State Fiscal Year 2022 Print Annual Reviews
Quarter 2

Count	Category/Medication
1.	Aldurazyme® (Laronidase) and Naglazyme® (Galsulfase)
2.	Alpha-1 Proteinase Inhibitors
3.	Antihistamine Medications (Systemic)
4.	Arcalyst® (Rilonacept)
5.	Bladder Control Medications
6.	Bowel Preparation Medications
7.	Carbaglu® (Carglumic Acid)
8.	Constipation and Diarrhea Medications
9.	Corticosteroid Special Formulations
10.	Crysvita® (Burosumab-twza)
11.	Elaprase® (Idursulfase)
12.	Fabry Disease Medications
13.	Fibromyalgia Medications
14.	Gattex® [Teduglutide (rDNA origin)]
15.	Gaucher Disease Medications
16.	Givlaari® (Givosiran) and Scenesse® (Afamelanotide)
17.	Iron Chelating Agents
18.	Luxturna® (Voretigene neparvovec-rzyl)
19.	Mycapssa® (Octreotide) and Signifor® LAR (Pasireotide)
20.	Naloxone Medications
21.	Northera® (Droxidopa)
22.	Otic Anti-Infective Medications
23.	Pancreatic Enzymes
24.	Pediculicide Medications
25.	Xiaflex® (Collagenase Clostridium Histolyticum)
26.	Zokinvy® (Lonafarnib)

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

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

Fiscal Year 2022 Annual Review of Aldurazyme® (Laronidase) and Naglazyme® (Galsulfase)

Oklahoma Health Care Authority
Fiscal Year 2022 Print Report

Current Prior Authorization Criteria

Aldurazyme® (Laronidase) Approval Criteria:

1. An FDA approved diagnosis of Hurler, Hurler-Scheie, or Scheie syndrome (mucopolysaccharidosis type I; MPS I) confirmed by:
   a. Enzyme assay demonstrating a deficiency of alpha-L-iduronidase (IDUA) enzyme activity; or
   b. Molecular genetic testing to confirm pathogenic mutations in the *IDUA* gene; and
2. For Scheie syndrome, the prescriber must document that the member has moderate-to-severe symptoms; and
3. Aldurazyme® must be administered by a health care professional prepared to manage anaphylaxis; and
4. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment; and
5. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling.

Naglazyme® (Galsulfase) Approval Criteria:

1. An FDA approved diagnosis of Maroteaux-Lamy syndrome (mucopolysaccharidosis type VI; MPS VI) confirmed by:
   a. Enzyme assay demonstrating a deficiency of arylsulfatase B (ASB) enzyme activity; or
   b. Genetic testing to confirm diagnosis of MPS VI; and
2. Naglazyme® must be administered by a health care professional prepared to manage anaphylaxis; and
3. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment; and
4. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling.

Utilization of Aldurazyme® (Laronidase) and Naglazyme® (Galsulfase): Fiscal Year 2022

There was no SoonerCare utilization, including pharmacy and medical claims, of Aldurazyme® (laronidase) or Naglazyme® (galsulfase) during fiscal year 2022 (07/01/2021 to 06/30/2022).

Prior Authorization of Aldurazyme® (Laronidase) and Naglazyme® (Galsulfase)

There were no prior authorization requests submitted for Aldurazyme® (laronidase) or Naglazyme® (galsulfase) during fiscal year 2022.

Recommendations

The College of Pharmacy does not recommend any changes to the current Aldurazyme® (laronidase) and Naglazyme® (galsulfase) prior authorization criteria at this time.

Fiscal Year 2022 Annual Review of Alpha$_1$-Proteinase Inhibitors

Oklahoma Health Care Authority
Fiscal Year 2022 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 2022

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	5	39	$331,998.16	$8,512.77	$305.99	728,343	1,085
2022	4	45	$442,086.39	$9,824.14	$350.86	954,972	1,260
% Change	**-20%**	**15.4%**	**33.2%**	**15.4%**	**14.7%**	**31.1%**	**16.1%**
Change	**-1**	**6**	**$110,088.23**	**$1,311.37**	**$44.87**	**226,629**	**175**

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

Comparison of Fiscal Years: Medical Claims

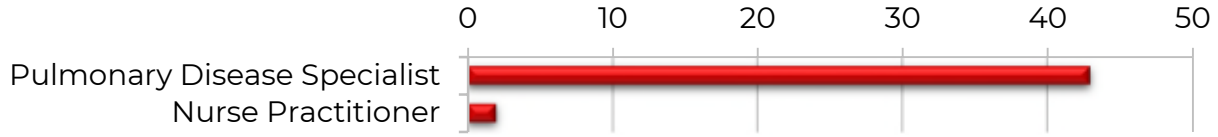
Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2021	1	1	$2,372.26	$2,372.26	1
2022	1	10	$20,467.69	$2,046.77	10
% Change	**0%**	**900%**	**762.8%**	**-13.7%**	**900%**
Change	**0**	**9**	**$18,095.43**	**-$325.49**	**9**

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

Demographics of Members Utilizing Alpha$_1$-Proteinase Inhibitors

- Due to the limited number of members utilizing alpha$_1$-proteinase inhibitors during fiscal year 2022, detailed demographic information could not be provided.

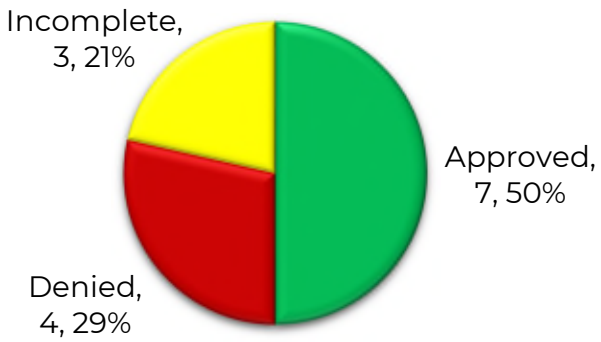
Top Prescriber Specialties of Alpha$_1$-Proteinase Inhibitors by Number of Claims: Pharmacy Claims



Prior Authorization of Alpha$_1$-Proteinase Inhibitors

There were 14 prior authorization requests submitted for alpha$_1$-proteinase inhibitors during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions



Market News and Updates[1,2]

Pipeline:

- **Inhaled Alpha$_1$-Antitrypsin (AAT):** Kamada is currently evaluating the safety and efficacy of an inhaled AAT therapy in the Phase 3 InnovAATe clinical trial for the treatment of AAT deficiency. Inhaled AAT 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, time associated with infusions, and administration by a health care professional. If approved, inhaled AAT is anticipated to be the first AAT product that is not required to be administered via IV infusion but instead is administered via a user-friendly, lightweight, and silent nebulizer in up to 2 short daily sessions. Kamada intends to meet with the U.S. Food and Drug Administration (FDA) during the first half of 2023 to discuss the Phase 3 trial progress and potential opportunities to shorten the regulatory pathway.

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 2022

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
PROLASTIN-C INJ 1,000MG	34	3	$353,455.62	$10,395.75	11.33	79.95%
GLASSIA INJ 1,000MG	11	1	$88,630.77	$8,057.34	11	20.05%
TOTAL	**45**	**4***	**$442,086.39**	**$9,824.14**	**11.25**	**100%**

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

Medical Claims

PRODUCT UTILIZED	+TOTAL CLAIMS	*TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
PROLASTIN C INJ 10MG J0256	10	1	$20,467.69	$2,046.77	10
TOTAL	**10**	**1**	**$20,467.69**	**$2,046.77**	**10**

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

[1] Kamada Pharmaceuticals Ltd. Science: Pipeline. Available online at: https://www.kamada.com/pipeline/. Last accessed 12/29/2022.
[2] Kamada Pharmaceuticals Ltd. Kamada Provides Update on Recent Progress Achieved in Ongoing Pivotal Phase 3 Clinical Trial of Inhaled AAT. Available online at: https://www.kamada.com/news/kamada-provides-update-on-recent-progress-achieved-in-ongoing-pivotal-phase-3-clinical-trial-of-inhaled-aat/. Issued 11/07/2022. Last accessed 12/29/2022.

Fiscal Year 2022 Annual Review of Antihistamine Medications (Systemic)

Oklahoma Health Care Authority
Fiscal Year 2022 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. 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. 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.

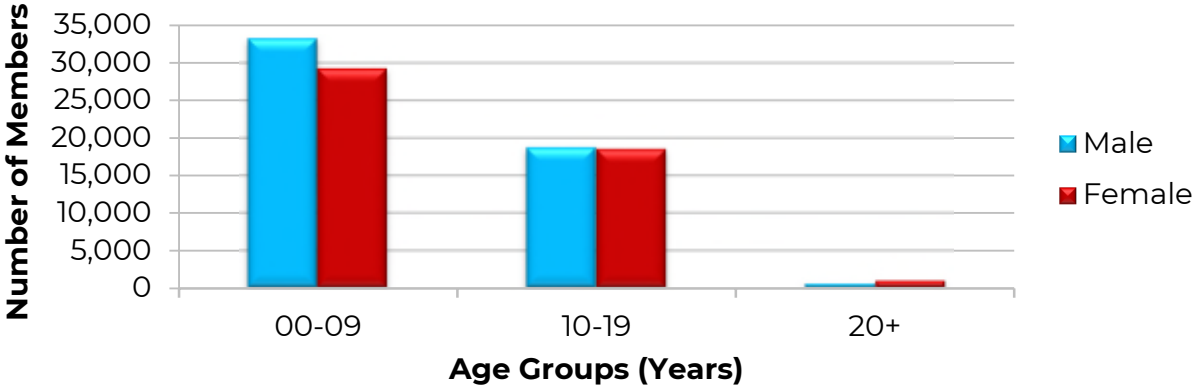
Utilization of Systemic Antihistamine Medications: Fiscal Year 2022

Comparison of Fiscal Years

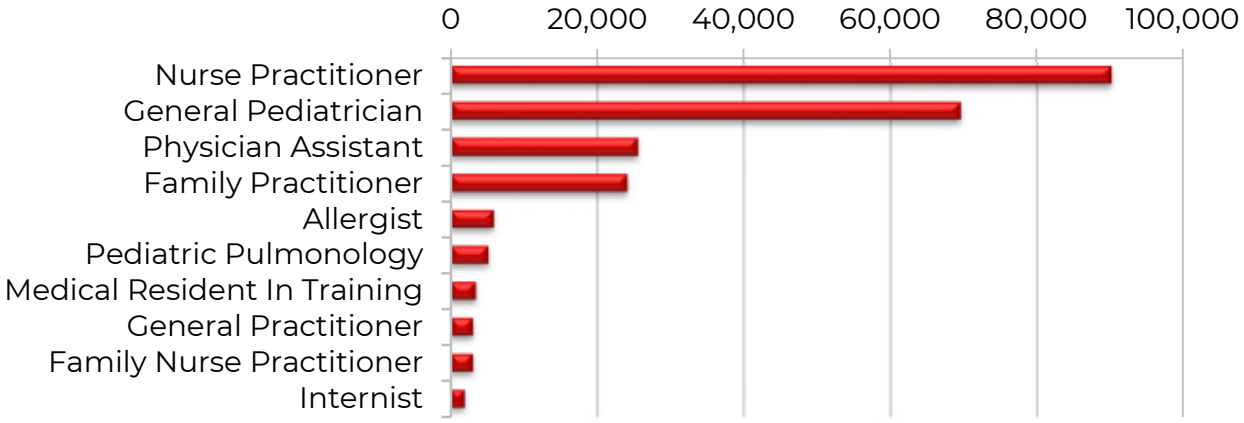
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	90,057	222,700	$2,567,796.24	$11.53	$0.35	21,523,638	7,426,333
2022	100,952	239,847	$2,903,029.35	$12.10	$0.36	23,624,800	980,080
% Change	**12.1%**	**7.7%**	**13.1%**	**4.9%**	**2.9%**	**9.8%**	**7.5%**
Change	**10,895**	**17,147**	**$335,233.11**	**$0.57**	**$0.01**	**2,101,162**	**553,747**

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

Demographics of Members Utilizing Systemic Antihistamine Medications



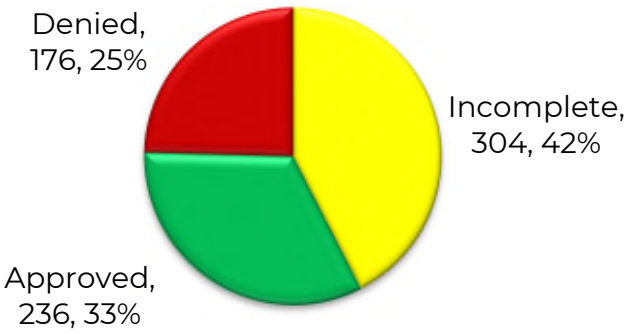
Top Prescriber Specialties of Systemic Antihistamine Medications by Number of Claims



Prior Authorization of Systemic Antihistamine Medications

There were 716 prior authorization requests submitted for systemic antihistamine medications during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions



Market News and Updates[1]

Anticipated Patent Expiration(s):

- 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 prior authorization criteria or Product Based Prior Authorization (PBPA) category at this time.

Utilization Details of Systemic Antihistamine Medications: Fiscal Year 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 PRODUCTS						
CETIRIZINE PRODUCTS						
CETIRIZINE SOL 1MG/ML	99,709	48,069	$1,331,506.10	$13.35	2.07	45.87%
CETIRIZINE TAB 10MG	75,448	31,464	$759,213.95	$10.06	2.4	26.15%
CETIRIZINE SOL 5MG/5ML	16,824	10,184	$251,701.01	$14.96	1.65	8.67%
CETIRIZINE TAB 5MG	4,176	1,931	$40,445.44	$9.69	2.16	1.39%
ALL DAY ALLG SOL 5MG/5ML	1,354	906	$18,887.71	$13.95	1.49	0.65%
ALLERGY RELIEF TAB 10MG	273	155	$3,395.61	$12.44	1.76	0.12%
ALL DAY ALLG SOL 1MG/ML	260	212	$3,830.73	$14.73	1.23	0.13%
ALL DAY ALLG TAB 10MG	133	75	$1,823.71	$13.71	1.77	0.06%
ALLERGY RELIEF SOL 1MG/ML	75	72	$868.99	$11.59	1.04	0.03%
ALLERGY RELIEF TAB 10MG	23	14	$276.40	$12.02	1.64	0.01%
GNP ALL DAY TAB ALLG 10MG	22	12	$297.93	$13.54	1.83	0.01%
SUBTOTAL	**198,297**	**93,094**	**$2,412,247.58**	**$12.16**	**2.13**	**83.09%**
LORATADINE PRODUCTS						
LORATADINE TAB 10MG	19,039	7,905	$177,337.74	$9.31	2.41	6.11%
LORATADINE SOL 5MG/5ML	17,903	8,939	$234,729.91	$13.11	2	8.09%
LORATADINE SYP 5MG/5ML	2,397	1,405	$37,327.70	$15.57	1.71	1.29%
ALLERGY RELIEF TAB 10MG	490	194	$6,201.48	$12.66	2.53	0.21%
SM ALLERGY SYP 5MG/5ML	219	176	$2,996.79	$13.68	1.24	0.10%
ALLERGY CHILD SYP 5MG/5ML	217	119	$3,613.16	$16.65	1.82	0.12%
SM LORATADINE TAB 10MG	33	18	$326.19	$9.88	1.83	0.01%
ALLERGY RELIEF SOL 5MG/5ML	8	6	$138.80	$17.35	1.33	0.00%
LORATADINE TAB 10MG	1	1	$22.80	$22.80	1	0.00%
SUBTOTAL	**40,307**	**18,763**	**$462,694.57**	**$11.48**	**2.15**	**15.94%**
TIER-1 SUBTOTAL	**238,604**	**100,823***	**$2,874,942.15**	**$12.05**	**2.37**	**99.03%**
TIER-2 PRODUCTS						
LEVOCETIRIZINE PRODUCTS						
LEVOCETIRIZINE TAB 5MG	795	188	$10,671.99	$13.42	4.23	0.37%
LEVOCETIRIZINE SOL 2.5MG/5ML	436	106	$17,129.58	$39.29	4.11	0.59%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ALLERGY RELIEF TAB 5MG	1	1	$16.03	$16.03	1	0.00%
TIER-2 SUBTOTAL	**1,232**	**291***	**$27,817.60**	**$22.58**	**4.23**	**0.96%**
TIER-3 PRODUCTS						
DESLORATADINE PRODUCTS						
DESLORATADINE TAB 5MG	11	3	$269.60	$24.51	3.67	0.01%
TIER-3 SUBTOTAL	**11**	**3***	**$269.60**	**$24.51**	**3.67**	**0.01%**
TOTAL	**239,847**	**100,952***	**$2,903,029.35**	**$12.10**	**2.38**	**100%**

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

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 11/2022. Last accessed 11/29/2022.

Fiscal Year 2022 Annual Review of Arcalyst® (Rilonacept)

Oklahoma Health Care Authority
Fiscal Year 2022 Print Report

Current Prior Authorization Criteria

Arcalyst® (Rilonacept) Approval Criteria [Cryopyrin-Associated Periodic Syndromes (CAPS) Diagnosis]:

1. An FDA approved indication of CAPS verified by genetic testing. This includes familial cold auto-inflammatory syndrome (FCAS) and Muckle-Wells syndrome (MWS) in adults and children 12 years of age and older; and
2. A patient-specific, clinically significant reason the member cannot utilize Kineret® (anakinra) or Ilaris® (canakinumab) must be provided. Tier structure rules apply; and
3. Member must not be using a tumor necrosis factor blocking agent (e.g., adalimumab, etanercept, infliximab) or anakinra concomitantly with Arcalyst®; and
4. Documentation that the member does not have active or chronic infection including hepatitis B, hepatitis C, human immunodeficiency virus (HIV), or tuberculosis must be provided; and
5. The following dosing restrictions will apply:
    a. Dosing should not be more often than once weekly; and
    b. Approved dosing schedule for members 18 years of age and older:
        i. Initial treatment: Loading dose of 320mg delivered as (2) 2mL subcutaneous (sub-Q) injections of 160mg each given on the same day at 2 different injection sites; and
        ii. Continued treatment: (1) 160mg injection given once weekly; or
    c. Approved dosing schedule for pediatric members 12 to 17 years of age (must have member's recent weight in kilograms):
        i. Initial treatment: Loading dose of 4.4mg/kg, up to a maximum of 320mg, delivered as 1 or 2 sub-Q injections, with a maximum single-injection volume of 2mL (given at 2 different injection sites if administered as 2 injections); and
        ii. Continued treatment: 2.2mg/kg, up to a maximum of 160mg, given once weekly; and
6. Approvals will be for the duration of 1 year.

Arcalyst® (Rilonacept) Approval Criteria [Deficiency of Interleukin-1 Receptor Antagonist (DIRA) Diagnosis]:

1. An FDA approved indication of maintenance of remission of DIRA verified by genetic testing; and
2. Member must weigh ≥10kg; and
3. Member must not be using a tumor necrosis factor blocking agent (e.g., adalimumab, etanercept, infliximab) or anakinra concomitantly with Arcalyst®; and
4. Documentation that the member does not have active or chronic infection including hepatitis B, hepatitis C, human immunodeficiency virus (HIV), or tuberculosis must be provided; and
5. Arcalyst® will be used for maintenance of remission following treatment with Kineret® (anakinra); and
6. A patient-specific, clinically significant reason the member cannot continue to utilize Kineret® (anakinra) instead of switching to Arcalyst® must be provided; 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. The following dosing restrictions will apply:
    a. Dosing should not be more often than once weekly; and
    b. Approved dosing schedule for adults and pediatric members weighing ≥10kg is 4.4mg/kg up to a maximum of 320mg, delivered as 1 or 2 injections (2mL/injection) once weekly; and
9. Approvals will be for the duration of 1 year.

Arcalyst® (Rilonacept) Approval Criteria [Recurrent Pericarditis Diagnosis]:

1. An FDA approved indication of recurrent pericarditis and reduction in risk of recurrence in members 12 years of age and older; and
2. Member has had at least 2 episodes of pericarditis; and
3. Member has had failure with colchicine, non-steroidal anti-inflammatory drugs (NSAIDs), and corticosteroids defined as symptomatic pericarditis recurrence; and
4. A patient-specific, clinically significant reason the member cannot utilize Kineret® (anakinra) must be provided; and
5. Member must not be using a tumor necrosis factor blocking agent (e.g., adalimumab, etanercept, infliximab) or anakinra concomitantly with Arcalyst®; and
6. Documentation that the member does not have active or chronic infection including hepatitis B, hepatitis C, human immunodeficiency virus (HIV), or tuberculosis must be provided; and
7. The following dosing restrictions will apply:
    a. Dosing should not be more often than once weekly; and
    b. Approved dosing schedule for members 18 years of age and older:

i. Initial treatment: Loading dose of 320mg delivered as (2) 2mL subcutaneous (sub-Q) injections of 160mg each given on the same day at 2 different injection sites; and
ii. Continued treatment: (1) 160mg injection given once weekly; or

c. Approved dosing schedule for pediatric members 12 to 17 years of age (must have member's recent weight in kilograms):
i. Initial treatment: Loading dose of 4.4mg/kg, up to a maximum of 320mg, delivered as 1 or 2 sub-Q injections, with a maximum single-injection volume of 2mL (given at 2 different injection sites if administered as 2 injections); and
ii. Continued treatment: 2.2mg/kg, up to a maximum of 160mg, given once weekly; and

8. Initial approvals will be for 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment as indicated by decreased recurrence of pericarditis or improvement in signs and symptoms of recurrent pericarditis (e.g., C-reactive protein, pericarditic chest pain, pericardial effusion). Subsequent approvals will be granted for the duration of 1 year.

Utilization of Arcalyst® (Rilonacept): Fiscal Year 2022

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

Prior Authorization of Arcalyst® (Rilonacept)

There were no prior authorization requests submitted for Arcalyst® (rilonacept) during fiscal year 2022 (07/01/2021 to 06/30/2022).

Recommendations

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

Fiscal Year 2022 Annual Review of Bladder Control Medications

Oklahoma Health Care Authority
Fiscal Year 2022 Print Report

Current Prior Authorization Criteria

Bladder Control Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
fesoterodine (Toviaz®)	tolterodine (Detrol®)	darifenacin (Enablex®)	desmopressin acetate SL tablets (Nocdurna®)+
oxybutynin (Ditropan®)	tolterodine ER (Detrol LA®)	mirabegron (Myrbetriq®)Δ tablets and granulesβ	oxybutynin patch (Oxytrol®)+
oxybutynin ER (Ditropan XL®)		oxybutynin gel (Gelnique®)	vibegron (Gemtesa®)+
solifenacin (VESIcare®)Δ		trospium ER (Sanctura XR®)	
solifenacin oral susp (VESIcare LS™)α			
trospium (Sanctura®)			

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 specific to Gemtesa® (vibegron), Nocdurna® (desmopressin acetate SL tablets), and Oxytrol® (oxybutynin patch) applies.
ΔUnique criteria specific to use of Myrbetriq® (mirabegron) in combination with VESIcare® (solifenacin) applies.
αAn age restriction of 2 to 10 years of age will apply for VESIcare LS™. Members older than 10 years of age will require a patient-specific, clinically significant reason why the oral tablet formulation cannot be used.
βThe Myrbetriq® granule formulation is covered for members 3 years of age or older weighing <35kg. Members weighing ≥35kg will require a patient-specific, clinically significant reason why the granule formulation is needed in place of the regular tablet formulation.
ER = extended-release; PA = prior authorization; SL = sublingual; susp = suspension

Bladder Control Medications Tier-2 Approval Criteria:

1. A trial of all Tier-1 medications that yielded an inadequate clinical response or adverse effects; or
2. A unique indication which the Tier-1 medications lack.

Bladder Control Medications Tier-3 Approval Criteria:

1. A trial of all Tier-2 medications that yielded inadequate clinical response or adverse effects; or
2. A unique indication which the Tier-2 medications lack; and

3. For use of Myrbetriq® (mirabegron) in combination with VESIcare® (solifenacin), the member must have failed monotherapy with either mirabegron or solifenacin (minimum 4-week trial) defined by continued symptoms of urge urinary incontinence, urgency, and urinary frequency. Current tier structure rules will also apply.

Gemtesa® (Vibegron) Approval Criteria:

1. An FDA approved indication of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency; and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why all lower tiered medications are not appropriate for the member must be provided; and
4. A quantity limit of 30 tablets per 30 days will apply.

Nocdurna® (Desmopressin Acetate Sublingual Tablet) Approval Criteria:

1. An FDA approved diagnosis of nocturia due to nocturnal polyuria in adult members who awaken at least 2 times per night to void; and
2. All other causes of nocturia have been ruled out or adequately treated [e.g., benign prostatic hyperplasia (BPH), overactive bladder (OAB), obstructive sleep apnea (OSA)]; and
3. Prescriber must confirm the member has a 6-month history of at least 2 nocturic episodes per night; and
4. Member has failed behavior modifications including reducing caffeine intake, alcohol intake, and nighttime fluid intake; and
5. Member must have failed a trial of DDAVP® (desmopressin acetate tablets) or have a patient-specific, clinically significant reason why the standard tablet formulation of desmopressin cannot be used; and
6. Prescriber must be willing to measure serum sodium levels prior to starting treatment and document levels are acceptable; and
7. Prescriber must agree to monitor serum sodium levels within the first week and approximately 1 month after starting treatment, and periodically during treatment; and
8. Prescriber must confirm the member is not taking loop diuretics; and
9. Prescriber must confirm the member does not have renal impairment with an estimated glomerular filtration rate (eGFR) <50mL/min/1.73m^2; and
10. Initial approvals will be for the duration of 3 months. For continued authorization, the prescriber must provide the following:
    a. Documentation that serum sodium levels are acceptable to the prescriber; and
    b. Documentation that the member is responding to treatment; and
11. Approvals will be limited to the 27.7mcg dose for female members; and

12. A quantity limit of 30 tablets per 30 days will apply.

Oxytrol® (Oxybutynin 3.9mg/Day Patch) Approval Criteria:

1. An FDA approved diagnosis of overactive bladder; and
2. A patient-specific, clinically significant reason why all lower tiered medications are not appropriate for the member must be provided; and
3. A quantity limit of 8 patches per 30 days will apply.

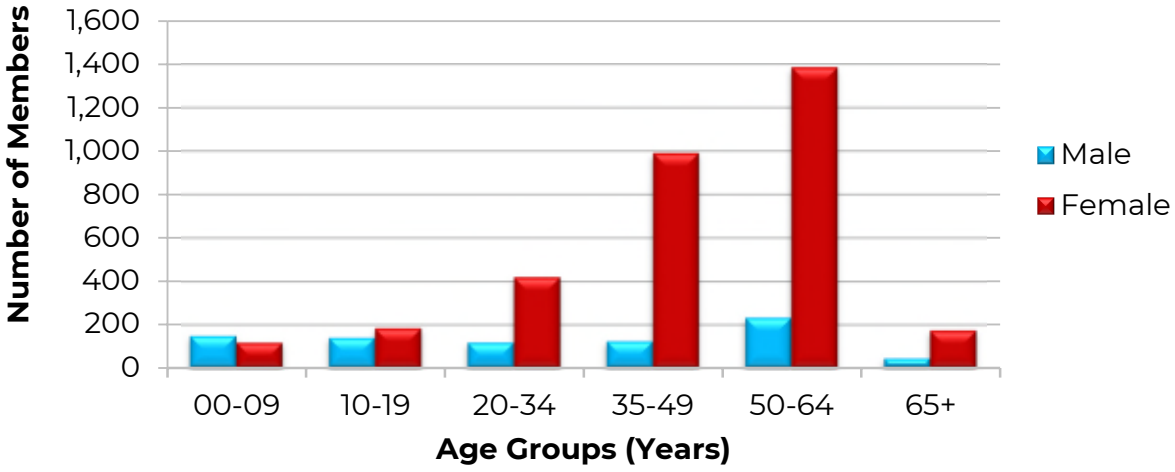
Utilization of Bladder Control Medications: Fiscal Year 2022

Comparison of Fiscal Years

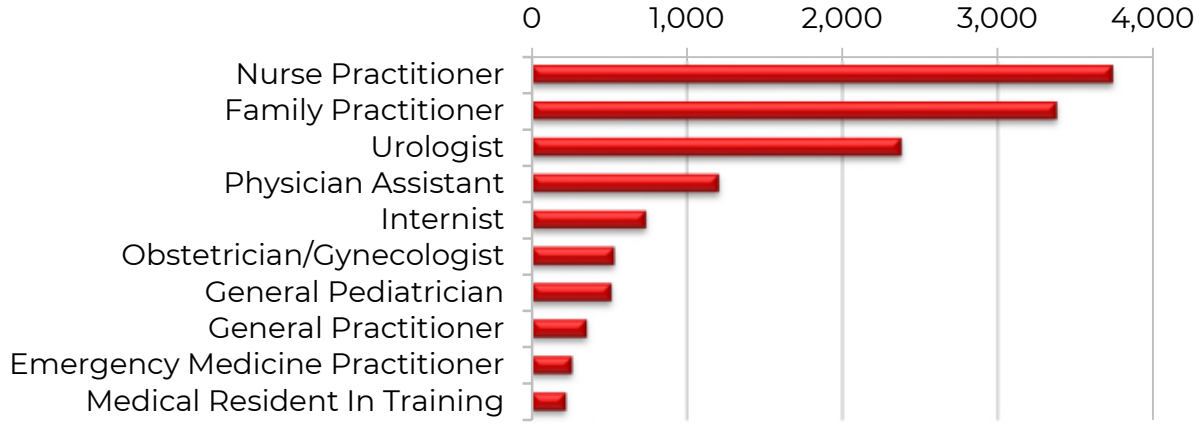
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	2,852	11,197	$658,672.05	$58.83	$1.50	830,609	439,007
2022	4,059	13,889	$767,139.62	$55.23	$1.35	968,672	569,251
% Change	**42.3%**	**24.0%**	**16.5%**	**-6.1%**	**-10.0%**	**16.6%**	**29.7%**
Change	**1,207**	**2,692**	**$108,467.57**	**-$3.60**	**-$0.15**	**138,063**	**130,244**

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

Demographics of Members Utilizing Bladder Control Medications



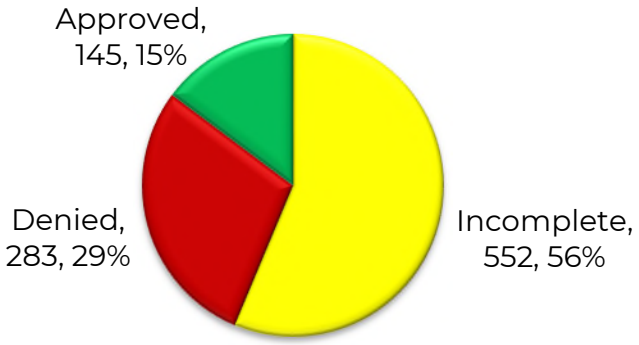
Top Prescriber Specialties of Bladder Control Medications by Number of Claims



Prior Authorization of Bladder Control Medications

There were 980 prior authorization requests submitted for bladder control medications during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions



Market News and Updates[1]

Anticipated Patent Expiration(s):

- Toviaz® (fesoterodine tablet): December 2027
- Myrbetriq® (mirabegron tablet): March 2030
- Nocdurna® (desmopressin acetate sublingual tablet): April 2030
- Gemtesa® (vibegron tablet): December 2030
- Gelnique® (oxybutynin gel): March 2031
- VESIcare LS™ (solifenacin oral suspension): May 2031
- Myrbetriq® (mirabegron granule): October 2036

Recommendations

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

Utilization Details of Bladder Control Medications: Fiscal Year 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 UTILIZATION						
OXYBUTYNIN PRODUCTS						
OXYBUTYNIN TAB 5MG	4,495	1,471	$69,076.58	$15.37	3.06	9.00%
OXYBUTYNIN TAB 10MG ER	2,634	903	$48,223.29	$18.31	2.92	6.29%
OXYBUTYNIN TAB 5MG ER	1,991	777	$33,716.17	$16.93	2.56	4.40%
OXYBUTYNIN TAB 15MG ER	878	251	$17,457.31	$19.88	3.5	2.28%
OXYBUTYNIN SYP 5MG/5ML	683	215	$11,917.45	$17.45	3.18	1.55%
SUBTOTAL	**10,681**	**3,617**	**$180,390.80**	**$16.89**	**2.95**	**23.51%**
SOLIFENACIN PRODUCTS						
SOLIFENACIN TAB 10MG	755	238	$14,438.88	$19.12	3.17	1.88%
SOLIFENACIN TAB 5MG	678	277	$12,245.15	$18.06	2.45	1.60%
VESICARE TAB 10MG	8	3	$6,894.23	$861.78	2.67	0.90%
VESICARE LS SUS 5MG/5ML	8	3	$1,496.64	$187.08	2.67	0.20%
VESICARE TAB 5MG	3	3	$1,953.78	$651.26	1	0.25%
SUBTOTAL	**1,452**	**524**	**$37,028.68**	**$25.50**	**2.77**	**4.83%**
FESOTERODINE PRODUCTS						
TOVIAZ TAB 8MG	410	96	$210,786.56	$514.11	4.27	27.48%
TOVIAZ TAB 4MG	373	115	$178,455.71	$478.43	3.24	23.26%
SUBTOTAL	**783**	**211**	**$389,242.27**	**$497.12**	**3.71**	**50.74%**
TROSPIUM PRODUCTS						
TROSPIUM CL TAB 20MG	229	74	$7,530.41	$32.88	3.09	0.98%
SUBTOTAL	**229**	**74**	**$7,530.41**	**$32.88**	**3.09**	**0.98%**
TIER-1 SUBTOTAL	**13,145**	**3,969***	**$614,192.16**	**$46.72**	**3.31**	**80.06%**
TIER-2 UTILIZATION						
TOLTERODINE PRODUCTS						
TOLTERODINE CAP 4MG ER	142	26	$6,323.01	$44.53	5.46	0.82%
TOLTERODINE TAB 2MG	129	14	$4,715.67	$36.56	9.21	0.61%
TOLTERODINE CAP 2MG ER	41	10	$2,069.38	$50.47	4.1	0.27%
TOLTERODINE TAB 1MG	8	2	$48.11	$6.01	4	0.01%
TIER-2 SUBTOTAL	**320**	**51***	**$13,156.17**	**$41.11**	**6.27**	**1.71%**
TIER-3 UTILIZATION						
MIRABEGRON PRODUCTS						
MYRBETRIQ TAB 50MG	175	29	$70,964.47	$405.51	6.03	9.25%
MYRBETRIQ TAB 25MG	93	18	$38,232.10	$411.10	5.17	4.98%
SUBTOTAL	**268**	**47**	**$109,196.57**	**$407.45**	**5.70**	**14.23%**
TROSPIUM PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TROSPIUM CL CAP 60MG ER	89	15	$11,373.33	$127.79	5.93	1.48%
SUBTOTAL	**89**	**15**	**$11,373.33**	**$127.79**	**5.93**	**1.48%**
DARIFENACIN PRODUCTS						
DARIFENACIN TAB 15MG	23	3	$1,510.60	$65.68	7.67	0.20%
SUBTOTAL	**23**	**3**	**$1,510.60**	**$65.68**	**7.67**	**0.20%**
OXYBUTYNIN PRODUCTS						
GELNIQUE GEL 10%	6	1	$2,441.64	$406.94	6	0.32%
SUBTOTAL	**6**	**1**	**$2,441.64**	**$406.94**	**6**	**0.32%**
TIER-3 SUBTOTAL	**386**	**63***	**$124,522.14**	**$322.60**	**6.13**	**16.23%**
SPECIAL PA UTILIZATION						
VIBEGRON PRODUCTS						
GEMTESA TAB 75MG	38	10	$15,269.15	$401.82	3.8	1.99%
SPECIAL PA SUBTOTAL	**38**	**10***	**$15,269.15**	**$401.82**	**3.8**	**1.99%**
TOTAL	**13,889**	**4,059***	**$767,139.62**	**$55.23**	**3.42**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; CL = chloride; ER = extended-release; PA = prior authorization; SUS = suspension; SYP = syrup; TAB = tablet
Fiscal Year 2022 = 07/01/2021 to 06/30/2022

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 10/2022. Last accessed 10/21/2022.

Fiscal Year 2022 Annual Review of Bowel Preparation Medications

Oklahoma Health Care Authority
Fiscal Year 2022 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®.

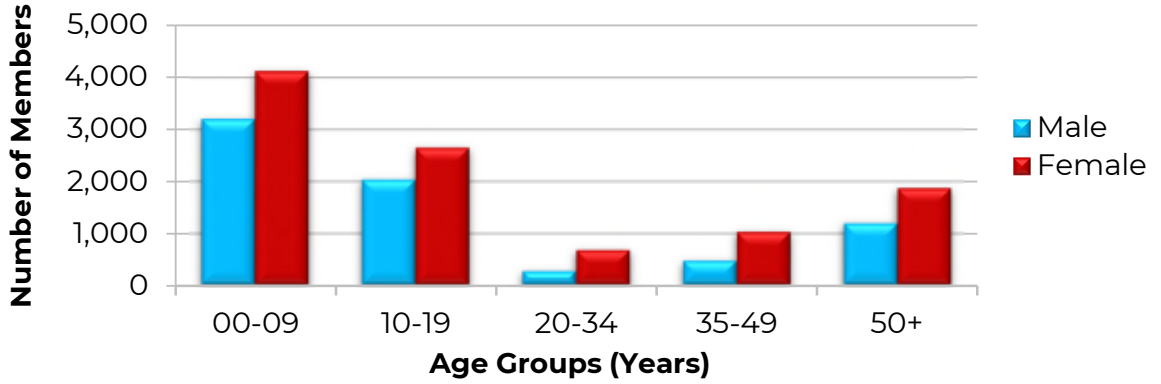
Utilization of Bowel Preparation Medications: Fiscal Year 2022

Comparison of Fiscal Years

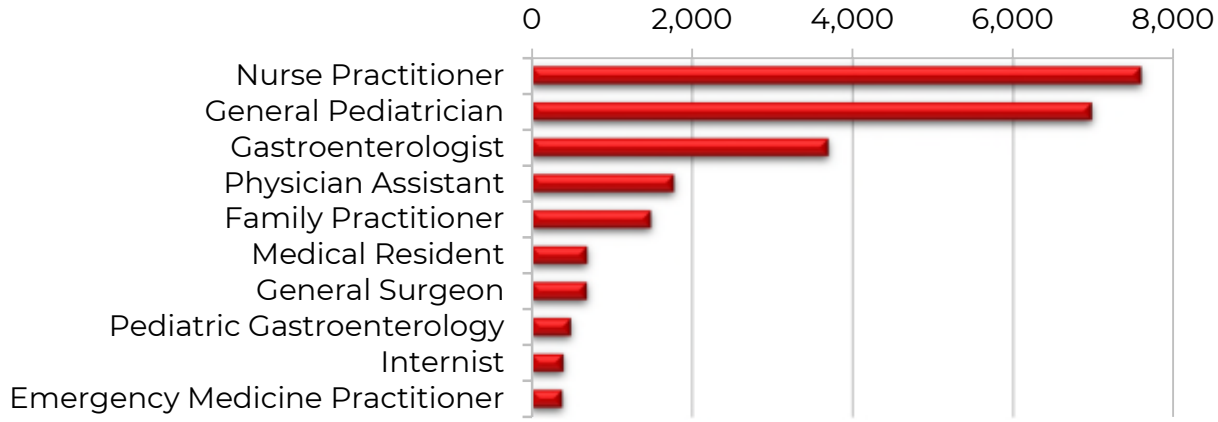
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	14,235	22,225	$432,654.01	$19.47	$0.76	17,791,647	570,951
2022	17,425	25,318	$527,432.58	$20.83	$0.91	31,013,785	580,844
% Change	**22.4%**	**13.9%**	**21.9%**	**7.0%**	**19.7%**	**74.3%**	**1.7%**
Change	**3,190**	**3,093**	**$94,778.57**	**$1.36**	**$0.15**	**13,222,138**	**9,893**

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

Demographics of Members Utilizing Bowel Preparation Medications



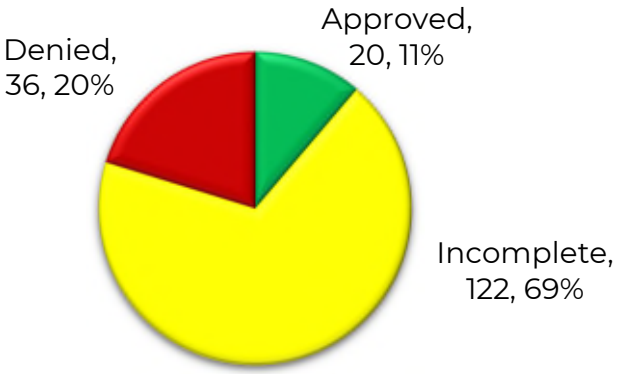
Top Prescriber Specialties of Bowel Preparation Medications by Number of Claims



Prior Authorization of Bowel Preparation Medications

There were 178 prior authorization requests submitted for bowel preparation medications during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions



Market News and Updates[1]

Anticipated Patent Expiration(s):

- SUPREP® (sodium sulfate/potassium sulfate/magnesium sulfate): March 2023
- 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 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
PEG-3350 POW NF	16,458	10,300	$294,215.64	$17.88	1.6	55.78%
PEG-3350/KCL/NABI/NASUL SOL	1,948	1,858	$39,915.41	$20.49	1.05	7.57%
GAVILYTE-G SOL	1,726	1,666	$33,785.21	$19.57	1.04	6.41%
PEG-3350/KCL/NABI/NACL SOL	1,051	1,017	$28,604.85	$27.22	1.03	5.42%
PEG-3350 POW NF PAK	893	718	$40,024.12	$44.82	1.24	7.59%
GAVILYTE-C SOL	800	779	$13,469.47	$16.84	1.03	2.55%
HM CLEARLAX POW	799	512	$13,903.49	$17.40	1.56	2.64%
CLEARLAX POW	628	394	$11,861.58	$18.89	1.59	2.25%
PEG-3350 POW	308	236	$6,012.57	$19.52	1.31	1.14%
PEG-3350/NASUL/NAAS/NACL/KCL SOL	247	237	$23,436.24	$94.88	1.04	4.44%
PEG-3350 POW PAK	210	128	$9,835.08	$46.83	1.64	1.86%
GNP CLEARLAX POW	143	122	$2,775.79	$19.41	1.17	0.53%
MOVIPREP SOL	64	62	$8,080.93	$126.26	1.03	1.53%
NATURA-LAX POW PEG-3350	10	7	$141.93	$14.19	1.43	0.03%
PEG-3350 POW	9	9	$78.29	$8.70	1	0.01%
GAVILYTE-N SOL FLAV PK	9	9	$216.21	$24.02	1	0.04%
SUTAB TAB	4	4	$608.27	$152.07	1	0.12%
SM CLEARLAX POW	4	3	$50.66	$12.67	1.33	0.01%
PEG-3350/KCL/NABI/NACL/NASUL SOL	3	3	$53.03	$17.68	1	0.01%
SUPREP BOWEL SOL PREP KIT	2	2	$209.16	$104.58	1	0.04%
PLENVU SOL	1	1	$129.64	$129.64	1	0.02%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
GOLYTELY SOL	1	1	$25.01	$25.01	1	0.00%
TOTAL	**25,318**	**17,425***	**$527,432.58**	**$20.83**	**1.45**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FLAV PK = flavor pack; KCL = potassium chloride; NAAS = sodium ascorbate; NABI = sodium bicarbonate; NACL = sodium chloride; NASUL = sodium sulfate; NF = national formulary; PAK = packet; PEG = polyethylene glycol; POW = powder; PREP = preparation; SOL = solution; TAB = tablet
Fiscal Year 2022 = 07/01/2021 to 06/30/2022

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 11/2022. Last accessed 11/21/2022.

Fiscal Year 2022 Annual Review of Carbaglu® (Carglumic Acid)

Oklahoma Health Care Authority
Fiscal Year 2022 Print Report

Current Prior Authorization Criteria

Carbaglu® (Carglumic Acid) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. Adjunctive therapy to the standard of care for the treatment of acute hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency; or
    b. Maintenance therapy for the treatment of chronic hyperammonemia due to NAGS deficiency; or
    c. Adjunctive therapy to the standard of care for the treatment of acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA); and
2. Carbaglu® must be prescribed by a geneticist or in consultation with a geneticist; and
3. For a diagnosis of hyperammonemia due to NAGS deficiency:
    a. Documentation of active management with a low protein diet; and
    b. Initial approvals will be for the duration of 1 year. After that time, reauthorization will require the prescriber to verify the member is responding well to therapy; or
4. For a diagnosis of acute hyperammonemia due to PA or MMA:
    a. Documentation that the member's plasma ammonia level is ≥50micromol/L; and
    b. Prescribed must confirm Carbaglu® is being used concurrently with other ammonia-lowering therapies [e.g., intravenous (IV) glucose, insulin, L-carnitine, protein restriction, dialysis]; and
    c. Number of days Carbaglu® was received while hospitalized must be provided; and
    d. Approvals will be for no longer than 7 days total (including treatment days while hospitalized) as there is currently no evidence to support the use of Carbaglu® for acute hyperammonemia due to PA or MMA beyond 7 days.

Utilization of Carbaglu® (Carglumic Acid): Fiscal Year 2022

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	1	13	$1,923,817.33	$147,985.95	$4,958.29	9,180	388
2022	1	12	$2,210,523.12	$184,210.26	$6,540.01	10,140	338
% Change	**0.0%**	**-7.7%**	**14.9%**	**24.5%**	**31.9%**	**10.5%**	**-12.9%**
Change	**0**	**-1**	**$286,705.79**	**$36,224.31**	**$1,581.72**	**960**	**-50**

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

Demographics of Members Utilizing Carbaglu® (Carglumic Acid)

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

Top Prescriber Specialties of Carbaglu® (Carglumic Acid) by Number of Claims

- There was 1 prescriber for Carbaglu® during fiscal year 2022, a medical geneticist.

Prior Authorization of Carbaglu® (Carglumic Acid)

There were 2 prior authorization requests submitted for 1 unique member for Carbaglu® (carglumic acid) during fiscal year 2022, both of which were approved.

Market News and Updates[1]

News:

- **December 2021:** Eton Pharmaceuticals and ANI Pharmaceuticals announced the commercial launch of generic carglumic acid tablets. The product is the first and only U.S. Food and Drug Administration (FDA) approved generic version of Carbaglu®, and it was approved by the FDA for the treatment of acute and chronic hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency. The generic product is AB-rated and is bioequivalent and therapeutically equivalent to Carbaglu®, which allows pharmacies to substitute it in place of branded Carbaglu®. The product application was granted Competitive Generic Therapy (CGT) designation by the FDA, and as a result, the product is expected to receive 180 days of generic exclusivity. Carglumic acid tablets are available exclusively through Anovo, a specialty pharmacy dedicated to serving patients with rare and chronic conditions. Anovo will administer the Eton Cares Program in partnership with Eton Pharmaceuticals which will provide prescription fulfillment, insurance

benefits investigation, educational support, and aid to qualified patients to obtain financial assistance, along with other services designed to help patients access treatment.

Recommendations

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

Utilization Details of Carbaglu® (Carglumic Acid): Fiscal Year 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
CARBAGLU TAB 200MG	12	1	$2,210,523.12	$184,210.26	12	100%
TOTAL	**12**	**1***	**$2,210,523.12**	**$184,210.26**	**12**	**100%**

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

[1] Eton Pharmaceuticals, Inc. Eton Pharmaceuticals and ANI Pharmaceuticals Announce Commercial Availability of Carglumic Acid Tablets, the First and Only FDA-Approved Generic Version of Carbaglu® (Carglumic Acid). *Globe Newswire*. Available online at: https://www.globenewswire.com/news-release/2021/12/20/2355160/0/en/Eton-Pharmaceuticals-and-ANI-Pharmaceuticals-Announce-Commercial-Availability-of-Carglumic-Acid-Tablets-the-First-and-Only-FDA-Approved-Generic-Version-of-Carbaglu-carglumic-acid.html. Issued 12/20/2021. Last accessed 12/08/2022.

Fiscal Year 2022 Annual Review of Constipation and Diarrhea Medications

Oklahoma Health Care Authority
Fiscal Year 2022 Print Report

Current Prior Authorization Criteria: Constipation Medications

Amitiza® (Lubiprostone) Approval Criteria [Chronic Idiopathic Constipation (CIC) or Irritable Bowel Syndrome with Constipation (IBS-C) Diagnosis]:

1. An FDA approved diagnosis of CIC in members 18 years of age or older, or IBS-C in female members 18 years of age or older; and
2. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
3. Documented and updated colon screening for members older than 50 years of age; and
4. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
5. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents member is responding well to treatment; and
6. A quantity limit of 60 capsules per 30 days will apply.

Amitiza® (Lubiprostone) Approval Criteria [Opioid-Induced Constipation (OIC) Diagnosis]:

1. An FDA approved diagnosis of OIC in members 18 years of age or older with chronic, non-cancer pain who are currently on chronic opioid therapy, except methadone, including members with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation; and
2. Documentation of the underlying cause of chronic pain, or reason why member is on chronic opioid therapy; and
3. Documented and updated colon screening for members older than 50 years of age; and
4. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be

within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
   a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
   b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
5. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents member is responding well to treatment; and
6. Amitiza® must be discontinued if treatment with the opioid pain medication is also discontinued; and
7. A quantity limit of 60 capsules per 30 days will apply.

Ibsrela® (Tenapanor) Approval Criteria:

1. An FDA approved diagnosis of irritable bowel syndrome with constipation (IBS-C) in members 18 years of age or older; and
2. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
3. Documented and updated colon screening for members older than 50 years of age; and
4. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
   a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
   b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
5. A patient-specific, clinically significant reason why the member cannot use Amitiza® (lubiprostone), Linzess® (linaclotide), or Trulance® (plecanatide) must be provided; and
6. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents the member is responding well to treatment; and
7. A quantity limit of 60 tablets per 30 days will apply.

Linzess® (Linaclotide) Approval Criteria:

1. An FDA approved diagnosis of chronic idiopathic constipation (CIC) or irritable bowel syndrome with constipation (IBS-C) in members 18 years of age or older; and
2. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
3. Documented and updated colon screening for members older than 50 years of age; and

4. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
5. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents the member is responding well to treatment; and
6. A quantity limit of 30 capsules per 30 days will apply.

Motegrity® (Prucalopride) Approval Criteria:

1. An FDA approved diagnosis of chronic idiopathic constipation (CIC) in members 18 years of age or older; and
2. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
3. Documented and updated colon screening for members older than 50 years of age; and
4. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
5. A patient-specific, clinically significant reason why the member cannot use Amitiza® (lubiprostone), Linzess® (linaclotide), or Trulance® (plecanatide) must be provided; and
6. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents the member is responding well to treatment; and
7. A quantity limit of 30 tablets per 30 days will apply.

Movantik® (Naloxegol) Approval Criteria:

1. An FDA approved diagnosis of opioid-induced constipation (OIC) in members 18 years of age or older with chronic, non-cancer pain who are currently on chronic opioid therapy including members with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation; and
2. Member must not have known or suspected gastrointestinal obstruction; and

3. Documentation of the underlying cause of chronic pain, or reason why member is on chronic opioid therapy; and
4. Documented and updated colon screening for members older than 50 years of age; and
5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
6. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and
7. Movantik® must be discontinued if treatment with the opioid pain medication is also discontinued; and
8. A quantity limit of 30 tablets per 30 days will apply.

Pizensy™ (Lactitol) Approval Criteria:

1. An FDA approved indication for treatment of chronic idiopathic constipation (CIC) in members 18 years of age or older; and
2. Member must not have a known contraindication to Pizensy™ (i.e., suspected gastrointestinal obstruction, galactosemia); and
3. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
4. Documented and updated colon screening for members older than 50 years of age; and
5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
6. A patient-specific, clinically significant reason why the member cannot use Linzess® (linaclotide), Amitiza® (lubiprostone), or Trulance® (plecanatide) must be provided; and
7. Use of the unit-dose packets will require a patient-specific, clinically significant reason why the member cannot use the multi-dose bottle; and
8. Approval will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and

9. A quantity limit of 560 grams per 28 days will apply.

Relistor® (Methylnaltrexone) Injection Approval Criteria [Opioid-Induced Constipation (OIC) in Chronic Non-Cancer Pain Diagnosis]:

1. An FDA approved diagnosis of OIC in members 18 years of age or older with chronic, non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation; and
2. Documentation of the underlying cause of chronic pain, or reason why the member is on chronic opioid therapy; and
3. Member must have current use of opioid medications; and
4. Documented and updated colon screening for members older than 50 years of age; and
5. Documentation of hydration attempts and trials of at least 3 different products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from trial requirements; and
6. Member must not have known or suspected gastrointestinal obstruction; and
7. A patient-specific, clinically significant reason why the member cannot use Amitiza® (lubiprostone), Movantik® (naloxegol), or Symproic® (naldemedine) must be provided; and
8. A patient-specific, clinically significant reason why the member cannot use the tablet formulation of Relistor® must be provided; and
9. The 12mg single-use vials, syringes, or kits will be the preferred products. Criteria for consideration of 8mg single-use syringes:
    a. Weight range of 38kg to 62kg; and/or
    b. Caregiver unable to draw up dose from vial; and
10. Approval will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and
11. Relistor® must be discontinued if treatment with the opioid pain medication is also discontinued; and
12. A quantity limit of 30 units per month will apply.

Relistor® (Methylnaltrexone) Injection Approval Criteria [Opioid-Induced Constipation (OIC) in Terminal Disease Diagnosis]:

1. An FDA approved diagnosis of OIC in members with severe terminal disease who are receiving only palliative care (life expectancy <6 months); and
2. Member must have current use of opioid medications; and

3. Documented treatment attempts with a minimum of 3 alternative products, excluding bulk forming laxatives; and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from trial requirements; and
4. Mechanical gastrointestinal obstruction has been ruled out; and
5. The 12mg single-use vials, syringes, or kits will be the preferred products. Criteria for consideration of 8mg single-use syringes:
    a. Weight range of 38kg to 62 kg; and/or
    b. Caregiver unable to draw up dose from vial; and
6. A quantity limit of 30 units per month will apply; and
7. Approvals will be for the duration of 16 weeks of therapy. Use of Relistor® beyond 4 months has not been studied in patients with severe terminal disease.

Relistor® (Methylnaltrexone) Tablets Approval Criteria:

1. An FDA approved diagnosis of opioid-induced constipation (OIC) in members 18 years of age or older with chronic, non-cancer pain who are currently on chronic opioid therapy, including members with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation; and
2. Member must not have known or suspected gastrointestinal obstruction; and
3. Documentation of the underlying cause of chronic pain, or reason why the member is on chronic opioid therapy; and
4. Documented and updated colon screening for members older than 50 years of age; and
5. Documentation of hydration attempts and trials of at least 3 different types of products that have failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from trial requirements; and
6. A patient-specific, clinically significant reason why the member cannot use Amitiza® (lubiprostone), Movantik® (naloxegol), or Symproic® (naldemedine) must be provided; and
7. Approval will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and
8. Relistor® must be discontinued if treatment with the opioid pain medication is also discontinued; and
9. A quantity limit of 90 tablets per 30 days will apply.

Symproic® (Naldemedine) Approval Criteria:

1. An FDA approved diagnosis of opioid-induced constipation (OIC) in members 18 years of age or older with chronic, non-cancer paid who are currently on chronic opioid therapy, including members with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation; and
2. Member must not have known or suspected gastrointestinal obstruction; and
3. Documentation of the underlying cause of chronic pain, or reason why member is on chronic opioid therapy; and
4. Documented and updated colon screening for members older than 50 years of age; and
5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
6. A patient-specific, clinically significant reason why member cannot use Amitiza® (lubiprostone) or Movantik® (naloxegol) must be provided; and
7. Approval will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and
8. Symproic® must be discontinued if treatment with the opioid pain medication is also discontinued; and
9. A quantity limit of 30 tablets per 30 days will apply.

Trulance® (Plecanatide) Approval Criteria:

1. An FDA approved diagnosis of chronic idiopathic constipation (CIC) or irritable bowel syndrome with constipation (IBS-C) in members 18 years of age or older; and
2. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
3. Documented and updated colon screening for members older than 50 years of age; and
4. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners; and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from the trial requirements; and

5. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and
6. A quantity limit of 30 tablets per 30 days will apply.

Zelnorm® (Tegaserod) Approval Criteria:

1. An FDA approved diagnosis of irritable bowel syndrome with constipation (IBS-C) in female members 18 to 64 years of age; and
2. Member must be female for authorization of Zelnorm® (the safety and efficacy of Zelnorm® in men with IBS-C have not been established); and
3. Member must not have any of the contraindications for use of Zelnorm® [i.e., history of myocardial infarction (MI), stroke, transient ischemic attack (TIA), or angina; history of ischemic colitis or other forms of intestinal ischemia; severe renal impairment (estimated glomerular filtration rate {eGFR} <15mL/min/1.73m^2) or end-stage renal disease (ESRD); moderate or severe hepatic impairment (Child-Pugh B or C); history of bowel obstruction, symptomatic gallbladder disease, suspected sphincter or Oddi dysfunction, or abdominal adhesions; hypersensitivity to tegaserod)]; and
4. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
5. Documented and updated colon screening for members older than 50 years of age; and
6. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be for polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
7. A patient-specific, clinically significant reason why the member cannot use Amitiza® (lubiprostone), Linzess® (linaclotide), or Trulance® (plecanatide) must be provided; and
8. Approval will initially be for 6 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment. Zelnorm® should be discontinued in patients who have not had adequate control of symptoms after 4 to 6 weeks of treatment; and
9. A quantity limit of 60 tablets per 30 days will apply.

Current Prior Authorization Criteria: Diarrhea Medications

Aemcolo® (Rifamycin) Approval Criteria:

1. An FDA approved diagnosis of traveler's diarrhea; and
2. Member must be 18 years of age or older; and
3. Traveler's diarrhea must be due to non-invasive strains of *Escherichia coli*; and
4. A patient-specific, clinically significant reason why the member cannot use Xifaxan® (rifaximin) oral tablets must be provided; and
5. A quantity limit of 12 tablets per 3 days will apply.

Motofen® (Difenoxin/Atropine) Approval Criteria:

1. An FDA approved diagnosis of acute nonspecific diarrhea or acute exacerbations of chronic functional diarrhea; and
2. Member must not be 2 years of age or younger;
3. Member must not have diarrhea associated with organisms that penetrate the intestinal mucosa (e.g., toxigenic *Escherichia coli*, *Salmonella* species, *Shigella*) or pseudomembranous colitis associated with broad spectrum antibiotics; and
4. A patient-specific, clinically significant reason why the member cannot use Lomotil® (diphenoxylate/atropine) and loperamide must be provided; and
5. A quantity limit of 16 tablets per 2 days will apply.

Viberzi® (Eluxadoline) Approval Criteria:

1. An FDA approved diagnosis of irritable bowel syndrome with diarrhea (IBS-D); and
2. Member must be 18 years of age or older; and
3. Member must not have any of the contraindications for use of Viberzi® (i.e., removed gallbladder; biliary duct obstruction or sphincter of Oddi disease or dysfunction; alcoholism, alcohol abuse, or alcohol addiction; history of pancreatitis or structural diseases of the pancreas; severe hepatic impairment; history of chronic or severe constipation; mechanical gastrointestinal obstruction); and
4. Documentation of trials of 2 of the following 3 medications that failed to relieve diarrhea: loperamide, dicyclomine, or diphenoxylate/atropine (each trial should be for at least 10 to 14 consecutive days at the recommended dosing). Trials must be within the past 90 days. Documentation should be provided including dates, dosing, and reason for trial failure; and
5. Approval will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents the member is responding well to treatment; and
6. A quantity limit of 60 tablets per 30 days will apply.

Xermelo® (Telotristat Ethyl) Approval Criteria:

1. An FDA approved diagnosis of carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy in adults inadequately controlled by SSA therapy; and
2. Member must be 18 years of age or older; and
3. Member must have been taking a stable dose of SSA therapy for the last 3 months and be inadequately controlled (4 or more bowel movements per day); and
4. Prescriber must verify member will continue taking SSA therapy in combination with Xermelo®; and
5. Approval will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and
6. A quantity limit of 90 tablets per 30 days will apply.

Xifaxan® (Rifaximin) 200mg Approval Criteria:

1. An FDA approved diagnosis of traveler's diarrhea; and
2. Member must be 12 years of age or older; and
3. Traveler's diarrhea must be due to noninvasive strains of *Escherichia coli*; and
4. A quantity limit of 9 tablets per 3 days will apply.

Xifaxan® (Rifaximin) 550mg Approval Criteria:

1. An FDA approved indication for the reduction in risk of overt hepatic encephalopathy (HE) recurrence; or
2. An FDA approved diagnosis of irritable bowel syndrome with diarrhea (IBS-D); and
    a. For the diagnosis of IBS-D: Documentation of trials of 2 of the following 3 medications that failed to relieve diarrhea: loperamide, dicyclomine, or diphenoxylate/atropine (each trial should be for at least 10 to 14 consecutive days at the recommended dosing). Trials must be within the past 90 days. Documentation should be provided including dates, dosing, and reason for trial failure; and
    b. For the diagnosis of IBS-D: Member must be 18 years of age or older; and
3. A quantity limit of 60 tablets per 30 days will apply. Patients with the diagnosis of IBS-D needing 42 tablets for a 14-day treatment regimen (550mg 3 times daily for 14 days) will be approved for a quantity limit override upon meeting Xifaxan® approval criteria. Patients with IBS-D who experience a recurrence of symptoms can be retreated up to 2 times with the same 14-day treatment regimen (550mg 3 times daily for 14 days).

Utilization of Constipation and Diarrhea Medications: Fiscal Year 2022

Comparison of Fiscal Years: Constipation Medications

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	245	1,074	$446,861.81	$416.07	$13.89	39,299	32,165
2022	314	1,376	$587,106.56	$426.68	$14.08	48,138	41,699
% Change	**28.20%**	**28.10%**	**31.40%**	**2.60%**	**1.40%**	**22.50%**	**29.60%**
Change	**69**	**302**	**$140,244.75**	**$10.61**	**$0.19**	**8,839**	**9,534**

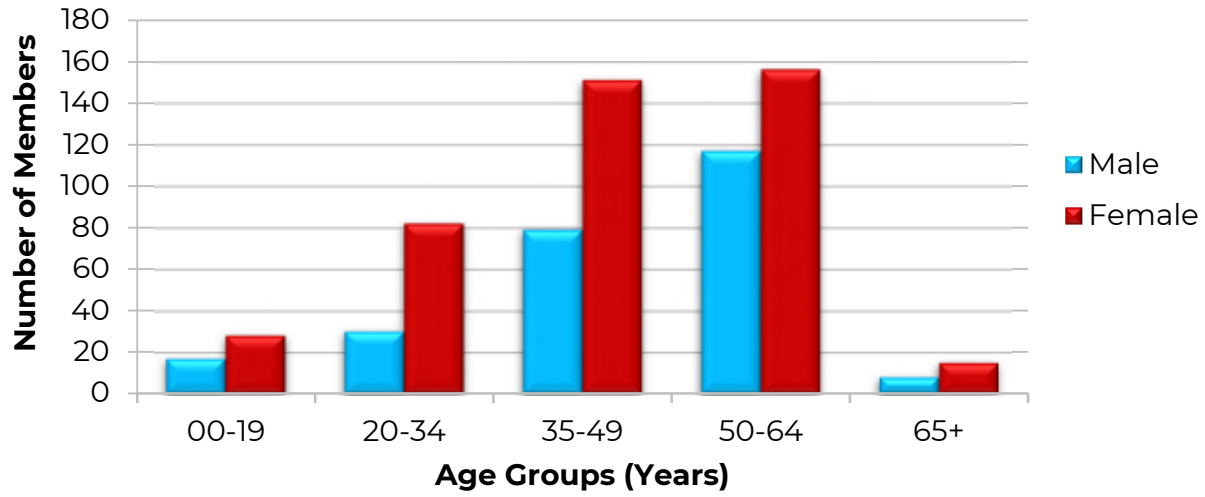
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021; Fiscal Year 2022 = 07/01/2021 to 06/30/2022

Comparison of Fiscal Years: Diarrhea Medications

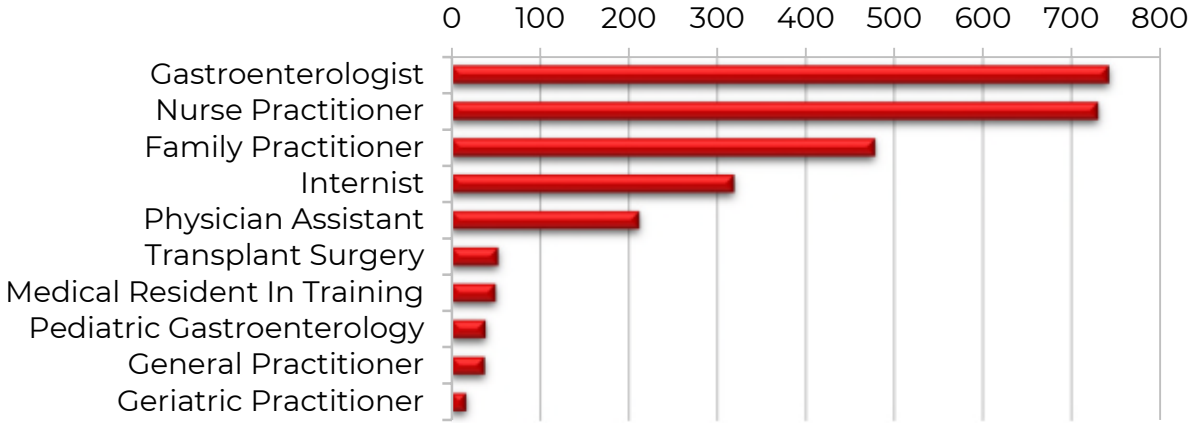
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	220	938	$2,159,687.92	$2,302.44	$82.00	54,575	26,339
2022	369	1,409	$3,621,132.93	$2,570.00	$90.37	81,786	40,070
% Change	**67.70%**	**50.20%**	**67.70%**	**11.60%**	**10.20%**	**49.90%**	**52.10%**
Change	**149**	**471**	**$1,461,445.01**	**$267.56**	**$8.37**	**27,211**	**13,731**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021; Fiscal Year 2022 = 07/01/2021 to 06/30/2022
The above table includes Xifaxan® (rifaximin), which was first FDA approved in 2004 and has a significant federal rebate. Please note, the majority of utilization of rifaximin was for the 550mg strength for the reduction in risk of overt hepatic encephalopathy (HE) recurrence.

Demographics of Members Utilizing Constipation and Diarrhea Medications



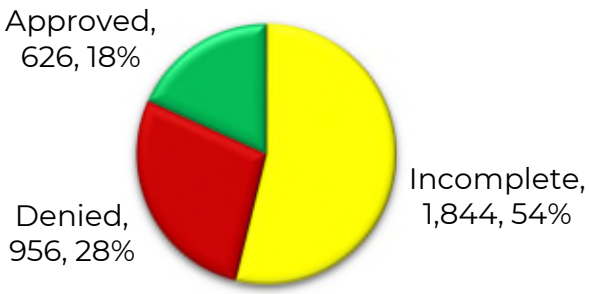
Top Prescriber Specialties of Constipation and Diarrhea Medications by Number of Claims



Prior Authorization of Constipation and Diarrhea Medications

There were 3,426 prior authorization requests submitted for constipation and diarrhea medications during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions



Market News and Updates[1,2,3,4,5]

Anticipated Patent Expiration(s):

- Aemcolo® (rifamycin): May 2025
- Amitiza® (lubiprostone): October 2027
- Xifaxan® (rifaximin): October 2029
- Ibsrela® (tenapanor): May 2030
- Relistor® (methylnaltrexone injection): December 2030
- Xermelo® (telotristat ethyl): February 2031
- Relistor® (methylnaltrexone tablet): March 2031
- Movantik® (naloxegol): April 2032
- Viberzi® (eluxadoline): March 2033
- Symproic® (naldemedine): May 2033

- Linzess® (linaclotide): August 2033
- Pizensy™ (lactitol): May 2037

News:

- **April 2022:** Ardelyx announced the United States launch of Ibsrela® (tenapanor) for the treatment of adults with irritable bowel syndrome with constipation (IBS-C). Ibsrela® was previously approved by the U.S. Food and Drug Administration (FDA) for this indication in September 2019. Tenapanor is a small molecule, locally acting inhibitor of the sodium/hydrogen exchanger 3 (NHE3) which is expressed on the apical surface of the small intestine and colon and is responsible for the absorption of sodium from the diet. Tenapanor inhibits NHE3, resulting in reduced absorption of sodium, increased retention of luminal water content, accelerated intestinal transit time, and softer stool consistency.
- **June 2022:** Alfasigma announced the voluntary withdrawal of Zelnorm® (tegaserod) from the United States market. The decision to withdraw the product was based purely on business reasons and does not reflect product efficacy or safety. Patients will have access to Zelnorm® while the existing product supply remains but should discuss alternative therapies with their health care providers.

Guideline Update(s):

- **July 2022:** The American Gastroenterological Association (AGA) published updated guidelines for IBS-C and irritable bowel syndrome with diarrhea (IBS-D), updating the previous AGA guidelines for IBS from 2014. The guidelines provide recommendations for newer medications approved by the FDA since 2014, such as plecanatide and tenapanor for IBS-C and eluxadoline for IBS-D, in addition to providing updated recommendations regarding older medications.
  Recommendations for the management of IBS-C include:
  - Strong recommendation for the use of linaclotide
  - Conditional recommendations for the use of lubiprostone, plecanatide, polyethylene glycol (PEG) laxatives, tegaserod, and tenapanor

  Recommendations for the management of IBS-D include:
  - Conditional recommendations for the use of alosetron, eluxadoline, loperamide, and rifaximin

  Recommendations for IBS (not specific to bowel subtype) include:
  - Conditional recommendations for the use of antispasmodics (e.g., dicyclomine) and tricyclic antidepressants (TCAs)
    - Due to anticholinergic effects, these may not be appropriate for some patients with prominent constipation
  - Conditional recommendation against the use of selective serotonin reuptake inhibitors (SSRIs)

Recommendations

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

Utilization Details of Constipation Medications: Fiscal Year 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
LINACLOTIDE PRODUCTS						
LINZESS CAP 290MCG	432	83	$200,638.02	$464.44	5.2	34.17%
LINZESS CAP 145MCG	254	73	$116,652.34	$459.26	3.48	19.87%
LINZESS CAP 72MCG	185	48	$84,564.76	$457.11	3.85	14.40%
SUBTOTAL	**871**	**204**	**$401,855.12**	**$461.37**	**4.27**	**68.45%**
LUBIPROSTONE PRODUCTS						
LUBIPROSTONE CAP 24MCG	129	35	$33,303.92	$258.17	3.69	5.67%
LUBIPROSTONE CAP 8MCG	46	13	$13,928.56	$302.79	3.54	2.37%
AMITIZA CAP 24MCG	42	18	$15,695.24	$373.70	2.33	2.67%
AMITIZA CAP 8MCG	34	10	$10,188.42	$299.66	3.4	1.74%
SUBTOTAL	**251**	**76**	**$73,116.14**	**$291.30**	**3.30**	**12.45%**
PLECANATIDE PRODUCTS						
TRULANCE TAB 3MG	145	46	$69,092.42	$476.50	3.15	11.77%
SUBTOTAL	**145**	**46**	**$69,092.42**	**$476.50**	**3.15**	**11.77%**
NALOXEGOL PRODUCTS						
MOVANTIK TAB 25MG	53	19	$19,515.67	$368.22	2.79	3.32%
MOVANTIK TAB 12.5MG	3	2	$1,096.37	$365.46	1.5	0.19%
SUBTOTAL	**56**	**21**	**$20,612.04**	**$368.07**	**2.67**	**3.51%**
PRUCALOPRIDE PRODUCTS						
MOTEGRITY TAB 2MG	39	7	$14,990.89	$384.38	5.57	2.55%
MOTEGRITY TAB 1MG	2	1	$911.80	$455.90	2	0.16%
SUBTOTAL	**41**	**8**	**$15,902.69**	**$387.87**	**5.13**	**2.71%**
NALDEMEDINE PRODUCTS						
SYMPROIC TAB 0.2MG	11	3	$4,431.64	$402.88	3.67	0.75%
SUBTOTAL	**11**	**3**	**$4,431.64**	**$402.88**	**3.67**	**0.75%**
METHYLNALTREXONE PRODUCTS						
RELISTOR TAB 150MG	1	1	$2,096.51	$2,096.51	1	0.36%
SUBTOTAL	**1**	**1**	**$2,096.51**	**$2,096.51**	**1**	**0.36%**
TOTAL	**1,376**	**314***	**$587,106.56**	**$426.68**	**4.38**	**100%**

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

Utilization Details of Diarrhea Medications: Fiscal Year 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
RIFAXIMIN PRODUCTS						
XIFAXAN TAB 550MG	1,353	355	$3,540,785.76	$2,616.99	3.81	97.78%
XIFAXAN TAB 200MG	36	8	$39,919.80	$1,108.88	4.5	1.10%
SUBTOTAL	**1,389**	**363**	**$3,580,705.56**	**$2,577.90**	**3.83**	**98.88%**
ELUXADOLINE PRODUCTS						
VIBERZI TAB 100MG	17	4	$22,982.69	$1,351.92	4.25	0.63%
VIBERZI TAB 75MG	1	1	$1,392.13	$1,392.13	1	0.04%
SUBTOTAL	**18**	**5**	**$24,374.82**	**$1,354.16**	**3.6**	**0.67%**
TELOTRISTAT ETHYL PRODUCTS						
XERMELO TAB 250MG	2	1	$16,052.55	$8,026.28	2	0.44%
SUBTOTAL	**2**	**1**	**$16,052.55**	**$8,026.28**	**2**	**0.44%**
TOTAL	**1,409**	**369***	**$3,621,132.93**	**$2,570.00**	**3.82**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
TAB = tablet
Fiscal Year 2022 = 07/01/2021 to 06/30/2022
Xifaxan® (rifaximin) was first FDA approved in 2004 and has a significant federal rebate. Please note, the majority of utilization of rifaximin was for the 550mg strength for the reduction in risk of overt hepatic encephalopathy (HE) recurrence.

[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 12/2022. Last accessed 12/05/2022.
[2] Ardelyx, Inc. Ardelyx Announces US Launch of Ibsrela®, a New First-in-Class Treatment for IBS-C in Adults. Available online at: https://ir.ardelyx.com/news-releases/news-release-details/ardelyx-announces-us-launch-ibsrelar-new-first-class-treatment. Issued 04/04/2022. Last accessed 12/05/2022.
[3] Alfasigma USA, Inc. Zelnorm® (Tegaserod) Notice of Withdrawal from Market. Available online at: https://www.prnewswire.com/news-releases/zelnorm-tegaserod-notice-of-withdrawal-from-market-301578099.html. Issued 06/30/2022. Last accessed 12/06/2022.
[4] Chang L, Sultan S, Lembo A, et al. AGA Clinical Practice Guideline on the Pharmacological Management of Irritable Bowel Syndrome with Constipation. *Gastroenterology* 2022; 163(1):118-136.
[5] Lembo A, Sultan S, Chang L, et al. AGA Clinical Practice Guideline on the Pharmacological Management of Irritable Bowel Syndrome with Diarrhea. *Gastroenterology* 2022; 163(1):137-151.

Fiscal Year 2022 Annual Review of Corticosteroid Special Formulations

Oklahoma Health Care Authority
Fiscal Year 2022 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 Tablets) 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 2022

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	652	862	$87,179.48	$101.14	$20.12	4,809	4,334
2022	869	1,181	$111,956.32	$94.80	$19.23	6,440	5,821
% Change	**33.3%**	**37.0%**	**28.4%**	**-6.3%**	**-4.4%**	**33.9%**	**34.3%**
Change	**217**	**319**	**$24,776.84**	**-$6.34**	**-$0.89**	**1,631**	**1,487**

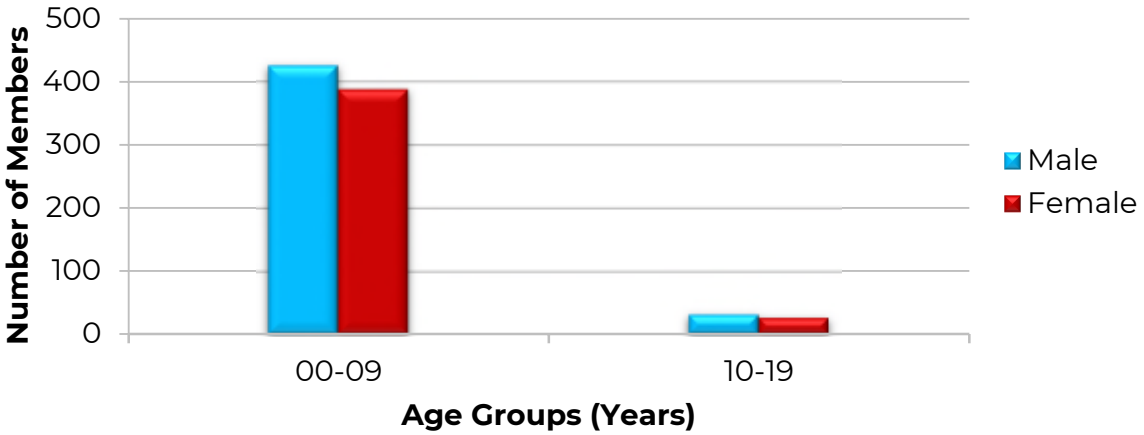
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021; Fiscal Year 2022 = 07/01/2021 to 06/30/2022

Comparison of Fiscal Years: Medical Claims

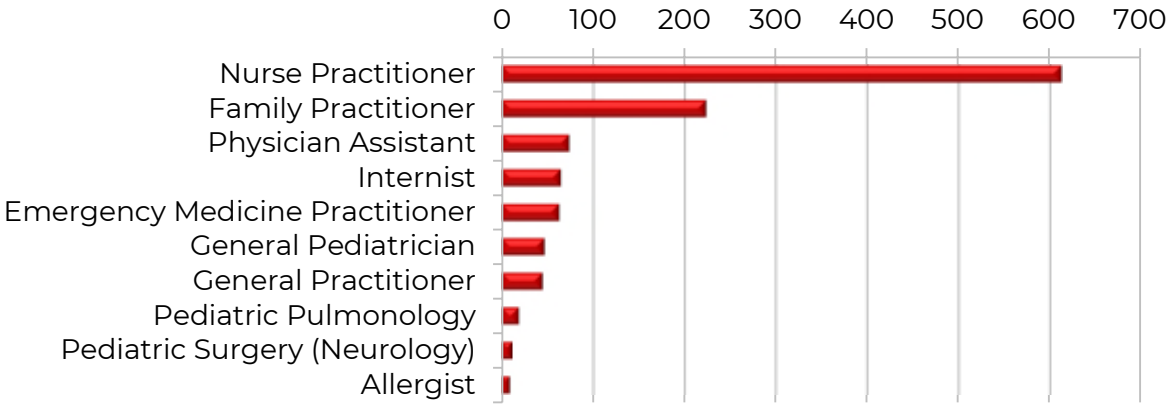
Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Total Units
2021	6	6	$2,894.33	$482.39	257
2022	1	1	$1,120.00	$1,120.00	64
% Change	**-83.33%**	**-83.33%**	**-61.30%**	**132.18%**	**-75.10%**
Change	**-5**	**-5**	**-$1,774.33**	**$637.61**	**-193**

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

Demographics of Members Utilizing Corticosteroid Special Formulations



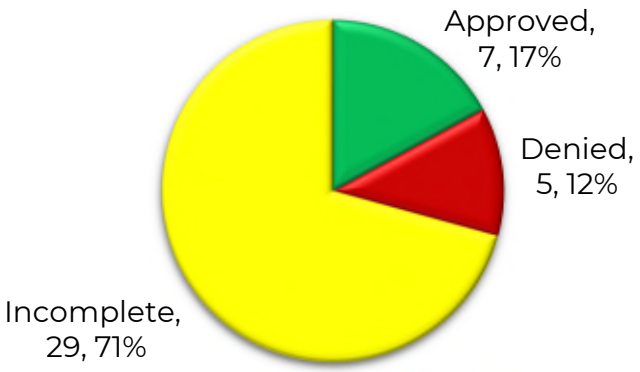
Top Prescriber Specialties of Corticosteroid Special Formulations by Number of Claims



Prior Authorization of Corticosteroid Special Formulations

There were 41 prior authorization requests submitted for corticosteroid special formulations during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions



Market News and Updates[1]

Anticipated Patent Expiration(s):

- 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 does not recommend any changes to the current corticosteroid special formulations prior authorization criteria at this time.

Utilization Details of Corticosteroid Special Formulations: Fiscal Year 2022

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
PREDNISOLONE ORALLY DISINTEGRATING TABLET (ODT) PRODUCTS						
PREDNISOLONE 15MG ODT	643	497	$67,494.51	$104.96	1.29	60.29%
PREDNISOLONE 10MG ODT	394	311	$25,338.87	$64.31	1.27	22.63%
PREDNISOLONE 30MG ODT	144	119	$19,122.94	$132.80	1.21	17.08%
TOTAL	**1,181**	**869***	**$111,956.32**	**$94.80**	**1.36**	**100%**

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

Medical Claims

PRODUCT UTILIZED	†TOTAL CLAIMS	*TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
ZILRETTA INJ 32MG J3304	1	1	$1,120.00	$1,120.00	1
TOTAL	**1**	**1**	**$1,120.00**	**$1,120.00**	**1**

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

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 12/2022. Last accessed 12/15/2022.

Fiscal Year 2022 Annual Review of Crysvita® (Burosumab-twza)

Oklahoma Health Care Authority
Fiscal Year 2022 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 (FGF-23)-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 2022

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	11	99	$1,263,578.79	$12,763.42	$462.85	210	2,730
2022	10	111	$2,070,561.22	$18,653.70	$666.20	230	3,108
% Change	**-9.10%**	**12.10%**	**63.90%**	**46.10%**	**43.90%**	**9.50%**	**13.80%**
Change	**-1**	**12**	**$806,982.43**	**$5890.58**	**$203.35**	**20**	**378**

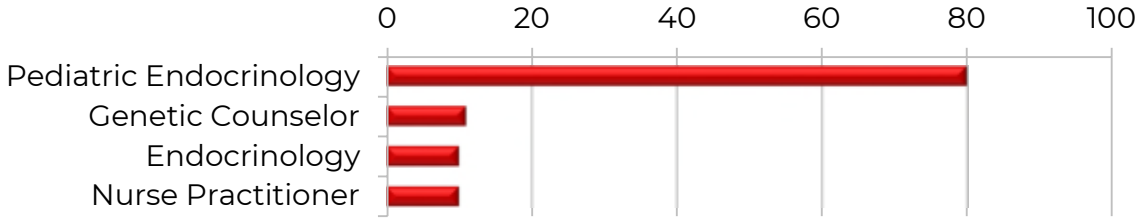
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021; Fiscal Year 2022 = 07/01/2021 to 06/30/2022

- There were no SoonerCare paid medical claims for Crysvita® (burosumab-twza) during fiscal year 2022.

Demographics of Members Utilizing Crysvita® (Burosumab-twza)

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

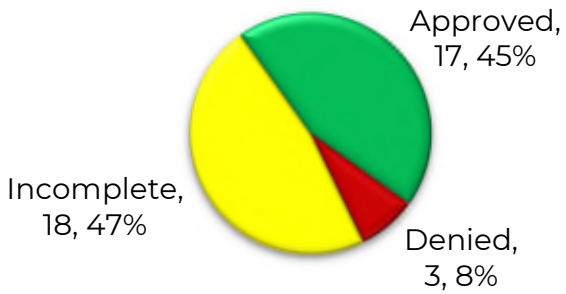
Top Prescriber Specialties of Crysvita® (Burosumab-twza) by Number of Claims



Prior Authorization of Crysvita® (Burosumab-twza)

There were 38 prior authorization requests submitted for Crysvita® (burosumab-twza) for 10 unique members during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions



Recommendations

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

Utilization Details of Crysvita® (Burosumab-twza): Fiscal Year 2022

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
CRYSVITA INJ 20MG/ML	58	9	$826,542.49	$14,250.73	6.44	39.92%
CRYSVITA INJ 30MG/ML	46	6	$1,196,345.86	$26,007.52	7.67	57.78%
CRYSVITA INJ 10MG/ML	7	4	$47,672.87	$6,810.41	1.75	2.30%
TOTAL	**111**	**10***	**$2,070,561.22**	**$18,653.70**	**11.10**	**100%**

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

Fiscal Year 2022 Annual Review of Elaprase® (Idursulfase)

Oklahoma Health Care Authority
Fiscal Year 2022 Print Report

Current Prior Authorization Criteria

Elaprase® (Idursulfase) Approval Criteria:

1. An FDA approved diagnosis of Hunter syndrome (mucopolysaccharidosis type II; MPS II) confirmed by:
   a. Enzyme assay demonstrating a deficiency of iduronate-2-sulfatase enzyme activity; or
   b. Molecular genetic testing confirming a hemizygous pathogenic variant in the *IDS* gene; and
2. 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 Elaprase® (Idursulfase): Fiscal Year 2022

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	1	5	$188,206.85	$37,641.37	$1,344.33	180	140
2022	1	12	$451,696.44	$37,641.37	$1,344.33	432	336
% Change	**0.0%**	**140.0%**	**140.0%**	**0.0%**	**0.0%**	**140.0%**	**140.0%**
Change	**0**	**7**	**$263,489.59**	**$0.00**	**$0.00**	**252**	**196**

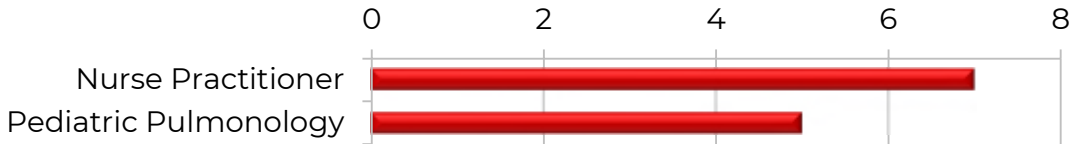
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021; Fiscal Year 2022 = 07/01/2021 to 06/30/2022

- There were no SoonerCare paid medical claims for Elaprase® (idursulfase) during fiscal year 2022.

Demographics of Members Utilizing Elaprase® (Idursulfase)

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

Top Prescriber Specialties of Elaprase® (Idursulfase) by Number of Claims



Prior Authorization of Elaprase® (Idursulfase)

There was 1 prior authorization request submitted and approved for Elaprase® (idursulfase) during fiscal year 2022.

Market News and Updates[1,2]

Pipeline:

- **DNL310:** Denali Therapeutics is developing DNL310 for the treatment of Hunter syndrome (mucopolysaccharidosis type II; MPS II). DNL310 is a recombinant iduronate 2-sulfatase (I2S) enzyme engineered to cross the blood-brain-barrier (BBB) to replace the missing or reduced I2S enzyme and treat neuropathic and systemic forms of MPS II. DNL310 is currently in the late clinical stage of development. In August 2022, Denali announced new interim data from a Phase 1/2 study for DNL310. All of the participants in the study achieved healthy normal levels of heparin sulfate which was accompanied by improvement or stabilization in clinical symptoms and functions. Denali is currently enrolling for the Phase 2/3 COMPASS study, which is designed to support the registration of DNL310 for the treatment of MPS II.

Recommendations

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

Utilization Details of Elaprase® (Idursulfase): Fiscal Year 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ELAPRASE INJ 6MG/3ML	12	1	$451,696.44	$37,641.37	12	100%
TOTAL	**12**	**1***	**$451,696.44**	**$37,641.37**	**12**	**100%**

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

[1] Denali Therapeutics, Inc. Denali Pipeline. Available online at: https://www.denalitherapeutics.com/pipeline. Last accessed 12/05/2022.
[2] Denali Therapeutics, Inc. Denali Therapeutics Announces New Interim Data from Phase 1/2 Study of DNL310 (ETV:IDS) in MPS II (Hunter Syndrome) at SSIEM 2022. Available online at: https://www.globenewswire.com/news-release/2022/08/31/2507598/0/en/Denali-Therapeutics-Announces-New-Interim-Data-from-Phase-1-2-Study-of-DNL310-ETV-IDS-in-MPS-II-Hunter-Syndrome-at-SSIEM-2022.html. Issued 08/31/2022. Last accessed 12/05/2022.

Fiscal Year 2022 Annual Review of Fabry Disease Medications

Oklahoma Health Care Authority
Fiscal Year 2022 Print Report

Current Prior Authorization Criteria

Fabrazyme® (Agalsidase Beta) Approval Criteria:

1. An FDA approved diagnosis of Fabry disease. Diagnosis must be confirmed by 1 of the following:
   a. Genetic testing confirming positive galactosidase alpha (*GLA*) gene mutation; or
   b. Decreased plasma levels of alpha-galactosidase A (<5% of normal); and
2. Fabrazyme® will initially be approved for 6 months. After that time, compliance will be required for continued authorization; and
3. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling.

Galafold® (Migalastat) Approval Criteria:

1. An FDA approved diagnosis of Fabry disease with a confirmed amenable galactosidase alpha (*GLA*) gene variant based on *in vitro* assay data; and
2. Galafold® must be prescribed by or in consultation with a geneticist or an advanced care practitioner with a supervising physician who is a geneticist; and
3. Member must have an estimated glomerular filtration rate (eGFR) of ≥30mL/min/1.73m^2; and
4. Galafold® will not be approved for concomitant use with enzyme replacement therapy (ERT); and
5. Galafold® will initially be approved for 6 months. After that time, compliance will be required for continued authorization; and
6. A quantity limit of 14 capsules per 28 days will apply.

Utilization of Fabry Disease Medications: Fiscal Year 2022

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	3	56	$660,885.38	$11,801.52	$518.75	1,951	1,274
2022	4	56	$789,930.30	$14,105.90	$641.18	2,380	1,232
% Change	**33.3%**	**0.0%**	**19.5%**	**19.5%**	**23.6%**	**22.0%**	**-3.3%**
Change	**1**	**0**	**$129,044.92**	**$2,304.38**	**$122.43**	**429**	**-42**

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

Comparison of Fiscal Years: Medical Claims

Fiscal Year	*Total Members	+Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2021	1	21	$277,661.30	$13,221.97	21
2022	1	19	$263,193.00	$13,852.26	19
% Change	**0.00%**	**-9.5%**	**-5.21%**	**4.77%**	**-9.5%**
Change	**0**	**-2**	**-$14,468.30**	**$630.35**	**-2**

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

Demographics of Members Utilizing Fabry Disease Medications

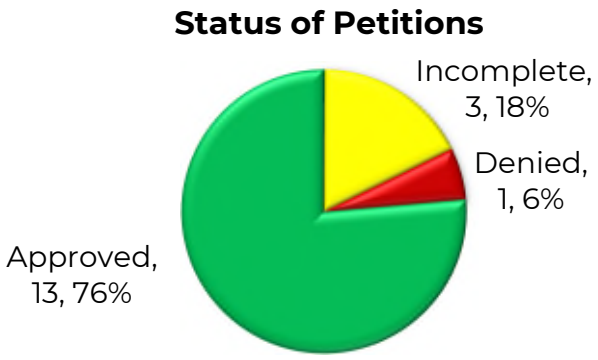
- Due to the limited number of members utilizing Fabry disease medications during fiscal year 2022, detailed demographic information could not be provided.

Top Prescriber Specialties of Fabry Disease Medications by Number of Claims: Pharmacy Claims

- The only prescriber specialty listed on paid pharmacy claims for Fabry disease medications during fiscal year 2022 was medical geneticist.

Prior Authorization of Fabry Disease Medications

There were 17 prior authorization requests submitted for Fabry disease medications during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.



Market News and Updates[1]

Anticipated Patent Expiration(s):

- Galafold® (migalastat): May 2038

Recommendations

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

Utilization Details of Fabry Disease Medications: Fiscal Year 2022

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
FABRAZYME INJ 5MG	31	2	$283,559.97	$9,147.10	15.5	35.90%
GALAFOLD CAP 123MG	14	2	$371,011.74	$26,500.84	7	46.97%
FABRAZYME INJ 35MG	11	1	$135,358.59	$12,307.78	11	17.13%
TOTAL	**56**	**4***	**$789,930.30**	**$14,105.90**	**14**	**100%**

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

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
AGALSIDASE INJ J0180	19	1	$263,193.00	$13,852.26	19	100%
TOTAL	**19**	**1**	**$263,193.00**	**$13,852.26**	**19**	**100%**

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

[1] 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 12/2022. Last accessed 12/07/2022.

Fiscal Year 2022 Annual Review of Fibromyalgia Medications

Oklahoma Health Care Authority
Fiscal Year 2022 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 2022

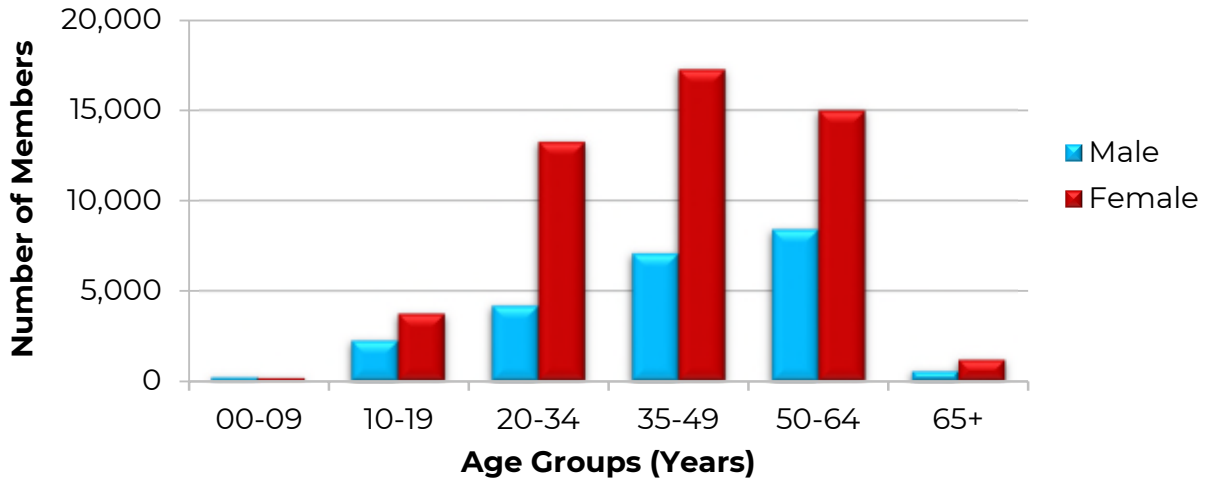
The utilization details include fibromyalgia medications used for all diagnoses and does not differentiate between fibromyalgia diagnoses and other diagnoses, for which use may be appropriate.

Comparison of Fiscal Years

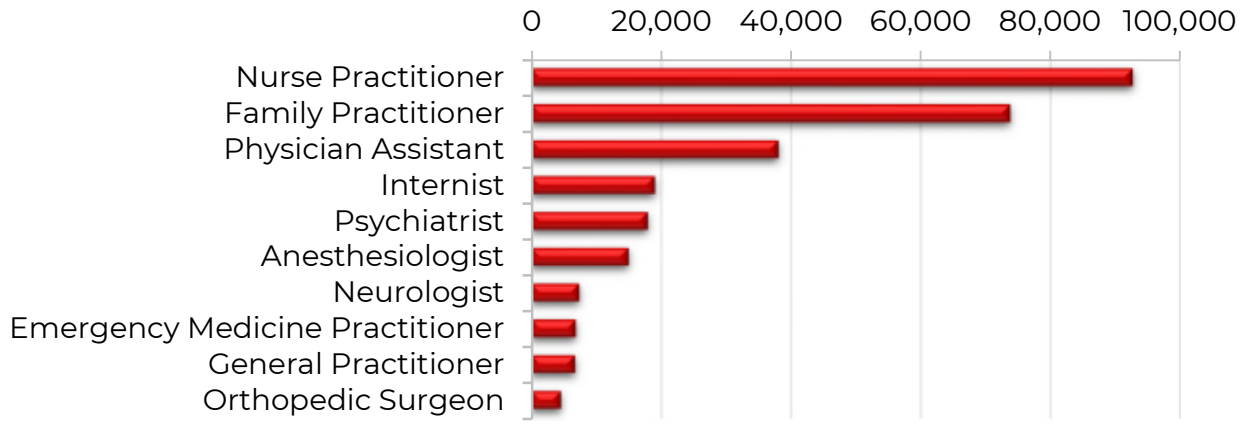
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	44,008	210,585	$3,544,256.78	$16.83	$0.51	17,194,678	6,925,425
2022	73,096	313,597	$5,016,639.49	$16.00	$0.48	25,300,419	10,529,144
% Change	**66.1%**	**48.9%**	**41.5%**	**-4.9%**	**-5.9%**	**47.1%**	**52.0%**
Change	**29,088**	**103,012**	**$1,472,382.71**	**-$0.83**	**-$0.03**	**8,105,741**	**3,603,719**

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

Demographics of Members Utilizing Fibromyalgia Medications

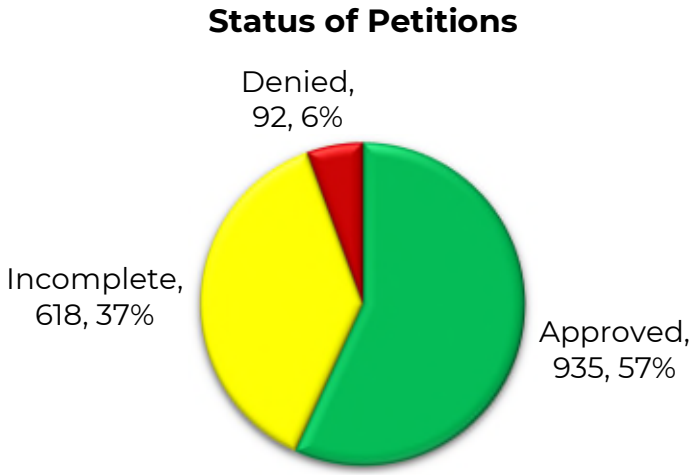


Top Prescriber Specialties of Fibromyalgia Medications by Number of Claims



Prior Authorization of Fibromyalgia Medications

There were 1,645 prior authorization requests submitted for fibromyalgia medications during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.



Market News and Updates[1]

Anticipated Patent Expiration(s):

- 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 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
GABAPENTIN PRODUCTS						
GABAPENTIN CAP 300MG	52,333	17,380	$766,877.80	$14.65	3.01	15.29%
GABAPENTIN TAB 600MG	28,458	6,790	$582,743.17	$20.48	4.19	11.62%
GABAPENTIN TAB 800MG	23,536	4,436	$553,511.56	$23.52	5.31	11.03%
GABAPENTIN CAP 100MG	17,495	7,631	$216,598.09	$12.38	2.29	4.32%
GABAPENTIN CAP 400MG	8,759	2,471	$137,978.43	$15.75	3.54	2.75%
GABAPENTIN SOL 250MG/5ML	1,560	283	$67,401.04	$43.21	5.51	1.34%
NEURONTIN CAP 300MG	9	1	$4,910.68	$545.63	9	0.10%
GABAPENTIN SOL 300MG/6ML	3	1	$274.20	$91.40	3	0.01%
SUBTOTAL	**132,155**	**38,994**	**$2,330,324.48**	**$17.63**	**4.48**	**46.46%**
CYCLOBENZAPRINE PRODUCTS						
CYCLOBENZAPRINE TAB 10MG	42,673	19,796	$438,077.63	$10.27	2.16	8.73%
CYCLOBENZAPRINE TAB 5MG	11,216	6,877	$118,249.58	$10.54	1.63	2.36%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**53,889**	**26,673**	**$556,327.21**	**$10.32**	**2.02**	**11.09%**
DULOXETINE PRODUCTS						
DULOXETINE CAP 60MG	26,732	7,395	$445,277.35	$16.66	3.61	8.88%
DULOXETINE CAP 30MG	19,136	7,451	$290,027.35	$15.16	2.57	5.78%
DULOXETINE CAP 20MG	4,464	1,858	$71,359.64	$15.99	2.4	1.42%
DULOXETINE CAP 40MG	24	4	$3,485.61	$145.23	6	0.07%
CYMBALTA CAP 60MG	11	2	$3,464.13	$314.92	5.5	0.07%
SUBTOTAL	**50,367**	**16,710**	**$813,614.08**	**$16.15**	**3.01**	**16.22%**
TRAMADOL PRODUCTS						
TRAMADOL HCL TAB 50MG	31,584	12,602	$339,844.24	$15.75	2.51	6.77%
TRAMADOL HCL TAB 100MG	2	1	$179.62	$89.81	2	0.00%
SUBTOTAL	**31,586**	**12,603**	**$340,023.86**	**$10.77**	**2.51**	**6.77%**
AMITRIPTYLINE PRODUCTS						
AMITRIPTYLINE TAB 25MG	7,580	2,894	$89,287.81	$11.78	2.62	1.78%
AMITRIPTYLINE TAB 50MG	5,532	1,794	$81,794.84	$14.79	3.08	1.63%
AMITRIPTYLINE TAB 10MG	4,442	1,792	$49,532.82	$11.15	2.48	0.99%
AMITRIPTYLINE TAB 100MG	3,029	733	$77,269.02	$25.51	4.13	1.54%
AMITRIPTYLINE TAB 75MG	1,304	409	$23,289.33	$17.86	3.19	0.46%
AMITRIPTYLINE TAB 150MG	1,150	261	$40,214.86	$34.97	4.41	0.80%
SUBTOTAL	**23,037**	**7,883**	**$361,388.68**	**$15.69**	**2.92**	**7.20%**
PREGABALIN PRODUCTS						
PREGABALIN CAP 150MG	5,225	1,215	$82,480.76	$15.79	4.3	1.64%
PREGABALIN CAP 75MG	4,993	1,753	$72,609.59	$14.54	2.85	1.45%
PREGABALIN CAP 100MG	4,304	1,196	$65,400.78	$15.20	3.6	1.30%
PREGABALIN CAP 50MG	2,892	1,251	$43,428.97	$15.02	2.31	0.87%
PREGABALIN CAP 200MG	2,141	426	$34,839.49	$16.27	5.03	0.69%
PREGABALIN CAP 300MG	1,375	246	$22,942.96	$16.69	5.59	0.52%
PREGABALIN CAP 25MG	753	399	$10,718.08	$14.23	1.89	0.21%
PREGABALIN CAP 225MG	332	67	$5,351.92	$16.12	4.96	0.11%
LYRICA CAP 150MG	107	27	$64,682.93	$604.51	3.96	1.29%
LYRICA CAP 200MG	103	15	$67,010.21	$650.58	6.87	1.34%
LYRICA CAP 100MG	72	18	$31,717.37	$440.52	4	0.63%
LYRICA CAP 300MG	55	11	$26,675.34	$485.01	5	0.53%
LYRICA CAP 75MG	49	10	$25,429.10	$518.96	4.9	0.51%
LYRICA CAP 50MG	32	9	$19,272.03	$602.25	3.56	0.38%
PREGABALIN SOL 20MG/ML	26	4	$1,133.20	$43.58	6.5	0.02%
LYRICA CAP 225MG	10	2	$7,096.87	$709.69	5	0.14%
LYRICA CAP 25MG	7	3	$614.00	$87.71	2.33	0.01%
SUBTOTAL	**22,476**	**6,652**	**$581,403.60**	**$25.87**	**3.38**	**11.58%**
MILNACIPRAN PRODUCTS						
SAVELLA TAB 50MG	46	9	$16,767.90	$518.96	4.9	0.33%
SAVELLA TAB 100MG	34	4	$14,062.58	$413.61	8.5	0.28%
SAVELLA TITR PAK	5	5	$1,894.07	$378.81	1	0.04%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SAVELLA TAB 12.5MG	1	1	$396.76	$396.76	1	0.01%
SAVELLA TAB 25MG	1	1	$436.27	$436.27	1	0.01%
SUBTOTAL	**87**	**20**	**$33,557.58**	**$385.72**	**4.63**	**0.67%**
TOTAL	**313,597**	**73,096***	**$5,016,639.49**	**$16.00**	**4.29**	**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 2022 = 07/01/2021 to 06/30/2022
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 11/2022. Last accessed 11/02/2022.

Fiscal Year 2022 Annual Review of Gattex® [Teduglutide (rDNA Origin)]

Oklahoma Health Care Authority
Fiscal Year 2022 Print Report

Current Prior Authorization Criteria

Gattex® [Teduglutide (rDNA Origin)] Approval Criteria:

1. An FDA approved diagnosis of severe short bowel syndrome; and
2. Member must have required parenteral nutrition at least 3 times per week, every week, for the past 12 months; and
3. Documentation of all of the following:
   a. Prior use of supportive therapies (e.g., anti-motility agents, proton pump inhibitors, bile acid sequestrants, octreotide); and
   b. Colonoscopy within the previous 6 months, with removal of polyps if present; and
   c. Gastrointestinal malignancy has been ruled out; and
4. Approval will be for the duration of 3 months, after which time, prescriber must verify benefit of medication by documented reduction of at least 20% in parenteral support. Subsequent approvals will be for the duration of 1 year.

Utilization of Gattex® [Teduglutide (rDNA Origin)]: Fiscal Year 2022

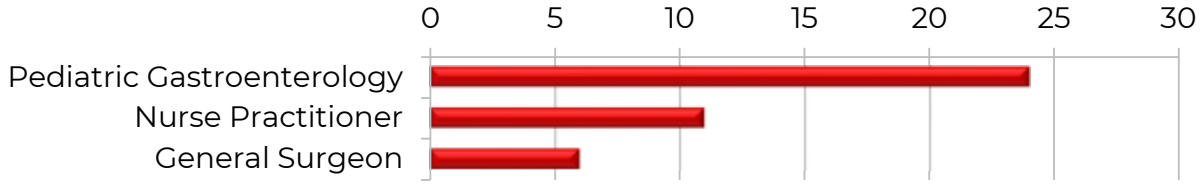
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	2	14	$577,381.80	$41,241.56	$1,374.72	14	420
2022	6	41	$1,734,921.06	$42,315.15	$1,410.50	41	1,230
% Change	**200.0%**	**192.9%**	**200.5%**	**2.6%**	**2.6%**	**192.9%**	**192.9%**
Change	**4**	**27**	**$1,157,539.26**	**$1,073.59**	**$35.78**	**27**	**810**

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

Demographics of Members Utilizing Gattex® [Teduglutide (rDNA Origin)]

- Due to the limited number of members utilizing Gattex® [teduglutide (rDNA Origin)] during fiscal year 2022, detailed demographic information could not be provided.

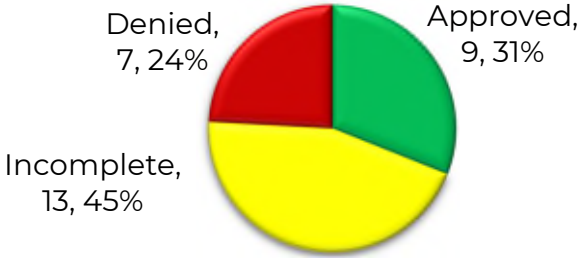
Top Prescriber Specialties of Gattex® [Teduglutide (rDNA Origin)] by Number of Claims



Prior Authorization of Gattex® [Teduglutide (rDNA Origin)]

There were 29 prior authorization requests submitted for Gattex® [teduglutide (rDNA origin)] during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions



Market News and Updates[1]

Anticipated Exclusivity Expiration(s):

- Gattex® [teduglutide (rDNA origin)]: May 2026

Recommendations

The College of Pharmacy does not recommend any changes to the current Gattex® [teduglutide (rDNA origin)] prior authorization criteria at this time.

Utilization Details of Gattex® [Teduglutide (rDNA Origin)]: Fiscal Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
GATTEX KIT 5MG	41	6	$1,734,921.06	$42,315.15	6.83	100%
TOTAL	**41**	**6***	**$1,734,921.06**	**$42,315.15**	**6.83**	**100%**

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

[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 12/2022. Last accessed 12/12/2022.

Fiscal Year 2022 Annual Review of Gaucher Disease Medications

Oklahoma Health Care Authority
Fiscal Year 2022 Print Report

Current Prior Authorization Criteria

Cerdelga® (Eliglustat) Approval Criteria:

1. An FDA approved diagnosis of type 1 Gaucher disease (GD1); and
2. Member is classified as 1 of the following as detected by an FDA-cleared test:
   a. CYP2D6 extensive metabolizers (EMs); or
   b. CYP2D6 intermediate metabolizers (IMs); or
   c. CYP2D6 poor metabolizers (PMs); and
3. Prescriber must verify the member will not take Cerdelga® concurrently with another therapy for GD1; and
4. For CYP2D6 EMs and IMs, a quantity limit of 56 capsules per 28 days will apply. For CYP2D6 PMs, a quantity limit of 28 capsules per 28 days will apply; and
5. Approvals will be for the duration of 6 months, at which time the prescriber must verify the member is responding well to the medication.

Cerezyme® (Imiglucerase), Elelyso® (Taliglucerase Alfa), and Vpriv® (Velaglucerase Alfa) Approval Criteria:

1. Diagnosis of symptomatic (e.g., anemia, thrombocytopenia, bone disease, splenomegaly, hepatomegaly) type 1 or type 3 Gaucher disease (GD); and
2. Member's weight (kg) must be provided and must have been taken within the last 4 weeks to ensure accurate weight based dosing; and
3. Prescriber must verify the member will not take the requested therapy concurrently with another therapy for GD; and
4. Approvals will be for the duration of 6 months, at which time the prescriber must verify the member is responding well to the medication.

Zavesca® (Miglustat) Approval Criteria:

1. An FDA approved diagnosis of mild/moderate type 1 Gaucher disease (GD1); and
2. A patient-specific, clinically significant reason why the member cannot use 1 of the following enzyme replacement therapies must be provided:
   a. Cerezyme® (imiglucerase); or

b. Elelyso® (taliglucerase alfa); or
c. Vpriv® (velaglucerase alfa); and

3. Prescriber must verify the member will not take Zavesca® concurrently with another therapy for GD1; and
4. A quantity limit of 90 capsules per 30 days will apply; and
5. Approvals will be for the duration of 6 months, at which time the prescriber must verify the member is responding well to the medication.

Utilization of Gaucher Disease Medications: Fiscal Year 2022

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	3	30	$773,970.12	$25,799.00	$921.39	1,226	840
2022	5	41	$1,137,859.80	$27,752.68	$984.31	1,579	1,156
% Change	**66.7%**	**36.7%**	**47.0%**	**7.6%**	**6.8%**	**28.8%**	**37.6%**
Change	**2**	**11**	**$363,889.68**	**$1,953.68**	**$62.92**	**353**	**316**

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

Comparison of Fiscal Years: Medical Claims

Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Total Units
2021	2	52	$498,635.04	$9,589.14	1,440
2022	2	46	$530,034.24	$11,522.48	1,476
% Change	**0%**	**-13.04%**	**5.92%**	**16.77%**	**2.5%**
Change	**0**	**-6**	**$31,399.20**	**$1,933.34**	**36**

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

Demographics of Members Utilizing Gaucher Disease Medications

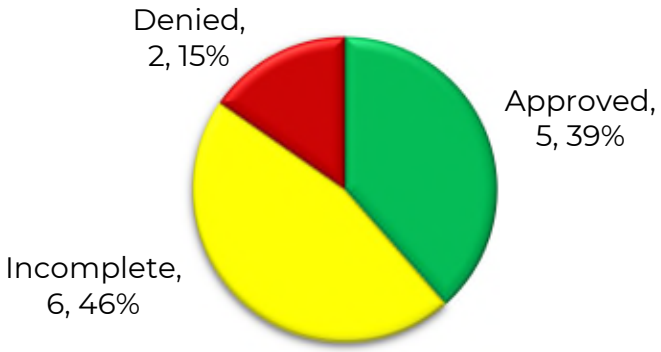
- Due to the limited number of members utilizing Gaucher disease medications during fiscal year 2022, detailed demographic information could not be provided.

Top Prescriber Specialties of Gaucher Disease Medications by Number of Claims

Prior Authorization of Gaucher Disease Medications

There were 13 prior authorization requests submitted for Gaucher disease medications during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions



Market News and Updates[1]

Anticipated Patent Expiration(s):

- Cerdelga® (eliglustat): December 2038

Recommendations

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

Utilization Details of Gaucher Disease Medications: Fiscal Year 2022

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
CEREZYME INJ 400 UNIT	19	3	$604,399.71	$31,810.51	6.33	53.12%
VPRIV INJ 400 UNIT	11	1	$268,150.10	$24,377.28	11	23.57%
MIGLUSTAT CAP 100MG	11	1	$265,309.99	$24,119.09	11	23.32%
TOTAL	**41**	**5***	**$1,137,859.80**	**$27,752.68**	**8.2**	**100%**

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

Medical Claims

PRODUCT UTILIZED	†TOTAL CLAIMS	*TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
VPRIV INJ 400 UNIT J3385	46	2	$530,034.24	$11,522.48	23
TOTAL	**46**	**2**	**$530,034.24**	**$11,522.48**	**23**

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

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

Fiscal Year 2022 Annual Review of Givlaari® (Givosiran) and Scenesse® (Afamelanotide)

Oklahoma Health Care Authority
Fiscal Year 2022 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 2022

Fiscal Year 2022 Utilization: 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

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
Please note: There was no SoonerCare utilization of Givlaari® (givosiran) or Scenesse® (afamelanotide) during fiscal year 2021 (07/01/2020 to 06/30/2021) to allow for a fiscal year comparison.

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

There were 3 prior authorization requests submitted for 2 unique members for Givlaari® (givosiran) during fiscal year 2022. There were no prior

authorization requests submitted for Scenesse® (afamelanotide) during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions

Market News and Updates[1,2]

Anticipated Patent Expiration(s):

- 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 2022

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	*TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
GIVOSIRAN INJ 0.5MG J0223	10	1	$403,371.36	$40,337.14	10	100%
TOTAL	**10**	**1**	**$403,371.36**	**$40,337.14**	**10**	**100%**

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

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 12/2022. Last accessed 12/14/2022.
[2] Clinuvel. Pharmaceutical Technology: Pipeline. Available online at: https://www.clinuvel.com/pharmaceutical-technology/#Pipeline. Last accessed 12/14/2022.

Fiscal Year 2022 Annual Review of Iron Chelating Agents

Oklahoma Health Care Authority
Fiscal Year 2022 Print Report

Current Prior Authorization Criteria

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

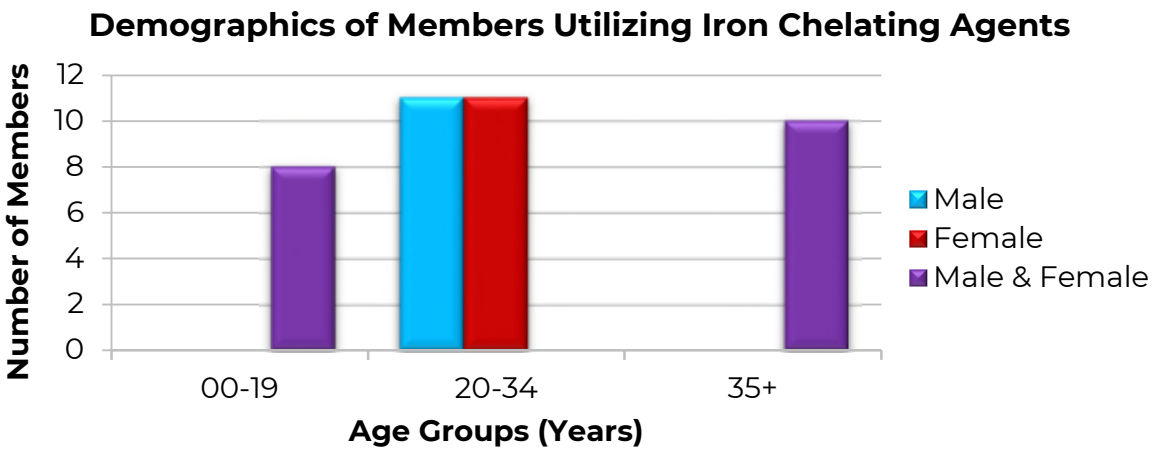
1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason other than convenience why the member cannot use Exjade® (deferasirox) must be provided; and
3. For Jadenu® Sprinkle (deferasirox oral granules), an age restriction of 6 years of age and younger will apply. Members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

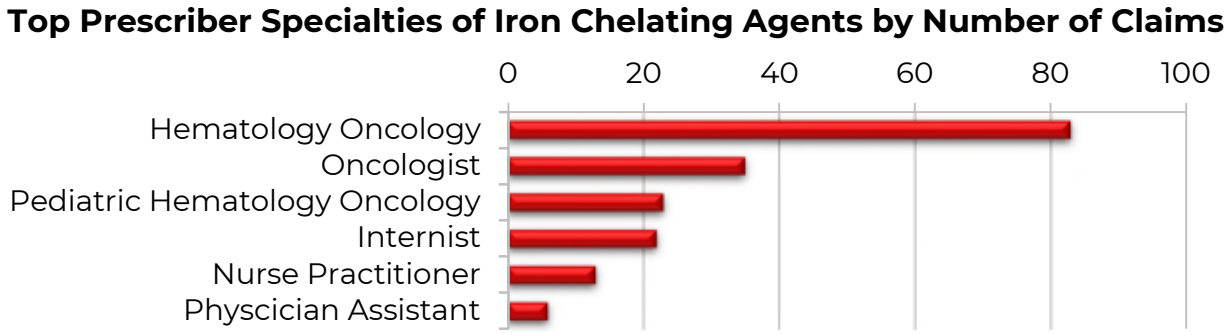
Utilization of Iron Chelating Agents: Fiscal Year 2022

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	37	170	$953,634.47	$5,609.61	$188.39	11,967	5,062
2022	40	182	$965,455.14	$5,304.70	$174.43	14,310	5,535
% Change	**8.1%**	**7.1%**	**1.2%**	**-5.4%**	**-7.4%**	**19.6%**	**9.3%**
Change	**3**	**12**	**$11,820.67**	**-$304.91**	**-$13.96**	**2,343**	**473**

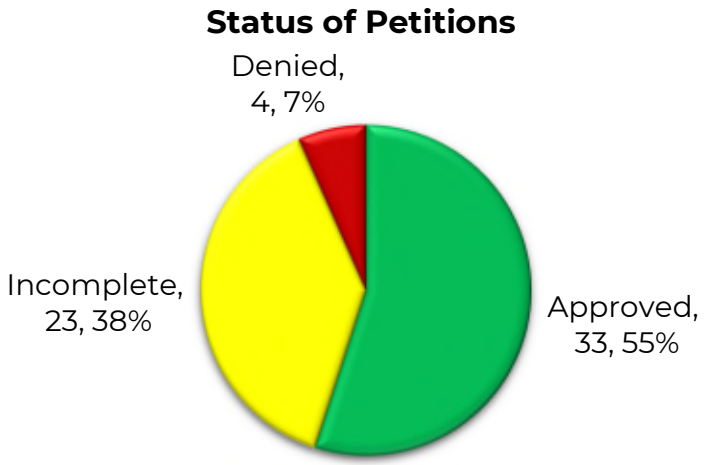
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021; Fiscal Year 2022 = 07/01/2021 to 06/30/2022





Prior Authorization of Iron Chelating Agents

There were 60 prior authorization requests submitted for iron chelating agents during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.



Market News and Updates[1]

Anticipated Patent Expiration(s):

- 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 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
DEFERASIROX PRODUCTS						
DEFERASIROX TAB 360MG	73	15	$172,954.84	$2,369.24	4.87	17.91%
DEFERASIROX TAB 500MG	32	15	$95,871.19	$2,995.97	2.13	9.93%
JADENU TAB 360MG	16	3	$223,083.36	$13,942.71	5.33	23.11%
DEFERASIROX TAB 180MG	14	2	$18,382.51	$1,313.04	7	1.90%
DEFERASIROX TAB 250MG	12	2	$9,531.39	$794.28	6	0.99%
EXJADE TAB 500MG	12	6	$157,197.62	$13,099.80	2	16.28%
JADENU SPRKL GRA 180MG	3	1	$7,635.18	$2,545.06	3	0.79%
DEFERASIROX TAB 125MG	3	2	$877.12	$292.37	1.5	0.09%
EXJADE TAB 125MG	2	2	$2,556.52	$1,278.26	1	0.26%
DEFERASIROX GRA 360MG	2	1	$8,629.06	$4,314.53	2	0.89%
DEFERASIROX GRA 90MG	1	1	$1,088.23	$1,088.23	1	0.11%
SUBTOTAL	**170**	**39***	**$697,807.02**	**$4,104.75**	**4.36**	**72.28%**
DEFERIPRONE PRODUCTS						
FERRIPROX TAB 1000MG	12	1	$267,648.12	$22,304.01	12	27.72%
SUBTOTAL	**12**	**1**	**$267,648.12**	**$22,304.01**	**12**	**27.72%**
TOTAL	**182**	**40***	**$965,455.14**	**$5,304.70**	**4.55**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
GRA = granule; SPRKL = sprinkle; TAB = tablet
Please note, Exjade® was first FDA approved in 2005 and has a significant federal rebate.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022

[1] U.S. Food and Drug Administration (FDA): Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 11/2022. Last Accessed 11/17/2022.

Fiscal Year 2022 Annual Review of Luxturna® (Voretigene Neparvovec-rzyl)

Oklahoma Health Care Authority
Fiscal Year 2022 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 2022

There was no SoonerCare utilization of Luxturna® (voretigene neparvovec-rzyl) during fiscal year 2022 (07/01/2021 to 06/30/2022).

Prior Authorization of Luxturna® (Voretigene Neparvovec-rzyl)

There were no prior authorization requests submitted for Luxturna® (voretigene neparvovec-rzyl) during fiscal year 2022.

Recommendations

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

Fiscal Year 2022 Annual Review of Mycapssa® (Octreotide) and Signifor® LAR (Pasireotide)

Oklahoma Health Care Authority
Fiscal Year 2022 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 2022

Fiscal Year 2022 Utilization

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

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
Please note: There was no SoonerCare utilization of Mycapssa® (octreotide) or Signifor® LAR (pasireotide) during fiscal year 2021 (07/01/2020 to 06/30/2021) to allow for a fiscal year comparison.

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 2022, 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 2022 was endocrinologist.

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

There were 2 prior authorization requests submitted for 1 unique member for Signifor® LAR (pasireotide) during fiscal year 2022. There were no prior authorization requests submitted for Mycapssa® (octreotide) during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions

Market News and Updates[1]

Anticipated Patent Expiration(s):

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

Recommendations

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

Utilization Details of Mycapssa® (Octreotide) and Signifor® LAR (Pasireotide): Fiscal Year 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIM/ MEMBER	% COST
SIGNIFOR LAR INJ 40MG	7	1	$100,183.71	$14,311.96	7	100%
TOTAL	**7**	**1***	**$100,183.71**	**$14,311.96**	**7**	**100%**

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

[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 09/2022. Last accessed 09/28/2022.

Fiscal Year 2022 Annual Review of Naloxone Medications

Oklahoma Health Care Authority
Fiscal Year 2022 Print Report

Current Prior Authorization Criteria

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

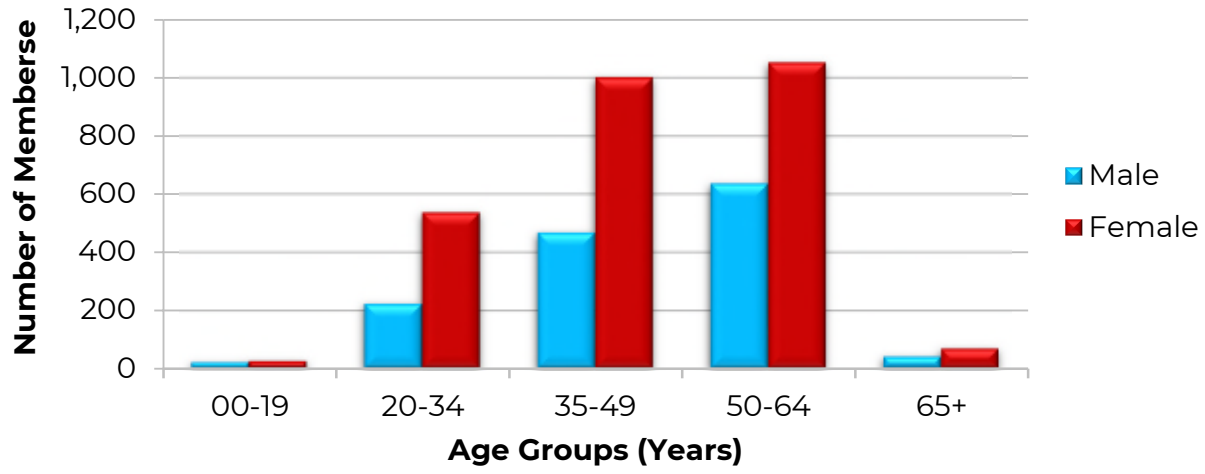
Utilization of Naloxone Medications: Fiscal Year 2022

Comparison of Fiscal Years

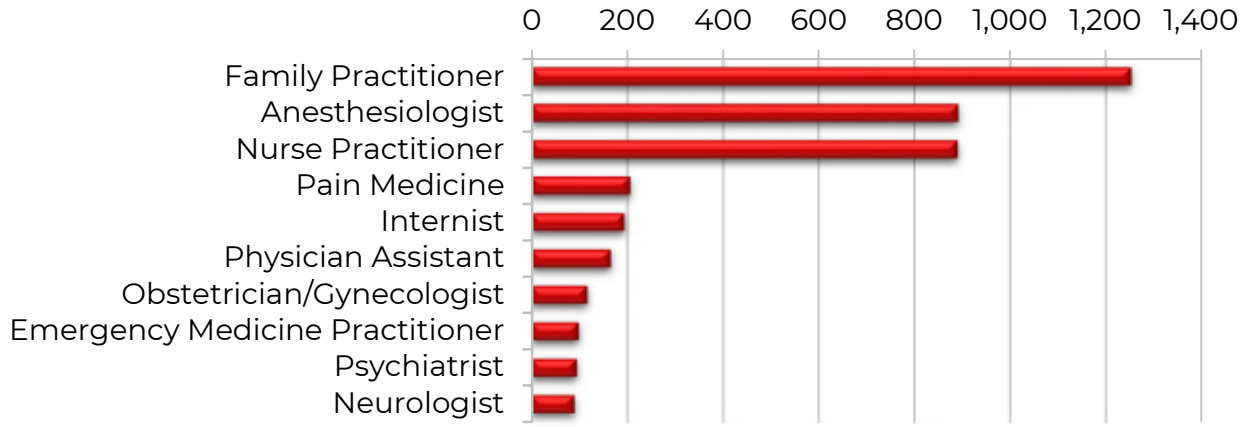
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	2,436	2,615	$339,108.83	$129.68	$4.28	5,237	79,264
2022	4,063	4,352	$510,307.04	$117.26	$3.87	8,680	131,924
% Change	**66.80%**	**66.40%**	**50.50%**	**-9.60%**	**-9.60%**	**65.70%**	**66.40%**
Change	**1,627**	**1,737**	**$171,198.21**	**-$12.42**	**-$0.41**	**3,443**	**52,660**

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

Demographics of Members Utilizing Naloxone Medications



Top Prescriber Specialties of Naloxone Medications by Number of Claims



Prior Authorization of Naloxone Medications

There were 6 prior authorization requests submitted for naloxone medications during fiscal year 2022. All 6 prior authorization requests were deemed incomplete, as naloxone medications currently do not require prior authorization.

Market News and Updates[1,2]

Anticipated Patent Expiration(s):

- Kloxxado® (naloxone nasal spray): August 2034
- Narcan® (naloxone nasal spray): March 2035

News:

- **November 2022:** The U.S. Food and Drug Administration (FDA) issued a Federal Register notice that included a preliminary assessment that certain naloxone drug products may be approvable as safe and effective for nonprescription use. The products included in this assessment are naloxone nasal spray (up to 4mg) and naloxone autoinjector for intramuscular (IM) or subcutaneous (sub-Q) use (up to 2mg). The preliminary assessment is intended to facilitate the development and approval of certain nonprescription naloxone drug products, including through the switch of certain naloxone drug products from prescription status to nonprescription status. However, the assessment is not a final determination and does not allow for the immediate switch to nonprescription availability for current naloxone products. The Federal Register notice from the FDA is open for comments until January 17, 2023.

Recommendations

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

Utilization Details of Naloxone Medications: Fiscal Year 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
NARCAN SPR 4MG	2,272	2,166	$293,659.90	$129.25	1.05	57.55%
NALOXONE HCL SPR 4MG	1,136	1,110	$106,411.70	$93.67	1.02	20.85%
NALOXONE SPR 4MG	908	884	$108,257.93	$119.23	1.03	21.21%
NALOXONE INJ 0.4MG/ML	14	14	$387.16	$27.65	1	0.08%
NALOXONE INJ 1MG/ML PFS	13	13	$733.02	$56.39	1	0.14%
KLOXXADO SPR 8MG	4	4	$491.48	$122.87	1	0.10%
NALOXONE INJ 0.4MG/ML CART	3	3	$246.09	$82.03	1	0.05%
NALOXONE INJ 0.4MG/ML	2	2	$119.76	$59.88	1	0.02%
TOTAL	**4,352**	**4,063***	**$510,307.04**	**$117.26**	**1.07**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CART = cartridge; HCL = hydrochloride; INJ = injection; PFS = prefilled syringe; SPR = spray
Fiscal Year 2022 = 07/01/2021 to 06/30/2022

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 12/2022. Last accessed 12/05/2022.
[2] U.S. FDA. FDA Announces Preliminary Assessment that Certain Naloxone Products Have the Potential to be Safe and Effective for Over-the-Counter Use. Available online at: https://www.fda.gov/news-events/press-announcements/fda-announces-preliminary-assessment-certain-naloxone-products-have-potential-be-safe-and-effective. Issued 11/15/2022. Last accessed: 12/05/2022.

Fiscal Year 2022 Annual Review of Northera® (Droxidopa)

Oklahoma Health Care Authority
Fiscal Year 2022 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 2022

Comparison of Fiscal Years

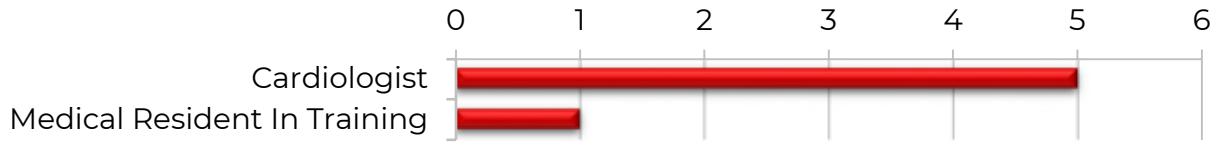
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	1	1	$58.08	$58.08	$4.15	42	14
2022	2	6	$657.80	$109.63	$5.14	534	128
% Change	**100.0%**	**500.0%**	**1,032.6%**	**88.8%**	**23.9%**	**1,171.4%**	**814.3%**
Change	**1**	**5**	**$599.72**	**$51.55**	**$0.99**	**492**	**114**

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

Demographics of Members Utilizing Northera® (Droxidopa)

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

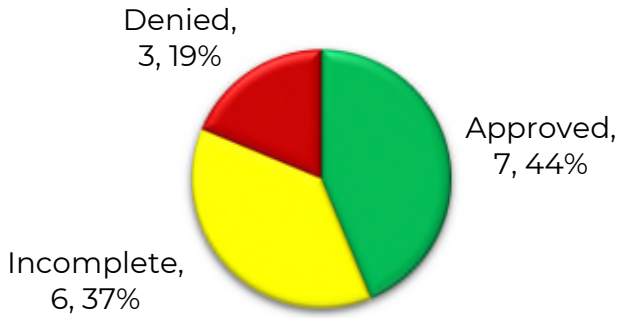
Top Prescriber Specialties of Northera® (Droxidopa) by Number of Claims



Prior Authorization of Northera® (Droxidopa)

There were 16 prior authorization requests submitted for Northera® (droxidopa) during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions



Market News and Updates[1]

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). It has a high affinity for binding to norepinephrine transporters and by blocking the action of these transporters, ampreloxetine causes an increase in extracellular concentrations of norepinephrine. A Phase 2 study of ampreloxetine showed positive 4-week results in patients with nOH, including durable improvements in patients' disease symptom severity after 4 weeks of treatment. Ampreloxetine is currently being evaluated in a registrational Phase 3 program 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 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
DROXIDOPA 100MG CAP	6	2	$657.80	$5.14	$109.63	100%
TOTAL	**6**	**2***	**$657.80**	**$5.14**	**$109.63**	**100%**

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

[1] Theravance Biopharma. Our Pipeline. Available online at: https://www.theravance.com/our-pipeline. Last accessed 11/29/2022.

Fiscal Year 2022 Annual Review of Otic Anti-Infective Medications

Oklahoma Health Care Authority
Fiscal Year 2022 Print Report

Current Prior Authorization Criteria

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

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

Otic Anti-Infective Medications Tier-2 Approval Criteria:

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

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

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

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

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

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

Utilization of Otic Anti-Infective Medications: Fiscal Year 2022

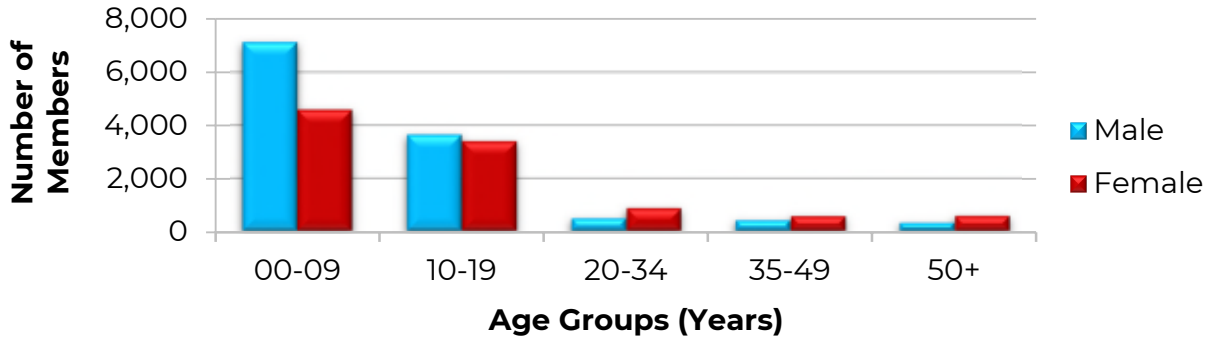
Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	18,341	21,820	$4,264,158.73	$195.42	$18.28	166,660	233,327
2022	24,985	30,517	$4,705,166.44	$154.18	$14.92	232,140	315,292
% Change	**36.2%**	**39.9%**	**10.3%**	**-21.1%**	**-18.4%**	**39.3%**	**35.1%**
Change	**6,644**	**8,697**	**$441,007.71**	**-$41.24**	**-$3.36**	**65,480**	**81,965**

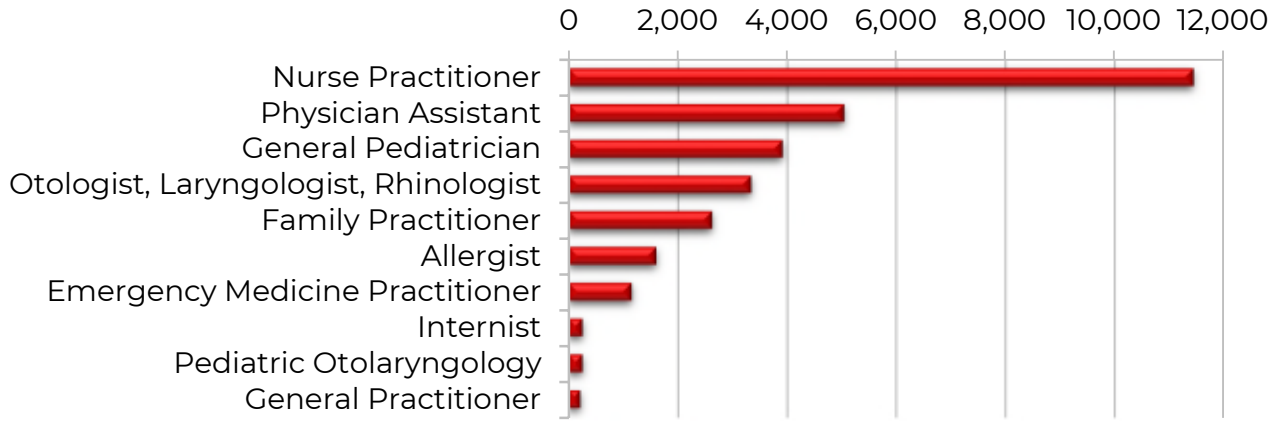
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021; Fiscal Year 2022 = 07/01/2021 to 06/30/2022

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

Demographics of Members Utilizing Otic Anti-Infective Medications



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



Prior Authorization of Otic Anti-Infective Medications

There were 266 prior authorization requests submitted for otic anti-infective medications during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions

Market News and Updates[1]

Anticipated Patent Expiration(s):

- Ciprodex® (ciprofloxacin/dexamethasone): June 2025
- Otovel® (ciprofloxacin/fluocinolone): March 2030
- Xtoro™ (finafloxacin): November 2033
- Otiprio® (ciprofloxacin): November 2038

Recommendations

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

Utilization Details of Otic Anti-Infective Medications: Fiscal Year 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 PRODUCTS						
CIPRO/DEXA SUS 0.3-0.1%	29,149	23,933	$4,419,970.64	$151.63	1.22	93.94%
CIPRODEX SUS 0.3-0.1%	587	565	$141,610.71	$241.24	1.04	3.01%
CIPRO HC SUS OTIC 0.2-1%	329	324	$101,421.24	$308.27	1.02	2.16%
ACETIC ACID SOL 2% OTIC	281	255	$7,767.39	$27.64	1.10	0.17%
CORTISPORIN SUS -TC 0.33-0.3-1-0.05%	146	135	$33,440.26	$229.04	1.08	0.71%
SUBTOTAL	**30,492**	**25,212**	**$4,704,210.24**	**$154.28**	**1.21**	**99.99%**
TIER-2 PRODUCTS						
OFLOXACIN DRO 0.3% OTIC	17	12	$494.14	$29.07	1.42	0.01%
NEO/POLY/HC SUS 1% OTIC	5	5	$318.60	$63.72	1.00	0.01%
NEO/POLY/HC SOL 1% OTIC	3	3	$143.46	$47.82	1	0.00%
SUBTOTAL	**25**	**20**	**$956.20**	**$38.25**	**1.25**	**0.02%**
TOTAL	**30,517**	**24,985***	**$4,705,166.44**	**$154.18**	**1.21**	**100%**

Please note: Tier-1 products may participate in supplemental rebates; therefore, costs shown do not reflect net costs.
*Total number of unduplicated utilizing members.
CIPRO/DEXA = ciprofloxacin/dexamethasone; DRO = drops; HC = hydrocortisone; NEO = neomycin; POLY = polymyxin; SOL = solution; SUS = suspension
Fiscal Year 2022 = 07/01/2021 to 06/30/2022

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 11/2022. Last Accessed 11/18/2022.

Fiscal Year 2022 Annual Review of Pancreatic Enzymes

Oklahoma Health Care Authority
Fiscal Year 2022 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.

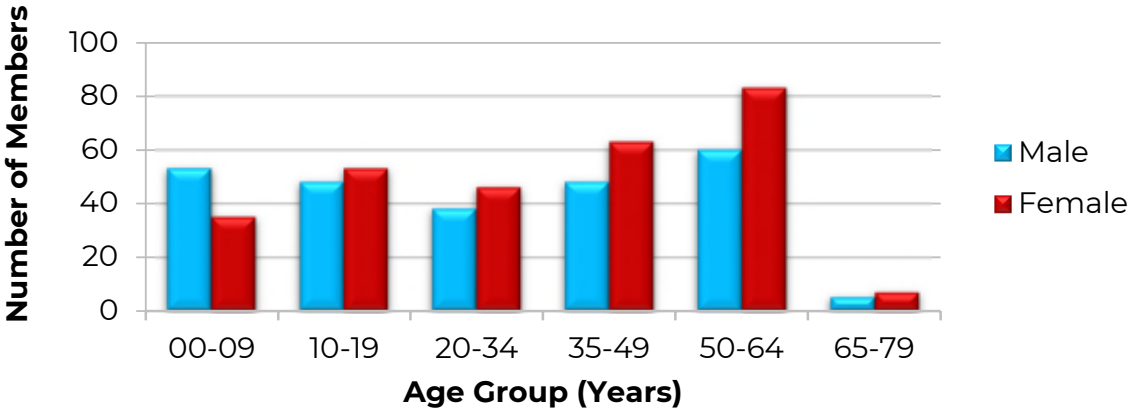
Utilization of Pancreatic Enzymes: Fiscal Year 2022

Comparison of Fiscal Years

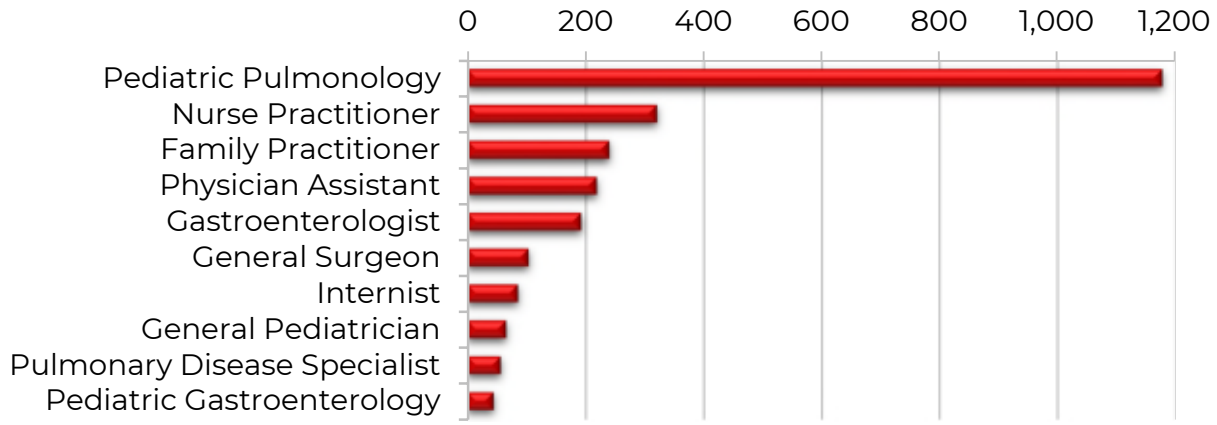
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	389	1,917	$3,731,482.81	$1,946.52	$68.61	660,965	54,388
2022	539	2,652	$5,985,083.62	$2,256.82	$77.40	887,410	77,329
% Change	**38.6%**	**38.3%**	**60.4%**	**15.9%**	**12.8%**	**34.3%**	**42.2%**
Change	**150**	**735**	**$2,253,600.81**	**$310.30**	**$8.79**	**226,445**	**22,941**

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

Demographics of Members Utilizing Pancreatic Enzymes



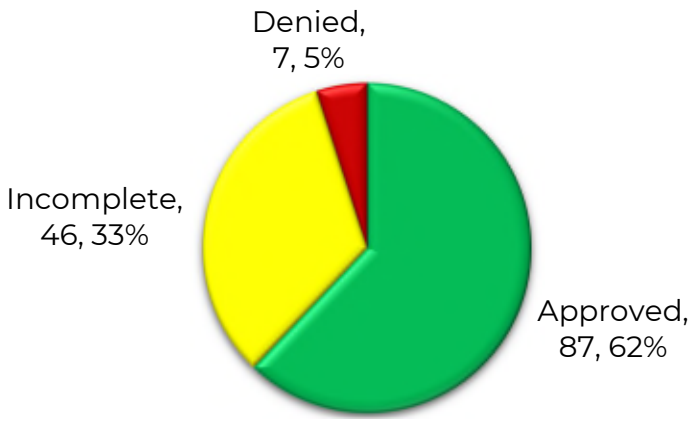
Top Prescriber Specialties of Pancreatic Enzymes by Number of Claims



Prior Authorization of Pancreatic Enzymes

There were 140 prior authorization requests submitted for pancreatic enzymes during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions



Recommendations

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

Utilization Details of Pancreatic Enzymes: Fiscal Year 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
CREON®						
CREON CAP 36,000 UNIT	585	164	$1,573,963.59	$2,690.54	3.57	26.30%
CREON CAP 24,000 UNIT	440	98	$1,028,815.77	$2,338.22	4.49	17.19%
CREON CAP 12,000 UNIT	358	89	$373,959.38	$1,044.58	4.02	6.25%
CREON CAP 6,000 UNIT	109	31	$55,032.10	$504.88	3.52	0.92%
CREON CAP 3,000 UNIT	60	23	$16,577.90	$276.30	2.61	0.28%
SUBTOTAL	**1,552**	**405**	**$3,048,348.74**	**$1,964.14**	**3.83**	**50.93%**
ZENPEP®						
ZENPEP CAP 40,000 UNIT	247	68	$986,185.68	$3,992.65	3.63	16.48%
ZENPEP CAP 10,000 UNIT	144	31	$178,128.14	$1,237.00	4.65	2.98%
ZENPEP CAP 25,000 UNIT	142	33	$474,710.84	$3,343.03	4.3	7.93%
ZENPEP CAP 5,000 UNIT	84	25	$62,490.74	$743.94	3.36	1.04%
ZENPEP CAP 20,000 UNIT	66	23	$144,640.73	$2,191.53	2.87	2.42%
ZENPEP CAP 15,000 UNIT	55	8	$129,354.43	$2,351.90	6.88	2.16%
ZENPEP CAP 3,000 UNIT	10	3	$3,503.12	$350.31	3.33	0.06%
SUBTOTAL	**748**	**191**	**$1,979,013.68**	**$2,645.74**	**3.92**	**33.07%**
PERTZYE®						
PERTZYE CAP 16,000 UNIT	131	20	$345,319.23	$2,636.02	6.55	5.77%
PERTZYE CAP 24,000 UNIT	114	17	$510,495.29	$4,478.03	6.71	8.53%
PERTZYE CAP 8,000 UNIT	64	13	$41,840.58	$653.76	4.92	0.70%
PERTZYE CAP 4,000 UNIT	1	1	$466.90	$466.90	1	0.01%
SUBTOTAL	**310**	**51**	**$898,122.00**	**$2,897.17**	**6.08**	**15.01%**
VIOKACE®						
VIOKACE TAB 10,440 UNIT	34	5	$51,154.59	$1,504.55	6.8	0.85%
VIOKACE TAB 20,880 UNIT	4	2	$2,064.46	$516.12	2	0.03%
SUBTOTAL	**38**	**7**	**$53,219.05**	**$1,400.50**	**5.43**	**0.89%**
PANCREAZE®						
PANCREAZE CAP 21,000 UNIT	4	1	$6,380.15	$1,595.04	4	0.11%
SUBTOTAL	**4**	**1**	**$6,380.15**	**$1,595.04**	**4**	**0.11%**
TOTAL	**2,652**	**539***	**$5,985,083.62**	**$2,256.82**	**4.92**	**100%**

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

Fiscal Year 2022 Annual Review of Pediculicide Medications

Oklahoma Health Care Authority
Fiscal Year 2022 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.

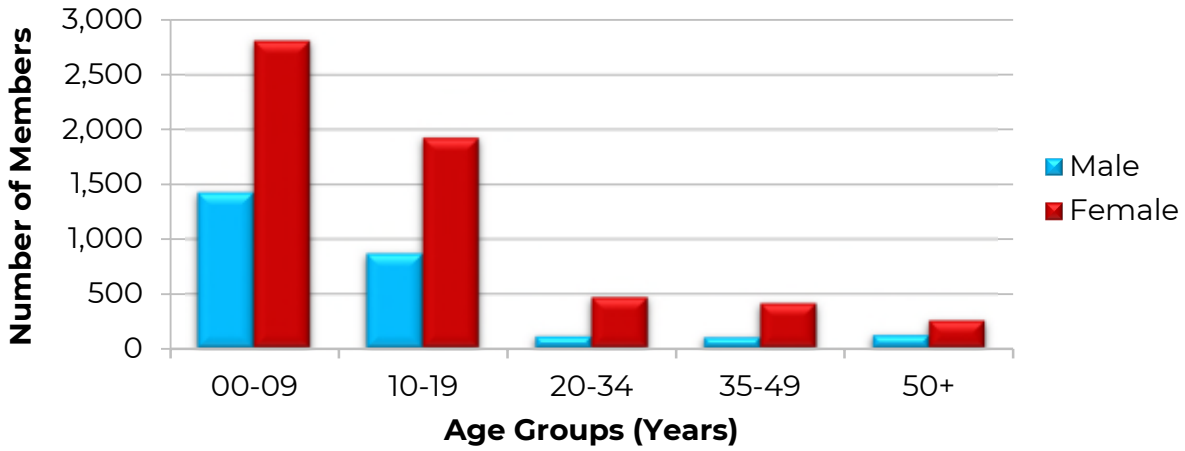
Utilization of Pediculicide Medications: Fiscal Year 2022

Comparison of Fiscal Years

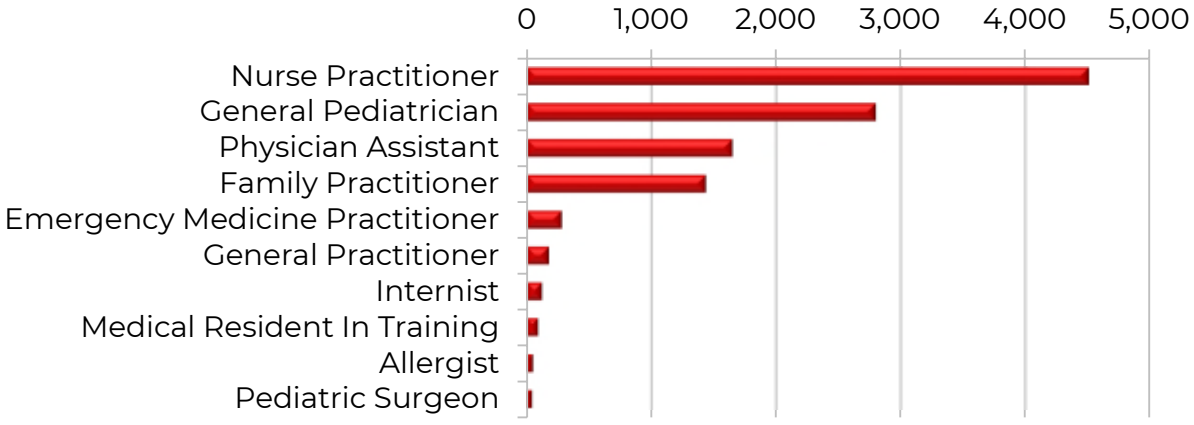
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	8,923	12,100	$2,034,436.58	$168.14	$15.67	1,146,683	129,795
2022	8,467	11,397	$1,811,932.13	$158.98	$14.44	1,069,788	125,442
% Change	**-5.1%**	**-5.8%**	**-10.9%**	**-5.4%**	**-7.8%**	**-6.7%**	**-3.4%**
Change	**-456**	**-7,030**	**-$222,504.45**	**-$9.16**	**-$1.23**	**-76,895**	**-4,353**

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

Demographics of Members Utilizing Pediculicide Medications

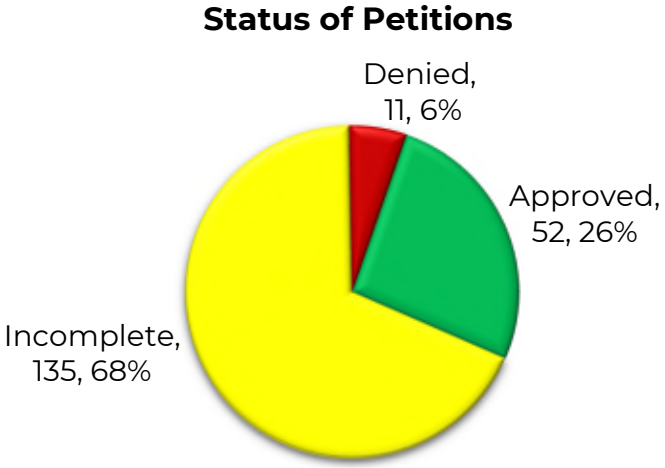


Top Prescriber Specialties of Pediculicide Medications by Number of Claims



Prior Authorization of Pediculicide Medications

There were 198 prior authorization requests submitted for pediculicide medications during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.



Market News and Updates[1]

Anticipated Patent Expiration(s):

- 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 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SPINOSAD PRODUCTS						
NATROBA SUS 0.9%	6,010	4,493	$1,650,221.25	$274.58	1.34	91.08%
SUBTOTAL	**6,010**	**4,493**	**$1,650,221.25**	**$274.58**	**1.34**	**91.08%**
PERMETHRIN AND PYRETHRIN OTC PRODUCTS						
PERMETHRIN CRE 5%	4,773	3,717	$143,377.78	$30.04	1.28	7.91%
LICE TRTMNT LIQ 1%	281	198	$4,893.97	$17.42	1.42	0.27%
LICE TREATMT LOT 1%	165	147	$2,298.99	$13.93	1.22	0.13%
VANALICE GEL 0.3-3.5%	104	73	$5,353.15	$51.47	1.42	0.30%
LICE TREATMT LIQ 1%	38	23	$666.89	$17.55	1.65	0.04%
GOODSENSE LIQ LICE RIN 1%	1	1	$14.30	$14.30	1	0.00%
SUBTOTAL	**5,362**	**4,159**	**$156,605.08**	**$29.20**	**1.29**	**8.64%**
IVERMECTIN PRODUCTS						
IVERMECTIN LOT 0.5%	25	25	$5,105.80	$204.23	1	0.28%
SUBTOTAL	**25**	**25**	**$5,105.80**	**$204.23**	**1**	**0.28%**
TOTAL	**11,397**	**8,467***	**$1,811,932.13**	**$158.98**	**1.35**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CRE = cream; LIQ = liquid; LOT = lotion; OTC = over-the-counter; RIN = rinse; SUS = suspension; TRTMNT = treatment
Fiscal Year 2022 = 07/01/2021 to 06/30/2022
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 12/2022. Last accessed 12/14/2022.

Fiscal Year 2022 Annual Review of Xiaflex® (Collagenase Clostridium Histolyticum)

Oklahoma Health Care Authority
Fiscal Year 2022 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 2022

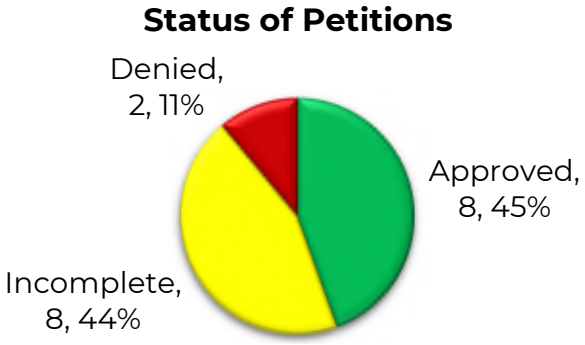
Comparison of Fiscal Years: Medical Claims

Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Total Units
2021	2	6	$27,682.20	$4,613.70	540
2022	3	11	$49,645.34	$4,513.21	862
% Change	**50.00%**	**83.33%**	**79.34%**	**-2.18%**	**59.63%**
Change	**1**	**5**	**$21,963.14**	**-$100.49**	**322**

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

Prior Authorization of Xiaflex® (Collagenase Clostridium Histolyticum)

There were 18 prior authorization requests submitted for 8 unique members for Xiaflex® (collagenase clostridium histolyticum) during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.



Recommendations

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

Utilization Details of Xiaflex® (Collagenase Clostridium Histolyticum): Fiscal Year 2022

PRODUCT UTILIZED	†TOTAL CLAIMS	*TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
J0775 XIAFLEX INJECTION 0.9MG	11	3	$49,645.34	$4,513.21	3.67
TOTAL	**11**	**3**	**$49,645.34**	**$4,513.21**	**3.67**

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

Fiscal Year 2022 Annual Review of Zokinvy® (Lonafarnib)

Oklahoma Health Care Authority
Fiscal Year 2022 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 2022

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

Prior Authorization of Zokinvy® (Lonafarnib)

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

Market News and Updates[1]

Anticipated Patent Expiration(s):

- Zokinvy® (lonafarnib): July 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 11/2022. Last accessed 11/11/2022.