels of AAT <11micromol/L; and
   c. Documented emphysema with airflow obstruction; and
3. Prescriber must document that member's forced expiratory volume in 1 second (FEV_1) is ≤65% predicted; and
4. Must be prescribed by a pulmonary disease specialist (or an advanced care practitioner with a supervising physician who is a pulmonary disease specialist); and
5. Prescriber must verify the member is a non-smoker; and
6. Prescriber must verify the member does not have antibodies to IgA; and
7. A patient-specific, clinically significant reason why the member cannot use Prolastin®-C must be provided; and
8. 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.

Prolastin®-C Liquid and Prolastin®-C [Alpha$_1$-Proteinase Inhibitor (Human)] Approval Criteria:

1. An FDA approved indication for augmentation and maintenance therapy of members 18 years of age or older with severe hereditary deficiency of alpha$_1$-antitrypsin (AAT) with clinical evidence of emphysema; and
2. Diagnosis confirmed by all of the following:

a. Genetic confirmation of PiZZ, PiZ(null) or Pi(null, null) phenotype alpha$_1$-antitrypsin deficiency (AATD) or other alleles determined to increase risk of AATD; and
b. Serum levels of AAT <11micromol/L; and
c. Documented emphysema with airflow obstruction; and

3. Prescriber must document that member's forced expiratory volume in 1 second (FEV_1) is ≤65% predicted; and
4. Must be prescribed by a pulmonary disease specialist (or an advanced care practitioner with a supervising physician who is a pulmonary disease specialist); and
5. Prescriber must verify the member is a non-smoker; and
6. Prescriber must verify the member does not have antibodies to IgA; and
7. 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 Alpha$_1$-Proteinase Inhibitors: Fiscal Year 2023

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	4	45	$442,086.39	$9,824.14	$350.86	954,972	1,260
2023	8	61	$575,247.23	$9,430.28	$340.99	1,221,984	1,687
% Change	**100%**	**35.6%**	**30.1%**	**-4.0%**	**-2.8%**	**28.0%**	**33.9%**
Change	**4**	**16**	**$133,160.84**	**-$393.86**	**-$9.87**	**267,012**	**427**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Comparison of Fiscal Years: Medical Claims

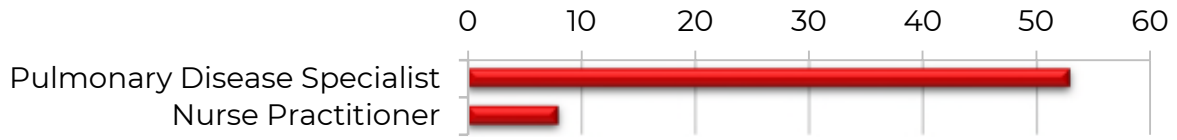
Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2022	1	10	$20,467.69	$2,046.77	10
2023	2	45	$91,237.11	$2,027.49	22.5
% Change	**100%**	**350%**	**345.8%**	**-0.9%**	**125%**
Change	**1**	**35**	**$70,769.42**	**-$19.28**	**12.5**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Demographics of Members Utilizing Alpha$_1$-Proteinase Inhibitors

- Due to the limited number of members utilizing alpha$_1$-proteinase inhibitors during fiscal year 2023, detailed demographic information could not be provided.

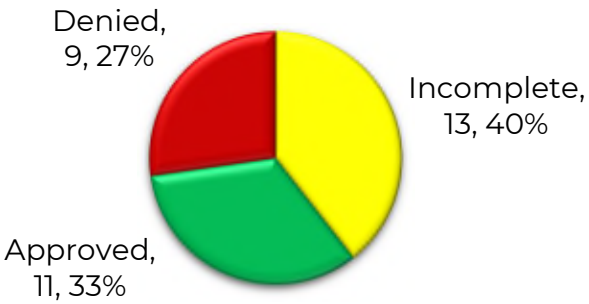
Top Prescriber Specialties of Alpha$_1$-Proteinase Inhibitors by Number of Claims: Pharmacy Claims



Prior Authorization of Alpha$_1$-Proteinase Inhibitors

There were 33 prior authorization requests submitted for alpha$_1$-proteinase inhibitors during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

Status of Petitions



Market News and Updates[1,2]

Pipeline:

- **Fazirsiran:** Fazirsiran is being studied by Arrowhead Pharmaceuticals for the treatment of liver disease associated with apha$_1$-antitrypsin (AAT) deficiency. It is designed to break down the hepatic production of the mutant AAT proteins that leads to progressive liver disease in AAT deficiency. Reducing the production of this protein is expected to stop the liver disease progression and allow the liver to regenerate and repair. Fazirsiran is currently in Phase 3 trials.
- **Inhaled AAT:** Kamada Pharmaceuticals is currently studying an inhaled AAT that has the potential to significantly improve the patient's disease condition and quality of life relative to current invasive weekly treatment that requires intravenous (IV) infusion. If approved, inhaled AAT is anticipated to be the first AAT product that is administered via a user-friendly, lightweight, and silent nebulizer in up to 2 short daily sessions. Inhaled AAT has been designated as an Orphan Drug in the United States

Recommendations

The College of Pharmacy does not recommend any changes to the current alpha$_1$-proteinase inhibitors prior authorization criteria at this time.

Utilization Details of Alpha$_1$-Proteinase Inhibitors: Fiscal Year 2023

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
PROLASTIN-C INJ 1,000MG	49	7	$491,564.56	$10,031.93	7	85.45%
GLASSIA INJ 1,000MG	12	1	$83,682.67	$6,973.56	12	14.55%
SUBTOTAL	**61**	**8***	**$575,247.23**	**$9,430.28**	**7.63**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
INJ = injection
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Medical Claims

PRODUCT UTILIZED	+TOTAL CLAIMS	*TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
PROLASTIN C INJ 10MG J0256	45	2	$91,237.11	$2,027.49	22.5
TOTAL	**45**	**2**	**$91,237.11**	**$2,027.49**	**22.5**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
+Total number of unduplicated claims.
INJ = injection
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

[1] Arrowhead Pharmaceuticals. Pipeline. Available online at: https://arrowheadpharma.com/pipeline/. Last accessed 12/13/2023.
[2] Kamada Pharmaceuticals Ltd. Science: Pipeline. Available online at: https://www.kamada.com/pipeline/. Last accessed 12/13/2023.

Fiscal Year 2023 Annual Review of Antihistamine Medications (Systemic)

Oklahoma Health Care Authority
Fiscal Year 2023 Print Report

Current Prior Authorization Criteria

Oral Antihistamine Medications		
Tier-1⁺	**Tier-2**	**Tier-3**
OTC cetirizine (Zyrtec®)	OTC levocetirizine (Xyzal®)*	clemastine
OTC loratadine (Claritin®)		desloratadine (Clarinex®)¥

⁺Tier-1 products are covered for pediatric members with no authorization necessary. OTC products are only covered for pediatric members.
*Xyzal® tablets are not covered for members younger than 6 years of age. Xyzal® solution is available for members 6 months to 6 years of age.
¥An age restriction of 6 years to 11 years of age applies for Clarinex® RediTabs®.
OTC = over-the-counter

Oral Antihistamine Medications Tier-2 Approval Criteria:

1. A diagnosis of a chronic allergic condition or asthma; and
2. Member must have a 14-day trial of all Tier-1 products within the last 30 days; and
3. Approvals will be for the duration of 1 year.

Oral Antihistamine Medications Tier-3 Approval Criteria:

1. A diagnosis of a chronic allergic condition or asthma; and
2. Member must have a 14-day trial of all Tier-1 and Tier-2 products within the last 60 days (unless no age-appropriate Tier-2 product exists); and
3. Approvals will be for the duration of 1 year.

Quzyttir® (Cetirizine Injection) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use an oral formulation of cetirizine (e.g., tablets, oral solution), must be provided.

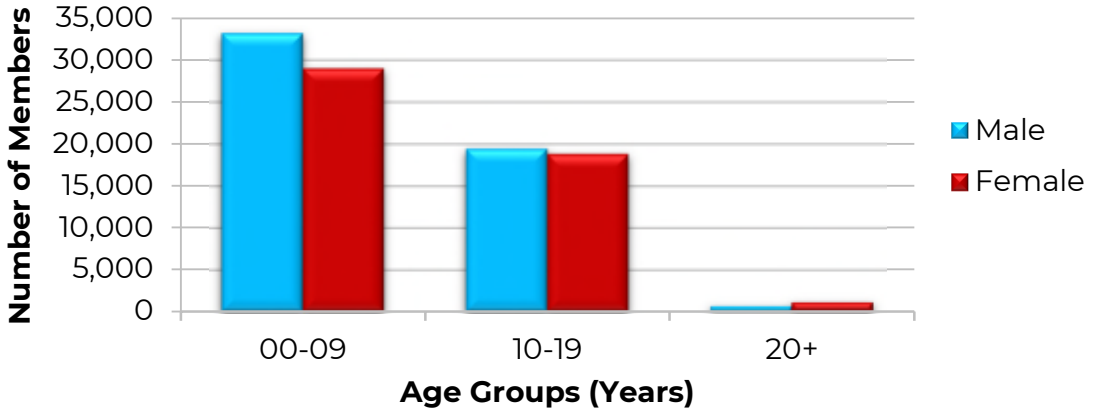
Utilization of Systemic Antihistamine Medications: Fiscal Year 2023

Comparison of Fiscal Years

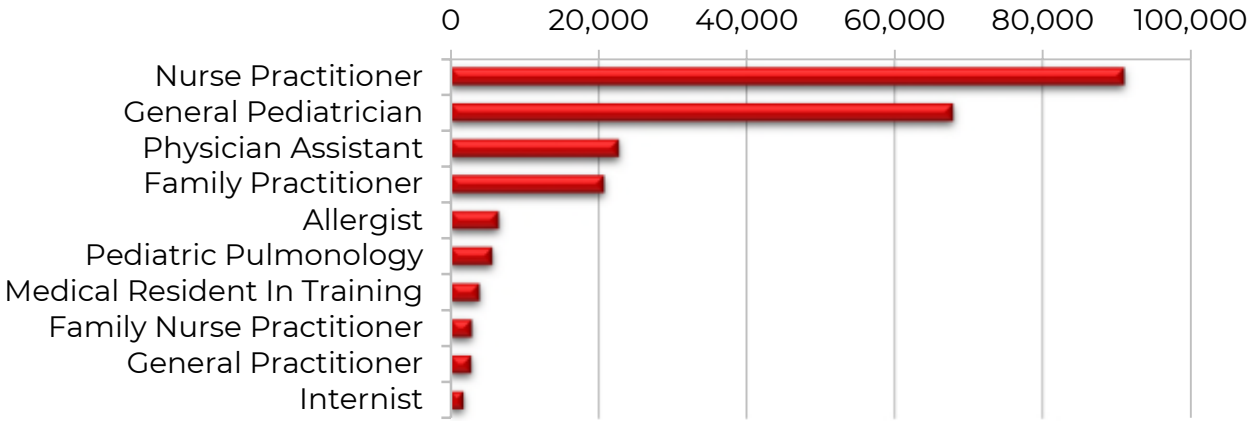
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	100,952	239,847	$2,903,029.35	$12.10	$0.36	23,624,800	7,980,080
2023	102,050	233,528	$2,817,043.38	$12.06	$0.36	22,568,486	7,900,582
% Change	**1.1%**	**-2.6%**	**-3.0%**	**-0.3%**	**0.0%**	**-4.5%**	**-1.0%**
Change	**1,098**	**-6,319**	**$85,985.97**	**$0.04**	**$0.00**	**-1,056,314**	**-79,498**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Demographics of Members Utilizing Systemic Antihistamine Medications



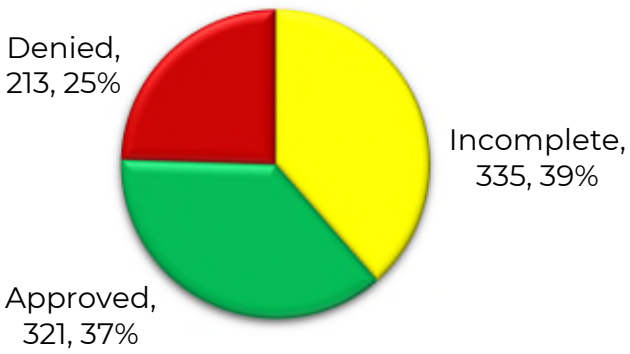
Top Prescriber Specialties of Systemic Antihistamine Medications by Number of Claims



Prior Authorization of Systemic Antihistamine Medications

There were 869 prior authorization requests submitted for systemic antihistamine medications during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

Status of Petitions



Market News and Updates[1]

Anticipated Patent Expiration(s):

- Xyzal® (levocetirizine dihydrochloride oral solution): October 2027
- Quzyttir® (cetirizine injection): February 2030

Recommendations

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

Utilization Details of Systemic Antihistamine Medications: Fiscal Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 PRODUCTS						
CETIRIZINE PRODUCTS						
CETIRIZINE SOL 1MG/ML	77,424	42,042	$1,074,722.06	$13.88	1.84	38.15%
CETIRIZINE TAB 10MG	77,161	33,591	$775,286.56	$10.05	2.3	27.52%
CETIRIZINE SOL 5MG/5ML	12,859	9,521	$174,382.05	$13.56	1.35	6.19%
ALLERGY RELIEF SOL 1MG/ML	11,054	7,617	$156,984.16	$14.20	1.45	5.57%
ALL DAY ALLG SOL 5MG/5ML	4,458	3,341	$58,779.73	$13.19	1.33	2.09%
CETIRIZINE TAB 5MG	4,157	1,944	$41,157.23	$9.90	2.14	1.46%
ALL DAY ALLG SOL 1MG/ML	2,284	1,492	$32,506.26	$14.23	1.53	1.15%
ALLERGY CHILD SOL 1MG/ML	637	556	$1,945.97	$3.05	1.15	0.07%
ALLERGY RELIEF TAB 10MG	610	353	$7,663.58	$12.56	1.73	0.27%
ALL DAY ALLG TAB 10MG	216	101	$2,924.46	$13.54	2.14	0.10%
ALLERGY RELIEF TAB 10MG	45	24	$527.55	$11.72	1.88	0.02%
GNP ALL DAY TAB ALLG 10MG	14	10	$181.23	$12.95	1.4	0.01%
SM ALL DAY TAB 10MG	2	2	$29.63	$14.82	1	0.00%
SM ALL DAY TAB ALLG 10MG	2	1	$33.20	$16.60	2	0.00%
ALLERGY RELIEF TAB 5MG	2	2	$3.14	$1.57	1	0.00%
SUBTOTAL	**190,925**	**100,597**	**$2,327,126.81**	**$12.19**	**1.9**	**82.61%**
LORATADINE PRODUCTS						
LORATADINE SOL 5MG/5ML	20,409	10,216	$262,418.40	$12.86	2	9.32%
LORATADINE TAB 10MG	18,856	7,989	$168,216.58	$8.92	2.36	5.97%
SM ALLERGY SOL 5MG/5ML	576	431	$7,880.26	$13.68	1.34	0.28%
ALLERGY CHILD SOL 5MG/5ML	413	254	$7,433.24	$18.00	1.63	0.26%
ALLERGY RELIEF TAB 10MG	370	172	$4,634.83	$12.53	2.15	0.16%
SM ALL DAY TAB ALLG REL 10MG	109	69	$930.81	$8.54	1.58	0.03%
ALLG RELIEF SOL 5MG/5ML	86	70	$1,587.41	$18.46	1.23	0.06%
LORATIDINE SOL 5MG/5ML	39	32	$481.15	$12.34	1.22	0.02%
SM LORATADINE TAB 10MG	29	17	$305.66	$10.54	1.71	0.01%
LORATADINE TAB 10MG	12	8	$303.99	$25.33	1.5	0.01%
ALLG RELIEF LIQ CHILD 5MG/5ML	4	4	$52.65	$13.16	1	0.00%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**40,903**	**19,262**	**$454,244.98**	**$11.11**	**2.12**	**16.12%**
TIER-1 SUBTOTAL	**231,828**	**101,871***	**$2,781,371.79**	**$12.00**	**2.28**	**98.73%**
TIER-2 PRODUCTS						
LEVOCETIRIZINE PRODUCTS						
LEVOCETIRIZINE TAB 5MG	1,125	262	$14,981.42	$13.32	4.29	0.53%
LEVOCETIRIZINE SOL 2.5MG/5ML	567	136	$20,527.65	$36.20	4.17	0.73%
ALLERGY RELIEF TAB 5MG	2	1	$27.08	$13.54	2	0.00%
TIER-2 SUBTOTAL	**1,694**	**394***	**$35,536.15**	**$20.98**	**4.3**	**1.26%**
TIER-3 PRODUCTS						
DESLORATADINE PRODUCTS						
DESLORATADINE TAB 5MG	5	1	$102.85	$20.57	5	0.00%
SUBTOTAL	**5**	**1**	**$102.85**	**$20.57**	**5**	**0.00%**
CLEMASTINE PRODUCTS						
CLEMASTINE TAB 2.68MG	1	1	$32.59	$32.59	1	0.00%
SUBTOTAL	**1**	**1**	**$32.59**	**$32.59**	**1**	**0.00%**
TIER-3 SUBTOTAL	**6**	**2***	**$135.44**	**$22.57**	**3**	**0.00%**
TOTAL	**233,528**	**102,050***	**$2,817,043.38**	**$12.06**	**2.29**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
ALLG = allergy; LIQ = liquid; SOL = solution; SYP = syrup; TAB = tablet
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 12/2023. Last accessed 12/15/2023.

Fiscal Year 2023 Annual Review of Bowel Preparation Medications

Oklahoma Health Care Authority
Fiscal Year 2023 Print Review

Current Prior Authorization Criteria

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

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

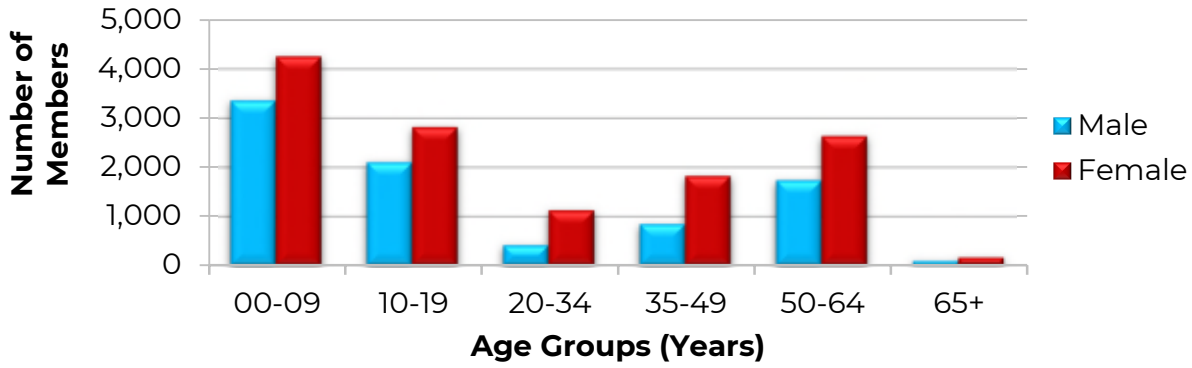
Utilization of Bowel Preparation Medications: Fiscal Year 2023

Comparison of Fiscal Years

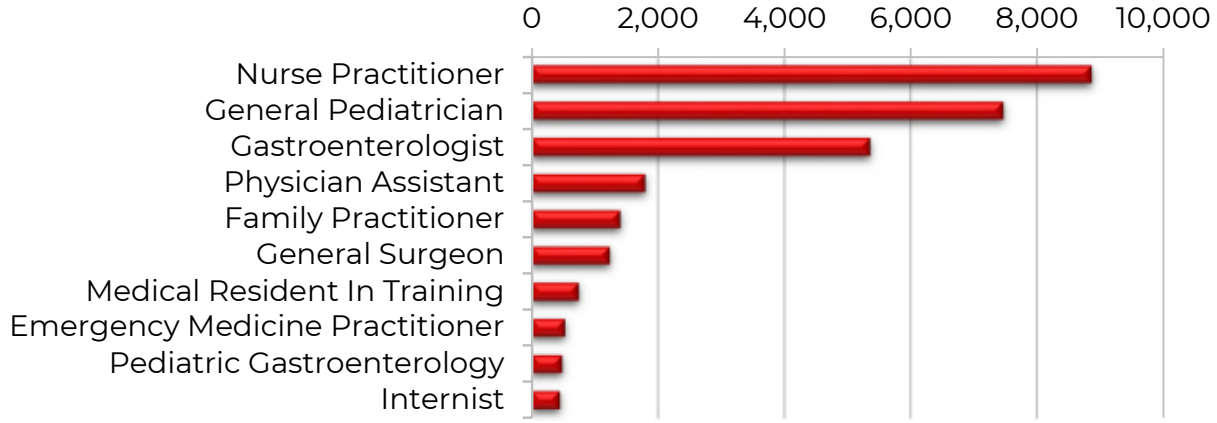
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	17,425	25,318	$527,432.58	$20.83	$0.91	31,013,785	580,844
2023	21,327	29,812	$662,432.91	$22.22	$1.10	44,993,986	600,648
% Change	**22.4%**	**17.8%**	**25.6%**	**6.7%**	**20.9%**	**45.1%**	**3.4%**
Change	**3,902**	**4,494**	**$135,000.33**	**$1.39**	**$0.19**	**13,980,201**	**19,804**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Demographics of Members Utilizing Bowel Preparation Medications



Top Prescriber Specialties of Bowel Preparation Medications by Number of Claims



Prior Authorization of Bowel Preparation Medications

There were 320 prior authorization requests submitted for bowel preparation medications during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

Status of Petitions

Market News and Updates[1]

Anticipated Patent Expiration(s):

- OsmoPrep® (sodium phosphate dibasic/sodium phosphate monobasic): June 2028
- Prepopik® (sodium picosulfate/magnesium oxide/anhydrous citric acid): October 2028
- Plenvu® [polyethylene glycol (PEG) 3350/sodium ascorbate/sodium sulfate/ascorbic acid/sodium chloride/potassium chloride]: March 2032
- Clenpiq® (sodium picosulfate/magnesium oxide/anhydrous citric acid): June 2034
- Sutab® (sodium sulfate/magnesium sulfate/potassium chloride): August 2037

Recommendations

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

Utilization Details of Bowel Preparation Medications: Fiscal Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
PEG-3350 POW NF	15,927	10,078	$289,736.34	$18.19	1.58	43.74%
GAVILYTE-G SOL	5,135	4,855	$105,309.60	$20.51	1.06	15.90%
PEG-3350 SOL ELECT 236GM	1,673	1,592	$36,184.57	$21.63	1.05	5.46%
PEG-3350/KCL/NABI/NACL SOL	1,211	1,161	$43,536.78	$35.95	1.04	6.57%
PEG-3350 POW NF PAK	1,111	852	$42,541.45	$38.29	1.3	2.71%
PEG-3350 POW	965	751	$18,258.99	$18.92	1.28	2.76%
HM CLEARLAX POW	953	624	$17,9321.15	$18.82	1.53	2.71%
GAVILYTE-C SOL	945	909	$16,968.33	$17.96	1.04	2.56%
CLEARLAX POW	821	520	$16,707.67	$20.35	1.58	2.52%
PEG-3350/KCL/NASUL/NAAS/NACL	542	524	$49,271.32	$90.91	1.03	7.44%
PEG-3350 POW PAK	277	126	$12,403.67	$44.78	2.2	1.87%
GNP CLEARLAX POW	91	56	$1,861.20	$20.45	1.63	0.28%
MOVIPREP SOL	58	58	$7,651.40	$131.92	1	1.16%
GOLYTELY SOL	51	51	$1,088.49	$21.34	1	0.16%
SM CLEARLAX POW	26	21	$387.59	$14.91	1.24	0.06%
SUTAB TAB	11	10	$1,733.92	$161.27	1.1	0.27%
PEG-3350 SOL ELECT 240GM	5	5	$94.79	$18.96	1	0.01%
NATURA-LAX POW PEG-3350 NF	3	2	$59.63	$19.88	1.5	0.01%
GNP CLEARLAX PAK PEG-3350 NF	2	1	$64.95	$32.48	2	0.01%
CLENPIQ SOL	2	1	$332.12	$166.06	1	0.05%
PLENVU SOL	1	1	$144.02	$144.02	1	0.02%
GAVILYTE-N SOL FLAV PK	1	1	$30.29	$30.29	1	0.00%
NASUL/KCL/MGSUL SOL	1	1	$94.64	$94.64	1	0.01%
TOTAL	**29,812**	**21,327***	**$662,432.91**	**$22.22**	**1.4**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
ELECT = electrolytes; FLAV PK = flavor pack; KCL = potassium chloride; MGSUL = magnesium sulfate; NAAS = sodium ascorbate; NABI = sodium bicarbonate; NACL = sodium chloride; NASUL = sodium sulfate; NF = national formulary; PAK = packet; PEG = polyethylene glycol; POW = powder; SOL = solution; TAB = tablet
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 12/2023. Last accessed 12/14/2023.

Fiscal Year 2023 Annual Review of Corticosteroid Special Formulations

Oklahoma Health Care Authority
Fiscal Year 2023 Print Report

Current Prior Authorization Criteria

Alkindi Sprinkle® (Hydrocortisone Oral Granule) Approval Criteria:

1. An FDA approved indication of replacement therapy in pediatric members with adrenocortical insufficiency; and
2. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use hydrocortisone tablets, even when tablets are crushed, must be provided.

Orapred ODT® [Prednisolone Sodium Phosphate Orally Disintegrating Tablet (ODT)] Approval Criteria:

1. Approval requires a patient-specific, clinically significant reason why the member cannot use prednisone tablets; and
2. A quantity limit of 10 ODTs per 30 days will be available without prior authorization for members 10 years of age or younger.

Rayos® (Prednisone Delayed-Release Tablet) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use immediate-release corticosteroid medications must be provided.

TaperDex™ (Dexamethasone Tablet) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use dexamethasone 1.5mg individual tablets, which are available without a prior authorization, must be provided.

Tarpeyo® [Budesonide Delayed Release (DR) Capsule] Approval Criteria:

1. An FDA approved indication to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression; and
2. The diagnosis of primary IgAN must be confirmed by the following:
    a. Kidney biopsy; and
    b. Secondary causes of IgAN have been ruled out (i.e., IgA vasculitis; IgAN secondary to virus, inflammatory bowel disease, autoimmune disease, or liver cirrhosis; IgA-dominant infection-related glomerulonephritis); and
3. Member must be 18 years of age or older; and
4. Must be prescribed by a nephrologist (or advanced care practitioner with a supervising physician who is a nephrologist); and

5. Member must be at risk of rapid disease progression as demonstrated by ≥1 of the following, despite maximal supportive care:
   a. Urine protein-to-creatinine ratio (UPCR) ≥1.5g/g; or
   b. Proteinuria >0.75g/day; and
6. Member must be on a stable dose of a maximally-tolerated angiotensin converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB), unless contraindicated or intolerant; and
7. A patient-specific, clinically significant reason why a 6-month trial of an alternative formulation of budesonide DR oral capsules (e.g., Entocort® EC) or alternative oral corticosteroids is not appropriate for the member must be provided; and
8. Approval duration will be for 9 months; and
9. A quantity limit of 120 capsules per 30 days will apply.

Veripred™ 20 (Prednisolone Sodium Phosphate Oral Solution 20mg/5mL) and Millipred™ (Prednisolone Sodium Phosphate Oral Solution 10mg/5mL) Approval Criteria:

1. Approval of Veripred™ 20 or Millipred™ requires a patient-specific, clinically significant reason why the member cannot use a tablet or an alternative strength liquid formulation.

Zilretta® [Triamcinolone Acetonide Extended-Release (ER) Injection] Approval Criteria:

1. An FDA approved diagnosis of osteoarthritis (OA) pain of the knee; and
2. Zilretta® will only be approvable for use in the knee(s) for OA pain; and
3. A patient-specific, clinically significant reason why the member cannot use Kenalog-40® (triamcinolone acetonide 40mg injection) and Depo-Medrol® (methylprednisolone injection) must be provided; and
4. A quantity limit of 1 injection per knee per 12 weeks will apply.

Utilization of Corticosteroid Special Formulations: Fiscal Year 2023

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	869	1,181	$111,956.32	$94.80	$19.23	6,440	5,821
2023	776	1,053	$211,531.78	$200.88	$39.21	6,559	5,395
% Change	**-10.70%**	**-10.8%**	**88.90%**	**111.90%**	**103.90%**	**1.80%**	**-7.30%**
Change	**-93**	**-128**	**$99,575.46**	**$106.08**	**$19.98**	**119**	**-426**

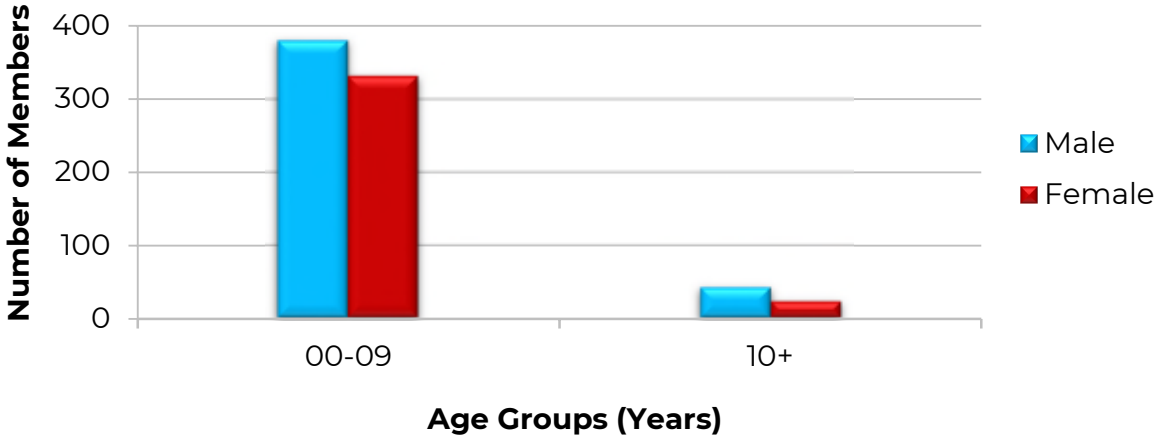
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Comparison of Fiscal Years: Medical Claims

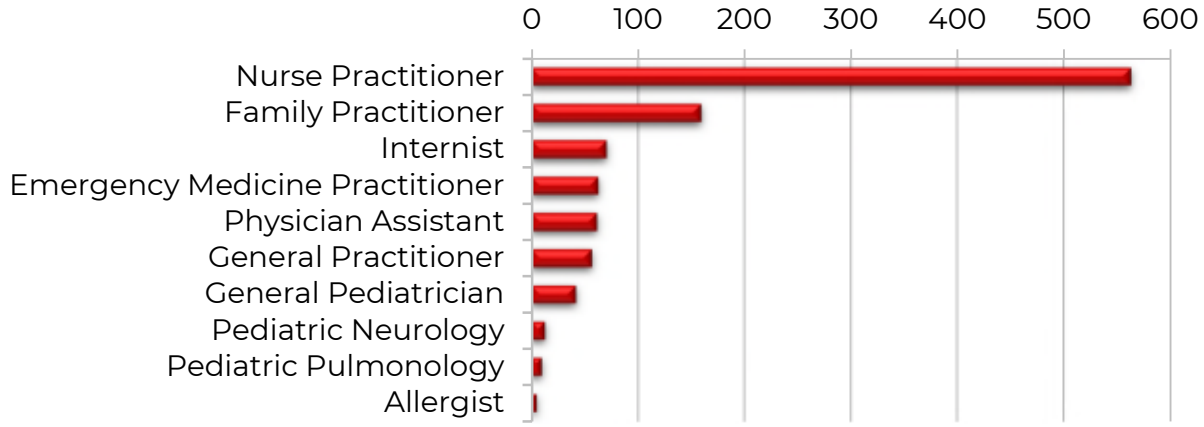
Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Total Units
2022	1	1	$1,120.00	$1,120.00	64
2023	14	18	$11,369.60	$631.64	673
% Change	**1,300%**	**1,800%**	**915.14%**	**-43.60%**	**951.56%**
Change	**13**	**17**	**$10,249.60**	**-$488.36**	**609**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2022 = 07/01/2022 to 06/30/2023

Demographics of Members Utilizing Corticosteroid Special Formulations



Top Prescriber Specialties of Corticosteroid Special Formulations by Number of Claims



Prior Authorization of Corticosteroid Special Formulations

There were 171 prior authorization requests submitted for corticosteroid special formulations during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

Status of Petitions

Market News and Updates[1]

Anticipated Patent Expiration(s):

- Alkindi® Sprinkle (hydrocortisone oral granule): May 2034
- Rayos® [prednisone delayed-release (DR) tablet]: January 2028
- Tarpeyo® (budesonide DR capsule): May 2029
- Zilretta® [triamcinolone acetonide extended-release (ER) injection]: August 2031

Recommendations

The College of Pharmacy recommends the removal of the prior authorization for Rayos® (prednisone delayed-release tablet) based on net cost.

~~**Rayos® (Prednisone Delayed-Release Tablet) Approval Criteria:**~~

~~1. A patient-specific, clinically significant reason why the member cannot use immediate-release corticosteroid medications must be provided.~~

Utilization Details of Corticosteroid Special Formulations: Fiscal Year 2023

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
PREDNISOLONE PRODUCTS						
PREDNISOLONE 15MG ODT	578	441	$58,293.16	$100.85	1.31	27.56%
PREDNISOLONE 10MG ODT	328	263	$21,077.13	$64.26	1.25	9.96%
PREDNISOLONE 30MG ODT	137	108	$17,440.98	$127.31	1.27	8.25%
PREDNISOLONE SOL 20MG/5ML	1	1	$112.44	$112.44	1	0.05%
SUBTOTAL	**1,044**	**813**	**$96,923.71**	**$92.84**	**1.28**	**45.82%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
BUDESONIDE PRODUCTS						
TARPEYO CAP 4MG	7	2	$104,011.92	$14,858.85	3.5	49.17%
SUBTOTAL	**7**	**2**	**$104,011.92**	**$14,858.85**	**3.5**	**49.17**
PREDNISONE PRODUCTS						
RAYOS 5MG TAB	2	2	$10,596.15	$5,298.08	1	5.01%
SUBTOTAL	**2**	**2**	**$10,596.15**	**$5,298.08**	**1**	**5.01%**
TOTAL	**1,053**	**776***	**$211,531.78**	**$200.88**	**1.36**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP=capsule; ODT=orally disintegrating tablet; SOL=solution; TAB = tablet
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Medical Claims

PRODUCT UTILIZED	†TOTAL CLAIMS	*TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
ZILRETTA INJ 32MG J3304	18	14	$11,369.60	$631.64	1.29
TOTAL	**18**	**14**	**$11,369.60**	**$631.64**	**1.29**

Costs do not reflect rebated prices or net costs.
†Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
INJ = Injection
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 12/2023. Last accessed 12/14/2023.

Fiscal Year 2023 Annual Review of Crohn's Disease (CD) and Ulcerative Colitis (UC) Medications

Oklahoma Health Care Authority
Fiscal Year 2023 Print Report

Current Prior Authorization Criteria

Apriso® (Mesalamine Extended-Release Capsule) Quantity Limit Approval Criteria:

1. A quantity limit of 120 capsules per 30 days will apply.

Asacol® HD (Mesalamine Delayed-Release Tablet) Approval Criteria:

1. An FDA approved indication for the treatment of moderately active ulcerative colitis (UC); and
2. A patient-specific, clinically significant reason the member cannot use other available mesalamine products that do not require prior authorization must be provided; and
3. Approvals will be for the duration of 6 weeks in accordance with manufacturer recommended duration of therapy; and
4. A quantity limit of 180 tablets per 30 days will apply.

Canasa® (Mesalamine Suppository) Quantity Limit Approval Criteria:

1. A quantity limit of 30 suppositories per 30 days will apply.
2. The first 6 weeks of treatment do not require prior authorization.
3. After 6 weeks of treatment:
    a. Provider must document a patient-specific, clinically significant reason why the member needs a longer duration of treatment.

Colazal® (Balsalazide Capsule) Quantity Limit Approval Criteria:

1. A quantity limit of 270 capsules per 30 days will apply.
2. The first 12 weeks of treatment do not require prior authorization.
3. After 12 weeks of treatment:
    a. Provider must document a patient-specific, clinically significant reason why the member needs a longer duration of treatment.
4. An age restriction of 5 years and older will apply.

Delzicol® (Mesalamine Delayed-Release Capsule) Quantity Limit Approval Criteria:

1. A quantity limit of 180 capsules per 30 days will apply.

Dipentum® (Olsalazine Capsule) Quantity Limit Approval Criteria:

1. A quantity limit of 120 capsules per 30 days will apply.

Lialda® (Mesalamine Delayed-Release Capsule) Quantity Limit Approval Criteria:

1. A quantity limit of 60 capsules per 30 days will apply.
2. For quantity limit requests for >2 capsules per day:
    a. An FDA approved indication for the induction of remission in members with active, mild-to-moderate ulcerative colitis (UC); and
    b. A patient-specific, clinically significant reason the member cannot use other available mesalamine products that are indicated to induce remission that do not require prior authorization must be provided; and
    c. Approvals will be for the duration of 8 weeks in accordance with manufacturer recommended duration of therapy; and
    d. A maximum approval of 120 capsules per 30 days will apply.

Ortikos® (Budesonide Extended-Release Capsule) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. For the treatment of mild-to-moderate active Crohn's disease (CD) involving the ileum and/or the ascending colon, in members 8 years of age or older; or
    b. For the maintenance of clinical remission of mild-to-moderate CD involving the ileum and/or the ascending colon for up to 3 months duration in adult members; and
2. Member must have previous failure of Entocort® EC (budesonide controlled ileal-release enteric coated capsule) within the last 3 months at recommended dosing and a reason for trial failure with Entocort® EC must be provided; or
3. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use other oral corticosteroids, including Entocort® EC, that are available without prior authorization must be provided; and
4. Dosing regimen and duration of therapy must be in accordance with package labeling; and
5. Approval length will be based on the manufacturer maximum recommended duration of therapy; and
6. A quantity limit of 30 capsules per 30 days will apply.

Pentasa® (Mesalamine Extended-Release Capsule) Approval Criteria:

1. Brand name Pentasa® does not require prior authorization for the first 8 weeks of treatment. Approval of the generic formulation requires a patient-specific, clinically significant reason the member cannot use the brand formulation (Pentasa®) and all other mesalamine products that do not require prior authorization; and

2. A quantity limit of 480 capsules per 30 days will apply for the 250mg strength and a quantity limit of 240 capsules per 30 days will apply for the 500mg strength; and
3. After 8 weeks of treatment:
    a. Provider must document a patient-specific, clinically significant reason why the member needs a longer duration of treatment.

Rowasa® (Mesalamine Rectal Suspension Enema) Approval Criteria:

1. The first 3 weeks of treatment do not require prior authorization.
2. An FDA approved indication for the treatment of active, mild-to-moderate, distal ulcerative colitis (UC), proctosigmoiditis, or proctitis; and
3. A patient-specific, clinically significant reason the member cannot use mesalamine suppositories (Canasa®) which do not require prior authorization must be provided; and
4. Provider documentation that member is still having active symptoms after 3 weeks of treatment; and
5. Approvals will be for the duration of 6 weeks in accordance with manufacturer recommended duration of therapy; and
6. A quantity limit of 30 enemas (1,800mL) per 30 days will apply.

Uceris® (Budesonide Extended-Release Tablet) Approval Criteria:

1. An FDA approved indication of induction of remission in members with active, mild-to-moderate ulcerative colitis (UC); and
2. Previous failure of at least 2 of the following (or a contraindication to all preferred medications):
    a. Oral aminosalicylates; or
    b. Topical mesalamine; or
    c. Topical corticosteroids; and
3. A patient-specific, clinically significant reason why the member cannot use other oral corticosteroids available without prior authorization must be provided; and
4. Approvals will be for the duration of 8 weeks in accordance with manufacturer maximum recommended duration of therapy; and
5. A quantity limit of 30 tablets per 30 days will apply.

Uceris® (Budesonide Rectal Foam) Approval Criteria:

1. An FDA approved indication of induction of remission in members with active, mild-to-moderate, distal ulcerative colitis (UC) extending up to 40cm from the anal verge; and
2. A patient-specific, clinically significant reason why the member cannot use oral aminosalicylates, topical mesalamine, or other topical (rectally administered) corticosteroids available without prior authorization must be provided; and

3. Approvals will be for the duration of 6 weeks in accordance with manufacturer recommended duration of therapy; and
4. A quantity limit of 133.6 grams per 42 days will apply.

The following medications do not require prior authorization: Colazal® (balsalazide) capsules, Cortenema® (hydrocortisone) enemas, Apriso® (mesalamine) extended-release (ER) capsules, Canasa® (mesalamine) suppositories, Delzicol® (mesalamine) delayed-release (DR) capsules, Lialda® (mesalamine) DR capsules, brand name Pentasa® (mesalamine) ER capsules, Rowasa® (mesalamine) rectal suspension enemas, Dipentum® (olsalazine) capsules, sulfasalazine 500mg tablets, and sulfasalazine DR 500mg tablets.

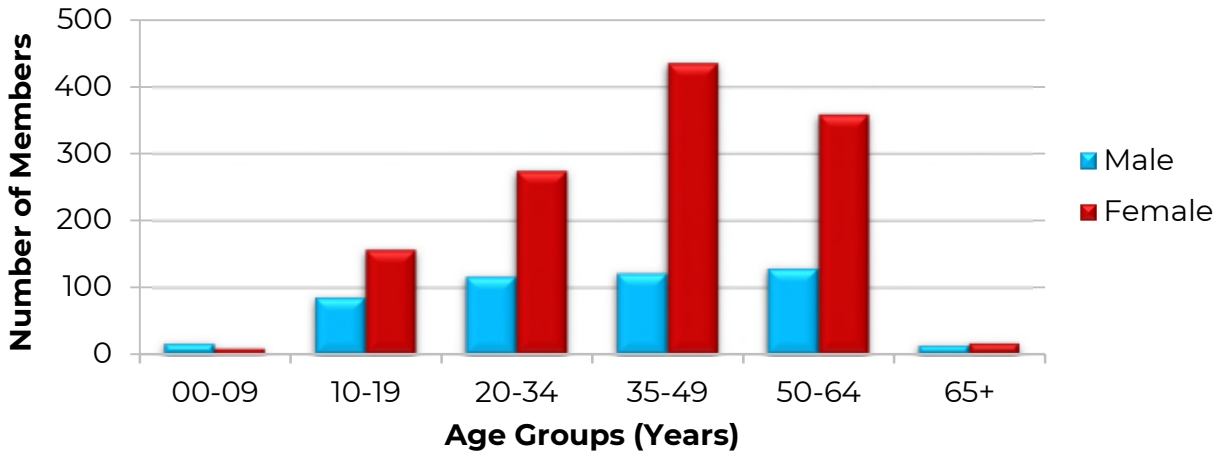
Utilization of CD and UC Medications: Fiscal Year 2023

Comparison of Fiscal Years

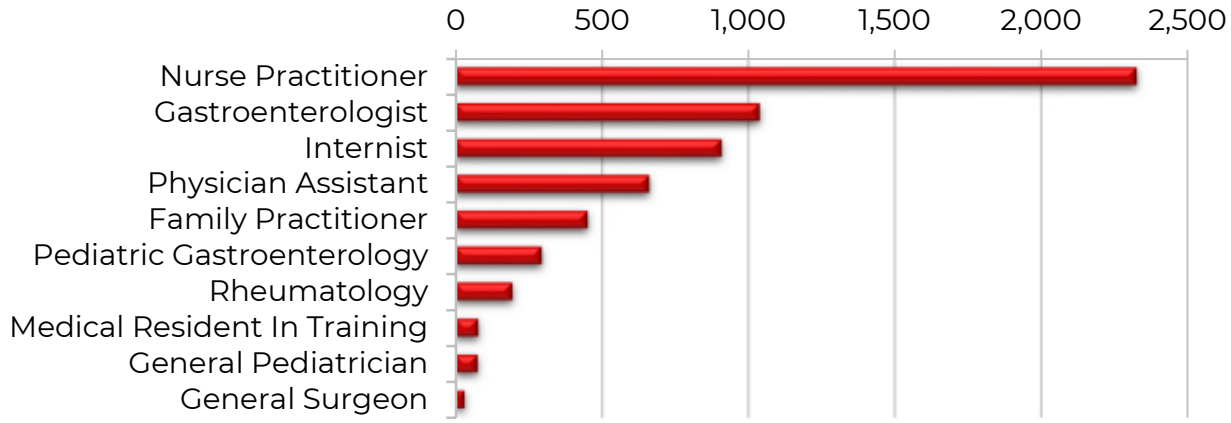
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	1,256	4,161	$509,458.91	$122.44	$4.06	459,510	125,604
2023	1,726	6,174	$591,349.55	$95.78	$3.14	713,602	188,257
% Change	**37.40%**	**48.40%**	**16.10%**	**-21.80%**	**-22.70%**	**55.30%**	**49.90%**
Change	**470**	**2,013**	**$81,890.64**	**-$26.66**	**-$0.92**	**254,092**	**62,653**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Demographics of Members Utilizing CD and UC Medications



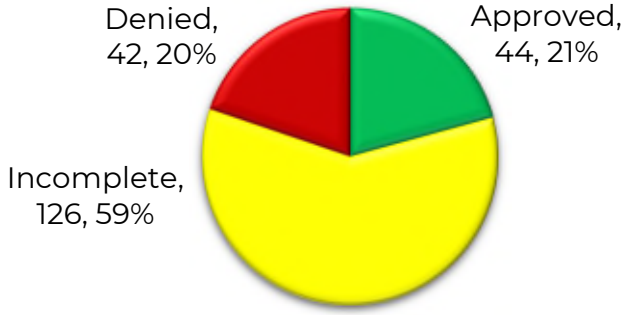
Top Prescriber Specialties of CD and UC Medications by Number of Claims



Prior Authorization of CD and UC Medications

There were 212 prior authorization requests submitted for CD and UC medications during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

Status of Petitions



Market News and Updates[1]

Anticipated Patent Expiration(s):

- Colazal® (balsalazide capsule): February 2027
- Canasa® (mesalamine suppository): June 2028
- Apriso® [mesalamine extended-release (ER) tablet]: May 2030
- Uceris® (budesonide ER tablet): September 2031
- Ortikos® (budesonide ER capsule): September 2036

Recommendations

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

Utilization Details of CD and UC Medications: Fiscal Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SULFASALAZINE PRODUCTS						
SULFASALAZINE TAB 500MG	2,593	746	$61,442.54	$23.70	3.48	10.39%
SULFASALAZINE TAB 500MG DR	1,160	404	$34,507.28	$29.75	2.87	5.84%
SULFASALAZINE POW	4	1	$458.50	$114.63	4	0.08%
AZULFIDINE TAB 500MG	1	1	$29.15	$29.15	1	0.00%
SUBTOTAL	**3,758**	**1,152**	**$96,437.47**	**$25.66**	**3.26**	**16.31%**
MESALAMINE PRODUCTS						
MESALAMINE TAB 1.2GM	937	214	$221,994.31	$236.92	4.38	37.54%
MESALAMINE CAP 0.375GM	208	45	$24,565.71	$118.10	4.62	4.15%
MESALAMINE SUP 1,000MG	192	104	$12,058.78	$62.81	1.85	2.04%
PENTASA CAP 250MG CR	112	25	$54,390.33	$485.63	4.48	9.20%
MESALAMINE CAP 400MG DR	86	29	$25,942.81	$301.66	2.97	4.39%
MESALAMINE CAP 500MG ER	64	25	$46,633.93	$728.66	2.56	7.89%
MESALAMINE ENE 4GM	47	31	$9,755.14	$207.56	1.52	1.65%
PENTASA CAP 500MG CR	46	18	$39,665.48	$862.29	2.56	6.71%
DELZICOL CAP 400MG	13	2	$8,877.21	$682.86	6.5	1.50%
MESALAMINE TAB 800MG DR	1	1	$533.17	$533.17	1	0.09%
CANASA SUP 1,000MG	1	1	$1,169.19	$1,169.19	1	0.20%
SUBTOTAL	**1,707**	**495**	**$445,586.06**	**$261.03**	**3.45**	**75.35%**
BUDESONIDE PRODUCTS						
BUDESONIDE CAP 3MG DR	603	214	$34,427.89	$57.09	2.82	5.82%
BUDESONIDE TAB ER 9MG	4	3	$3,721.37	$930.34	1.33	0.63%
UCERIS AER 2MG/ACT	3	2	$2,273.80	$757.93	1.5	0.38%
SUBTOTAL	**610**	**219**	**$40,423.06**	**$66.27**	**2.79**	**6.84%**
BALSALAZIDE PRODUCTS						
BALSALAZIDE CAP 750MG	84	26	$6,206.40	$73.89	3.23	1.05%
SUBTOTAL	**84**	**26**	**$6,206.40**	**$73.89**	**3.23**	**1.05%**
HYDROCORTISONE PRODUCTS						
HYDROCORTISONE ENE 100MG	15	8	$2,696.56	$179.77	1.88	0.46%
SUBTOTAL	**15**	**8**	**$2,696.56**	**$179.77**	**1.88**	**0.46%**
TOTAL	**6,174**	**1,726***	**$591,349.55**	**$95.78**	**3.58**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; DR = delayed-release; ENE = enema; ER = extended-release; POW = powder; SUP = suppository; TAB = tablet
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 12/2023. Last accessed 12/06/2023.

Fiscal Year 2023 Annual Review of Crysvita® (Burosumab-twza)

Oklahoma Health Care Authority
Fiscal Year 2023 Print Report

Current Prior Authorization Criteria

Crysvita® (Burosumab-twza) Approval Criteria [Tumor-Induced Osteomalacia (TIO) Diagnosis]:

1. An FDA approved diagnosis of fibroblast growth factor 23 (FGF23)-related hypophosphatemia in TIO associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized in members 2 years of age and older; and
2. Member's diagnosis must be confirmed by elevated serum FGF23 level that was not amenable to cure by surgical excision of the underlying tumor/lesion; and
3. Member's serum phosphorus level must be below the normal range for member age; and
4. Member must not have any contraindications to taking Crysvita® including the following:
    a. Concomitant use with oral phosphate and active vitamin D analogs; and
    b. Serum phosphorus within or above the normal range for member age; and
    c. Severe renal impairment or end-stage renal disease; and
5. Crysvita® must be administered by a health care professional. Approvals will not be granted for self-administration. Prior authorization requests must indicate how Crysvita® will be administered; and
    a. Crysvita® must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment; or
    b. Crysvita® must be shipped via cold chain supply to the member's home and administered by a home health care provider if the member's caregiver has been trained on the proper storage of Crysvita®; and
6. Prescriber must agree to assess serum phosphorus levels on a monthly basis for the first 3 months of treatment and thereafter as appropriate and follow the package labeling for dose adjustments; and
7. Prescriber must agree to monitor 25-hydroxy vitamin D levels; and
8. Crysvita® must be prescribed by an endocrinologist or specialist with expertise in the treatment of TIO (or an advanced care practitioner with a supervising physician who is an endocrinologist or specialist with expertise in treating TIO); and

9. The member's recent weight (within the last 3 months) must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
10. Initial authorizations will be for the duration of 6 months, at which time the prescriber must verify the member is responding to the medication as demonstrated by serum phosphorus levels within the normal range for member age or clinically significant improvement in bone-related symptoms; and
11. Early refill requests for dose changes more frequently than every 4 weeks will not be approved; and
12. The maximum approvable dosing regimen is 180mg every 2 weeks; and
13. A quantity limit of 12 single-dose vials per month will apply.

Crysvita® (Burosumab-twza) Approval Criteria [X-linked hypophosphatemia (XLH) Diagnosis]:

1. An FDA approved diagnosis of XLH in adult and pediatric members 6 months of age and older. Diagnosis of XLH must be confirmed by 1 of the following:
    a. Genetic testing; or
    b. Elevated serum fibroblast growth factor 23 (FGF23) level; and
2. Member's serum phosphorus level must be below the normal range for member age; and
3. Member must not have any contraindications to taking Crysvita® including the following:
    a. Concomitant use with oral phosphate and active vitamin D analogs; and
    b. Serum phosphorus within or above the normal range for member age; and
    c. Severe renal impairment or end-stage renal disease; and
4. Crysvita® must be administered by a health care professional. Approvals will not be granted for self-administration. Prior authorization requests must indicate how Crysvita® will be administered; and
    a. Crysvita® must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment; or
    b. Crysvita® must be shipped via cold chain supply to the member's home and administered by a home health care provider if the member's caregiver has been trained on the proper storage of Crysvita®; and
5. Member must have clinical signs and symptoms of XLH (symptoms beyond hypophosphatemia alone); and
6. Every 2 week dosing will not be approved for members 18 years of age or older; and

7. Prescriber must agree to assess serum phosphorus levels on a monthly basis for the first 3 months of treatment, and thereafter as appropriate; and
8. Crysvita® must be prescribed by a nephrologist, endocrinologist, or specialist with expertise in the treatment of XLH (or an advanced care practitioner with a supervising physician who is a nephrologist, endocrinologist, or specialist with expertise in the treatment of XLH); and
9. Initial authorizations will be for the duration of 6 months, at which time the prescriber must verify the member is responding to the medication as demonstrated by serum phosphorus levels within the normal range for member age or clinically significant improvement in bone-related symptoms; and
10. 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 Crysvita® (Burosumab-twza): Fiscal Year 2023

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	10	111	$2,070,561.22	$18,653.70	$666.20	230	3,108
2023	8	108	$2,581,064.28	$23,898.74	$859.21	253	3,004
% Change	**-20.0%**	**-2.7%**	**24.7%**	**28.1%**	**29.0%**	**10.0%**	**-3.3%**
Change	**-2**	**-3**	**$510,503.06**	**$5,245.04**	**$193.01**	**23**	**-104**

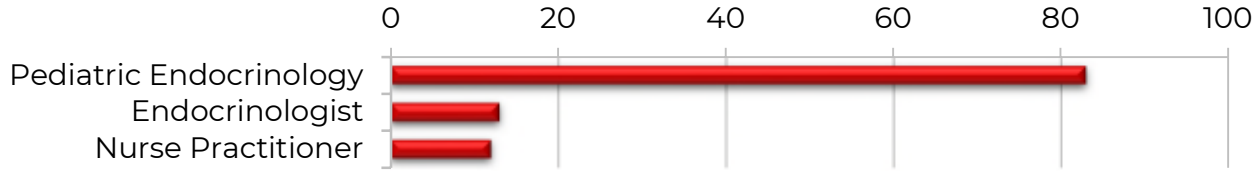
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

- There were no SoonerCare paid medical claims for Crysvita® (burosumab-twza) during fiscal year 2023.

Demographics of Members Utilizing Crysvita® (Burosumab-twza)

- Due to the limited number of members utilizing Crysvita® (burosumab-twza) during fiscal year 2023, detailed demographic information could not be provided.

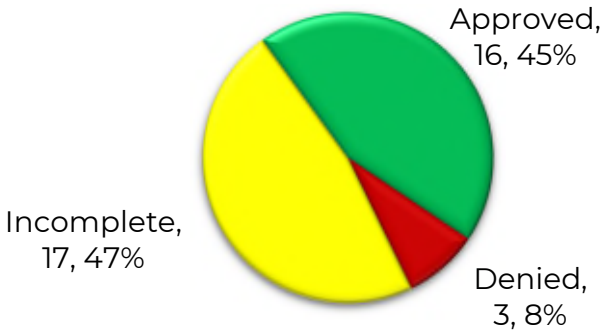
Top Prescriber Specialties of Crysvita® (Burosumab-twza) by Number of Claims



Prior Authorization of Crysvita® (Burosumab-twza)

There were 36 prior authorization requests submitted for Crysvita® (burosumab-twza) for 8 unique members during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

Status of Petitions



Recommendations

The College of Pharmacy does not recommend any changes to the current Crysvita® (burosumab-twza) prior authorization criteria at this time.

Utilization Details of Crysvita® (Burosumab-twza): Fiscal Year 2023

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
CRYSVITA INJ 30MG/ML	58	7	$1,590,165.78	$27,416.65	8.29	61.61%
CRYSVITA INJ 20MG/ML	50	6	$990,898.50	$19,817.97	8.33	38.39%
TOTAL	**108**	**8***	**$2,581,064.28**	**$23,898.74**	**13.5**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
INJ = injection
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Fiscal Year 2023 Annual Review of Fibromyalgia Medications

Oklahoma Health Care Authority
Fiscal Year 2023 Print Report

Current Prior Authorization Criteria

Fibromyalgia Medications	
Tier-1	**Tier-2**
amitriptyline (Elavil®)	milnacipran (Savella®)
cyclobenzaprine (Flexeril®)	
duloxetine (Cymbalta®)	
tramadol 50mg* (Ultram®)	
pregabalin (Lyrica®)	

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).
*Unique criteria applies for use of tramadol 100mg tablets.

Fibromyalgia Medications Tier-2 Approval Criteria:

1. Member must have a documented, recent (within the last 6 months) trial of 2 Tier-1 medications (must include 1 trial with duloxetine) at least 3 weeks in duration that did not provide an adequate response or resulted in intolerable adverse effects; or
2. Contraindication(s) to all available lower tiered medications; or
3. Current stabilization on a Tier-2 medication.

Tramadol 100mg Tablet Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use 2 tramadol 50mg tablets to achieve a 100mg dose must be provided; and
2. An age restriction will apply for members younger than 12 years of age. For members younger than 12 years of age, the provider must submit patient-specific, clinically significant information supporting the use of tramadol despite the medication being contraindicated for the member's age.

Utilization of Fibromyalgia Medications: Fiscal Year 2023

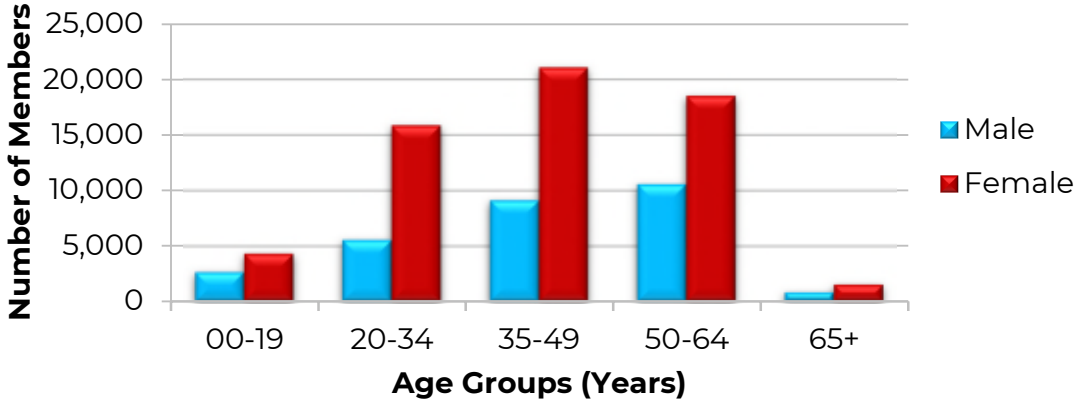
The utilization details include fibromyalgia medications used for all diagnoses and does not differentiate between fibromyalgia diagnoses and other diagnoses, for which use may be appropriate.

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	73,096	313,597	$5,016,639.49	$16.00	$0.48	25,300,419	10,529,144
2023	89,728	381,405	5,738,363.25	$15.05	$0.44	31,145,641	13,184,436
% Change	**22.80%**	**21.60%**	**14.40%**	**-5.90%**	**-8.30%**	**23.10%**	**25.20%**
Change	**16,632**	**67,808**	**$721,718.94**	**-$0.95**	**-$0.04**	**5,845,152**	**2,655,272**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

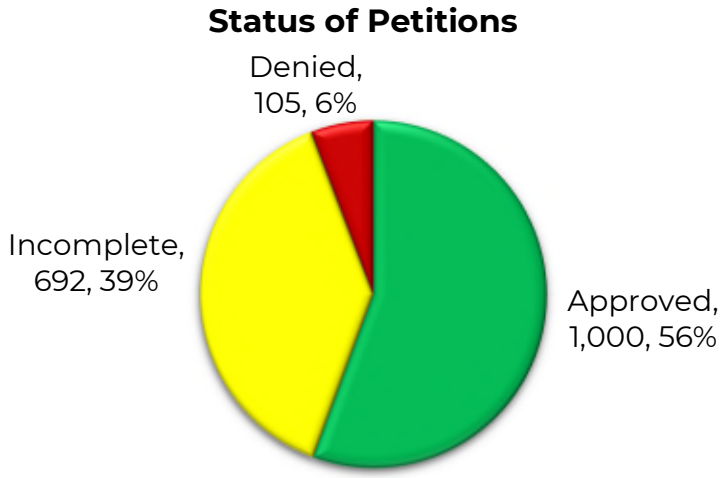
Demographics of Members Utilizing Fibromyalgia Medications



Top Prescriber Specialties of Fibromyalgia Medications by Number of Claims

Prior Authorization of Fibromyalgia Medications

There were 1,797 prior authorization requests submitted for fibromyalgia medications during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.



Market News and Updates[1]

Anticipated Patent Expiration(s):

- Savella® (milnacipran): September 2029

Recommendations

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

Utilization Details of Fibromyalgia Medications: Fiscal Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
GABAPENTIN PRODUCTS						
GABAPENTIN CAP 300MG	63,534	21,254	$903,434.54	$14.22	2.99	15.74%
GABAPENTIN TAB 600MG	33,542	7,947	$666,677.70	$19.88	4.22	11.62%
GABAPENTIN TAB 800MG	25,269	4,866	$588,797.09	$23.30	5.19	10.26%
GABAPENTIN CAP 100MG	22,582	9,915	$274,043.73	$12.14	2.28	4.78%
GABAPENTIN CAP 400MG	10,127	2,915	$152,722.74	$15.08	3.47	2.66%
GABAPENTIN SOL 250MG/5ML	1,768	342	$70,242.49	$39.73	5.17	1.22%
NEURONTIN CAP 300MG	12	1	$6,698.55	$558.21	12	0.12%
SUBTOTAL	**156,834**	**47,240**	**$2,662,616.84**	**$16.98**	**3.32**	**46.40%**
CYCLOBENZAPRINE PRODUCTS						
CYCLOBENZAPRINE TAB 10MG	53,621	24,804	$553,873.40	$10.33	2.16	9.65%
CYCLOBENZAPRINE TAB 5MG	15,318	9,313	$160,172.34	$10.46	1.64	2.79%
CYCLOBENZAPRINE TAB 7.5MG	1	1	$36.95	$36.95	1	0.00%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**68,940**	**34,118**	**$714,082.69**	**$10.36**	**2.02**	**12.44%**
DULOXETINE PRODUCTS						
DULOXETINE CAP 60MG	31,992	8,803	$520,156.61	$16.26	3.63	9.06%
DULOXETINE CAP 30MG	22,581	8,930	$332,672.12	$14.73	2.53	5.80%
DULOXETINE CAP 20MG	5,950	2,538	$89,269.35	$15.00	2.34	1.56%
DULOXETINE CAP 40MG	20	7	$2,139.72	$106.99	2.86	0.04%
CYMBALTA CAP 60MG	12	2	$6,721.40	$560.12	6	0.12%
CYMBALTA CAP 30MG	1	1	$273.12	$273.12	1	0.00%
SUBTOTAL	**60,556**	**20,281**	**$951,232.32**	**$15.71**	**2.99**	**16.58%**
TRAMADOL PRODUCTS						
TRAMADOL HCL TAB 50MG	37,768	14,820	$411,547.69	$10.90	4.41	7.17%
SUBTOTAL	**37,768**	**14,820**	**$411,547.69**	**$10.90**	**4.41**	**7.17%**
PREGABALIN PRODUCTS						
PREGABALIN CAP 150MG	7,255	1,567	$109,393.88	$15.08	4.63	1.91%
PREGABALIN CAP 75MG	6,459	2,218	$92,083.10	$14.26	2.91	1.60%
PREGABALIN CAP 100MG	5,782	1,609	$81,791.79	$14.15	3.59	1.43%
PREGABALIN CAP 50MG	4,071	1,633	$57,765.39	$14.19	2.49	1.01%
PREGABALIN CAP 200MG	3,081	573	$46,032.04	$14.94	5.38	0.80%
PREGABALIN CAP 300MG	1,851	303	$29,026.79	$15.68	6.11	0.51%
PREGABALIN CAP 25MG	1,137	608	$15,151.20	$13.33	1.87	0.26%
PREGABALIN CAP 225MG	401	85	$5,935.50	$14.80	4.72	0.10%
LYRICA CAP 200MG	98	16	$58,543.94	$597.39	6.13	1.02%
LYRICA CAP 150MG	52	13	$37,012.95	$711.779	4	0.65%
LYRICA CAP 300MG	43	7	$15,859.81	$368.83	6.14	0.28%
LYRICA CAP 75MG	40	10	$20,263.98	$506.60	4	0.35%
PREGABALIN SOL 20MG/5ML	38	11	$1,575.28	$41.45	3.45	0.03%
LYRICA CAP 100MG	37	8	$13,878.88	$375.10	4.63	0.24%
LYRICA CAP 50MG	25	6	$16,014.40	$640.58	4.17	0.28%
LYRICA CAP 25MG	18	6	$4,131.46	$229.53	3	0.07%
LYRICA CAP 225MG	2	2	$2,155.07	$1,077.54	1	0.04%
SUBTOTAL	**30,390**	**8,675**	**$606,615.46**	**$19.96**	**3.5**	**10.57%**
AMITRIPTYLINE PRODUCTS						
AMITRIPTYLINE TAB 25MG	8,777	3,356	$94,260.49	$10.74	2.62	1.64%
AMITRIPTYLINE TAB 50MG	6,288	2,014	$76,586.82	$12.18	3.12	1.33%
AMITRIPTYLINE TAB 10MG	5,468	2,179	$58,040.20	$10.61	2.51	1.01%
AMITRIPTYLINE TAB 100MG	3,294	819	$57,327.45	$17.40	4.02	1.00%
AMITRIPTYLINE TAB 75MG	1,588	450	$21,556.34	$13.57	3.53	0.38%
AMITRIPTYLINE TAB 150MG	1,361	301	$28,673.41	$21.07	4.52	0.50%
SUBTOTAL	**26,776**	**9,119**	**$336,444.71**	**$12.57**	**2.94**	**5.86%**
MILNACIPRAN PRODUCTS						
SAVELLA TAB 50MG	81	16	$30,869.53	$381.11	5.06	0.54%
SAVELLA TAB 100MG	46	7	$18,942.46	$411.79	6.57	0.33%
SAVELLA TAB 25MG	9	4	$4,045.93	$449.55	2.25	0.54%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SAVELLA MIS TITR PAK	5	5	$1,965.62	$393.12	1	0.03%
SUBTOTAL	**141**	**32**	**$55,823.54**	**$395.91**	**4.41**	**0.97%**
TOTAL	**381,405**	**89,728***	**$5,738,363.25**	**$15.05**	**4.25**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; HCL = hydrochloride; SOL = solution; TAB = tablet; TITR PAK = titration pack
Fiscal Year 2023 = 07/01/2022 to 06/30/2023
The utilization details include fibromyalgia medications used for all diagnoses and does not differentiate between fibromyalgia diagnoses and other diagnoses, for which use may be appropriate.

[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 12/2023. Last accessed 12/14/2023.

Fiscal Year 2023 Annual Review of Givlaari® (Givosiran) and Scenesse® (Afamelanotide)

Oklahoma Health Care Authority
Fiscal Year 2023 Print Report

Current Prior Authorization Criteria

Givlaari® (Givosiran) Approval Criteria:

1. An FDA approved diagnosis of acute hepatic porphyria (AHP) confirmed by:
   a. Genetic testing; or
   b. Elevated urinary porphobilinogen (PBG) and signs/symptoms of AHP; and
2. Member must be 18 years of age or older; and
3. Givlaari® must be administered in a health care setting by a health care professional prepared to manage anaphylaxis; and
   a. Givlaari® must be shipped to the health care setting where the member is scheduled to receive treatment; and
4. Prescriber must agree to monitor liver function tests prior to initiating treatment with Givlaari®, every month during the first 6 months of treatment, and as clinically indicated thereafter; and
5. Prescriber must agree to monitor renal function during treatment with Givlaari® as clinically indicated; and
6. Member must not be taking sensitive CYP1A2 or CYP2D6 substrates (e.g., caffeine, dextromethorphan, duloxetine, amitriptyline, olanzapine, fluoxetine, paroxetine, hydrocodone, tramadol) concomitantly with Givlaari®; and
7. 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
8. Initial approvals will be for the duration of 6 months. Further approval may be granted if the prescriber documents that the member is responding well to treatment as indicated by fewer porphyria attacks and that the member does not have elevated transaminase levels.

Scenesse® (Afamelanotide) Approval Criteria:

1. An FDA approved indication to increase pain-free light exposure in adult members with a history of phototoxic reactions from erythropoietic protoporphyria (EPP); and
   a. Diagnosis of EPP must be confirmed by genetic testing; and
2. Member must be 18 years of age or older; and

3. Scenesse® must be administered by a health care professional who is proficient in the subcutaneous implantation procedure and has completed the training program provided by the manufacturer prior to administration of the Scenesse® implant; and
    a. Scenesse® must be shipped via cold chain supply shipping and delivery to the health care setting where the member is scheduled to receive the implant administration; and
    b. Scenesse® must be stored under refrigeration (36 to 46°F) and protected from light prior to implantation; and
4. The Scenesse® implant should be inserted using an SFM Implantation Cannula or other implantation device that has been determined by the manufacturer to be suitable for implantation of Scenesse®; and
5. Prescriber must agree that the member will be monitored by a health care provider for at least 30 minutes after the implant administration; and
6. Prescriber must agree that the member will have a full body skin examination performed at least twice yearly while the member is being treated with Scenesse® to monitor pre-existing and new skin pigmentary lesions; and
7. Documentation that member will maintain sun and light protection measures during treatment with Scenesse® to prevent phototoxic reactions related to EPP; and
8. A quantity limit of 1 implant per 60 days will apply. Initial approvals will be for 2 implants for the duration of 4 months. Further approval may be granted if the prescriber documents the member is responding well to treatment as indicated by increased tolerance of sunlight (i.e., fewer phototoxic reactions).

Utilization of Givlaari® (Givosiran) and Scenesse® (Afamelanotide): Fiscal Year 2023

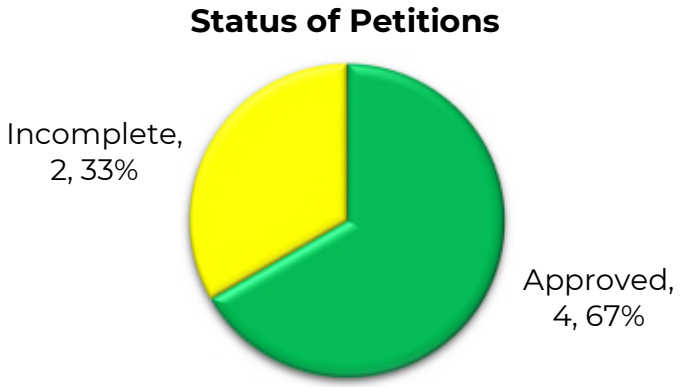
Comparison of Fiscal Years: Medical Claims

Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Total Units
2022	1	10	$403,371.36	$40,337.14	3,780
2023	2	15	$613,952.34	$40,930.16	5,610
% Change	**100.00%**	**50.00%**	**52.21%**	**1.47%**	**48.41%**
Change	**1**	**5**	**$210,580.98**	**$593.02**	**1,830**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Prior Authorization of Givlaari® (Givosiran) and Scenesse® (Afamelanotide)

There were 6 prior authorization requests submitted for 2 unique members for Givlaari® (givosiran) during fiscal year 2023. There were no prior authorization requests submitted for Scenesse® (afamelanotide) during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.



Market News and Updates[1,2]

Anticipated Patent Expiration(s):

- Scenesse® (afamelanotide): March 2029
- Givlaari® (givosiran): October 2034

Pipeline:

- **Afamelanotide:** Clinuvel is currently evaluating afamelanotide for multiple additional indications, including for the treatment of vitiligo, variegate porphyria, xeroderma pigmentosum, and arterial ischemic stroke, with all new investigational indications in Phase 2 clinical studies.

Recommendations

The College of Pharmacy does not recommend any changes to the current Givlaari® (givosiran) and Scenesse® (afamelanotide) prior authorization criteria at this time.

Utilization Details of Givlaari® (Givosiran) and Scenesse® (Afamelanotide): Fiscal Year 2023

Medical Claims

PRODUCT UTILIZED	+TOTAL CLAIMS	*TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
GIVOSIRAN INJ 0.5MG J0223	15	2	$613,952.34	$40,930.16	7.5	100%
TOTAL	**15**	**2**	**$613,952.34**	**$40,930.16**	**7.5**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
+Total number of unduplicated claims.
INJ = injection
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 12/2023. Last accessed 12/08/2023.
[2] Clinuvel. Pharmaceutical Technology: Pipeline. Available online at: https://www.clinuvel.com/pharmaceutical-technology/#Pipeline. Last accessed 12/08/2023.

Fiscal Year 2023 Annual Review of Gonadotropin-Releasing Hormone (GnRH) Medications

Oklahoma Health Care Authority
Fiscal Year 2023 Print Report

Current Prior Authorization Criteria

Gonadotropin-Releasing Hormone (GnRH) Agonist Medications		
Tier-1	**Tier-2**	**Tier-3**
histrelin (Supprelin® LA)		
leuprolide (Fensolvi®)		
leuprolide (Lupron Depot®)		
leuprolide (Lupron Depot-Ped®)		
nafarelin (Synarel®)		
triptorelin (Triptodur®)		

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).

Lupaneta Pack® [Leuprolide Acetate for Depot Suspension (3.75mg for Intramuscular Injection) and Norethindrone Acetate Tablet (5mg for Oral Administration)] Approval Criteria:

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

Myfembree® (Relugolix/Estradiol/Norethindrone) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women; or
    b. Moderate-to-severe pain associated with endometriosis in premenopausal women; and
2. Member must be 18 years of age or older; and
3. Member must not have any contraindications to therapy including:
    a. Osteoporosis; and
    b. Pregnancy; and
        i. Female members must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
        ii. Female members of reproductive potential must be willing to use effective non-hormonal contraception during treatment and for at least 1 week after discontinuing treatment; and
    c. Hepatic impairment or disease; and
    d. Undiagnosed abnormal uterine bleeding; and

e. High risk of arterial, venous thrombotic, or thromboembolic disease, including uncontrolled hypertension; and
f. Current or history of breast cancer or other hormonally-sensitive malignancies; and
g. Known hypersensitivity to ingredients in Myfembree®; and
4. Must be prescribed by, or in consultation with, an obstetrician/gynecologist or a specialist with expertise in the treatment of uterine leiomyomas (fibroids) or endometriosis; and
5. A failed trial at least 1 month in duration with nonsteroidal anti-inflammatory drugs (NSAIDs) or a patient-specific, clinically significant reason why the member cannot use NSAIDs; and
6. A failed trial at least 3 months in duration of hormonal contraceptives or a patient-specific, clinically significant reason why the member cannot use hormonal contraceptives; and
7. A quantity limit of 28 tablets per 28 days will apply; and
8. Lifetime approval duration will be limited to a maximum of 24 months. For members previously approved for Oriahnn® or Orilissa®, a combined cumulative maximum treatment duration of 24 months will apply.

Oriahnn® (Elagolix/Estradiol/Norethindrone and Elagolix) Approval Criteria:

1. An FDA approved diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women; and
2. Member must be 18 years of age or older; and
3. Member must not have any contraindications to therapy including:
   a. Osteoporosis; and
   b. Pregnancy; and
      i. Female members must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
      ii. Female members of reproductive potential must be willing to use effective non-hormonal contraception during treatment and for at least 1 week after discontinuing treatment; and
   c. Hepatic impairment or disease; and
   d. Undiagnosed abnormal uterine bleeding; and
   e. High risk of arterial, venous thrombotic, or thromboembolic disease, including uncontrolled hypertension; and
   f. Current or history of breast cancer or other hormonally-sensitive malignancies; and
   g. Known hypersensitivity to ingredients in Oriahnn®; and
   h. Prescriber must verify the member will not use Oriahnn® concomitantly with an organic anion transporting polypeptide (OATP) 1B1 inhibitor (e.g., cyclosporine, gemfibrozil); and

4. Must be prescribed by, or in consultation with, an obstetrician/gynecologist or a specialist with expertise in the treatment of uterine leiomyomas (fibroids); and
5. A failed trial at least 1 month in duration with nonsteroidal anti-inflammatory drugs (NSAIDs) or a patient-specific, clinically significant reason why the member cannot use NSAIDs; and
6. A failed trial at least 3 months in duration of hormonal contraceptives or a patient-specific, clinically significant reason why the member cannot use hormonal contraceptives; and
7. A patient-specific, clinically significant reason why the member cannot use leuprolide depot formulations available without prior authorization must be provided; and
8. A patient-specific, clinically significant reason why the member cannot use Myfembree® (relugolix/estradiol/norethindrone) must be provided; and
9. A quantity limit of 56 tablets per 28 days will apply; and
10. Lifetime approval duration will be limited to a maximum of 24 months. For members previously approved for Myfembree®, a combined cumulative maximum treatment duration of 24 months will apply.

Orilissa® (Elagolix) Approval Criteria:

1. An FDA approved diagnosis of moderate-to-severe pain associated with endometriosis; and
2. Member must be 18 years of age or older; and
3. Member must not have known osteoporosis; and
4. Female members must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
5. Female members of reproductive potential must be willing to use effective non-hormonal contraception during treatment with Orilissa® and for at least 1 week after discontinuing treatment; and
6. Member must not have severe hepatic impairment (Child-Pugh C); and
7. Member must not be taking a strong organic anion transporting polypeptide (OATP) 1B1 inhibitor (e.g., cyclosporine, gemfibrozil); and
8. Orilissa® must be prescribed by, or in consultation with, an obstetrician/gynecologist or a specialist with expertise in the treatment of endometriosis; and
9. A failed trial at least 1 month in duration with nonsteroidal anti-inflammatory drugs (NSAIDs) or a patient-specific, clinically significant reason why the member cannot use NSAIDs must be provided; and
10. A failed trial at least 3 months in duration of hormonal contraceptives or a patient-specific, clinically significant reason why the member cannot use hormonal contraceptives must be provided; and
11. Dosing and lifetime approval duration will be limited based on the following:

a. Coexisting condition of moderate hepatic impairment (Child-Pugh B):
    i. 150mg once daily for a maximum of 6 months; or
b. Normal liver function or mild hepatic impairment (Child-Pugh A):
    i. 150mg once daily for a maximum of 24 months; or
    ii. 200mg twice daily for a maximum of 6 months.

Utilization of GnRH Medications: Fiscal Year 2023

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	213	525	$2,729,468.39	$5,198.99	$79.89	8,809	34,166
2023	310	860	$4,031,336.69	$4,687.60	$81.86	16,740	49,248
% Change	**45.50%**	**63.80%**	**47.70%**	**-9.80%**	**2.50%**	**90.00%**	**44.10%**
Change	**97**	**335**	**$1,301,868.30**	**-$511.39**	**$1.97**	**7,931**	**15,082**

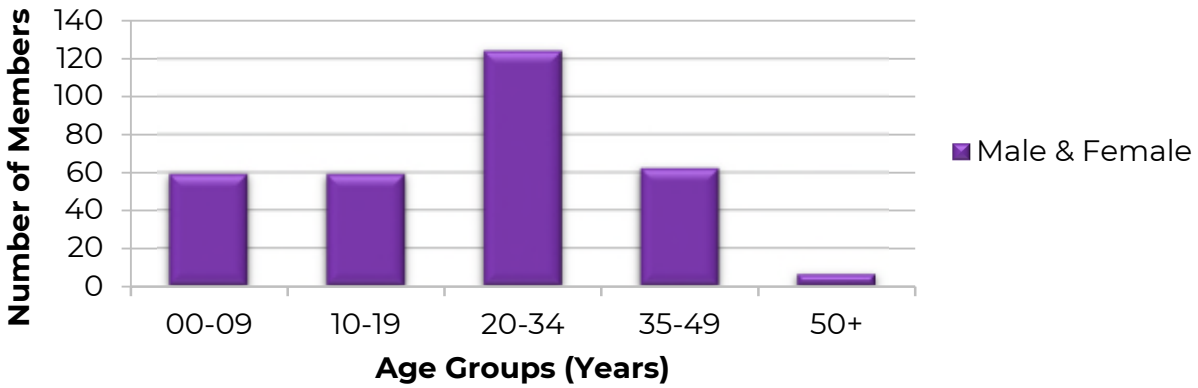
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Comparison of Fiscal Years: Medical Claims

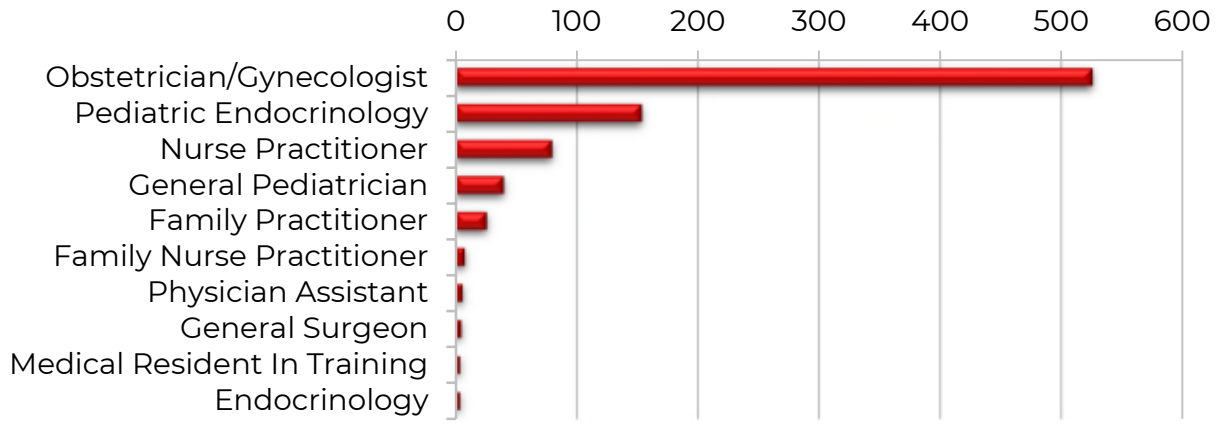
Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2022	137	364	$361,206.58	$992.33	2.66
2023	181	485	$532,786.62	$1,098.53	2.68
% Change	**32.12%**	**33.24%**	**47.50%**	**10.70%**	**0.75%**
Change	**44**	**121**	**$171,580.04**	**$106.20**	**0.02**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Demographics of Members Utilizing GnRH Medications: Pharmacy Claims



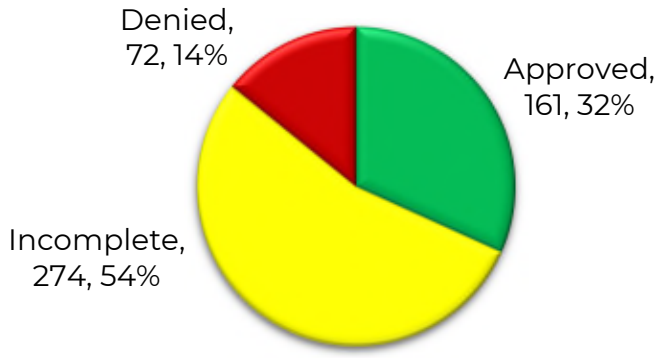
Top Prescriber Specialties of GnRH Medications by Number of Claims: Pharmacy Claims



Prior Authorization of GnRH Medications

There were 507 prior authorization requests submitted for GnRH medications during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

Status of Petitions



Market News and Updates[1,2,3]

Anticipated Patent Expiration(s):

- Supprelin® LA (histrelin implant): June 2026
- Triptodur® (triptorelin injection): June 2029
- Lupron Depot-Ped® (leuprolide 45mg injection): February 2031
- Myfembree® (relugolix/estradiol/norethindrone tablet): May 2038
- Oriahnn® (elagolix/estradiol/norethindrone and elagolix capsule): August 2040
- Orilissa® (elagolix tablet): August 2040
- Fensolvi® (leuprolide acetate injection): December 2041

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

- **April 2023:** The FDA approved a new 45mg strength of Lupron Depot-Ped® (leuprolide) for the treatment of pediatric patients with central precocious puberty (CPP). The 45mg strength is administered as an intramuscular (IM) injection every 6 months. Previously, Lupron Depot-Ped® was available in 7.5mg, 11.25mg, or 15mg strengths (for IM injection every month) or 11.25mg or 30mg strengths (for IM injection every 3 months).

Recommendations

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

Utilization Details of GnRH Medications: Fiscal Year 2023

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
GONADOTROPIN-RELEASING HORMONE (GnRH) ANTAGONIST PRODUCTS						
ORILISSA TAB 150MG	318	90	$327,395.70	$1,029.55	3.53	8.12%
ORILISSA TAB 200MG	67	31	$66,963.31	$999.45	2.16	1.66%
ORIAHNN CAP 300-1-0.5MG & 300MG	59	10	$61,136.47	$1,036.21	5.9	1.52%
MYFEMBREE TAB 40-1-0.5MG	14	7	$14,826.66	$1,059.05	2	0.37%
SUBTOTAL	**458**	**136***	**$470,322.14**	**$1,026.90**	**3.37**	**11.67%**
GONADOTROPIN-RELEASING HORMONE (GnRH) AGONIST PRODUCTS						
LUPRON DEPOT INJ 3.75MG	101	33	$157,148.24	$1,555.92	3.06	3.90%
TRIPTODUR SUS 22.5MG	87	54	$1,526,540.71	$17,546.44	1.61	37.87%
LUPRON DEP-PED INJ 30MG	87	27	$999,714.57	$11,490.97	3.22	24.80%
LUPRON DEPOT INJ 11.25MG	62	36	$288,919.44	$4,659.99	1.72	7.17%
LUPRON DEP-PED INJ 15MG	16	3	$22,013.61	$1,375.85	5.33	0.55%
LUPRON DEPOT INJ 22.5MG	15	8	$83,563.95	$5,570.93	1.88	2.07%
FENSOLVI INJ 45MG	15	11	$344,675.85	$22,978.39	1.36	8.55%
LUPRON DEP-PED INJ 11.25MG	12	8	$124,502.28	$10,375.19	1.5	3.09%
LUPRON DEPOT INJ 7.5MG	3	2	$5,682.80	$1,894.27	1.5	0.14%
LEUPROLIDE INJ 1MG/0.2ML	2	2	$1,434.16	$717.08	1	0.04%
LUPRON DEP-PED INJ 11.25MG	2	1	$6,818.94	$3,409.47	2	0.17%
SUBTOTAL	**402**	**176***	**$3,561,014.55**	**$8,858.25**	**2.28**	**88.33%**
TOTAL	**860**	**310***	**$4,031,336.69**	**$4,687.60**	**2.77**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; DEP = depot; INJ = injection; PED= pediatric; SUS = suspension; TAB = tablet
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
J9217 LEUPROLIDE DEPOT 7.5MG	292	122	$151,551.98	$519.01	2.39
J1950 LEUPROLIDE DEPOT 3.75MG	184	51	$380,857.59	$2,069.88	3.61
J9218 LEUPROLIDE INJ 1MG	9	8	$377.05	$41.89	1.13
TOTAL	**485**	**181**	**$532,786.62**	**$1,098.53**	**2.68**

Costs do not reflect rebated prices or net costs.
+Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
INJ = injection
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 12/2023. Last accessed 12/11/2023.
[2] U.S. FDA. Supplemental Approval Letter. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/020263Orig1s053ltr.pdf. Issued 04/14/2023. Last accessed 12/11/2023.
[3] Lupron Depot-Ped® (Leuprolide Acetate for Depot Suspension) Prescribing Information. AbbVie, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020263s053lbl.pdf. Last revised 04/2023. Last accessed 12/11/2023.

Fiscal Year 2023 Annual Review of Iron Chelating Agents

Oklahoma Health Care Authority
Fiscal Year 2023 Print Report

Current Prior Authorization Criteria

Jadenu® (Deferasirox), Jadenu® Sprinkle (Deferasirox), and Ferriprox® (Deferiprone) Approval Criteria:

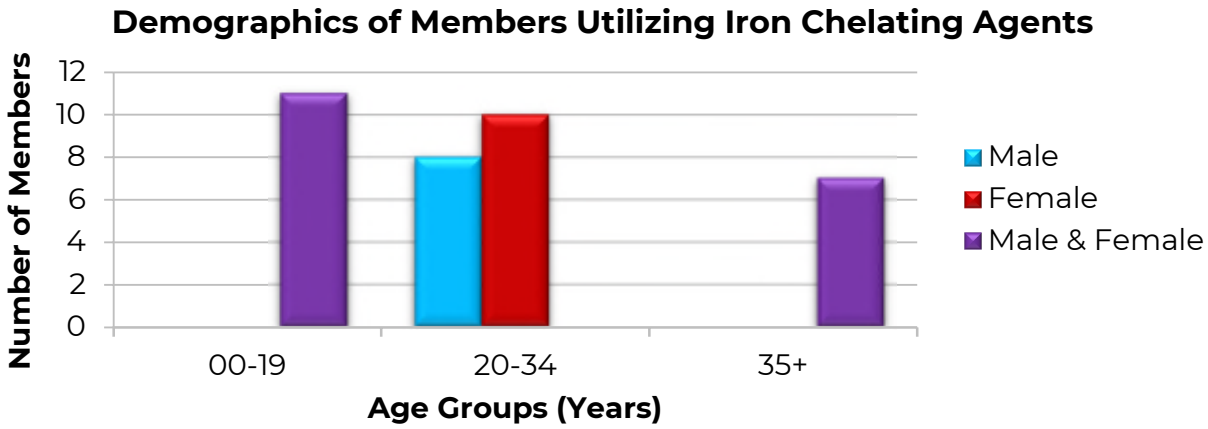
1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason other than convenience why the member cannot use Exjade® (deferasirox) must be provided; and
3. For Jadenu® Sprinkle (deferasirox oral granules), an age restriction of 6 years of age and younger will apply. Members older than 6 years of age will require a patient-specific, clinically significant reason why Jadenu® oral tablets cannot be used even when the tablets are crushed; 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.

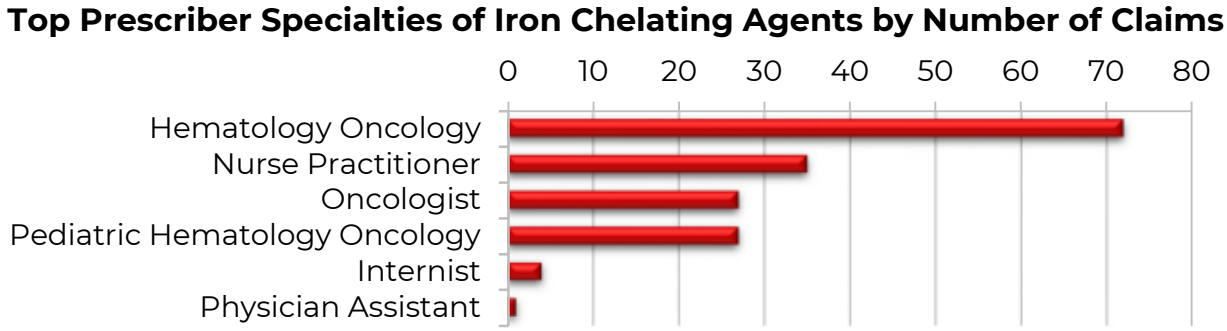
Utilization of Iron Chelating Agents: Fiscal Year 2023

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	40	182	$965,455.14	$5,304.70	$174.43	14,310	5,535
2023	36	166	$571,972.46	$3,445.62	$110.53	13,710	5,175
% Change	**-10.00%**	**-8.80%**	**-40.80%**	**-35.00%**	**-36.60%**	**-4.20%**	**-6.50%**
Change	**-4**	**-16**	**-$393,482.68**	**-$1,859.08**	**-$63.90**	**-600**	**-360**

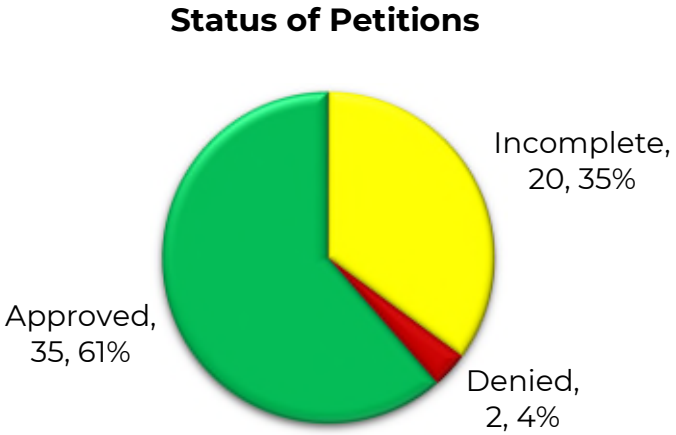
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023





Prior Authorization of Iron Chelating Agents

There were 57 prior authorization requests submitted for iron chelating agents during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.



Market News and Updates[1]

Anticipated Patent Expiration(s):

- Jadenu® (deferasirox): November 2034
- Ferriprox® (deferiprone): October 2038

Recommendations

The College of Pharmacy does not recommend any changes to the current iron chelating agents prior authorization criteria at this time.

Utilization Details of Iron Chelating Agents: Fiscal Year 2023

BRAND NAME	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
DEFERASIROX PRODUCTS						
DEFERASIROX TAB 360MG	71	18	$17,355.02	$244.44	3.94	3.03%
DEFERASIROX TAB 500MG	23	9	$33,953.99	$1,476.26	2.56	5.94%
DEFERASIROX GRA 360MG	16	2	$90,588.08	$5,661.76	8	15.84%
DEFERASIROX TAB 180MG	13	4	$3,338.57	$256.81	3.25	0.58%
DEFERASIROX TAB 250MG	12	2	$8,618.74	$718.23	6	1.51%
JADENU TAB 360MG	11	1	$121,898.51	$11,081.68	11	21.31%
DEFERASIROX GRA 90MG	5	2	$5,441.15	$1,088.23	2.5	0.95%
EXJADE TAB 500MG	2	2	$33,526.40	$16,763.20	1	5.86%
EXJADE TAB 125MG	1	1	$4,001.98	$4,001.98	1	0.70%
DEFERASIROX TAB 125MG	1	1	$762.40	$762.40	1	0.13%
SUBTOTAL	**155**	**42**	**$319,484.84**	**$2,061.19**	**3.69**	**55.86%**
DEFERIPRONE PRODUCTS						
FERRIPROX TAB 1,000MG	11	1	$252,487.62	$22,953.42	11	44.14%
SUBTOTAL	**11**	**1**	**$252,487.62**	**$22,953.42**	**11**	**44.14%**
TOTAL	**166**	**36***	**$571,972.46**	**$3,445.62**	**4.61**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
GRA = granule; TAB = tablet
Please note, Exjade® was first FDA approved in 2005 and has a significant federal rebate.
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

[1] U.S. Food and Drug Administration (FDA): Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 12/2023. Last Accessed 12/04/2023.

Fiscal Year 2023 Annual Review of Luxturna® (Voretigene Neparvovec-rzyl)

Oklahoma Health Care Authority
Fiscal Year 2023 Print Report

Current Prior Authorization Criteria

Luxturna® (Voretigene Neparvovec-rzyl) Approval Criteria:

1. An FDA approved diagnosis of biallelic *RPE65* mutation-associated retinal dystrophy; and
    a. Diagnosis must be confirmed by genetic testing; and
2. Member must have sufficient viable retinal cells in both eyes as determined by the treating physician(s); and
3. Member must have best corrected visual acuity of 20/60 or worse in both eyes and/or visual field <20 degrees in any meridian in both eyes; and
4. Member must be 4 years of age or older; and
5. Member must not have participated in a previous *RPE65* gene therapy study or have previously received treatment with Luxturna®; and
6. Member must not have had intraocular surgery in the past 6 months; and
7. Female members of childbearing age must not be pregnant and must have a negative pregnancy test immediately prior to administration of Luxturna®; and
8. Male and female members of childbearing age must be willing to use effective contraception during treatment with Luxturna® and for at least 4 months after administration of Luxturna®; and
9. Member must take the recommended systemic oral corticosteroid regimen, starting 3 days prior to administration of Luxturna® to each eye, and continuing after administration of Luxturna®, as per package labeling; and
10. Luxturna® must be prescribed and administered by a retinal surgeon with expertise in the treatment of biallelic *RPE65* mutation-associated retinal dystrophy and in the administration of Luxturna® at an Ocular Gene Therapy Treatment Center; and
    a. Luxturna® must be shipped via cold chain supply shipping and delivery to the Ocular Gene Therapy Treatment Center where the member is scheduled to receive treatment; and
    b. Luxturna® must be stored frozen prior to preparation for administration (Luxturna® should be administered within 4 hours of preparation); and

c. The receiving facility must have a mechanism in place to track patient-specific Luxturna® from receipt to storage to administration; and

11. Luxturna® must be administered subretinally to each eye on separate days within a close interval, but no fewer than 6 days apart; and
    a. The scheduled procedure date for each eye must be provided; and
12. Only 1 single-dose vial per eye will be approved per member per lifetime; and
    a. Each single-dose vial of Luxturna® is to be dispensed immediately prior to the scheduled procedure for the specific eye; or
13. A prior authorization request with patient-specific information may be submitted for consideration of Luxturna® for members not meeting all of the current prior authorization criteria requirements.

Utilization of Luxturna® (Voretigene Neparvovec-rzyl): Fiscal Year 2023

Fiscal Year 2023 Utilization: Medical Claims

Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2023	1	2	$636,009.62	$318,004.81	2

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
Fiscal Year 2023 = 07/01/2022 to 06/30/2023
Please note: There were no paid medical claims for Luxturna® during fiscal year 2022 (07/01/2021 to 06/30/2022) to allow for a fiscal year comparison.

Demographics of Members Utilizing Luxturna® (Voretigene Neparvovec-rzyl)

- Due to the limited number of members utilizing Luxturna® (voretigene neparvovec-rzyl) detailed demographic information could not be provided.

Top Prescriber Specialties of Luxturna® (Voretigene Neparvovec-rzyl) by Number of Claims

- The only prescriber specialty listed on approved prior authorization requests for Luxturna® (voretigene neparvovec-rzyl) during fiscal year 2023 was ophthalmologist.

Prior Authorization of Luxturna® (Voretigene Neparvovec-rzyl)

There was 1 prior authorization request submitted for Luxturna® (voretigene neparvovec-rzyl) during fiscal year 2023 which was approved.

Recommendations

The College of Pharmacy does not recommend any changes to the current Luxturna® (voretigene neparvovec-rzyl) prior authorization criteria at this time.

Utilization Details of Luxturna® (Voretigene Neparvovec-rzyl): Fiscal Year 2023

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
LUXTURNA INJ J3398	2	1	$636,009.62	$318,004.81	2
TOTAL	**2†**	**1***	**$636,009.62**	**$318,004.81**	**2**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Fiscal Year 2023 Annual Review of Mycapssa® (Octreotide) and Signifor® LAR (Pasireotide)

Oklahoma Health Care Authority
Fiscal Year 2023 Print Report

Current Prior Authorization Criteria

Mycapssa® (Octreotide) Approval Criteria:

1. An FDA approved indication for long-term maintenance treatment in members with acromegaly who have responded to and tolerated treatment with octreotide or lanreotide; and
2. Member has elevated insulin-like growth factor-1 (IGF-1) levels for age and/or gender; and
3. Member has a documented trial with injectable octreotide or lanreotide, and the prescriber must verify that the member responded to and tolerated treatment with octreotide or lanreotide; and
4. A patient-specific, clinically significant reason why the member cannot continue treatment with injectable octreotide or lanreotide must be provided; and
5. Must be prescribed by, or in consultation with, an endocrinologist; and
6. Prescriber must document that the member has had an inadequate response to surgery or is not a candidate for surgery; and
7. Initial approvals will be for the duration of 12 months. Reauthorization may be granted if the prescriber documents the member's IGF-1 level has decreased or normalized since initiating treatment; and
8. A quantity limit of 120 capsules per 30 days will apply.

Signifor® LAR (Pasireotide) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. Members with acromegaly who have had an inadequate response to surgery or for whom surgery is not an option; or
    b. Members with Cushing's disease from a pituitary tumor for whom pituitary surgery is not an option or has not been curative; and
2. For a diagnosis of acromegaly, the member must have a documented trial with long-acting octreotide or lanreotide depot with an inadequate response or have a patient-specific, clinically significant reason why the other long-acting release (LAR) somatostatin analogs (SSAs) are not appropriate for the member; and
3. Must be prescribed by, or in consultation with, an endocrinologist; and
4. Must be administered by a health care professional; and
5. Prescriber must document that the member has had an inadequate response to surgery or is not a candidate for surgery; and

6. Prescriber must verify liver function tests (LFTs) (e.g., ALT, AST, bilirubin) will be monitored when starting treatment and periodically thereafter; and
7. Authorizations will be for the duration of 12 months; and
8. Reauthorization may be granted if the prescriber documents the member is responding well to treatment.

Utilization of Mycapssa® (Octreotide) and Signifor® LAR (Pasireotide): Fiscal Year 2023

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	1	7	$100,183.71	$14,311.96	$511.14	7	196
2023	1	12	$185,541.39	$15,461.78	$552.21	12	336
% Change	**0.00%**	**71.40%**	**85.20%**	**8.00%**	**8.00%**	**71.40%**	**71.40%**
Change	**0**	**5**	**$85,357.68**	**$1,149.82**	**$41.07**	**5**	**140**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Demographics of Members Utilizing Mycapssa® (Octreotide) and Signifor® LAR (Pasireotide)

- Due to the limited number of members utilizing Mycapssa® (octreotide) and Signifor® LAR (pasireotide) during fiscal year 2023, detailed demographic information could not be provided.

Top Prescriber Specialties of Mycapssa® (Octreotide) and Signifor® LAR (Pasireotide) by Number of Claims

- The only prescriber specialty listed on paid pharmacy claims for Mycapssa® (octreotide) and Signifor® LAR (pasireotide) during fiscal year 2023 was endocrinologist.

Prior Authorization of Mycapssa® (Octreotide) and Signifor® LAR (Pasireotide)

There were 4 prior authorization requests submitted for 2 unique members for Signifor® LAR (pasireotide) and 1 prior authorization request submitted for 1 member for Mycapssa® (octreotide) during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

Status of Petitions

Market News and Updates[1,2,3]

Anticipated Patent Expiration(s):

- Signifor® LAR (pasireotide): May 2028
- Mycapssa® (octreotide): February 2036

Pipeline:

- **Octreotide Subcutaneous (Sub-Q) Depot:** A 24-week Phase 3, randomized, double-blind, placebo-controlled study, ACROINNOVA 1, evaluated the safety and efficacy of a sub-Q formulation of octreotide in patients with acromegaly. The sub-Q formulation is given once monthly in a prefilled syringe that can be self-administered by patients. The primary and key secondary endpoints were both met. An open-label, Phase 3 long-term safety and extension study of octreotide sub-Q depot, ACROINNOVA 2, is currently ongoing.
- **Paltusotine:** Paltusotine is a once-daily oral drug being studied for patients with acromegaly. It was studied in the Phase 3 PATHFNDR-1 study which assessed paltusotine in patients who were already controlled on octreotide or lanroetide depot monotherapy. Patients were randomized 1:1 to receive paltusotine or placebo. The primary endpoint was the proportion of patients maintaining the insulin-like growth factor-1 (IFG-1) level after switching from octreotide and lanroetide. The results showed that 83% of patients on paltusotine maintained IGF-1 ≤1.0 x upper limit of normal (ULN) versus 4% on placebo. PATHFNDR-2, a Phase 3 study, is currently ongoing and is studying the use of paltusotine in patients with acromegaly who are treatment naïve or not currently receiving medical therapy.

Recommendations

The College of Pharmacy does not recommend any changes to the current Mycapssa® (octreotide) and Signifor® LAR (pasireotide) prior authorization criteria at this time.

Utilization Details of Mycapssa® (Octreotide) and Signifor® LAR (Pasireotide): Fiscal Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SIGNIFOR LAR INJ 40MG	11	1	$169,587.99	$15,417.09	11	91.40%
SIGNIFOR LAR INJ 60MG	1	1	$15,953.40	$15,953.40	1	8.60%
TOTAL	**12**	**1***	**$185,541.39**	**$15,461.78**	**12**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
INJ = injection
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

[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 12/2023. Last accessed 12/06/2023.
[2] Camurus. Camurus' Octreotide SC Depot (CAM2029) Achieves Superior Treatment Response Compared to Placebo in Phase 3 Acromegaly Trial. Available online at: https://www.camurus.com/media/press-releases/2023/camurus-octreotide-sc-depot-cam2029-achieves-superior-treatment-response-compared-to-placebo-in-phase-3-acromegaly-trial/. Issued 06/20/2023. Last accessed 12/08/2023.
[3] Crinetics Pharmaceuticals. Crinetics' Once-Daily Oral Paltusotine Achieved the Primary and All Secondary Endpoints in the Phase 3 PATHFNDR-1 Study Evaluating Treatment of Patients with Acromegaly. Available online at: https://crinetics.com/crinetics-paltusotine-achieved-primary-and-secondary-endpoints-in-phase-3-pathfndr-1-acromegaly-study/. Issued 09/10/2023. Last accessed 12/12/2023.

Fiscal Year 2023 Annual Review of Northera® (Droxidopa)

Oklahoma Health Care Authority
Fiscal Year 2023 Print Report

Current Prior Authorization Criteria

Northera® (Droxidopa) Approval Criteria:

1. An FDA approved diagnosis of symptomatic neurogenic orthostatic hypotension caused by primary autonomic failure (e.g., Parkinson's disease, multiple system atrophy, pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy; and
2. Member must be 18 years of age or older; and
3. Member must have tried and failed 2 of the following medications at recommended dosing within the last 90 days (or have a contraindication to all preferred medications):
   a. Midodrine; or
   b. Fludrocortisone; or
   c. Pyridostigmine; and
4. Initial approval will be for the duration of 2 weeks of treatment only; and
5. Continued approvals will require the prescriber to provide information regarding improved member response/effectiveness of this medication to determine whether Northera® is continuing to provide a benefit; and
6. Continued approvals will be for the duration of 3 months. Each approval will require prescriber documentation of member response/ effectiveness of Northera®.

Utilization of Northera® (Droxidopa): Fiscal Year 2023

Comparison of Fiscal Years

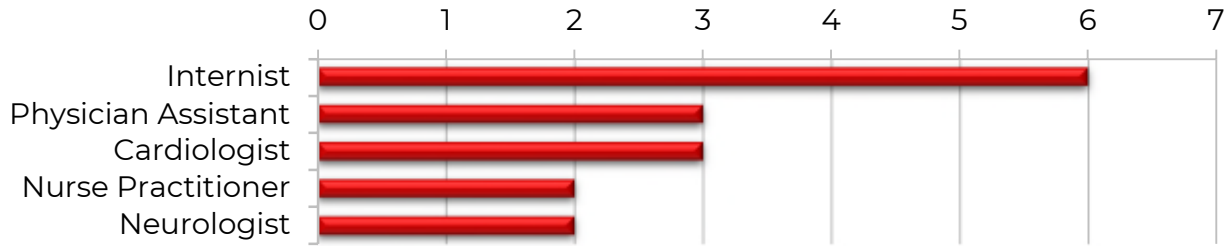
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	2	6	$657.80	$109.63	$5.14	534	128
2023	3	16	$2,250.30	$140.64	$5.26	1,884	428
% Change	**50.0%**	**166.7%**	**242.1%**	**28.3%**	**2.3%**	**252.8%**	**234.4%**
Change	**1**	**10**	**$1,592.50**	**$31.01**	**$0.12**	**1,350**	**300**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Demographics of Members Utilizing Northera® (Droxidopa)

- Due to the limited number of members utilizing Northera® (droxidopa) during fiscal year 2023, detailed demographic information could not be provided.

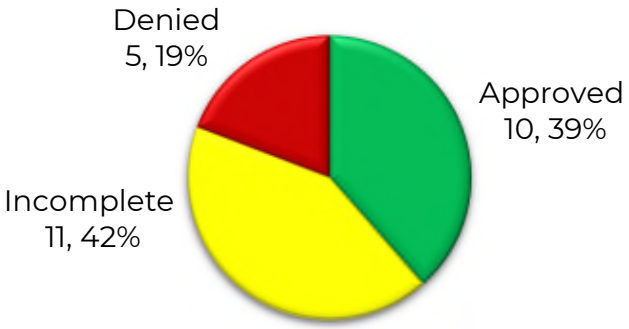
Top Prescriber Specialties of Northera® (Droxidopa) by Number of Claims



Prior Authorization of Northera® (Droxidopa)

There were 26 prior authorization requests submitted for Northera® (droxidopa) during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

Status of Petitions



Market News and Updates[1]

Pipeline

- **Ampreloxetine (TD-9855):** Ampreloxetine is an investigational, once-daily norepinephrine reuptake inhibitor (NRI) that is currently in development for the treatment of patients with symptomatic neurogenic orthostatic hypotension (nOH). Ampreloxetine binds to norepinephrine transporters and increases extracellular norepinephrine concentrations by blocking the action of these transporters. A Phase 3 16-week open label/6-week randomized withdrawal study of ampreloxetine showed positive results in patients with nOH, including preventing symptom worsening and blood pressure decreases. Ampreloxetine is currently being evaluated in an extension Phase 3 study in patients with symptomatic nOH.

Recommendations

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

Utilization Details of Northera® (Droxidopa): Fiscal Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
DROXIDOPA 100MG CAP	16	3	$2,250.30	$5.26	$140.64	100%
TOTAL	**16**	**3***	**$2,250.30**	**$5.26**	**$140.64**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

[1] Theravance Biopharma. Our Pipeline. Available online at: https://www.theravance.com/our-pipeline. Last accessed 10/02/2023.

Fiscal Year 2023 Annual Review of Pancreatic Enzymes

Oklahoma Health Care Authority
Fiscal Year 2023 Print Report

Current Prior Authorization Criteria

Pancreaze®, Pertzye®, and Viokace® Approval Criteria:

1. An FDA approved diagnosis of pancreatic insufficiency; and
2. Documented trials of inadequate response to Creon® and Zenpep® or a patient-specific, clinically significant reason why the member cannot use Creon® or Zenpep® must be provided.

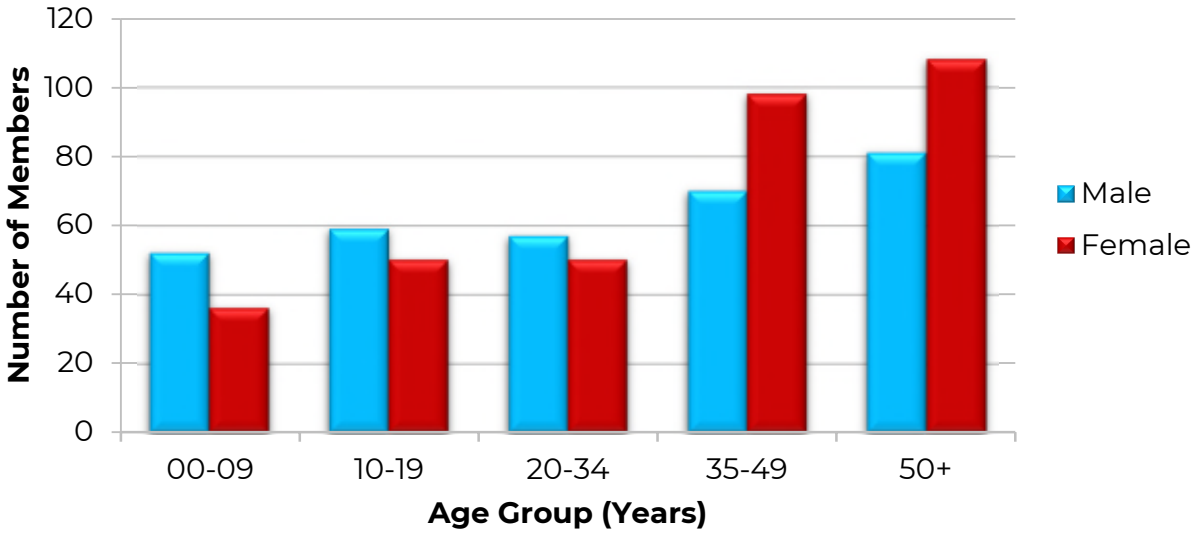
Utilization of Pancreatic Enzymes: Fiscal Year 2023

Comparison of Fiscal Years

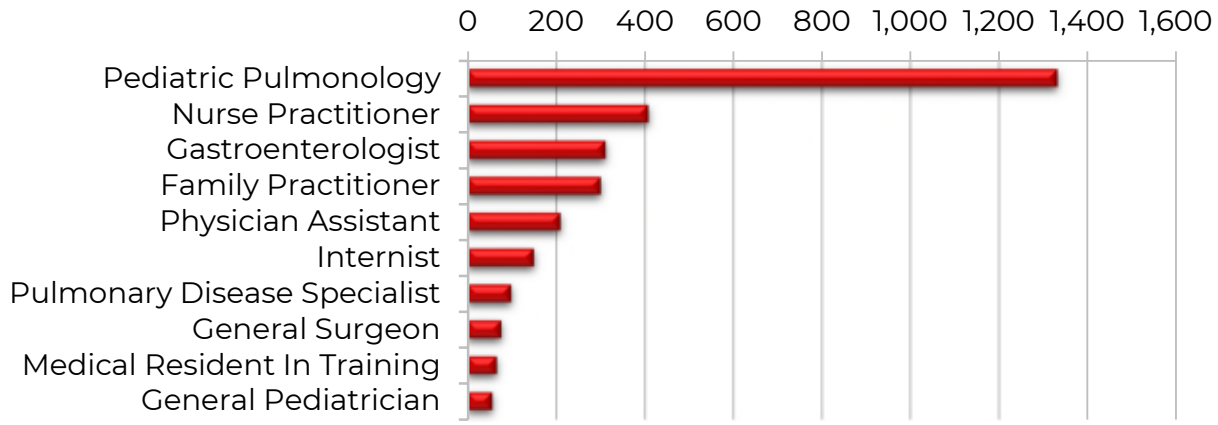
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	539	2,652	$5,985,083.62	$2,256.82	$77.40	887,410	77,329
2023	661	3,250	$7,597,956.86	$2,337.83	$79.85	1,062,049	95,154
% Change	**22.6%**	**22.5%**	**26.9%**	**3.6%**	**3.2%**	**19.7%**	**23.1%**
Change	**122**	**598**	**$1,612,873.24**	**$81.01**	**$2.45**	**174,639**	**17,825**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Demographics of Members Utilizing Pancreatic Enzymes



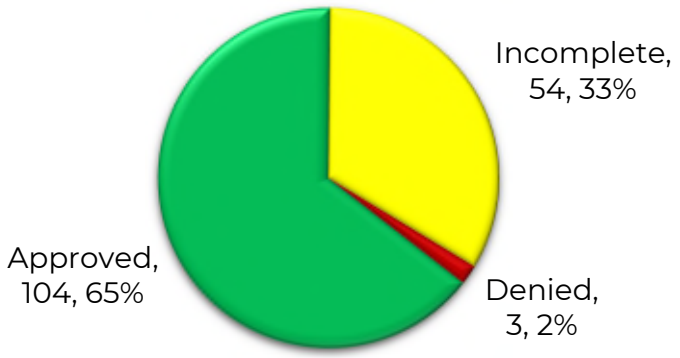
Top Prescriber Specialties of Pancreatic Enzymes by Number of Claims



Prior Authorization of Pancreatic Enzymes

There were 161 prior authorization requests submitted for pancreatic enzymes during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

Status of Petitions



Recommendations

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

Utilization Details of Pancreatic Enzymes: Fiscal Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
CREON®						
CREON CAP 36,000 UNIT	766	203	$2,107,256.76	$2,750.99	3.77	27.73%
CREON CAP 12,000 UNIT	474	118	$495,830.48	$1,046.06	4.02	6.53%
CREON CAP 24,000 UNIT	468	104	$1,132,761.31	$2,420.43	4.5	14.91%
CREON CAP 6,000 UNIT	150	40	$67,406.50	$449.38	3.75	0.89%
CREON CAP 3,000 UNIT	63	23	$15,059.80	$239.04	2.74	0.20%
SUBTOTAL	**1,921**	**488**	**$3,818,314.85**	**$1,987.67**	**3.94**	**50.25%**
ZENPEP®						
ZENPEP CAP 40,000 UNIT	352	91	$1,375,911.99	$3,908.84	3.87	18.11%
ZENPEP CAP 10,000 UNIT	187	35	$283,591.69	$1,516.53	5.34	3.73%
ZENPEP CAP 25,000 UNIT	132	25	$484,698.67	$3,671.96	5.28	6.38%
ZENPEP CAP 20,000 UNIT	107	23	$245,555.72	$2,294.91	4.65	3.23%
ZENPEP CAP 5,000 UNIT	73	18	$43,754.30	$599.37	4.06	0.58%
ZENPEP CAP 15,000 UNIT	46	9	$106,726.59	$2,320.14	5.11	1.40%
ZENPEP CAP 3,000 UNIT	12	5	$4,003.59	$333.63	2.4	0.05%
SUBTOTAL	**909**	**206**	**$2,544,242.55**	**$2,798.95**	**4.41**	**33.49%**
PERTZYE®						
PERTZYE CAP 24,000 UNIT	153	21	$742,087.12	$4,850.24	7.29	9.77%
PERTZYE CAP 16,000 UNIT	130	15	$342,751.97	$2,636.55	8.67	4.51%
PERTZYECAP 8,000 UNIT	86	13	$89,172.29	$1,036.89	6.62	1.17%
PERTZYECAP 4,000 UNIT	18	4	$8,611.08	$478.39	4.5	0.11%
SUBTOTAL	**387**	**53**	**$1,182,622.46**	**$3,055.87**	**7.3**	**15.57%**
VIOKACE®						
VIOKACE TAB 10,440 UNIT	24	3	$38,808.97	$1,617.04	8	0.51%
VIOKACE TAB 20,880 UNIT	5	2	$6,328.65	$1,265.73	2.5	0.08%
SUBTOTAL	**29**	**5**	**$45,137.62**	**$1,556.47**	**5.8**	**0.59%**
PANCREAZE®						
PANCREAZE CAP 21,000 UNIT	3	1	$6,126.47	$2,042.16	3	0.08%
PANCREAZE CAP 10,500 UNIT	1	1	$1,512.91	$1,512.91	1	0.02%
SUBTOTAL	**4**	**2**	**$7,639.38**	**$1,909.85**	**2**	**0.10%**
TOTAL	**3,250**	**661***	**$7,597,956.86**	**$2,337.83**	**4.92**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; TAB = tablet
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Fiscal Year 2023 Annual Review of Pediculicide Medications

Oklahoma Health Care Authority
Fiscal Year 2023 Print Report

Current Prior Authorization Criteria

Pediculicide Medications		
Tier-1	**Tier-2**	**Tier-3**
Covered OTC Lice Medications	ivermectin lotion (Sklice®)	lindane shampoo
Generics with SMAC Pricing		malathion (Ovide®)
spinosad (Natroba™) **– Brand Preferred**		

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

- Over-the-counter (OTC) treatments for lice are a covered benefit for pediatric members. A prescription is required for coverage, and prescriptions are limited to 1 individual package size for a 7-day supply.

Pediculicide Medications Tier-2 Approval Criteria:

1. An FDA approved diagnosis; and
2. A recent trial with 1 Tier-1 medication with inadequate response or adverse effect; and
3. Requested medication must be age-appropriate; and
4. A clinical exception applies if there is known resistance to Tier-1 medications.

Pediculicide Medications Tier-3 Approval Criteria:

1. An FDA approved diagnosis; and
2. A recent trial with 1 Tier-1 medication with inadequate response or adverse effect; and
3. Recent trials with all available Tier-2 medication(s) with inadequate response or adverse effect; and
4. If no Tier-2 medications are available, then a trial with all Tier-1 medications will be required prior to authorization of a Tier-3 medication; and
5. Requested medication must be age-appropriate; and
6. A clinical exception to Tier-1 medications applies if there is known resistance to Tier-1 medications.

The following restrictions also apply for each individual product based on U.S. Food and Drug Administration (FDA) approved package labeling:

1. **Crotamiton (Eurax® and Crotan™) Cream and Lotion:**
    a. An FDA approved diagnosis of scabies or pruritic skin; and
    b. Member must be 18 years of age or older; and
    c. For a diagnosis of scabies, member must have used permethrin 5% cream in the past 7 to 14 days with inadequate results; and
    d. For a diagnosis of pruritic skin, a patient-specific, clinically significant reason why the member cannot use other available topical treatments used for pruritic skin must be provided; and
    e. For authorization of Crotan™, a patient-specific, clinically significant reason why the member cannot use Eurax® must be provided; and
    f. A quantity limit of 1 tube or bottle per 30 days will apply.
2. **Ivermectin (Sklice®) Lotion:**
    a. Member must be 6 months of age or older; and
    b. A quantity limit of 117mL per 7 days will apply.
3. **Lindane Shampoo:**
    a. Member must be 13 years of age or older or weigh ≥110 pounds; and
    b. A quantity limit of 60mL per 7 days will apply; and
    c. A maximum quantity of one 7-day supply per 30 days will apply.
4. **Malathion (Ovide®) Lotion:**
    a. Member must be 6 years of age or older; and
    b. A quantity limit of 60mL per 7 days will apply; treatment may be repeated once if needed for current infestation after 7 days from original fill date.
5. **Spinosad (Natroba™) Suspension:**
    a. Member must be 6 months of age or older; and
    b. A quantity limit of 120mL per 7 days will apply; treatment may be repeated once if needed for current infestation after 7 days from original fill date; and
    c. The brand formulation of Natroba™ is preferred. Requests for the generic formulation of spinosad require a patient-specific, clinically significant reason why the brand formulation cannot be used.

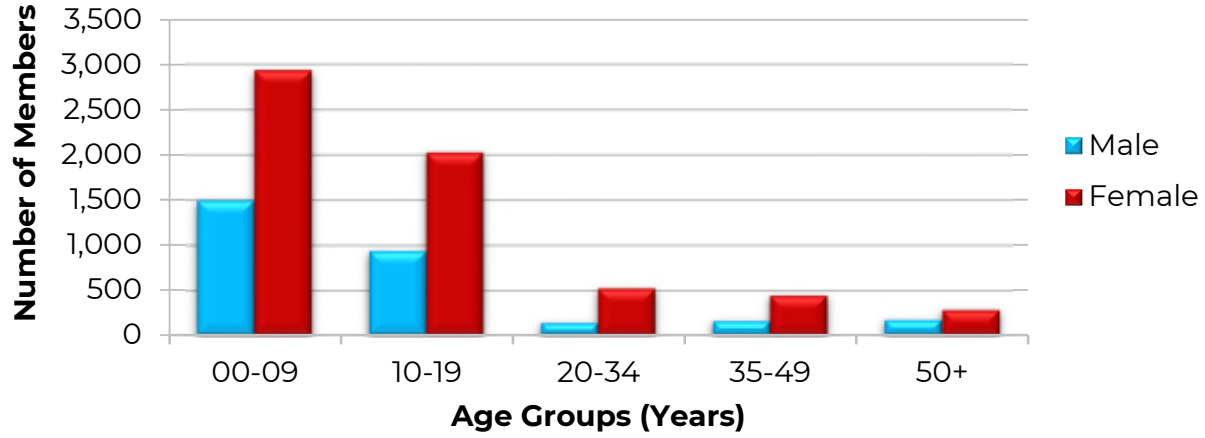
Utilization of Pediculicide Medications: Fiscal Year 2023

Comparison of Fiscal Years

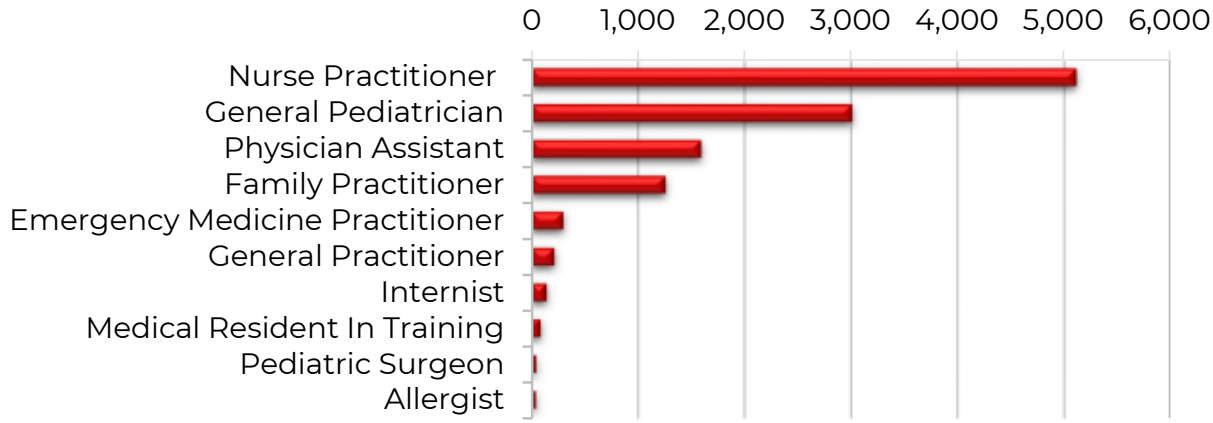
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	8,467	11,397	$1,811,932.13	$158.98	$14.44	1,069,788	125,442
2023	9,081	12,027	$2,037,819.12	$169.44	$14.74	1,167,702	138,252
% Change	**7.30%**	**5.50%**	**12.50%**	**6.60%**	**2.10%**	**9.20%**	**10.20%**
Change	**614**	**630**	**$225,886.99**	**$10.46**	**$0.30**	**97,914**	**12,810**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Demographics of Members Utilizing Pediculicide Medications

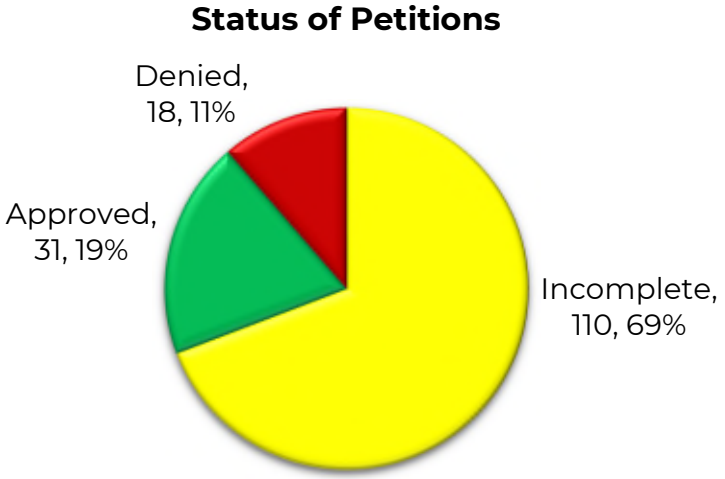


Top Prescriber Specialties of Pediculicide Medications by Number of Claims



Prior Authorization of Pediculicide Medications

There were 159 prior authorization requests submitted for pediculicide medications during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.



Market News and Updates[1]

Anticipated Patent Expiration(s):

- Natroba™ (spinosad): November 2033
- Ovide® (malathion): February 2027

Recommendations

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

Utilization Details of Pediculicide Medications: Fiscal Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SPINOSAD PRODUCTS						
NATROBA SUS 0.9%	6,952	5,247	$1,896,431.01	$272.79	1.32	93.06%
SUBTOTAL	**6,952**	**5,247**	**$1,896,431.01**	**$272.79**	**1.32**	**93.06%**
PERMETHRIN AND PYRETHRIN OTC PRODUCTS						
PERMETHRIN CRE 5%	4,523	3,573	$125,074.23	$27.65	1.27	6.14%
LICE TRTMNT LOT 1%	283	244	$4,719.31	$16.68	1.16	0.23%
VANALICE GEL 0.3-3.5%	125	88	$6,367.83	$50.94	1.42	0.31%
LICE TRTMNT LIQ 1%	120	103	$2,296.98	$19.14	1.17	0.11%
GOODSENSE LIQ LICE RIN 1%	8	8	$142.60	17.83	1	0.01%
SUBTOTAL	**5,059**	**4,016**	**$138,600.95**	**$27.40**	**1.26**	**6.80%**
IVERMECTIN PRODUCTS						
IVERMECTIN LOT 0.5%	14	13	$2,351.46	$167.96	1.08	0.12%
SUBTOTAL	**14**	**13**	**$2,351.46**	**$167.96**	**1.08**	**0.12%**
MALATHION PRODUCTS						
MALATHION LOT 0.5%	2	2	$435.70	$217.85	1	0.02%
SUBTOTAL	**2**	**2**	**$435.70**	**$217.85**	**1**	**0.02%**
TOTAL	**12,027**	**9,081***	**$2,037,819.12**	**$169.44**	**1.32**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CRE = cream; LIQ = liquid; LOT = lotion; SUS = suspension; TRTMNT = treatment
Fiscal Year 2023 = 07/01/2022 to 06/30/2023
Please note: Some Tier-1 products participate in supplemental rebates; therefore, costs shown do not reflect net costs.

[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 12/2023. Last accessed 12/14/2023.

Fiscal Year 2023 Annual Review of Xiaflex® (Collagenase Clostridium Histolyticum)

Oklahoma Health Care Authority
Fiscal Year 2023 Print Report

Current Prior Authorization Criteria

Xiaflex® (Collagenase Clostridium Histolyticum) Approval Criteria [Dupuytren's Contracture Diagnosis]:

1. An FDA approved diagnosis of Dupuytren's contracture with palpable cord, functional impairment, and fixed-flexion contractures of the metacarpophalangeal (MP) joint or proximal interphalangeal (PIP) joint of 30 degrees or more; and
2. Member must be 18 years of age or older; and
3. Member must not be a candidate for needle aponeurotomy; and
4. Prescriber must be trained in the treatment of Dupuytren's contracture and injections of the hand; and
5. A quantity limit of 3 doses (1 dose per 4 weeks) per cord will apply.

Xiaflex® (Collagenase Clostridium Histolyticum) Approval Criteria [Peyronie's Disease Diagnosis]:

1. An FDA approved diagnosis of stable Peyronie's disease with a palpable plaque and curvature deformity of at least 30 degrees and less than 90 degrees at the start of therapy; and
2. Member must be 18 years of age or older; and
3. Member must have pain outside the circumstances of intercourse that is refractory to other available treatments; and
4. Peyronie's plaques must not involve the penile urethra; and
5. Member must have intact erectile function (with or without the use of medications); and
6. Prescriber must be certified to administer Xiaflex® through the Xiaflex® Risk Evaluation and Mitigation Strategy (REMS) program; and
7. A maximum of 8 injection procedures will be approved.

Utilization of Xiaflex® (Collagenase Clostridium Histolyticum): Fiscal Year 2023

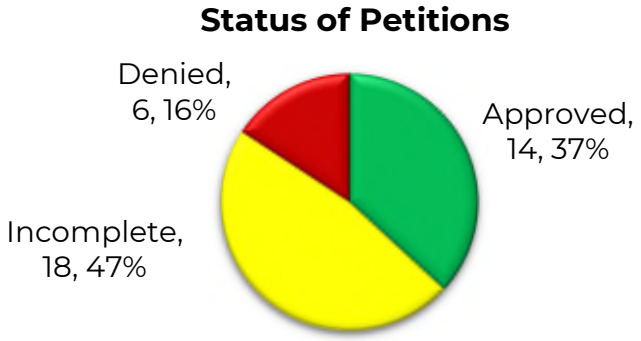
Comparison of Fiscal Years: Medical Claims

Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2022	3	11	$49,645.34	$4,513.21	3.67
2023	8	22	$122,184.88	$5,553.86	2.75
% Change	**166.67%**	**100.00%**	**146.12%**	**23.06%**	**-25.07%**
Change	**5**	**11**	**$72,539.54**	**$1,040.65**	**-0.92**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Prior Authorization of Xiaflex® (Collagenase Clostridium Histolyticum)

There were 38 prior authorization requests submitted for 18 unique members for Xiaflex® (collagenase clostridium histolyticum) during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.



Recommendations

The College of Pharmacy does not recommend any changes to the current Xiaflex® (collagenase clostridium histolyticum) prior authorization criteria at this time.

Utilization Details of Xiaflex® (Collagenase Clostridium Histolyticum): Fiscal Year 2023

PRODUCT UTILIZED	†TOTAL CLAIMS	*TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
J0775 XIAFLEX INJECTION 0.9MG	22	8	$122,184.88	$5,553.86	2.75
TOTAL	**22**	**8**	**$122,184.88**	**$5,553.86**	**2.75**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Fiscal Year 2023 Annual Review of Zokinvy® (Lonafarnib)

Oklahoma Health Care Authority
Fiscal Year 2023 Print Review

Current Prior Authorization Criteria

Zokinvy® (Lonafarnib) Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. To reduce the risk of mortality in Hutchinson-Gilford Progeria Syndrome (HGPS); or
   b. Treatment of processing-deficient Progeroid Laminopathies (PL) with either:
      i. Heterozygous *LMNA* mutation with progerin-like protein accumulation; or
      ii. Homozygous or compound heterozygous *ZMPSTE24* mutations; and
2. Member must have confirmatory mutational analysis showing mutation in the *LMNA* gene; and
3. Zokinvy® will not be approved for other progeroid syndromes or processing-proficient PL (based upon its mechanism of action, Zokinvy® would not be effective in these populations); and
4. Member must be 1 year of age or older; and
5. Member must have a body surface area (BSA) ≥0.39m^2; and
6. Member must have clinical signs of progeria (e.g., characteristic facial features, growth deficiency, atherosclerosis); and
7. Zokinvy® must be prescribed by, or in consultation with, a specialist with expertise in treating HGPS or PL (or an advanced care practitioner with a supervising physician who is a specialist in treating HGPS or PL); and
8. Member must not be taking any of the following medications: strong/moderate CYP3A inhibitors, CYP2C9 inhibitors, midazolam, lovastatin, simvastatin, atorvastatin, or loperamide if younger than 2 years of age; and
9. Prior to and during treatment, the potential for drug interactions should be considered, concomitant medications reviewed, and members should be monitored for adverse reactions; and
10. Member should have ophthalmological evaluations performed at regular intervals and at the onset of any new visual changes; and
11. Prescriber must verify the member will be monitored for changes in electrolytes, complete blood counts, renal function, and liver enzymes; and

12. Member's recent BSA must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to the package labeling; and
13. The maximum approvable dose of Zokinvy® is 300mg/m^2 per day; and
14. Initial approvals will be for 6 months. After 6 months of utilization, compliance and information regarding efficacy, such as a positive response to treatment including no new or worsening heart failure and no stroke incidence, will be required for continued approval. Subsequent approvals will be for 12 months and compliance and documentation of a positive response to Zokinvy® therapy will be required on each continuation request.

Utilization of Zokinvy® (Lonafarnib): Fiscal Year 2023

There was no SoonerCare utilization of Zokinvy® (lonafarnib) during fiscal year 2023 (07/01/2022 to 06/30/2023).

Prior Authorization of Zokinvy® (Lonafarnib)

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

Market News and Updates[1]

Anticipated Patent Expiration(s):

- Zokinvy® (lonafarnib): October 2024

Recommendations

The College of Pharmacy does not recommend any changes to the current Zokinvy® (lonafarnib) 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/. Last revised 11/2023. Last accessed 11/03/2023.