Print Annual Reviews for Fiscal Year 2019

Count	Category/Medication	Review
1.	Actinic Keratosis Medications	Fiscal Year
2.	Alpha$_1$-Proteinase Inhibitor Medications	Fiscal Year
3.	Alzheimer's Medications	Fiscal Year
4.	Amyotrophic Lateral Sclerosis (ALS) Medications	Fiscal Year
5.	Antifungals (systemic)	Fiscal Year
6.	Antihistamines (oral)	Fiscal Year
7.	Anti-Ulcer Medications	Fiscal Year
8.	Arcalyst® (rilonacept)	Fiscal Year
9.	Benzodiazepines	Fiscal Year
10.	Benign Prostatic Hypertrophy (BPH) Medications	Fiscal Year
11.	Bladder Control Medications	Fiscal Year
12.	Bowel Preparation Medications	Fiscal Year
13.	Brineura® (cerliponase alfa)	Fiscal Year
14.	Butalbital Medications	Fiscal Year
15.	Cholbam® (cholic acid)	Fiscal Year
16.	Chorionic Gonadotropin Medications	Fiscal Year
17.	Corticosteroid Special Formulations	Fiscal Year
18.	Defitelio® (defibrotide)	Fiscal Year
19.	Diabetic Supplies	Fiscal Year
20.	Elaprase® (idursulfase)	Fiscal Year
21.	Erythropoiesis-Stimulating Agents (ESAs)	Fiscal Year
22.	Fabry Disease Medications	Fiscal Year
23.	Fibromyalgia	Fiscal Year
24.	Gattex® [teduglutide (rDNA origin)]	Fiscal Year
25.	Gaucher Disease medications	Fiscal Year
26.	Gonadotropin-Releasing Hormone Medications	Fiscal Year
27.	Gout Medications	Fiscal Year
28.	Growth Hormone	Fiscal Year
29.	H.P. Acthar® Gel (repository corticotropin injection)	Fiscal Year
30.	Heart Failure Medications	Fiscal Year
31.	Hereditary Angioedema (HAE) Medications	Fiscal Year
32.	Hyperkalemia Medications	Fiscal Year
33.	Inhaled Anti-Infective Medications	Fiscal Year
34.	Injectable and Vaginal Progesterone Products	Fiscal Year
35.	Iron Chelating Agents	Fiscal Year
36.	Jynarque (tolvaptan)	Fiscal Year
37.	Kanuma® (sebelipase alfa)	Fiscal Year
38.	Keveyis® (dichlorphenamide)	Fiscal Year
39.	Leukotriene Modulators	Fiscal Year
40.	Lidocaine Topical Products	Fiscal Year
41.	Lumizyme® (alglucosidase alfa)	Fiscal Year

Count	Category/Medication	Review
42.	Luxturna® (voretigene neparvovec-rzyl)	Fiscal Year
43.	Mepsevii™ (vestronidase alfa-vjbk)	Fiscal Year
44.	Mozobil® (plerixafor)	Fiscal Year
45.	Muscle Relaxant Medications	Fiscal Year
46.	Myalept® (metreleptin)	Fiscal Year
47.	Mytesi® (crofelemer) [formerly Fulyzaq®]	Fiscal Year
48.	Naloxone Medications	Fiscal Year
49.	Nasal Allergy Medications	Fiscal Year
50.	Nonsteroidal Anti-Inflammatory Drugs (NSAIDs; systemic)	Fiscal Year
51.	Northera® (droxidopa)	Fiscal Year
52.	Nuedexta® (dextromethorphan/quinidine)	Fiscal Year
53.	Ocaliva® (obeticholic acid)	Fiscal Year
54.	Ophthalmic Allergy Medications	Fiscal Year
55.	Ophthalmic Antibiotics	Fiscal Year
56.	Otic Anti-Infective Medications	Fiscal Year
57.	Pancreatic Enzymes	Fiscal Year
58.	Parathyroid Medications	Fiscal Year
59.	Pediculocides	Fiscal Year
60.	Phosphate Binders	Fiscal Year
61.	Prenatal Vitamins	Fiscal Year
62.	Procysbi® (cysteamine bitartrate)	Fiscal Year
63.	Pulmonary Hypertension Medications	Fiscal Year
64.	Qbrexa™ (glycopyrronium)	Fiscal Year
65.	Qualaquin® (quinine sulfate)	Fiscal Year
66.	Qutenza® (capsaicin 8% patch)	Fiscal Year
67.	Ravicti® (glycerol phenylbutyrate)	Fiscal Year
68.	Smoking Cessation	Fiscal Year
69.	Strensiq® (asfotase alfa)	Fiscal Year
70.	Symlin® (pramlintide)	Fiscal Year
71.	Sylvant® (siltuximab)	Fiscal Year
72.	Testosterone Medications	Fiscal Year
73.	Topical Acne Products	Fiscal Year
74.	Topical Antibiotics	Fiscal Year
75.	Topical Antifungals	Fiscal Year
76.	Ulcerative Colitis (UC) and Crohn's Disease Medications	Fiscal Year
77.	Vasomotor Symptom Medications	Fiscal Year
78.	Vesicular Monoamine Transporter 2 (VMAT2) Medications	Fiscal Year
79.	Vimizim® (elosulfase alfa)	Fiscal Year
80.	Xgeva® (denosumab)	Fiscal Year
81.	Xiaflex® (collagenase clostridium histolyticum)	Fiscal Year
82.	Xuriden™ (uridine triacetate)	Fiscal Year
83.	Zinplava™ (bezlotoxumab)	Fiscal Year

Fiscal Year 2019 = July 1, 2018 – June 30, 2019

Fiscal Year 2019 Annual Review of Actinic Keratosis Medications

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Carac® (Fluorouracil 0.5% Cream) Approval Criteria:

1. An FDA approved diagnosis of multiple actinic or solar keratoses of the face and anterior scalp in adult members; and
2. Carac® must be prescribed by a dermatologist or an advanced care practitioner with a supervising physician who is a dermatologist; and
3. A patient-specific, clinically significant reason why the member cannot use fluorouracil 5% cream, fluorouracil 5% solution, or fluorouracil 2% solution must be provided.

Picato® (Ingenol Mebutate Gel) Approval Criteria:

1. An FDA approved diagnosis of actinic keratosis (AK); and
2. Member must be 18 years of age or older; and
3. Patient-specific information must be documented on the prior authorization form, including all of the following:
    a. Number of AK lesions being treated; and
    b. Size of each lesion being treated; and
    c. Location of lesions being treated; and
4. Approval quantity and length will be based on patient-specific information provided, in accordance with Picato® prescribing information and FDA approved dosing regimen(s).

Solaraze® (Diclofenac 3% Gel) Approval Criteria:

1. An FDA approved diagnosis of actinic keratosis (AK); and
2. Patient-specific information must be documented on the prior authorization form, including all of the following:
    a. Number of AK lesions being treated; and
    b. Sizes of each lesion being treated; and
    c. Anticipated duration of treatment; and
3. Approval quantity and length will be based on patient-specific information provided, in accordance with Solaraze® prescribing information and FDA approved dosing regimen(s).

Zyclara® (Imiquimod 2.5% and 3.75% Cream) Approval Criteria:

1. An FDA approved diagnosis of actinic keratosis (AK) of the full face or balding scalp in immunocompetent adult members or topical treatment of external genital and perianal warts/condyloma acuminate (EGW) in members 12 years and older; and
2. Member must be 12 years of age or older; and
3. Requests for a diagnosis of molluscum contagiosum in children 2 to 12 years of age will generally not be approved; and

4. A patient-specific, clinically significant reason why the member cannot use generic imiquimod 5% cream in place of Zyclara® (imiquimod 2.5% and 3.75% cream) must be provided.

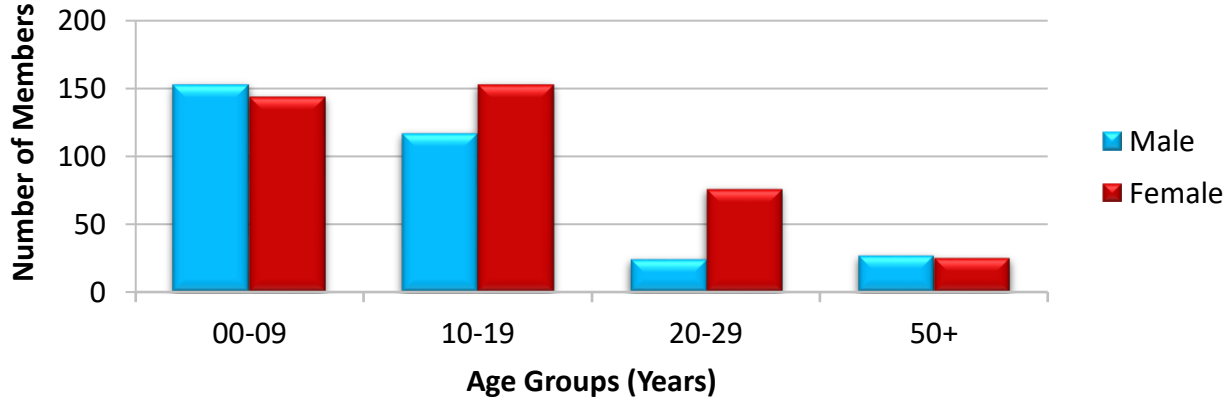
Utilization of Actinic Keratosis Medications: Fiscal Year 2019

Comparison of Fiscal Years

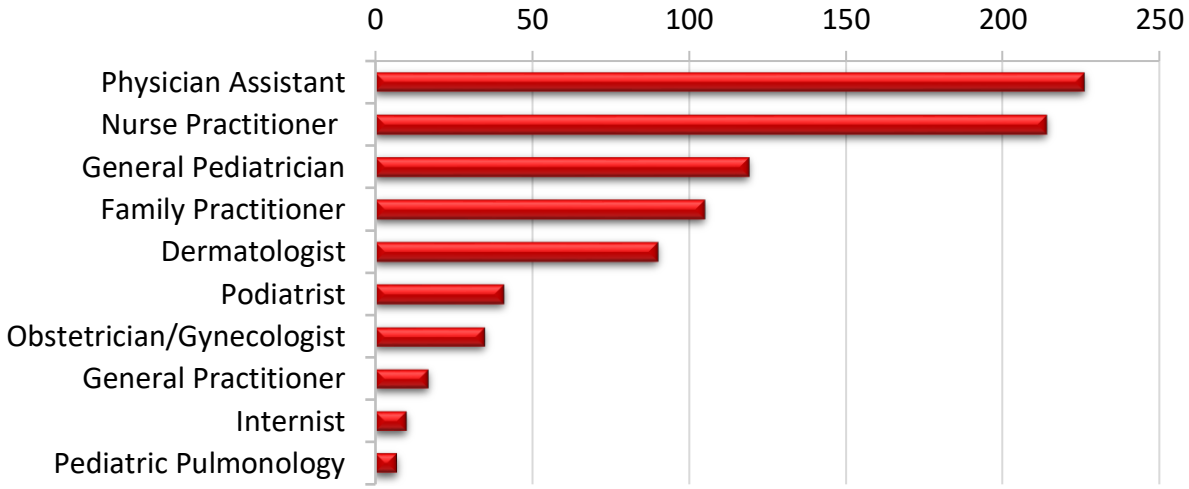
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	745	945	$43,210.72	$45.73	$1.19	16,276	36,454
2019	719	896	$34,083.70	$38.04	$1.04	15,967	32,708
% Change	**-3.49%**	**-5.19%**	**-21.12%**	**-16.81%**	**-12.43%**	**-1.90%**	**-10.28%**
Change	**-26**	**-49**	**-$9,127.02**	**-$7.69**	**-$0.15**	**-309**	**-3746**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Demographics of Members Utilizing Actinic Keratosis Medications

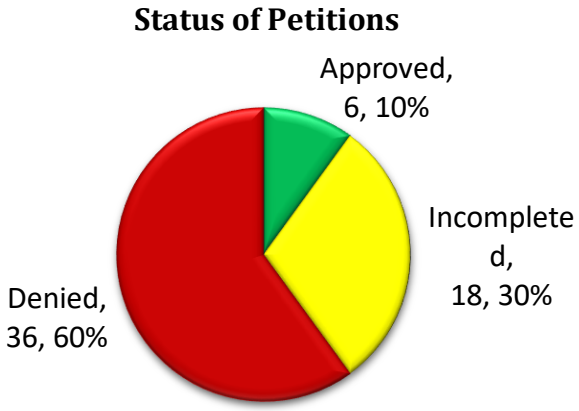


Top Prescriber Specialties of Actinic Keratosis Medications by Number of Claims



Prior Authorization of Actinic Keratosis Medications

There were 60 prior authorization requests submitted for actinic keratosis medications during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.



Market News and Updates

Anticipated Patent Expiration(s):[1]

- Tolak® (fluorouracil 4% cream): July 2023
- Picato® (ingenol mebutate gel): July 2027
- Zyclara® (imiquimod 2.5% and 3.75% cream): December 2029

Pipeline:

- **March 2019:** Athenex reported that 2 Phase 3 trials of its skin ointment for precancerous lesions, KX-01, saw 100% clearance of the actinic keratosis (AK) lesions at day 57 within the face or scalp treatment areas. The placebo-controlled studies randomized a total of 702 adult participants, with the 1% ointment, KX-01, being applied once daily for 5 days. KX-01, also known as KX2-391, is a dual Src kinase and tubulin polymerization inhibitor. Each study demonstrated statistical significance, and both studies are ongoing through 1 year of follow-up.[2,3]

Recommendations

The College of Pharmacy does not recommend any changes to the current actinic keratosis medications 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: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 01/2019. Last accessed 08/18/2019.

[2] Anthenex, Inc. Athenex Announces Positive Topline Results from Two Phase III Studies of KX2-391 Ointment 1% Featured in Late Breaker Program at the 2019 American Academy of Dermatology Annual Meeting. *Globe Newswire*. Available online at: http://ir.athenex.com/news-releases/news-release-details/athenex-announces-positive-topline-results-two-phase-iii-studies. Issued 03/04/2019. Last Accessed 08/18/2019.

[3] Src Kinase Inhibition. Anthenex, Inc. Available online at: http://www.athenex.com/oncology-innovation/src-kinase-inhibitors/. Last Accessed 08/18/2019.

Utilization Details of Actinic Keratosis Medications: Fiscal Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
IMIQUIMOD PRODUCTS					
IMIQUIMOD CRE 5%	786	646	$24,138.71	$0.80	$30.71
SUBTOTAL	**786**	**646**	**$24,138.71**	**$0.80**	**$30.71**
FLUOROURACIL PRODUCTS					
FLUOROURACIL CRE 5%	102	73	$9,027.23	$3.71	$88.50
FLUOROURACIL CRE 4%	1	1	$269.37	$8.89	$269.37
FLUOROURACIL SOL 2%	1	1	$55.21	$11.04	$55.00
SUBTOTAL	**104**	**75**	**$9,351.81**	**$3.79**	**$89.92**
DICLOFENAC PRODUCTS					
DICLOFENAC GEL 3%	6	4	$593.18	$3.71	$98.86
SUBTOTAL	**6**	**4**	**$593.18**	**$3.71**	**$98.86**
TOTAL	**896**	**719***	**$34,083.70**	**$1.04**	**$38.04**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Fiscal Year 2019 Annual Review of Alpha$_1$-Proteinase Inhibitors

Oklahoma Health Care Authority
Fiscal Year 2019 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 patients 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 <11µmol/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 advanced care practitioner specializing in pulmonary disease; and
5. The prescriber must verify the member is a non-smoker; and
6. The 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 or Prolastin®-C Liquid 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 patients 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 <11µmol/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 advanced care practitioner specializing in pulmonary disease; and

5. The prescriber must verify the member is a non-smoker; and
6. The 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 2019

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	8	70	$648,360.52	$9,262.29	$334.38	1,374,846	1,939
2019	8	55	$434,721.42	$7,904.03	$282.29	957,656	1,540
% Change	**0.00%**	**-21.40%**	**-33.00%**	**-14.70%**	**-15.60%**	**-30.30%**	**-20.60%**
Change	**0**	**-15**	**-$213,639.10**	**-$1,358.26**	**-$52.09**	**-417,190**	**-399**

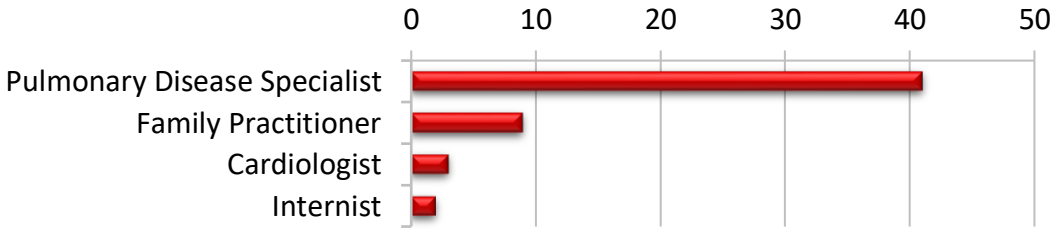
*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal year 2018 = 07/01/2017 to 06/30/2018; Fiscal year 2019 = 07/01/2018 to 06/30/2019

- There were no paid medical claims for alpha$_1$-proteinase inhibitors during fiscal year 2019.

Demographics of Members Utilizing Alpha$_1$-Proteinase Inhibitors

- Due to the small number of members utilizing alpha$_1$-proteinase inhibitors, detailed demographic information could not be provided.

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

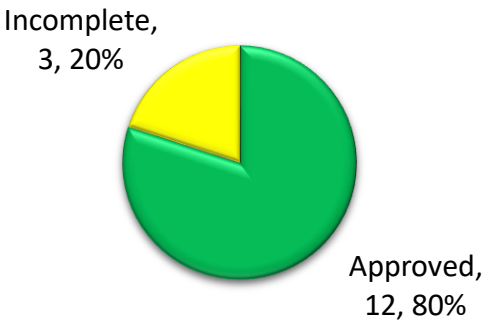


- For all claims under specialties other than pulmonary disease specialist, the members' therapy was initiated by a pulmonary disease specialist.

Prior Authorization of Alpha$_1$-Proteinase Inhibitors

There were 15 prior authorization requests submitted for alpha$_1$-proteinase inhibitors during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.

Status of Petitions



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 2019

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	% COST
PROLASTIN-C INJ 1000MG	39	6	$335,391.20	$8,599.77	77.15%
GLASSIA INJ 1000MG/50ML	12	1	$66,999.92	$5,583.33	15.41%
ZEMAIRA INJ 1000MG	2	1	$17,083.10	$8,541.55	3.93%
PROLASTIN-C INJ 1000MG/20ML	2	2	$15,247.20	$7,623.60	3.51%
TOTAL	**55**	**8***	**$434,721.42**	**$7,904.03**	**100%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal year 2019 = 07/01/2018 to 06/30/2019

Fiscal Year 2019 Annual Review of Alzheimer's Medications

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Alzheimer's Medications Approval Criteria:

1. Special formulation products including oral solutions, transdermal patches, and other convenience formulations require prior authorization with the following approval criteria:
    a. A patient-specific, clinically significant reason why the special formulation is necessary in place of the standard formulation.
2. An age restriction for ages 0 to 50 years applies to all Alzheimer's medications. Members older than 50 years of age can receive regular formulations without prior authorization. Members younger than 50 years of age will require prior authorization with the following criteria:
    a. An FDA approved diagnosis; or
    b. Other patient-specific, clinically significant information supporting the use of the medication.

Namzaric™ [Memantine Extended-Release (ER)/Donepezil] Approval Criteria:

1. Member must have a patient-specific, clinically significant reason why the separate products cannot be used over this combination product; and
2. A quantity limit of 30 capsules per 30 days will apply.

Namenda XR® [Memantine Extended-Release (ER) Capsule] Approval Criteria:

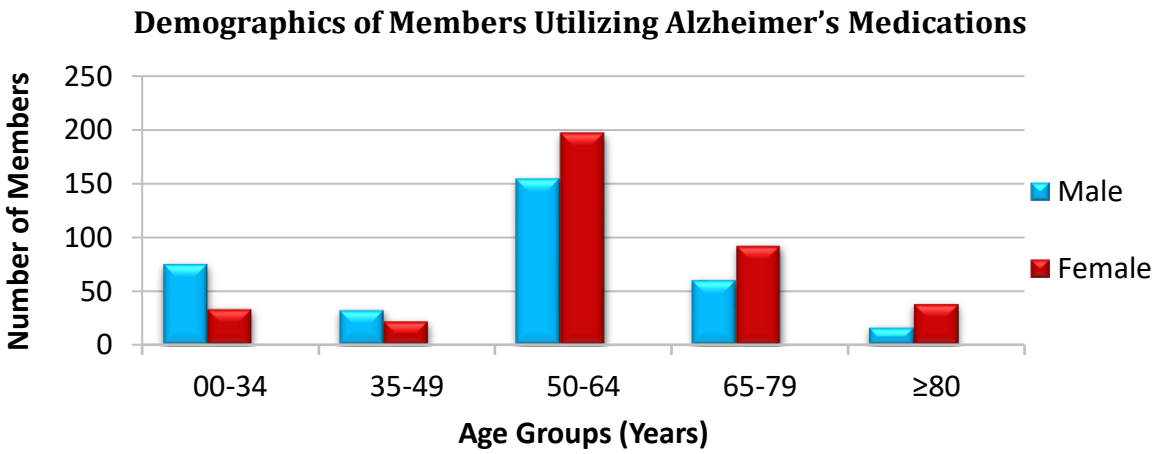
1. An FDA approved diagnosis for the treatment of moderate-to-severe Alzheimer's type dementia; and
2. A patient-specific, clinically significant reason why the member cannot use memantine immediate-release tablets must be provided.

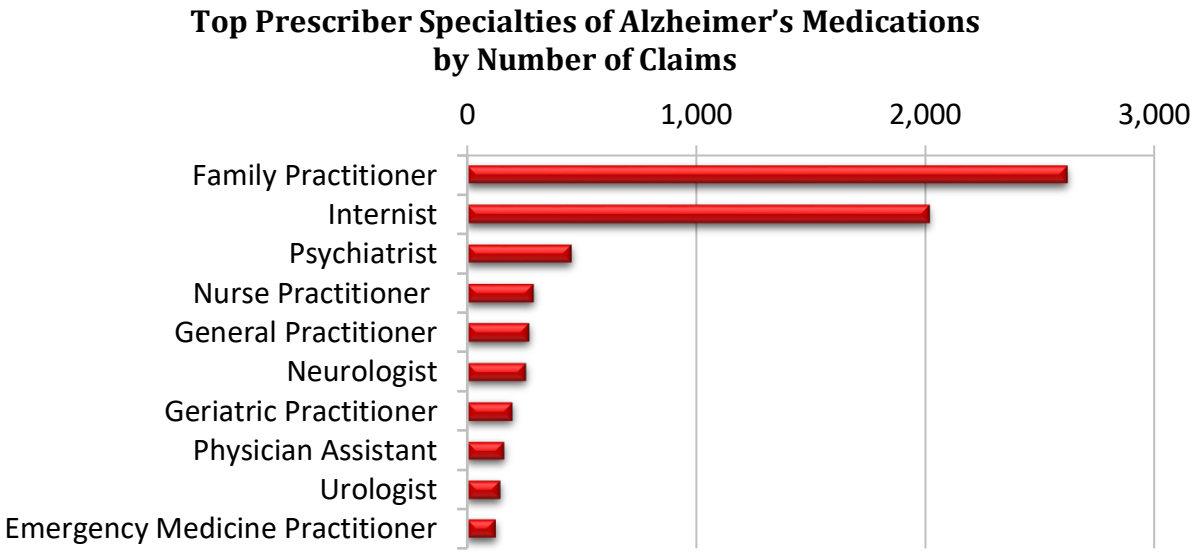
Utilization of Alzheimer's Medications: Fiscal Year 2019

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	717	6,683	$421,045.24	$63.00	$2.04	309,129	206,511
2019	719	6,595	$153,030.10	$23.20	$0.75	317,512	203,808
% Change	**0.30%**	**-1.30%**	**-63.70%**	**-63.20%**	**-63.20%**	**2.70%**	**-1.30%**
Change	**2**	**-88**	**-$268,015.14**	**-$39.80**	**-$1.29**	**8,383**	**-2,703**

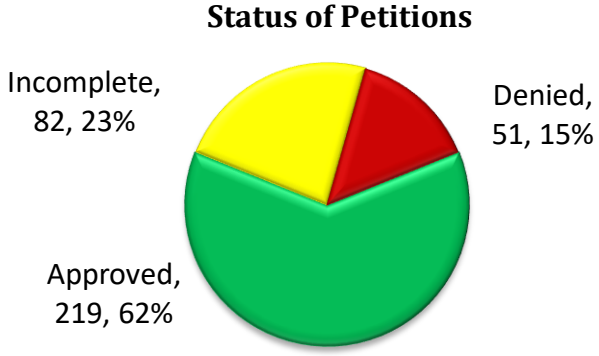
*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019





Prior Authorization of Alzheimer's Medications

There were 352 prior authorization requests submitted for Alzheimer's medications during fiscal year 2019. The following chart shows the status of the submitted petitions during fiscal year 2019.



Market News and Updates

Anticipated Patent Expiration(s):[4]

- Namzaric™ [memantine extended-release (ER)/donepezil capsule]: December 2029

Pipeline:

- **July 2019:** Oryzon Genomics presented data from the ongoing ETHERAL (Epigenetic THERapy in ALzheimer's Disease) Phase 2a study with vafidemstat, also known as ORY-2001, in Alzheimer's disease (AD) at the 2019 Alzheimer's Association International Conference (AAIC-2019) in July 2019. ETHERAL is a randomized, double-blind, 3-arm, parallel-group study with a 24-week placebo-controlled period followed by a 24-week extension where placebo patients are randomized to vafidemstat therapy, to evaluate the safety, tolerability, and preliminary efficacy of vafidemstat in patients with mild to moderate AD. Secondary endpoints include measures of cognition, function, and behavior. Several traditional and novel cerebral spinal fluid (CSF) biomarkers are also measured. Positive safety data from the first 104 patients recruited in ETHERAL were presented, suggesting that the drug is safe and well tolerated in AD patients. With 87.5% (91/104) of patients having completed at least 1 month of treatment, no clinically relevant effects on platelets, neutrophils, and other hematological parameters have arisen, consistent with the previous vafidemstat safety data from other clinical studies. In addition, 36 patients have already passed the 6-month threshold and no significant safety issues have been reported. The initial blind analysis performed in certain functional parameters in the first 33 individual patients that had completed the first 24 weeks of treatment showed that while some patients showed disease progression, in others the baseline values were maintained or even improved in memory performance values measured by Mini-Mental State Examination (MMSE) or in aggressivity values measured by Cohen-Mansfield Agitation Inventory (CMAI).[5]
- **July 2019:** Novartis, Amgen, and Banner Alzheimer's Institute announced the decision to discontinue investigation of the BACE1 inhibitor CNP520 (umibecestat) in 2 pivotal Phase 2/3 studies in the Alzheimer's Prevention Initiative Generation Program. An assessment of unblinded data during a regular pre-planned review identified worsening in some measures of cognitive function. Given these findings, the sponsors concluded that the potential benefits for patients in the studies did not outweigh the risks.[6]
- **November 2019:** Cortexyme announced that its lead investigational medicine, COR388, will be the subject of an oral presentation at Clinical Trials on Alzheimer's Disease (CTAD) 2019. Scientific experts have discovered that a bacteria called *Porphyromonas*

---

[4] 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/default.cfm?resetfields=1. Last revised 12/2019. Last accessed 12/30/2019.

[5] Oryzon Genomics, S.A. Oryzon Presents Data from ETHERAL Phase IIa Trial at the 2019 Alzheimer's Association International Conference in Los Angeles. Available online at: https://www.oryzon.com/sites/default/files/PRESS_RELEASE_20-2019.pdf. Issued 07/16/2019. Last accessed 12/30/2019.

[6] Novartis. Novartis, Amgen, and Banner Alzheimer's Institute Discontinue Clinical Program with BACE Inhibitor CNP520 for Alzheimer's Prevention. Available online at: https://www.novartis.com/news/media-releases/novartis-amgen-and-banner-alzheimers-institute-discontinue-clinical-program-bace-inhibitor-cnp520-alzheimers-prevention. Issued 07/11/2019. Last accessed 12/30/2019.

gingivalis (P. gingivalis), most commonly associated with degenerative gum disease, can infect the brain in older people who are more susceptible to infection. Once in the brain, the bacteria releases toxic proteins called gingipains, which have been shown to destroy neurons and cause other signature signs of AD in the brain in animal studies. Once the brain is infected, the brain's natural defenses gather around the infected cells causing the inflammation and buildup of plaques associated with AD. COR388 has been developed to block the toxic proteins (gingipains) created by the bacteria and to stop or slow further damage to healthy brain cells. The GAIN Trial is a Phase 2/3 randomized, double-blind, placebo-controlled study assessing the efficacy, safety, and tolerability of 2 dose levels of COR388 oral capsules in patients with mild-to-moderate AD. The trial is currently enrolling patients in the United States and Europe, and top-line results from the trial are anticipated in the fourth quarter of 2021.[7,8]

Recommendations

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

Utilization Details of Alzheimer's Medications: Fiscal Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
MEMANTINE PRODUCTS						
MEMANTINE TAB HCL 10MG	3,428	412	$54,833.77	$0.54	$16.00	35.83%
MEMANTINE TAB HCL 5MG	461	107	$7,625.13	$0.53	$16.54	4.98%
MEMANTINE HC CAP 28MG ER	300	32	$37,502.57	$4.50	$125.01	24.51%
NAMENDA XR CAP 28MG	51	11	$20,272.86	$14.21	$397.51	13.25%
MEMANTINE HC CAP 7MG ER	6	1	$870.84	$4.84	$145.14	0.57%
MEMANTINE HC SOL 2MG/ML	6	2	$1,987.02	$11.04	$331.17	1.30%
SUBTOTAL	**4,252**	**565**	**$123,092.19**	**$0.97**	**$28.95**	**80.44%**
DONEPEZIL PRODUCTS						
DONEPEZIL TAB 10MG	1,674	272	$19,795.58	$0.36	$11.83	12.94%
DONEPEZIL TAB 5MG	568	143	$6,483.16	$0.34	$11.41	4.24%
DONEPEZIL TAB HCL 23MG	9	1	$439.58	$1.63	$48.84	0.29%
SUBTOTAL	**2,251**	**416**	**$26,718.32**	**$0.36**	**$11.87**	**17.47%**
RIVASTIGMINE PRODUCTS						
RIVASTIGMINE CAP 1.5MG	30	4	$1,115.89	$1.16	$37.20	0.73%
RIVASTIGMINE CAP 3MG	25	2	$889.41	$1.19	$35.58	0.58%
RIVASTIGMINE CAP 6MG	12	1	$400.42	$1.11	$33.37	0.26%
RIVASTIGMINE DIS 13.3/24¥	1	1	$0.00	$0.00	$0.00	0.00%
SUBTOTAL	**68**	**8**	**$2,405.72**	**$1.15**	**$35.38**	**1.57%**
GALANTAMINE PRODUCTS						

[7] Cortexyme, Inc. Cortexyme Announces Oral Presentation on COR388 at Clinical Trials on Alzheimer's Disease 2019. *Business Wire*. Available online at: https://www.cortexyme.com/?p=6940. Issued 11/01/2019. Last accessed 12/30/2019.

[8] Cortexyme, Inc. Gain Trial. Available online at: https://gaintrial.com/en/new-alzheimers-approach. Last revised 01/2019. Last accessed 12/30/2019.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
GALANTAMINE TAB 4MG	24	2	$813.87	$1.13	$33.91	0.53%
SUBTOTAL	**24**	**2**	**$813.87**	**$1.13**	**$33.91**	**0.53%**
TOTAL	**6,595**	**719***	**$153,030.10**	**$0.75**	**$23.20**	**100%**

*Total number of unduplicated members.

¥Claims for rivastigmine patches in Fiscal Year 2019 consist of claims for 1 member for which SoonerCare was not the primary payer; therefore, the reimbursed amount is not a true reflection of the cost of the medication for SoonerCare.

Costs do not reflect rebated prices or net costs.

Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Fiscal Year 2019 Annual Review of Amyotrophic Lateral Sclerosis (ALS) Medications [Radicava® (Edaravone) and Tiglutik™ (Riluzole Oral Suspension)]

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Radicava® (Edaravone) Approval Criteria:

1. An FDA approved diagnosis of amyotrophic lateral sclerosis (ALS); and
2. Member must have been evaluated by a physician specializing in the treatment of ALS within the last 3 months; and
3. Disease duration of ≤2 years (for initial approval); and
    a. A prior authorization request with patient-specific information may be submitted for consideration of edaravone for members with disease duration >2 years, including but not limited to disease progression, specific symptoms related to the disease, activities of daily living currently affected by the disease, or prognosis; and
4. Approvals will be for the duration of 6 months. For each subsequent approval, the prescriber must document that the member is responding to the medication, as indicated by a slower progression in symptoms and/or decline in quality of life compared to the typical ALS disease progression.

Tiglutik™ (Riluzole Oral Suspension) Approval Criteria:

1. An FDA approved indication for the treatment of amyotrophic lateral sclerosis (ALS); and
2. A patient-specific, clinically significant reason why the member cannot use riluzole tablets, even when tablets are crushed, must be provided; and
3. A quantity limit of 20mL per day or 600mL per 30 days will apply.

Utilization of ALS Medications: Fiscal Year 2019

There was no SoonerCare utilization of Radicava® (edaravone) or Tiglutik™ (riluzole oral suspension) during fiscal year 2019.

Prior Authorization of ALS Medications

There were no prior authorization requests submitted for Radicava® (edaravone) or Tiglutik™ (riluzole oral suspension) during fiscal year 2019.

Market News and Updates

Anticipated Patent Expiration(s):[9]

- Radicava® (edaravone): November 2020
- Tiglutik™ (riluzole oral suspension): March 2029

News:

- **September 2019:** The U.S. Food and Drug Administration (FDA) issued a Guidance for Industry document to assist in the development of clinical trials for drugs to support an indication for the treatment of ALS. The document includes specific recommendations for trial design, effectiveness endpoints, study procedures, timing of assessments, and statistical considerations. In addition, the guidance provides information regarding accelerated approval of medications for ALS.[10]

Pipeline:

- **AMX0035:** Amlyx Pharmaceuticals is developing AMX0035 for the treatment of ALS. AMX0035 is designed to target pathways originating in the mitochondria and endoplasmic reticulum which lead to neuronal death and degradation. AMX0035 is currently in Phase 2 clinical studies for both ALS and Alzheimer's disease.[11]
- **APB-102:** Apic Bio is developing APB-102 for the treatment of genetic ALS caused by superoxide dismutase (SOD1) mutations. ABB-102 is designed as a 1-time gene therapy administered by intrathecal injection. In July 2019, ABP-102 received Orphan Drug designation from the FDA for the treatment of genetic SOD1 ALS. Apic Bio expects to submit an investigational new drug (IND) application to the FDA in 2020.[12,13]
- **Arimoclomol:** Orphazyme is developing arimoclomol for 4 indications, including ALS. Orphazyme is currently in Phase 3 clinical studies with arimoclomol for ALS. The study is an 18-month, placebo-controlled study including 212 patients which will assess the combination of function and survival as the primary endpoint. Orphazyme plans to release headline results from the trial in the first half of 2021.[14]
- **BIIB067 (Tofersen):** Biogen is developing BIIB067 for the treatment of genetic SOD1 ALS. BIIB067 is thought to decrease the production of the SOD1 protein and is being evaluated to see if it can slow the fatal progression of SOD1 ALS. Biogen announced

---

[9] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 10/2019. Last accessed 10/02/2019.

[10] FDA. Amyotrophic Lateral Sclerosis: Developing Drugs for Treatment Guidance for Industry. Available online at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/amyotrophic-lateral-sclerosis-developing-drugs-treatment-guidance-industry. Issued 09/2019. Last accessed 10/02/2019.

[11] Amylyx Pharmaceuticals, Inc. Amylyx Pipeline. Available online at: https://amylyx.com/researchers-physicians/pipeline/. Last accessed 10/02/2019.

[12] Apic Bio, Inc. Apic Bio Programs: About APB-102. Available online at: https://www.apic-bio.com/new-index/#programs. Last accessed 10/02/2019.

[13] Apic Bio, Inc. Apic Bio's APB-102 Receives Orphan Drug Designation from the FDA for the Treatment of Genetic SOD1 ALS. *Business Wire.* Available online at: https://www.businesswire.com/news/home/20190722005351/en/Apic-Bio%E2%80%99s-APB-102-Receives-Orphan-Drug-Designation. Issued 07/22/2019. Last accessed 10/02/2019.

[14] Orphazyme. Orphazyme Pipeline. Available online at: https://www.orphazyme.com/clinical-programme. Last accessed 10/02/2019.

results from its Phase 1/2 study of BIIB067 in May 2019 and is currently conducting the Phase 3 VALOR study in adults with ALS with a confirmed SOD1 mutation.[15,16]

- **Exservan™ (Riluzole Oral Film):** Aquestive Therapeutics announced that the FDA has accepted their New Drug Application (NDA) for their oral film formulation of riluzole (Exservan™) for the treatment of ALS. The oral film formulation is designed to provide options for patients with ALS who have difficulty swallowing or administering traditional forms of medications.[17]
- **Masitinib:** AB Science is developing masitinib for the treatment of ALS in combination with riluzole. Masitinib is an orally administered selective tyrosine kinase inhibitor which modulates the activity of mast cells and macrophages. By targeting a limited number of kinases, it is thought that masitinib does not inhibit other kinases associated with known toxicities. AB Science announced positive results from their Phase 2/3 study of masitinib in ALS in July 2019.[18,19]
- **NurOwn® (Autologous MSC-NTF):** BrainStorm Cell Therapeutics is developing NurOwn® for the treatment of ALS. NurOwn® cells are autologous, bone marrow-derived mesenchymal stem cells (MSCs) that have been converted ex-vivo into MSC-NTF cells which secrete high levels of neurotrophic factors (NTFs). It is expected that these cells can deliver NTFs and immunomodulatory cytokines directly to sites of damage to ultimately slow or stabilize ALS disease progression.[20,21]

Recommendations

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

---

[15] Biogen. Biogen Pipeline: BIIB067 (tofersen). Available online at: https://www.biogen.com/en_us/pipeline.html. Last accessed 10/02/2019.

[16] Biogen. Biogen to Present New Interim Data from Its Phase 1/2 Clinical Study of Tofersen (BIIB067) for the Potential Treatment of a Subtype of Familial Amyotrophic Lateral Sclerosis (ALS). Available online at: https://investors.biogen.com/news-releases/news-release-details/biogen-present-new-interim-data-its-phase-12-clinical-study. Issued 05/01/2019. Last accessed 10/03/2019.

[17] Aquestive Therapeutics, Inc. Aquestive Therapeutics Announces U.S. Food and Drug Administration (FDA) Acceptance of New Drug Application for Riluzole Oral Film for Treatment of ALS. *Cision PR Newswire.* Available online at: https://www.prnewswire.com/news-releases/aquestive-therapeutics-announces-us-food-and-drug-administration-fda-acceptance-of-new-drug-application-for-riluzole-oral-film-for-treatment-of-als-300832795.html. Issued 04/16/2019. Last accessed 10/03/2019.

[18] AB Science. AB Science Pipeline: Masitinib. Available online at: http://www.ab-science.com/pipeline/masitinib/masitinib-general-overview. Last accessed 10/03/2019.

[19] AB Science. AB Science Announces the Publication of the Positive Phase 2/3 Clinical Trial with Masitinib in ALS in the Journal Amyotrophic Lateral Sclerosis and Frontotemporal Degeneration. *Globe Newswire.* Available online at: https://www.globenewswire.com/news-release/2019/07/08/1879227/0/en/AB-Science-announces-the-publication-of-the-positive-phase-2-3-clinical-trial-with-masitinib-in-ALS-in-the-journal-Amyotrophic-Lateral-Sclerosis-and-Frontotemporal-Degeneration.html. Issued 07/08/2019. Last accessed 10/03/2019.

[20] BrainStorm Cell Therapeutics, Inc. BrainStorm Pipeline. Available online at: https://brainstorm-cell.com/pipeline/. Last accessed 10/03/2019.

[21] BrainStorm Cell Therapeutics, Inc. Science: MSC-NTF Cells. Available online at: https://brainstorm-cell.com/science/#msc-cells. Last accessed 10/03/2019.

Fiscal Year 2019 Annual Review of Antifungal Medications (Systemic)

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Cresemba® (Isavuconazonium Sulfate) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Invasive aspergillosis; or
    b. Invasive mucormycosis; and
2. For the treatment of invasive aspergillosis, a patient-specific, clinically significant reason why voriconazole cannot be used must be provided.

Ketoconazole Oral Tablet Approval Criteria:

Consideration for approval requires the following:

1. An FDA approved indication of systemic fungal infections with 1 of the following:
    a. Blastomycosis; or
    b. Coccidioidomycosis; or
    c. Histoplasmosis; or
    d. Chromomycosis; or
    e. Paracoccidioidomycosis; and
2. Member is 3 years of age or older; and
3. Member does not have underlying hepatic disease; and
4. Trials with other effective oral antifungal therapies, including fluconazole, itraconazole, and voriconazole, have failed to resolve infection; or
5. Other effective oral antifungal therapies are not tolerated or potential benefits outweigh the potential risks; and
6. Hepatic function tests must be done at baseline and weekly during treatment; and
7. A clinical exception may apply for members with a diagnosis of Cushing's disease when other modalities are not available.

Noxafil® (Posaconazole) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Prophylaxis of invasive *Aspergillus* and *Candida* infections in high-risk patients due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graft-versus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy; or
    b. Treatment of oropharyngeal candidiasis (OPC), including OPC refractory (rOPC) to itraconazole and/or fluconazole; or
2. Treatment of invasive mucormycosis; or
3. Other appropriate diagnoses for which Noxafil® is not FDA approved may be considered with submission of a manual prior authorization; and

4. For the diagnosis of OPC, only the oral suspension may be used.

Onmel® (Itraconazole Oral Tablet) Approval Criteria:

1. An FDA approved diagnosis of onychomycosis of the toenail caused by *Trichophyton rubrum* or *T. mentagrophytes;* and
2. A patient-specific, clinically significant reason why itraconazole 100mg oral capsules cannot be used in place of Onmel® 200mg tablets must be provided.

Oravig® (Miconazole Buccal Tablet) Approval Criteria:

1. An FDA-approved diagnosis of oropharyngeal candidiasis in adults 18 years of age and older; and
2. Recent trials (within the last month) of the following medications at the recommended dosing and duration of therapy:
   a. Clotrimazole troches; and
   b. Nystatin suspension; and
   c. Fluconazole tablets; or
3. Contraindication(s) to all available alternative medications.

Tolsura™ (Itraconazole Oral Capsule) Approval Criteria:

1. An FDA approved indication of 1 of the following fungal infections in immunocompromised and non-immunocompromised adult patients:
   a. Blastomycosis, pulmonary and extrapulmonary; or
   b. Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, non-meningeal histoplasmosis; or
   c. Aspergillosis, pulmonary and extrapulmonary, in patients who are intolerant of or who are refractory to amphotericin B therapy; and
2. A patient-specific, clinically significant reason why the member cannot use itraconazole 100mg capsules, which are available without prior authorization, must be provided.

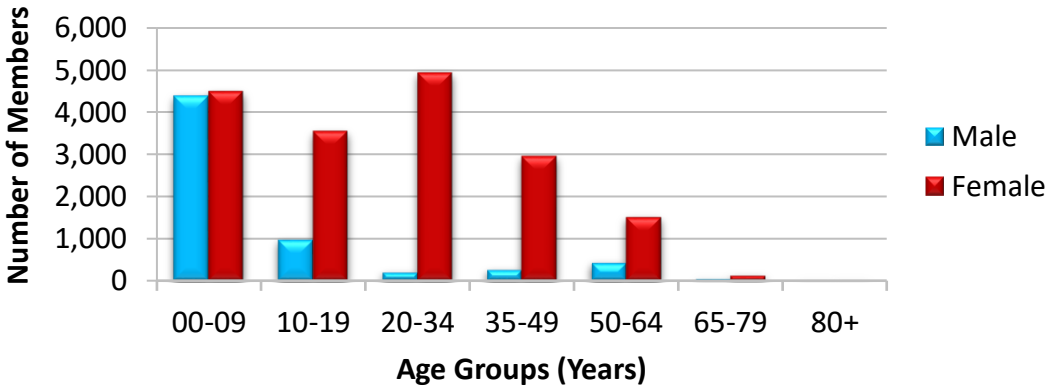
Utilization of Systemic Antifungal Medications: Fiscal Year 2019

Comparison of Fiscal Years

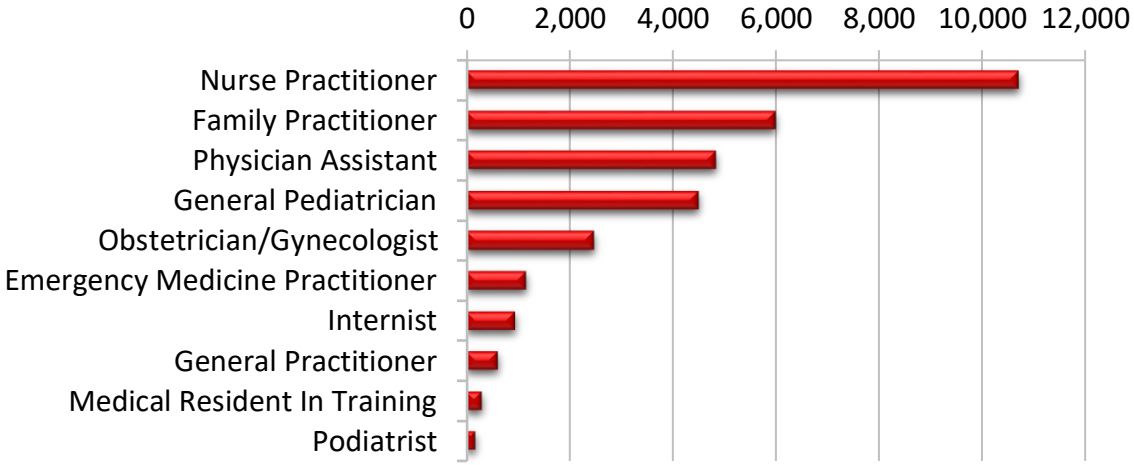
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	25,169	35,644	$1,167,554.33	$32.76	$2.91	2,139,892	400,738
2019	23,768	33,700	$2,457,804.81	$72.93	$6.55	1,938,057	375,481
% Change	**-5.6%**	**-5.5%**	**110.5%**	**122.6%**	**125.1%**	**-9.4%**	**-6.3%**
Change	**-1,401**	**-1,944**	**$1,290,250.48**	**$40.17**	**$3.64**	**-201,835**	**-25,257**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Demographics of Members Utilizing Systemic Antifungal Medications



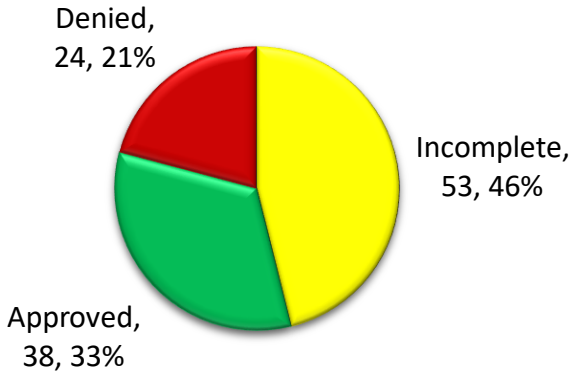
Top Prescriber Specialties of Systemic Antifungal Medications by Number of Claims



Prior Authorization of Systemic Antifungal Medications

There were 115 prior authorization requests submitted for systemic antifungal medications during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[22]

- Cresemba® [isavuconazonium capsule and intravenous (IV) powder for solution]: October 2020
- Noxafil® (posaconazole oral suspension): April 2022
- Oravig® (miconazole buccal tablet): September 2022
- Onmel® (itraconazole tablet): October 2028
- Noxafil® (posaconazole IV solution): February 2033
- Tolsura® (itraconazole capsule): June 2033

Pipeline:

- **Ibrexafungerp:** Scynexis announced positive top-line results for its Phase 3 VANISH-303 study investigating the safety and efficacy of oral ibrexafungerp as a treatment for women with vulvovaginal candidiasis (VVC). The study was conducted at 28 centers in the United States and enrolled 376 patients randomized to oral ibrexafungerp (single-day 600mg dose regimen consisting of 2 doses of 300mg administered 12 hours apart). Ibrexafungerp achieved superiority over placebo for the primary endpoint of clinical cure, which was defined as complete resolution of all signs and symptoms at the day 10 test-of-cure (TOC) visit. The observed clinical cure for ibrexafungerp was 50.5%, showing statistically significant superiority to placebo (P=0.001), and oral ibrexafungerp was generally safe and well tolerated. Scynexis plans to submit a New Drug Application (NDA) for ibrexafungerp to the U.S. Food and Drug Administration (FDA) for the treatment of VVC in the second half of 2020.[23]

Recommendations

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

Utilization Details of Systemic Antifungal Medications: Fiscal Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
FLUCONAZOLE PRODUCTS					
FLUCONAZOLE TAB 150MG	14,085	10,059	$169,757.15	$2.81	$12.05
FLUCONAZOLE TAB 200MG	1,985	1,470	$36,345.99	$1.74	$18.31
FLUCONAZOLE TAB 100MG	1,613	1,323	$22,970.13	$1.56	$14.24
FLUCONAZOLE SUS 40MG/ML	1,405	1,194	$53,458.26	$3.45	$38.05
FLUCONAZOLE SUS 10MG/ML	1,377	1,170	$32,965.53	$2.31	$23.94
FLUCONAZOLE TAB 50MG	24	23	$369.70	$0.97	$15.40

[22] U.S. Food and Drug Administration (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 12/2019. Last accessed 12/05/2019.
[23] Scynexis, Inc. Scynexis Reports Positive Top-Line Results from First Phase 3 Registration Study of Oral Ibrexafungerp in Vulvovaginal Candidiasis (VANISH-303). *PR Newswire*. Available online at: https://www.biospace.com/article/releases/scynexis-reports-positive-top-line-results-from-first-phase-3-registration-study-of-oral-ibrexafungerp-in-vulvovaginal-candidiasis-vanish-303-/. Issued 11/07/2019. Last accessed 12/10/2019.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
FLUCONAZOLE INJ 400MG	1	1	$67.22	$9.60	$67.22
SUBTOTAL	**20,490**	**15,240**	**$315,933.98**	**$2.50**	**$15.42**
NYSTATIN PRODUCTS					
NYSTATIN SUSP 100000 U/ML	8,146	6,810	$143,810.70	$1.50	$17.65
NYSTATIN TAB 500000 UNITS	77	61	$1,991.51	$1.67	$25.86
SUBTOTAL	**8,223**	**6,871**	**$145,802.21**	**$1.50**	**$17.73**
TERBINAFINE PRODUCTS					
TERBINAFINE TAB 250MG	2,185	1,532	$32,652.83	$0.39	$14.94
SUBTOTAL	**2,185**	**1,532**	**$32,652.83**	**$0.39**	**$14.94**
GRISEOFULVIN PRODUCTS					
GRISEOFULVIN SUS 125MG/5ML	1,553	1,196	$125,615.92	$3.31	$80.89
GRISEOFULVIN MICRO 500MG	346	266	$82,129.50	$8.51	$237.37
GRISEOFULVIN ULTRA 250MG	221	177	$41,688.11	$6.35	$188.63
GRISEOFULVIN ULTRA 125MG	50	40	$8,972.48	$6.30	$179.45
SUBTOTAL	**2,170**	**1,679**	**$258,406.01**	**$4.65**	**$119.08**
ITRACONAZOLE PRODUCTS					
ITRACONAZOLE CAP 100MG	206	109	$24,347.94	$4.95	$118.19
ITRACONAZOLE SOL 10MG/ML	44	37	$16,237.76	$21.34	$369.04
SPORANOX SOL 10MG/ML	13	13	$7,150.90	$32.07	$550.07
SUBTOTAL	**263**	**159**	**$47,736.60**	**$8.08**	**$181.51**
VORICONAZOLE PRODUCTS					
VORICONAZOLE TAB 200MG	94	27	$31,065.94	$11.98	$330.49
VORICONAZOLE INJ 200MG	44	40	$161,012.70	$123.86	$3,659.38
VORICONAZOLE SUS 40MG/ML	20	4	$1,249,944.37	$3,378.23	$62,497.22
VORICONAZOLE TAB 50MG	14	5	$4,872.06	$13.10	$348.00
SUBTOTAL	**172**	**76**	**$1,446,895.07**	**$312.10**	**$8,412.18**
CLOTRIMAZOLE PRODUCTS					
CLOTRIMAZOLE LOZ 10MG	81	73	$2,194.32	$2.39	$27.09
CLOTRIMAZOLE TRO 10MG	28	25	$685.35	$2.21	$24.48
SUBTOTAL	**109**	**98**	**$2,879.67**	**$2.35**	**$26.42**
POSACONAZOLE PRODUCTS					
NOXAFIL TAB 100MG	14	7	$69,384.41	$159.87	$4,956.03
NOXAFIL SUS 40MG/ML	2	1	$2,828.80	$101.03	$1,414.40
SUBTOTAL	**16**	**8**	**$72,213.21**	**$156.31**	**$4,513.33**
AMPHOTERICIN B PRODUCTS					
AMBISOME INJ 50MG	52	5	$129,262.22	$314.51	$2,485.81
AMPHOTERICIN POW B	6	4	$562.16	$7.21	$93.69
SUBTOTAL	**58**	**9**	**$129,824.38**		**$2,238.35**
MICONAZOLE PRODUCTS					
MICONAZOLE POWDER	13	12	$430.54	$1.10	$33.12
SUBTOTAL	**13**	**12**	**$430.54**	**$1.10**	**$33.12**
ISAVUCONAZONIUM PRODUCTS					
CRESEMBA CAP 186 MG	1	1	$5,030.31	$167.68	$5,030.31

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
SUBTOTAL	**1**	**1**	**$5,030.31**	**$167.68**	**$5,030.31**
TOTAL	**33,700**	**23,768***	**$2,457,804.81**	**$6.55**	**$72.93**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Fiscal Year 2019 Annual Review of Antihistamine Medications (Oral)

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

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

OTC = over-the-counter

[+]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.

Oral Antihistamine Medications Tier-2 Approval Criteria:

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

Oral Antihistamine Medications Tier-3 Approval Criteria:

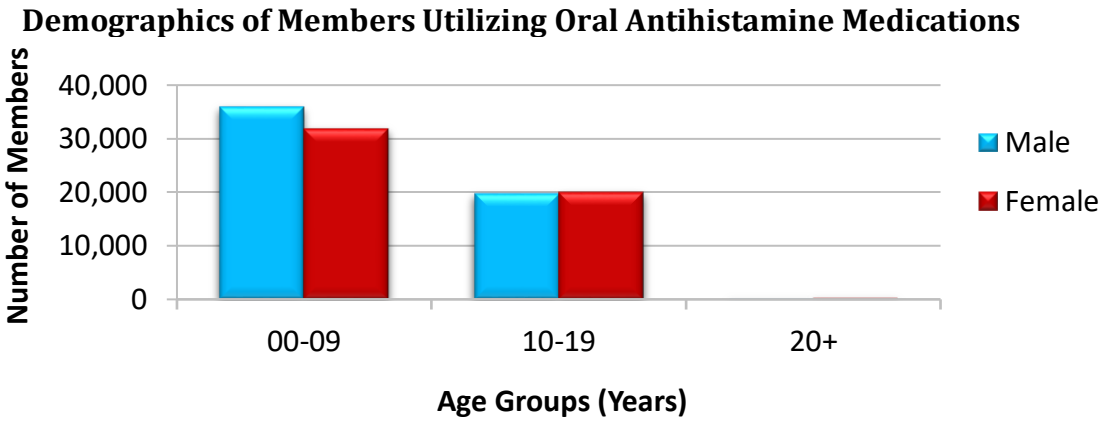
1. A diagnosis of a chronic allergic condition or asthma; and
2. A 14-day trial of all Tier-1 and Tier-2 products within the last 60 days (unless no age-appropriate Tier-2 product exists); and
3. Approvals will be for the duration of 1 year.

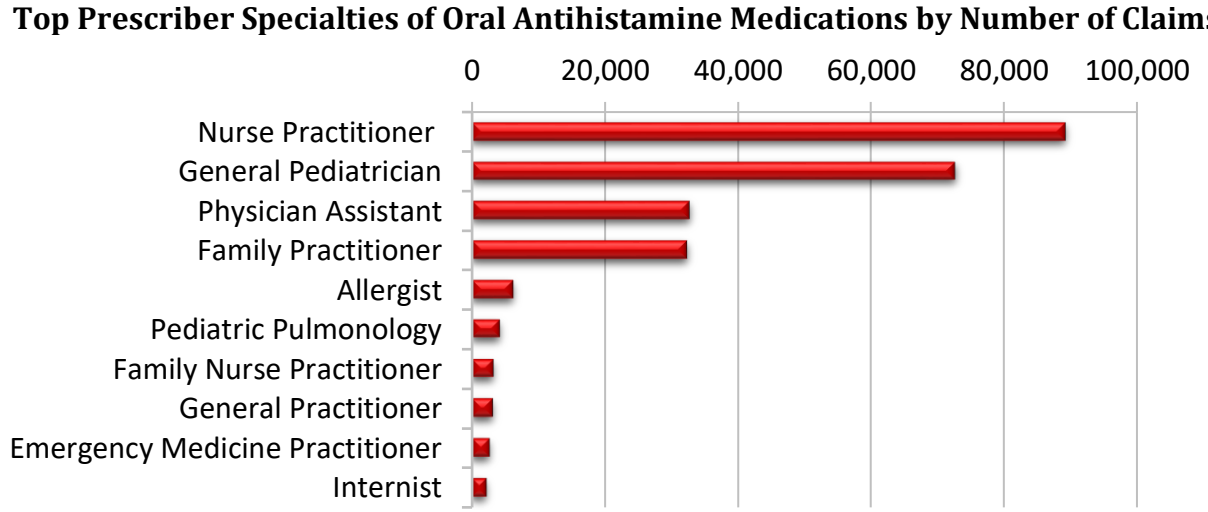
Utilization of Oral Antihistamine Medications: Fiscal Year 2019

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	110,257	267,874	$3,082,528.76	$11.51	$0.37	24,418,325	8,327,521
2019	107,680	256,324	$2,941,615.46	$11.48	$0.36	23,868,956	8,142,830
% Change	**-2.34%**	**-4.31%**	**-4.57%**	**-0.29%**	**-2.36%**	**-2.25%**	**-2.22%**
Change	**-2,577**	**-11,550**	**-$140,913.30**	**-$0.03**	**-$0.01**	**-549,369**	**-184,691**

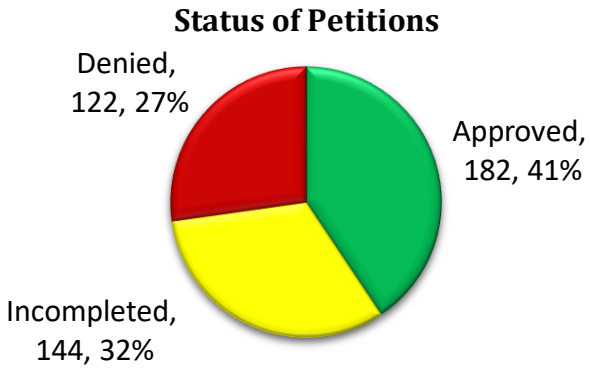
*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019





Prior Authorization of Oral Antihistamine Medications

There were 448 prior authorization requests submitted for the oral antihistamine medications during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.



Recommendations

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

Utilization Details of Oral Antihistamine Medications: Fiscal Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
TIER-1 UTILIZATION					
CETIRIZINE PRODUCTS					
CETIRIZINE SOL 1MG/ML	99,400	48,024	$1,287,232.84	2.07	$12.95
CETIRIZINE TAB 10MG	79,319	32,574	$666,893.86	2.44	$8.41
CETIRIZINE SOL 5MG/5ML	21,298	12,360	$295,489.90	1.72	$13.87
CETIRIZINE TAB 5MG	4,468	2,106	$41,546.28	2.12	$9.30
ALL DAY ALLG TAB 10MG	1,600	1,006	$18,536.90	1.59	$11.59
ALL DAY ALLG SOL 5MG/5ML	925	510	$12,892.93	1.81	$13.94
ALL DAY ALLG SOL 1MG/ML	150	97	$2,224.72	1.55	$14.83
GNP ALL DAY TAB ALLERGY 10MG	125	66	$1,576.18	1.89	$12.61
CETIRIZINE SYP 1MG/ML	16	11	$218.76	1.45	$13.67
SM ALL DAY TAB ALLERGY 10MG	1	1	$12.27	1.00	$12.27
SUBTOTAL	**207,302**	**90,876**	**$2,326,624.64**	**2.28**	**$11.22**
LORATADINE PRODUCTS					
LORATADINE TAB 10MG	24,150	10,175	$278,231.32	2.37	$11.52
LORATADINE SOL 5MG/5ML	20,064	10,492	$259,776.74	1.91	$12.95
LORATADINE SYP 5MG/5ML	2,589	1,440	$39,009.05	1.80	$15.07
ALLERGY TAB 10MG	869	395	$9,955.67	2.20	$11.46
ALLERGY CHLD SYP 5MG/5ML	134	82	$2,172.14	1.63	$16.21
SM LORATADIN TAB 10MG	117	58	$565.65	2.02	$4.83
ALLERGY RELF TAB 10MG	101	54	$1,153.56	1.87	$11.42
SM ALLERGY SYP 5MG/5ML	43	39	$184.03	1.10	$4.28
ALLERGY RELF TAB 10MG	3	3	$36.54	1.00	$12.18
ALLERGY CHLD SOL 5MG/5ML	2	1	$29.62	2.00	$14.81
SUBTOTAL	**48,072**	**21,952**	**$591,114.32**	**2.19**	**$12.30**
TIER-1 SUBTOTAL	**255,374**	**107,596**	**$2,917,738.96**	**2.37**	**$11.43**
LEVOCETIRIZINE PRODUCTS					
TIER-2 UTILIZATION					
LEVOCETIRIZI TAB 5MG	671	132	$9,157.37	5.08	$13.65
LEVOCETIRIZI SOL 2.5/5ML	254	58	$14,135.86	4.38	$55.65
TIER-2 SUBTOTAL	**925**	**186**	**$23,293.23**	**4.97**	**$25.18**
DESLORATADINE PRODUCTS					
TIER-3 UTILIZATION					
DESLORATADIN TAB 5MG	25	4	$583.27	6.25	$23.33
TIER-3 SUBTOTAL	**25**	**4**	**$583.27**	**6.25**	**$23.33**
TOTAL	**256,324**	**107,680***	**$2,941,615.46**	**2.38**	**$11.48**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Fiscal Year 2019 Annual Review of Anti-Ulcer Medications

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Anti-Ulcer Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA+**
dexlansoprazole cap (Dexilant®)	esomeprazole packet for susp (Nexium®)	esomeprazole IV (Nexium® IV)	aspirin/omeprazole DR tab (Yosprala™)
lansoprazole cap (Prevacid®)	lansoprazole ODT (Prevacid® SoluTab)	esomeprazole strontium cap	cimetidine tab (Tagamet®)
omeprazole cap (Prilosec®)	pantoprazole IV (Protonix® IV)	dexlansoprazole ODT (Dexilant® SoluTab)	esomeprazole kit (Esomep-EZS™)
pantoprazole tab (Protonix®)	rabeprazole tab (Aciphex®)	omeprazole powder for susp (Prilosec®)	famotidine susp (Pepcid®)
esomeprazole cap (Nexium®)		pantoprazole packet for susp (Protonix®)	glycopyrrolate tab (Glycate®)
		rabeprazole sprinkle cap (Aciphex® Sprinkles)	nizatidine cap, soln (Axid®)
			omeprazole/sodium bicarbonate (Zegerid®)
			ranitidine cap
			sucralfate susp (unit dose cup)

ODT = orally disintegrating tablet; cap = capsule; tab = tablet; IV = intravenous; susp = suspension; DR = delayed-release; soln = solution

*Special formulations including ODTs, granules, suspension, sprinkle capsules, and solution for IV require special reason(s) for use.

+Individual criteria specific to each product applies.

Anti-Ulcer Medications Tier-2 Approval Criteria:

1. A 14-day trial of all available Tier-1 medications titrated up to the recommended dose that has resulted in inadequate relief of symptoms or intolerable adverse effects; or
2. Contraindication(s) to all available Tier-1 medications; or
3. An indication not covered by lower tiered medications.

Anti-Ulcer Medications Tier-3 Approval Criteria:

1. A 14-day trial of all available Tier-1 and Tier-2 medications that has resulted in inadequate relief of symptoms or intolerable adverse effects; or
2. Contraindication(s) to all available Tier-1 and Tier-2 medications; or
3. An indication not covered by lower tiered medications; and
4. Special formulations including orally disintegrating tablets (ODTs), sprinkle capsules, granules, suspensions, solutions, and intravenous (IV) solutions require special reason(s) for use.

Proton Pump Inhibitors for Pediatric Members Approval Criteria:

1. A recent 14-day trial of an H_2 receptor antagonist that has resulted in inadequate relief of symptoms or intolerable adverse effects; or
2. Recurrent or severe disease such as:
    a. Gastrointestinal (GI) bleed; or
    b. Zollinger-Ellison Syndrome or similar disease.

Anti-Ulcer Medications Special Prior Authorization (PA) Approval Criteria:

1. Pepcid® (famotidine suspension):
    a. A previous 14-day trial of ranitidine syrup or a patient-specific, clinically significant reason why ranitidine syrup is not appropriate for the member must be provided; and
    b. Pepcid® suspension (famotidine) will have an age restriction of 6 years of age and younger. Members older than 6 years of age will require a reason why the member needs the liquid formulation and cannot use the oral tablet formulation.
2. Zegerid® (omeprazole/sodium bicarbonate): A patient-specific, clinically significant reason why the member cannot use omeprazole and over-the-counter (OTC) sodium bicarbonate separately must be provided.
3. Ranitidine capsule: A patient-specific, clinically significant reason why the member cannot use ranitidine tablets must be provided.
4. Sucralfate suspension (unit dose cup): A patient-specific, clinically significant reason why the member cannot use the bulk medication must be provided.
5. Tagamet® (cimetidine tablet): A previous 14-day trial of ranitidine and famotidine or a patient-specific, clinically significant reason why ranitidine and famotidine are not appropriate for the member must be provided.
6. Axid® (nizatidine capsule): A previous 14-day trial of ranitidine and famotidine or a patient-specific, clinically significant reason why ranitidine and famotidine are not appropriate for the member must be provided.
7. Axid® (nizatidine solution):
    a. A previous 14-day trial of ranitidine syrup or a patient-specific, clinically significant reason why ranitidine syrup is not appropriate for the member must be provided; and
    b. Nizatidine solution (Axid®) will have an age restriction of 6 years of age and younger. Members older than 6 years of age will require a reason why the member needs the liquid formulation and cannot use the oral capsule formulation.
8. Yosprala™ (aspirin/omeprazole delayed-release tablet): A patient-specific, clinically significant why the separate products (aspirin and omeprazole) cannot be used in place of this combination product must be provided.
9. Esomep-EZS™ (esomeprazole kit):
    a. A previous 14-day trial of esomeprazole magnesium and a patient-specific, clinically significant reason why other lower tiered proton pump inhibitors including omeprazole and esomeprazole along with over-the-counter (OTC) pill swallowing spray are not appropriate for the member must be provided; and
    b. Current Tier structure rules will also apply.

10. Glycate® (glycopyrrolate 1.5mg tablets):
    a. An FDA approved indication of adjunctive therapy in the treatment of peptic ulcer disease (PUD) in patients 12 years of age and older; and
    b. A patient-specific, clinically significant reason why the member cannot use glycopyrrolate 1mg and 2mg tablets, which are available without prior authorization, must be provided.

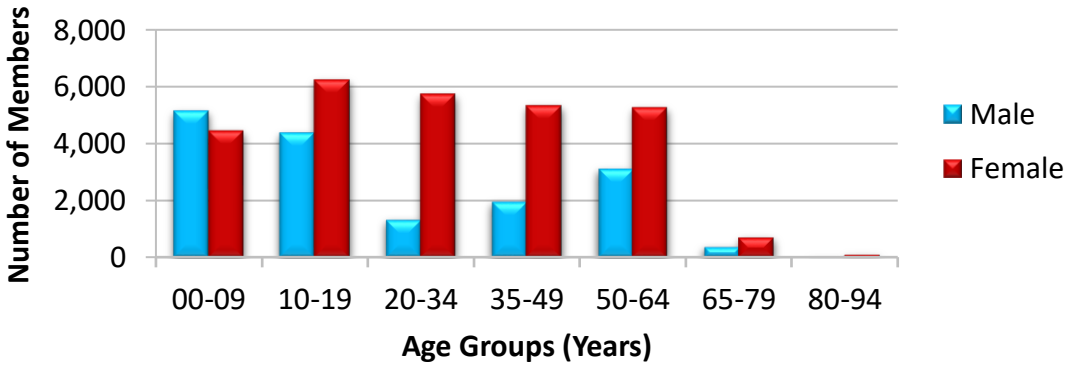
Utilization of Anti-Ulcer Medications: Fiscal Year 2019

Comparison of Fiscal Years

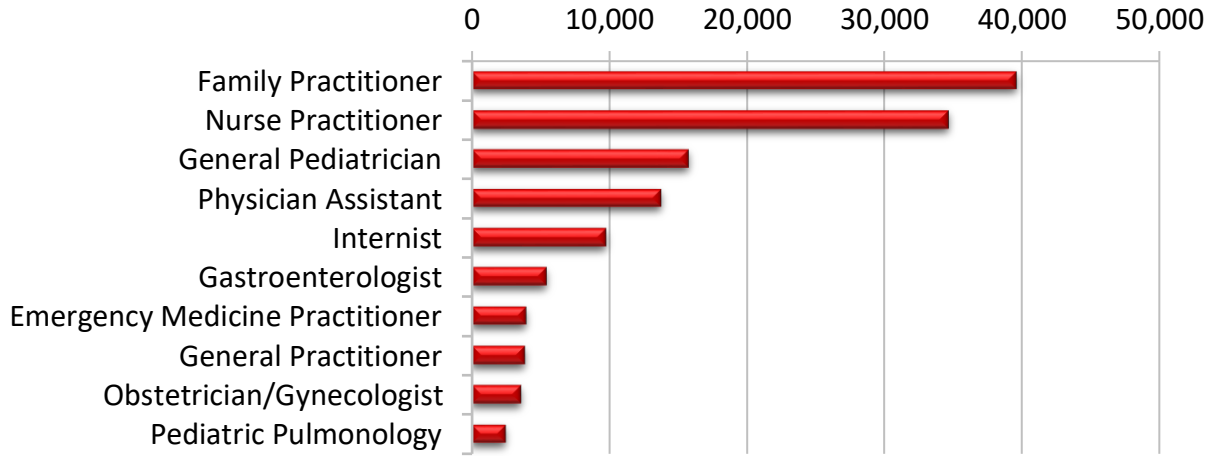
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	45,153	151,636	$3,572,548.56	$23.56	$0.67	10,110,787	5,317,446
2019	44,028	145,332	$3,339,984.80	$22.98	$0.63	9,891,652	5,289,821
% Change	**-2.5%**	**-4.0%**	**-6.5%**	**-2.6%**	**-6.0%**	**-2.2%**	**-0.5%**
Change	**-1,125**	**-6,304**	**-$232,563.76**	**-$0.58**	**-$0.04**	**-219,135**	**-27,625**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Demographics of Members Utilizing Anti-Ulcer Medications

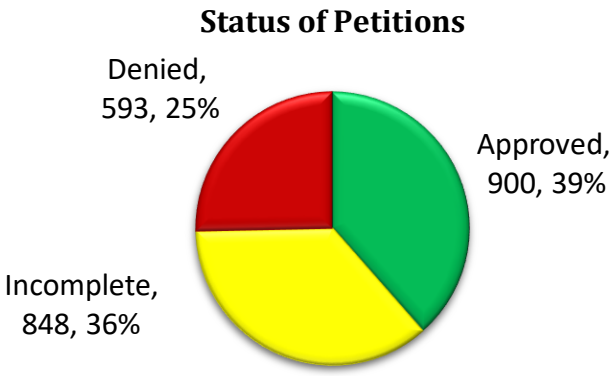


Top Prescriber Specialties of Anti-Ulcer Medications by Number of Claims



Prior Authorization of Anti-Ulcer Medications

There were 2,341 prior authorization requests submitted for anti-ulcer medications during fiscal year 2019. Computer edits are in place to detect lower tiered medications in a member's recent claims history and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions for fiscal year 2019.



Market News and Updates

Anticipated Patent Expiration(s):[24]

- Prilosec® (omeprazole powder for suspension): November 2019
- Nexium® (esomeprazole packet for suspension): May 2020
- Protonix® IV [pantoprazole intravenous (IV) powder for solution]: May 2022
- Protonix® (pantoprazole packet for suspension): December 2026
- Dexilant® SoluTab [dexlansoprazole orally disintegrating tablet (ODT)]: March 2029
- Dexilant® (dexlansoprazole capsule): March 2030
- Yosprala™ (aspirin/omeprazole tablet): March 2033

News:

- **February 2019:** Examining a large population-based health maintenance organization (HMO) cohort, researchers found an association between proton pump inhibitor (PPI) use and an increased risk of acute kidney injury (AKI) and chronic kidney disease (CKD). Patients older than 18 years of age and continuously enrolled for at least 12 months between July 1993 and September 2008 were identified in an HMO database. In 93,335 patients in the AKI cohort and 84,600 patients in the CKD cohort, the incidence rate of AKI and CKD was higher in the PPI group than in non-PPI users (36.4 vs 3.54 per 1,000 person-years and 34.3 vs 8.75 per 1,000 person-years, P<0.0001, respectively).[25]
- **September 2019**: A large placebo-controlled trial confirmed the safety of PPIs for long-term use in patients receiving Xarelto® (rivaroxaban) or aspirin. The trial included 17,598 patients with stable cardiovascular (CV) disease; patients received either pantoprazole

[24] 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 10/2019. Last accessed 10/04/2019.

[25] Hart E, Dunn TE, Feuerstein S, Jacobs DM. Proton Pump Inhibitors and Risk of Acute and Chronic Kidney Disease: A Retrospective Cohort Study. *Pharmacother J Hum Pharmacol Drug Ther* 2019; 39(4):443-453. doi:10.1002/phar.2235.

40mg daily or placebo. Outcomes of interest were the development of *Clostridium difficile* infection, other enteric infections, fractures, gastric atrophy, CKD, diabetes (DM), chronic obstructive lung disease (COPD), dementia, CV disease, cancer, hospitalizations, and all-cause mortality every 6 months. No statistically significant difference was found between the pantoprazole and placebo groups in any safety events except for enteric infections [1.4% vs. 1.0%; odds ratio (OR), 1.33; 95% confidence interval (CI), 1.01 to 1.75].[26]

Recommendations

The College of Pharmacy does not recommend any changes to the current Anti-Ulcer Medication Product Based Prior Authorization (PBPA) criteria at this time.

Utilization Details of Anti-Ulcer Medications: Fiscal Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
TIER-1 UTILIZATION					
CIMETIDINE PRODUCTS					
CIMETIDINE SOL 300MG/5ML	300	183	$8,120.57	1.64	$27.07
SUBTOTAL	**300**	**183**	**$8,120.57**	**1.64**	**$27.07**
FAMOTIDINE PRODUCTS					
FAMOTIDINE TAB 20MG	8,167	3,035	$91,545.26	2.69	$11.21
FAMOTIDINE TAB 40MG	1,469	652	$18,703.87	2.25	$12.73
FAMOTIDINE INJ 10MG/1ML	22	2	$462.45	11.00	$21.02
FAMOTIDINE INJ 200/20ML	35	10	$623.54	3.50	$17.82
SUBTOTAL	**9,693**	**3,651**	**$111,335.12**	**2.65**	**$11.49**
OMEPRAZOLE PRODUCTS					
OMEPRAZOLE CAP 20MG	35,261	12,022	$391,628.13	2.93	$11.11
OMEPRAZOLE CAP 40MG	22,078	7,411	$268,985.34	2.98	$12.18
OMEPRAZOLE CAP 10MG	2,216	792	$33,682.35	2.80	$15.20
SUBTOTAL	**59,555**	**19,257**	**$694,295.82**	**3.09**	**$11.66**
PANTOPRAZOLE PRODUCTS					
PANTOPRAZOLE TAB 40MG	22,153	7269	$263,370.82	3.05	$11.89
PANTOPRAZOLE TAB 20MG	3737	1285	$46,391.04	2.91	$12.41
PANTOPRAZOLE TAB 40MG DR	19	10	$239.11	1.90	$12.58
SUBTOTAL	**25,909**	**8,367**	**$310,000.97**	**3.10**	**$11.96**
RANITIDINE PRODUCTS					
RANITIDINE SYP 75MG/5ML	18,820	8,417	$262,674.66	2.24	$13.96
RANITIDINE TAB 150MG	14,356	5,884	$176,204.12	2.44	$12.27
RANITIDINE TAB 300MG	1,962	759	$26,576.51	2.58	$13.55
RANITIDINE SYP 15MG/ML	80	63	$1,100.27	1.27	$13.75
RANITIDINE INJ 150/6ML	33	2	$1,076.51	16.50	$32.62
RANITIDINE SYP 150/10ML	1	1	$14.18	1.00	$14.18
SUBTOTAL	**35,252**	**14,992**	**$467,646.25**	**2.35**	**$13.27**
SUCRALFATE PRODUCTS					

[26] Moayyedi P, Eikelboom JW, Bosch J, et al. Safety of Proton Pump Inhibitors Based on a Large, Multi-Year, Randomized Trial of Patients Receiving Rivaroxaban or Aspirin. *Gastroenterology* 2019; 157(3):682-691.e2. doi:10.1053/j.gastro.2019.05.056.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
CARAFATE SUS 1GM/10ML	1,291	686	$352,763.10	1.88	$273.25
SUCRALFATE TAB 1GM	4,724	2,576	$121,798.60	1.83	$25.78
SUBTOTAL	**6,015**	**3,199**	**$474,561.70**	**1.88**	**$78.90**
DEXLANSOPRAZOLE PRODUCTS					
DEXILANT CAP 60MG DR	1,970	324	$533,660.52	6.08	$270.89
DEXILANT CAP 30MG DR	355	78	$97,843.11	4.55	$275.61
SUBTOTAL	**2,325**	**391**	**$631,503.63**	**5.95**	**$271.61**
ESOMEPRAZOLE PRODUCTS					
ESOMEPRA MAG CAP 40MG DR	247	28	$5,257.06	8.82	$21.28
NEXIUM CAP 40MG	21	2	$5,204.59	10.50	$247.84
ESOMEPRA MAG CAP 20MG DR	14	2	$353.92	7.00	$25.28
SUBTOTAL	**282**	**32**	**$10,815.57**	**8.81**	**$38.35**
LANSOPRAZOLE PRODUCTS					
LANSOPRAZOLE CAP 30MG DR	1,650	324	$23,082.91	5.09	$13.99
LANSOPRAZOLE CAP 15MG DR	232	68	$5,081.62	3.41	$21.90
SUBTOTAL	**1,882**	**381**	**$28,164.53**	**4.94**	**$14.97**
TIER-1 SUBTOTAL	**140,931**	**43,455**	**$2,736,444.16**	**3.24**	**$19.42**
TIER-2 UTILIZATION					
LANSOPRAZOLE PRODUCTS					
LANSOPRAZOLE TAB 30MG	243	39	$81,434.50	6.23	$335.12
LANSOPRAZOLE TAB 15MG	238	56	$84,584.14	4.25	$355.40
PREVACID STB 15MG ODT	200	41	$86,277.38	4.88	$431.39
PREVACID STB 30MG ODT	132	20	$52,116.14	6.60	$394.82
LANSOPRAZOLE TAB 30MG ODT	38	18	$10,027.02	2.11	$263.87
LANSOPRAZOLE TAB 15MG ODT	28	11	$9,479.04	2.55	$338.54
SUBTOTAL	**879**	**18**	**$323,918.22**	**6.37**	**$368.51**
RABEPRAZOLE PRODUCTS					
RABEPRAZOLE TAB 20MG	330	52	$6,664.18	6.35	$20.19
ACIPHEX TAB 20MG	10	1	$5,099.90	10.00	$509.99
SUBTOTAL	**340**	**53**	**$11,764.08**	**6.42**	**$34.60**
ESOMEPRAZOLE PRODUCTS					
NEXIUM GRA 10MG DR	122	37	$34,946.39	3.30	$286.45
NEXIUM GRA 20MG DR	74	17	$23,345.61	4.35	$315.48
NEXIUM GRA 5MG DR	62	21	$17,711.89	2.95	$285.68
NEXIUM GRA 40MG DR	53	12	$13,675.14	4.42	$258.02
NEXIUM GRA 2.5MG DR	20	11	$5,096.51	1.82	$254.83
SUBTOTAL	**331**	**89**	**$94,775.54**	**3.72**	**$286.33**
PANTOPRAZOLE PRODUCTS					
PANTOPRAZOLE INJ SOD 40MG	22	3	$976.14	7.33	$44.37
PROTONIX INJ 40MG	2	1	$86.10	2.00	$43.05
SUBTOTAL	**24**	**4**	**$1,062.24**	**6.00**	**$44.26**
TIER-2 SUBTOTAL	**1,574**	**281**	**$431,520.08**	**5.60**	**$274.16**
TIER-3 UTILIZATION					
OMEPRAZOLE PRODUCTS					
PRILOSEC POW 2.5MG	25	1,350	$14,263.81	2.78	$570.55
PRILOSEC POW 10MG	13	390	$3,869.42	2.60	$297.65
SUBTOTAL	**38**	**14**	**$18,133.23**	**2.71**	**$477.19**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
PANTOPRAZOLE PRODUCTS					
PROTONIX PAK 40MG	36	1,080	$15,579.27	6.00	$432.76
SUBTOTAL	**36**	**1,080**	**$15,579.27**	**6.00**	**$432.76**
TIER-3 SUBTOTAL	**74**	**20**	**$33,712.50**	**3.70**	**$455.57**
SPECIAL PRIOR AUTHORIZATION (PA) UTILIZATION					
FAMOTIDINE PRODUCTS					
FAMOTIDINE SUS 40MG/5ML	82	31	$4,342.37	2.65	$52.96
SUBTOTAL	**82**	**31**	**$4,342.37**	**2.65**	**$52.96**
NIZATIDINE PRODUCTS					
NIZATIDINE SOL 15MG/ML	496	166	$67,721.81	2.99	$136.54
NIZATIDINE CAP 150MG	12	3	$272.58	4.00	$22.72
SUBTOTAL	**508**	**169**	**$67,994.39**	**3.01**	**$133.85**
GLYCOPYRROLATE PRODUCTS					
GLYCOPYRROL TAB 1MG	1,313	258	$33,715.69	5.09	$25.68
GLYCOPYRROL TAB 2MG	776	109	$29,115.66	7.12	$37.52
SUBTOTAL	**2,089**	**359**	**$62,831.35**	**5.82**	**$30.08**
CIMETIDINE PRODUCTS					
CIMETIDINE TAB 200MG	5	4	$171.15	1.25	$34.23
CIMETIDINE TAB 300MG	23	18	$687.12	1.28	$29.87
CIMETIDINE TAB 400MG	13	9	$577.27	1.44	$44.41
CIMETIDINE TAB 800MG	33	17	$1,704.41	1.94	$51.65
SUBTOTAL	**74**	**4383**	**$3,139.95**	**1.54**	**$42.43**
SPECIAL PA SUBTOTAL	**2,753**	**605**	**$138,308.06**	**4.55**	**$50.24**
TOTAL	**145,332**	**44,028**	**$3,339,984.80**	**3.30**	**$22.98**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Fiscal Year 2019 Annual Review of Arcalyst® (Rilonacept)

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Arcalyst® (Rilonacept) Approval Criteria:

1. An FDA approved indication of Cryopyrin-Associated Periodic Syndrome (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. The member should not be using a tumor necrosis factor blocking agent (e.g., adalimumab, etanercept, infliximab) or anakinra; and
3. Documentation that the member does not have active or chronic infection including hepatitis B, hepatitis C, human immunodeficiency virus (HIV), or tuberculosis; and
4. The following dosing restrictions will apply:
    a. Dosing should not be more 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 (subQ) 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 weight in kilograms):
        i. Initial treatment: Loading dose of 4.4mg/kg, up to a maximum of 320mg, delivered as 1 or 2 subQ 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
5. Approvals will be for the duration of 1 year.

Utilization of Arcalyst®: Fiscal Year 2019

There was no SoonerCare utilization of Arcalyst® (rilonacept) during fiscal year 2019.

Prior Authorization of Arcalyst®

There were no prior authorization requests submitted for Arcalyst® (rilonacept) during fiscal year 2019.

Recommendations

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

Fiscal Year 2019 Annual Review of Benign Prostatic Hypertrophy (BPH) Medications

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Benign Prostatic Hyperplasia (BPH) Medications		
Tier-1	**Tier-2**	**Tier-3**
alfuzosin (Uroxatral®)	doxazosin (Cardura XL®)	tadalafil 5mg (Cialis®)
doxazosin (Cardura®)	dutasteride/tamsulosin (Jalyn®)	
dutasteride (Avodart®)	silodosin (Rapaflo®)	
finasteride (Proscar®)		
tamsulosin (Flomax®)		
terazosin (Hytrin®)		

BPH Medications Tier-2 Prior Authorization Criteria:

1. An FDA approved diagnosis; and
2. A four-week trial of 2 Tier-1 medications from different pharmacological classes within the past 90 days; or
3. Documented adverse effect, drug interaction, or contraindication to all available Tier-1 medications.

BPH Medications Tier-3 Prior Authorization Criteria:

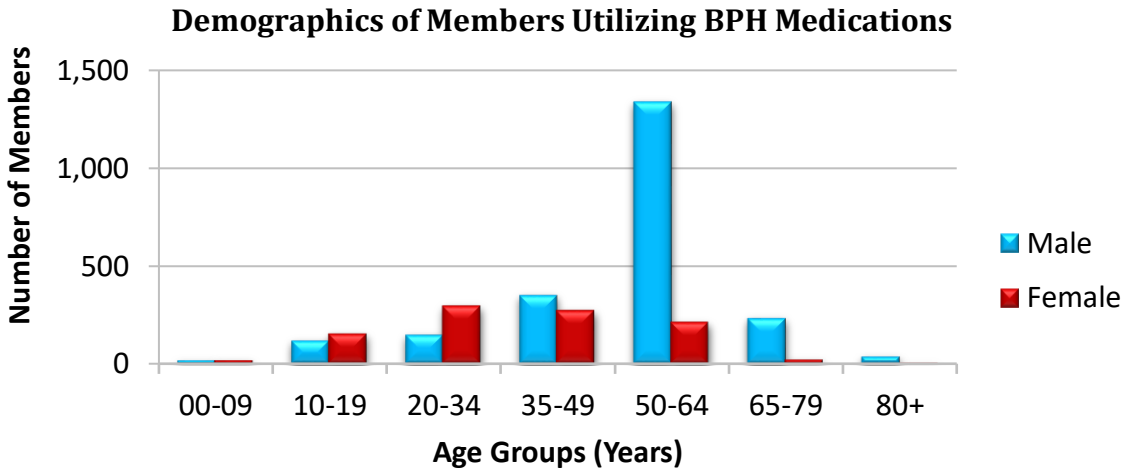
1. An FDA approved diagnosis of BPH; and
2. A trial of at least 2 Tier-1 medications from different pharmacological classes; and
3. A four-week trial of all Tier-2 medications within the past 5 months; or
4. Documented adverse effect, drug interaction, contraindication, or lack of efficacy to all available Tier-1 and Tier-2 medications; and
5. Authorizations for Cialis® (tadalafil) will be granted for 5mg tablets only.

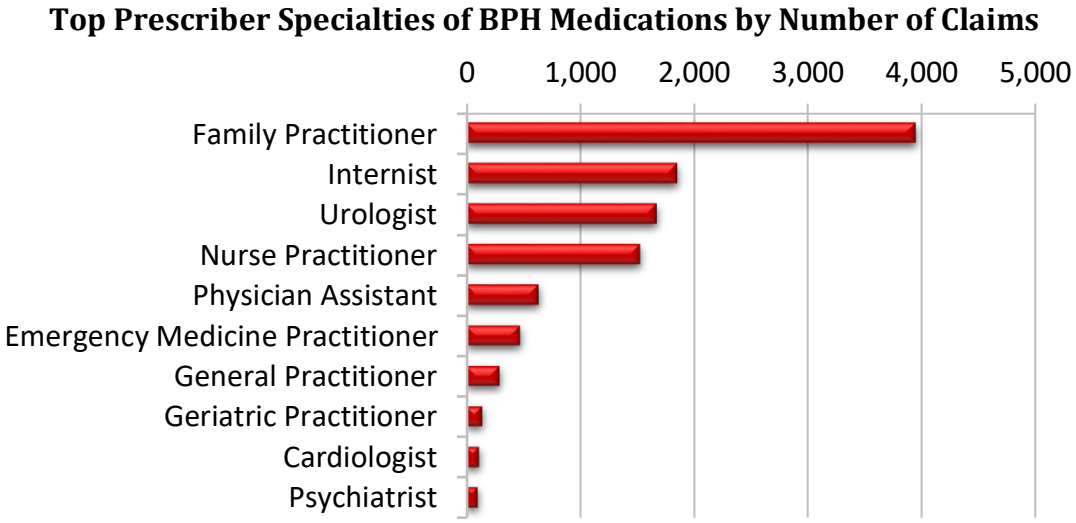
Utilization of BPH Medications: Fiscal Year 2019

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	3,192	11,282	$183,144.61	$16.23	$0.41	485,304	441,948
2019	3,212	11,400	$166,187.27	$14.58	$0.36	504,041	458,657
% Change	**0.60%**	**1.00%**	**-9.30%**	**-10.20%**	**-12.20%**	**3.90%**	**3.80%**
Change	**20**	**118**	**-$16,957.34**	**-$1.65**	**-$0.05**	**18,737**	**16,709**

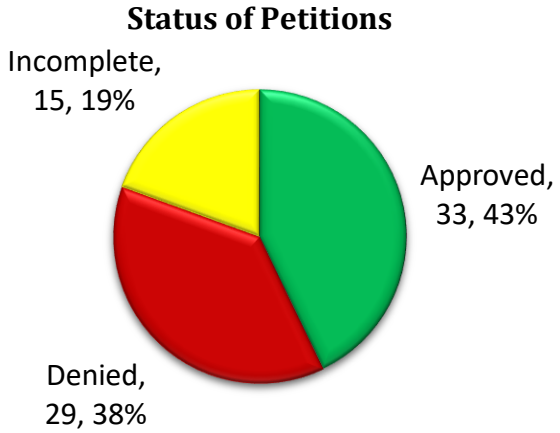
*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019





Prior Authorization of BPH Medications

There were 77 prior authorization requests submitted for BPH medications during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.



Market News and Updates

Anticipated Patent Expiration(s):[27]

- Cialis (tadalafil): August 2021

Recommendations

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

Utilization Details of BPH Medications: Fiscal Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 UTILIZATION						
TAMSULOSIN CAP 0.4MG	7,966	2,648	$101,609.92	$12.76	3.01	61.14%
FINASTERIDE TAB 5MG	956	244	$12,295.51	$12.86	3.92	7.40%
DOXAZOSIN TAB 4MG	734	167	$12,739.56	$17.36	4.4	7.67%
DOXAZOSIN TAB 2MG	411	105	$6,837.42	$16.64	3.91	4.11%
DOXAZOSIN TAB 8MG	403	77	$7,490.56	$18.59	5.23	4.51%
ALFUZOSIN TAB 10MG ER	157	38	$2,183.81	$13.91	4.13	1.31%
TERAZOSIN CAP 1MG	146	43	$1,887.38	$12.93	3.4	1.14%
DUTASTERIDE CAP 0.5MG	145	31	$2,584.48	$17.82	4.68	1.56%
DOXAZOSIN TAB 1MG	118	46	$2,040.48	$17.29	2.57	1.23%
TERAZOSIN CAP 2MG	118	36	$1,556.32	$13.19	3.28	0.94%
TERAZOSIN CAP 10MG	90	22	$1,112.01	$12.36	4.09	0.67%
TERAZOSIN CAP 5MG	87	33	$1,078.10	$12.39	2.64	0.65%
SUBTOTAL	**11,331**	**3,209***	**$153,415.55**	**$13.54**	**3.53**	**92.31%**
TIER-2 UTILIZATION						
RAPAFLO CAP 8MG	22	4	$4,993.94	$227.00	5.5	3.01%
SILODOSIN CAP 8MG	22	4	$869.89	$39.54	5.5	0.52%
DUTAST/TAMSU CAP 0.5-0.4MG	5	2	$1,263.02	$252.60	2.5	0.76%
SUBTOTAL	**49**	**7***	**$7,126.85**	**$145.45**	**7**	**4.29%**
TIER-3 UTILIZATION						
CIALIS TAB 5MG	13	2	$4,323.12	$332.55	6.5	2.60%
TADALAFIL TAB 5MG	7	3	$1,321.75	$188.82	2.33	0.80%
SUBTOTAL	**20**	**3***	**$5,644.87**	**$282.24**	**6.67**	**3.40%**
TOTAL	**11,400**	**3,212***	**$166,187.27**	**$14.58**	**3.55**	**100%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

[27] U.S. Food and Drug Administration (FDA): Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 03/2020. Last accessed 03/16/2020.

Fiscal Year 2019 Annual Review of Benzodiazepine Medications

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

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

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

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

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

Niravam™ (Alprazolam Orally Disintegrating Tablet) Approval Criteria:

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

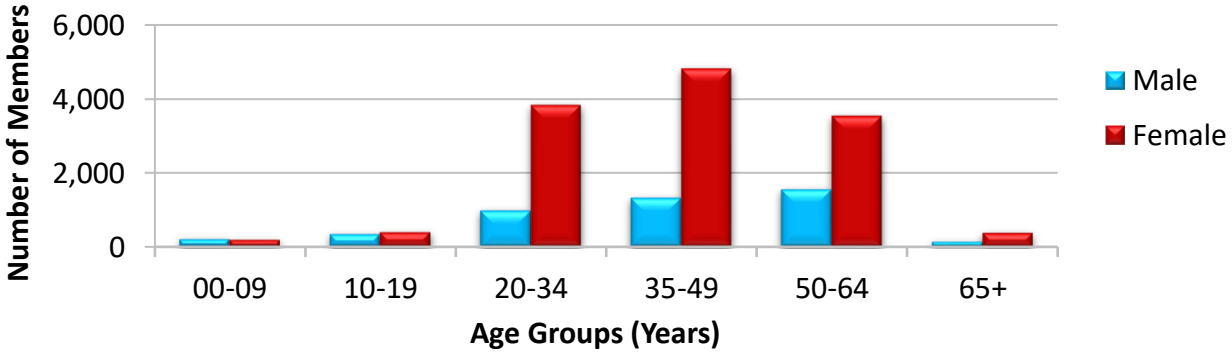
Utilization of Benzodiazepine Medications: Fiscal Year 2019

Comparison of Fiscal Years

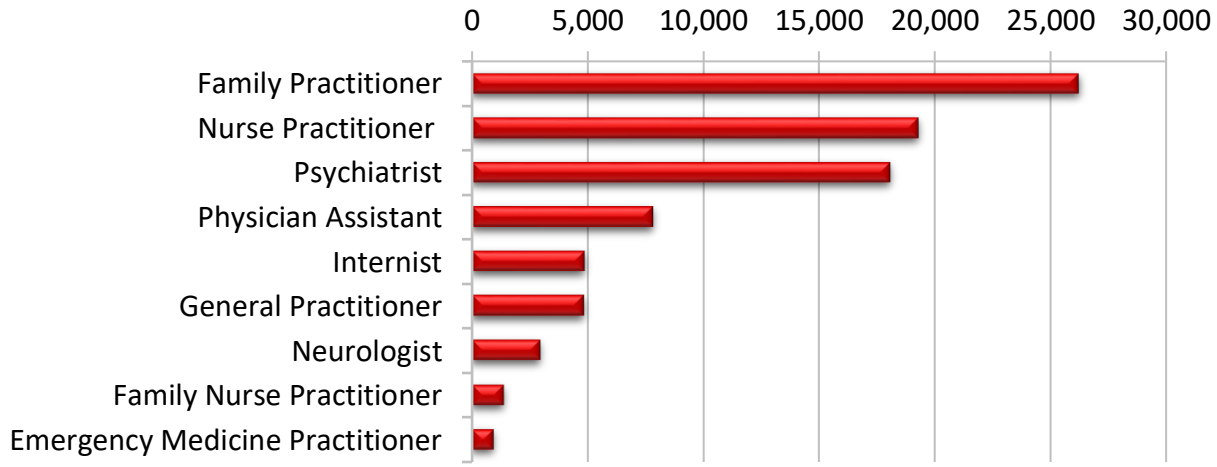
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	21,327	116,753	$1,312,913.54	$11.25	$0.41	7,193,230	3,240,787
2019	17,668	92,616	$1,087,179.24	$11.74	$0.43	5,529,051	2,528,619
% Change	**-17.2%**	**-20.7%**	**-17.2%**	**4.4%**	**4.9%**	**-23.1%**	**-22.0%**
Change	**-3,659**	**-24,137**	**-$225,734.30**	**$0.49**	**$0.02**	**-1,664,179**	**-712,168**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Demographics of Members Utilizing Benzodiazepine Medications

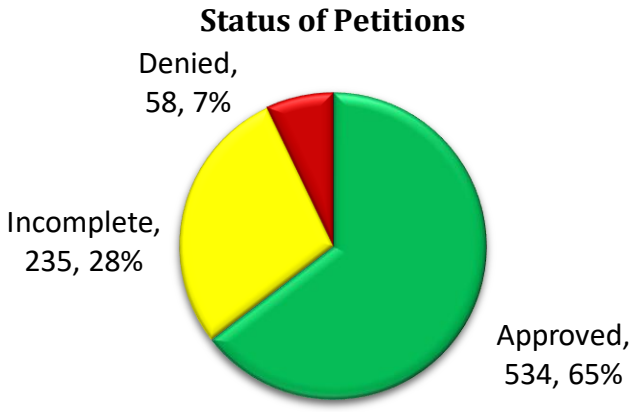


Top Prescriber Specialties of Benzodiazepine Medications by Number of Claims



Prior Authorization of Benzodiazepine Medications

There were 827 prior authorization request submitted for benzodiazepine medications during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.



Market News and Updates

News:

- **January 2019:** Benzodiazepine-related overdose mortality has risen dramatically, from 0.6 per 100,000 adults in 1999 to 4.4 per 100,000 adults in 2016. In a serial cross-sectional study of 386,457 ambulatory care visits from 2003 through 2015 using the National Ambulatory Medical Care Survey (NAMCS), it was discovered that the use of benzodiazepines in ambulatory care increased substantially from 3.8% to 7.4% of visits, including co-prescribing with other sedating medications. Primary care physicians accounted for the most benzodiazepine-related visits, and benzodiazepine use has risen substantially for indications other than anxiety and insomnia. The study emphasized the need to address benzodiazepines prescribing patterns in order to halt the growing use of benzodiazepines.[28]
- **May 2019:** A study examined the prevalence of benzodiazepine use among older patients with schizophrenia spectrum disorder using data from the Cohort of individuals with Schizophrenia Aged 55 years or more (CSA) in order find prevalence of benzodiazepine use and the clinical factors associated with such use. The study found that the prevalence of benzodiazepine use was 29.8% in older patients with schizophrenia spectrum disorder as part of a short-term therapeutic strategy toward patients with more severe trouble or comorbid disorders.[29]

Recommendations

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

---

[28] Agarwal SD, Landon BE. Patterns in Outpatient Benzodiazepine Prescribing in the United States. *JAMA Network Open* 2019; 2(1)e187399. doi:10.1001/jamanetworkopen.2018.7399.

[29] Schuster JP, Hoertel N, von Gunten A, et al. Benzodiazepine use among older adults with schizophrenia spectrum disorder: prevalence and associated factors in a multicenter study. *Int Psychogeriatr* 2020; 32(4):441-451. doi: 10.1017/S1041610219000358.

Utilization Details of Benzodiazepine Medications: Fiscal Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
ALPRAZOLAM PRODUCTS					
ALPRAZOLAM TAB 1MG	19,698	3,494	$197,401.27	5.64	$10.02
ALPRAZOLAM TAB 0.5MG	9,461	2,530	$94,231.67	3.74	$9.96
ALPRAZOLAM TAB 2MG	9,286	1,413	$106,440.27	6.57	$11.46
ALPRAZOLAM TAB 0.25MG	2,540	903	$24,730.37	2.81	$9.74
ALPRAZOLAM TAB 2MG ER	199	43	$3,493.01	4.63	$17.55
ALPRAZOLAM TAB 1MG ER	151	48	$2,419.93	3.15	$16.03
ALPRAZOLAM TAB 3MG ER	120	21	$2,305.63	5.71	$19.21
ALPRAZOLAM TAB 0.5MG ER	48	22	$769.45	2.18	$16.03
ALPRAZOLAM TAB 2MG XR	21	6	$362.79	3.50	$17.28
ALPRAZOLAM TAB 1MG XR	13	8	$206.76	1.63	$15.90
ALPRAZOLAM TAB 0.5MG XR	12	2	$163.15	6.00	$13.60
ALPRAZOLAM CON 1 MG/ML	1	1	$98.49	1.00	$98.49
SUBTOTAL	**41,550**	**7176**	**$432,622.79**	**5.79**	**$10.41**
CHLORDIAZEPOXIDE PRODUCTS					
CHLORDIAZEP CAP 25MG	180	101	$2,035.43	1.78	$11.31
CHLORDIAZEP CAP 10MG	119	57	$1,379.94	2.09	$11.60
CHLORDIAZEP CAP 5MG	47	31	$600.90	1.52	$12.79
SUBTOTAL	**346**	**172**	**$4,016.27**	**2.01**	**$11.61**
CLONAZEPAM PRODUCTS					
CLONAZEPAM TAB 1MG	12,431	2,564	$129,197.95	4.85	$10.39
CLONAZEPAM TAB 0.5MG	10,626	2,830	$108,353.47	3.75	$10.20
CLONAZEPAM TAB 2MG	3,458	640	$36,880.38	5.40	$10.67
CLONAZEP ODT 0.25MG	1,096	311	$39,144.66	3.52	$35.72
CLONAZEP ODT 0.125MG	570	203	$22,312.48	2.81	$39.14
CLONAZEP ODT 0.5MG	554	180	$23,591.64	3.08	$42.58
CLONAZEP ODT 1MG	305	105	$13,347.99	2.90	$43.76
CLONAZEP ODT 2MG	42	15	$2,230.76	2.80	$53.11
KLONOPIN TAB 2MG	12	1	$2,308.07	12.00	$192.34
SUBTOTAL	**29,094**	**5,931**	**$377,367.40**	**4.91**	**$12.97**
CLORAZEPATE PRODUCTS					
CLORAZ DIPOT TAB 3.75MG	207	32	$20,904.88	6.47	$100.99
CLORAZ DIPOT TAB 7.5MG	166	34	$15,585.67	4.88	$93.89
CLORAZ DIPOT TAB 15MG	106	15	$15,014.64	7.07	$141.65
SUBTOTAL	**479**	**76**	**$51,505.19**	**6.30**	**$107.53**
DIAZEPAM PRODUCTS					
DIAZEPAM TAB 10MG	5,828	1,492	$56,371.47	3.91	$9.67
DIAZEPAM TAB 5MG	5,092	1,778	$48,494.74	2.86	$9.52
DIAZEPAM TAB 2MG	955	341	$9,499.63	2.80	$9.95
DIAZEPAM SOL 5MG/5ML	233	55	$7,473.02	4.24	$32.07
DIAZEPAM INJ 5MG/ML	13	2	$2,354.96	6.50	$181.15
DIAZEPAM CON 5MG/ML	11	6	$408.95	1.83	$37.18
SUBTOTAL	**12,132**	**3,371**	**$124,602.77**	**3.60**	**$10.27**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
LORAZEPAM PRODUCTS					
LORAZEPAM TAB 1MG	4,474	1,337	$44,398.15	3.35	$9.92
LORAZEPAM TAB 0.5MG	3,293	1,083	$33,888.96	3.04	$10.29
LORAZEPAM TAB 2MG	1,099	273	$12,134.77	4.03	$11.04
LORAZEPAM CON 2MG/ML	81	44	$2,758.46	1.84	$34.06
LORAZEPAM INJ 2MG/ML	18	5	$406.53	3.60	$22.59
SUBTOTAL	**8,965**	**2,497**	**$93,586.87**	**3.59**	**$10.44**
OXAZEPAM PRODUCTS					
OXAZEPAM CAP 15MG	21	5	$1,043.52	4.20	$49.69
OXAZEPAM CAP 30MG	18	3	$1,957.73	6.00	$108.76
OXAZEPAM CAP 10MG	11	5	$476.70	2.20	$43.34
SUBTOTAL	**50**	**13**	**$3,477.95**	**3.85**	**$69.56**
TOTAL	**92,616**	**17,668***	**$1,087,179.24**	**5.24**	**$11.74**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Fiscal Year 2019 Annual Review of Bladder Control Medications

Oklahoma Health Care Authority
Fiscal Year 2019 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 nasal spray (Noctiva™)+
oxybutynin (Ditropan®)	tolterodine ER (Detrol LA®)	mirabegron (Myrbetriq®)Δ	desmopressin acetate SL tablets (Nocdurna®)+
oxybutynin ER (Ditropan XL®)		oxybutynin gel (Gelnique®)	oxybutynin patch (Oxytrol®)+
solifenacin (VESIcare®)Δ		trospium ER (Sanctura XR®)	
trospium (Sanctura®)			

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition costs (NADAC) or Whole Sale Acquisition Costs (WAC) if MADAC is unavailable.
ER = extended release; PA = prior authorization; SL = sublingual
+Unique criteria specific to Oxytrol® (oxybutynin patch), Noctiva™ (desmopressin acetate nasal spray), and Nocdurna® (desmopressin acetate sublingual tablets) applies.
ΔUnique criteria specific to use of Myrbetriq® (mirabegron) in combination with VESIcare® (solifenacin) applies.

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 for which the Tier-1 medications lack.

Bladder Control Medications Tier-3 Approval Criteria:

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

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. The 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 cannot be used; and
6. The prescriber must be willing to measure serum sodium levels prior to starting treatment and document levels are acceptable; and
7. The 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. The prescriber must confirm the member is not taking loop diuretics; and
9. The 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.

Noctiva™ (Desmopressin Acetate Nasal Spray) Approval Criteria:

1. An FDA approved diagnosis of nocturia due to nocturnal polyuria in adult members; 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. The 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) tablets or have a patient-specific, clinically significant reason why the tablet formulation cannot be used; and
6. The prescriber must be willing to measure serum sodium levels within 7 days of anticipated start of treatment and document levels are acceptable; and
7. The prescriber must agree to monitor serum sodium levels within 1 month of starting treatment or increasing the dose; and
8. The prescriber must confirm the member is not taking any of the following:
    a. Other medications via the nasal route; or
    b. Loop diuretics; and
9. The prescriber must confirm the member does not have renal impairment with 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. A quantity limit of one bottle (3.8g) 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; and
3. A quantity limit of 8 patches every 30 days will apply.

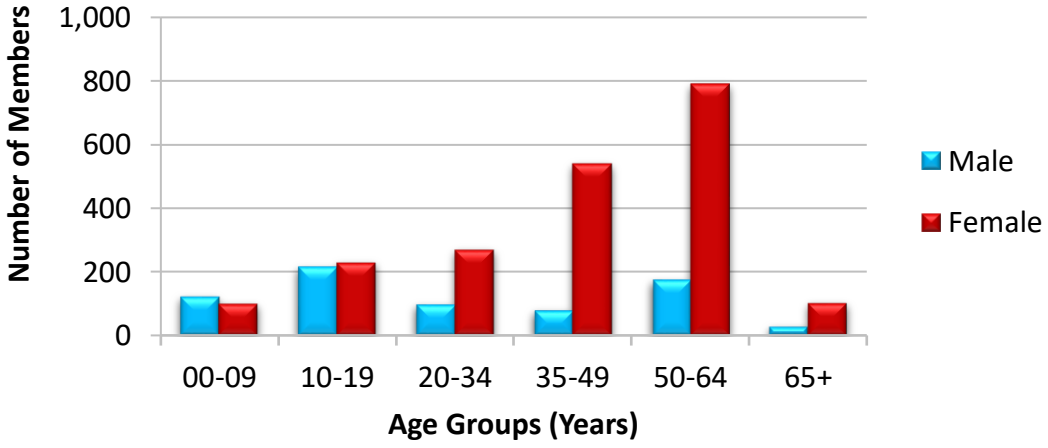
Utilization of Bladder Control Medications: Fiscal Year 2019

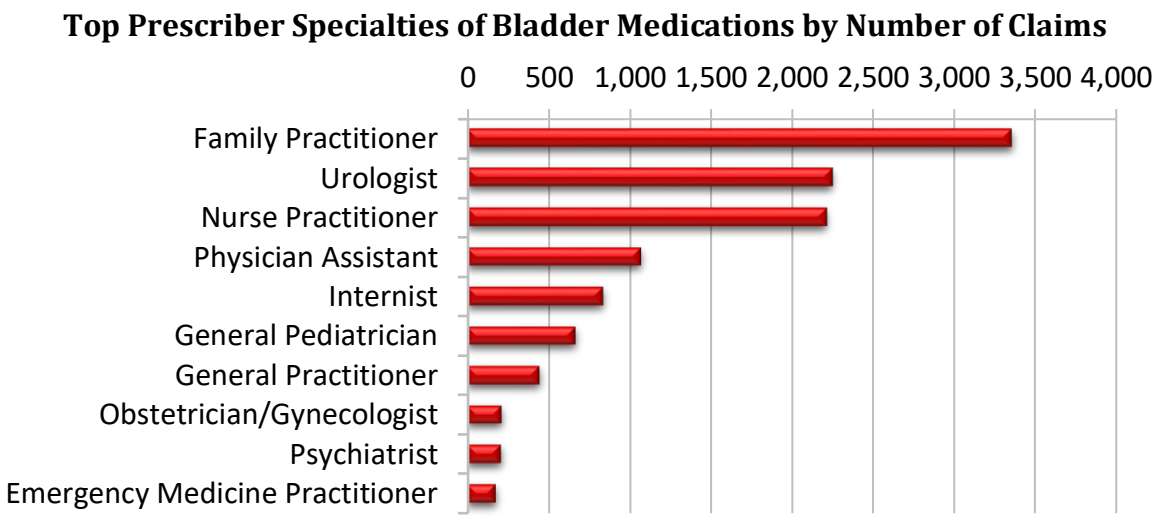
Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	2,629	11,789	$743,373.92	$63.06	$1.91	611,982	389,350
2019	2,733	11,967	$749,607.52	$62.64	$1.89	611,746	396,921
% Change	**4.0%**	**1.5%**	**0.8%**	**-0.7%**	**-1.0%**	**0.0%**	**1.9%**
Change	**104**	**178**	**$6,233.60**	**-$0.42**	**-$0.02**	**-236**	**7,571**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

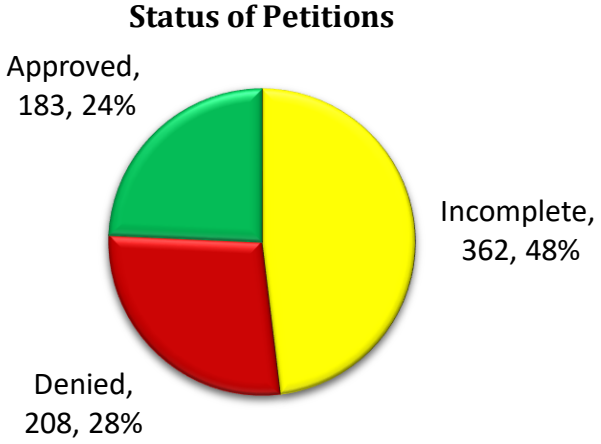
Demographics of Members Utilizing Bladder Control Medications





Prior Authorization of Bladder Control Medications

There were 753 prior authorization requests submitted for the bladder control medications during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.



Market News and Updates

Anticipated Patent Expiration(s):[30]

- Oxytrol® (oxybutynin patch): April 2020
- Detrol LA® [tolterodine extended-release (ER) capsule]: May 2020
- Toviaz® (fesoterodine tablet): June 2027
- Myrbetriq® (mirabegron tablet): October 2028
- Nocdurna® (desmopressin acetate sublingual tablet): April 2030
- Noctiva™ (desmopressin acetate nasal spray): June 2030
- Gelnique® (oxybutynin gel): March 2031

[30] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 10/2019. Last accessed 10/04/2019.

News:

- **December 2018:** A systematic review of studies published between 1980 and 2017 that included 3,072 patients concluded that low-dose oral desmopressin therapy alone is an effective treatment for nocturia associated with lower urinary tract symptoms (LUTS) in patients with benign prostatic hyperplasia (BPH). Overall, the evidence indicated desmopressin used alone or in combination with α-blockers led to a significant reduction in nocturia and an increase in the first sleep period.[31]
- **May 2019:** Astellas Pharma announced results from the Phase 4, 12-week PLUS trial evaluating the efficacy and safety of mirabegron vs. placebo in men with overactive bladder (OAB) symptoms receiving tamsulosin for underlying benign BPH at the American Urological Association (AUA) 2019 Annual Meeting in Chicago. The results showed that among men with OAB symptoms receiving tamsulosin for LUTS due to underlying BPH, mirabegron was statistically superior to placebo as an add-on therapy in reducing mean number of micturitions (episodes of urination) per 24 hours from baseline to the end of treatment, with a statistically significant adjusted mean difference between groups [-0.39; 95% confidence interval (CI): -0.76, -0.02].[32]
- **February 2019:** Avadel announced that it will no longer market Noctiva™ (desmopressin nasal spray) in the United States, less than a year after launch. Avadel Specialty Pharmaceuticals, a subsidiary, responsible solely for the sales, marketing, and distribution of Noctiva™ has filed for Chapter 11 bankruptcy. According to Avadel, the performance of Noctiva™ since launch has been highly disappointing despite a substantial investment of resources.[33]

Pipeline:

- **Vibegron:** Vibegron is an oral, once-daily, small molecule beta-3 agonist. In March 2019, Urovant announced positive topline results from an international, double-blind, placebo-controlled, multicenter Phase 3 clinical trial evaluating the efficacy and safety of vibegron 75mg in 1,518 adults with symptoms of OAB. Urovant intends to file a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) by early 2020.[34]

Recommendations

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

---

[31] Taha DE, Aboumarzouk OM, Shokeir AA. Oral desmopressin in nocturia with benign prostatic hyperplasia: a systematic review of the literature. *Arab J Urol* 2018; 16(4):404–410. doi: doi.org/10.1016/j.aju.2018.06.007

[32] Astellas Pharma, Inc. New Data Show Mirabegron Reduced OAB Symptoms in Men with Benign Prostatic Hyperplasia Currently Treated with Tamsulosin. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/new-data-show-mirabegron-reduced-oab-symptoms-in-men-with-benign-prostatic-hyperplasia-currently-treated-with-tamsulosin-300843944.html. Issued 05/05/2019. Last accessed 10/04/2019.

[33] Avadel Pharmaceuticals. Avadel Pharmaceuticals Announces Restructuring to Focus on FT218 Clinical Development Program. Available online at: http://investors.avadel.com/news-releases/news-release-details/avadel-pharmaceuticals-announces-restructuring-focus-ft218?ID=2386544&c=67519&p=irol-newsArticle. Issued 02/07/2019. Last accessed 10/04/2019.

[34] Urovant Sciences. Pipeline. Available online at: https://urovant.com/pipeline/. Last accessed 10/04/2019.

Utilization Details of Bladder Control Medications: Fiscal Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
TIER-1 UTILIZATION					
FESOTERODINE PRODUCTS					
TOVIAZ TAB 8MG	506	107	$154,860.13	4.73	$306.05
TOVIAZ TAB 4MG	467	139	$142,210.34	3.36	$304.52
SUBTOTAL	**973**	**235**	**$297,070.47**	**4.14**	**$305.31**
OXYBUTYNIN PRODUCTS					
OXYBUTYNIN TAB 5MG	5,075	1,268	$106,190.22	4	$20.92
OXYBUTYNIN TAB 10MG ER	2,017	569	$49,655.60	3.54	$24.62
OXYBUTYNIN TAB 5MG ER	1,420	448	$36,406.66	3.17	$25.64
OXYBUTYNIN TAB 15MG ER	829	193	$22,630.03	4.3	$27.30
SUBTOTAL	**9,341**	**2,268**	**$214,882.51**	**4.12**	**$23.00**
SOLIFENACIN PRODUCTS					
VESICARE TAB 10MG	47	9	$21,994.65	5.22	$467.97
VESICARE TAB 5MG	45	7	$15,864.10	6.43	$352.54
SOLIFENACIN TAB 10MG	6	4	$1,262.07	1.5	$210.35
SOLIFENACIN TAB 5MG	5	4	$945.68	1.25	$189.14
SUBTOTAL	**103**	**17**	**$40,066.50**	**4.29**	**$389.00**
TROSPIUM PRODUCTS					
TROSPIUM TAB 20MG	169	61	$6,627.09	2.77	$39.21
SUBTOTAL	**169**	**61**	**$6,627.09**	**2.77**	**$39.21**
TIER-1 SUBTOTAL	**10,586**	**2,488**	**$558,646.57**	**4.25**	**$52.77**
TIER-2 UTILIZATION					
TOLTERODINE PRODUCTS					
TOLTERODINE TAB 2MG	265	34	$12,556.74	7.79	$47.38
TOLTERODINE TAB 1MG	26	7	$868.63	3.71	$33.41
TOLTERODINE CAP 4MG ER	131	26	$7,459.03	5.04	$56.94
TOLTERODINE CAP 2MG ER	10	6	$619.30	1.67	$61.93
SUBTOTAL	**432**	**69**	**$21,503.70**	**6.26**	**$49.78**
TIER-2 SUBTOTAL	**432**	**69**	**$21,503.70**	**6.26**	**$49.78**
TIER-3 UTILIZATION					
DARIFENACIN PRODUCTS					
DARIFENACIN TAB 15MG	43	4	$5,321.02	10.75	$123.74
DARIFENACIN TAB 7.5MG	10	1	$1,314.17	10	$131.42
SUBTOTAL	**53**	**5**	**$6,635.19**	**10.6**	**$125.19**
MIRABEGRON PRODUCTS					
MYRBETRIQ TAB 25MG	81	16	$29,737.03	5.06	$367.12
MYRBETRIQ TAB 50MG	80	15	$25,315.68	5.33	$316.45
SUBTOTAL	**161**	**29**	**$55,052.71**	**5.55**	**$341.94**
OXYBUTYNIN PRODUCTS					
GELNIQUE GEL 10%	12	2	$4,253.36	6	$354.45
SUBTOTAL	**12**	**2**	**$4,253.36**	**6**	**$354.45**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
TROSPIUM PRODUCTS					
TROSPIUM CAP 60MG ER	236	42	$44,044.21	5.62	$186.63
SUBTOTAL	**236**	**42**	**$44,044.21**	**5.62**	**$186.63**
TIER-3 SUBTOTAL	**462**	**77**	**$109,985.47**	**6**	**$238.06**
SPECIAL PRIOR AUTHORIZATION (PA) UTILIZATION					
DESMOPRESSIN PRODUCTS					
DESMOPRESSIN SPR 0.01%	487	148	$59,471.78	3.29	$122.12
SUBTOTAL	**487**	**148**	**$59,471.78**	**3.29**	**$122.12**
SPECIAL PA SUBTOTAL	**487**	**148**	**$59,471.78**	**3.29**	**$122.12**
TOTAL	**11,967**	**2,733***	**$749,607.52**	**4.38**	**$62.64**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Fiscal Year 2019 Annual Review of Bowel Preparation Medications

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

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

1. An FDA approved indication for use in cleansing of the colon as a preparation for colonoscopy; and
2. A patient-specific, clinically significant reason other than convenience the member cannot use other bowel preparation medications available without prior authorization must be provided.
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®.

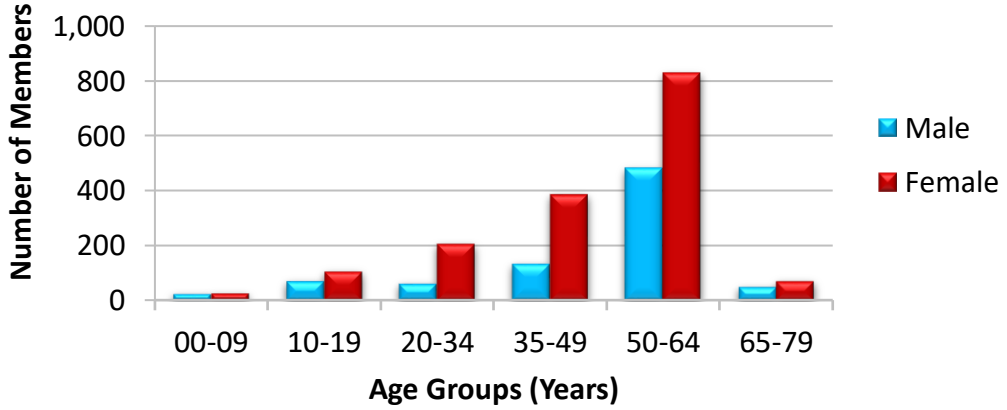
Utilization of Bowel Preparation Medications: Fiscal Year 2019

Comparison of Fiscal Years

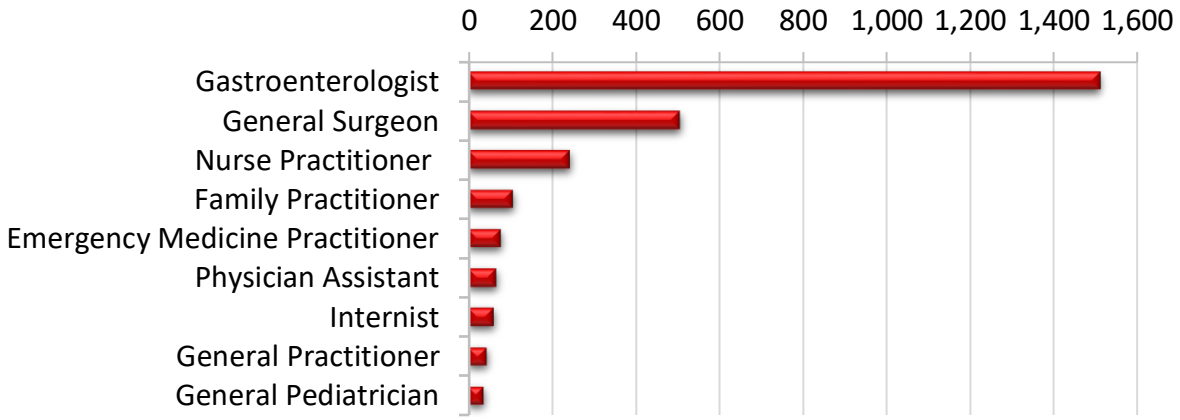
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	2,449	2,795	$87,887.99	$31.44	$11.49	9,416,687	7,646
2019	1,981	2,214	$61,163.50	$27.63	$12.94	8,114,813	4,725
% Change	**-19.1%**	**-20.8%**	**-30.4%**	**-12.1%**	**12.6%**	**-13.8%**	**-38.2%**
Change	**-468**	**-581**	**-$26,724.49**	**-$3.81**	**$1.45**	**-1,301,874**	**-2,921**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Demographics of Members Utilizing Bowel Preparation Medications



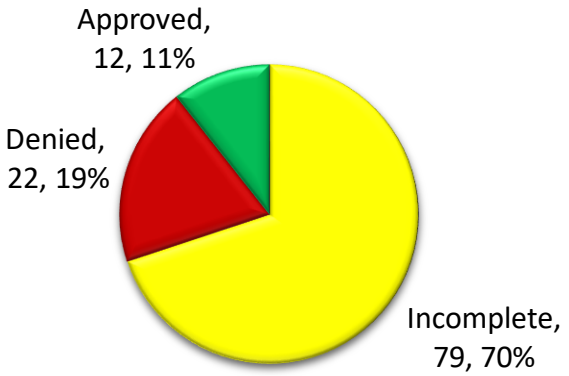
Top Prescriber Specialties of Bowel Preparation Medications by Number of Claims



Prior Authorization of Bowel Preparation Medications

There were 113 prior authorization requests submitted for the bowel preparation medications during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[35]

- 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]: September 2033
- Clenpiq™ (sodium picosulfate/magnesium oxide/anhydrous citric acid): June 2034

[35] 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 10/2019. Last accessed 10/09/2019.

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

- **August 2018:** The FDA approved Prepopik® (sodium picosulfate/magnesium oxide/ anhydrous citric acid), for cleansing of the colon as a preparation for colonoscopy in adults and pediatric patients 9 years of age and older. This approval is supported by an active-controlled study in 78 pediatric patients 9 to 16 years of age. Patients were randomized to 2 doses of Prepopik® or an oral PEG-based solution. Successful colon cleansing in patients 9 to 12 years of age and 13 to 16 years of age was demonstrated in 88% and 81%, respectively, of patients taking Prepopik®.[36]
- **August 2019:** The FDA approved Clenpiq™ (sodium picosulfate/magnesium oxide/ anhydrous citric acid) for cleansing of the colon as a preparation for colonoscopy in adults and pediatric patients 9 years of age and older. The approval is supported by a single study in 78 pediatric patients 9 to 16 years of age evaluating successful colon cleansing of Clenpiq™ versus PEG. Successful colon cleansing was achieved in 88% [95% confidence interval (CI): 62, 98] and 81% (95% CI: 54, 96) receiving Clenpiq™ in patients aged 9 to 12 years and patients aged 13 to 16 years, respectively.[37]

News:

- **February 2019:** A prospective, real-world study comparing the effectiveness of all the commercially available bowel preparation medications, published in the *American Journal of Gastroenterology*, found that MiraLAX® with Gatorade®, MoviPrep®, and Suprep® were prospectively associated with superior tolerability and bowel cleansing compared with Golytely® (all P<0.05). There were no significant differences among the remaining bowel preparation medications. The study included 5,253 patients aged 18 years and older who presented for an outpatient colonoscopy; patients were assessed prospectively at the time of colonoscopy using the Boston Bowel Preparation Scale (BBPS). The primary outcome was bowel cleansing measured using the BBPS. Bowel preparation tolerability was assessed as a secondary outcome by determining whether the patient completed the bowel preparation as prescribed.[38]

Recommendations

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

---

[36] U.S. Food and Drug Administration (FDA). New Pediatric Labeling Information Database. Available online at: https://www.accessdata.fda.gov/scripts/sda/sdDetailNavigation.cfm?sd=labelingdatabase&id=776CFD9B58D76793E053554DA8C06DD5&rownum=27. Last revised 10/04/2018. Last accessed 10/09/2019.

[37] FDA. Supplemental Approval of Clenpiq™. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/209589Orig1s005ltr.pdf. Issued 08/08/2019. Last accessed 10/09/2019.

[38] Gu P, Lew D, Oh SJ, et al. Comparing the Real-World Effectiveness of Competing Colonoscopy Preparations: Results of a Prospective Trial. *Am J Gastroenterol* 2019; 114(2):305-314. doi: 10.14309/ajg.0000000000000057.

Utilization Details of Bowel Preparation Medications: Fiscal Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
GAVILYTE-G SOL	1,227	1,106	$23,451.56	1.11	$19.11
PEG-3350/KCL SOL /SODIUM	405	366	$8,839.72	1.11	$21.83
PEG 3350 SOL ELECTROL	343	319	$5,070.87	1.08	$14.78
MOVIPREP SOL	321	312	$33,859.99	1.03	$105.48
GAVILYTE-C SOL	136	124	$2,389.64	1.1	$17.57
GAVILYTE-N SOL FLAV PK	132	124	$2,986.04	1.06	$22.62
PEG-3350 SOL ELECTROL	129	106	$2,506.41	1.22	$19.43
TRILYTE SOL	28	17	$667.48	1.04	$23.84
GOLYTELY SOL	15	15	$291.23	1	$19.42
SUPREP BOWEL SOL PREP KIT	4	4	$399.54	1	$99.89
OSMOPREP TAB 1.5GM	3	3	$644.25	1	$214.75
SUBTOTAL	**2,743**	**2,446**	**$81,106.73**	**1.12**	**$29.57**
TOTAL	**2,743**	**2,446***	**$81,106.73**	**1.12**	**$29.57**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Fiscal Year 2019 Annual Review of Brineura® (Cerliponase Alfa)

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Brineura® (Cerliponase Alfa) Approval Criteria:

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

Utilization of Brineura® (Cerliponase Alfa): Fiscal Year 2019

There was no SoonerCare utilization of Brineura® (cerliponase alfa) during fiscal year 2019.

Prior Authorization of Brineura® (Cerliponase Alfa)

There were no prior authorization requests submitted for Brineura® (cerliponase alfa) during fiscal year 2019.

Market News and Updates[39]

Pipeline:

- **January 2019:** Spark Therapeutics announced that it is investigating SPK-1001 as an investigational central nervous system (CNS)-directed adeno-associated viral (AAV) gene therapy that has demonstrated compelling preclinical proof-of-concept in a naturally occurring model of tripeptidyl peptidase-1 (TPP-1) deficiency, a form of Batten disease. Spark Therapeutics has received Orphan Drug designation from the U.S. Food and Drug Administration (FDA) for SPK-1001 for the treatment of ceroid lipofuscinosis type 2 (CLN2) caused by TPP-1 deficiency. Spark Therapeutics retains global rights to SPK-1001.

Recommendations

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

[39] Spark Therapeutics. Spark Therapeutics Announces Presentation of Preclinical Data in Pompe Disease and CLN2 Disease at 15th Annual WORLDSymposium™. *Globe Newswire*. Available online at: http://ir.sparktx.com/news-releases/news-release-details/spark-therapeutics-announces-presentation-preclinical-data-pompe. Issued 01/31/2019. Last accessed 12/13/2019.

Fiscal Year 2019 Annual Review of Butalbital Medications

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

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

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

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

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

Miscellaneous Butalbital Medications Approval Criteria:

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

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

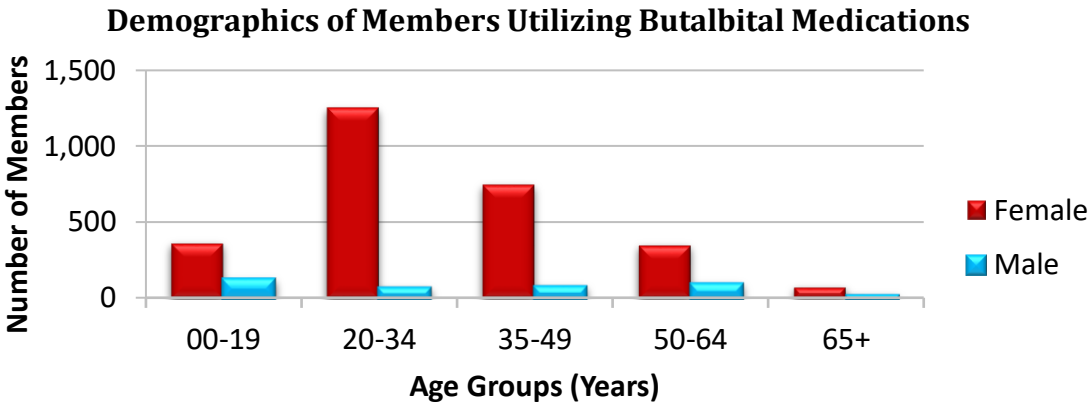
1. An FDA approved indication for the treatment of the symptom complex of tension (or muscle contraction) headache; and
2. A patient-specific, clinically significant reason why a liquid formulation is needed in place of the generic tablets even when the tablets are crushed must be provided; and
3. Members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

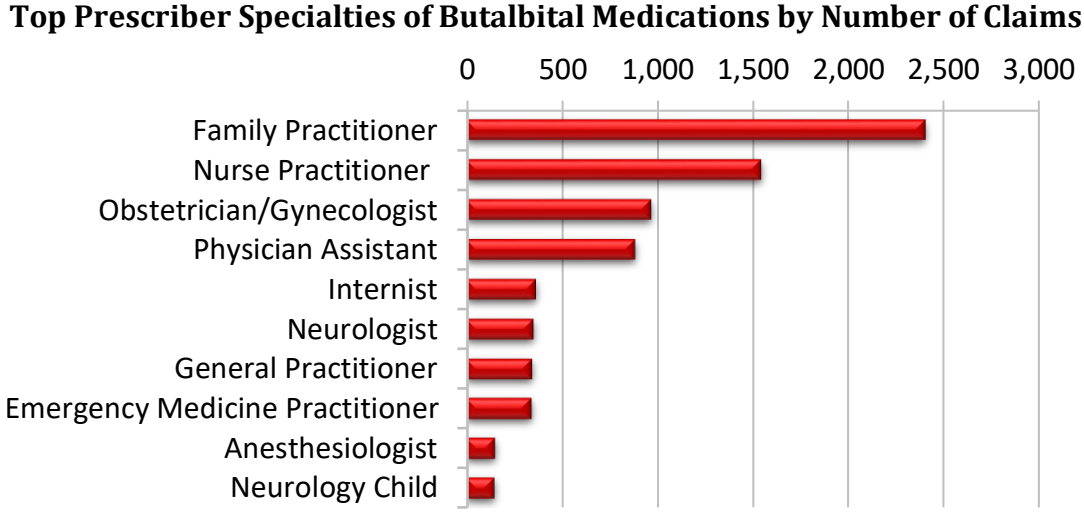
Utilization of Butalbital Medications: Fiscal Year 2019

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	3,892	9,474	$381,404.64	$40.26	$2.55	473,875	149,296
2019	3,130	7,918	$237,155.15	$29.95	$1.90	378,142	124,963
% Change	**19.6%**	**-16.4%**	**-37.8%**	**-25.6%**	**-25.5%**	**-20.2%**	**-16.3%**
Change	**-762**	**-1,556**	**-$144,249.49**	**-$10.31**	**-$0.65**	**-95,733**	**-24,333**

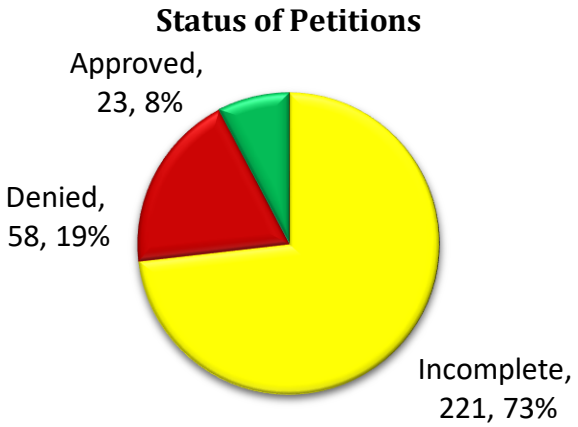
*Total number of unduplicated members. Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019





Prior Authorization of Butalbital Medications

There were 302 prior authorization requests submitted for butalbital medications during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.



Market News and Updates

News:

- **July 2019:** Cret and colleagues reported a case study of a 54-year-old female who developed posterior reversible encephalopathy syndrome after taking 2 tablets of Fioricet® (butalbital/acetaminophen/caffeine) every 6 hours for 3 days. She presented to the emergency department with the "worst headache ever" and a blood pressure of 178/87mmHg. Brain MRI showed edema in the subcortical white matter of the right occipital lobe, right parietal lobe, and left occipital lobe.[40]

Recommendations

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

Utilization Details of Butalbital Medications: Fiscal Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
BUTALBITAL PRODUCTS					
BUT/APAP/CAF TAB 50/325/40MG	6,841	2,810	$167,090.52	2.43	$24.42
BUT/ASA/CAF CAP 50/325/40MG	436	189	$21,417.74	2.31	$49.12
BUTAL/APAP TAB 50/325MG	43	16	$3,483.33	2.69	$81.01
BUT/ASA/CAF CAP 50/325/40MG	5	4	$222.99	1.25	$44.60
SUBTOTAL	**7,325**	**2,976**	**$192,214.58**	**2.46**	**$26.24**
BUTALBITAL/CODEINE PRODUCTS					
BUT/APAP/CAF/COD CAP 50/325/40/30MG	341	160	$18,479.72	2.13	$54.19
BUT/ASA/CAF/COD CAP 50/325/40/30MG	189	64	$20,320.31	2.95	$107.51
ASCOMP/COD CAP 50/325/40/30MG	63	27	$6,140.54	2.33	$97.47
SUBTOTAL	**593**	**224**	**$44,940.57**	**2.65**	**$75.79**
TOTAL	**7,918**	**3,130***	**$237,155.15**	**2.53**	**$29.95**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
APAP = acetaminophen; ASA = aspirin; CAF = caffeine; COD = Codeine; BUT = butalbital
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

[40] Cret N, Halalau M, Rezvani S, et al. Posterior Reversible Encephalopathy Syndrome Caused by Fioricet® (Butalbital-Acetaminophen-Caffeine). *Case Rep Med* 2019; 2019:5410872. doi: 10.1155/2019/5410872.

Fiscal Year 2019 Annual Review of Cholbam™ (Cholic Acid)

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Cholbam™ (Cholic Acid) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
   a. Treatment of bile acid disorders due to single enzyme defects (SEDs); or
   b. Adjunctive treatment of peroxisomal disorders (PDs) including Zellweger spectrum disorders in members who exhibit manifestations of liver disease, steatorrhea, or complications from decreased fat-soluble vitamin absorption; and
2. Treatment with Cholbam™ should be initiated and monitored by a hematologist or pediatric gastroenterologist; and
3. The prescriber must verify that AST, ALT, GGT, alkaline phosphatase, bilirubin and INR will be monitored every month for the first 3 months, every 3 months for the next 9 months, every 6 months during the next 3 years, and annually thereafter; and
4. Cholbam™ should be discontinued if liver function does not improve within 3 months of starting treatment, if complete biliary obstruction develops, or if there are persistent clinical or laboratory indicators of worsening liver function or cholestasis; and
5. Initial approval will be for 3 months to monitor for compliance and liver function tests; and
6. Continuation approvals will be granted for the duration of 1 year; and
7. A quantity limit of 120 capsules per 30 days will apply. Quantity limit requests will be based on members' recent weight taken within the last 30 days.

Utilization of Cholbam™ (Cholic Acid): Fiscal Year 2019

There was 1 approved prior authorization and 1 paid claim for Cholbam™ (cholic acid) during fiscal year 2019.

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	1	1	$8,285.55	$8,285.55	$276.19	30	30

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Recommendations

The College of Pharmacy does not recommend any changes to the current Cholbam™ (cholic acid) prior authorization criteria at this time.

Fiscal Year 2019 Annual Review of Chorionic Gonadotropin Medications

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Novarel® and Pregnyl® (Chorionic Gonadotropin) Approval Criteria:

1. An FDA approved diagnosis of prepubertal cryptorchidism not due to anatomic obstruction or hypogonadotropic hypogonadism (hypogonadism secondary to a pituitary deficiency); and
2. Requests for any of the following diagnoses will not be approved:
   a. Ovulation induction; or
   b. Spermatogenesis induction; or
   c. Weight loss; and
3. Member must be male; and
4. For the diagnosis of prepubertal cryptorchidism, the member must be 4 to 10 years of age; or
5. For the diagnosis of hypogonadotropic hypogonadism, the member must be of peripubertal age; and
   a. A patient-specific, clinically significant reason why testosterone therapy is not appropriate must be provided.

Utilization of Chorionic Gonadotropin Medications: Fiscal Year 2019

Fiscal Year 2019 Utilization

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	1	1	$142.92	$142.92	$142.92	1	1

There was no SoonerCare utilization of chorionic gonadotropin medications during fiscal year 2018.
*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Demographics of Members Utilizing Chorionic Gonadotropin Medications

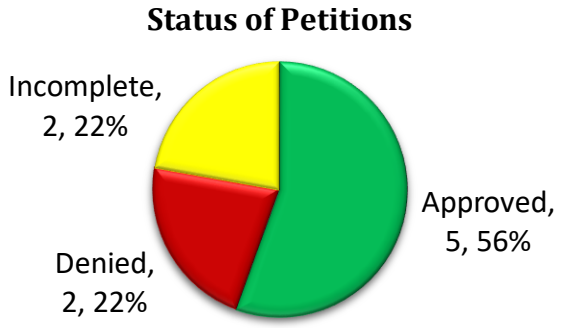
- Due to the limited number of members utilizing chorionic gonadotropin medications, detailed demographic information could not be provided.

Top Prescriber Specialties of Chorionic Gonadotropin Medications by Number of Claims

- The only prescriber specialty listed on paid pharmacy claims for chorionic gonadotropin medications during fiscal year 2019 was pediatric endocrinology.

Prior Authorization of Chorionic Gonadotropin Medications

There were 9 prior authorization requests submitted for 3 unique members for chorionic gonadotropin medications during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.



Recommendations

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

Utilization Details of Chorionic Gonadotropin Medications: Fiscal Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS*	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
NOVAREL INJ 5000UNIT	1	1	$142.92	1	$142.92
TOTAL	**1**	**1**	**$142.92**	**1**	**$142.92**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Fiscal Year 2019 Annual Review of Corticosteroid Special Formulations

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

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

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

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.

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

1. Authorization of Veripred™ 20 or Millipred™ requires a patient-specific, clinically significant reason why the member cannot use generic prednisolone oral solution 15mg/5mL, generic prednisolone oral solution 5mg/5mL, generic dexamethasone oral solution 0.5mg/5mL, or other cost-effective therapeutic equivalent medication(s).

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 2019

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	1,690	2,112	$202,714.79	$95.98	$19.53	12,655	10,381
2019	1,556	1,994	$180,342.82	$90.44	$18.55	11,530	9,722
% Change	**-7.90%**	**-5.60%**	**-11.00%**	**-5.80%**	**-5.00%**	**-8.90%**	**-6.30%**
Change	**-134**	**-118**	**-$22,371.97**	**-$5.54**	**-$0.98**	**-1,125**	**-659**

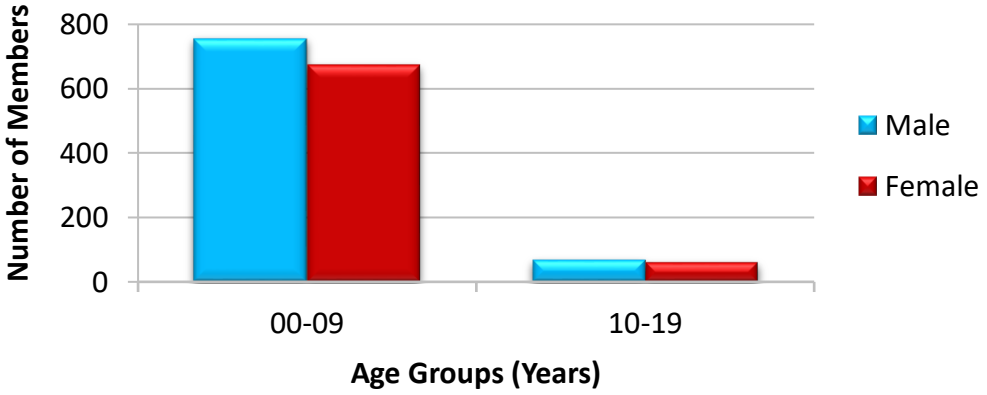
*Total number of unduplicated members. Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Fiscal Year 2019 Utilization: Medical Claims

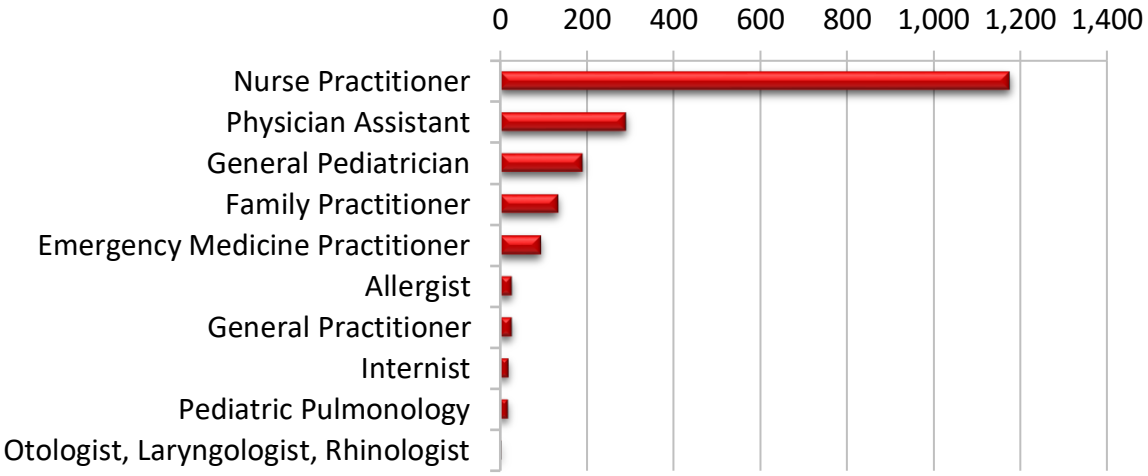
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Total Units
2019	1	1	$141.71	$141.71	32

*Total number of unduplicated members. Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Demographics of Members Utilizing Corticosteroid Special Formulations

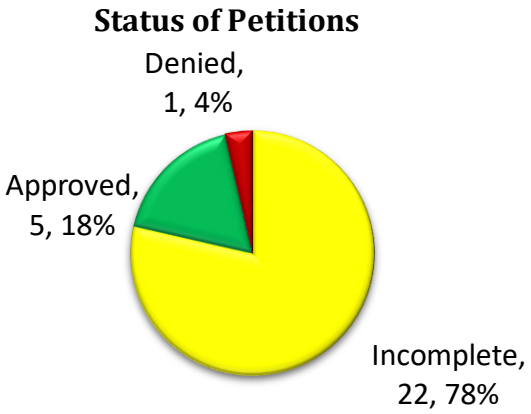


Top Prescriber Specialties of Corticosteroid Special Formulations by Number of Claims



Prior Authorization of Corticosteroid Special Formulations

There were 28 prior authorization requests submitted for corticosteroid special formulations during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.



Recommendations

The College of Pharmacy recommends 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 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
PREDNISOLONE ORALLY DISINTEGRATING PRODUCTS					
PREDNISOLONE 15MG ODT	944	793	$91,109.86	1.19	$96.51
PREDNISOLONE 10MG ODT	764	577	$55,225.31	1.32	$72.28
PREDNISOLONE 30MG ODT	286	267	$34,007.65	1.07	$118.91
TOTAL	**1,994**	**1,556***	**$180,342.82**	**1.28**	**$90.44**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Fiscal Year 2019 Annual Review of Defitelio® (Defibrotide)

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Defitelio® (Defibrotide) Approval Criteria:

1. An FDA approved diagnosis of hepatic veno-occlusive disease (VOD), also known as sinusoidal obstruction syndrome (SOS), with renal or pulmonary dysfunction following hematopoietic stem-cell transplantation (HSCT); and
2. Initial approvals will be for 1 month of therapy. An additional month of therapy (maximum of 60 days) may be granted if the physician documents the continued need for therapy.

Utilization of Defitelio® (Defibrotide): Fiscal Year 2019

There was no SoonerCare utilization of Defitelio® (defibrotide) during fiscal year 2019 (fiscal year 2019 = 07/01/2018 to 06/30/2019).

Prior Authorization of Defitelio® (Defibrotide)

There were no prior authorization requests submitted for Defitelio® (defibrotide) during fiscal year 2019.

Market News and Updates

Anticipated Exclusivity Expiration(s):[41]

- Defitelio® (defibrotide): March 2023

Recommendations

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

[41] 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 09/2019. Last accessed 09/11/2019.

Fiscal Year 2019 Annual Review of Diabetic Supplies

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

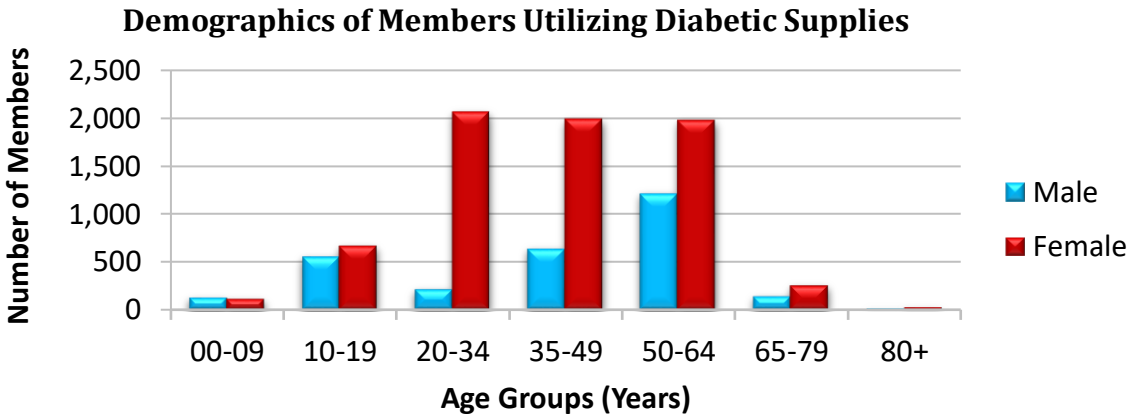
- The preferred brands for SoonerCare members are OneTouch®, FreeStyle™, and Precision™ test strips and meters. Other brands of test strips and glucometers are not covered.
- In addition to test strips and glucometers, lancets, syringes, pen needles, and control solution are also covered in the pharmacy claims system. Supplies for insulin pumps remain durable medical equipment (DME) claims.
- Glucometers are limited to 1 meter per member per year. Test strips/lancets are limited to 300 per 30 days for members using insulin and 100 per 100 days for members using oral medications. Members diagnosed with gestational diabetes are limited to 300 strips/lancets per 30 days. Syringes and pen needles are limited to 200 per 30 days.
- Diabetic supplies have a $0 copay and do not count against the monthly prescription limit.
- An automated prior authorization process looks for insulin and other diabetic medications in the member's claims history. If the medication is not found in claims history or if the quantity submitted exceeds the maximum allowed, the claim will deny for prior authorization. It will also look for a diagnosis of gestational diabetes. Pharmacies should be instructed to submit the medication claims for new orders for insulin or medications first and then the supply claims second.
- Automated refills of diabetic supplies are not allowed. Refills should be ordered by the member or the member's representative.

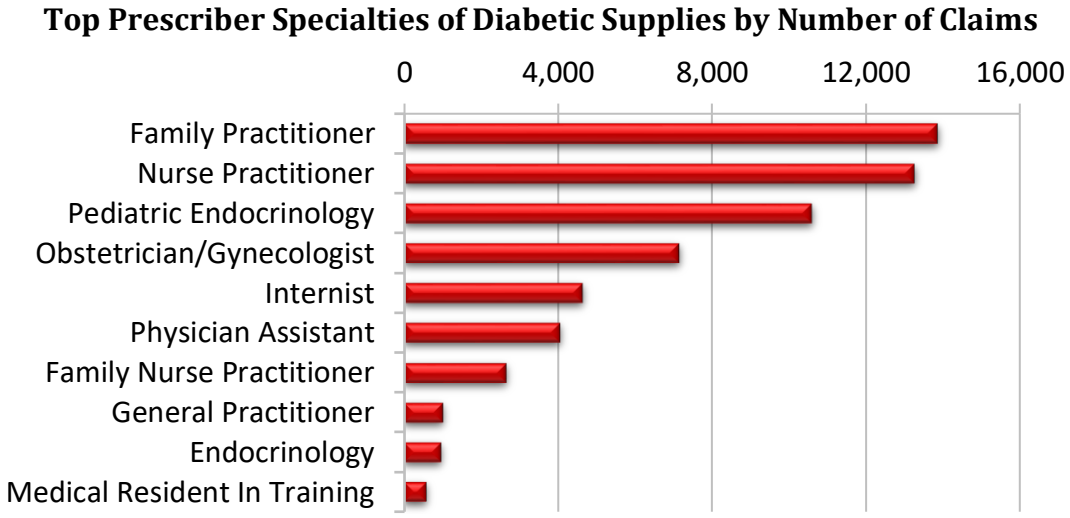
Utilization of Diabetic Supplies: Fiscal Year 2019

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	10,272	63,231	$5,051,538.47	$79.89	$2.04	7,251,149	2,476,653
2019	9,981	61,446	$4,786,114.04	$77.89	$2.01	7,019,004	2,377,224
% Change	**-2.80%**	**-2.80%**	**-5.30%**	**-2.50%**	**-1.50%**	**-3.20%**	**-4.00%**
Change	**-291**	**-1,785**	**-$265,424.43**	**-$2.00**	**-$0.03**	**-232,145**	**-99,429**

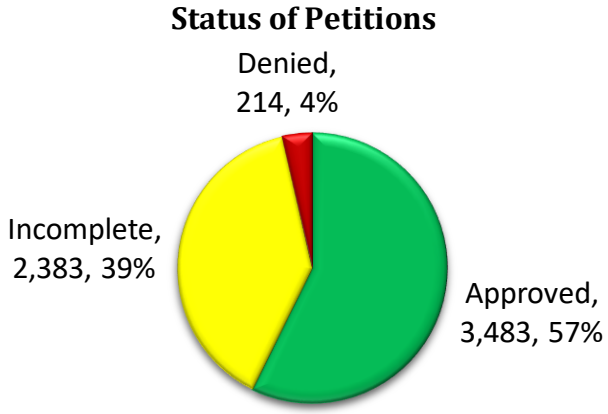
*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019





Prior Authorization of Diabetic Supplies

There were 6,080 prior authorization requests submitted for diabetic supplies during fiscal year 2019. Computer edits are in place to detect insulin and other diabetic medications in a member's recent claims history and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions for fiscal year 2019.



Recommendations

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

Utilization Details of Diabetic Supplies: Fiscal Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
DIABETIC TEST STRIPS						
FREESTYLE TES LITE	12,977	4,169	$2,426,413.82	$186.98	3.11	50.70%
ONETOUCH TES ULTRA BL	8,768	2,869	$1,126,521.88	$128.48	3.06	23.54%
ONETOUCH TES VERIO	2,387	906	$189,082.54	$79.21	2.63	3.95%
CONTOUR TES NEXT	1,946	464	$322,969.91	$165.97	4.19	6.75%
FREESTYLE TES	386	151	$66,440.77	$172.13	2.56	1.39%
FREESTYLE TES INSULINX	206	63	$45,618.94	$221.45	3.27	0.95%
PRECISION TES XTRA	79	30	$10,462.10	$132.43	2.63	0.22%
PRODIGY NO TES CODING	42	17	$1,554.39	$37.01	2.47	0.03%
EASYMAX TES	9	4	$288.80	$32.09	2.25	0.01%
SUBTOTAL	**26,800**	**8,255***	**$4,189,353.15**	**$156.32**	**3.25**	**87.53%**
GLUCOMETERS						
FREESTYLE MIS LITE	2,209	2,155	$32,945.91	$14.91	1.03	0.69%
ONETOUCH KIT ULTRA 2	1,193	1,172	$17,464.36	$14.64	1.02	0.36%
FREESTYLE KIT FREEDOM	340	336	$5,005.85	$14.72	1.01	0.10%
ONETOUCH KIT ULT MINI	277	274	$4,111.50	$14.84	1.01	0.09%
ONETOUCH KIT VERIO	185	177	$2,744.26	$14.83	1.05	0.06%
ONETOUCH KIT VERIO FL	122	121	$1,821.82	$14.93	1.01	0.04%
ONETOUCH KIT VERIO IQ	44	42	$990.65	$22.51	1.05	0.02%
PRECISION MIS XTRA	12	12	$169.94	$14.16	1	0.00%
FREESTYLE KIT INSULINX	6	6	$228.00	$38.00	1	0.00%
PRODIGY AUTO KIT MONITOR	3	3	$23.85	$7.95	1	0.00%
SUBTOTAL	**4,391**	**4,257***	**$65,506.14**	**$14.92**	**1.03**	**1.37%**
GLUCOMETER CONTROL SOLUTION						
FREESTYLE LIQ CONTROL	60	59	$226.21	$3.77	1.02	0.00%
ONETOUCH SOL ULT CONT	23	23	$116.56	$5.07	1	0.00%
ONETOUCH SOL VERIO	6	6	$20.28	$3.38	1	0.00%
SUBTOTAL	**89**	**88***	**$363.05**	**$4.08**	**1.01**	**0.01%**
LANCETS AND LANCING DEVICES						
FREESTYLE MIS LANCETS	4,503	2,196	$7,986.36	$1.77	2.05	0.17%
ONETOUCH MIS LANCETS	2,205	1,132	$3,459.65	$1.57	1.95	0.07%
ONETOUCH MIS 30G	918	524	$1,397.87	$1.52	1.75	0.03%
TRUPLUS LANC MIS 30G	501	225	$886.99	$1.77	2.23	0.02%
EASY TOUCH MIS LANC/32G	387	215	$603.50	$1.56	1.8	0.01%
TRUPLUS LANC MIS 33G	353	188	$527.80	$1.50	1.88	0.01%
MICROLET MIS LANCETS	270	119	$533.14	$1.97	2.27	0.01%
ONETOUCH US MIS LANCETS	233	148	$380.56	$1.63	1.57	0.01%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TRUPLUS LANC MIS 28G	208	124	$344.97	$1.66	1.68	0.01%
KROGER LANCE MIS 33G	184	88	$260.57	$1.42	2.09	0.01%
KROGER LANCE MIS 30G	162	81	$242.82	$1.50	2	0.01%
EASY TOUCH MIS	137	134	$206.15	$1.50	1.02	0.00%
FASTCLIX MIS LANCETS	135	41	$296.48	$2.20	3.29	0.01%
SURE COMFORT MIS LANCETS	66	39	$127.80	$1.94	1.69	0.00%
GLOBAL 30G MIS LANCETS	62	26	$89.46	$1.44	2.38	0.00%
LANCET ULTRA MIS THIN 30G	58	23	$85.21	$1.47	2.52	0.00%
BAYER MICRLT MIS LANCETS	53	39	$109.35	$2.06	1.36	0.00%
LANCETS MIS 33G	40	14	$65.32	$1.63	2.86	0.00%
LANCETS ULTR MIS THIN	35	24	$49.70	$1.42	1.46	0.00%
EMBRACE LANC MIS THIN 30G	34	19	$48.28	$1.42	1.79	0.00%
COMFORTOUCH MIS LANCET	28	8	$56.80	$2.03	3.5	0.00%
GNP LANCETS MIS 21G	26	13	$44.02	$1.69	2	0.00%
TRUPLUS LANC MIS 26G	23	14	$36.92	$1.61	1.64	0.00%
PRODIGY MIS 28G	22	17	$32.66	$1.48	1.29	0.00%
AQUALANCE MIS 30G	21	8	$29.11	$1.39	2.63	0.00%
EASY TOUCH MIS LANC/28G	20	8	$28.40	$1.42	2.5	0.00%
ONETOUCH MIS LANC DEV	20	19	$82.16	$4.11	1.05	0.00%
SURE COMFORT MIS LANC PEN	14	14	$29.68	$2.12	1	0.00%
UNILET GP 28 MIS ULT THIN	13	8	$18.46	$1.42	1.63	0.00%
EASY COMFORT MIS 30G	13	10	$19.88	$1.53	1.3	0.00%
STERILANCE MIS TL 30G	12	9	$17.04	$1.42	1.33	0.00%
ULTRA THIN MIS 31G	9	4	$12.78	$1.42	2.25	0.00%
LANCING DEVI MIS	8	8	$16.96	$2.12	1	0.00%
THIN LANCETS MIS 30G	7	4	$11.36	$1.62	1.75	0.00%
TECHLITE MIS LANCETS	6	4	$10.22	$1.70	1.5	0.00%
SOFTCLIX MIS LANCETS	6	5	$11.36	$1.89	1.2	0.00%
LANCETS MIS	5	4	$7.10	$1.42	1.25	0.00%
BAYER MICRLT MIS LANC DVC	4	4	$8.48	$2.12	1	0.00%
LANCETS MIS 28G	3	3	$4.26	$1.42	1	0.00%
RELION ULTRA MIS THIN 30G	3	2	$2.84	$0.95	1.5	0.00%
ACCU-CHEK MIS MLTICLIX	3	3	$2.90	$0.97	1	0.00%
PRODIGY MIS LANC DEV	2	2	$4.24	$2.12	1	0.00%
ADV LANCING MIS DEVICE	2	2	$4.24	$2.12	1	0.00%
LANCETS MIS 30G	2	2	$4.26	$2.13	1	0.00%
LB LANCING MIS DEVICE	1	1	$2.12	$2.12	1	0.00%
AUTOLET LANC MIS DEVICE	1	1	$2.12	$2.12	1	0.00%
GLUCOLET 2 MIS LANCING	1	1	$2.12	$2.12	1	0.00%
LANCING MIS DEVICE	1	1	$2.12	$2.12	1	0.00%
LANCET SUPER MIS THIN 30G	1	1	$1.42	$1.42	1	0.00%
SOFT TOUCH MIS LANCETS	1	1	$1.42	$1.42	1	0.00%
GLOBAL 28G MIS LANCETS	1	1	$1.42	$1.42	1	0.00%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
UNILET LANCE MIS 28G	1	1	$1.42	$1.42	1	0.00%
ASSURE LANCE MIS MICRO	1	1	$1.42	$1.42	1	0.00%
BD LANCET UF MIS 33G	1	1	$1.42	$1.42	1	0.00%
EASY TOUCH MIS LANC/30G	1	1	$1.42	$1.42	1	0.00%
SOFT TOUCH MIS LAN DEVC	1	1	$2.12	$2.12	1	0.00%
AGAMATRIX MIS 33G	1	1	$1.42	$1.42	1	0.00%
ON CALL MIS LANCETS	1	1	$1.42	$1.42	1	0.00%
SM LANCETS MIS THIN 30G	1	1	$1.42	$1.42	1	0.00%
LANCETS THIN MIS	1	1	$1.42	$1.42	1	0.00%
BD LANCET UF MIS 30G	1	1	$1.42	$1.42	1	0.00%
RELION LANCE MIS THIN 30G	1	1	$1.42	$1.42	1	0.00%
SUBTOTAL	**10,834**	**5,080***	**$18,227.17**	**$1.68**	**2.13**	**0.38%**
PEN NEEDLES						
BD PEN NEEDL MIS 32GX4MM	3,564	1,153	$134,231.15	$37.66	3.09	2.80%
BD PEN NEEDL MIS 31GX5MM	1,577	659	$48,176.47	$30.55	2.39	1.01%
BD PEN NEEDL MIS 31GX8MM	1,120	473	$32,129.69	$28.69	2.37	0.67%
PEN NEEDLES MIS 32GX4MM	972	372	$26,494.41	$27.26	2.61	0.55%
RELION PEN MIS 32GX4MM	546	189	$10,514.25	$19.26	2.89	0.22%
UNFINE PNTP MIS 32GX4MM	388	153	$6,764.69	$17.43	2.54	0.14%
RELION PEN MIS 31GX6MM	371	148	$6,549.00	$17.65	2.51	0.14%
PEN NEEDLES MIS 31GX6MM	344	135	$6,608.74	$19.21	2.55	0.14%
PEN NEEDLES MIS 31GX5MM	297	110	$8,676.95	$29.22	2.7	0.18%
PEN NEEDLES MIS 31GX8MM	283	96	$5,409.11	$19.11	2.95	0.11%
EASY TOUCH MIS 31GX3/16	275	113	$3,792.57	$13.79	2.43	0.08%
RELION PEN MIS 31GX8MM	273	114	$4,385.05	$16.06	2.39	0.09%
NOVOFINE MIS 32GX6MM	268	105	$9,235.06	$34.46	2.55	0.19%
NOVOTWIST MIS 32GX5MM	246	68	$11,882.98	$48.30	3.62	0.25%
COMFORT EZ MIS 32GX4MM	225	53	$9,724.00	$43.22	4.25	0.20%
SURE COMFORT MIS 32GX5/32	222	92	$7,545.86	$33.99	2.41	0.16%
SURE COMFORT MIS 31GX3/16	217	78	$6,109.58	$28.15	2.78	0.13%
COMFORT EZ MIS 31GX5MM	204	62	$7,250.00	$35.54	3.29	0.15%
UNIFINE PNTP MIS 31GX8MM	190	86	$2,828.64	$14.89	2.21	0.06%
EASY TOUCH MIS 31GX5/16	187	85	$2,684.93	$14.36	2.2	0.06%
PEN NEEDLES MIS 31GX5/16	176	74	$5,155.38	$29.29	2.38	0.11%
UNIFINE PNTP MIS 31GX6MM	175	73	$2,690.31	$15.37	2.4	0.06%
SURE COMFORT MIS 31GX5/16	166	56	$4,312.00	$25.98	2.96	0.09%
UNIFINE PNTP MIS 31GX3/16	158	58	$2,670.97	$16.90	2.72	0.06%
NOVOFINE PLS MIS 32GX4MM	155	65	$5,828.53	$37.60	2.38	0.12%
BD PEN NEEDL MIS 32GX6MM	140	63	$3,697.20	$26.41	2.22	0.08%
EASY COMFORT MIS 32GX5/32	124	46	$4,193.00	$33.81	2.7	0.09%
BD PEN NEEDL MIS 29GX12.7	119	48	$3,191.78	$26.82	2.48	0.07%
EASY TOUCH MIS 32GX6MM	118	40	$2,086.69	$17.68	2.95	0.04%
EASY TOUCH MIS 31GX1/4"	103	40	$1,454.88	$14.13	2.58	0.03%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
COMFORT EZ MIS 31GX8MM	103	27	$3,038.00	$29.50	3.81	0.06%
EASY COMFORT MIS 31GX5/16	83	25	$2,192.00	$26.41	3.32	0.05%
EASY COMFORT MIS 31GX3/16	78	34	$2,563.60	$32.87	2.29	0.05%
EASY TOUCH MIS 32GX5MM	71	30	$1,223.65	$17.23	2.37	0.03%
COMFORT EZ MIS 31GX6MM	58	22	$2,288.00	$39.45	2.64	0.05%
AUTOSHIELD MIS 30GX5MM	54	13	$1,872.00	$34.67	4.15	0.04%
COMFORT EZ MIS 32GX5MM	39	12	$1,482.00	$38.00	3.25	0.03%
PEN NEEDLES MIS 31GX3/16	35	17	$943.80	$26.97	2.06	0.02%
PEN NEEDLES MIS 29GX12MM	30	10	$756.00	$25.20	3	0.02%
SURE COMFORT MIS 32GX6MM	29	11	$881.50	$30.40	2.64	0.02%
UNIFINE PNTP MIS 31GX5MM	27	10	$536.50	$19.87	2.7	0.01%
INSUPEN ULTR MIS 31GX6MM	25	11	$560.60	$22.42	2.27	0.01%
SURE COMFORT MIS 30GX5/16	25	10	$676.67	$27.07	2.5	0.01%
EASY TOUCH MIS 32GX5/32	23	9	$431.73	$18.77	2.56	0.01%
UNIFINE PNTP MIS 29GX12MM	22	7	$305.80	$13.90	3.14	0.01%
UNIFINE PNTP MIS 31GX5/16	20	6	$479.67	$23.98	3.33	0.01%
CLICKFINE MIS 31GX1/4"	17	4	$400.00	$23.53	4.25	0.01%
NOVOFINE AUT MIS 30GX8MM	17	12	$624.00	$36.71	1.42	0.01%
SURE COMFORT MIS 29GX1/2"	14	3	$351.50	$25.11	4.67	0.01%
EASY COMFORT MIS 31GX1/4"	13	11	$338.00	$26.00	1.18	0.01%
RELION PEN MIS 29GX12MM	13	6	$225.00	$17.31	2.17	0.00%
PEN NEEDLES MIS 32GX5/32	11	2	$135.84	$12.35	5.5	0.00%
UNIFINE PNTP MIS 32GX5/32	11	7	$352.71	$32.06	1.57	0.01%
INSUPEN SENS MIS 32GX6MM	11	3	$364.00	$33.09	3.67	0.01%
ULTICARE MIC MIS 32GX4MM	10	5	$468.00	$46.80	2	0.01%
PEN NEEDLES MIS 29GX12.7	10	2	$131.00	$13.10	5	0.00%
UNIFINE PNTP MIS 32GX4MM	9	6	$255.94	$28.44	1.5	0.01%
PRO COMFORT MIS 32GX5MM	8	5	$286.00	$35.75	1.6	0.01%
PEN NEEDLES MIS 33GX4MM	8	3	$338.00	$42.25	2.67	0.01%
PEN NEEDLES MIS 32GX6MM	7	4	$234.00	$33.43	1.75	0.00%
NOVOFINE MIS 30GX8MM	7	7	$182.00	$26.00	1	0.00%
ULTICARE PEN MIS 31GX8MM	7	4	$182.00	$26.00	1.75	0.00%
PENTIPS MIS 31GX5MM	5	2	$74.10	$14.82	2.5	0.00%
PEN NEEDLES MIS 29GX1/2"	5	1	$73.60	$14.72	5	0.00%
PENTIPS MIS 32GX4MM	4	2	$49.40	$12.35	2	0.00%
EASY TOUCH MIS 32GX3/16	4	1	$143.84	$35.96	4	0.00%
PEN NEEDLES MIS 29GX1/2"	3	2	$45.30	$15.10	1.5	0.00%
PEN NEEDLES MIS 31GX1/4"	2	1	$29.44	$14.72	2	0.00%
COMFORT EZ MIS 29GX12MM	2	1	$52.00	$26.00	2	0.00%
ULTICARE PEN MIS 31GX6MM	2	2	$52.00	$26.00	1	0.00%
PEN NEEDLES MIS 30GX5/16	2	2	$25.98	$12.99	1	0.00%
CLICKFINE MIS 31GX5/16	1	1	$23.00	$23.00	1	0.00%
INSUPEN ULTR MIS 30GX8MM	1	1	$26.00	$26.00	1	0.00%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
LITETOUCH MIS 29GX12.7	1	1	$26.00	$26.00	1	0.00%
EASY TOUCH MIS 29GX1/2"	1	1	$12.99	$12.99	1	0.00%
PEN NEEDLE MIS 29GX1/2"	1	1	$26.00	$26.00	1	0.00%
COMFORT EZ MIS 32GX6MM	1	1	$26.00	$26.00	1	0.00%
SUBTOTAL	**14,133**	**4,346***	**$412,059.03**	**$29.16**	**3.25**	**8.61%**
INSULIN SYRINGES						
INSULIN SYRG MIS 1ML/31G	964	333	$21,231.01	$22.02	2.89	0.44%
INSULIN SYRG MIS 0.5/31G	851	317	$18,542.40	$21.79	2.68	0.39%
INSULIN SYRG MIS 0.3/31G	733	260	$15,609.77	$21.30	2.82	0.33%
INSULIN SYRG MIS 0.5/31G	248	99	$5,125.12	$20.67	2.51	0.11%
INSULIN SYRG MIS 1ML/31G	209	85	$4,233.44	$20.26	2.46	0.09%
INSULIN SYRG MIS 1ML/30G	205	68	$3,659.42	$17.85	3.01	0.08%
INSULIN SYRG MIS 0.3/31G	204	98	$5,732.56	$28.10	2.08	0.12%
INSULIN SYRG MIS 1ML/30G	163	53	$3,384.31	$20.76	3.08	0.07%
INSULIN SYRG MIS 0.5/30G	136	65	$2,573.64	$18.92	2.09	0.05%
INSULIN SYRG MIS 0.5/30G	126	55	$2,939.75	$23.33	2.29	0.06%
INSULIN SYRG MIS 0.5/29G	108	41	$1,972.38	$18.26	2.63	0.04%
INSULIN SYRG MIS 0.3/30G	90	40	$2,030.22	$22.56	2.25	0.04%
INSULIN SYRG MIS 1ML/29G	78	33	$1,694.29	$21.72	2.36	0.04%
INSULIN SYRG MIS 0.3/30G	51	20	$1,003.56	$19.68	2.55	0.02%
INSULIN SYRG MIS 1ML/28G	28	13	$570.27	$20.37	2.15	0.01%
INSULIN SYRG MIS 0.3/29G	17	9	$349.76	$20.57	1.89	0.01%
INSULIN SYRG MIS 0.5/28G	13	5	$306.98	$23.61	2.6	0.01%
INSULIN SYRG MIS 1ML/27G	7	2	$182.00	$26.00	3.5	0.00%
BD U-500 MIS 31GX6MM	4	4	$79.47	$19.87	1	0.00%
INSULIN SYRG MIS 1ML/25G	1	1	$26.00	$26.00	1	0.00%
INSULIN SYRG MIS 1ML/25G	1	1	$1.04	$1.04	1	0.00%
SUBTOTAL	**4,237**	**1,326***	**$91,247.39**	**$21.54**	**3.20**	**1.91%**
KETONE TEST STRIPS						
KETOSTIX TES STRIP	640	324	$6,294.25	$9.83	1.98	0.13%
KETONE TES	303	167	$2,869.49	$9.47	1.81	0.06%
KETONE TEST TES	13	13	$141.36	$10.87	1	0.00%
RELION TES KETONE	4	4	$41.23	$10.31	1	0.00%
RELION KETON TES	2	2	$11.78	$5.89	1	0.00%
SUBTOTAL	**962**	**470***	**$9,358.11**	**$9.73**	**2.05**	**0.20%**
TOTAL	**61,446**	**9,981***	**$4,786,114.04**	**$77.89**	**6.16**	**100%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Fiscal Year 2019 Annual Review of Elaprase® (Idursulfase)

Oklahoma Health Care Authority
Fiscal Year 2019 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 2019

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	1	10	$752,704.70	$75,270.47	$2,688.23	720	280
2019	1	6	$451,624.10	$75,270.68	$2,688.24	432	168
% Change	**0.00%**	**-40.00%**	**-40.00%**	**0.00%**	**0.00%**	**-40.00%**	**-40.00%**
Change	**0**	**-4**	**-$301,080.60**	**$0.21**	**$0.01**	**-288**	**-112**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Demographics of Members Utilizing Elaprase® (Idursulfase)

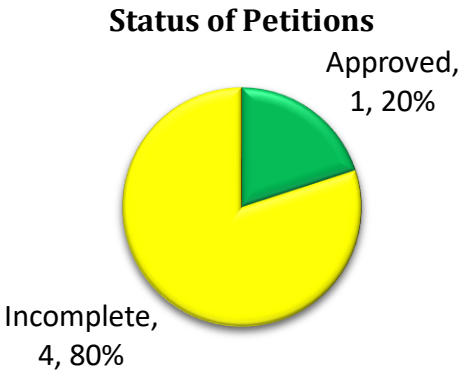
- Due to the small number of members utilizing Elaprase® (idursulfase) during fiscal year 2019, detailed demographic information could not be provided.

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

- The only prescriber specialty listed on paid claims for Elaprase® (idursulfase) during fiscal year 2019 was general pediatrician.

Prior Authorization of Elaprase® (Idursulfase): Fiscal Year 2019

There were 5 prior authorization requests submitted for 1 unique member for Elaprase® (idursulfase) during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.



Market News and Updates

Pipeline:

- **RGX-121:** Regenxbio is developing RGX-121 for the treatment of Hunter syndrome (mucopolysaccharidosis type II or MPS II). RGX-121 uses the adeno-associated virus serotype 9 (AAV9) vector to deliver the iduronate-2-sulfatase (IDS) gene to the central nervous system (CNS) in an attempt to address the neurological manifestations of disease and prevent or stabilize cognitive decline. RGX-121 is administered intracisternally intro the ventricles of the brain which could provide a permanent source of secreted IDS beyond the blood-brain-barrier (BBB). Regenxbio is currently enrolling participants in a Phase 1/2 clinical study of RGX-121. RGX-121 has received Orphan Drug, Rare Pediatric Disease, and Fast Track designations from the U.S. Food and Drug Administration (FDA).[42]
- **DNL310:** Denali Therapeutics is developing DNL310 for the treatment of Hunter syndrome (MPS II). DNL310 is a recombinant IDS enzyme engineered to cross the BBB to replace the IDS enzyme and treat neuropathic and systemic forms of the disease. DNL310 is currently in the early clinical stage of development.[43]
- **AGT-182:** ArmaGen is developing AGT-182 for the treatment of Hunter syndrome (MPS II). AGT-182 is a fusion protein of IDS which is engineered to cross the BBB by binding to insulin receptors on the BBB. AGT-182 is currently in Phase 1 clinical trials.[44]
- **SB-913:** Sangamo Therapeutics is developing SB-913 for the treatment of Hunter syndrome (MPS II). SB-913 involves the use of genome editing treatments which are one-time experimental gene therapies. SB-913 is designed to specifically insert a functional copy of the gene for the missing IDS enzyme in the liver. The liver then produces the missing enzyme inside the body with the hope of improving or curing the disease, potentially eliminating the need for lifelong enzyme replacement. SB-913 uses Sangamo's zinc finger nuclease genome editing technology. Sangamo is currently

[42] Regenxbio Inc. Regenxbio Therapeutic Programs: RGX-121. Available online at: https://www.regenxbio.com/rgx-121. Last accessed 03/18/2020.
[43] Denali Therapeutics. Denali Pipeline: DNL310 (ETV:IDS). Available online at: https://denalitherapeutics.com/pipeline. Last accessed 03/18/2020.
[44] ArmaGen. ArmaGen Pipeline Chart: AGT-182 for Hunter syndrome. Available online at: http://armagen.com/compounds/agt-182/. Last accessed 03/18/2020.

conducting the Phase 1/2 CHAMPIONS study to evaluate the safety, tolerability, and effect on IDS enzyme activity of SB-913.[45,46,47]

Recommendations

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

[45] Sangamo Therapeutics. Sangamo Pipeline. Available online at: https://www.sangamo.com/pipeline. Last accessed 03/18/2020.
[46] Sangamo Therapeutics. Patients: MPS I + II. Available online at: https://www.sangamo.com/patients/mps-i-ii. Last accessed 03/18/2020.
[47] Sangamo Therapeutics. Clinical Trials: MPS II: CHAMPIONS Study. Available online at: https://www.sangamo.com/clinical-trials. Last accessed 03/18/2020.

Fiscal Year 2019 Annual Review of Erythropoietin Stimulating Agents (ESAs)

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Aranesp® (Darbepoetin Alfa) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Anemia due to chemotherapy in members with non-myeloid malignancies; or
    b. Anemia associated with chronic renal failure; and
        i. For the diagnosis of anemia associated with chronic renal failure, the member must not be receiving dialysis [erythropoietin stimulating agents (ESAs) are included in the bundled dialysis payment if member is on any form of dialysis and cannot be billed separately]; and
2. Recent hemoglobin levels must be provided; and
3. Approvals will be for the duration of 16 weeks of therapy. Recent hemoglobin levels must be provided with continuation requests, and further approval may be granted if the member's recent hemoglobin level is <11g/dL.

Procrit® (Epoetin Alfa), Epogen® (Epoetin Alfa), and Retacrit™ (Epoetin Alfa-epbx) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Anemia due to chemotherapy in members with non-myeloid malignancies; or
    b. Anemia in zidovudine-treated Human Immunodeficiency Virus (HIV)-infected members; or
    c. For the reduction of allogeneic blood transfusion(s) in surgery patients; or
    d. Anemia associated with chronic renal failure; and
        i. For the diagnosis of anemia associated with chronic renal failure, the member must not be receiving dialysis [erythropoietin stimulating agents (ESAs) are included in the bundled dialysis payment if member is on any form of dialysis and cannot be billed separately]; and
2. Recent hemoglobin levels must be provided; and
3. Approvals will be for the duration of 16 weeks of therapy. Recent hemoglobin levels must be provided with continuation requests, and further approval may be granted if the member's recent hemoglobin level is <11g/dL.

Utilization of ESAs: Fiscal Year 2019

Fiscal Year Comparison: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	28	204	$62,745.49	$307.58	$22.68	206	2,767
2019	27	304	$93,364.23	$307.12	$24.31	293	3,841
% Change	**-3.60%**	**49.00%**	**48.80%**	**-0.10%**	**7.20%**	**42.20%**	**38.80%**
Change	**-1**	**100**	**$30,618.74**	**-$0.46**	**$1.63**	**87**	**1,074**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Fiscal Year 2019 Utilization of ESAs: Medical Claims

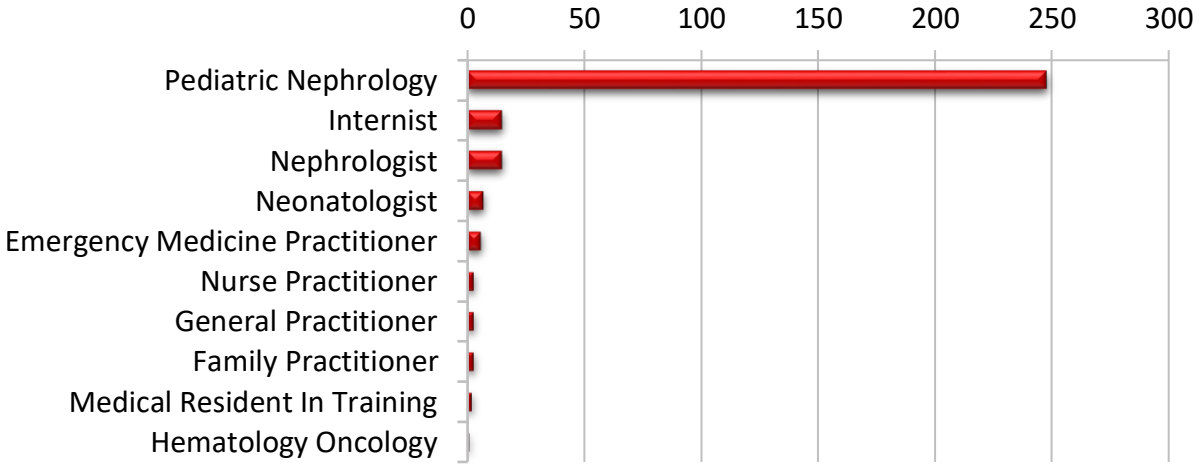
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Total Units
2019	36	204	$136,269.33	$667.99	30,281

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Demographics of Members Utilizing ESAs

- Due to the small number of members utilizing ESAs during fiscal year 2019, detailed demographic information could not be provided.

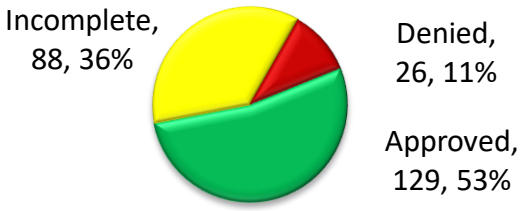
Top Prescriber Specialties of ESAs by Number of Claims



Prior Authorization of ESAs

There were 243 prior authorization requests submitted for ESAs during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.

Status of Petitions



Recommendations

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

Utilization Details of ESAs: Fiscal Year 2019

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
DARBEPOETIN ALFA PRODUCTS						
ARANESP INJ 150MCG	5	1	$828.87	$6.23	$165.77	0.89%
ARANESP INJ 40MCG	3	1	$3,558.33	$41.38	$1,186.11	3.81%
SUBTOTAL	**8**	**2**	**$4,387.20**	**$20.03**	**$548.40**	**4.70%**
EPOETIN ALFA PRODUCTS						
PROCRIT INJ 20000/ML	222	16	$52,345.25	$24.41	$235.79	56.07%
EPOGEN INJ 20000/ML	51	5	$17,543.21	$20.69	$343.98	18.79%
PROCRIT INJ 10000/ML	11	1	$12,171.39	$36.44	$1,106.49	13.04%
EPOGEN INJ 10000/ML	9	1	$3,081.27	$14.67	$342.36	3.30%
PROCRIT INJ 2000/ML	2	2	$1,050.42	$18.11	$525.21	1.13%
PROCRIT INJ 3000/ML	1	1	$2,785.49	$99.48	$2,785.49	2.98%
SUBTOTAL	**296**	**26**	**$88,977.03**	**$24.57**	**$300.60**	**95.31%**
TOTAL	**304**	**27***	**$93,364.23**	**$24.31**	**$307.12**	**100%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
EPOETIN ALFA PRODUCTS					
PROCRIT INJ J0885	117	21	$50,812.25	5.57	$434.29
SUBTOTAL	**117**	**21**	**$50,812.25**	**5.57**	**$434.29**
DARBEPOETIN ALFA PRODUCTS					
ARANESP INJ J0881	87	15	$85,457.08	5.8	$982.27
SUBTOTAL	**87**	**15**	**$85,457.08**	**5.8**	**$982.27**
TOTAL	**204**	**36***	**$136,269.33**	**5.67**	**$667.99**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Fiscal Year 2019 Annual Review of Fabry Disease Medications

Oklahoma Health Care Authority
Fiscal Year 2019 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® (agalsidase beta) 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 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 initially be approved for 6 months. After that time, compliance will be required for continued authorization; and
5. A quantity limit of 14 capsules per 28 days will apply.

Utilization of Fabry Disease Medications: Fiscal Year 2019

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	3	19	$283,292.23	$14,910.12	$778.28	325	364
2019	2	19	$506,074.29	$26,635.49	$1,090.68	596	464
% Change	**-33.30%**	**0.00%**	**78.60%**	**78.60%**	**40.10%**	**83.40%**	**27.50%**
Change	**-1**	**0**	**$222,782.06**	**$11,725.37**	**$312.40**	**271**	**100**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal year 2018 = 07/01/2017 to 06/30/2018; Fiscal year 2019 = 07/01/2018 to 06/30/2019

Comparison of Fiscal Years: Medical Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Total Units
2018	1	18	$287,898.80	$15,994.38	1,680
2019	1	21	$259,557.90	$12,359.90	1,470
% Change	**0.00%**	**16.67%**	**-9.84%**	**-22.72%**	**-12.50%**
Change	**0**	**3**	**-$28,340.90**	**-$3,634.48**	**-210**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal year 2018 = 07/01/2017 to 06/30/2018; Fiscal year 2019 = 07/01/2018 to 06/30/2019

Demographics of Members Utilizing Fabry Disease Medications

- Due to the limited number of members utilizing Fabry disease medications during fiscal year 2019, detailed member demographic information could not be provided.

Top Prescriber Specialties of Fabry Disease Medications by Number of Claims

- The only prescriber specialty listed on paid pharmacy claims for Fabry disease medications during fiscal year 2019 was medical geneticist.

Prior Authorization of Fabry Disease Medications

There were 19 prior authorization requests for 4 unique members submitted for Fabry disease medications during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.

Status of Petitions

Market News and Updates

Anticipated Patent Expiration(s):

- Galafold® (migalastat): May 2038[48]

[48] U.S. Food and Drug Administration (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 12/2019. Last accessed 12/12/2019.

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 2019

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	% COST
FABRAZYME INJ 5MG	19	2	$506,074.29	$26,635.49	100%
TOTAL	**19**	**2***	**$506,074.29**	**$26,635.49**	**100%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal year 2019 = 07/01/2018 to 06/30/2019

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	% COST
J0810 FABRAZYME	21	1	$259,557.90	$12,359.90	100%
TOTAL	**21**	**1***	**$259,557.90**	**$12,359.90**	**100%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal year 2019 = 07/01/2018 to 06/30/2019

Fiscal Year 2019 Annual Review of Fibromyalgia Medications

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

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

Tier structure based on supplemental rebate participation, and/or National Average Drug Acquisition Costs (NADAC), or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

Fibromyalgia Medications Tier-2 Approval Criteria:

1. 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.

Utilization of Fibromyalgia Medications: Fiscal Year 2019

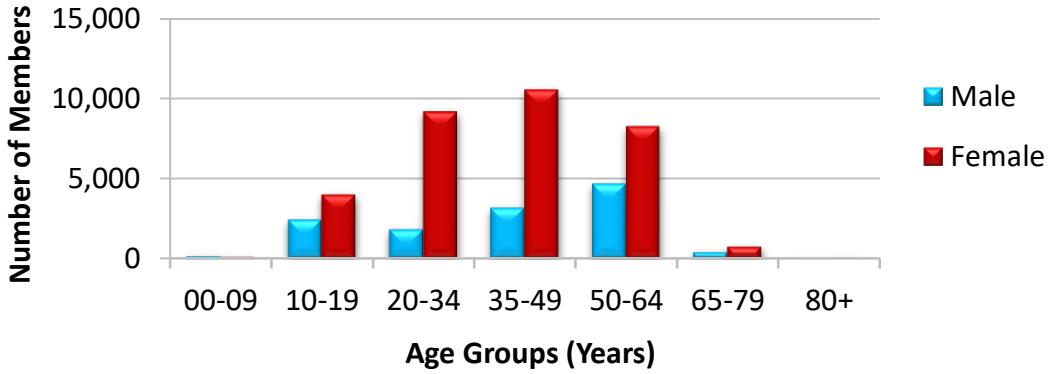
The following utilization data includes fibromyalgia medications used for all diagnoses and does not differentiate between fibromyalgia diagnoses and other diagnoses, for which use may be appropriate.

Comparison of Fiscal Years

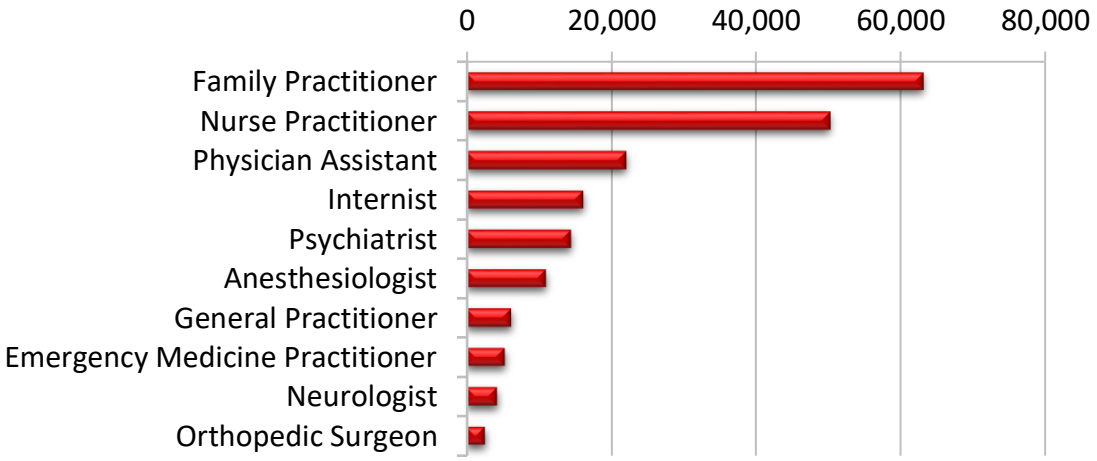
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	48,638	226,852	$7,318,352.77	$32.26	$1.12	17,143,551	6,554,946
2019	45,423	216,663	$7,626,701.79	$35.20	$1.19	16,439,030	6,407,696
% Change	**-6.60%**	**-4.50%**	**4.20%**	**9.10%**	**6.20%**	**-4.10%**	**-2.20%**
Change	**-3,215**	**-10,189**	**$308,349.02**	**$2.94**	**$0.07**	**-704,521**	**-147,250**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal year 2018 = 07/01/2017 to 06/30/2018; Fiscal year 2019 = 07/01/2018 to 06/30/2019

Demographics of Members Utilizing Fibromyalgia Medications



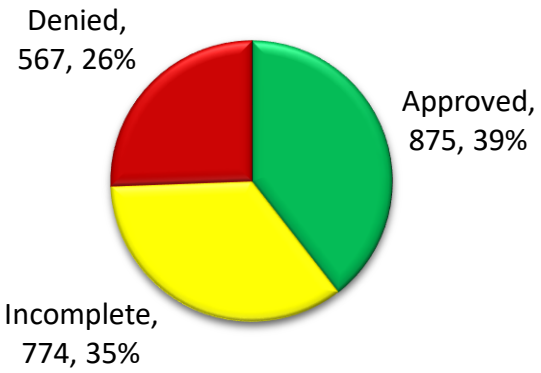
Top Prescriber Specialties of Fibromyalgia Medications by Number of Claims



Prior Authorization of Fibromyalgia Medications

There were 2,216 prior authorization requests submitted for fibromyalgia medications during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):

- Savella® (milnacipran): September 2029[49]

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

- **July 2019:** The FDA approved multiple applications for the first generics of Lyrica (pregabalin) for the management of neuropathic pain associated with diabetic peripheral neuropathy, for the management of postherpetic neuralgia, as an adjunctive therapy for the treatment of partial onset seizures in patients 17 years of age and older, for the management of fibromyalgia, and for the management of neuropathic pain associated with spinal cord injury.[50]

Recommendations

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

Utilization Details of Fibromyalgia Medications: Fiscal Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
GABAPENTIN PRODUCTS					
GABAPENTIN CAP 300MG	35,216	10,355	$451,027.13	$0.37	$12.81
GABAPENTIN TAB 600MG	24,410	5,015	$444,806.84	$0.59	$18.22
GABAPENTIN TAB 800MG	18,366	3,039	$383,945.47	$0.70	$20.91
GABAPENTIN CAP 100MG	9,942	3,702	$119,315.35	$0.40	$12.00
GABAPENTIN CAP 400MG	6,121	1,611	$91,923.89	$0.50	$15.02
GABAPENTIN SOL 250/5ML	786	152	$42,756.71	$1.79	$54.40
NEURONTIN CAP 300MG	6	1	$5,626.16	$15.63	$937.69
SUBTOTAL	**94,847**	**23,875**	**$1,539,401.55**	**$0.51**	**$16.23**
CYCLOBENZAPRINE PRODUCTS					
CYCLOBENZAPR TAB 10MG	29,034	12,947	$285,355.07	$0.42	$9.83
CYCLOBENZAPR TAB 5MG	6,637	4,007	$68,529.11	$0.53	$10.33
SUBTOTAL	**35,671**	**16,954**	**$353,884.18**	**$0.43**	**$9.92**
DULOXETINE PRODUCTS					
DULOXETINE CAP 60MG	17,673	4,370	$290,351.90	$0.44	$16.43
DULOXETINE CAP 30MG	10,527	3,956	$171,678.03	$0.47	$16.31
DULOXETINE CAP 20MG	1,928	795	$34,649.22	$0.56	$17.97
CYMBALTA CAP 60MG	9	1	$2,136.40	$7.91	$237.38
DULOXETINE CAP 40MG	1	1	$51.67	$7.38	$51.67
SUBTOTAL	**30,138**	**9,123**	**$498,867.22**	**$0.46**	**$16.55**
TRAMADOL PRODUCTS					

[49] U.S. Food and Drug Administration (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 12/2019. Last accessed 12/14/2019.
[50] FDA. FDA approves first generics of Lyrica. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-generics-lyrica. Issued 07/22/2019. Last accessed 12/14/2019.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
TRAMADOL HCL TAB 50MG	29,642	11,423	$303,872.90	$0.52	$10.25
SUBTOTAL	**29,642**	**11,423**	**$303,872.90**	**$0.52**	**$10.25**
AMITRIPTYLINE PRODUCTS					
AMITRIPTYLIN TAB 25MG	5,749	2,116	$78,799.75	$0.38	$13.71
AMITRIPTYLIN TAB 50MG	4,011	1,227	$82,347.37	$0.54	$20.53
AMITRIPTYLIN TAB 10MG	3,516	1,335	$43,828.79	$0.37	$12.47
AMITRIPTYLIN TAB 100MG	2,421	627	$86,528.03	$0.87	$35.74
AMITRIPTYLIN TAB 75MG	841	271	$24,347.16	$0.70	$28.95
AMITRIPTYLIN TAB 150MG	821	181	$46,041.62	$1.39	$56.08
SUBTOTAL	**17,359**	**5,757**	**$361,892.72**	**$0.56**	**$20.85**
PREGABALIN PRODUCTS					
LYRICA CAP 150MG	2,942	582	$1,555,468.38	$17.87	$528.71
LYRICA CAP 75MG	1,591	528	$766,516.82	$16.64	$481.78
LYRICA CAP 100MG	1,584	408	$874,053.10	$18.61	$551.80
LYRICA CAP 300MG	1,014	149	$444,120.66	$14.55	$437.99
LYRICA CAP 50MG	737	290	$391,802.89	$18.02	$531.62
LYRICA CAP 200MG	645	133	$310,509.59	$16.27	$481.41
LYRICA CAP 225MG	248	40	$121,947.75	$16.52	$491.72
LYRICA CAP 25MG	116	64	$55,278.08	$16.44	$476.54
LYRICA SOL 20MG/ML	14	2	$10,329.58	$24.42	$737.83
SUBTOTAL	**8,891**	**2,196**	**$4,530,026.85**	**$17.25**	**$509.51**
MILNACIPRAN PRODUCTS					
SAVELLA TAB 50MG	71	9	$23,177.82	$10.92	$326.45
SAVELLA TAB 100MG	42	5	$14,941.87	$11.86	$355.76
SAVELLA MIS TITR PAK	2	2	$636.68	$10.98	$318.34
SUBTOTAL	**115**	**16**	**$38,756.37**	**$11.27**	**$337.01**
TOTAL	**216,663**	**45,423***	**$7,626,701.79**	**$1.19**	**$35.20**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal year 2019 = 07/01/2018 to 06/30/2019
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.
Effective 01/01/2019, claims for brand name Lyrica processed without prior authorization.

Fiscal Year 2019 Annual Review of Gattex® [Teduglutide (rDNA origin)]

Oklahoma Health Care Authority
Fiscal Year 2019 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 require 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. Gastro-intestinal malignancy has been ruled out.
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 2019

There was no SoonerCare utilization of Gattex® [teduglutide (rDNA origin)] during fiscal year 2019 (fiscal year 2019 = 07/01/2018 to 06/30/2019).

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

There were no prior authorization requests submitted for Gattex® [teduglutide (rDNA origin)] during fiscal year 2019.

Market News and Updates

Anticipated Exclusivity Expiration(s):[51]

- 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.

[51] 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 09/2019. Last accessed 09/16/2019.

Fiscal Year 2019 Annual Review of Gaucher Disease Medications

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Cerdelga® (Eliglustat) Approval Criteria:

1. An FDA approved indication 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 that 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 to the medication.

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

1. A 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 have been taken within the last 4 weeks to ensure accurate weight-based dosing; and
3. Prescriber must verify that the member will not take 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 to the medication.

Zavesca® (Miglustat) Approval Criteria:

1. An FDA approved indication 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:
    a. Cerezyme® (imiglucerase); or
    b. Elelyso® (taliglucerase alfa); or
    c. Vpriv® (velaglucerase alfa); and
3. Prescriber must verify that 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 to the medication.

Utilization of Gaucher Disease Medications: Fiscal Year 2019

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	5	48	$492,729.00	$10,265.19	$355.50	2,512	1,386
2019	4	34	$696,776.46	$20,493.43	$725.81	636	960
% Change	**-20.00%**	**-29.20%**	**41.40%**	**99.60%**	**104.20%**	**-74.70%**	**-30.70%**
Change	**-1**	**-14**	**$204,047.46**	**$10,228.24**	**$370.31**	**-1,876**	**-426**

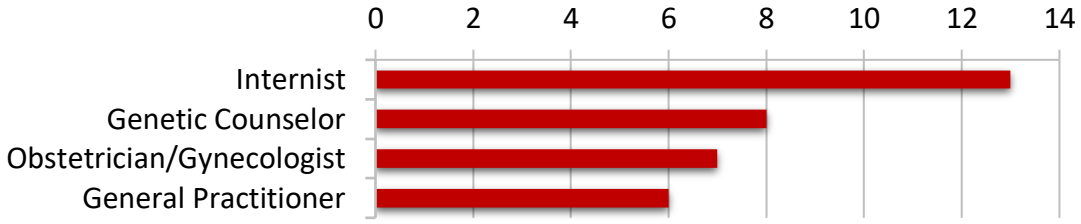
*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

- There were no pharmacy claims for Cerdelga® (eliglustat) or Elelyso® (taliglucerase alfa) during fiscal year 2019.
- There were no medical claims for Elelyso® (taliglucerase alfa) or Cerezyme® (imiglucerase) during fiscal year 2019. Details of medical claims for Vpriv® (velaglucerase alfa) during fiscal year 2019 can be found in the *Utilization Details* section at the end of this report.

Demographics of Members Utilizing Gaucher Disease Medications

- Due to the small number of members utilizing Gaucher disease medications, detailed demographic information could not be provided.

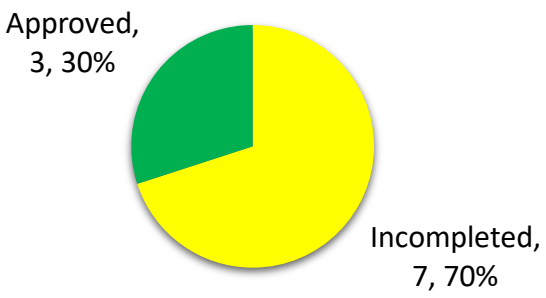
Top Prescriber Specialties of Gaucher Disease Medications by Number of Claims



Prior Authorization of Gaucher Disease Medications

There were 10 prior authorization requests submitted for Gaucher disease medications during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[52]

- Elelyso® (taliglucerase alfa): October 2025
- Cerdelga® (eliglustat): June 2026

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 2019

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
CEREZYME INJ 400UNIT	21	2	$419,254.35	$708.20	$19,964.49	60.17%
VPRIV INJ 400UNIT	11	1	$272,744.61	$885.53	$24,794.96	39.14%
MIGLUSTAT CAP 100MG	2	1	$4,777.50	$79.63	$2,388.75	0.69%
TOTAL	**34**	**4***	**$696,776.46**	**$725.81**	**$20,493.43**	**100%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs. Claims included may include members for which SoonerCare is not the primary payer; therefore, the reimbursed amount shown may not be a true reflection of the cost of the medication for SoonerCare.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Fiscal Year 2019: Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM
VPRIV INJ 400 UNIT J3385	50	2	$414,527.04	$8,290.54
TOTAL	**50**	**2***	**$414,527.04**	**$8,290.54**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

[52] 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/default.cfm?resetfields=1. Last revised 07/2019. Last accessed 08/19/2019.

Fiscal Year 2019 Annual Review of Gonadotropin-Releasing Hormone (GnRH) Medications

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

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

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

Supprelin® LA (Histrelin) and Synarel® (Nafarelin) Approval Criteria:

1. An FDA approved diagnosis of central precocious puberty confirmed by submitting the following:
    a. Documentation of onset of symptoms <8 years of age in females and 9 years of age in males; and
    b. Documentation that bone age is advanced 1 year beyond the chronological age; and
    c. Lab assessment:
        i. Documentation of abnormal basal gonadotropin levels; or
        ii. Documentation of pubertal response to a gonadotropin-releasing hormone analog stimulation test; and
2. Approvals may be granted with documentation of failed trials of lower tiered products or an FDA approved indication not covered by a lower tiered product.

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

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

Orilissa™ (Elagolix) Approval Criteria:

1. An FDA approved diagnosis of moderate-to-severe pain associated with endometriosis; and
2. Member must be 18 years of age or older; and
3. Member must not have known osteoporosis; and
4. Female members must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
5. Female members of reproductive potential must be willing to use effective non-hormonal contraception during treatment with Orilissa™ and for at least 1 week after discontinuing treatment; and

6. Member must not have severe hepatic impairment (Child-Pugh C); and
7. Member must not be taking a strong organic anion transporting polypeptide (OATP) 1B1 inhibitor (e.g., cyclosporine, gemfibrozil); and
8. Orilissa™ must be prescribed by, or in consultation with, an obstetrician/gynecologist or a specialist with expertise in the treatment of endometriosis; and
9. A failed trial at least 1 month in duration with nonsteroidal anti-inflammatory drugs (NSAIDs) or a patient-specific, clinically significant reason why the member cannot use NSAIDs must be provided; and
10. A failed trial at least 3 months in duration of hormonal contraceptives or a patient-specific, clinically significant reason why the member cannot use hormonal contraceptives must be provided; and
11. Dosing and lifetime approval duration will be limited based on the following:
    a. Coexisting condition of moderate hepatic impairment (Child-Pugh B):
        i. 150mg once daily for a maximum of 6 months; and
    b. Normal liver function or mild hepatic impairment (Child-Pugh A):
        i. 150mg once daily for a maximum of 24 months; or
        ii. 200mg twice daily for a maximum of 6 months.

Utilization of GnRH Medications: Fiscal Year 2019

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	Total Members*	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	140	369	$1,554,500.63	$4,212.74	$66.17	379	23,493
2019	121	318	$1,580,898.26	$4,971.38	$73.22	1,676	21,590
% Change	**-13.6%**	**-13.8%**	**1.7%**	**18.0%**	**10.7%**	**342.2%**	**-8.1%**
Change	**-19**	**-51**	**$26,397.63**	**$758.64**	**$7.05**	**1,297**	**-1,903**

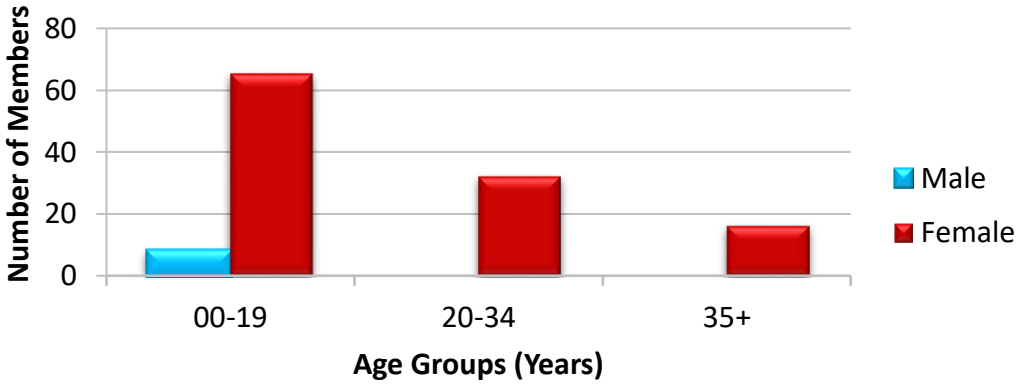
*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Fiscal Year 2019 Utilization of GnRH Medications: Medical Claims

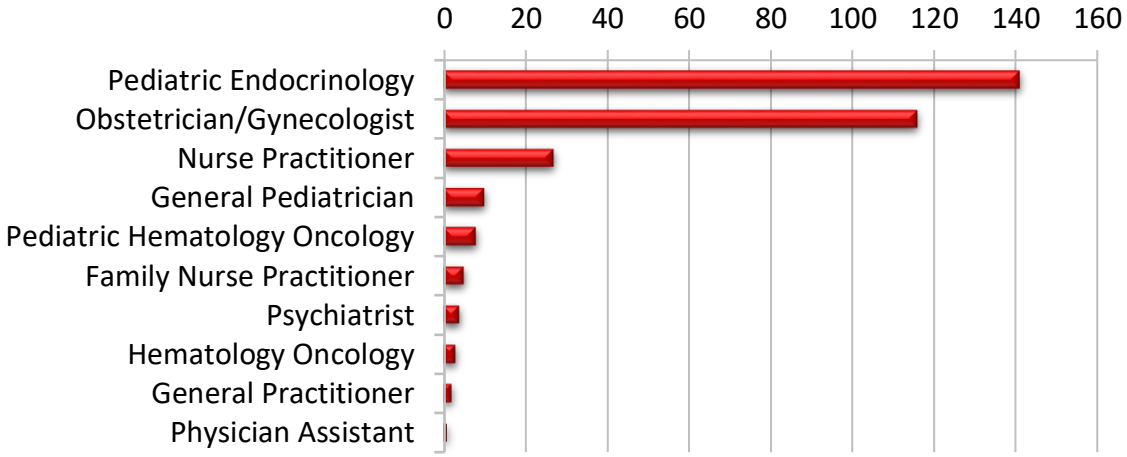
Fiscal Year	Total Members*	Total Claims+	Total Cost	Cost/ Claim	Total Units
2019	53	119	$135,656.91	$1,139.97	301

*Total number of unduplicated members.
+Total number of unduplicated claims.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Demographics of Members Utilizing GnRH Medications: Pharmacy Claims



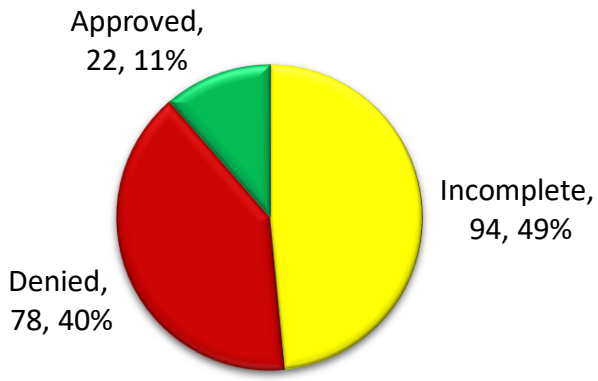
Top Prescriber Specialties of GnRH Medications by Number of Claims: Pharmacy Claims



Prior Authorization of GnRH Medications

There were 194 prior authorization requests submitted for GnRH medications during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[53]

- Supprelin® LA (histrelin): June 2026
- Triptodur® (triptorelin): June 2029
- Lupron Depot® (leuprolide): February 2031
- Orilissa™ (elagolix): September 2036

Pipeline:

- **August 2019:** AbbVie and Neurocrine Biosciences announced their submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for elagolix (Orilissa™) for the management of heavy menstrual bleeding (HMB) in women associated with uterine fibroids. Elagolix is an oral GnRH antagonist which had previously received U.S. FDA approval for endometriosis-associated pain management. The NDA submission is a result of promising data from the elagolix Phase 3 uterine fibroid program. It comprised of 2 pivotal studies, ELARIS UF-I (n=412) and ELARIS UF-II (n=378), which evaluated nearly 800 premenopausal women with HMB associated with uterine fibroids. The studies evaluated the safety, tolerability, and efficacy of elagolix alone and in combination with a low-dose hormone (add-back) therapy. Both studies showed that elagolix with add-back therapy met the primary endpoint in reducing HMB compared to placebo.[54]
- **November 2019:** A study that investigated the long-term safety and efficacy of uninterrupted treatment with the selective progesterone receptor modulator asoprisnil in women with HMB associated with uterine fibroids has concluded that uninterrupted treatment with asoprisnil should be avoided due to endometrial safety concerns and unknown potential long-term consequences. Long-term, uninterrupted treatment with asoprisnil led to prominent cystic endometrial changes consistent with the 'late progesterone receptor modulator' effects, which prompted invasive diagnostic procedures, although treatment efficacy is maintained. Although endometrial cancers were uncommon during both treatment and follow-up, these findings raise concerns regarding endometrial safety during uninterrupted long-term treatment with asoprisnil.[55]

Recommendations

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

---

[53] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 03/2020. Last accessed 03/18/2020.

[54] AbbVie Inc. AbbVie Submits New Drug Application to US FDA for Investigational Elagolix for Management of Heavy Menstrual Bleeding Associated with Uterine Fibroids in Women. Available Online at: https://news.abbvie.com/news/press-releases/abbvie-submits-new-drug-application-to-us-fda-for-investigational-elagolix-for-management-heavy-menstrual-bleeding-associated-with-uterine-fibroids-in-women.htm. Issued 08/05/2019. Last Accessed 03/18/2020.

[55] Diamond MP, Stewart EA, Williams ARW, et al. A 12-month extension study to evaluate the safety and efficacy of asoprisnil in women with heavy menstrual bleeding and uterine fibroids. *Hum Reprod Open* 2019;2019(hoz027). doi:10.1093/hropen/hoz027.

Utilization Details of GnRH Medications: Fiscal Year 2019

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
GONADOTROPIN-RELEASING HORMONE (GnRH) AGONISTS						
LUPR DEP-PED INJ 3M 30MG	98	39	$855,291.66	$101.03	$8,727.47	54.10%
LUPRON DEPOT INJ 11.25MG	56	37	$203,824.74	$41.23	$3,639.73	12.89%
LUPR DEP-PED INJ 11.25MG	41	13	$308,167.27	$90.11	$7,516.27	19.49%
LUPRON DEPOT INJ 3.75MG	40	14	$49,071.62	$40.19	$1,226.79	3.10%
LUPR DEP-PED INJ 7.5MG	24	2	$36,799.05	$58.23	$1,533.29	2.33%
LUPRON DEPOT INJ 22.5MG	14	6	$61,740.31	$49.47	$4,410.02	3.91%
LUPR DEP-PED INJ 11.25MG	1	1	$2,850.93	$31.68	$2,850.93	0.18%
SUPPRELIN LA KIT 50MG	1	1	$30,452.45	$83.43	$30,452.45	1.93%
LUPRON DEPOT INJ 7.5MG	1	1	$1,422.78	$50.81	$1,422.78	0.09%
SUBTOTAL	**276**	**110***	**$1,549,620.81**	**$75.91**	**$5,614.57**	**98.02%**
ELAGOLIX PRODUCTS						
ORILISSA TAB 150MG	34	11	$25,332.11	$26.61	$745.06	1.60%
ORILISSA TAB 200MG	8	6	$5,945.34	$26.54	$743.17	0.38%
SUBTOTAL	**42**	**16***	**$31,277.45**	**$26.60**	**$744.70**	**1.98%**
TOTAL	**318**	**121***	**$1,580,898.26**	**$73.22**	**$4,971.38**	**100.00%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM
J1950 LEUPROLIDE DEPOT 3.75MG	50	18	$93,855.91	$1,877.12
J9217 LEUPROLIDE DEPOT 7.5MG	66	34	$41,426.00	$627.67
J9218 LEUPROLIDE INJ 1MG	3	2	$375.00	$125.00
TOTAL	**119+**	**53***	**$135,656.91**	**$1,139.97**

+Total number of unduplicated claims.
*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Fiscal Year 2019 Annual Review of Gout Medications

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

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

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

Duzallo® (Lesinurad/Allopurinol) Approval Criteria:

1. Member must be 18 years of age or older; and
2. An FDA approved indication for the treatment of symptomatic hyperuricemia associated with gout in patients who have not achieved target serum uric acid (sUA) levels with a medically appropriate daily dose of allopurinol alone; and
3. Failure of allopurinol or febuxostat alone defined by serum urate levels >6.0mg/dL; and
4. Prior to starting treatment with Duzallo®, member must be on at least 300mg of allopurinol daily, unless creatinine clearance (CrCl) is <60mL/min then 200mg daily is required. Duzallo® 200mg/200mg will only be approved for members with a CrCl <60mL/min; and
5. Prescriber must verify that member has a CrCl >45mL/min prior to initiating treatment. For continued approval, prescriber must verify CrCl is >45mL/min and serum creatinine is not greater than 2 times baseline when Duzallo® was initiated; and
6. Prescriber must document that member has no contraindications for use of Duzallo® including any of the following: Tumor lysis syndrome or Lesch-Nyhan syndrome, severe renal impairment (CrCl <30mL/min), end-stage renal disease, kidney transplant recipients, or patients on dialysis; and
7. A quantity limit of 1 tablet per day will apply.

Krystexxa® (Pegloticase) Approval Criteria:

1. An FDA approved diagnosis of gout; and
2. Member must have symptomatic gout with:
    a. ≥3 gout flares in the previous 18 months; or

   b. ≥1 gout tophus; or
   c. Gouty arthritis; and
3. Failure of the following urate lowering therapies: allopurinol, febuxostat, lesinurad, and probenecid titrated to the maximum tolerable dose for at least 3 months; and
4. Pegloticase must be administered in a health care setting by a health care provider prepared to manage anaphylaxis; and
5. Prescriber must attest that the member will be pre-medicated with antihistamines and corticosteroids to reduce the risk of anaphylaxis; and
6. Prescriber must document that member does not have glucose-6-phosphate dehydrogenase (G6PD) deficiency prior to starting pegloticase; and
7. Member must discontinue oral urate-lowering agents prior to starting pegloticase; and
8. Member must receive gout flare prophylaxis with non-steroidal anti-inflammatory drug(s) (NSAIDs) or colchicine at least 1 week before initiation of pegloticase therapy and continue for at least 6 months unless medically contraindicated or member is unable to tolerate therapy; and
9. Approvals will be for the duration of 6 months. Reauthorizations may be granted if the prescriber documents the member is responding well to treatment, and member has not exceeded >4 consecutive weeks without therapy.

Uloric® (Febuxostat) Approval Criteria:

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

Zurampic™ (Lesinurad) Approval Criteria:

1. Member must be 18 years of age or older; and
2. An FDA approved diagnosis of gout in patients who have not achieved target serum uric acid (sUA) levels with a xanthine oxidase inhibitor (XOI) alone; and
3. Failure of allopurinol or febuxostat alone defined by serum urate levels >6.0mg/dL; and
4. Prescriber must verify that member has a creatinine clearance (CrCl) >45mL/min prior to initiating treatment and for continued approval; and
5. Prescriber must verify that member will take Zurampic™ concomitantly with a XOI; and
6. Prescriber must document that member is not taking more than 325mg of aspirin per day and member is not taking any epoxide hydrolase inhibitors; and
7. Prescriber must document that member has no contraindications for use of Zurampic™ including any of the following: Tumor lysis syndrome or Lesch-Nyhan syndrome, severe renal impairment (CrCl <30mL/min), end stage renal disease, kidney transplant recipients, or patients on dialysis; and
8. A quantity limit of 1 tablet per day will apply.

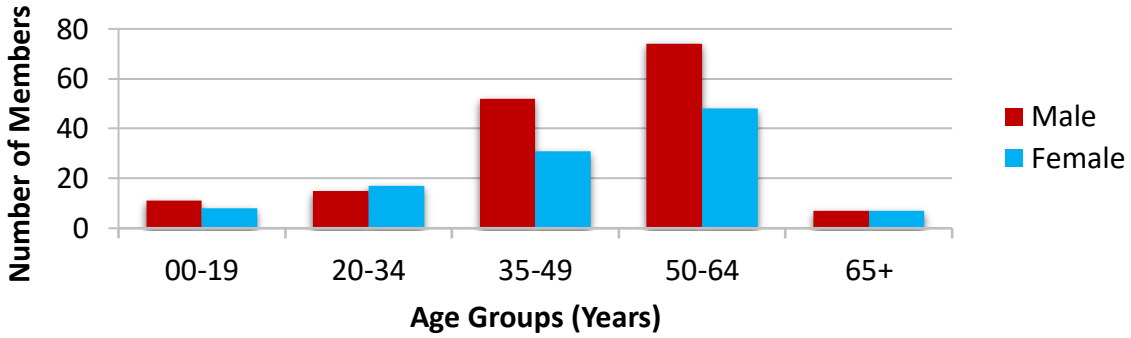
Utilization of Gout Medications: Fiscal Year 2019

Comparison of Fiscal Years

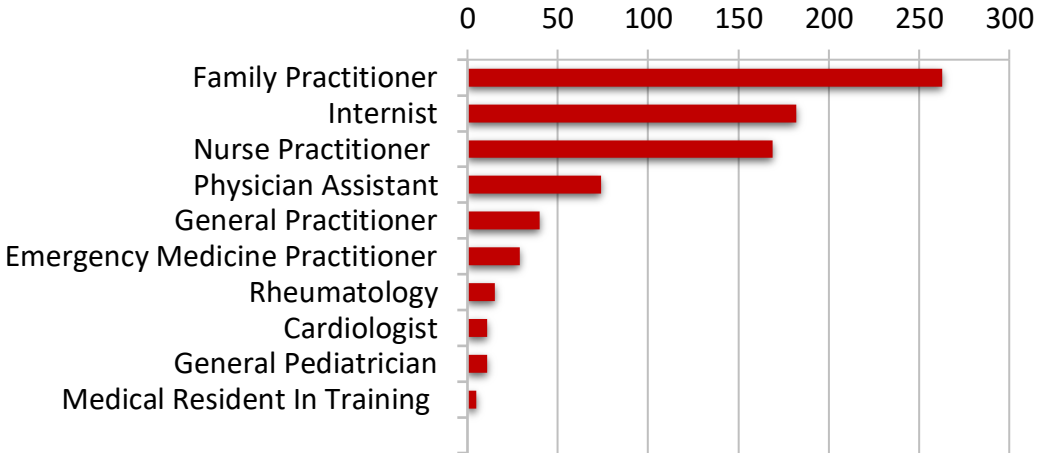
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	274	936	$112,267.01	$119.94	$9.05	13,961	12,412
2019	270	815	$107,177.49	$131.51	$9.31	12,477	11,513
% Change	**-1.5%**	**-12.9%**	**-4.5%**	**9.6%**	**2.9%**	**-10.6%**	**-7.2%**
Change	**-4**	**-121**	**-$5,089.52**	**$11.57**	**$0.26**	**-1,484**	**-899**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Demographics of Members Utilizing Gout Medications

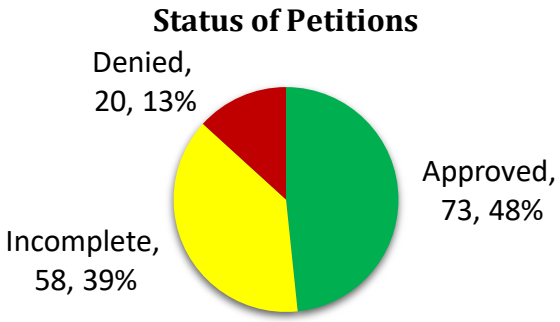


Top Prescriber Specialties of Gout Medications by Number of Claims



Prior Authorization of Gout Medications

There were 151 prior authorization requests submitted for gout medications during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.



Market News and Updates

Anticipated Patent Expiration(s): [56]

- Colcrys® (colchicine tablet): February 2029
- Uloric® (febuxostat tablet): September 2031
- Zurampic™ (lesinurad tablet): February 2032
- Duzallo® (lesinurad/allopurinol tablet): February 2032
- Mitigare® (colchicine capsule): August 2033
- Gloperba® (colchicine oral solution): December 2037

News:

- **February 2019:** The U.S. Food and Drug Administration (FDA) added a *Boxed Warning* to Uloric® (febuxostat) labeling due an increased risk of cardiovascular (CV) and all-cause mortality compared with allopurinol. The decision was based on the outcome of a joint meeting of the Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee to discuss the "Cardiovascular Safety of Febuxostat and Allopurinol in Patients with Gout and Cardiovascular Morbidities (CARES)" trial results and the benefit-risk assessment of febuxostat. In the CARES trial, the rate of CV death was higher among patients assigned to febuxostat compared to allopurinol, which contributed to a higher rate of deaths from all causes.[57]

Pipeline:

- **RDEA3170 (Verinurad):** RDEA3170 is a novel URAT1 inhibitor found to have a high affinity for URAT1 and >1,000-fold higher potency compared to other known uricosuric medications. Results for the Phase 2, randomized, open-label studies evaluating the pharmacodynamic effects and safety of RDEA3170 administered in combination with febuxostat and in combination with allopurinol versus febuxostat and allopurinol monotherapy, respectively, are pending.[58]

---

[56] 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 10/2019. Last accessed 10/31/2019.

[57] U.S. FDA. FDA Adds Boxed Warning for Increased Risk of Death With Gout Medicine Uloric (Febuxostat). Available online at: https://www.fda.gov/drugs/fda-drug-safety-podcasts/fda-adds-boxed-warning-increased-risk-death-gout-medicine-uloric-febuxostat. Issued 02/27/2019. Last accessed 10/31/2019.

[58] Miner JN, Tan P. FRI0389 RDEA3170, a novel, high affinity URAT1 inhibitor binds to a central domain within URAT1. *Ann Rheum Dis* 2013; 71(3):446. doi:10.1136/annrheumdis-2012-eular.2846.

- **Arhalofenate:** Arhalofenate, a novel uricosuric medication that blocks URAT1 and a peroxisome proliferator-activated receptor gamma (PPAR-γ) partial agonist, was discovered to have urate lowering properties. In a Phase 2, open-label, single center study, the combination of febuxostat with arhalofenate was well tolerated, appeared safe, and was more efficacious in decreasing serum uric acid than febuxostat alone. Arhalofenate is currently in development as monotherapy and as combination therapy for the treatment of gout.[59]

News:

- **March 2019:** Ironwood Pharmaceuticals discontinued the marketing and sales of both lesinurad (Zurampic®) and the combination drug of lesinurad and allopurinol (Duzallo®) in the United States effective February 1, 2019. The company stated that this was a financial decision unrelated to the efficacy or safety of lesinurad.[60]
- **June 2019:** Horizon Therapeutics announced the initiation of a clinical trial evaluating Krystexxa® (pegloticase injection) in combination with methotrexate as a strategy to increase the durability of response for patients living with chronic gout refractory to conventional therapies. The trial initiation is informed by the positive results of an independent case series, which demonstrated that the use of methotrexate with pegloticase was well tolerated and led to an improved overall response. In the series, all of the 10 sequential patients sustained lower serum uric acid levels over the course of the observation period (target <6mg/dL) when receiving pegloticase combined with pre-treatment and co-administration of methotrexate 15mg orally once weekly.[61]

Guideline Update(s):

- **March 2019:** An updated clinical practice guideline for the management of gout is being developed by the American College of Rheumatology (ACR). Specifically, the panel aims to develop recommendation for indications for urate-lowering therapy, approaches to initiating urate-lowering therapy, ongoing management of urate-lowering therapy, management of gout flares, lifestyle factors in patients with gout, and asymptomatic hyperuricemia. Final publication of the updated ACR guideline is anticipated in early 2020.[62]

---

[59] Steinberg A, Vince B, Choi Y-J, et al. FRI0329 A Study to Evaluate the Pharmacodynamics, Pharmacokinetics and Safety of Arhalofenate in Combination with Febuxostat when Treating Hyperuricemia Associated with Gout. *Ann Rheum Dis* 2015; 74(2):543. doi:10.1136/annrheumdis-2015-eular.1814.

[60] Ironwood Pharmaceuticals, Inc. Ironwood Retreats from the U.S. Gout Market. *RheumNow*. Available online at: http://rheumnow.com/content/ironwood-retreats-us-gout-market. Issued 03/18/2019. Last accessed 10/31/2019.

[61] Horizon Therapeutics plc. Horizon Therapeutics plc Initiates MIRROR Randomized Controlled Trial Evaluating Krystexxa® (Pegloticase Injection) in Combination with Methotrexate to Increase Response Rates and Duration of Therapy. *Business Wire*. Available online at: https://www.businesswire.com/news/home/20190620005141/en/Horizon-Therapeutics-plc-Initiates-MIRROR-Randomized-Controlled. Issued 06/20/2019. Last accessed 10/31/2019.

[62] American College of Rheumatology. Updated Guideline for the Management of Gout. Available online at: https://www.rheumatology.org/Portals/0/Files/Gout-Guideline-Project-Plan.pdf. Last revised 03/2019. Last accessed 10/31/2019.

Recommendations

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

Utilization Details of Gout Medications: Fiscal Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
COLCHICINE PRODUCTS					
COLCHICINE TAB 0.6MG	448	184	$22,425.98	2.43	$50.06
COLCRYS TAB 0.6MG	53	37	$2,187.89	1.43	$41.28
COLCHICINE CAP 0.6MG	50	29	$4,071.44	1.72	$81.43
MITIGARE CAP 0.6MG	1	1	$45.03	1.00	$45.03
SUBTOTAL	**552**	**251**	**$28,730.34**	**2.20**	**$52.05**
FEBUXOSTAT PRODUCTS					
ULORIC TAB 40MG	175	26	$50,309.25	6.73	$287.48
ULORIC TAB 80MG	88	12	$28,137.90	7.33	$319.75
SUBTOTAL	**263**	**38**	**$78,447.15**	**6.92**	**$298.28**
TOTAL	**815**	**270***	**$107,177.49**	**3.02**	**$131.51**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Fiscal Year 2019 Annual Review of Growth Hormone Products

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Growth Hormone Products	
Tier-1*	**Tier-2**
Genotropin® (Pfizer) - Cartridge, MiniQuick	**Humatrope®** (Eli Lilly) - Vials, Cartridge Kits
	Norditropin® (NovoNordisk) - FlexPro® Pens
	Nutropin® and Nutropin AQ® (Genentech) - Vials, Pen Cartridge, NuSpin®
	Omnitrope® (Sandoz) - Vials, Cartridge
	Saizen® (EMD Serono) - Vials, click.easy®
	Serostim® (EMD Serono) - Vials
	Zomacton™ and Zoma-Jet™ (Ferring) - Vials, Injection Device
	Zorbtive® (EMD Serono) - Vials

*Supplementally rebated product(s); tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Cost (NADAC), or Wholesale Acquisition Cost (WAC) if NADAC unavailable.
[All products contain the identical 191 amino acid sequence found in pituitary-derived human growth hormone (hGH).]

Growth Hormone Covered Indications *(prior to epiphyseal closure)*:

1. Classic human growth hormone (hGH) deficiency as determined by childhood hGH stimulation tests
2. Panhypopituitarism with history of pituitary or hypothalamic injury due to tumor, trauma, surgery, whole brain radiation, irradiation, hemorrhage or infarction, or a congenital anomaly, and 1 of the following:
    a. Deficiency of 3 or more pituitary hormones and insulin-like growth factor (IGF)-1 ≥2.5 standard deviations (SD) below the mean for the member's age and gender; or
    b. No deficiency or deficiency in <3 pituitary hormones and IGF-1 <50th percentile and failure of a growth hormone stimulation test; or
    c. Member is 12 months post trauma or surgery and does not have evidence of tumor recurrence and member's growth has not restarted; the member must still meet all the other criteria, however authorization does not require height to be ≥2.25 SD below the mean for age and gender in these circumstances
3. Panhypopituitarism in children with height ≥2.25 SD below the mean for age and gender and MRI evidence of pituitary stalk agenesis, empty sella, or ectopic posterior pituitary "bright spot"
4. Short stature associated with Prader-Willi Syndrome
5. Short stature associated with Noonan Syndrome
6. Short stature associated with chronic renal insufficiency (pre-transplantation)
7. History of intrauterine growth restriction who have not reached a normal height (≥2.25 SD below the mean for age and gender) by age 2 years

8. Idiopathic short stature (ISS) who are ≥2.25 SD below the mean for height (based on age and gender) and are unlikely to catch up in height
9. Turner syndrome or 45X, 46XY mosaicism
10. Hypoglycemia with evidence for hGH deficiency
11. Short-stature homeobox-containing gene (SHOX) deficiency with genetic evidence for SHOX deficiency
12. Other evidence for hGH deficiency submitted for panel review and decision

Growth Hormone Products Tier-2 Approval Criteria:

1. Documented allergic reaction to non-active components of all available Tier-1 products; or
2. A clinical exception applies to members with a diagnosis of acquired immunodeficiency syndrome (AIDS) wasting syndrome, in which case Serostim® can be used, regardless of its current Tier status.

Discontinuation of Therapy or Transition to Adult Therapy Criteria:

1. Failure to show improvement in height percentile on growth chart after 1 year of treatment; or
2. Growth velocity <2.5cm/year unless associated with another growth-limiting and treatable medical condition (i.e., hypothyroidism); or
3. Epiphyseal closure; or
4. Covered height has been reached:
    a. 152.4cm (60 inches) for girls; or
    b. 165.1cm (65 inches) for boys; or
5. Inadequate compliance; or
6. Significant adverse effects.

Insulin-Like Growth Factor-1 (IGF-1) Analog Medications: Increlex® and Iplex™ [Mecasermin (rDNA Origin) Injection] Approval Criteria:

1. Therapy initiated by an endocrinologist; and
2. Diagnosis of Primary IGF-1 Deficiency with all of the following:
    a. Height >3 standard deviations (SD) below the mean; and
    b. Basal IGF-1 >3 SD below the mean; and
    c. Normal or elevated growth hormone (GH); and
3. Documentation of mutation in GH receptor (GHR) or mutation in post-GHR signaling pathway or IGF-1 gene defects (Laron Syndrome); and
4. IGF-1 analog medications will not be approved for use in secondary IGF-1 deficiencies related to GH deficiency, malnutrition, hypothyroidism, or chronic steroid therapy.

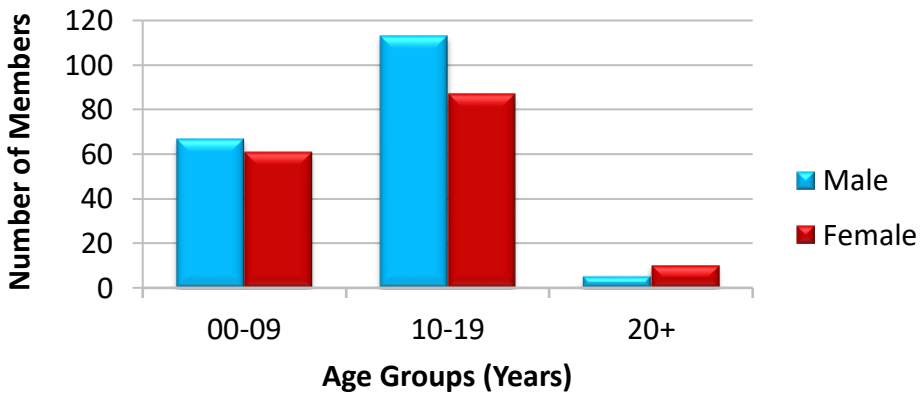
Utilization of Growth Hormone Products: Fiscal Year 2019

Comparison of Fiscal Years

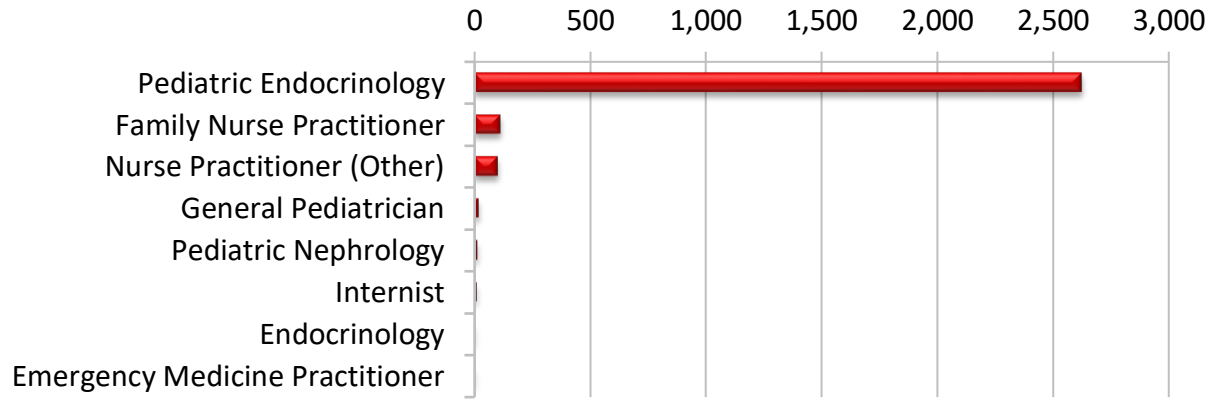
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	306	2,697	$8,860,134.27	$3,285.18	$116.40	38,603	76,120
2019	343	2,895	$9,885,546.47	$3,414.70	$120.04	45,026	82,351
% Change	**12.10%**	**7.30%**	**11.60%**	**3.90%**	**3.10%**	**16.60%**	**8.20%**
Change	**37**	**198**	**$1,025,412.20**	**$129.52**	**$3.64**	**6,423**	**6,231**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs. The growth hormone product category is heavily influenced by supplemental rebate participation.
There was no utilization of insulin-like growth factor-1 (IGF-1) analog medications during fiscal year 2018 or 2019.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Demographics of Members Utilizing Growth Hormone Products

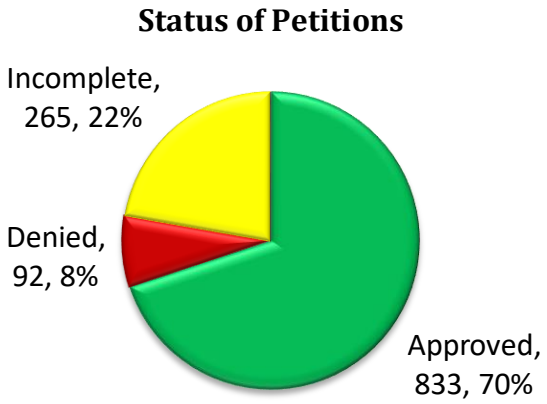


Top Prescriber Specialties of Growth Hormone Products by Number of Claims



Prior Authorization of Growth Hormone Products

There were 1,190 prior authorization requests submitted for 389 unique members for growth hormone products during fiscal year 2019. The following chart shows the status of the submitted petitions.



Market News and Updates

Anticipated Patent Expiration(s):[63]

- Norditropin® FlexPro® [somatropin (rDNA origin) for injection]: September 2027

News:

- **November 2019:** The American Association of Clinical Endocrinologists (AACE) and American College of Endocrinology (ACE) published updated guidelines for the management of growth hormone (GH) deficiency in adults and patients transitioning from pediatric to adult care.[64] Key recommendations include:
  - In patients with GH deficiency, resumption of GH replacement therapy in transitioning patients after achieving final height is recommended based on the long-term beneficial effects on improvement in body composition, bone health, quality of life, and lipid metabolism in adulthood.
  - Adults with childhood-onset GH deficiency should followed closely during transition because these patients tend to have:
    - Lower bone mineral density; and
    - Impaired bone microarchitecture; and
    - More adverse body composition abnormalities and cardiovascular risk markers.
  - Most patients transitioning from pediatric care should be re-evaluated for GH deficiency after GH has been discontinued for at least 1 month.
  - Retesting is not recommended, and GH therapy may be continued without interruption, for transitioning patients with:
    - ≥3 pituitary hormone deficiencies and low serum IGF-1 levels (>2 SD below the mean); or
    - Genetic defects affecting the hypothalamic-pituitary axes; or
    - Hypothalamic-pituitary structural brain defects.

---

[63] U.S. Food and Drug Administration (FDA): Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 03/2020. Last accessed 03/05/2020.

[64] Yuen KCJ, Biller BMK, Radovick S, et al. American Association of Clinical Endocrinologists and American College of Endocrinology Guidelines for the Management of Growth Hormone Deficiency in Adults and Patients Transitioning from Pediatric to Adult Care. *Endocr Pract* 2019; 25(11):1191-1232.

- The insulin tolerance test (ITT) is the gold-standard test to diagnose adult GH deficiency. If the ITT is contraindicated or not feasible, the glucagon-stimulation test (GST) or macimorelin test are considered alternatives.
- Recommended initial adult doses range from 0.1 to 0.5 mg/day depending on age and comorbidities. For transitioning patients, it is recommended to resume GH therapy at 50% of the dose used in childhood.

Pipeline:

- **TransCon hGH:** Ascendis Pharma is developing TransCon hGH, a long-acting, once weekly GH therapy for adults and pediatric patients with GH deficiency. TransCon hGH is formulated with an inert polyethylene glycol (PEG)-containing carrier molecule designed to extend the half-life and reduce dosing from daily to once-weekly. In 2019, data from the Phase 3 heiGHt and fliGHt trials were reported. TransCon hGH is currently in Phase 3 trials, and Ascendis plans to file a Biologics License Application (BLA) with the U.S. Food and Drug Administration (FDA) in the first half of 2020.[65]
- **Somapacitan:** Novo Nordisk is developing somapacitan, a once-weekly, albumin-binding hGH derivative. Somapacitan is currently in Phase 2 trials.[66]

Recommendations

The College of Pharmacy does not recommend any changes to the growth hormone products prior authorization criteria at this time.

Utilization Details of Growth Hormone Products: Fiscal Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST / CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 PRODUCTS						
GENOTROPIN PRODUCTS						
GENOTROPIN INJ 5MG	1,074	143	$3,305,743.47	$3,077.97	7.51	33.44%
GENOTROPIN INJ 12MG	280	39	$1,611,874.94	$5,756.70	7.18	16.31%
GENOTROPIN INJ 0.4MG	236	32	$324,407.80	$1,374.61	7.38	3.28%
GENOTROPIN INJ 1MG	220	34	$832,727.07	$3,785.12	6.47	8.42%
GENOTROPIN INJ 0.6MG	178	29	$373,290.87	$2,097.14	6.14	3.78%
GENOTROPIN INJ 0.2MG	153	23	$107,401.15	$701.97	6.65	1.09%
GENOTROPIN INJ 1.2MG	146	23	$669,469.15	$4,585.41	6.35	6.77%
GENOTROPIN INJ 0.8MG	142	26	$416,098.23	$2,930.27	5.46	4.21%
GENOTROPIN INJ 1.4MG	118	20	$619,416.69	$5,249.29	5.9	6.27%
GENOTROPIN INJ 2MG	110	16	$856,190.22	$7,783.55	6.88	8.66%
GENOTROPIN INJ 1.6MG	72	13	$440,570.96	$6,119.04	5.54	4.46%
GENOTROPIN INJ 1.8MG	24	6	$162,629.24	$6,776.22	4	1.65%

[65] Ascendis Pharma. Ascendis Pipeline: TransCon hGH. Available online at: https://ascendispharma.com/product-pipeline/endocrinology/transcon-hgh/. Last accessed 03/05/2020.

[66] Novo Nordisk. New phase 2 data for somapacitan demonstrate its potential as an efficacious once-weekly treatment for childhood growth hormone deficiency. Available online at: https://www.novonordisk.com/content/Denmark/HQ/www-novonordisk-com/en_gb/home/media/news-details.1772461.html. Issued 09/28/2018. Last accessed 03/05/2020.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST / CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**2,753**	**324***	**$9,719,819.79**	**$3,530.63**	**8.5**	**98.32%**
TIER-2 PRODUCTS[+]						
NORDITROPIN PRODUCTS						
NORDITROPIN INJ 5/1.5ML	59	5	$60,035.51	$1,017.55	11.8	0.61%
NORDITROPIN INJ 15/1.5ML	34	6	$65,362.11	$1,922.42	5.67	0.66%
NORDITROPIN INJ 10/1.5ML	27	8	$24,743.26	$916.42	3.38	0.25%
SUBTOTAL	**120**	**18***	**$150,140.88**	**$1,251.17**	**6.67**	**1.52%**
OMNITROPE PRODUCTS						
OMNITROPE INJ 10/1.5ML	11	2	$3,863.71	$351.25	5.5	0.04%
OMNITROPE INJ 5/1.5ML	5	1	$5,798.17	$1,159.63	5	0.06%
OMNITROPE INJ 5.8MG	2	1	$4,432.06	$2,216.03	2	0.04%
SUBTOTAL	**18**	**4***	**$14,093.94**	**$783.00**	**4.5**	**0.14%**
NUTROPIN PRODUCTS						
NUTROPIN AQ 10MG/2ML	3	1	$476.64	$158.88	3	0.00%
SUBTOTAL	**3**	**1***	**$476.64**	**$158.88**	**3**	**0.00%**
HUMATROPE PRODUCTS						
HUMATROPE INJ 12MG	1	1	$1,015.22	$1,015.22	1	0.01%
SUBTOTAL	**1**	**1***	**$1,015.22**	**$1,015.22**	**1**	**0.01%**
TIER-2 SUBTOTAL	**142**	**24***	**$165,726.68**	**$1167.09**	**5.92**	**1.68%**
TOTAL	**2,895**	**343***	**$9,885,546.47**	**$3,414.70**	**8.44**	**100%**

*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

[+]Claims for Tier-2 products largely consist of claims for which SoonerCare is not the primary payer and therefore the reimbursed amount is not a true reflection of the cost of the medication for SoonerCare.

Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Fiscal Year 2019 Annual Review of H.P. Acthar® Gel (Repository Corticotropin Injection)

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

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

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

Utilization of H.P. Acthar® Gel (Repository Corticotropin Injection): Fiscal Year 2019

Comparison of Fiscal Years: Pharmacy Claims

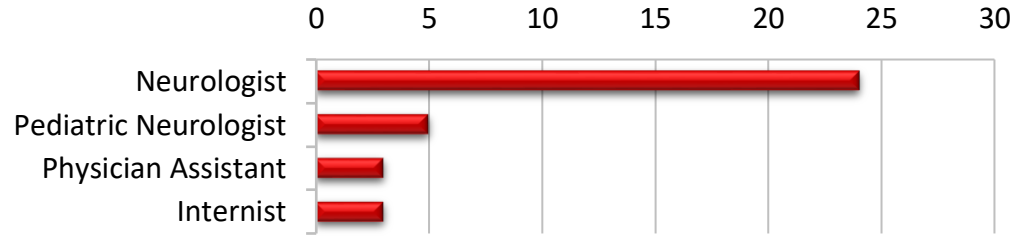
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	13	24	$1,663,736.36	$69,322.35	$3,047.14	225	546
2019	13	35	$2,178,310.07	$62,237.43	$3,275.65	280	665
% Change	**0.00%**	**45.80%**	**30.90%**	**-10.20%**	**7.50%**	**24.40%**	**21.80%**
Change	**0**	**11**	**$514,573.71**	**-$7,084.92**	**$228.51**	**55**	**119**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

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

- Due to the small number of members utilizing H.P. Acthar® Gel during fiscal year 2019, detailed demographic information could not be provided. Of the 13 patients utilizing H.P. Acthar® Gel during fiscal year 2019, 6 were pediatric members.

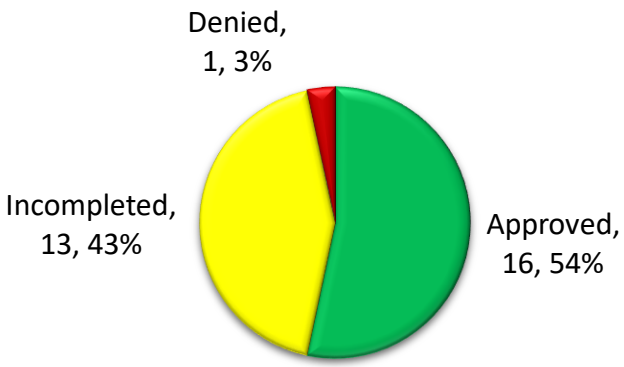
Top Prescriber Specialties of H.P. Acthar® Gel (Repository Corticotropin Injection) by Number of Claims



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

There were 30 prior authorization requests submitted for H.P. Acthar® Gel during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.

Status of Petitions



Market News and Updates

News:

- **July 2019:** Mallinckrodt Pharmaceuticals shut down the Phase 2b PENNANT clinical trial assessing the effectiveness and safety of H.P. Acthar® Gel (repository corticotropin injection) for amyotrophic lateral sclerosis (ALS). ALS patients receiving H.P. Acthar® Gel (repository corticotropin injection) during the trial had an increased incidence of pneumonia compared to placebo-treated patients in a control group. It was announced that enrollment was immediately discontinued and patients who had been taking the drug would be tapered off the treatment.[67]

Recommendations

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

[67] Inacio P. Clinical Trial Testing H.P. Acthar Gel for ALS Terminated Due to Pneumonia Concerns. *ALS News Today*. Available online at: https://alsnewstoday.com/2019/07/19/pennant-clinical-trial-h-p-acthar-gel-als-terminated/. Issued 07/19/2019. Last accessed 08/19/2019.

Fiscal Year 2019 Annual Review of Heart Failure Medications [Corlanor® (Ivabradine) and Entresto® (Sacubitril/Valsartan)]

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Corlanor® (Ivabradine) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. To reduce the risk of hospitalization for worsening heart failure (HF) in adult patients with stable, symptomatic chronic HF with reduced left ventricular ejection fraction; or
    b. For the treatment of stable, symptomatic HF due to dilated cardiomyopathy (DCM) in patients 6 months of age and older; and
2. For a diagnosis of worsening HF in adults:
    a. The prescriber must verify that the member has left ventricular ejection fraction ≤35%; and
    b. The prescriber must verify that the member is in sinus rhythm with a resting heart rate ≥70 beats per minute (bpm); and
    c. The member must be on maximal/maximally tolerated doses of beta-blockers or have a contraindication to beta-blockers; and
3. For a diagnosis of DCM in patients 6 months of age or older:
    a. The prescriber must verify that the member has left ventricular ejection fraction ≤45%; and
    b. The prescriber must verify that the member is in sinus rhythm with a resting heart rate (HR) as follows:
        i. Age 6 to 12 months, HR ≥105 bpm; or
        ii. Age 1 to 3 years, HR ≥95 bpm; or
        iii. Age 3 to 5 years, HR ≥75 bpm; or
        iv. Age 5 to 18 years, HR ≥70 bpm; and
    c. The prescriber must verify that dose titration will be followed according to package labeling; and
    d. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
4. Authorization of Corlanor® solution for members >40kg requires a patient-specific, clinically significant reason why Corlanor® tablets cannot be used; and
5. For Corlanor® tablets, a quantity limit of 60 tablets per 30 days will apply; and
6. For Corlanor® solution, a quantity limit of 56 ampules (2 boxes) per 28 days will apply.

Entresto® (Sacubitril/Valsartan) Approval Criteria:

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

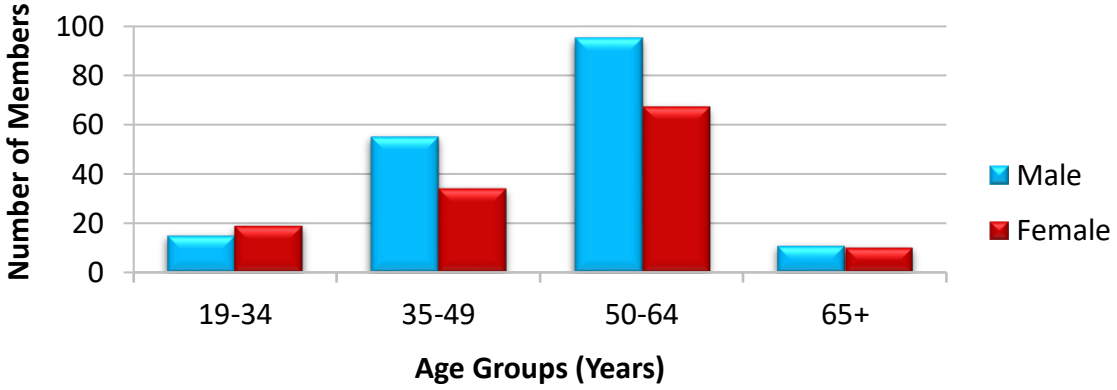
Utilization of Heart Failure Medications: Fiscal Year 2019

Comparison of Fiscal Years

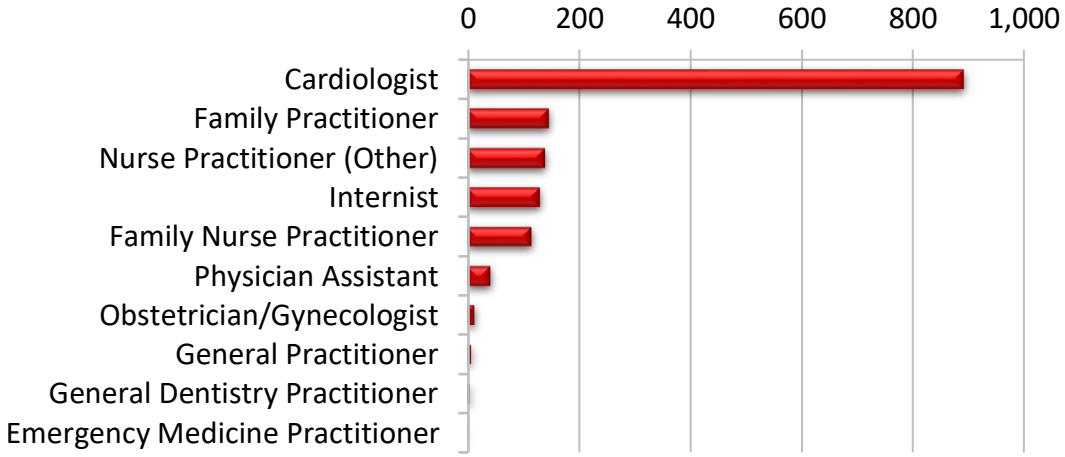
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	198	1,022	$439,609.18	$430.15	$14.39	60,948	30,554
2019	306	1,492	$685,320.59	$459.33	$15.48	87,682	44,276
% Change	**54.50%**	**46.00%**	**55.90%**	**6.80%**	**7.60%**	**43.90%**	**44.90%**
Change	**108**	**470**	**$245,711.41**	**$29.18**	**$1.09**	**26,734**	**13,722**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs. Effective January 2019, claims for Entresto® will process without a prior authorization for members with a diagnosis of heart failure in claims history, based on supplemental rebate participation.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Demographics of Members Utilizing Heart Failure Medications



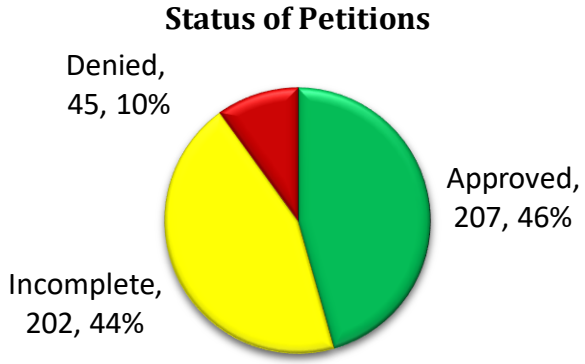
Top Prescriber Specialties of Heart Failure Medications by Number of Claims



Prior Authorization of Heart Failure Medications

There were 454 prior authorization requests submitted for 194 unique members for heart failure medications during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019. Effective January 2019, claims for Entresto® will

process without a prior authorization for members with a diagnosis of heart failure (HF) in claims history.



Market News and Updates

Anticipated Patent Expiration(s):[68]

- Corlanor® (ivabradine): October 2026
- Entresto® (sacubitril/valsartan): November 2027

Pipeline:

- **Cimaglermin (GGF2):** Acorda Therapeutics was in early clinical trials with cimaglermin (GGF2), a recombinant form of neuregulin, which is an endogenous protein that is essential for cardiac repair. GGF2 had shown positive effects on cardiac function in 2 Phase 1 studies; however, enrollment was discontinued and an U.S. Food and Drug Administration (FDA) clinical hold was received after the occurrence of a case of markedly elevated bilirubin and liver enzymes. The FDA clinical hold has been lifted, but Acorda has not restarted clinical studies and is deferring further investment in the program.[69]
- **Serelaxin (RLX030):** Novartis published results from the Phase 3 RELAX-AHF-2 study with serelaxin. Serelaxin did not meet the primary endpoints of reduced cardiovascular (CV) death or worsening HF in patients with acute HF. Additionally, serelaxin is no longer listed as being in development in the Novartis Global Pipeline.[70,71]
- **RT-100:** Renova Therapeutics is currently developing RT-100 for the treatment of HF. RT-100 is a first-in-class, single-dose gene therapy candidate designed to safely improve heart function. RT-100 has been granted Fast Track designation by the FDA. The Phase 3 FLOURISH study is expected to start soon across 60 medical centers in the United States.[72]

---

[68] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 03/2020. Last accessed 03/09/2020.

[69] Acorda Therapeutics Product Pipeline. Cimaglermin alfa (GGF2). Available online at: http://www.acorda.com/products/pipeline#GGF2. Last accessed 03/09/2020.

[70] Metra M, Teerlink JR, Cotter G, et al. Effects of Serelaxin in Patients with Acute Heart Failure. *N Engl J Med* 2019; 381:716-26.

[71] Novartis Global Pipeline. Available online at: https://www.novartis.com/our-science/novartis-global-pipeline. Last accessed 03/09/2020.

[72] Renova Therapeutics. Therapies: RT-100 (AC6 Gene Transfer). Available online at: https://renovatherapeutics.com/therapies/rt-100-congestive-heart-failure/. Last accessed 03/09/2020.

- **RT-110/RT-400:** Renova Therapeutics is also developing RT-110 for congestive HF and RT-400 for acute decompensated HF. RT-110 is a paracrine gene therapy, while RT-400 is a peptide therapy.[73]
- **Praliciguat:** Cyclerion Therapeutics announced that they are discontinuing development of praliciguat for the treatment of HF with preserved ejection fraction (HFpEF). Topline data from the Phase 2 CAPACITY-HFpEF study were released in October 2019, showing that praliciguat failed to meet statistical significance for its primary endpoint of improved exercise capacity from baseline when compared with placebo.[74]
- **Entresto® (Sacubitril/Valsartan) for HFpEF:** In November 2019, Novartis released information regarding subgroup analyses of its Phase 3 PARAGON-HF study which showed greater benefit of the drug when used in specific patient subgroups with HFpEF, including women and those with a recent hospitalization for HF. However, in the overall analysis, the PARAGON-HF study showed a statistically non-significant 13% reduction in the primary endpoint of CV death and total (first and recurrent) HF hospitalization.[75]

Recommendations

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

Utilization Details of Heart Failure Medications: Fiscal Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SACUBITRIL/VALSARTAN PRODUCTS						
ENTRESTO TAB 24-26MG	658	173	$300,949.87	$457.37	3.8	43.91%
ENTRESTO TAB 49-51MG	368	112	$172,100.80	$467.67	3.29	25.11%
ENTRESTO TAB 97-103MG	344	74	$160,561.17	$466.75	4.65	23.43%
SUBTOTAL	**1,370**	**296**	**$633,611.84**	**$462.49**	**4.63**	**92.45%**
IVABRADINE PRODUCTS						
CORLANOR TAB 5MG	95	17	$40,239.46	$423.57	5.59	5.87%
CORLANOR TAB 7.5MG	27	5	$11,469.29	$424.79	5.4	1.67%
SUBTOTAL	**122**	**21**	**$51,708.75**	**$423.84**	**5.81**	**7.55%**
TOTAL	**1,492**	**306***	**$685,320.59**	**$459.33**	**4.88**	**100%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

[73] Renova Therapeutics. Pipeline Overview. Available online at: https://renovatherapeutics.com/therapies/pipeline-overview/. Last accessed 03/09/2020.
[74] Cyclerion Therapeutics News Release. Cyclerion Therapeutics Announces Topline Phase 2 Results for sGC Stimulator Praliciguat in Heart Failure with Preserved Ejection Fraction (HFpEF). Available online at: https://ir.cyclerion.com/news-releases/news-release-details/cyclerion-therapeutics-announces-topline-phase-2-results-sgc. Issued 10/30/2019. Last accessed 03/09/2020.
[75] Novartis News Release. Novartis PARAGON-HF analyses suggest Entresto® benefit beyond HFrEF. Available online at: https://www.pharma.us.novartis.com/news/media-releases/novartis-paragon-hf-analyses-suggest-entresto-benefit-beyond-hfref. Issued 11/17/2019. Last accessed 03/09/2020.

Fiscal Year 2019 Annual Review of Hereditary Angioedema (HAE) Medications

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Berinert® (C1 Esterase Inhibitor) and Firazyr® (Icatibant) Approval Criteria:

1. An FDA approved diagnosis of hereditary angioedema (HAE); and
2. Berinert® or Firazyr® must be used for the *treatment* of acute attacks of HAE.

Cinryze® (C1 Esterase Inhibitor), Haegarda® (C1 Esterase Inhibitor), and Takhzyro® (Lanadelumab-flyo) Approval Criteria:

1. An FDA approved diagnosis of hereditary angioedema (HAE); and
2. Must be used for *prophylaxis* of HAE; and
3. Member must not be currently taking an angiotensin converting enzyme (ACE) inhibitor or estrogen replacement therapy; and
4. Member must have a history of ≥1 abdominal or respiratory HAE attack(s) per month, history of laryngeal attacks, or ≥3 emergency medical treatments per year; or
5. Approval consideration will be given if the member has a recent hospitalization for a severe episode of angioedema; and
6. Authorization of Takhzyro® (lanadelumab-flyo) will also require a patient-specific, clinically significant reason why the member cannot use Cinryze® or Haegarda® (C1 esterase inhibitor); and
7. Cinryze® Dosing:
    a. The recommended dose of Cinryze® is 1,000 units intravenously (IV) every 3 to 4 days, approximately 2 times per week, to be infused at a rate of 1mL/min; and
    b. Initial doses should be administered in an outpatient setting by a health care provider (members can be taught by their health care provider to self-administer Cinryze® IV); and
    c. A quantity limit of 8,000 units per month will apply (i.e., 2 treatments per week or 8 treatments per 28 days); or
8. Haegarda® Dosing:
    a. The recommended dose of Haegarda® is 60 IU/kg subcutaneously (sub-Q) twice weekly; and
    b. 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
    c. A quantity limit of 2 treatments per week or 8 treatments per 28 days will apply; or
9. Takhzyro® Dosing:
    a. The recommended dose of Takhzyro® is 300mg sub-Q every 2 weeks (dosing every 4 weeks may be considered in some members); and

b. Prescriber must verify member or caregiver has been trained by a health care professional on proper storage and sub-Q administration of Takhzyro®; and
c. A quantity limit of (2) 300mg/2mL vials per 28 days will apply.

Ruconest® (C1 Esterase Inhibitor) and Kalbitor® (Ecallantide) Approval Criteria:

1. An FDA approved diagnosis of hereditary angioedema (HAE); and
2. Ruconest® and Kalbitor® must be used for *treatment* of acute attacks of HAE; and
3. A patient-specific, clinically significant reason why the member cannot use Berinert® (C1 esterase inhibitor) and Firazyr® (icatibant) must be provided.

Utilization of HAE Medications: Fiscal Year 2019

There was no SoonerCare pharmacy or medical utilization of HAE medications during fiscal year 2019 (fiscal year 2019 = 07/01/2018 to 06/30/2019).

Prior Authorization of HAE Medications

There were no prior authorization requests submitted for HAE medications during fiscal year 2019.

Market News and Updates

News:

- **December 2019:** BioCryst Pharmaceuticals submitted a new drug application (NDA) to the U.S. Food and Drug Administration (FDA) for berotralstat (BCX7353), an oral plasma kallikrein inhibitor, for the prevention of HAE attacks. In the APEX-2 study, a total of 121 patients entered a 14-to-56-day run-in period to identify a baseline HAE attack rate. The researchers randomly assigned individuals with ≥2 HAE attacks to placebo, berotralstat 110mg daily, or berotralstat 150mg daily for 24 weeks. Of the initial 121 patients who were randomly assigned at baseline, 108 individuals completed the 24-week dosing period. Compared with placebo, there were lower rates of investigator-confirmed HAE attacks over 24 weeks with berotralstat 110mg (P=0.024) and berotralstat 150mg (P<0.001). Half of the patients who received berotralstat 150mg had a ≥70% reduction in the HAE attack rate at 24 weeks compared with 15% in patients who received placebo (P=0.002). There were no reports of drug-related serious adverse events.[76,77]

Recommendations

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

---

[76] BioCryst Pharmaceuticals, Inc. BioCryst Submits New Drug Application for Oral, Once Daily Berotralstat (BCX7353) to Prevent HAE Attacks. *Globe Newswire*. Available online at: https://www.globenewswire.com/news-release/2019/12/11/1959132/0/en/BioCryst-Submits-New-Drug-Application-for-Oral-Once-Daily-Berotralstat-BCX7353-to-Prevent-HAE-Attacks.html. Issued 12/11/2019. Last accessed 12/11/2019.

[77] May B. BCX7353 Reduced Hereditary Angioedema Attacks Over 24 Weeks. *Pulmonology Advisor*. Available online at: https://www.pulmonologyadvisor.com/home/meetings/acaai-2019/hereditary-angioedema-attacks-reduced-with-oral-plasma-kallikrein-inhibitor/. Issued 11/08/2019. Last accessed 12/11/2019.

Fiscal Year 2019 Annual Review of Hyperkalemia Medications

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Lokelma™ (Sodium Zirconium Cyclosilicate) Approval Criteria:

1. An FDA approved diagnosis of hyperkalemia; and
2. Medications known to cause hyperkalemia [e.g., angiotensin-converting enzyme (ACE) inhibitors, angiotensin II receptor blockers (ARBs), aldosterone antagonists, nonsteroidal anti-inflammatory drugs (NSAIDs)] have been discontinued or reduced to the lowest effective dose where clinically appropriate; and
3. A trial of a potassium-eliminating diuretic or documentation why a diuretic is not appropriate for the member; and
4. Documentation of a low potassium diet; and
5. A quantity limit of 30 packets per month will apply. Quantity limit overrides will be granted to allow for initial 3 times daily dosing.

Veltassa® (Patiromer) Approval Criteria:

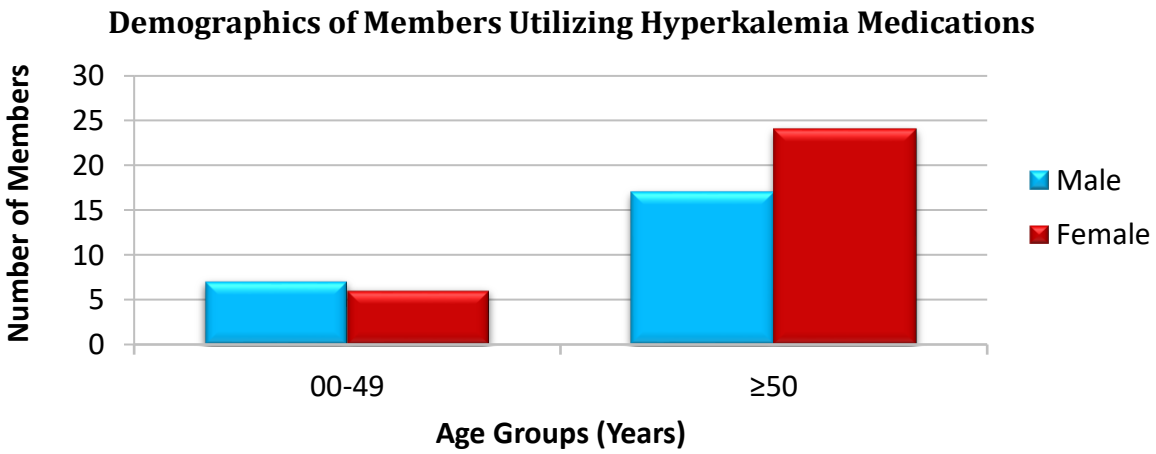
1. An FDA approved diagnosis of hyperkalemia; and
2. Medications known to cause hyperkalemia [e.g., angiotensin-converting enzyme (ACE) inhibitors, angiotensin II receptor blockers (ARBs), aldosterone antagonists, nonsteroidal anti-inflammatory drugs (NSAIDs)] have been discontinued or reduced to the lowest effective dose where clinically appropriate; and
3. A trial of a potassium-eliminating diuretic or documentation why a diuretic is not appropriate for the member; and
4. Documentation of a low potassium diet; and
5. A quantity limit of 30 packets per month will apply.

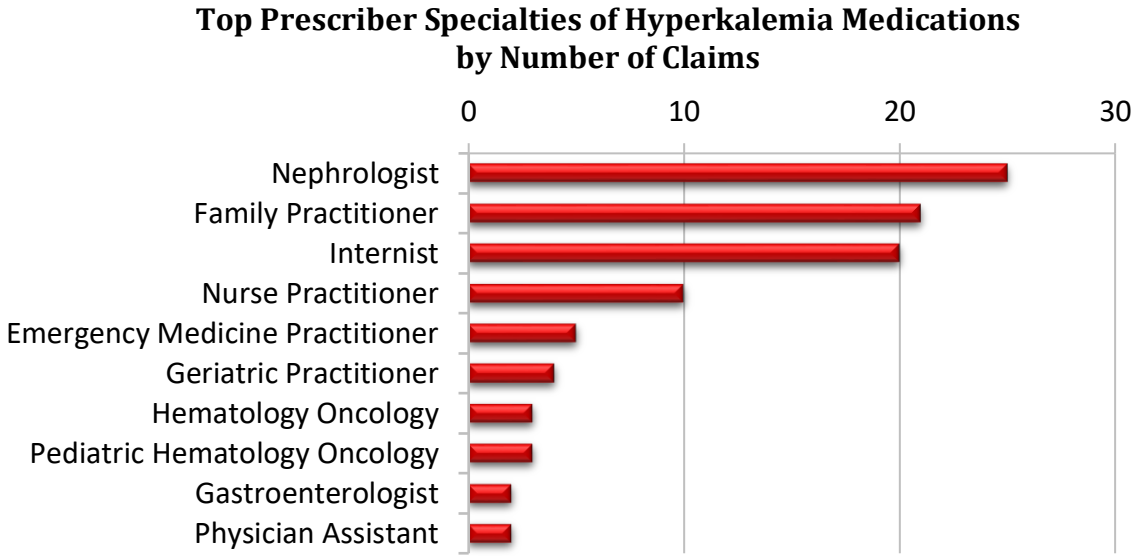
Utilization of Hyperkalemia Medications: Fiscal Year 2019

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	68	115	$13,266.15	$115.36	$8.87	46,797	1,496
2019	54	107	$26,264.95	$245.47	$14.63	19,572	1,795
% Change	**-20.60%**	**-7.00%**	**98.00%**	**112.80%**	**64.90%**	**-58.20%**	**20.00%**
Change	**-14**	**-8**	**$12,998.80**	**$130.11**	**$5.76**	**-27,225**	**299**

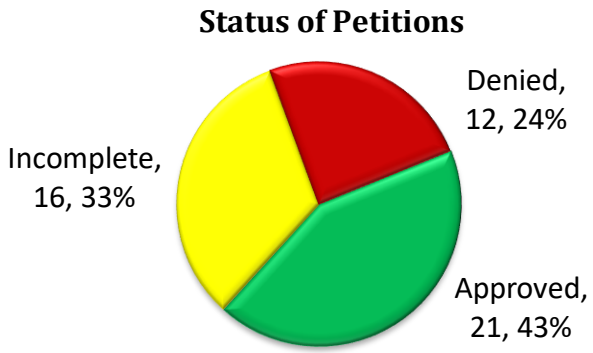
*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019





Prior Authorization of Hyperkalemia Medications

There were 49 prior authorization requests submitted for hyperkalemia medications during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.



Market News and Updates

Anticipated Patent Expiration(s):[78]

- Veltassa® (patiromer): October 2033
- Lokelma™ (sodium zirconium cyclosilicate): October 2035

Recommendations

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

Utilization Details of Hyperkalemia Medications: Fiscal Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
SODIUM POLYSTYRENE SULFONATE (SPS) PRODUCTS						
SPS SUS 15GM/60ML	38	28	$1,040.69	$4.69	$27.39	3.96%
SOD POLY SUL POW	21	19	$833.37	$2.92	$39.68	3.17%
KIONEX SUS 15GM/60ML	5	5	$189.87	$3.72	$37.97	0.72%
SOD POLY SUL SUS 15GM/60ML	1	1	$11.77	$11.77	$11.77	0.04%
SUBTOTAL	**65**	**53**	**$2,075.70**	**$0.09**	**$31.93**	**7.89%**
PATIROMER PRODUCTS						
VELTASSA POW 8.4GM	32	8	$16,119.06	$17.22	$503.72	61.37%
VELTASSA POW 16.8GM	10	1	$8,070.19	$26.90	$807.02	30.73%
SUBTOTAL	**42**	**9**	**$24,189.25**	**$19.57**	**$575.93**	**92.10%**
TOTAL	**107**	**54***	**$26,264.95**	**$14.63**	**$245.47**	**100%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

[78] 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/default.cfm?resetfields=1. Last revised 01/2020. Last accessed 01/10/2020.

Fiscal Year 2019 Annual Review of Inhaled Anti-Infective Medications

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Arikayce® (Amikacin Liposome Inhalation Suspension) Approval Criteria:

1. An FDA approved indication for the treatment of *Mycobacterium avium* complex (MAC) lung disease in adults who have limited or no alternative treatment options; and
2. Member must have had a minimum of 6 consecutive months of a multidrug background regimen therapy used compliantly and not achieved negative sputum cultures within the last 12 months. Dates of previous treatments and regimens must be listed on the prior authorization request; and
    a. If claims for a multidrug background regimen are not in the member's claim history, the pharmacy profile should be submitted or detailed information regarding dates and doses should be included along with the signature from the prescriber; and
3. Member must continue a multidrug background regimen therapy while on Arikayce®, unless contraindicated, or provide reasoning why continuation of a multidrug background regimen is not appropriate for the member; and
4. A patient-specific, clinically significant reason why the member requires an inhaled aminoglycoside in place of an intravenous or intramuscular aminoglycoside (e.g., amikacin, streptomycin) must be provided; and
5. Arikayce® will not be approved for patients with non-refractory MAC lung disease; and
6. Arikayce® must be prescribed by, or in consultation with, a pulmonary disease or infectious disease specialist (or be an advanced care practitioner with a supervising physician who is a pulmonary disease or infectious disease specialist); and
7. Initial approvals will be for the duration of 6 months after which time the prescriber must document the member is responding to treatment for continued approval; and
8. A quantity limit of 28 vials per 28 days will apply.

Inhaled Tobramycin Products (Bethkis®, Tobi®, Tobi® Podhaler™, and Kitabis® Pak), Pulmozyme® (Dornase Alfa), and Cayston® (Aztreonam) Approval Criteria:

1. Use of inhaled tobramycin products, Pulmozyme® (dornase alfa), and Cayston® (aztreonam) is reserved for members who have a diagnosis of cystic fibrosis (CF).
    a. Authorization of Tobi® Podhaler™ requires a trial of tobramycin nebulized solution or a patient-specific, clinically significant reason why tobramycin nebulized solution is not appropriate for the member.
    b. Tobramycin nebulized solution (including Bethkis®, Kitabis® Pak, and generic nebulized solution), dornase alfa, and aztreonam inhalation will not require a prior authorization and claims will pay at the point of sale if member has a reported diagnosis of CF within the past 12 months of claims history.

c. If the member does not have a reported diagnosis, a manual prior authorization will be required for coverage consideration.

2. Use of inhaled tobramycin products and Cayston® (aztreonam) is restricted to 28 days of therapy per every 56 days to ensure cycles of 28 days on therapy followed by 28 days off therapy.
   a. Use outside of this recommended regimen may be considered for coverage via a manual prior authorization submission with a patient-specific, clinically significant reason why the member would need treatment outside of the FDA approved dosing.
   b. Pharmacies should process the prescription claim with a 56-day supply.

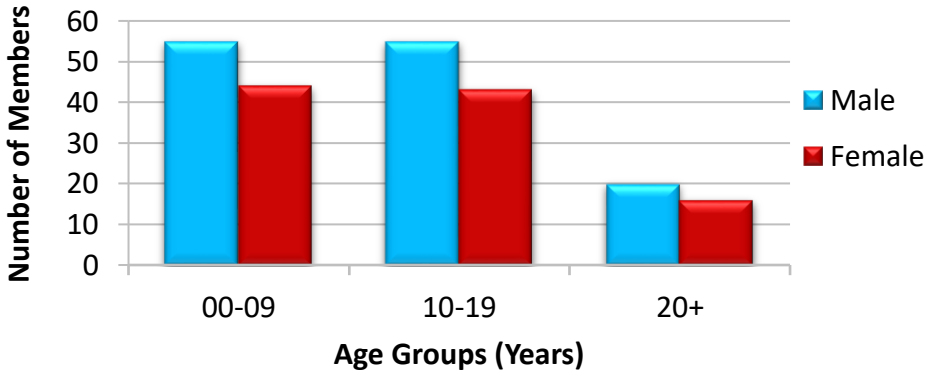
Utilization of Inhaled Anti-Infective Medications: Fiscal Year 2019

Comparison of Fiscal Years

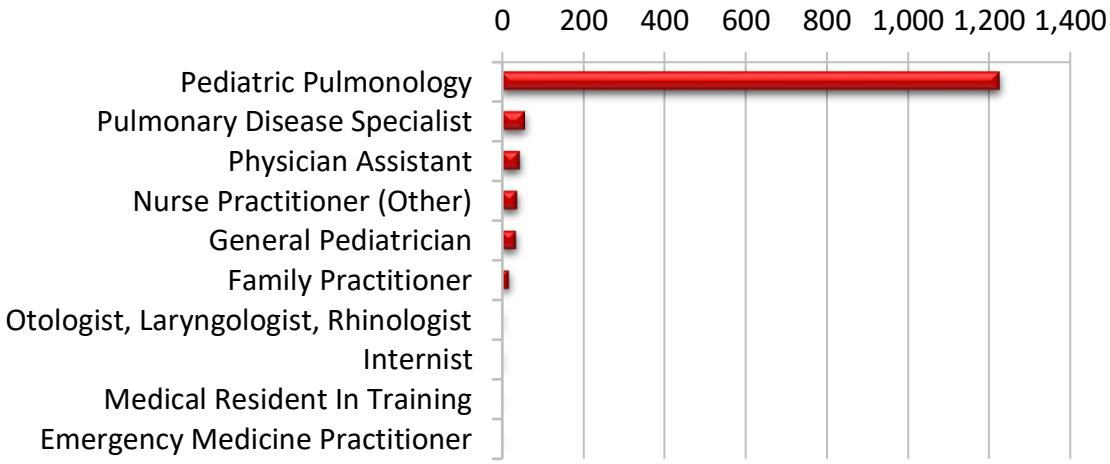
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	230	1,379	$4,941,872.58	$3,583.66	$93.27	177,467	52,983
2019	233	1,440	$5,000,041.36	$3,472.25	$91.10	187,892	54,884
% Change	**1.30%**	**4.40%**	**1.20%**	**-3.10%**	**-2.30%**	**5.90%**	**3.60%**
Change	**3**	**61**	**$58,168.78**	**-$111.41**	**-$2.17**	**10,425**	**1,901**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Demographics of Members Utilizing Inhaled Anti-Infective Medications

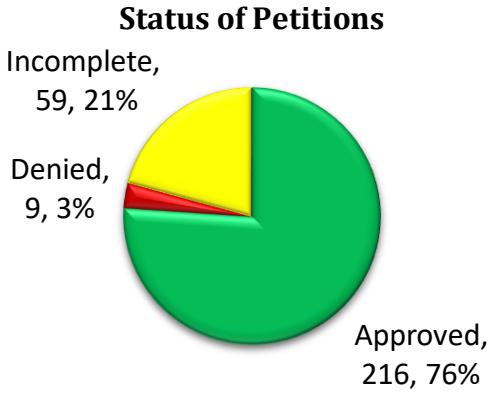


Top Prescriber Specialties of Inhaled Anti-Infective Medications by Number of Claims



Prior Authorization of Inhaled Anti-Infective Medications

There were 284 prior authorization requests submitted for inhaled anti-infective medications during fiscal year 2019. Computer edits are in place to detect a cystic fibrosis (CF) diagnosis in a member's recent diagnosis claims history and generate automated prior authorizations for tobramycin nebulized solution, dornase alfa, and aztreonam inhalation where possible. The following chart shows the status of the submitted petitions.



Market News and Updates

Anticipated Patent Expiration(s):[79]

- Cayston® (aztreonam inhalation solution): December 2021
- Bethkis® (tobramycin inhalation solution): September 2022
- Tobi® Podhaler™ (tobramycin inhalation powder): November 2030
- Arikayce® (amikacin liposome inhalation suspension): May 2035

[79] 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 03/2020. Last accessed 03/03/2020.

Pipeline:

- **ARD-3150/ARD-3100**: Aradigm is developing 2 different liposomal formulations of ciprofloxacin for inhalation for the indications of bronchiectasis (BE) and CF. ARD-3150 for BE is beginning Phase 3 trials; ARD-3100 for CF is currently in Phase 2 trials.[80]

Recommendations

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

Utilization Details of Inhaled Anti-Infective Medications: Fiscal Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
DORNASE ALFA PRODUCTS						
PULMOZYME SOL 1MG/ML	967	154	$3,210,745.02	$3,320.32	6.28	64.21%
SUBTOTAL	**967**	**154***	**$3,210,745.02**	**$3,320.32**	**6.28**	**64.21%**
TOBRAMYCIN NEBULIZED PRODUCTS						
TOBRAMYCIN NEB 300/5ML	322	113	$615,201.35	$1,910.56	2.85	12.30%
BETHKIS NEB 300/4ML	43	10	$249,718.42	$5,807.41	4.3	4.99%
KITABIS PAK NEB 300/5ML	8	3	$37,661.96	$4,707.75	2.67	0.75%
SUBTOTAL	**373**	**124***	**$902,581.73**	**$2,419.79**	**3.01**	**18.04%**
TOBRAMYCIN POWDER PRODUCTS						
TOBI PODHALR CAP 28MG	30	11	$290,448.12	$9,681.60	2.73	5.81%
SUBTOTAL	**30**	**11***	**$290,448.12**	**$9,681.60**	**2.73**	**5.81%**
AZTREONAM PRODUCTS						
CAYSTON INH 75MG	70	23	$596,266.49	$8,518.09	3.04	11.93%
SUBTOTAL	**70**	**23***	**$596,266.49**	**$8,518.09**	**3.04**	**11.93%**
TOTAL	**1440**	**233***	**$5,000,041.36**	**$3,472.25**	**6.18**	**100%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

[80] Aradigm. Product Pipeline. Available online at: http://www.aradigm.com/products_pipeline.html. Last accessed 03/04/2020.

Fiscal Year 2019 Annual Review of Injectable and Vaginal Progesterone Products

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Crinone® (Progesterone Vaginal Gel) Approval Criteria:

1. Current singleton pregnancy; and
2. Member must not have history of previous singleton spontaneous preterm delivery (SPTD); and
3. Cervical length of ≤20mm; and
4. Gestational age between 20 weeks, 0 days and 26 weeks, 6 days of gestation; and
5. A patient-specific, clinically significant reason why the member cannot use Endometrin® (progesterone vaginal insert); and
6. Authorizations will be given for treatment through 36 weeks, 6 days of gestation; and
7. Crinone® will not be covered for use with assisted reproductive technology (ART) for female infertility.

Endometrin® (Progesterone Vaginal Insert) Approval Criteria:

1. Current singleton pregnancy; and
2. Member must not have history of previous singleton spontaneous preterm delivery (SPTD); and
3. Cervical length of ≤20mm; and
4. Gestational age between 20 weeks, 0 days and 26 weeks, 6 days of gestation; and
5. Authorizations will be given for treatment through 36 weeks, 6 days of gestation; and
6. Endometrin® will not be covered for use with assisted reproductive technology (ART) for female infertility.

Hydroxyprogesterone Caproate 250mg/mL Injection (Generic Delalutin®/Delta-Lutin®) Approval Criteria:

1. An FDA approved indication of 1 of the following in non-pregnant women:
    a. For the treatment of advanced adenocarcinoma of the uterine corpus (Stage III or IV); or
    b. For the management of amenorrhea (primary and secondary) or abnormal uterine bleeding due to hormonal imbalance in the absence of organic pathology, such as submucous fibroids or uterine cancer; or
    c. As a test for endogenous estrogen production or for the production of secretory endometrium and desquamation; and
2. The quantity approved will be patient-specific depending on patient diagnosis, maximum recommended dosage, and manufacturer packaging; and
3. Requests for the prevention of preterm birth in pregnant women with a history of previous singleton spontaneous preterm delivery (SPTD) prior to 37 weeks gestation will

not be approved for generic Delalutin®/Delta-Lutin® and should be resubmitted for authorization of Makena® (hydroxyprogesterone caproate).

Makena® [Hydroxyprogesterone Caproate Intramuscular (IM) Injection and Subcutaneous (Sub-Q) Auto-Injector] Approval Criteria:

1. Documented history of previous singleton spontaneous preterm delivery (SPTD) prior to 37 weeks gestation; and
2. Current singleton pregnancy; and
3. Gestational age between 16 weeks, 0 days and 26 weeks, 6 days of gestation; and
4. Authorizations will be for once weekly administration by a health care professional through 36 weeks, 6 days of gestation; and
5. For Makena® sub-Q auto-injector:
    a. Initial dose must be administered by a health care professional; and
    b. Member and caregiver must be trained by a health care professional on sub-Q administration and storage of Makena® sub-Q auto-injector; and
    c. A patient-specific, clinically significant reason why Makena® IM injection cannot be used must be provided.* (*The manufacturer of Makena® has currently provided a supplemental rebate to make the net cost per injection of the sub-Q auto-injector equivalent to the IM injection and therefore make the sub-Q auto-injector available with the current Makena® criteria; however, use of Makena® sub-Q auto-injector will require a reason why Makena® IM injection cannot be used if the manufacturer chooses not to participate in supplemental rebates.)

When it is determined to be appropriate to use the compounded hydroxyprogesterone caproate product, this product is covered through SoonerCare as a medical-only benefit without a prior authorization requirement.

Utilization of Injectable and Vaginal Progesterone Products: Fiscal Year 2019

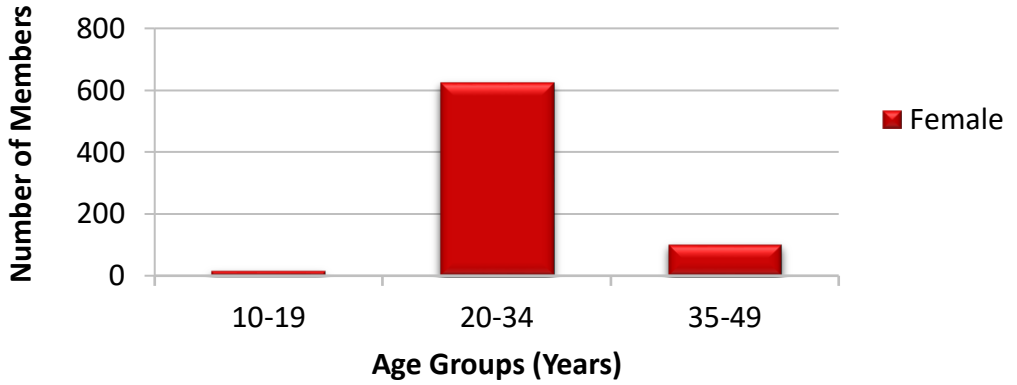
Please note, the compounded hydroxyprogesterone caproate product is billed by medical claims only and not reflected in the following pharmacy claims data. Fiscal year 2019 medical claim utilization details for the compounded hydroxyprogesterone caproate product can be found at the end of this report. The following utilization details include pharmacy claims data only.

Comparison of Fiscal Years: Pharmacy Claims

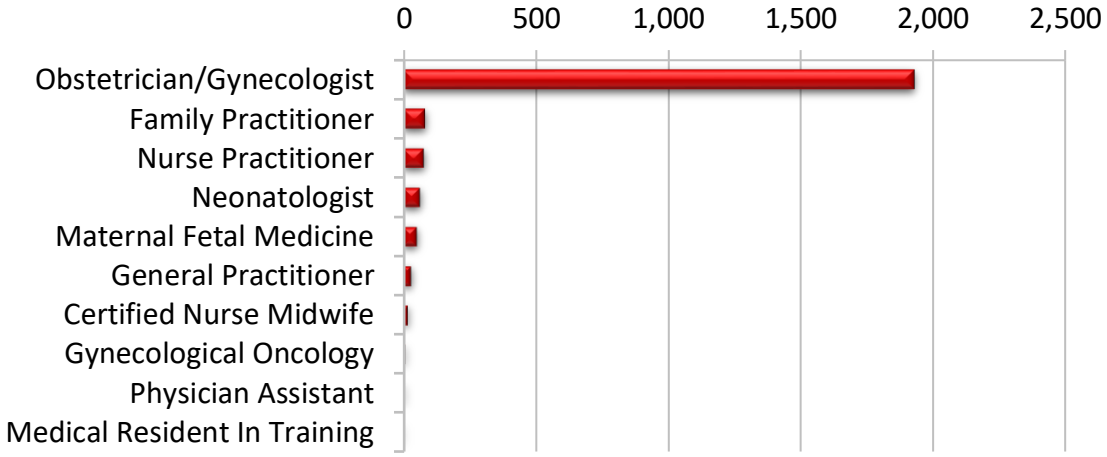
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	707	2,110	$6,645,725.14	$3,149.63	$109.43	8,915	60,731
2019	738	2,278	$6,645,412.03	$2,917.21	$103.51	9,618	64,201
% Change	**4.40%**	**8.80%**	**0.00%**	**-7.40%**	**-5.40%**	**7.90%**	**5.70%**
Change	**31**	**168**	**-$313.11**	**-$232.42**	**-$5.92**	**703**	**3,470**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Demographics of Members Utilizing Injectable and Vaginal Progesterone Products



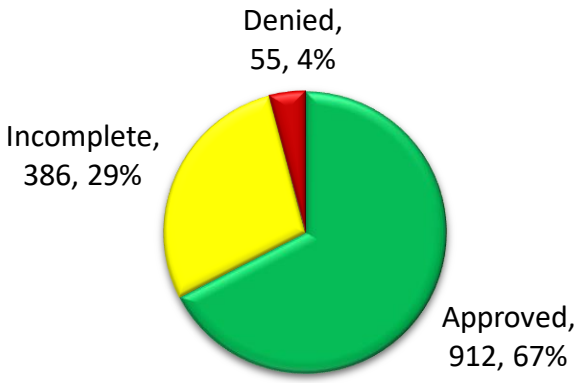
Top Prescriber Specialties of Injectable and Vaginal Progesterone Products by Number of Claims



Prior Authorization of Injectable and Vaginal Progesterone Products

There were 1,353 prior authorization requests submitted for injectable and vaginal progesterone products during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[81]

- Makena® [hydroxyprogesterone subcutaneous (sub-Q) auto-injector]: May 2036

News:

- **March 2019:** AMAG Pharmaceuticals announced topline data from the PROLONG trial which was a randomized, double-blinded, placebo-controlled post-marketing trial of Makena® that found no statistically significant difference between treatment and placebo arms for the co-primary endpoints: the incidence of preterm delivery at <35 weeks gestation (Makena treated group 11.0% vs. placebo 11.5%, p=0.72) and the percentage of patients who met criteria for the pre-specified neonatal morbidity and mortality composite index (Makena treated group 5.4% vs placebo 5.2%, p=0.84). AMAG plans to continue assessing and analyzing the data from this trial and plans to submit the findings to the U.S. Food and Drug Administration (FDA). The results of this trial were published in the *American Journal of Perinatology* in January 2020.[82,83]
- **October 2019:** The American College of Obstetricians and Gynecologists (ACOG) issued a Practice Advisory in response to the lack of statistical significance found in the PROLONG trial in order to provide clinical guidance regarding these findings. Due to guidance published in 2008, a possible unintentional selection bias may have occurred in women enrolled in the United States that resulted in women with a higher risk for recurrent preterm birth not being offered or agreeing to participate in the PROLONG trial in order to avoid the risk of not receiving active hydroxyprogesterone treatment. The ACOG is not changing its clinical recommendation at this time and continues to recommend offering hydroxyprogesterone caproate for the prevention of preterm birth.[84]

Pipeline:

- **LPCN 1107:** Lipocine is currently developing LPCN 1107, an oral product candidate of 17-alpha hydroxyprogesterone caproate, for the indication of prevention of recurrent preterm birth. LPCN 1107 has the potential to become the first oral hydroxyprogesterone caproate product for the prevention of preterm birth in women with a prior history of at least 1 preterm birth. Potential benefits of this oral product candidate relative to current injectable products include the elimination of pain and injection site reactions associated with weekly injections, as well as the elimination of

---

[81] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 03/2020. Last accessed 03/16/2020.

[82] AMAG Pharmaceuticals, Inc. AMAG Pharmaceuticals Announces Topline Results from the PROLONG Trial Evaluating Makena® (Hydroxyprogesterone Caproate Injection). Available online at: https://www.amagpharma.com/news/amag-pharmaceuticals-announces-topline-results-from-the-prolong-trial-evaluating-makena-hydroxyprogesterone-caproate-injection/. Issued 03/08/2019. Last accessed 03/16/2020.

[83] Blackwell SC, Gyamfi-Bannerman C, Biggio RJ Jr, et al. 17-OHPC to Prevent Recurrent Preterm Birth in Singleton Gestations (PROLONG Study): A Multicenter, International, Randomized Double-Blind Trial. *Am J Perinatol* 2020; 37(2):127-136.

[84] American College of Obstetricians and Gynecologists (ACOG). ACOG Practice Advisory: Clinical Guidance for Integration of the Findings of the PROLONG Study: Progestin's Role in Optimizing Neonatal Gestation. Available online at: https://www.acog.org/Clinical-Guidance-and-Publications/Practice-Advisories/Clinical-guidance-for-integration-of-the-findings-of-The-PROLONG-study-Progestins-Role-in-Optimizing. Issued 10/25/2019. Last accessed 03/16/2020.

weekly doctor visits or visits from the nurse to administer the weekly injections. Lipocine is working with the FDA to define a Phase 3 development plan for LPCN 1107, and the FDA has granted Orphan Drug designation to LPCN 1107 based on a major contribution to patient care.[85]

Recommendations

The College of Pharmacy does not recommend any changes to the current injectable and vaginal progesterone products prior authorization criteria at this time.

Utilization Details of Injectable and Vaginal Progesterone Products: Fiscal Year 2019

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
HYDROXYPROGESTERONE INJECTABLE PRODUCTS						
HYDROXYPROG 250MG/ML	1,054	349	$2,837,172.65	$2,691.81	3.02	42.69%
MAKENA INJ 275MG	904	301	$2,689,248.21	$2,974.83	3	40.47%
MAKENA INJ 250MG/ML	294	176	$1,078,165.98	$3,667.23	1.67	16.22%
HYDROXY CAPR INJ 1.25/5ML	23	12	$39,454.66	$1,715.42	1.92	0.59%
SUBTOTAL	**2,275**	**735***	**$6,644,041.50**	**$2,920.46**	**3.10**	**99.98%**
PROGESTERONE VAGINAL PRODUCTS						
ENDOMETRIN SUP 100MG	3	3	$1,370.53	$456.84	1	0.02%
SUBTOTAL	**3**	**3***	**$1,370.53**	**$456.84**	**1**	**0.02%**
TOTAL	**2,278**	**738***	**$6,645,412.03**	**$2,917.21**	**3.09**	**100%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	*TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
HYDROXYPROGESTERONE CAPROATE INJ S5000	48	47	$221.98	$4.62	1.02
TOTAL	**48**	**47**	**$221.98**	**$4.62**	**1.02**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

[85] Lipocine, Inc. Lipocine Pipeline: LPCN 1107. Available online at: https://www.lipocine.com/pipeline/lpcn-1107/. Last accessed 03/16/2020.

Fiscal Year 2019 Annual Review of Iron Chelating Agents

Oklahoma Health Care Authority
Fiscal Year 2019 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 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.

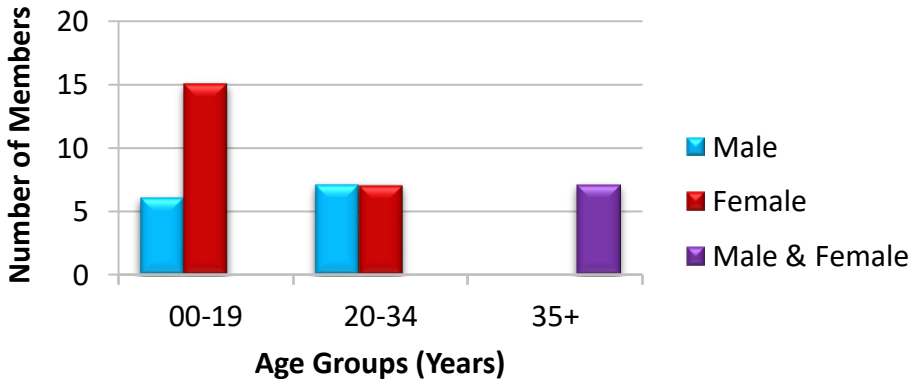
Utilization of Iron Chelating Agents: Fiscal Year 2019

Comparison of Fiscal Years

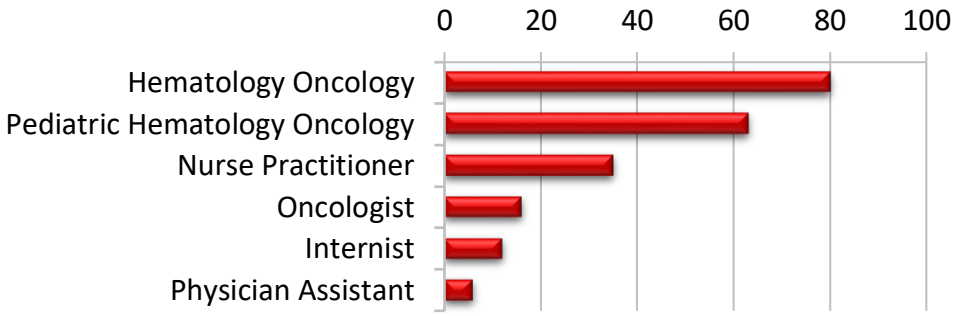
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	45	245	$2,480,406.06	$10,124.11	$324.96	20,110	7,633
2019	42	212	$2,137,740.49	$10,083.68	$321.95	16,605	6,640
% Change	**-6.70%**	**-13.50%**	**-13.80%**	**-0.40%**	**-0.90%**	**-17.40%**	**-13.00%**
Change	**-3**	**-33**	**-$342,665.57**	**-$40.43**	**-$3.01**	**-3,505**	**-993**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2018 = 07/01/2018 to 06/30/2019

Demographics of Members Utilizing Iron Chelating Agents



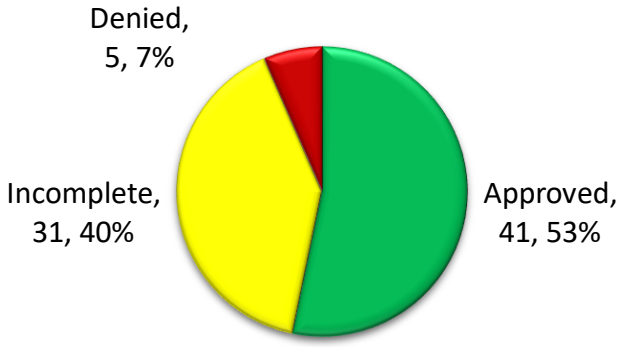
Top Prescriber Specialties of Iron Chelating Agents by Number of Claims



Prior Authorization of Iron Chelating Agents

There were 77 prior authorization requests submitted for 35 unique members for iron chelating agents during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[86]

- Exjade® (deferasirox): There are no unexpired patents for Exjade® and generic formulations are currently available.
- Ferriprox® (deferiprone): October 2029
- Jadenu® (deferasirox): November 2034

News:[87]

- **April 2019:** Generic formulations of Exjade® became available in March 2019. The generic deferasirox tablets for oral suspension are available in 125 mg, 250 mg, and 500 mg strengths.

---

[86] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 03/2020. Last accessed 03/10/2020.

[87] Teva News Release. Teva Announces Launch of a Generic Version of EXJADE® (deferasirox) Tablets for Oral Suspension in the United States. Available online at: https://www.tevapharm.com/news-and-media/latest-news/teva-announces-launch-of-a-generic-version-of-exjade-deferasirox-tablets-for-oral-suspension-in-the-un/. Issued on 03/22/2019. Last accessed 03/11/2020.

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 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
DEFERASIROX PRODUCTS						
JADENU TAB 360MG	123	31	$1,450,211.83	$11,790.34	3.97	67.84%
EXJADE TAB 500MG	37	8	$360,448.48	$9,741.85	4.63	16.86%
JADENU SPRKL GRA 180MG	16	3	$57,837.60	$3,614.85	5.33	2.71%
JADENU TAB 90MG	16	3	$24,383.24	$1,523.95	5.33	1.14%
JADENU TAB 180MG	3	2	$7,257.88	$2,419.29	1.5	0.34%
EXJADE TAB 250MG	2	1	$4,713.36	$2,356.68	2	0.22%
DEFERASIROX TAB 500MG	2	2	$15,032.94	$7,516.47	1	0.70%
JADENU SPRKL GRA 90MG	1	1	$1,183.88	$1,183.88	1	0.06%
SUBTOTAL	**200**	**41***	**$1,921,069.21**	**$9,605.35**	**4.88**	**89.87%**
DEFERIPRONE PRODUCTS						
FERRIPROX TAB 500MG	12	1	$216,671.28	$18,055.94	12	10.14%
SUBTOTAL	**12**	**1***	**$216,671.28**	**$18,055.94**	**12**	**10.14%**
TOTAL	**212**	**42***	**$2,137,740.49**	**$10,083.68**	**5.05**	**100.01%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Please note, Exjade® was first FDA approved in 2005 and has a significant federal rebate.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Fiscal Year 2019 Annual Review of Jynarque® (Tolvaptan)

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Jynarque® (Tolvaptan) Approval Criteria:

1. An FDA approved indication to slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD); and
2. Member must be 18 years of age or older; and
3. Member must not have any contraindications to taking Jynarque® including the following:
    a. Taking any concomitant strong CYP3A inhibitors (e.g., ketoconazole, itraconazole, lopinavir/ritonavir, indinavir/ritonavir, ritonavir, conivaptan); and
    b. History of signs or symptoms of significant liver impairment or injury (does not include uncomplicated polycystic liver disease); and
    c. Uncorrected abnormal blood sodium concentrations; and
    d. Unable to sense or respond to thirst; and
    e. Hypovolemia; and
    f. Hypersensitivity to tolvaptan or any of its components; and
    g. Uncorrected urinary outflow obstruction; and
    h. Anuria; and
4. Member must not be taking any of the following medications concomitantly with Jynarque®:
    a. Strong CYP3A inhibitors (e.g., ketoconazole, itraconazole, lopinavir/ritonavir, indinavir/ritonavir, ritonavir, conivaptan); and
    b. Strong CYP3A inducers (e.g., rifampin); and
    c. OATP1B1/3 and OAT3 transporter substrates (e.g., statins, bosentan, glyburide, nateglinide, repaglinide, methotrexate, furosemide); and
    d. BCRP transporter substrates (e.g., rosuvastatin); and
    e. V_2-receptor agonists (e.g., desmopressin); and
5. Jynarque® must be prescribed by a nephrologist or specialist with expertise in the treatment of ADPKD (or be an advanced care practitioner with a supervising physician who is a nephrologist or specialist with expertise in the treatment of ADPKD); and
6. Prescriber must agree to assess ALT, AST, and bilirubin prior to initiation of Jynarque®, at 2 weeks and 4 weeks after initiation, then monthly for 18 months, and every 3 months thereafter; and
7. Female members must not be pregnant and must have a negative pregnancy test prior to therapy initiation; and
8. Prescriber, pharmacy, and member must be enrolled in the Jynarque® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy.

Utilization of Jynarque® (Tolvaptan): Fiscal Year 2019

Fiscal Year 2019 Utilization

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	1	1	$13,704.03	$13,704.03	$489.43	56	28

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal year 2019 = 07/01/2018 to 06/30/2019

Demographics of Members Utilizing Jynarque® (Tolvaptan)

- Due to the small number of members utilizing Jynarque® (tolvaptan) during fiscal year 2019, detailed demographic information could not be provided.

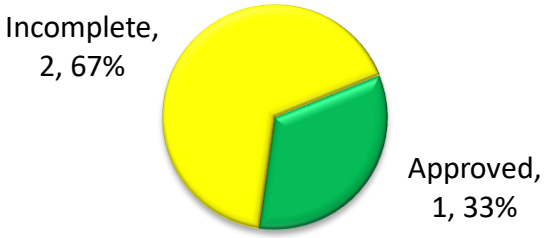
Top Prescriber Specialties of Jynarque® (Tolvaptan) by Number of Claims

- The only prescriber specialty listed on paid claims for Jynarque® (tolvaptan) during fiscal year 2019 was nephrologist.

Prior Authorization of Jynarque® (Tolvaptan)

There were 3 prior authorization requests submitted for 2 unique members for Jynarque® (tolvaptan) during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[88]

- Jynarque® (tolvaptan): September 2026

Recommendations

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

[88] 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/default.cfm?resetfields=1. Last revised 01/2020. Last accessed 01/15/2020.

Utilization Details of Jynarque® (Tolvaptan): Fiscal Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
TOLVAPTAN PRODUCTS						
JYNARQUE PAK 45-15MG	1	1	$13,704.03	$489.43	$13,704.03	100%
TOTAL	**1**	**1***	**$13,704.03**	**$489.43**	**$13,704.03**	**100%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Fiscal Year 2019 Annual Review of Kanuma® (Sebelipase Alfa)

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Kanuma® (Sebelipase Alfa) Approval Criteria:

1. An FDA approved diagnosis of lysosomal acid lipase deficiency (LAL-D); and
2. Kanuma® (sebelipase alfa) must be administered in a health care setting by a health care professional prepared to manage anaphylaxis; and
3. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling.

Utilization of Kanuma® (Sebelipase Alfa): Fiscal Year 2019

There was no SoonerCare utilization of Kanuma® (sebelipase alfa) during fiscal year 2019.

Prior Authorization of Kanuma® (Sebelipase Alfa): Fiscal Year 2019

There were no prior authorization requests submitted for Kanuma® (sebelipase alfa) during fiscal year 2019.

Recommendations

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

Fiscal Year 2019 Annual Review of Keveyis® (Dichlorphenamide)

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Keveyis™ (Dichlorphenamide) Approval Criteria:

1. An FDA approved indication for the treatment of primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, or related variants; and
2. Prescriber documentation that all non-pharmacological treatments failed including the following:
    a. Hyperkalemic periodic paralysis:
        i. Acute attacks can be aborted with sugar or mild exercise; and
        ii. Avoiding foods rich in potassium; and
        iii. Avoiding fasting; and
        iv. High-carbohydrate diet; and
        v. Avoiding strenuous activity; and
        vi. Avoiding prolonged cold exposure; or
    b. Hypokalemic periodic paralysis:
        i. Low-carbohydrate diet (avoiding carbohydrate loading); and
        ii. Avoiding vigorous exercise (some mild attacks can be aborted by low level exercise); and
3. Prescriber documentation of frequent and severe attacks requiring pharmacological treatment (at least 1 attack per week but no more than 3 attacks per day); and
4. A 4-week trial within the last 90 days of acetazolamide in combination with:
    a. Hydrochlorothiazide in hyperkalemic periodic paralysis; or
    b. Spironolactone or triamterene in hypokalemic periodic paralysis; and
5. A quantity limit of 4 tablets per day will apply; and
6. Initial approvals will be for the duration of 3 months after which time compliance will be required for continued approval. Additionally, for continuation the prescriber must include information regarding reduced frequency or severity of attacks.

Utilization of Keveyis™ (Dichlorphenamide): Fiscal Year 2019

There have been no SoonerCare utilization of Keveyis™ (dichlorphenamide) since it was FDA approved in August 2015 to current date.

Prior Authorization of Keveyis™ (Dichlorphenamide)

There have been no prior authorization requests submitted for Keveyis™ (dichlorphenamide) since it was FDA approved in August 2015 to current date.

Market News and Updates

Anticipated Exclusivity Expiration(s):[89]

- Keveyis™ (dichlorphenamide): August 2022

Recommendations

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

[89] 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/default.cfm?resetfields=1. Last revised 01/2020. Last accessed 01/15/2020.

Fiscal Year 2019 Annual Review of Leukotriene Modulators

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Singulair® (Montelukast) Approval Criteria:

1. Montelukast tablets and chewable tablets are available without prior authorization.
2. For Insure Oklahoma members, a prior authorization is required. This medication is not covered for a diagnosis of allergic rhinitis for those members.
3. A prior authorization is required for the granule formulation of montelukast.
    a. Use of the granule formulation requires a patient-specific, clinically significant reason why the member cannot use montelukast tablets or chewable tablets.

Zyflo CR® (Zileuton) Approval Criteria:

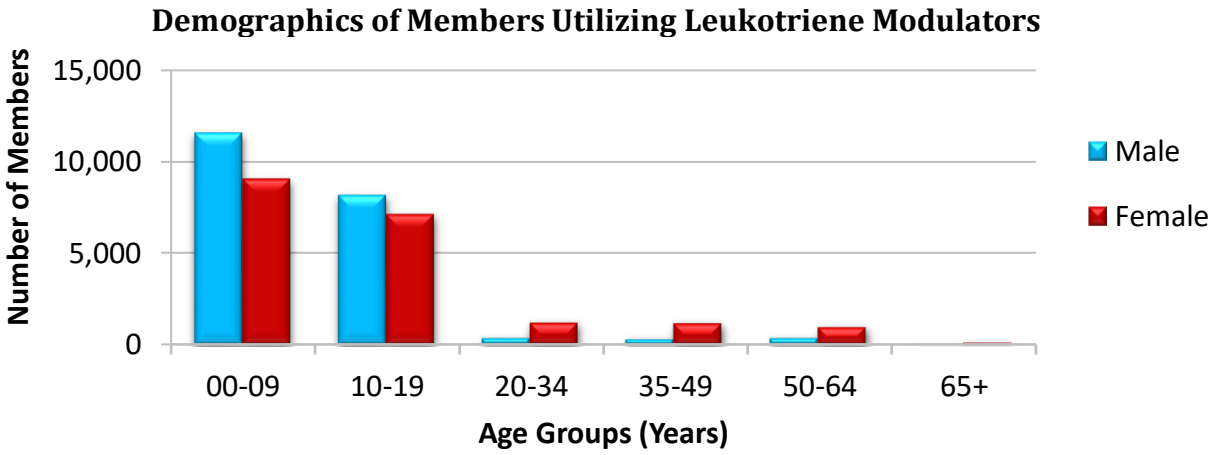
1. Member must be 12 years of age or older; and
2. An FDA approved diagnosis of mild or moderate persistent asthma; and
    a. For a diagnosis of asthma, the member must meet the following:
        i. A trial of an inhaled corticosteroid (ICS) and ICS/long-acting beta$_2$ agonist (LABA) therapy within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

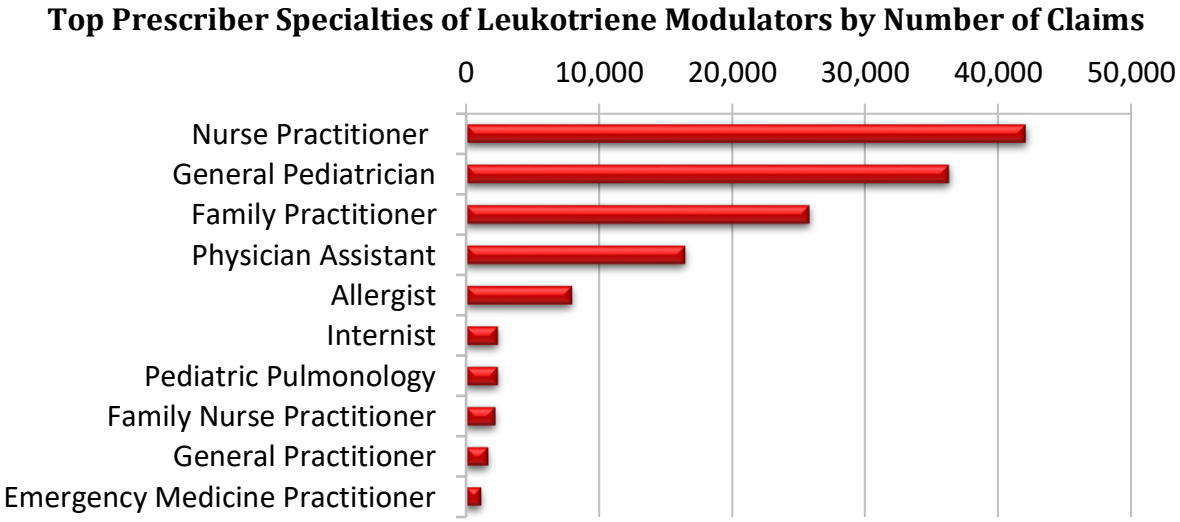
Utilization of Leukotriene Modulators: Fiscal Year 2019

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	40,204	141,638	$2,332,183.98	$16.47	$0.55	4,240,971	4,244,873
2019	40,251	142,753	$2,207,952.32	$15.47	$0.52	4,274,972	4,279,157
% Change	**0.1%**	**0.8%**	**-5.3%**	**-6.1%**	**-5.5%**	**0.8%**	**0.8%**
Change	**47**	**1,115**	**-$124,231.66**	**-$1.00**	**-$0.03**	**34,001**	**34,284**

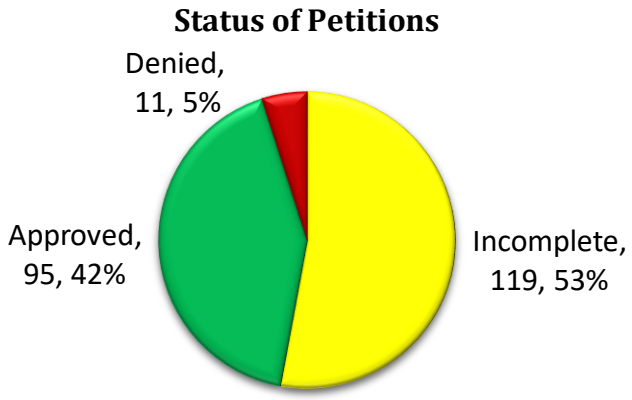
*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019





Prior Authorization of Leukotriene Modulators

There were 225 prior authorization requests submitted for leukotriene modulators during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.



Market News and Updates

News:

- **September 2019:** A joint meeting of the Pediatric Advisory Committee (PAC) and Drug Safety and Risk Management (DSaRM) Advisory Committee was held to discuss a pediatric-focused safety review of neuropsychiatric events with the use of montelukast. Based upon their review, the U.S. Food and Drug Administration (FDA) Advisory Committees did not believe that there was new information to elevate the risk of neuropsychiatric events associated with montelukast to a *Boxed Warning*. A major concern voiced by external stakeholders was the lack of awareness in both patients/ caregivers as well as health care providers/prescribers of the potential risk of neuropsychiatric events with montelukast. In order to address this concern, the FDA is considering requiring a Medication Guide. Another labeling strategy to consider would be to make the current *Warning and Precaution* more prominent by moving it in the label. The FDA will be seeking further input on the montelukast labeling.[90]
- **September 2019:** A single-site, randomized controlled trial at Emory University was conducted to compare the effects of montelukast versus placebo on memory and thinking abilities, as well as on brain imaging and markers of brain degeneration. It is hypothesized that the leukotriene signaling pathway, which mediates various aspects of Alzheimer's disease (AD) pathology, is a drug target in AD.[91,92]

Pipeline Update(s):

- **Acebilustat:** Acebilustat is a once-daily, oral, small molecule inhibitor of leukotriene A4 hydrolase (LTA4H), the key enzyme in the production of the potent inflammatory mediator leukotriene B4 (LTB4). LTB4 can create an over activation of neutrophil-mediated immune response and inflammation which has been strongly implicated in the pathogenesis of many diseases including cystic fibrosis (CF). Acebilustat modulates the neutrophil driven immune response, preventing overactive inflammation. Results from the EMPIRE-CF Phase 2 trial showed that acebilustat-treated patients exhibited a 19% reduction in pulmonary exacerbations and a 22% reduced risk in progressing to first pulmonary exacerbations versus placebo on a per protocol basis.[93]

---

[90] U.S. Food and Drug Administration (FDA). Pediatric Advisory Committee Meeting September 27, 2019: Neuropsychiatric Events with Use of Montelukast in Pediatric Patients. Available online at: https://www.fda.gov/media/131035/download. Issued 09/27/2019. Last accessed 11/21/2019.

[91] Montelukast Therapy on Alzheimer's disease. ClinicalTrials.gov. Available online at: https://clinicaltrials.gov/ct2/show/NCT03991988. Last updated 09/30/2019. Last accessed 11/21/2019.

[92] Michael J, Marschallinger J, Aigner L. The leukotriene signaling pathway: a druggable target in Alzheimer's disease. *Drug Discov Today*. 2019;24(2):505-516. doi:10.1016/j.drudis.2018.09.008

[93] Celtaxsys, Inc. Results from Celtaxsys' Acebilustat Phase 2 Trial in Cystic Fibrosis Patients Showing Clinically Meaningful Improvement in Pulmonary Exacerbations Presented at the North American Cystic Fibrosis Conference. Available online at: https://celtaxsys.com/2018/10/22/results-from-celtaxsys-acebilustat-phase-2-trial-in-cystic-fibrosis-patients-showing-clinically-meaningful-improvement-in-pulmonary-exacerbations-presented-at-the-north-american-cystic-fibros/. Issued 10/22/2018. Last accessed 11/21/2019.

Recommendations

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

Utilization Details of Leukotriene Modulators: Fiscal Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ CLIENT	COST/ CLAIM
MONTELUKAST PRODUCTS					
MONTELUKAST CHW 5MG	55,461	15,720	$779,131.32	3.5	$14.05
MONTELUKAST TAB 10MG	42,801	12,276	$503,482.26	3.5	$11.76
MONTELUKAST CHW 4MG	40,163	12,424	$589,920.46	3.2	$14.69
MONTELUKAST GRA 4MG	4,149	1,811	$305,073.22	2.3	$73.53
SINGULAIR CHW 4MG	9	1	$2,151.57	9	$239.06
SINGULAIR CHW 5MG	4	1	$955.72	4	$238.93
SUBTOTAL	**142,587**	**40,229**	**$2,180,714.55**	**3.5**	**$15.29**
ZILEUTON PRODUCTS					
ZILEUTON ER TAB 600MG	7	1	$17,422.52	7	$2,488.93
SUBTOTAL	**7**	**1**	**$17,422.52**	**7**	**$2,488.93**
ZAFIRLUKAST PRODUCTS					
ZAFIRLUKAST TAB 20MG	133	23	$8,618.11	5.8	$64.80
ZAFIRLUKAST TAB 10MG	26	7	$1,197.14	3.7	$46.04
SUBTOTAL	**159**	**29**	**$9,815.25**	**5.5**	**$61.73**
TOTAL	**142,753**	**40,251***	**$2,207,952.32**	**3.6**	**$15.47**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Fiscal Year 2019 Annual Review of Lidocaine Topical Products

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Synera® (Lidocaine/Tetracaine Topical Patch) Approval Criteria:

1. Member must be 3 years of age or older; and
2. Member must have an FDA approved need for local dermal analgesia for superficial venous access or superficial dermatological procedures; and
3. A patient-specific, clinically significant reason why the member cannot use EMLA® (lidocaine/prilocaine) cream, which is available without a prior authorization, must be provided; and
4. The total number of procedures must be provided on the prior authorization request; and
5. A quantity limit of 2 patches per day will apply.

ZTlido™ (Lidocaine 1.8% Topical System) Approval Criteria:

1. An FDA approved diagnosis of pain due to postherpetic neuralgia (PHN); and
2. Documented treatment attempts, at recommended dosing, of at least 1 agent from 2 of the following drug classes that failed to provide adequate relief or contraindication(s) to all of the following classes:
   a. Tricyclic antidepressants; or
   b. Anticonvulsants; or
   c. Topical or oral analgesics; and
3. A patient-specific, clinically significant reason why the member cannot use lidocaine 5% topical patches, which are available without prior authorization, must be provided; and
4. A quantity limit of 3 patches per day with a maximum of 90 patches per month will apply.

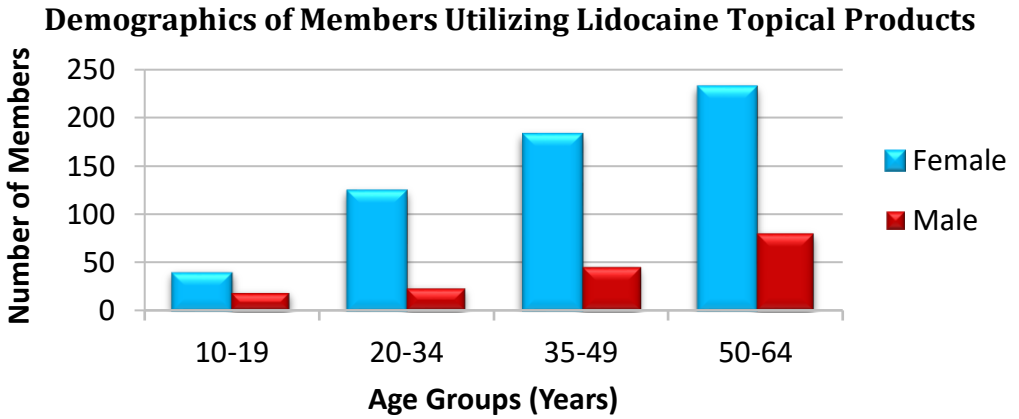
Utilization of Lidocaine Topical Products: Fiscal Year 2019

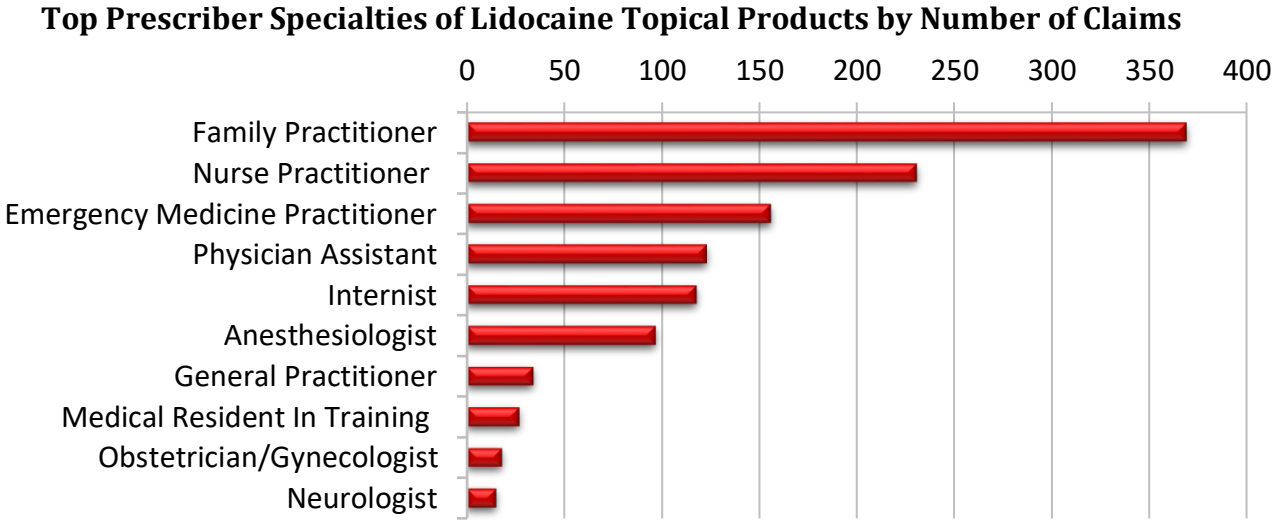
Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	104	133	$13,215.29	$99.36	$3.89	4,213	3,399
2019	739	1,301	$119,258.54	$91.67	$3.57	40,333	33,403
% Change	**610.6%**	**878.2%**	**802.4%**	**-7.7%**	**-8.2%**	**857.3%**	**882.7%**
Change	**635**	**1,168**	**$106,043.25**	**-$7.69**	**-$0.32**	**36,120**	**30,004**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

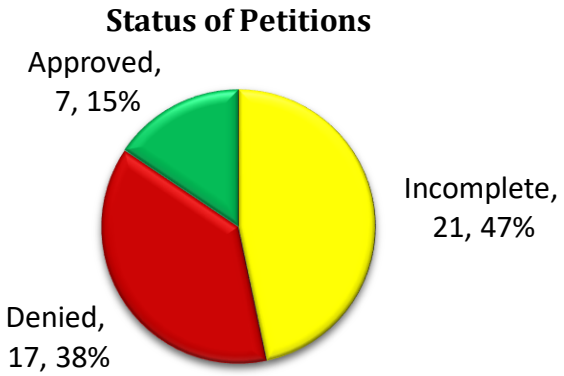
- Based on the National Average Drug Acquisition Cost (NADAC) of generic lidocaine 5% topical patches and after an analysis of cost-effectiveness, the prior authorization requirement for lidocaine 5% topical patches (Lidoderm®) was removed in May 2018.
- There were no paid claims for Synera® (lidocaine/tetracaine patch) during fiscal year 2019.





Prior Authorization of Lidocaine Topical Products

There were 45 prior authorization requests submitted for lidocaine topical products during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.



Market News and Updates

Anticipated Patent Expiration(s):[94]

- Synera® (lidocaine/tetracaine patch): July 2020
- ZTlido™ (lidocaine 1.8% topical system): May 2031

Recommendations

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

Utilization Details of Lidocaine Topical Products: Fiscal Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
LIDOCAINE PRODUCTS					
LIDOCAINE PAD 5%	1,300	738	$118,731.50	1.76	$91.33
ZTLIDO PAD 1.8%	1	1	$527.04	1	$527.04
TOTAL	**1,301**	**739***	**$119,258.54**	**1.76**	**$91.66**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

[94] 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?resetfields=1. Last revised 11/2019. Last accessed 11/21/2019.

Fiscal Year 2019 Annual Review of Lumizyme® (Alglucosidase Alfa)

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Lumizyme® (Alglucosidase Alfa) Infantile-Onset Approval Criteria:

1. An FDA approved diagnosis of infantile-onset Pompe disease [acid alpha-glucosidase (GAA) deficiency]; and
2. Documentation of diagnosis confirmation of GAA enzyme deficiency through specific genetic laboratory test(s); and
3. Lumizyme® must be prescribed by a geneticist or a physician that specializes in the treatment of Pompe disease and/or inherited genetic disorders; and
4. Member's weight must be provided and must have been taken within the last 4 weeks to ensure accurate dosing.

Lumizyme® (Alglucosidase Alfa) Late-Onset (Non-Infantile) Approval Criteria:

1. An FDA approved diagnosis of late-onset (non-infantile) Pompe disease [acid alpha-glucosidase (GAA) deficiency]; and
2. Documentation of diagnosis confirmation of GAA enzyme deficiency through specific genetic laboratory test(s); and
3. Provider must document presence of symptoms of Pompe disease; and
4. Lumizyme® must be prescribed by a geneticist or a physician that specializes in the treatment of Pompe disease and/or inherited genetic disorders; and
5. Member's weight must be provided and must have been taken within the last 4 weeks to ensure accurate dosing; and
6. Initial approvals will be for the duration of 6 months, at which time compliance and information regarding efficacy, such as improvement or stabilization in Forced Vital Capacity (FVC) and/or 6-minute walk test (6MWT), will be required for continued approval. Additional authorizations will be for the duration of 1 year.

Utilization of Lumizyme® (Alglucosidase Alfa): Fiscal Year 2019

There was no SoonerCare utilization of Lumizyme® (alglucosidase alfa) during fiscal year 2019.

Prior Authorization of Lumizyme® (Alglucosidase Alfa)

There were no prior authorization requests submitted for Lumizyme® (alglucosidase alfa) during fiscal year 2019.

Recommendations

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

Fiscal Year 2019 Annual Review of Luxturna™ (Voretigene Neparvovec-rzyl)

Oklahoma Health Care Authority
Fiscal Year 2019 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 less than 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 child bearing 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 child bearing 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 of Luxturna™; 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 in place a mechanism 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 2019

There was no SoonerCare utilization of Luxturna™ (voretigene neparvovec-rzyl) during fiscal year 2019.

Prior Authorization of Luxturna™ (Voretigene Neparvovec-rzyl)

There were no prior authorization requests submitted for Luxturna™ (voretigene neparvovec-rzyl) during fiscal year 2019.

Market News and Updates

News:

- **September 2019:** Results from aggregated data taken from patients in Phase 1 and Phase 3 studies of voretigene neparvovec-rzyl were published in *Ophthalmology* in September 2019. Included in this report are patients from the Phase 1 dose-escalation study who were subsequently enrolled into a Phase 1 follow-on study. This report also includes patients from the Phase 3 study who had initially been randomized 2:1 to receive intervention (voretigene neparvovec) or control (no intervention). After 1 year, patients in the control group crossed over to the intervention group and received voretigene neparvovec. The Phase 1 follow-on study includes assessments of safety and efficacy taken over 4 years, while the Phase 3 data includes assessments of safety and efficacy over 2 years for patients in the original intervention group and over 1 year for patients originally in the control-intervention crossover group. In the Phase 1 group at year 4, there was a 2.4 increase from baseline in the Multi-Luminance Mobility Test, suggesting durability of the effects of voretigene neparvovec for at least 4 years. The safety analyses show adverse events that are consistent with vitrectomy and the subretinal administration procedure over the 4 year duration, with the majority of events occurring during the first year after administration and resolving with minimal or no intervention. Assessment of these Phase 1 and Phase 3 patients is planned to continue annually for 15 years.[95]

Pipeline:

- **QR-110 (Sepofarsen):** ProQR Therapeutics is developing QR-110 (sepofarsen) for the treatment of Leber's congenital amaurosis 10 (LCA10). LCA10 is caused by mutations in the *CEP290* gene, of which the p.Cys998X mutation is the most common. QR-110 is designed to repair the genetic defect in the RNA, such that it leads to a normal "wild-type" mRNA, leading to the production of normal *CEP290* protein. QR-110 is intended to be administered through intravitreal injections and has been granted Orphan Drug and

[95] Maguire AM, Russell S, Wellman JA, et al. Efficacy, Safety, and Durability of Voretigene Neparvovec-rzyl in RPE65 Mutation-Associated Inherited Retinal Dystrophy: Results of Phase 1 and 3 Trials. *Ophthalmology* 2019; 126(9):1273-1285.

Fast Track designations by the U.S. Food and Drug Administration (FDA). ProQR is currently conducting the Phase 2/3 Illuminate study which began in April 2019.[96,97]

- **QR-1123:** ProQR Therapeutics is also developing QR-1123 for the treatment of autosomal dominant retinitis pigmentosa (adRP). There are over 20 known genes that can cause adRP when they are mutated but most often the disease is caused by a mutation in the rhodopsin (*RHO*) gene; in the United States, the P23H mutation is the most common. QR-1123 aims to block the formation of the mutated toxic version of the rhodopsin protein by specifically binding to the mutated *RHO* mRNA, with the goal of stopping the progression or reversing the effects of the disease. ProQR is currently conducting the Phase 1/2 Aurora study and expects initial results to be available in 2021. The study will evaluate safety, tolerability, and patient benefit of QR-1123.[98]
- **QR-421a:** ProQR Therapeutics is developing QR-421a for the treatment of retinitis pigmentosa (RP) in patients with Usher syndrome type 2 (USH2). USH2 is the most common type of Usher syndrome and causes moderate to severe hearing impairment from birth and night blindness occurring in the 2nd decade of life. This is followed by progressive loss of vision, until complete blindness occurs by the 3rd or 4th decade of life. USH2 is caused by mutations in the USH2A gene which encodes a protein, known as usherin, which is important for photo transduction in retinal photoreceptors. QR-421a is designed for patients with a specific mutation in USH2A in exon 13 and functions by excluding exon 13 from USH2 mRNA, resulting in a shortened but functional usherin protein. QR-421a is administered by intravitreal injection. ProQR is currently conducting the Phase 1/2 STELLAR study with interim results expected in the first quarter of 2020.[99]
- **GS010:** GenSight Biologics is developing GS010, an adeno-associated virus serotype 2 (AAV2) gene therapy vector that encodes the human wild-type ND4 protein, for the treatment of Leber's hereditary optic neuropathy (LHON) caused by mutation of the *ND4* gene. LHON is a rare, maternally inherited mitochondrial genetic disease that causes irreversible and severe vision loss, eventually leading to blindness and disability, mostly in teens and young adults. Phase 3 studies (RESCUE and REVERSE) were completed in 2019, and patients were invited to enroll in a long-term follow-up study to monitor safety and efficacy over 5 years after treatment. Two additional studies (REFLECT and REALITY LHON) are currently underway.[100]
- **GS030:** GenSight Biologics is also developing GS030 for the treatment of RP. GS030 uses optogenetics, a biologic technique that involves the transfer of a gene that encodes for a light-sensitive protein, which in turn causes neuronal cells to respond to light stimulation. GS030 is an innovative combination of 2 complementary components, a

---

[96] ProQR Therapeutics N.V. ProQR Science & Pipeline: Sepofarsen for Leber's Congenital Amaurosis 10. Available online at: https://www.proqr.com/sepofarsen-for-lca10/. Last accessed 03/18/2020.

[97] ProQR Therapeutics N.V. Illuminate Clinical Trial Website. Available online at: https://www.lcastudy.com/. Last accessed 03/18/2020.

[98] ProQR Therapeutics N.V. ProQR Science & Pipeline: QR-1123 for Autosomal Dominant Retinitis Pigmentosa. Available online at: https://www.proqr.com/qr-1123-for-adrp/. Last accessed 03/18/2020.

[99] ProQR Therapeutics N.V. ProQR Science & Pipeline: QR-421a for Usher syndrome type 2. Available online at: https://www.proqr.com/qr-421a-for-usher-syndrome-type-2/. Last accessed 03/18/2020.

[100] GenSight Biologics. GenSight Products & Pipeline: GS010 for LHON. Available online at: https://www.gensight-biologics.com/product/gs010-for-lhon/. Last accessed 03/18/2020.

gene therapy product encoding a photoactivatable channelrhodopsin protein (delivered via a modified AAV2 vector known as AAV2 7m8) and biomimetic goggles that stimulate the engineered retinal cells (images are projected onto the retina by a light source that uses a specific wavelength). GenSight has initiated the PIONEER study, a Phase 1/2 dose-escalation study to evaluate the safety and tolerability of GS030 in patients with RP. After completion of the PIONEER study, GenSight plans to investigate the use of GS030 to treat Geographic Atrophy (GA) in dry age-related macular degeneration (Dry-AMD).[101,102]

Recommendations

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

[101] GenSight Biologics. GenSight Products & Pipeline: GS030 for Retinitis Pigmentosa. Available online at: https://www.gensight-biologics.com/product/gs030-for-retinitis-pigmentosa/. Last accessed 03/18/2020.

[102] GenSight Biologics. GenSight Products & Pipeline: GS030 for Geographic Atrophy in Dry-AMD. Available online at: https://www.gensight-biologics.com/product/gs030-for-geographic-atrophy-in-dry-amd/. Last accessed 03/18/2020.

Fiscal Year 2019 Annual Review of Mepsevii™ (Vestronidase Alfa-vjbk)

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Mepsevii™ (Vestronidase Alfa-vjbk) Approval Criteria:

1. An FDA approved diagnosis of Sly syndrome (mucopolysaccharidosis VII; MPS VII) confirmed by:
   a. Enzyme analysis demonstrating a deficiency of beta-glucuronidase activity; or
   b. Genetic testing to confirm diagnosis of MPS VII; and
2. Mepsevii™ must be administered by a health care professional prepared to manage anaphylaxis; and
3. Initial approvals will be for the duration of 12 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment; and
4. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling.

Utilization of Mepsevii™ (Vestronidase Alfa-vjbk): Fiscal Year 2019

There was no SoonerCare utilization of Mepsevii™ (vestronidase alfa-vjbk) during fiscal year 2019.

Prior Authorization of Mepsevii™ (Vestronidase Alfa-vjbk)

There were no prior authorization requests submitted for Mepsevii™ (vestronidase alfa-vjbk) during fiscal year 2019.

Market News and Updates

News:

- **March 2019:** A review of the use of vestronidase alfa in mucopolysaccharidosis VII (MPS VII) was published in the journal *BioDrugs*. According to the review, prior to the approval of vestronidase alfa, there were no disease-specific treatments for MPS VII and disease management primarily consisted of symptomatic and supportive care. Bone marrow transplants (BMTs) have been performed in a small number of patients with MPS VII and some have experienced marked clinical improvements, especially in motor function, but effects on neurological manifestations were equivocal. The efficacy of BMT is variable in this population and there are considerable limitations with BMT. Currently, there are no global treatment guidelines available for MPS VII; however, vestronidase alfa is indicated for all ages. It is argued that enzyme replacement therapy (ERT) should be initiated as soon as possible after diagnosis of MPS, including before the onset of clinical disease. According to the review, despite the clinical benefits of vestronidase alfa

in patients with MPS VII, it is associated with several limitations. The first limitation is that ERT is a life-long intravenous treatment and may be associated with infusion-related reactions. The second limitation is that the effects of vestronidase alfa on neurological manifestations originating in the central nervous system has not been determined, but vestronidase alfa is not expected to cross the blood brain barrier. Another limitation is the financial burden associated with the treatment. The authors of the review concluded that given the lack of treatment options and the clinical benefits vestronidase alfa provides, it is an important emerging ERT for pediatric and adults patients with MPS VII.[103]

Recommendations

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

[103] McCafferty EH, Scott LJ. Vestronidase Alfa: A Review in Mucopolysaccharidosis VII. *BioDrugs*. 2019; 33(2): 233-240. doi: 10.1007/s40259-019-00344-7.

Fiscal Year 2019 Annual Review of Mozobil® (Plerixafor)

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Mozobil® (Plerixafor) Approval Criteria:

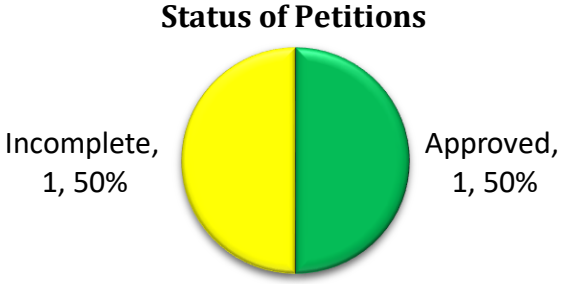
1. An FDA approved indication for use in combination with granulocyte-colony stimulating factor (G-CSF) to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin's lymphoma (NHL) and multiple myeloma (MM); and
2.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

Utilization of Mozobil® (Plerixafor): Fiscal Year 2019

There was no SoonerCare utilization of Mozobil® (plerixafor) during fiscal year 2019.

Prior Authorization of Mozobil® (Plerixafor)

There were 2 prior authorization requests submitted for Mozobil® (plerixafor) during fiscal year 2019; 1 prior authorization request was approved in late June 2019; however, there were no paid claims in fiscal year 2019 (7/1/2018 through 6/30/2019). The following chart shows the status of the submitted petitions for fiscal year 2019.



Market News and Updates

News:

- **March 2019:** The European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorization for plerixafor (Mozobil®). The new indication is to enhance mobilization of hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in children with lymphoma or solid malignant tumors either pre-emptively, when circulating stem cell count on the predicted day of collection after adequate mobilization with G-CSF (with or without chemotherapy) is expected to be insufficient regarding the desired hematopoietic stem cell yield, or who previously failed to collect sufficient hematopoietic stem cells.[104]

Recommendations

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

[104] European Society for Medical Oncology. EMA Recommends Extension of Indications for Plerixafor. Available online at: https://www.esmo.org/Oncology-News/EMA-Recommends-Extension-of-Indications-for-Plerixafor. Issued 04/02/2019. Last accessed 12/02/2019.

Fiscal Year 2019 Annual Review of Muscle Relaxant Medications

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

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

ASA = aspirin; ER = extended-release
*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

Muscle Relaxant Medications Tier-2 Approval Criteria:

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

Baclofen 5mg Tablet Approval Criteria:

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

Soma® (Carisoprodol 250mg) Approval Criteria:

1. Authorization requires detailed documentation regarding member's inability to use other skeletal muscle relaxants including carisoprodol 350mg, and a specific reason why

the member cannot be drowsy for even a short time period. Member must not have other sedating medications in current claims history; and
2. A diagnosis of acute musculoskeletal pain, in which case, the approval will be for the duration of 14 days per 365 day period. Conditions requiring chronic use will not be approved.

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

1. Members may receive 3 months of carisoprodol 350mg per rolling 365 days without prior authorization; and
2. After the member has used the 3 months, and additional approval for 1 month may be granted to allow titration or change to a Tier-1 muscle relaxant. This additional 1-month approval is granted 1 time only. Further authorization will not be granted; or
3. Clinical exceptions may be made for members with the following diagnosis and approvals will be granted for the duration of 1 year: multiple sclerosis, cerebral palsy, muscular dystrophy, paralysis, or cancer pain; and
4. A quantity limit of 120 tablets per 30 days will apply for carisoprodol and carisoprodol combination products.

Lorzone™ (Chlorzoxazone) Approval Criteria:

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

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

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

Zanaflex® (Tizanidine Capsule) Approval Criteria:

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

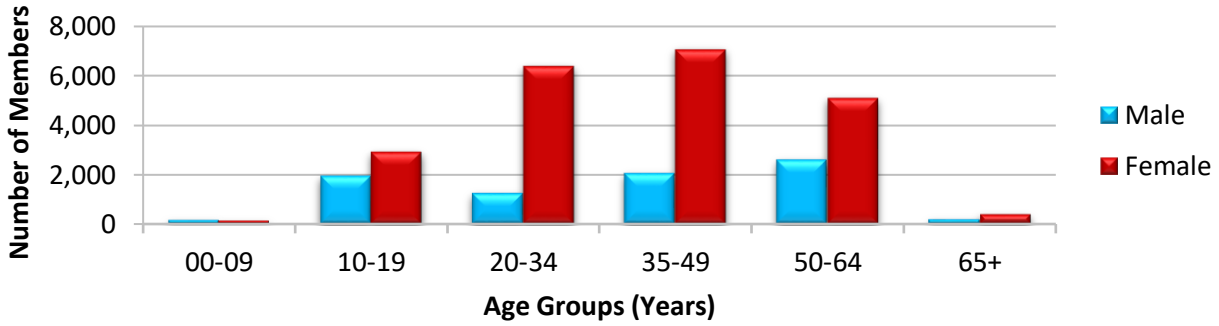
Utilization of Muscle Relaxant Medications: Fiscal Year 2019

Comparison of Fiscal Years

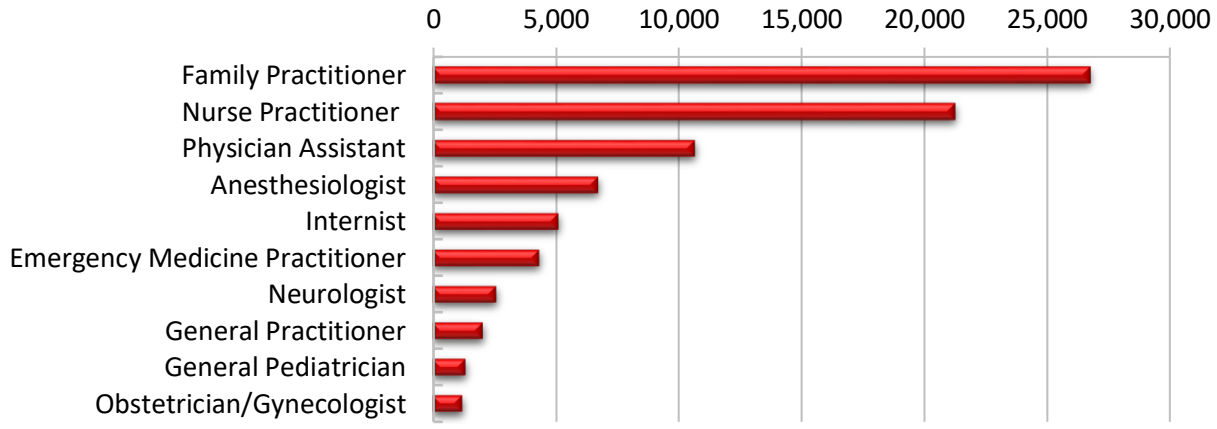
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	31,818	94,902	$1,418,265.27	$14.94	$0.60	6,423,216	2,364,066
2019	30,116	91,184	$1,291,203.14	$14.16	$0.57	6,086,814	2,265,172
% Change	**-5.3%**	**-3.9%**	**-9.0%**	**-5.2%**	**-5.0%**	**-5.2%**	**-4.2%**
Change	**-1,702**	**-3,718**	**-$127,062.13**	**-$0.78**	**-$0.03**	**-336,402**	**-98,894**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Demographics of Members Utilizing Muscle Relaxant Medications

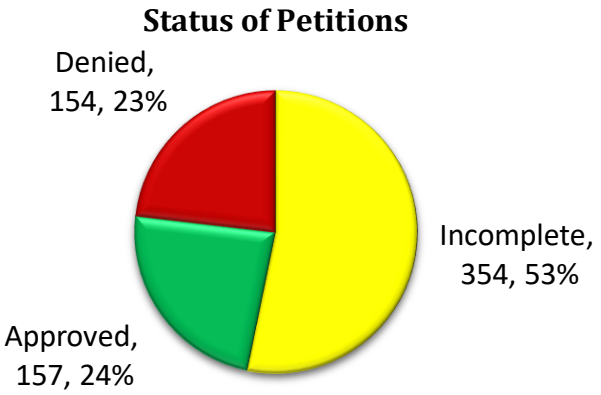


Top Prescriber Specialties of Muscle Relaxant Medications by Number of Claims



Prior Authorization of Muscle Relaxant Medications

There were 665 prior authorization requests for muscle relaxant medications submitted during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.



Market News and Updates

Anticipated Patent Expiration(s):[105]

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

News:

- **November 2019:** A new population-based cohort study using linked healthcare data compared the 30-day risk of encephalopathy in patients with chronic kidney disease (CKD) who were newly prescribed a high dose of baclofen versus a low dose of baclofen (≥20mg/day vs. <20mg/day) and the risk in baclofen users versus non-users. The cohort included 15,942 patients with CKD. An increased risk of hospital admission with encephalopathy in older adults with CKD was seen with high dose baclofen (1.11%) compared to the low dose group (0.42%). Weighted risk ratios (wRR) were 3.54 [95% confidence interval (CI): 2.24, 5.59] and the weighted risk differences (wRD) was 0.80% (95% CI: 0.55%, 1.04%). The absolute risk increased progressively as estimated glomerular filtration rate (eGFR) declined. In the secondary comparison with 284,263 non-users, both low-dose and high-dose users had a higher risk of encephalopathy: wRR: 5.90 (95% CI: 3.59, 9.70) and 19.8 (95% CI: 14.0, 28.0), respectively.[106]

Recommendations

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

---

[105] 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 11/2019. Last accessed 12/06/2019.

[106] Muanda FT, Weir MA, Bathini L, et al. Association of Baclofen with Encephalopathy in Patients with Chronic Kidney Disease. *JAMA* 2019; 322(20): 1987-1995. doi: 10.1001/jama.2019.17725.

Utilization Details of Muscle Relaxant Medications: Fiscal Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
TIER-1 UTILIZATION					
BACLOFEN PRODUCTS					
BACLOFEN TAB 10MG	12,130	3,536	$192,585.20	3.43	$15.88
BACLOFEN TAB 20MG	5,992	1,243	$143,954.38	4.82	$24.02
LIORESAL INJ 40MG/20ML	10	1	$18,975.86	10.00	$1,897.59
SUBTOTAL	**18,132**	**4,562**	**$355,515.44**	**3.97**	**$19.60**
CHLORZOXAZONE PRODUCTS					
CHLORZOXAZON TAB 500MG	1,232	508	$29,701.18	2.43	$24.11
SUBTOTAL	**1,232**	**508**	**$29,701.18**	**2.43**	**$24.11**
CYCLOBENZAPRINE PRODUCTS					
CYCLOBENZAPR TAB 10MG	29,034	12,948	$285,355.07	2.24	$9.83
CYCLOBENZAPR TAB 5MG	6,637	4,008	$68,529.11	1.66	$10.33
SUBTOTAL	**35,671**	**16,396**	**$353,884.18**	**2.18**	**$9.92**
METHOCARBAMOL PRODUCTS					
METHOCARBAM TAB 500MG	3,817	2,105	$53,669.60	1.81	$14.06
METHOCARBAM TAB 750MG	3,326	1,386	$52,937.31	2.40	$15.92
SUBTOTAL	**7,143**	**3,344**	**$106,606.91**	**2.14**	**$14.92**
ORPHENADRINE PRODUCTS					
ORPHENADRINE TAB 100MG ER	2,598	1,761	$49,573.29	1.48	$19.08
ORPHENADRINE INJ 30MG/ML	1	1	$79.05	1.00	$79.05
SUBTOTAL	**2,599**	**1,761**	**$49,652.34**	**1.48**	**$19.10**
TIZANIDINE PRODUCTS					
TIZANIDINE TAB 4MG	21,997	6,629	$314,131.98	3.32	$14.28
TIZANIDINE TAB 2MG	3,037	1,340	$43,642.62	2.27	$14.37
SUBTOTAL	**25,034**	**7,762**	**$357,774.60**	**3.23**	$14.29
TIER-1 SUBTOTAL	**89,811**	**29,784**	**$1,253,134.65**	**3.02**	**$13.95**
TIER-2 UTILIZATION					
METAXALONE PRODUCTS					
METAXALONE TAB 800MG	227	73	$18,820.25	3.11	$82.91
METAXALONE TAB 400MG	10	2	$4,710.86	5.00	$471.09
TIER-2 SUBTOTAL	**237**	**74**	**$23,531.11**	**3.20**	**$99.29**
SPECIAL PRIOR AUTHORIZATION (PA) UTILIZATION					
BACLOFEN PRODUCTS					
BACLOFEN TAB 5MG	1	1	$30.19	1.00	$30.19
SUBTOTAL	**1**	**1**	**$30.19**	**1.00**	**$30.19**
CARISOPRODOL PRODUCTS					
CARISOPRODOL TAB 350MG	1,131	553	$13,750.93	2.05	$12.16
SUBTOTAL	**1,131**	**553**	**$13,750.93**	**2.05**	**$12.16**
CYCLOBENZAPRINE PRODUCTS					
CYCLOBENZAPR CAP 15MG ER	1	1	$346.45	1.00	$346.45
SUBTOTAL	**1**	**1**	**$346.45**	**1.00**	**$346.45**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
TIZANIDINE PRODUCTS					
TIZANIDINE CAP 6MG	2	1	$343.85	2.00	$171.93
TIZANIDINE CAP 2MG	1	1	$65.96	1.00	$65.96
SUBTOTAL	**3**	**2**	**$409.81**	**1.50**	**$136.60**
SPECIAL PA SUBTOTAL	**1,136**	**557**	**$14,537.38**	**2.04**	**$12.80**
TOTAL	**91,184**	**30,116***	**$1,291,203.14**	**3.03**	**$14.16**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Fiscal Year 2019 Annual Review of Myalept® (Metreleptin)

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Myalept® (Metreleptin) Approval Criteria:

1. An FDA approved diagnosis of leptin deficiency in patients with congenital or acquired generalized lipodystrophy; and
2. Approvals will not be granted for the following diagnoses:
   a. Metabolic disease without current evidence of generalized lipodystrophy; or
   b. HIV-related lipodystrophy; or
   c. General obesity not associated with congenital leptin deficiency; and
3. Myalept® must be prescribed by an endocrinologist; and
4. The prescriber must agree to test for neutralizing antibodies in patients who experience severe infections or if they suspect Myalept® is no longer effective; and
   a. Baseline hemoglobin A1c (HbA1c), fasting glucose, and fasting triglycerides must be stated on the prior authorization request; and
   b. Re-approvals will require recent lab values (HbA1c, fasting glucose, and fasting triglycerides) to ensure neutralizing antibodies have not developed; and
5. Prescriber and pharmacy must be enrolled in the Myalept® REMS program; and
6. Approvals will be for the duration of 3 months to evaluate compliance and ensure the prescriber is assessing continued efficacy; and
7. A quantity limit of 1 vial per day will apply.

Utilization of Myalept® (Metreleptin): Fiscal Year 2019

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	1	12	$482,908.20	$40,242.35	$1,341.41	120	360
2019	1	13	$577,263.03	$44,404.85	$1,480.16	130	390
% Change	**0.0%**	**8.3%**	**19.5%**	**10.3%**	**10.3%**	**8.3%**	**8.3%**
Change	**0**	**1**	**$94,354.83**	**$4,162.50**	**$138.75**	**10**	**30**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Demographics of Members Utilizing Myalept® (Metreleptin)

- Due to the small number of members utilizing Myalept® (metreleptin), detailed demographic information could not be provided.

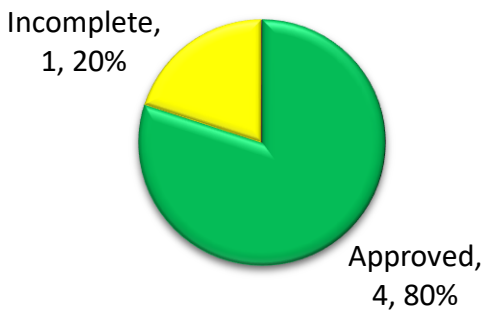
Top Prescriber Specialties of Myalept® (Metreleptin) by Number of Claims

- The only prescriber specialty list on paid claims for Myalept® (metreleptin) during fiscal year 2019 was pediatric endocrinology.

Prior Authorization of Myalept® (Metreleptin)

There were 5 prior authorization requests submitted for 1 unique member for Myalept® (metreleptin) during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.

Status of Petitions



Recommendations

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

Fiscal Year 2019 Annual Review of Mytesi® (Crofelemer) [Formerly Known As Fulyzaq®]

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Mytesi® (Crofelemer) [Formerly Known As Fulyzaq®] Approval Criteria:

1. An FDA approved diagnosis of non-infectious diarrhea in adult patients with HIV/AIDS currently on anti-retroviral therapy; and
2. Duration of diarrhea has been ≥4 weeks; and
3. Dietary modifications have failed; and
4. Prescribers must verify that infectious diarrhea has been ruled out via confirmation of all of the following:
    a. CD4 count has been measured and possible opportunistic infections have been ruled out; and
    b. Member does not have fever; and
    c. Stool studies for pathogens are negative including:
        i. Bacterial cultures; and
        ii. Ova, Parasite, Cryptosporidium, and/or Giardia; and
        iii. *Clostridium difficile* (*Clostridium difficile* testing should include a glutamate dehydrogenase screen and if positive, followed by a confirmatory test or nucleic acid amplification test in patients with documented diarrhea. A toxin enzyme immunoassay should not be used as a stand-alone test.); and
5. If stool study results are negative and the patient has severe symptoms, particularly in the case of advanced immunodeficiency, an endoscopy with biopsy is recommended, at the doctor's discretion, to rule out inflammatory bowel disease, cancer, cytomegalovirus (CMV) infection, microsporidium, or mycobacterium avium complex (MAC); and
6. A quantity limit of 60 tablets per 30 days will apply. Initial approvals will be for 4 weeks of therapy. An additional 6-month approval may be granted if the prescriber documents the member is responding well to treatment.

Utilization of Mytesi® (Crofelemer): Fiscal Year 2019

There was no SoonerCare utilization of Mytesi® (crofelemer) during fiscal year 2019.

Prior Authorization of Mytesi® (Crofelemer)

There were no prior authorization requests submitted for Mytesi® (crofelemer) during fiscal year 2019.

Market News and Updates

Anticipated Patent Expiration(s): Mytesi® (crofelemer): October 2031[107]

Recommendations

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

[107] 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?resetfields=1. Last revised 12/2019. Last accessed 12/13/2019.

Fiscal Year 2019 Annual Review of Naloxone Medications

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

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

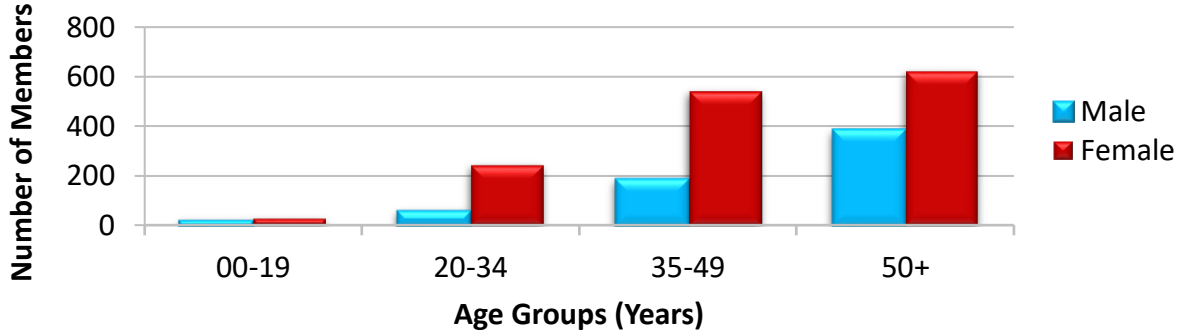
Utilization of Naloxone Medications: Fiscal Year 2019

Comparison of Fiscal Years

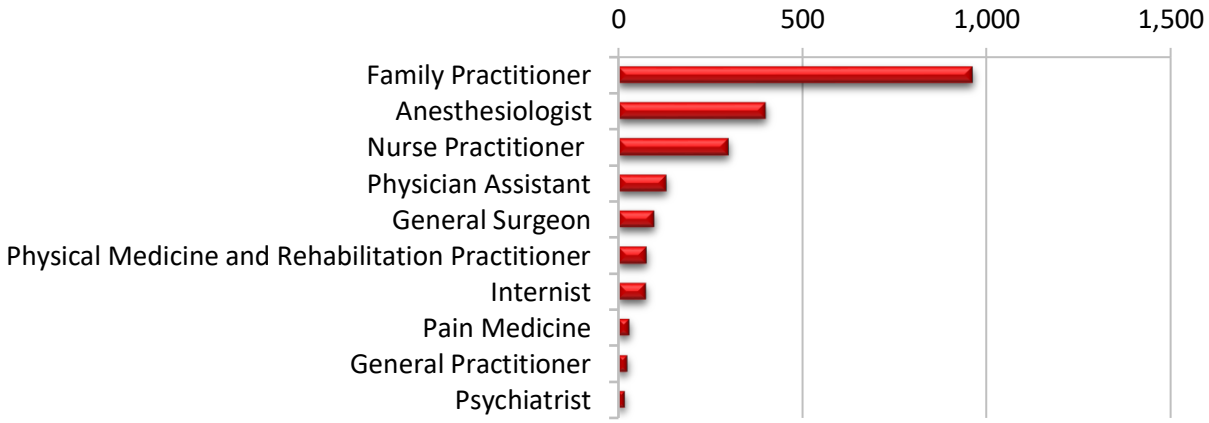
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	1,356	1,394	$159,385.28	$114.34	$3.76	2,859	42,380
2019	2,069	2,191	$273,817.98	$124.97	$4.16	4,429	65,787
% Change	**52.6%**	**57.2%**	**71.8%**	**9.3%**	**10.6%**	**54.9%**	**55.2%**
Change	**713**	**797**	**$114,432.70**	**$10.63**	**$0.40**	**1,570**	**23,407**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Demographics of Members Utilizing Naloxone Medications



Top Prescriber Specialties of Naloxone Medications by Number of Claims



Market News and Updates

Anticipated Patent Expiration(s):[108]

- Evzio® (naloxone auto-injector): July 2034
- Narcan® (naloxone nasal spray): March 2035

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

- **April 2019:** The FDA granted final approval of the first generic naloxone hydrochloride nasal spray (generic Narcan®) to stop or reverse the effects of an opioid overdose in a community setting by individuals without medical training. The FDA had previously tentatively approved this generic drug product in June 2018. Teva Pharmaceuticals has received final FDA approval to market generic naloxone nasal spray.[109]

News:

- **January 2019:** According to Douglas Throckmorton, M.D., deputy center director for regulatory programs, the FDA announced action to help facilitate an over-the-counter (OTC) naloxone product. The FDA posted 2 models of Drug Fact Labels (DFLs) and supporting FDA review in an effort to jump start the development of OTC naloxone products. Sponsors can use these labeling models to obtain approval for OTC naloxone. Additionally, the FDA held a 2-day advisory committee meeting to solicit input and advice on strategies to increase the availability of naloxone products intended for use in the community.[110]

Recommendations

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

Utilization Details of Naloxone Medications: Fiscal Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
NARCAN SPR 4MG/0.1ML	2,080	1,977	$268,356.47	$4.26	$129.02
NALOXONE INJ 1MG/ML	108	106	$5,386.83	$1.97	$49.88
NALOXONE INJ 0.4MG/ML	2	2	$50.88	$16.96	$25.44
NALOXONE INJ 0.4MG/ML	1	1	$23.80	$23.80	$23.80
TOTAL	**2,191**	**2,069***	**$273,817.98**	**$4.16**	**$124.97**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs. Fiscal Year 2019 = 07/01/2018 to 06/30/2019

[108] 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 12/2019. Last accessed 01/09/2020.
[109] FDA approves first generic naloxone nasal spray to treat opioid overdose. *FDA News Release*. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-generic-naloxone-nasal-spray-treat-opioid-overdose. Last revised 04/09/2019. Last accessed 01/09/2020.
[110] Statement from FDA Commissioner Scott Gottlieb, M.D., on unprecedented new efforts to support development of over-the-counter naloxone to help reduce opioid overdose deaths. *FDA Statement*. Available online at: https://kaleo.com/in-the-news/authorized-generic-for-evzio-naloxone-hcl-injection-to-be-available-at-a-reduced-list-price-of-178/. Published 12/12/2018. Last accessed 03/31/2019.

Fiscal Year 2019 Annual Review of Nasal Allergy Medications

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

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

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), or Wholesale Acquisition Costs (WAC) if NADAC unavailable.
*Xhance™: Unique criteria applies.

Nasal Allergy Medications Tier-2 Approval Criteria:

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

Nasal Allergy Medications Tier-3 Approval Criteria:

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

Xhance™ (Fluticasone Propionate Nasal Spray) Approval Criteria:

1. An FDA approved diagnosis of nasal polyps; and

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

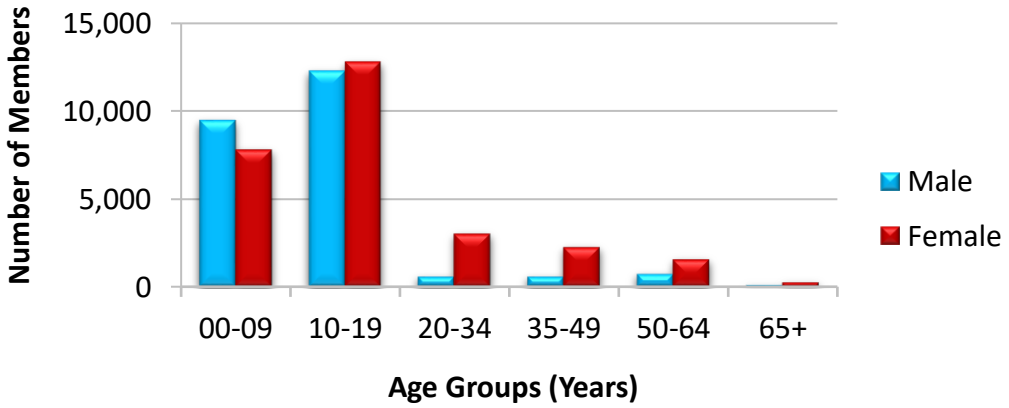
Utilization of Nasal Allergy Medications: Fiscal Year 2019

Comparison of Fiscal Years

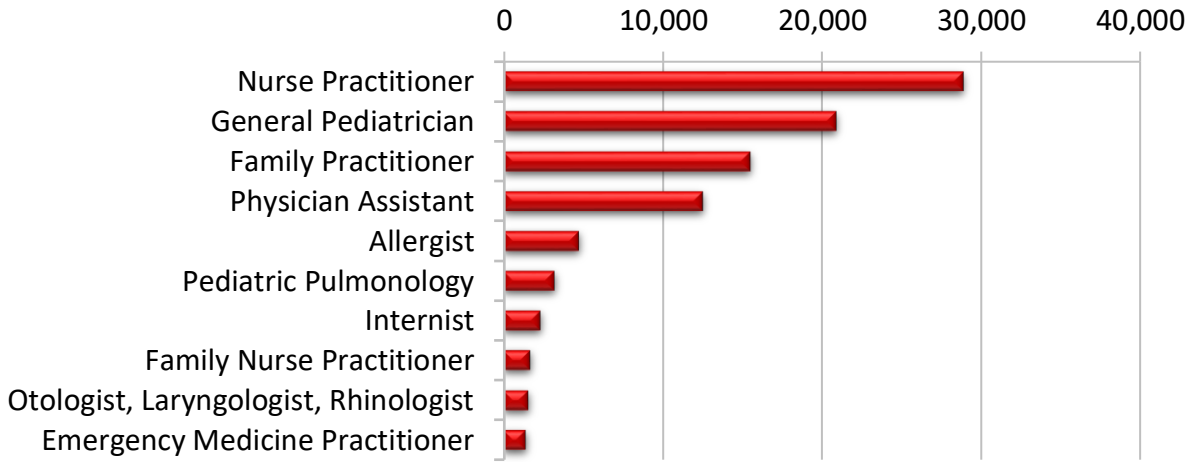
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	51,822	98,760	$1,720,497.65	$17.42	$0.47	1,591,821	3,659,086
2019	51,311	96,828	$1,752,698.34	$18.10	$0.48	1,563,393	3,662,649
% Change	**-1.00%**	**-2.00%**	**1.90%**	**3.90%**	**2.10%**	**-1.80%**	**0.10%**
Change	**-511**	**-1,932**	**$32,200.69**	**$0.68**	**$0.01**	**-28,428**	**3,563**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Demographics of Members Utilizing Nasal Allergy Medications

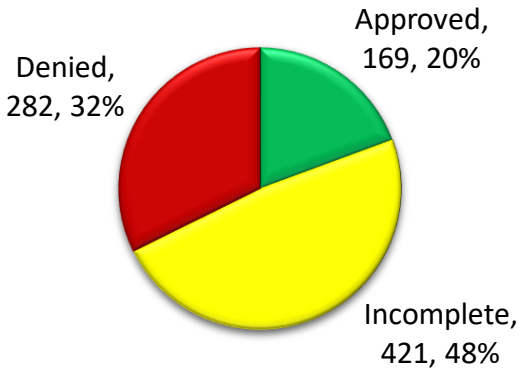


Top Prescriber Specialties of Nasal Allergy Medications by Number of Claims



Prior Authorization of Nasal Allergy Medications

There were 872 prior authorization requests submitted for nasal allergy medications during fiscal year 2019. Computer edits are in place to detect lower tiered medications in a member's recent claims history and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions for fiscal year 2019.



Market News and Updates

Anticipated Patent Expiration(s):[111]

- Patanase® (olopatadine): August 2023
- Dymista® (azelastine/fluticasone): August 2026
- Omnaris® (ciclesonide): February 2028
- Zetonna® (ciclesonide): February 2028
- Astepro® (azelastine): June 2028
- Qnasl® (beclomethasone): October 2031
- Xhance® (fluticasone): July 2035

Recommendations

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

Utilization Details of Nasal Allergy Medications: Fiscal Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 PRODUCTS						
FLUTICASONE SPR 50MCG	95,124	50,873	$1,368,055.02	$14.38	1.87	78.05%
BECONASE AQ SUS 0.042%	1,162	585	$334,410.49	$287.79	1.99	19.08%
SUBTOTAL	**96,286**	**51,247***	**$1,702,465.51**	**$17.68**	**1.88**	**97.13%**
TIER-2 PRODUCTS						
AZELASTINE SPR 0.1%	262	105	$5,653.25	$21.58	2.5	0.32%
QNASL AER 80MCG	89	27	$18,196.83	$204.46	3.3	1.04%

[111] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 03/2020. Last accessed 03/11/2020.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**351**	**130***	**$23,850.08**	**$67.95**	**2.7**	**1.36%**
TIER-3 PRODUCTS						
DYMISTA SPR 137-50	74	15	$13,075.16	$176.69	4.93	0.75%
MOMETASONE SPR 50MCG	43	23	$2,664.43	$61.96	1.87	0.15%
QNASL CHILD SPR 40MCG	33	7	$7,089.05	$214.82	4.71	0.40%
OLOPATADINE SPR 0.6%	24	3	$2,165.21	$90.22	8	0.12%
FLUNISOLIDE SPR 0.025%	10	1	$620.62	$62.06	10	0.04%
AZELASTINE SPR 0.15%	6	2	$308.01	$51.34	3	0.02%
XHANCE MIS 93MCG	1	1	$460.27	$460.27	1	0.03%
SUBTOTAL	**191**	**52***	**$26,382.75**	**$138.13**	**3.67**	**1.51%**
TOTAL	**96,828**	**51,311***	**$1,752,698.34**	**$18.10**	**1.89**	**100%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Fiscal Year 2019 Annual Review of Nonsteroidal Anti-Inflammatory Drugs (NSAIDs; Systemic)

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)		
Tier-1	**Tier-2**	**Special PA**
celecoxib (Celebrex®) 50mg, 100mg, & 200mg caps	diclofenac potassium (Cataflam®)	celecoxib (Celebrex®) 400mg caps
diclofenac epolamine (Flector® Patch)	diclofenac sodium/ misoprostol (Arthrotec®)	diclofenac (Zorvolex®)
diclofenac ER (Voltaren® XR)	diclofenac sodium (Voltaren®) 25mg tabs	diclofenac potassium (Cambia®) powder pack
diclofenac sodium (Voltaren®) 50mg & 75mg tabs	etodolac (Lodine®) 200mg & 300mg caps	diclofenac potassium (Zipsor®) caps
diclofenac sodium 1% (Voltaren® Gel)	etodolac ER (Lodine® XL)	diclofenac sodium (Dyloject™)
etodolac (Lodine®) 400mg & 500mg tabs	naproxen sodium (Anaprox®) 275mg & 550mg tabs	diclofenac sodium (Pennsaid®) topical drops
flurbiprofen (Ansaid®)	oxaprozin (Daypro®)	fenoprofen (Nalfon®)
ibuprofen (Motrin®)	piroxicam (Feldene®)	ibuprofen/famotidine (Duexis®)
ketoprofen (Orudis®)	tolmetin (Tolectin®)	indomethacin (Indocin®) susp & ER caps
meloxicam (Mobic®)		indomethacin (Tivorbex®)
nabumetone (Relafen®)		ketoprofen ER (Oruvail®)
naproxen (Naprosyn®)		ketorolac tromethamine (Sprix®) nasal spray
naproxen EC (Naprosyn®)		meclofenamate (Meclomen®)
sulindac (Clinoril®)		mefenamic acid (Ponstel®)
		meloxicam (Vivlodex®) caps
		meloxicam ODT (Qmiiz ODT™)
		nabumetone 1,000mg (Relafen DS®)
		naproxen sodium ER (Naprelan®)
		naproxen/esomeprazole (Vimovo®)

ER = extended-release; EC = enteric coated; caps = capsules; tabs = tablets; susp = suspension; PA = prior authorization; ODT = orally disintegrating tablet
Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

NSAIDs Tier-2 Approval Criteria:

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

NSAIDs Special Prior Authorization (PA) Approval Criteria:

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

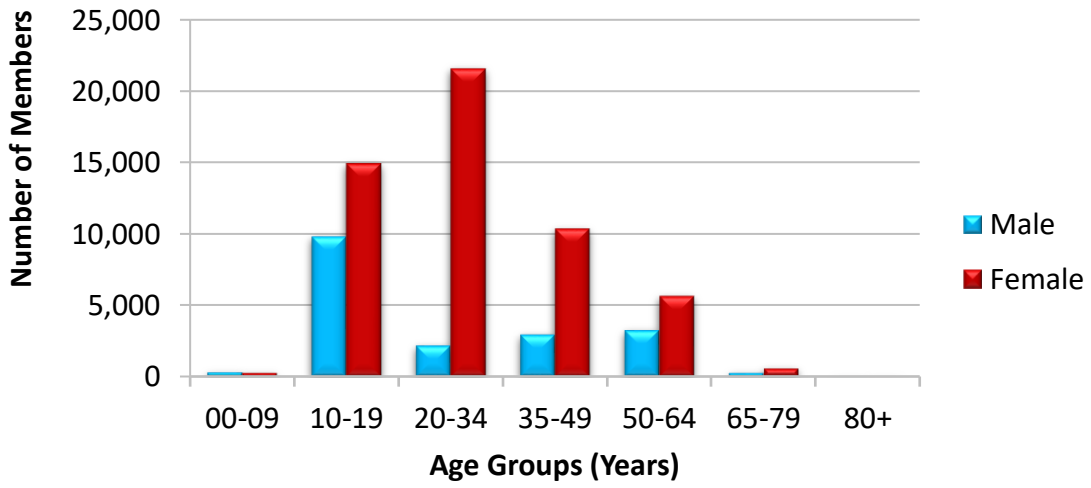
Utilization of NSAIDs: Fiscal Year 2019

Comparison of Fiscal Years

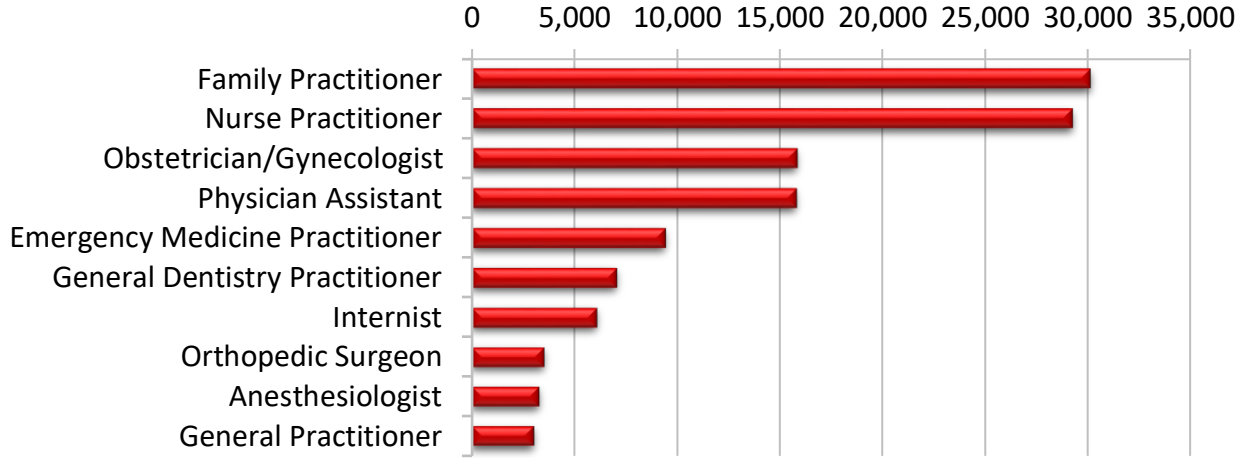
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	72,538	136,757	$1,827,085.23	$13.36	$0.59	6,560,679	3,123,174
2019	72,131	137,031	$1,949,639.44	$14.23	$0.62	6,750,006	3,124,294
% Change	**-0.60%**	**0.20%**	**6.70%**	**6.50%**	**5.10%**	**2.90%**	**0.00%**
Change	**-407**	**274**	**$122,554.21**	**$0.87**	**$0.03**	**189,327**	**1,120**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Demographics of Members Utilizing NSAIDs

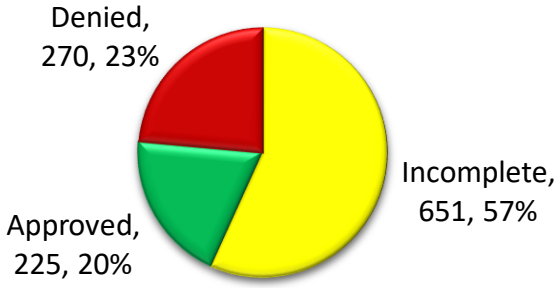


Top Prescriber Specialties of NSAIDs by Number of Claims



Prior Authorization of NSAIDs

There were 1,146 prior authorization requests submitted for NSAIDs during fiscal year 2019. Computer edits are in place to detect lower tiered medications in a member's recent claims history and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions for fiscal year 2019.



Market News and Updates

Anticipated Patent Expiration(s):[112]

- Cambia® (diclofenac potassium powder pack): June 2026
- Duexis® (ibuprofen/famotidine tablet): July 2026
- Dyloject™ (diclofenac sodium for injection): March 2027
- Zipsor® (diclofenac potassium capsule): February 2029
- Tivorbex® (indomethacin capsule): April 2030
- Zorvolex® (diclofenac capsule): April 2030
- Pennsaid® (diclofenac sodium 2% topical drops): August 2030
- Vimovo® (naproxen/esomeprazole tablet): October 2031
- Vivlodex® (meloxicam capsule): March 2035

[112] 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 01/2020. Last accessed 01/10/2020.

News:

- **October 2019:** The American College of Rheumatology (ACR) and Arthritis Foundation published updated guidelines for the management of osteoarthritis (OA) of the hand, hip, and knee. These guidelines update the 2012 OA guidelines from the ACR. Key pharmacologic recommendations include:
  - **Topical NSAIDs:** Topical NSAIDs are strongly recommended for knee OA and conditionally recommended for hand OA and should be considered prior to use of oral NSAIDs. For hip OA, topical NSAIDs are unlikely to be beneficial due to the depth of the joint.
  - **Oral NSAIDs:** Oral NSAIDs are strongly recommended for knee, hip, and hand OA and remain the mainstay of pharmacotherapy for OA. Oral NSAIDs should be the initial oral medication for all types of OA and are preferred over all other oral medications. It is recommended that doses should be as low as possible and should continue for the shortest duration possible.
  - **Tramadol:** Tramadol is conditionally recommended for use in knee, hip, and hand OA. If treatment with an opioid is being considered, tramadol is recommended over all other non-tramadol opioids.
  - **Non-tramadol opioids:** All other non-tramadol opioids are conditionally recommended against in knee, hip, and hand OA due to a lack of evidence for the benefits of long-term opioid therapy, considered with the high risk of toxicity and dependence. However, the recommendation recognizes that non-tramadol opioids may be used in certain instances, primarily when all alternatives have been exhausted.
  - **Tumor necrosis factor (TNF) inhibitors and interleukin-1 (IL-1) receptor antagonists:** These agents have not been demonstrated to be effective for OA and, when considered with their known risk of toxicity, are strongly recommended against in knee, hip, and hand OA.[113]

Recommendations

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

Utilization Details of NSAIDs: Fiscal Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
IBUPROFEN PRODUCTS						
IBUPROFEN TAB 800MG	42,826	28,713	$502,551.78	$11.73	1.49	25.78%
IBUPROFEN TAB 600MG	11,207	9,376	$123,160.53	$10.99	1.2	6.32%
IBU TAB 800MG	4,903	3,516	$60,789.53	$12.40	1.39	3.12%
IBUPROFEN TAB 400MG	3,077	2,235	$35,639.15	$11.58	1.38	1.83%

[113] ACR Clinical Practice Guidelines – Osteoarthritis. Available online at: https://www.rheumatology.org/Practice-Quality/Clinical-Support/Clinical-Practice-Guidelines/Osteoarthritis. Last accessed 01/10/2020.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
IBU TAB 600MG	1,062	873	$12,898.39	$12.15	1.22	0.66%
IBU TAB 400MG	314	262	$3,765.51	$11.99	1.2	0.19%
IBUPROFEN SUS 100/5ML	1	1	$27.90	$27.90	1	0.00%
SUBTOTAL	**63,390**	**44,976**	**$738,832.79**	**$11.66**	**1.41**	**37.90%**
MELOXICAM PRODUCTS						
MELOXICAM TAB 15MG	17,675	8,210	$152,962.15	$8.65	2.15	7.85%
MELOXICAM TAB 7.5MG	8,603	4,500	$79,284.19	$9.22	1.91	4.07%
SUBTOTAL	**26,278**	**12,710**	**$232,246.34**	**$8.84**	**2.07**	**11.91%**
NAPROXEN PRODUCTS						
NAPROXEN TAB 500MG	19,848	12,913	$233,591.30	$11.77	1.54	11.98%
NAPROXEN TAB 375MG	2,179	1,631	$26,718.99	$12.26	1.34	1.37%
NAPROXEN TAB 250MG	1,771	1,209	$21,734.69	$12.27	1.46	1.11%
NAPROXEN SUS 125/5ML	586	354	$110,952.39	$189.34	1.66	5.69%
NAPROXEN DR TAB 500MG	468	288	$8,835.66	$18.88	1.63	0.45%
NAPROXEN SOD TAB 550MG	123	72	$4,736.16	$38.51	1.71	0.24%
NAPROXEN DR TAB 375MG	113	68	$1,727.76	$15.29	1.66	0.09%
EC-NAPROXEN TAB 500MG	25	24	$453.38	$18.14	1.04	0.02%
NAPROXEN SOD TAB 275MG	5	4	$322.25	$64.45	1.25	0.02%
SUBTOTAL	**25,118**	**16,563**	**$409,072.58**	**$16.29**	**1.52**	**20.98%**
DICLOFENAC PRODUCTS						
DICLOFENAC TAB 75MG DR	5,786	2,715	$87,525.28	$15.13	2.13	4.49%
DICLOFENAC TAB 50MG DR	2,108	1,100	$34,993.04	$16.60	1.92	1.79%
DICLOFENAC GEL 1%	2,052	1,325	$83,954.37	$40.91	1.55	4.31%
DICLOFEN POT TAB 50MG	260	131	$9,099.42	$35.00	1.98	0.47%
DICLOFENAC TAB 100MG ER	206	97	$8,741.26	$42.43	2.12	0.45%
FLECTOR DIS 1.3%	70	47	$24,318.23	$347.40	1.49	1.25%
DICLOFENAC TAB 25MG DR	26	14	$1,414.56	$54.41	1.86	0.07%
DICLOFENAC DIS 1.3%	17	15	$4,349.62	$255.86	1.13	0.22%
VOLTAREN GEL 1%	10	9	$905.87	$90.59	1.11	0.05%
PENNSAID SOL 2%	5	5	$11,986.52	$2,397.30	1	0.61%
CAMBIA POW 50MG	3	2	$3,697.98	$1,232.66	1.5	0.19%
DICLOFENAC SOL 1.5%	2	1	$96.04	$48.02	2	0.00%
SUBTOTAL	**10,545**	**5,461**	**$271,082.19**	**$25.71**	**1.93**	**13.90%**
CELECOXIB PRODUCTS						
CELECOXIB CAP 200MG	2,625	1,093	$46,497.32	$17.71	2.4	2.38%
CELECOXIB CAP 100MG	1,028	417	$19,815.99	$19.28	2.47	1.02%
CELECOXIB CAP 50MG	28	16	$625.55	$22.34	1.75	0.03%
CELEBREX CAP 200MG	9	1	$6,454.57	$717.17	9	0.33%
SUBTOTAL	**3,690**	**1,527**	**$73,393.43**	**$19.89**	**2.42**	**3.76%**
NABUMETONE PRODUCTS						
NABUMETONE TAB 750MG	1,384	536	$29,074.33	$21.01	2.58	1.49%
NABUMETONE TAB 500MG	1,055	481	$19,903.99	$18.87	2.19	1.02%
SUBTOTAL	**2,439**	**1,017**	**$48,978.32**	**$20.08**	**2.40**	**2.51%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
KETOROLAC PRODUCTS						
KETOROLAC TAB 10MG	2,396	2,064	$58,381.52	$24.37	1.16	2.99%
KETOROLAC INJ 60MG/2ML	28	11	$352.70	$12.60	2.55	0.02%
KETOROLAC INJ 30MG/ML	8	7	$101.27	$12.66	1.14	0.01%
KETOROLAC INJ 15MG/ML	4	1	$50.92	$12.73	4	0.00%
SUBTOTAL	**2,436**	**2,083**	**$58,886.41**	**$24.17**	**1.17**	**3.02%**
ETODOLAC PRODUCTS						
ETODOLAC TAB 400MG	1,209	721	$35,325.22	$29.22	1.68	1.81%
ETODOLAC TAB 500MG	594	218	$22,656.41	$38.14	2.72	1.16%
ETODOLAC CAP 300MG	98	58	$4,823.83	$49.22	1.69	0.25%
ETODOLAC CAP 200MG	52	34	$2,249.34	$43.26	1.53	0.12%
ETODOLAC ER TAB 400MG	21	7	$1,828.27	$87.06	3	0.09%
ETODOLAC ER TAB 600MG	20	5	$2,991.19	$149.56	4	0.15%
ETODOLAC ER TAB 500MG	2	2	$231.83	$115.92	1	0.01%
SUBTOTAL	**1,996**	**1,045**	**$70,106.09**	**$35.12**	**1.91**	**3.60%**
INDOMETHACIN PRODUCTS						
INDOMETHACIN CAP 50MG	408	252	$5,093.53	$12.48	1.62	0.26%
INDOMETHACIN CAP 25MG	282	198	$3,798.80	$13.47	1.42	0.19%
INDOCIN SUS 25MG/5ML	32	7	$22,723.10	$710.10	4.57	1.17%
INDOMETHACIN CAP 75MG ER	17	7	$289.43	$17.03	2.43	0.01%
SUBTOTAL	**739**	**464**	**$31,904.86**	**$43.17**	**1.59**	**1.64%**
SULINDAC PRODUCTS						
SULINDAC TAB 150MG	147	52	$2,410.03	$16.39	2.83	0.12%
SULINDAC TAB 200MG	107	52	$1,985.95	$18.56	2.06	0.10%
SUBTOTAL	**254**	**104**	**$4,395.98**	**$17.31**	**2.44**	**0.23%**
FLURBIPROFEN PRODUCTS						
FLURBIPROFEN TAB 100MG	44	23	$1,179.49	$26.81	1.91	0.06%
FLURBIPROFEN TAB 50MG	6	2	$110.66	$18.44	3	0.01%
SUBTOTAL	**50**	**25**	**$1,290.15**	**$25.80**	**2**	**0.07%**
DICLOFENAC/MISOPROSTOL PRODUCTS						
DICLO/MISOPR TAB 75-0.2MG	28	9	$3,286.13	$117.36	3.11	0.17%
DICLO/MISOPR TAB 50-0.2MG	2	2	$267.31	$133.66	1	0.01%
SUBTOTAL	**30**	**11**	**$3,553.44**	**$118.45**	**2.73**	**0.18%**
KETOPROFEN PRODUCTS						
KETOPROFEN CAP 25MG	17	14	$1,686.40	$99.20	1.21	0.09%
KETOPROFEN CAP 50MG	4	4	$78.76	$19.69	1	0.00%
KETOPROFEN CAP 75MG	4	4	$66.76	$16.69	1	0.00%
SUBTOTAL	**25**	**22**	**$1,831.92**	**$73.28**	**1.14**	**0.09%**
OXAPROZIN PRODUCTS						
OXAPROZIN TAB 600MG	22	6	$1,315.85	$59.81	3.67	0.07%
SUBTOTAL	**22**	**6**	**$1,315.85**	**$59.81**	**3.67**	**0.07%**
FENOPROFEN PRODUCTS						
FENOPROFEN TAB 600MG	6	1	$1,242.86	$207.14	6	0.06%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
FENOPROFEN CAP 400MG	4	1	$1,183.60	$295.90	4	0.06%
SUBTOTAL	**10**	**2**	**$2,426.46**	**$242.65**	**5**	**0.12%**
PIROXICAM PRODUCTS						
PIROXICAM CAP 10MG	7	5	$274.89	$39.27	1.4	0.01%
PIROXICAM CAP 20MG	2	2	$47.74	$23.87	1	0.00%
SUBTOTAL	**9**	**7**	**$322.63**	**$35.85**	**1.29**	**0.02%**
TOTAL	**137,031**	**72,131***	**$1,949,639.44**	**$14.23**	**1.90**	**100.00%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019
Please note, effective 01/01/2019, Voltaren® Gel (diclofenac topical gel) and Flector® Patch (diclofenac topical patch) moved to Tier-1.

Fiscal Year 2019 Annual Review of Northera™ (Droxidopa)

Oklahoma Health Care Authority
Fiscal Year 2019 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:
    a. Midodrine; or
    b. Fludrocortisone; or
    c. Pyridostigmine; or
    d. Have a contraindication to all preferred medications; and
4. Initial approval will be for the duration of 2 weeks of treatment only; and
5. Continued approval 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 approval will be for the duration of 3 months. Each approval will require prescriber documentation of member response/effectiveness to Northera™.

Utilization of Northera™ (Droxidopa): Fiscal Year 2019

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	1	1	$1,012.91	$1,012.91	$72.35	42	14
2019	1	9	$134,578.75	$14,953.19	$498.44	4,860	270
% Change	**0.00%**	**800.00%**	**13,186.30%**	**1,376.30%**	**588.90%**	**11,471.40%**	**1,828.60%**
Change	**0**	**8**	**$133,565.84**	**$13,940.28**	**$426.09**	**4,818**	**256**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Demographics of Members Utilizing Northera™ (Droxidopa)

- Due to the limited number of members utilizing Northera™ (droxidopa), detailed demographic information could not be provided.

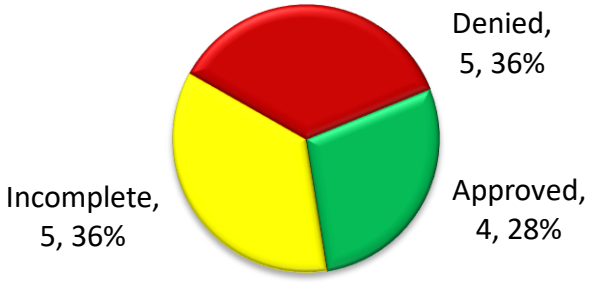
Top Prescriber Specialties of Northera™ by Number of Claims

- The only prescriber specialty listed on paid pharmacy claims for Northera™ (droxidopa) during fiscal year 2019 was cardiologist.

Prior Authorization of Northera™ (Droxidopa)

There were 14 prior authorization requests submitted for Northera™ (droxidopa) during fiscal year 2019. The 4 approved prior authorization requests were for 1 member, and there were 9 paid claims during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.

Status of Petitions



Market News and Updates

Anticipated Exclusivity Expiration(s):[114]

- Northera® (droxidopa): February 2021

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 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
NORTHERA 100MG	9	1	$134,578.75	$498.44	$14,953.19	100%
TOTAL	**9**	**1***	**$134,578.75**	**$498.4**	**$14,953.19**	**100%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

[114] 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/default.cfm?resetfields=1. Last revised 03/2020. Last accessed 03/24/2020.

Fiscal Year 2019 Annual Review of Nuedexta® (Dextromethorphan/Quinidine)

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Nuedexta® (Dextromethorphan/Quinidine) Approval Criteria:

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

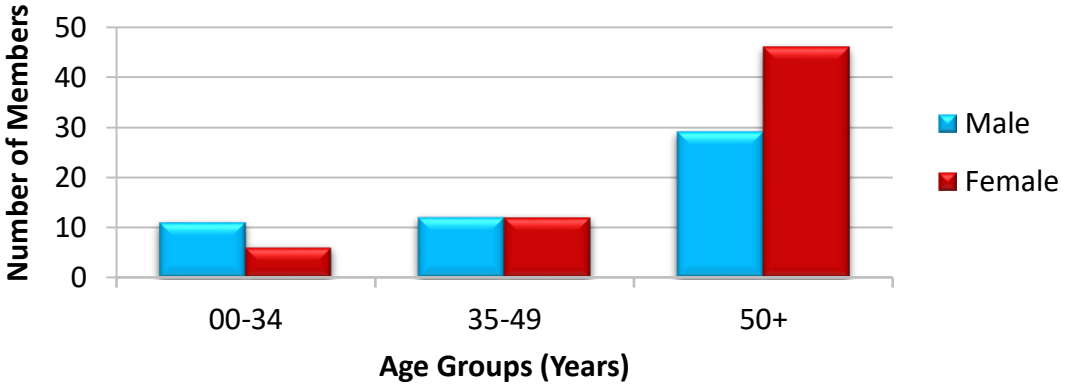
Utilization of Nuedexta® (Dextromethorphan/Quinidine): Fiscal Year 2019

Comparison of Fiscal Years

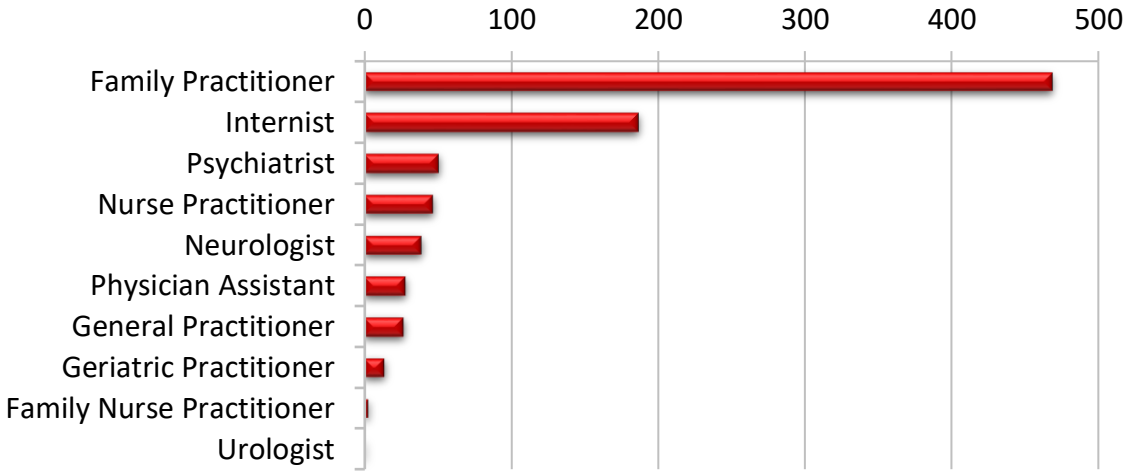
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	192	1,429	$1,012,865.72	$708.79	$26.29	74,829	38,526
2019	116	866	$827,763.95	$955.85	$34.37	46,164	24,081
% Change	**-39.6%**	**-39.4%**	**-18.3%**	**34.9%**	**30.7%**	**-38.3%**	**-37.5%**
Change	**-76**	**-563**	**-$185,101.77**	**$247.06**	**$8.08**	**-28,665**	**-14,445**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Demographics of Members Utilizing Nuedexta® (Dextromethorphan/Quinidine)

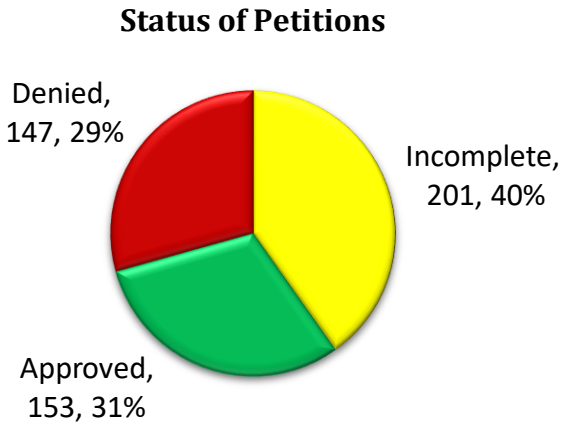


Top Prescriber Specialties of Nuedexta® (Dextromethorphan/Quinidine) by Number of Claims



Prior Authorization of Nuedexta® (Dextromethorphan/Quinidine)

There were 501 prior authorization requests submitted for Nuedexta® during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.



Market News and Updates

Anticipated Patent Expiration(s):[115]

- Nuedexta® (dextromethorphan/quinidine): August 2026

News:

- **September 2019:** Avanir Pharmaceuticals announced that the second phase 3 trial investigating the efficacy, safety, and tolerability of AVP-786 (deudextromethorphan hydrobromide/quinidine sulfate) for the treatment of moderate-to-severe agitation in patients with Alzheimer's dementia did not meet its primary and key secondary endpoints. Patients treated with AVP-786 did not experience a statistically significant improvement in agitation compared to patients treated with placebo, as measured by the Cohen-Mansfield Agitation Inventory (CMAI). The most common adverse events in patients receiving AVP-786 compared to placebo were falls, urinary tract infection, and somnolence.[116]
- **September 2019:** The U.S. Department of Justice (DOJ) reported that Avanir Pharmaceuticals has agreed to pay over $95 million to resolve kickback allegations as well as "false and misleading" marketing of the drug Nuedexta® in long-term care (LTC) facilities in a bid to get providers to prescribe it off-label for patients with dementia. The government alleged that Avanir paid physicians and other health care providers to write prescriptions for Nuedexta®, with payment provided in the form of money, honoraria, travel, and food. In particular, the DOJ said Avanir sought to capitalize on efforts by the Centers for Medicare & Medicaid Services (CMS) to reduce the use of antipsychotics in patients with dementia in LTC facilities because of concerns that these drugs may be used as a form of chemical restraint in patients.

---

[115] 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 03/2020. Last accessed 03/26/2020.
[116] Avanir Pharmaceuticals, Inc. Avanir Pharmaceuticals, Inc. Reports Data from the Second Phase 3 Study Evaluating Investigational AVP-786 for the Treatment of Moderate-to-Severe Agitation in Patients with Alzheimer's Dementia. Available online at: https://www.avanir.com/press/avanir-pharmaceuticals-inc-reports-data-second-phase-3-study-evaluating-investigational-avp. Issued 09/27/2019. Last accessed 03/26/2020.

Recommendations

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

Utilization Details of Nuedexta® (Dextromethorphan/Quinidine): Fiscal Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM	% COST
DEXTROMETHORPHAN/QUINIDINE PRODUCTS						
NUEDEXTA CAP 20-10MG	866	116	$827,763.95	7.47	$955.85	100%
TOTAL	**866**	**116***	**$827,763.95**	**7.47**	**$955.85**	**100%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Fiscal Year 2019 Annual Review of Ocaliva® (Obeticholic Acid)

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Ocaliva® (Obeticholic Acid) Approval Criteria:

1. An FDA approved diagnosis of primary biliary cholangitis (PBC); and
2. Member must have taken ursodeoxycholic acid (UDCA) at an appropriate dose for at least 1 year and prescriber must confirm patient compliance with UDCA and a lack of improvement in liver function tests; and
3. The prescriber must also confirm all of the following:
    a. PBC is not caused by a superimposed liver disease; and
    b. If the member has a superimposed liver disease, it is being adequately treated; and
    c. Proper timing of bile acid sequestrants if co-administered with UDCA (4 hours before or 4 hours after); and
4. Ocaliva® must be taken in combination with UDCA. For Ocaliva® monotherapy consideration, the prescriber must document a patient-specific, clinically significant reason why the member is unable to take UDCA; and
5. A quantity limit of 1 tablet per day will apply.

Utilization of Ocaliva® (Obeticholic Acid): Fiscal Year 2019

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	1	12	$73,611.60	$6,134.30	$204.48	360	360
2019	2	12	$79,125.24	$6,593.77	$219.79	360	360
% Change	**100.00%**	**0.00%**	**7.50%**	**7.50%**	**7.50%**	**0.00%**	**0.00%**
Change	**1**	**0**	**$5,513.64**	**$459.47**	**$15.31**	**0**	**0**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Demographics of Members Utilizing Ocaliva® (Obeticholic Acid)

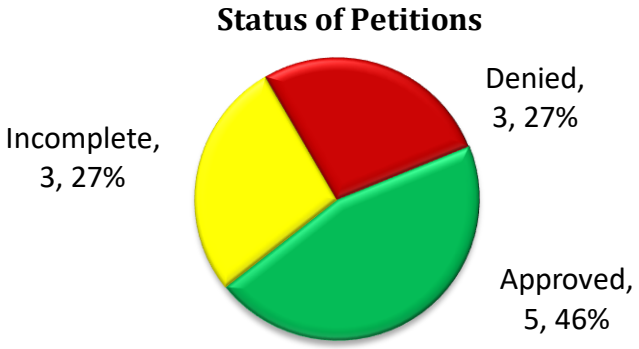
- Due to the limited number of members utilizing Ocaliva® (obeticholic acid), detailed demographic information could not be provided.

Top Prescriber Specialties of Ocaliva® (Obeticholic Acid) by Number of Claims

- The top prescribers of Ocaliva® (obeticholic acid) were nurse practitioner and gastroenterologist. The nurse practitioner is supervised by a gastroenterologist.

Prior Authorization of Ocaliva® (Obeticholic Acid)

There were 11 prior authorization requests submitted for Ocaliva® (obeticholic acid) during fiscal year 2019. The following chart shows the status of the submitted petitions.



Market News and Updates

Anticipated Exclusivity Expiration(s):[117]

- Ocaliva® (obeticholic acid): April 2036

News:

- **February 2018:** The U.S. Food and Drug Administration (FDA) issued a drug safety communication warning that Ocaliva® (obeticholic acid) has been incorrectly dosed daily instead of weekly in patients with moderate to severe primary biliary cholangitis (PBC), a rare chronic liver disease, increasing the risk of serious liver injury. The FDA has received reports that Ocaliva® is being given to PBC patients with moderate to severe liver impairment more often than is recommended in the prescribing information, resulting in liver decompensation, liver failure, and sometimes death. To ensure correct dosing and reduce the risk of liver problems, the FDA is clarifying the current recommendations for screening, dosing, monitoring, and managing PBC patients with moderate to severe liver disease taking Ocaliva®. The FDA is adding a *Boxed Warning* to highlight this information in the prescribing information for Ocaliva® and is also requiring a Medication Guide for patients to inform them about this issue. As a condition of approval, FDA required the manufacturer of Ocaliva®, Intercept Pharmaceuticals, to continue studying the medication in patients with advanced PBC. These clinical trials are currently ongoing and the FDA expects to receive results in 2023. FDA will continue to monitor this medication and will update the public if new information becomes available.[118]
- **November 2019:** Intercept Pharmaceuticals announced that the FDA has accepted a New Drug Application (NDA) for obeticholic acid (Ocaliva®), seeking accelerated

[117] 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/default.cfm?resetfields=1. Last revised 03/2020. Last accessed 03/04/2020.

[118] U.S. FDA Drug Safety Communication. FDA Adds Boxed Warning to Highlight Correct Dosing of Ocaliva® (Obeticholic Acid) for Patients with a Rare Chronic Liver Disease. Available online at: https://www.fda.gov/media/111167/download. Issued 02/01/2018. Last accessed 03/04/2020.

approval for the treatment of fibrosis due to nonalcoholic steatohepatitis (NASH) and has been granted Priority Review. The FDA grants Priority Review designation to drugs that have the potential to treat a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) target action date of March 26, 2020 for the NDA.[119]

Recommendations

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

Utilization Details of Ocaliva® (Obeticholic Acid): Fiscal Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	% COST
OCALIVA 10MG	9	2	$59,344.41	$6,593.82	75.00%
OCALIVA 5MG	3	1	$19,780.83	$6,593.61	25.00%
TOTAL	**12**	**2**	**$79,125.24**	**$6,593.77**	**100%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

[119] Intercept Pharmaceuticals, Inc. FDA Accepts Intercept's NDA for OCA for the Treatment of Liver Fibrosis due to NASH and Grants Priority Review. Globe Newswire. Available online at: http://ir.interceptpharma.com/news-releases/news-release-details/fda-accepts-intercepts-nda-oca-treatment-liver-fibrosis-due-nash. Issued 11/25/2019. Last accessed 03/04/2020.

Fiscal Year 2019 Annual Review of Ophthalmic Allergy Medications

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Ophthalmic Allergy Medications		
Tier-1	**Tier-2**	**Tier-3**
cromolyn (Crolom®)	azelastine (Optivar®)	alcaftadine (Lastacaft®)
ketotifen (Alaway®, Zaditor® OTC)	epinastine (Elestat®)	bepotastine (Bepreve®)
	olopatadine 0.1% (Patanol®)	cetirizine (Zerviate™)
	olopatadine 0.7% (Pazeo®)	emedastine (Emadine®)
		lodoxamide (Alomide®)
		loteprednol (Alrex®)
		nedocromil (Alocril®)
		olopatadine 0.2% (Pataday®)

OTC = Over-the-counter
Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC) or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

Ophthalmic Allergy Medications Tier-2 Approval Criteria:

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

Ophthalmic Allergy Medications Tier-3 Approval Criteria:

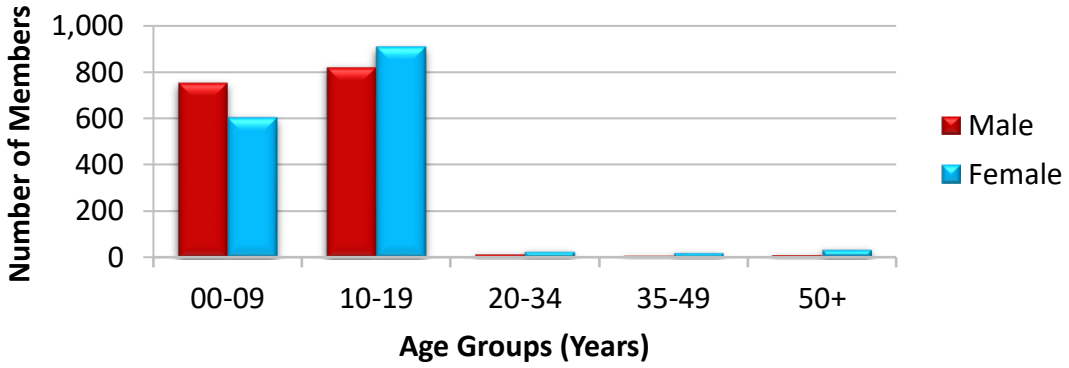
1. An FDA approved diagnosis; and
2. Recent trials of 1 Tier-1 product and all available Tier-2 medications for a minimum of 2 weeks each that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or
3. A contraindication to all lower tiered medications.

Utilization of Ophthalmic Allergy Medications: Fiscal Year 2019

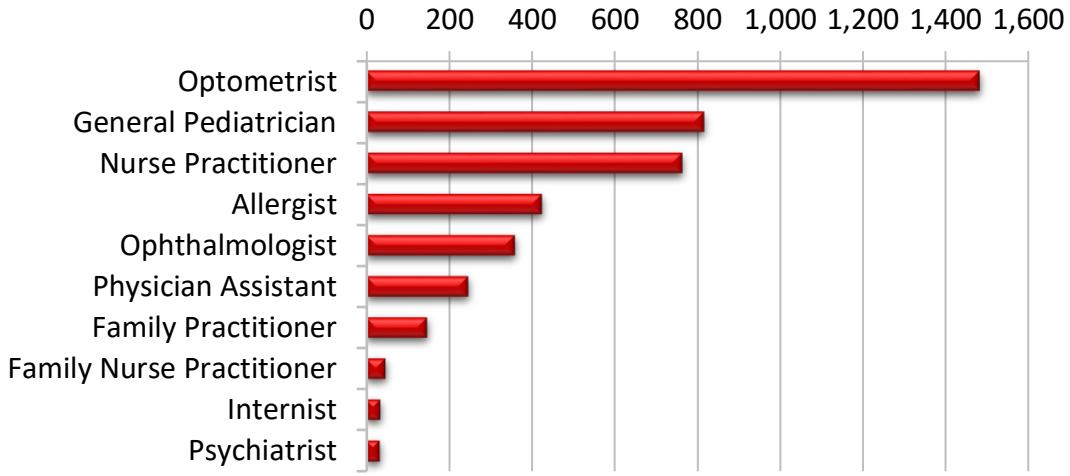
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	3,339	4,686	$93,393.85	$19.93	$0.61	31,236	153,907
2019	3,191	4,460	$81,852.53	$18.35	$0.56	29,019	145,998
% Change	**-4.40%**	**-4.80%**	**-12.40%**	**-7.90%**	**-8.20%**	**-7.10%**	**-5.10%**
Change	**-148**	**-226**	**-$11,541.32**	**-$1.58**	**-$0.05**	**-2,217**	**-7,909**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Demographics of Members Utilizing Ophthalmic Allergy Medications



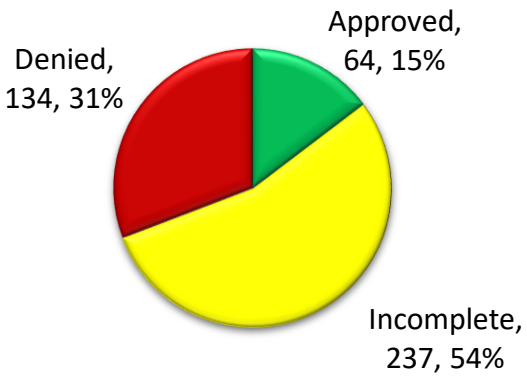
Top Prescriber Specialties of Ophthalmic Allergy Medications by Number of Claims



Prior Authorization of Ophthalmic Allergy Medications

There were 435 prior authorization requests submitted for ophthalmic allergy medications during fiscal year 2019. Computer edits are in place to detect lower tiered medications in a member's recent claims history and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions for fiscal year 2019.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[120]

- Pataday® (olopatadine): May 2024
- Bepreve® (bepotastine): September 2024
- Lastacaft® (alcaftadine): December 2027
- Pazeo® (olopatadine): May 2032
- Zerviate™ (cetirizine): January 2033

Pipeline:[121,122]

- **Reproxalap:** Aldeyra Therapeutics is developing reproxalap for the treatment of allergic conjunctivitis. Reproxalap is a novel immune-modulating reactive aldehyde species (RASP) inhibitor. RASP levels are generally elevated in ocular and systemic inflammatory disease. Reproxalap covalently binds to free aldehydes and lowers RASP levels, leading to reduced ocular inflammation in allergic conjunctivitis. Aldeyra is also developing reproxalap for an indication of dry eye disease. If approved for both indications, reproxalap would become the first U.S. Food and Drug Administration (FDA)-approved medication to treat both allergic conjunctivitis and dry eye disease. Results from the Phase 3 ALLEVIATE trial of reproxalap in allergic conjunctivitis were announced in October 2019 and showed a statistically significant reduction in ocular itching with reproxalap compared to placebo.

Recommendations

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

Utilization Details of Ophthalmic Allergy Medications: Fiscal Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 PRODUCTS						
KETOTIFEN PRODUCTS						
KETOTIF FUM DRO 0.025% OP	2,730	2,154	$41,089.08	$15.05	1.27	50.20%
ALAWAY DRO 0.025% OP	1,048	724	$15,217.25	$14.52	1.45	18.59%
ALAWAY CHILD DRO 0.025% OP	18	15	$268.50	$14.92	1.2	0.33%
EYE ITCH SOL RELIEF	17	13	$294.95	$17.35	1.31	0.36%
EYE ITCH REL DRO 0.025% OP	4	4	$68.02	$17.01	1	0.08%
ZADITOR DRO 0.025% OP	1	1	$16.49	$16.49	1	0.02%
SUBTOTAL	**3,818**	**2,911**	**$56,954.29**	**$14.92**	**1.31**	**69.58%**

[120] 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/default.cfm?resetfields=1. Last revised 03/2020. Last accessed 03/20/2020.

[121] Aldeyra Therapeutics, Inc. Aldeyra Pipeline & Disease Areas: Allergic Conjunctivitis. Available online at: https://www.aldeyra.com/pipeline-disease-areas/ocular-diseases/allergic-conjunctivitis/. Last accessed 03/20/2020.

[122] Park B. Reproxalap for Allergic Conjunctivitis Meets End Points in Phase 3 Trial. *MPR*. Available online at: https://www.empr.com/home/mpr-first-report/aao/aao-2019/reproxalap-for-allergic-conjunctivitis-meets-end-points-in-phase-3-trial/. Issued 10/13/2019. Last accessed 03/20/2020.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
CROMOLYN PRODUCTS						
CROMOLYN SOD SOL 4% OP	337	262	$5,244.16	$15.56	1.29	6.41%
SUBTOTAL	**337**	**262**	**$5,244.16**	**$15.56**	**1.29**	**6.41%**
TIER-1 SUBTOTAL	**4,155**	**3,133***	**$62,198.45**	**$14.97**	**1.33**	**75.99%**
TIER-2 PRODUCTS						
OLOPATADINE PRODUCTS						
OLOPATADINE DRO 0.1%	171	56	$4,196.19	$24.54	3.05	5.13%
PAZEO DRO 0.7%	72	10	$13,572.70	$188.51	7.2	16.58%
SUBTOTAL	**243**	**66**	**$17,768.89**	**$73.12**	**3.68**	**21.71%**
AZELASTINE PRODUCTS						
AZELASTINE DRO 0.05%	41	16	$829.85	$20.24	2.56	1.01%
SUBTOTAL	**41**	**16**	**$829.85**	**$20.24**	**2.56**	**1.01%**
EPINASTINE PRODUCTS						
EPINASTINE DRO 0.05%	4	4	$165.64	$41.41	1	0.20%
SUBTOTAL	**4**	**4**	**$165.64**	**$41.41**	**1**	**0.20%**
TIER-2 SUBTOTAL	**288**	**80***	**$18,764.38**	**$65.15**	**3.6**	**22.92%**
TIER-3 PRODUCTS						
OLOPATADINE PRODUCTS						
OLOPATADINE SOL 0.2%	16	6	$479.78	$29.99	2.67	0.59%
SUBTOTAL	**16**	**6**	**$479.78**	**$29.99**	**2.67**	**0.59%**
BEPOTASTINE PRODUCTS						
BEPREVE DRO 1.5%	1	1	$409.92	$409.92	1	0.50%
SUBTOTAL	**1**	**1**	**$409.92**	**$409.92**	**1**	**0.50%**
TIER-3 SUBTOTAL	**17**	**7***	**$889.70**	**$52.34**	**2.43**	**1.09%**
TOTAL	**4,460**	**3,191***	**$81,852.53**	**$18.35**	**1.40**	**100%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Fiscal Year 2019 Annual Review of Ophthalmic Antibiotic Medications

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Ophthalmic Antibiotics: Liquids		
Tier-1	**Tier-2**	**Tier-3**
ciprofloxacin (Ciloxan®)	levofloxacin (Quixin®)	azithromycin (Azasite®)
gentamicin (Gentak®)		besifloxacin (Besivance®)
neomycin/polymixin B/gramicidin (Neosporin®)		gatifloxacin (Zymaxid®)
ofloxacin (Ocuflox®)		moxifloxacin (Vigamox®, Moxeza®)
polymyxin B/trimethoprim (Polytrim®)		
sulfacetamide sodium (Bleph-10®)		
tobramycin (Tobrex®)		

Ophthalmic Antibiotics: Ointments	
Tier-1	**Tier-2**
bacitracin/polymyxin B (AK-Poly-Bac®)	bacitracin (AK-Tracin®)
erythromycin (Ilotycin™, Romycin®)	ciprofloxacin (Ciloxan®)
gentamicin (Gentak®)	sodium sulfacetamide (Bleph-10®)
neomycin/polymyxin B/bacitracin (Neosporin®)	
tobramycin (Tobrex®)	

Ophthalmic Antibiotics/Steroid Combination Products	
Tier-1	**Tier-2**
neomycin/polymyxin B/dexamethasone (Maxitrol®) susp & oint	bacitracin/polymyxin B/neomycin/hydrocortisone (Neo-Polycin® HC) oint
sulfacetamide/prednisolone 10%/0.23% solution	gentamicin/prednisolone (Pred-G®) susp & oint
tobramycin/dexamethasone 0.3%/0.1% (Tobradex®) susp*	neomycin/polymyxin B/hydrocortisone (Cortisporin®) susp
	sulfacetamide/prednisolone (Blephamide®) susp & oint
	tobramycin/dexamethasone (Tobradex®) oint
	tobramycin/dexamethasone (Tobradex® ST) oint
	tobramycin/loteprednol (Zylet®) susp

*Brand preferred
oint= ointment; susp= suspension; HC= hydrocortisone
Tier structure(s) based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

Ophthalmic Antibiotic Medications Tier-2 Approval Criteria:

1. An approved indication/suspected infection by an organism not known to be covered by Tier-1 products, or failure of a Tier-1 product; or
2. Known contraindication to all indicated Tier-1 medications; or
3. Prescriptions written by optometrists/ophthalmologists; or
4. When requested medication is being used for pre/post-operative prophylaxis.

Ophthalmic Antibiotic Medications Tier-3 Approval Criteria:

1. An approved indication/suspected infection by an organism not known to be covered by Tier-2 products, or failure of a Tier-2 product; or
2. Known contraindication to all indicated Tier-2 medications; or
3. Prescription written by optometrists/ophthalmologists; or
4. When requested medication is being used for pre/post-operative prophylaxis.

Ophthalmic Antibiotic/Steroid Combination Products Tier-2 Approval Criteria:

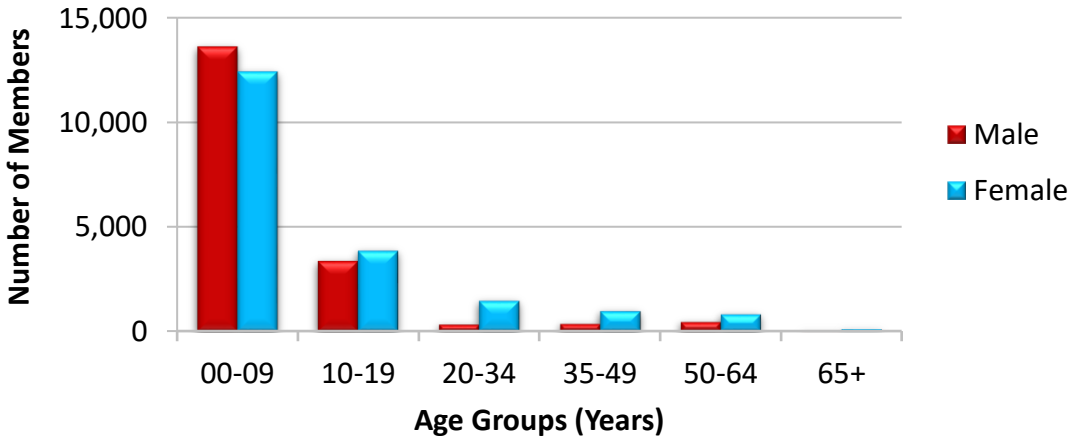
1. Prescription written by optometrists/ophthalmologists; or
2. When requested medication is being used for pre/post-operative prophylaxis.

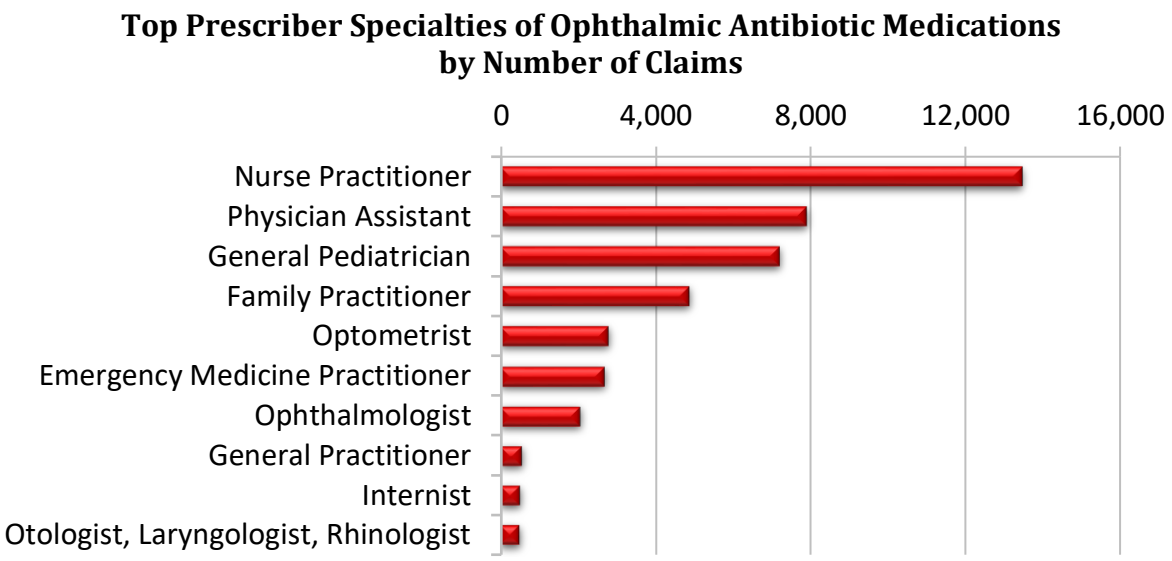
Utilization of Ophthalmic Antibiotic Medications: Fiscal Year 2019

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	39,020	45,840	$928,167.11	$20.25	$1.63	303,134	570,909
2019	37,901	44,261	$937,288.20	$21.18	$1.61	297,833	581,373
% Change	**-2.90%**	**-3.40%**	**1.00%**	**4.60%**	**-1.20%**	**-1.70%**	**1.80%**
Change	**-1,119**	**-1,579**	**$9,121.09**	**$0.93**	**-$0.02**	**-5,301**	**10,464**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

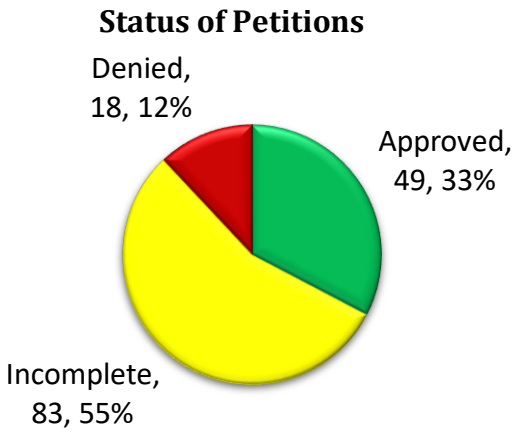
Demographics of Members Utilizing Ophthalmic Antibiotic Medications





Prior Authorization of Ophthalmic Antibiotic Medications

There were 150 prior authorization requests submitted for ophthalmic antibiotic medications during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.



Market News and Updates

Anticipated Patent Expiration(s):[123]

- Tobradex® ST (tobramycin/dexamethasone ophthalmic suspension): August 2028
- Moxeza® (moxifloxacin ophthalmic solution): May 2029
- Besivance® (besifloxacin ophthalmic suspension): January 2031

[123] 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/default.cfm?resetfields=1. Last revised 03/2020. Last accessed 03/20/2020.

Recommendations

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

Utilization Details of Ophthalmic Antibiotic Medications: Fiscal Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
OPHTHALMIC ANTIBIOTIC LIQUIDS						
TIER-1 PRODUCTS						
POLYMYXIN B/ SOL TRIMETHP	12,747	12,178	$199,366.84	$15.64	1.05	21.27%
OFLOXACIN DRO 0.3% OP	7,812	7,174	$185,955.37	$23.80	1.09	19.84%
TOBRAMYCIN SOL 0.3% OP	3,874	3,675	$57,759.60	$14.91	1.05	6.16%
GENTAMICIN SOL 0.3% OP	3,762	3,530	$54,921.64	$14.60	1.07	5.86%
SULFACET SOD SOL 10% OP	1,139	1,115	$47,105.89	$41.36	1.02	5.03%
CIPROFLOXACN SOL 0.3% OP	1,003	943	$15,571.08	$15.52	1.06	1.66%
SOD SULFACET SOL 10% OP	372	349	$17,314.20	$46.54	1.07	1.85%
NEO/POLY/GRA SOL OP	113	110	$5,674.69	$50.22	1.03	0.61%
TRIMETHOPRIM SOL POLYMYXN	85	85	$1,330.30	$15.65	1	0.14%
BLEPH-10 SOL 10% OP	18	18	$496.54	$27.59	1	0.05%
SUBTOTAL	**30,925**	**27,921***	**$585,496.15**	**$18.93**	**1.11**	**62.47%**
TIER-2 PRODUCTS						
LEVOFLOXACIN SOL 0.5%	1	1	$42.07	$42.07	1	0.00%
SUBTOTAL	**1**	**1***	**$42.07**	**$42.07**	**1**	**0.00%**
TIER-3 PRODUCTS						
MOXIFLOXACIN SOL HCL 0.5%	375	259	$12,047.29	$32.13	1.45	1.29%
BESIVANCE SUS 0.6%	112	88	$18,096.64	$161.58	1.27	1.93%
GATIFLOXACIN SOL 0.5%	53	43	$3,228.63	$60.92	1.23	0.34%
AZASITE SOL 1%	10	9	$1,753.64	$175.36	1.11	0.19%
MOXEZA SOL 0.5%	9	6	$1,166.93	$129.66	1.5	0.12%
SUBTOTAL	**559**	**397***	**$36,293.13**	**$64.93**	**1.41**	**3.87%**
LIQUID SUBTOTAL	**31,485**	**28,250***	**$621,831.35**	**$19.75**	**1.11**	**66.34%**
OPHTHALMIC ANTIBIOTIC OINTMENTS						
TIER-1 PRODUCTS						
ERYTHROMYCIN OIN OP	6,902	6,449	$121,931.89	$17.67	1.07	13.01%
ERYTHROMYCIN OIN 5MG/GM	1,830	1,735	$34,703.75	$18.96	1.05	3.70%
BACIT/POLYMY OIN OP	145	137	$2,906.51	$20.04	1.06	0.31%
TOBREX OIN 0.3% OP	100	97	$21,174.16	$211.74	1.03	2.26%
NEO-POLYCIN OIN OP	48	40	$1,741.07	$36.27	1.2	0.19%
GENTAK OIN 0.3% OP	30	30	$634.79	$21.16	1	0.07%
POLYCIN OIN OP	30	28	$599.34	$19.98	1.07	0.06%
NEO/BAC/POLY OIN OP	11	11	$430.65	$39.15	1	0.05%
AK-POLY-BAC OIN OP	2	2	$40.56	$20.28	1	0.00%
SUBTOTAL	**9,098**	**8,396***	**$184,162.72**	**$20.24**	**1.08**	**19.65%**
TIER-2 PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
BACITRACIN OIN OP	64	47	$6,249.53	$97.65	1.36	0.67%
CILOXAN OIN 0.3% OP	15	3	$3,250.07	$216.67	5	0.35%
SUBTOTAL	**79**	**50***	**$9,499.60**	**$120.25**	**1.58**	**1.01%**
OINTMENT SUBTOTAL	**9,177**	**8,434***	**$193,662.32**	**$21.10**	**1.09**	**20.66%**
OPHTHALMIC ANTIBIOTIC/STEROID COMBINATION PRODUCTS						
TIER-1 PRODUCTS						
NEO/POLY/DEX SUS 0.1% OP	2,267	2,071	$44,680.66	$19.71	1.09	4.77%
NEO/POLY/DEX OIN 0.1% OP	737	647	$14,959.83	$20.30	1.14	1.60%
TOBRA/DEXAME SUS 0.3-0.1%	455	423	$34,913.50	$76.73	1.08	3.72%
TOBRADEX SUS 0.3-0.1%	42	30	$6,111.33	$145.51	1.4	0.65%
SULF/PRED NA SOL OP	2	2	$75.40	$37.70	1	0.01%
SUBTOTAL	**3,503**	**3,087***	**$100,740.72**	**$28.76**	**1.13**	**10.75%**
TIER-2 PRODUCTS						
TOBRADEX OIN 0.3-0.1%	59	48	$12,516.00	$212.14	1.23	1.34%
ZYLET SUS 0.5-0.3%	28	26	$7,223.29	$257.97	1.08	0.77%
TOBRADEX ST SUS 0.3-0.05	3	3	$626.88	$208.96	1	0.07%
NEO/POLY/HC SUS OP	2	2	$278.85	$139.43	1	0.03%
NEO/POLY/BAC/HC OIN 1% OP	2	2	$112.30	$56.15	1	0.01%
BLEPHAMIDE OIN S.O.P.	1	1	$150.93	$150.93	1	0.02%
PRED-G SUS OP	1	1	$145.56	$145.56	1	0.02%
SUBTOTAL	**96**	**81***	**$21,053.81**	**$219.31**	**1.19**	**2.25%**
COMBINATION SUBTOTAL	**3,599**	**3,156***	**$121,794.53**	**$33.84**	**1.14**	**12.99%**
TOTAL	**44,261**	**37,901***	**$937,288.20**	**$21.18**	**1.17**	**100.00%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Fiscal Year 2019 Annual Review of Otic Anti-Infective Medications

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

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

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

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) Approval Criteria:

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

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

1. An FDA approved indication of 1 of the following:
   a. For the treatment of bilateral otitis media with effusion undergoing tympanostomy tube placement; or
   b. For the treatment of acute otitis externa due to *S. aureus* or *P. aeruginosa;* 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 2019

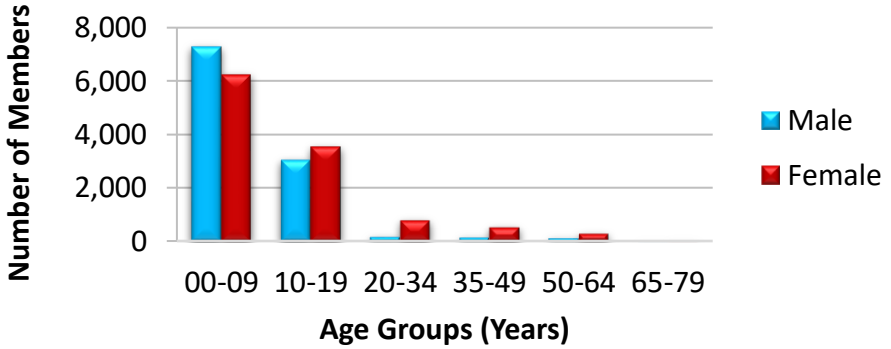
Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	24,547	29,804	$6,036,576.32	$202.54	$18.83	228,141	320,500
2019	22,270	27,447	$5,975,573.16	$217.71	$19.99	209,205	298,880
% Change	**-9.30%**	**-7.90%**	**-1.00%**	**7.50%**	**6.20%**	**-8.30%**	**-6.70%**
Change	**-2,277**	**-2,357**	**-$61,003.16**	**$15.17**	**$1.16**	**-18,936**	**-21,620**

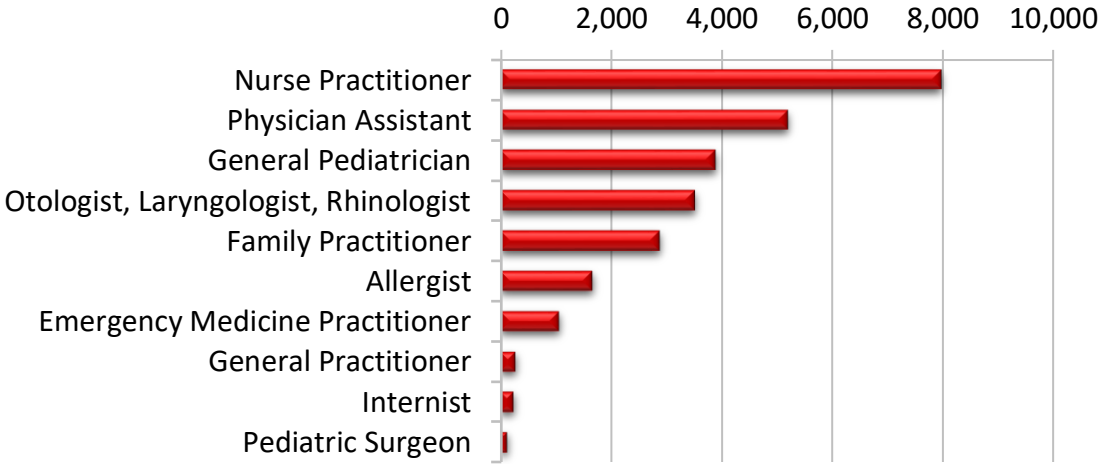
Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

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

Demographics of Members Utilizing Otic Anti-Infective Medications

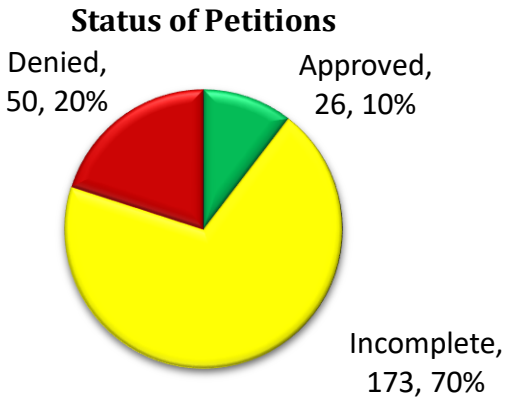


Top Prescriber Specialties of Otic Anti-Infective Medications by Number of Claims



Prior Authorization of Otic Anti-Infective Medications

There were 249 prior authorization requests submitted for otic anti-infective medications during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.



Market News and Updates[124]

Anticipated Patent Expiration(s):

- Ciprodex® (ciprofloxacin/dexamethasone): June 2025
- Otovel® (ciprofloxacin/fluocinolone): March 2030
- Otiprio® (ciprofloxacin): July 2035

Recommendations

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

Utilization Details of Otic Anti-Infective Medications: Fiscal Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 PRODUCTS						
CIPRODEX SUS 0.3-0.1% OTIC	26,573	21,640	$5,798,413.04	$218.21	1.23	97.04%
CIPRO HC SUS 0.2%-1% OTIC	462	438	$135,267.59	$292.79	1.05	2.26%
ACETIC ACID SOL 2% OTIC	235	215	$6,848.36	$29.14	1.09	0.11%
COLY-MYCIN S 0.33-0.3-1-0.05%	159	144	$34,123.02	$214.61	1.1	0.57%
TIER-1 SUBTOTAL	**27,429**	**22,267***	**$5,974,652.01**	**$217.82**	**1.23**	**99.98%**
TIER-2 PRODUCTS						
OFLOXACIN DRO 0.3%OTIC	9	9	$390.87	$43.43	1	0.01%
NEO/POLY/HC SOL 1% OTIC	5	5	$312.93	$62.59	1	0.01%
NEO/POLY/HC SUS 1% OTIC	3	3	$123.65	$41.22	1	0.00%
CIPROFLOXACN SOL 0.2%	1	1	$93.70	$93.70	1	0.00%
TIER-2 SUBTOTAL	**18**	**18***	**$921.15**	**$51.18**	**1**	**0.02%**
TOTAL	**27,447**	**22,270***	**$5,975,573.16**	**$217.71**	**1.23**	**100%**

*Total number of unduplicated members.
Tier-1 products may participate in supplemental rebates; therefore, costs shown do not reflect net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

[124] 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?resetfields=1. Last revised 03/2020. Last accessed 03/02/2020.

Fiscal Year 2019 Annual Review of Pancreatic Enzymes

Oklahoma Health Care Authority
Fiscal Year 2019 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.

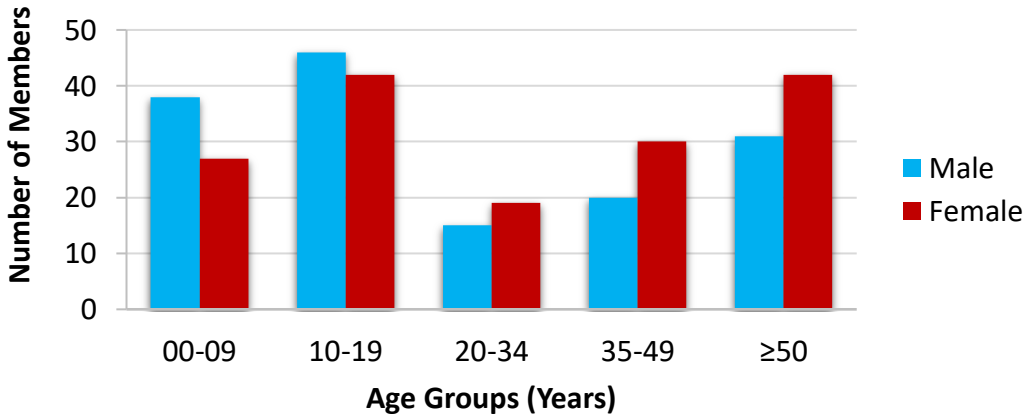
Utilization of Pancreatic Enzymes: Fiscal Year 2019

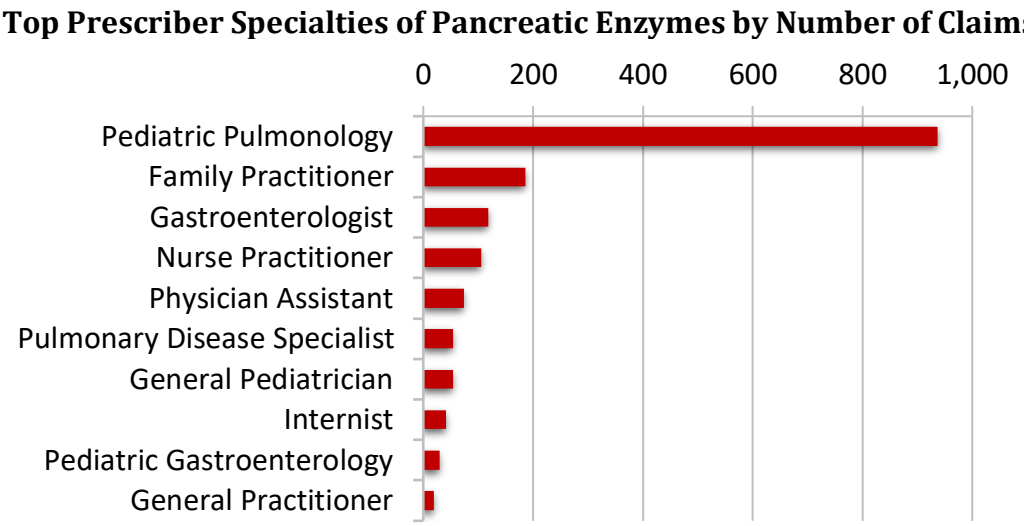
Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	301	1,596	$2,594,038.12	$1,625.34	$56.97	539,492	45,532
2019	310	1,689	$3,029,521.15	$1,793.68	$62.61	577,898	48,391
% Change	**3.00%**	**5.80%**	**16.80%**	**10.40%**	**9.90%**	**7.10%**	**6.30%**
Change	**9**	**93**	**$435,483.03**	**$168.34**	**$5.64**	**38,406**	**2,859**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

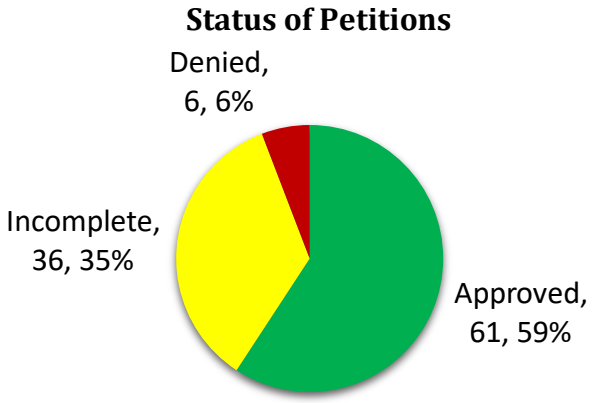
Demographics of Members Utilizing Pancreatic Enzymes





Prior Authorization of Pancreatic Enzymes

There were 103 prior authorization requests submitted for pancreatic enzymes during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.



Market News and Updates

Anticipated Patent Expiration(s):[125]

- Pancreaze®: February 2028
- Zenpep®: February 2028
- Creon®: February 2030

Recommendations

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

[125] 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 07/2019. Last accessed 08/19/2019.

Utilization Details of Pancreatic Enzymes: Fiscal Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
CREON®						
CREON CAP 36000UNT	307	73	$691,360.17	$78.33	$2,251.99	22.82%
CREON CAP 24000UNT	304	78	$657,495.32	$75.41	$2,162.81	21.70%
CREON CAP 12000UNT	216	45	$184,445.66	$29.67	$853.92	6.09%
CREON CAP 6000UNIT	63	17	$40,016.32	$22.79	$635.18	1.32%
CREON CAP 3000UNIT	17	10	$4,799.37	$11.01	$282.32	0.16%
SUBTOTAL	**907**	**223**	**$1,578,116.84**	**$60.80**	**$1,739.93**	**52.1%**
ZENPEP®						
ZENPEP CAP 25000	124	20	$340,861.42	$91.68	$2,748.88	11.25%
ZENPEP CAP 5000UNIT	92	21	$58,005.05	$21.65	$630.49	1.91%
ZENPEP CAP 40000	82	19	$261,987.79	$110.08	$3,194.97	8.65%
ZENPEP CAP 20000UNT	78	22	$121,747.82	$54.40	$1,560.87	4.02%
ZENPEP CAP 10000UNT	64	14	$30,854.42	$17.23	$482.10	1.02%
ZENPEP CAP 15000UNT	59	11	$84,528.55	$45.37	$1,432.69	2.79%
ZENPEP CAP 3000UNIT	7	3	$4,762.97	$26.61	$680.42	0.16%
ZENPEP CAP 40000UNT	1	1	$3,771.69	$125.72	$3,771.69	0.12%
SUBTOTAL	**507**	**111**	**$906,519.71**	**$60.93**	**$1,788.01**	**29.9%**
PERTZYE®						
PERTZYE CAP 16000U	155	23	$284,687.10	$63.95	$1,836.69	9.40%
PERTZYE CAP 24000U	55	10	$217,416.51	$139.91	$3,953.03	7.18%
PERTZYE CAP 8000UNIT	51	10	$32,180.27	$26.51	$630.99	1.06%
PERTZYE CAP 4000UNIT	6	2	$4,386.12	$36.55	$731.02	0.14%
SUBTOTAL	**267**	**45**	**$538,670.00**	**$73.39**	**$2,017.49**	**17.8%**
PANCREAZE®						
PANCREAZE CAP 21000UNT	2	1	$2,647.88	$44.13	$1,323.94	0.09%
PANCREAZE CAP 10500UNT	2	1	$622.34	$15.56	$311.17	0.02%
PANCREAZE CAP 2600UNIT	1	1	$530.97	$18.31	$530.97	0.02%
SUBTOTAL	**5**	**3**	**$3,801.19**	**$29.47**	**$760.24**	**0.1%**
VIOKACE®						
VIOKACE TAB 20880	2	1	$2,108.66	$35.14	$1,054.33	0.07%
VIOKACE TAB 10440	1	1	$304.75	$10.16	$304.75	0.01%
SUBTOTAL	**3**	**2**	**$2,413.41**	**$26.82**	**$804.47**	**0.1%**
TOTAL	**1,689**	**310***	**$3,029,521.15**	**$62.61**	**$1,793.68**	**100%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Fiscal Year 2019 Annual Review of Parathyroid Medications

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Hectorol® (Doxercalciferol Capsule) Approval Criteria:

1. An FDA approved diagnosis; and
2. Member must have a documented failure or a clinically-significant reason why the member cannot use calcitriol.

Natpara® (Parathyroid Hormone) Approval Criteria:

1. An FDA approved indication for use as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism; and
    a. Natpara® is not FDA approved for hypoparathyroidism caused by calcium-sensing receptor mutations; and
    b. Natpara® is not FDA approved for hypoparathyroidism due to acute post-surgery; and
2. Magnesium deficiency must be ruled out; and
3. Member must have pretreatment serum calcium >7.5mg/dL before starting Natpara®; and
4. Prescriber must verify the member has sufficient 25-hydroxyvitamin D level per standard of care; and
5. Member must be unable to be adequately well-controlled on calcium supplements and active forms of vitamin D alone; and
6. The health care provider and dispensing pharmacy must be certified through the Natpara® REMS Program; and
7. A quantity limit of 2 cartridges [each package contains (2) 14-day cartridges] per 28 days will apply. The maximum covered dose will be 100mcg per day.

Parsabiv™ (Etelcalcetide Injection) Approval Criteria:

1. An FDA approved indication for the treatment of secondary hyperparathyroidism (SHPT) in adult patients with chronic kidney disease (CKD) on hemodialysis; and
2. Parsabiv™ will not be approved for parathyroid carcinoma, primary hyperparathyroidism, or in patients with CKD who are not on hemodialysis (Parsabiv™ is not recommended for use in these populations); and
3. Member's corrected serum calcium should be at or above the lower limit of normal (≥8.3mg/dL) prior to initiation, dose increase, or re-initiation of Parsabiv™; and
4. Parsabiv™ must be prescribed by a nephrologist, endocrinologist, or provider who specializes in the treatment of SHPT; and
5. Member must have a documented failure or a clinically-significant reason why the member cannot use available generic vitamin D analogs including calcitriol; and
6. Member must have a documented failure or a clinically-significant reason why the member cannot use Sensipar® (cinacalcet); and

7. A quantity limit of 12 vials per month will apply.

Rayaldee® [Calcifediol Extended-Release (ER) Capsule] Approval Criteria:

1. An FDA approved indication for the treatment of secondary hyperparathyroidism (SHPT) in adults with chronic kidney disease (CKD) stage 3 or 4; and
2. Member must not have CKD stage 5 or end-stage renal disease on dialysis; and
3. Member should have a serum total 25-hydroxyvitamin D level <30ng/mL before starting treatment; and
4. Member should have a serum calcium level <9.8mg/dL before initiating treatment; and
5. Rayaldee® must be prescribed by a nephrologist, endocrinologist, or provider who specializes in the treatment of SHPT; and
6. Member must have a documented failure or clinically-significant reason why the member cannot use available generic vitamin D analogs including calcitriol; and
7. Initial approval will be for 30mcg daily for 3 months; and
    a. After 3 months, approval for 60mcg daily for 12 months can be considered if intact parathyroid hormone (iPTH) is above the treatment goal and serum calcium is <9.8mg/dL, phosphorus is <5.5mg/dL, and 25-hydroxyvitamin D is <100ng/mL; and
    b. Additional approvals will not be granted if iPTH is persistently abnormally low, serum calcium is consistently above the normal range, or serum 25-hydroxyvitamin D is consistently >100ng/mL; and
8. A quantity limit of 60 capsules per 30 days will apply.

Zemplar® (Paricalcitol Capsule) Approval Criteria:

1. Member must be 10 years of age or older; and
2. An FDA approved indication for the prevention and treatment of secondary hyperparathyroidism (SHPT) associated with 1 of the following:
    a. Chronic kidney disease (CKD) stage 3 or 4; or
    b. CKD stage 5 in patients on hemodialysis or peritoneal dialysis; and
        i. Members with CKD stage 5 should have a corrected total serum calcium ≤9.5mg/dL before initiating treatment; and
3. Zemplar® must be prescribed by a nephrologist, endocrinologist, or provider who specializes in the treatment of SHPT; and
4. Member must have a documented failure or a clinically-significant reason why the member cannot use other generic vitamin D analogs available without prior authorization including calcitriol and Zemplar® injection; and
5. A quantity limit of 30 capsules per 30 days will apply.

Utilization of Natpara®, Calcimimetics, and Vitamin D Analogs: Fiscal Year 2019

Comparison of Fiscal Years: Natpara® (Parathyroid Hormone Injection)

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	5	39	$360,036.85	$9,231.71	$329.70	78	1,092
2019	5	52	$503,454.29	$9,681.81	$342.02	104	1,472
% Change	**0.00%**	**33.30%**	**39.80%**	**4.90%**	**3.70%**	**33.30%**	**34.80%**
Change	**0**	**13**	**$143,417.44**	**$450.10**	**$12.32**	**26**	**380**

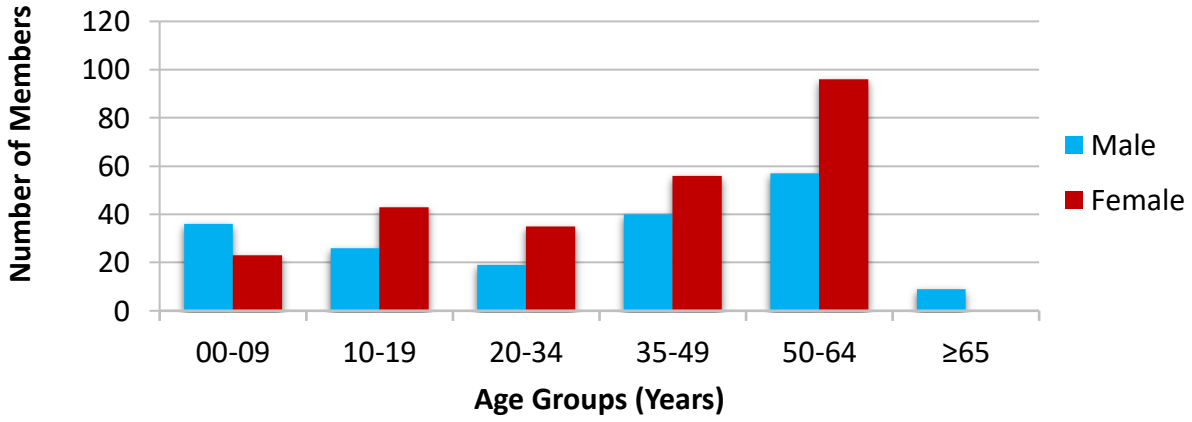
*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Comparison of Fiscal Years: Calcimimetics and Vitamin D Analogs

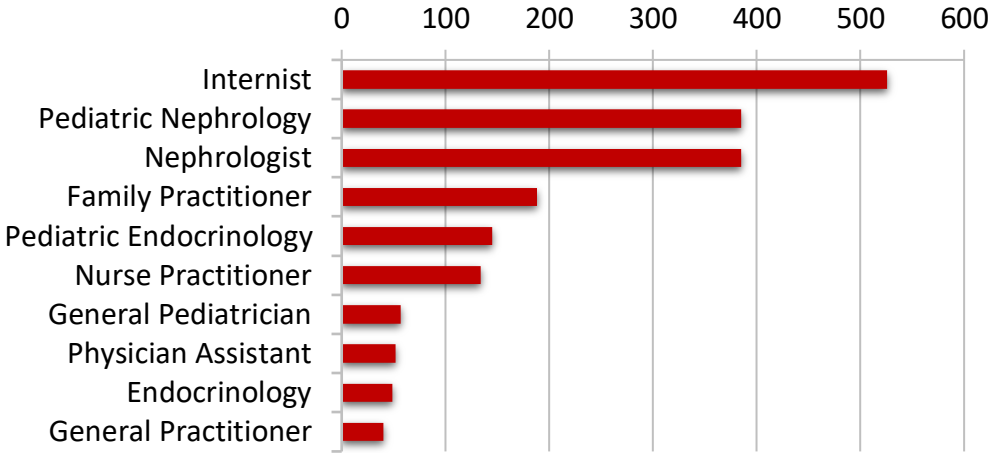
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	428	1,949	$991,772.54	$508.86	$13.24	81,136	74,921
2019	459	2,071	$841,981.31	$406.56	$10.71	82,888	78,640
% Change	**7.20%**	**6.30%**	**-15.10%**	**-20.10%**	**-19.10%**	**2.20%**	**5.00%**
Change	**31**	**122**	**-$149,791.23**	**-$102.30**	**-$2.53**	**1,752**	**3,719**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Demographics of Members Utilizing Natpara®, Calcimimetics, and Vitamin D Analogs



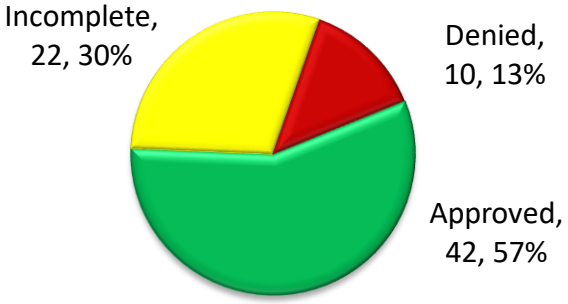
Top Prescriber Specialties of Natpara®, Calcimimetics, and Vitamin D Analogs by Number of Claims



Prior Authorization of Natpara®, Calcimimetics, and Vitamin D Analogs

There were 74 prior authorization requests submitted for Natpara®, calcimimetics, and vitamin D analogs during fiscal year 2019. Of those 74 requests, there were 8 prior authorization requests submitted for Natpara® for 5 unique members. The following chart shows the status of the submitted petitions for fiscal year 2019.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[126]

- Sensipar® (cinacalcet tablet): September 2026
- Rayaldee® [calcifediol extended-release (ER) capsule]: August 2028
- Parsabiv™ (etelcalcetide injection): June 2034

Recommendations

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

[126] 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 03/2020. Last accessed 03/25/2020.

Utilization Details of Calcimimetics and Vitamin D Analogs: Fiscal Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
CALCIMIMETIC PRODUCTS						
CINACALCET PRODUCTS						
SENSIPAR TAB 30MG	289	69	$282,675.03	$28.44	$978.11	33.57%
SENSIPAR TAB 60MG	125	31	$240,450.58	$59.50	$1,923.60	28.56%
SENSIPAR TAB 90MG	46	15	$131,399.46	$82.07	$2,856.51	15.61%
CINACALCET TAB 30MG	44	19	$27,483.68	$18.46	$624.63	3.26%
CINACALCET TAB 60MG	32	14	$53,470.83	$46.90	$1,670.96	6.35%
CINACALCET TAB 90MG	20	7	$38,650.78	$64.42	$1,932.54	4.59%
SUBTOTAL	**556**	**155**	**$774,130.36**	**$41.16**	**$1,392.32**	**91.94%**
VITAMIN-D ANALOG PRODUCTS						
CALCITRIOL PRODUCTS						
CALCITRIOL CAP 0.25MCG	840	224	$14,351.84	$0.40	$17.09	1.70%
CALCITRIOL CAP 0.5MCG	354	90	$10,957.92	$0.86	$30.95	1.30%
CALCITRIOL SOL 1MCG/ML	177	48	$25,188.89	$3.53	$142.31	2.99%
SUBTOTAL	**1,371**	**362**	**$50,498.65**	**$0.91**	**$36.83**	**5.99%**
PARICALCITOL PRODUCTS						
PARICALCITOL CAP 1MCG	90	19	$4,698.95	$1.72	$52.21	0.56%
PARICALCITOL CAP 2MCG	53	9	$12,385.48	$7.96	$233.69	1.47%
PARICALCITOL CAP 4MCG	1	1	$267.87	$8.93	$267.87	0.03%
SUBTOTAL	**144**	**29**	**$17,352.30**	**$4.01**	**$120.50**	**2.06%**
TOTAL	**2,071**	**459***	**$841,981.31**	**$10.71**	**$406.56**	**100%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Utilization Details of Natpara® (Parathyroid Hormone Injection): Fiscal Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
PARATHYROID HORMONE ANALOG PRODUCTS						
PARATHYOID HORMONE PRODUCTS						
NATPARA INJ 75MCG	27	4	$261,370.11	$338.56	$9,680.37	51.92%
NATPARA INJ 100MCG	25	4	$242,084.18	$345.83	$9,683.37	48.08%
TOTAL	**52**	**5***	**$503,454.29**	**$342.02**	**$9,681.81**	**100%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Fiscal Year 2019 Annual Review of Pediculicide Medications

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Pediculicide Medications		
Tier-1	**Tier-2**	**Tier-3**
Covered OTC Lice Medications	Sklice® (ivermectin lotion)	lindane shampoo
Natroba® (spinosad suspension)*		Ovide® (malathion)

Tier structure based on supplemental rebate participation, and/or National Average Drug Acquisition Costs (NADAC), or Wholesale Acquisition Costs (WAC) if NADAC unavailable.
*Brand Preferred
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 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 to Tier-1 medications applies if there is known resistance to OTC permethrin and pyrethrin.

Pediculicide Medications Tier-3 Approval Criteria:

1. An FDA approved diagnosis; and
2. A trial with 1 Tier-1 medication with inadequate response or adverse effect; and
3. 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 OTC permethrin and pyrethrin.

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

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 at least 6 months of age; and
   b. A quantity limit of 117mL per 7 days will apply.
3. **Lindane Shampoo:**
   a. Member must be at least 13 years of age or weigh ≥110 pounds; and
   b. A quantity limit of 60mL per 7 days will apply; and
   c. One 7-day supply per 30 days maximum.
4. **Malathion (Ovide®) Lotion:**
   a. Member must be at least 6 years of age; and
   b. A quantity limit of 60mL per 7 days will apply; may be repeated once if needed for current infestation after 7 days from original fill date.
5. **Spinosad (Natroba®) Suspension:**
   a. Member must be at least 6 months of age; and
   b. A quantity limit of 120mL per 7 days will apply; may be repeated once if needed for current infestation after 7 days from original fill date; and
   c. The brand formulation 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 2019

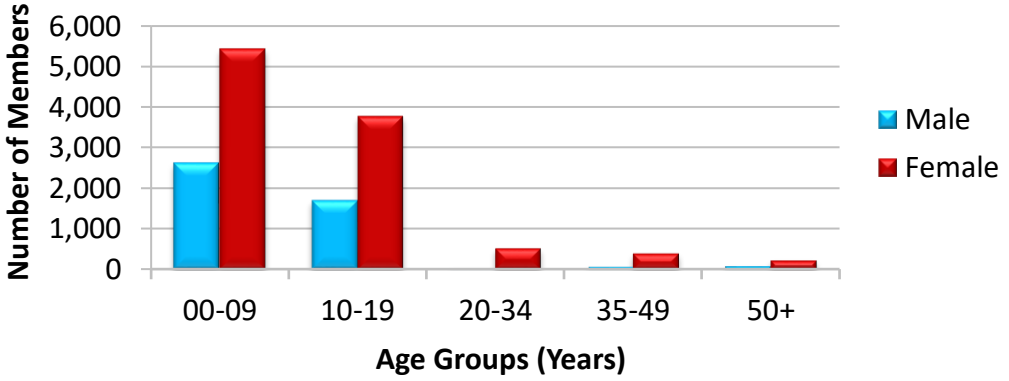
Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	16,309	23,231	$4,081,424.56	$175.69	$19.03	2,075,248	214,459
2019	14,882	21,502	$4,316,069.00	$200.73	$21.77	2,055,403	198,234
% Change	**-8.70%**	**-7.40%**	**5.70%**	**14.30%**	**14.40%**	**-1.00%**	**-7.60%**
Change	**-1,427**	**-1,729**	**$234,644.44**	**$25.04**	**$2.74**	**-19,845**	**-16,225**

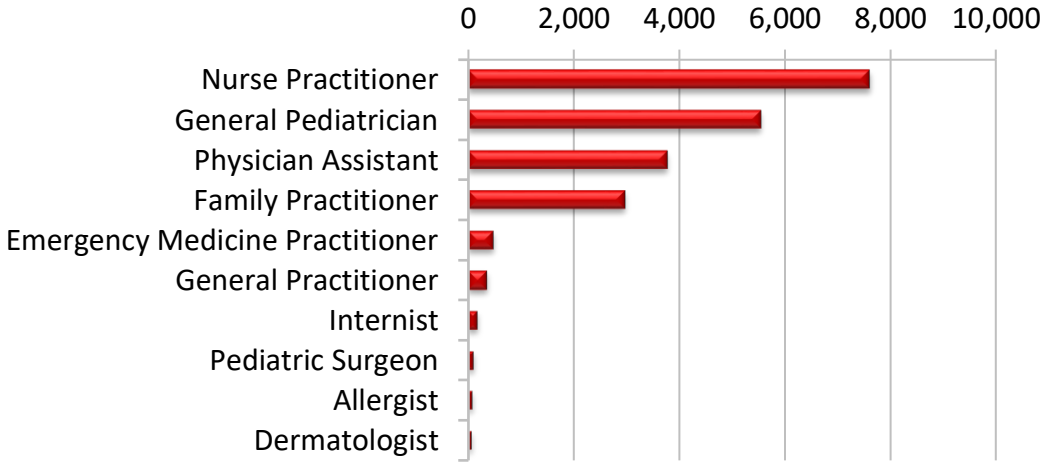
*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

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

Demographics of Members Utilizing Pediculicide Medications



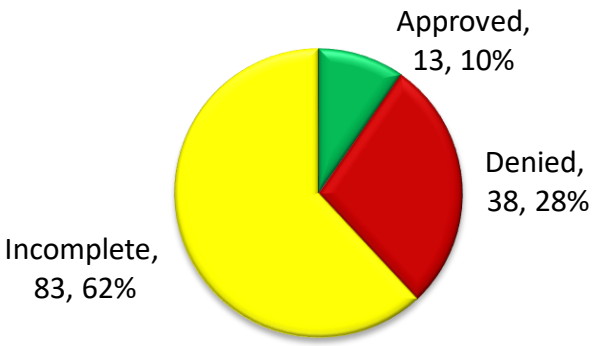
Top Prescriber Specialties of Pediculicide Medications by Number of Claims



Prior Authorization of Pediculicide Medications

There were 134 prior authorization requests submitted for pediculicide medications during fiscal year 2019. Computer edits are in place to detect lower tiered medications in a member's recent claims history and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions for fiscal year 2019.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[127]

- Natroba® (spinosad): July 2023
- Ovide® (malathion): August 2026
- Sklice® (ivermectin): October 2027

Recommendations

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

Utilization Details of Pediculicide Medications: Fiscal Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
PERMETHRIN PRODUCTS					
PERMETHRIN CRE 5%	7,499	5,873	$309,099.92	1.28	$41.22
LICE TREATMT LOT 1%	480	367	$6,688.59	1.31	$13.93
LICE TRTMNT LIQ 1%	384	303	$6,460.60	1.27	$16.82
SUBTOTAL	**8,363**	**6,487**	**$322,249.11**	**1.29**	**$38.53**
IVERMECTIN PRODUCTS					
SKLICE LOT 0.5%	9,253	6,365	$3,062,449.25	1.45	$330.97
SUBTOTAL	**9,253**	**6,365**	**$3,062,449.25**	**1.45**	**$330.97**
SPINOSAD PRODUCTS					
SPINOSAD SUS 0.9%	1,993	1,583	$426,838.46	1.26	$214.17
NATROBA SUS 0.9%	1,892	1,501	$504,416.45	1.26	$266.60
SUBTOTAL	**3,885**	**2,896**	**$931,254.91**	**1.34**	**$239.71**
LINDANE PRODUCTS					
LINDANE SHA 1%	1	1	$115.73	1	$115.73
SUBTOTAL	**1**	**1**	**$115.73**	**1**	**$115.73**
TOTAL	**21,502**	**14,882***	**$4,316,069.00**	**1.44**	**$200.73**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

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

[127] 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 11/2018. Last accessed 01/14/2019.

Fiscal Year 2019 Annual Review of Phosphate Binders

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

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

Auryxia® (Ferric Citrate) Approval Criteria:

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

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

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

5. Fosrenol® 500mg or 750mg chewable tablets are brand preferred. Authorization of the generic formulation requires a patient-specific, clinically significant reason why the member cannot use the brand formulation.

Velphoro® (Sucroferric Oxyhydroxide) Approval Criteria:

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

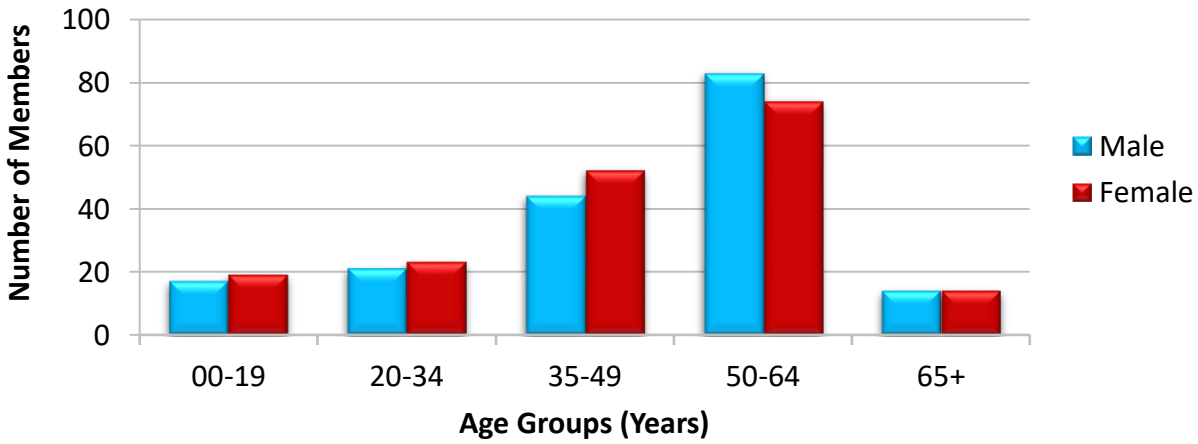
Utilization of Phosphate Binders: Fiscal Year 2019

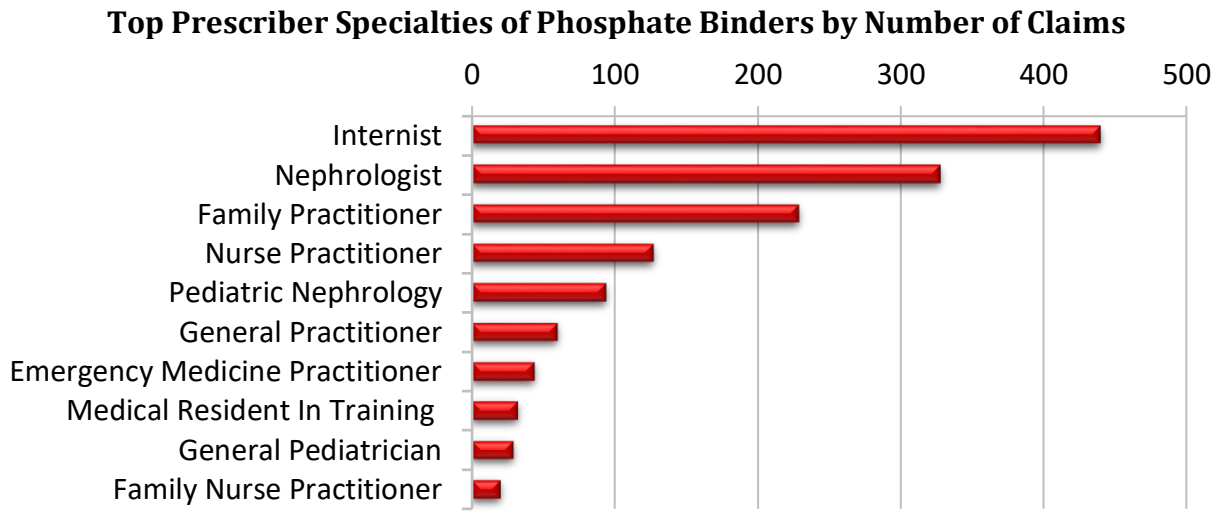
Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	346	1,502	$914,991.72	$609.18	$21.25	365,075	43,066
2019	361	1,466	$534,312.42	$364.47	$12.45	312,756	42,911
% Change	**4.3%**	**-2.3%**	**-41.6%**	**-40.2%**	**-41.4%**	**-14.3%**	**-0.3%**
Change	**15**	**-35**	**-$380,611.94**	**-$245.07**	**-$8.81**	**-52,049**	**-125**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

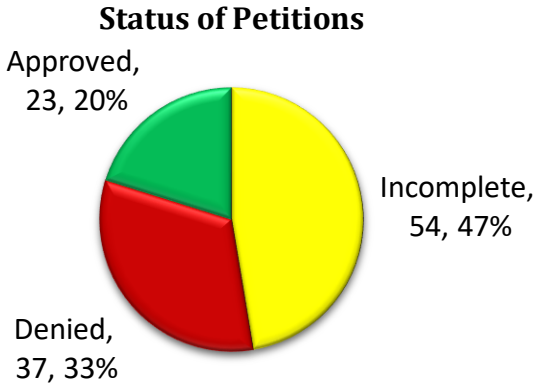
Demographics of Members Utilizing Phosphate Binders





Prior Authorization of Phosphate Binders

There were 114 prior authorization requests submitted for phosphate binders during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.



Market News and Updates

Anticipated Patent Expiration(s):[128]

- Renagel® (sevelamer hydrochloride): October 2020
- PhosLo® (calcium acetate): July 2021
- Fosrenol® (lanthanum carbonate): August 2024
- Velphoro® (sucroferric oxyhydroxide): January 2030
- Phoslyra® (calcium acetate): February 2030
- Auryxia® (ferric citrate): July 2030
- Renvela® (sevelamer carbonate): December 2030

[128] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 03/2020. Last accessed 03/26/2020.

Recommendations

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

Utilization Details of Phosphate Binders: Fiscal Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM	% COST
SEVELAMER CARBONATE PRODUCTS						
SEVELAMER TAB 800MG	623	172	$128,824.77	3.62	$206.78	24.11%
SEVELAMER POW 0.8GM	38	13	$60,332.56	2.92	$1,587.70	11.29%
SEVELAMER POW 2.4GM	31	9	$29,327.72	3.44	$946.06	5.49%
RENVELA TAB 800MG	14	8	$14,768.00	1.75	$1,054.86	2.76%
RENVELA POW 2.4GM	1	1	$1,471.81	1.00	$1,471.81	0.28%
SUBTOTAL	**707**	**191**	**$234,724.86**	**3.70**	**$332.00**	**43.93%**
CALCIUM ACETATE PRODUCTS						
CALC ACETATE CAP 667MG	559	181	$22,519.04	3.09	$40.28	4.21%
CALC ACETATE TAB 667MG	19	11	$1,395.11	1.73	$73.43	0.26%
PHOSLYRA SOL 667MG/5ML	5	3	$1,105.94	1.67	$221.19	0.21%
SUBTOTAL	**583**	**190**	**$25,020.09**	**3.07**	**$42.92**	**4.68%**
LANTHANUM CARBONATE PRODUCTS						
LANTHANUM CHW 750MG	31	9	$47,958.16	3.44	$1,547.04	8.98%
LANTHANUM CHW 500MG	18	5	$33,351.73	3.60	$1,852.87	6.24%
LANTHANUM CHW 1000MG	2	2	$2,185.98	1.00	$1,092.99	0.41%
SUBTOTAL	**51**	**15**	**$83,495.87**	**3.40**	**$1,637.17**	**15.63%**
FERRIC CITRATE PRODUCTS						
AURYXIA TAB 210MG	24	8	$29,724.77	3.00	$1,238.53	5.56%
SUBTOTAL	**24**	**8**	**$29,724.77**	**3.00**	**$1,238.53**	**5.56%**
SUCROFERRIC OXYHYDROXIDE PRODUCTS						
VELPHORO CHW 500MG	85	21	$146,305.43	4.05	$1,721.24	27.38%
SUBTOTAL	**85**	**21**	**$146,305.43**	**4.05**	**$1,721.24**	**27.38%**
SEVELAMER HYDROCHLORIDE PRODUCTS						
RENAGEL TAB 800MG	13	4	$12,486.00	3.25	$960.46	2.34%
SEVELAMER TAB 800MG	3	3	$2,555.40	1.00	$851.80	0.48%
SUBTOTAL	**16**	**6**	**$15,041.40**	**2.67**	**$940.09**	**2.82%**
TOTAL	**1,466**	**361***	**$534,312.42**	**4.06**	**$364.47**	**100%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Fiscal Year 2019 Annual Review of Prenatal Vitamins

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Prenatal Vitamins Approval Criteria:

- Most brand formulation prenatal vitamins require prior authorization for SoonerCare members. Preferred products do not require prior authorization. Products that are not listed on the preferred product list are non-preferred and require prior authorization.
- Updated versions of the preferred products list can be downloaded from www.okhca.org/rx.
- The SoonerCare prenatal vitamin category is modified throughout the fiscal year and adjusted for price fluctuations and supplemental rebate participation.

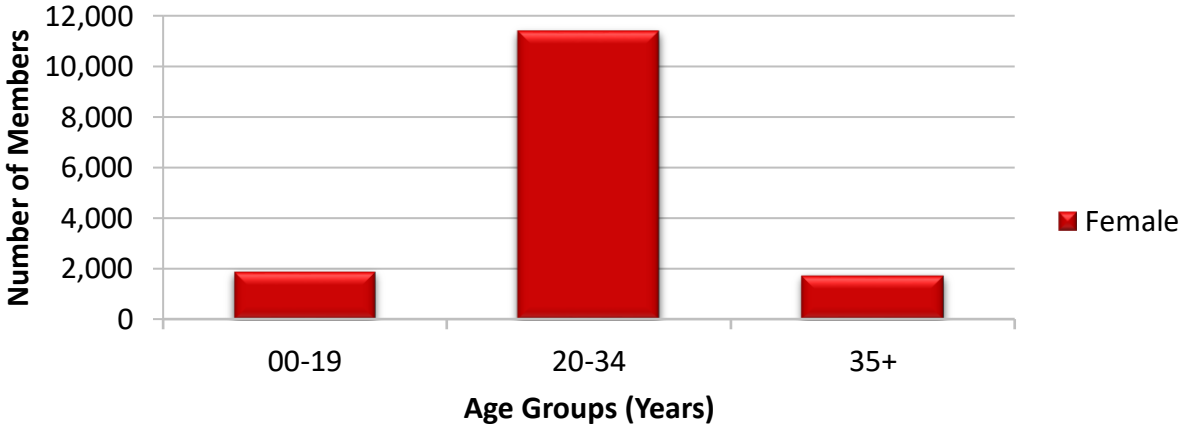
Utilization of Prenatal Vitamins: Fiscal Year 2019

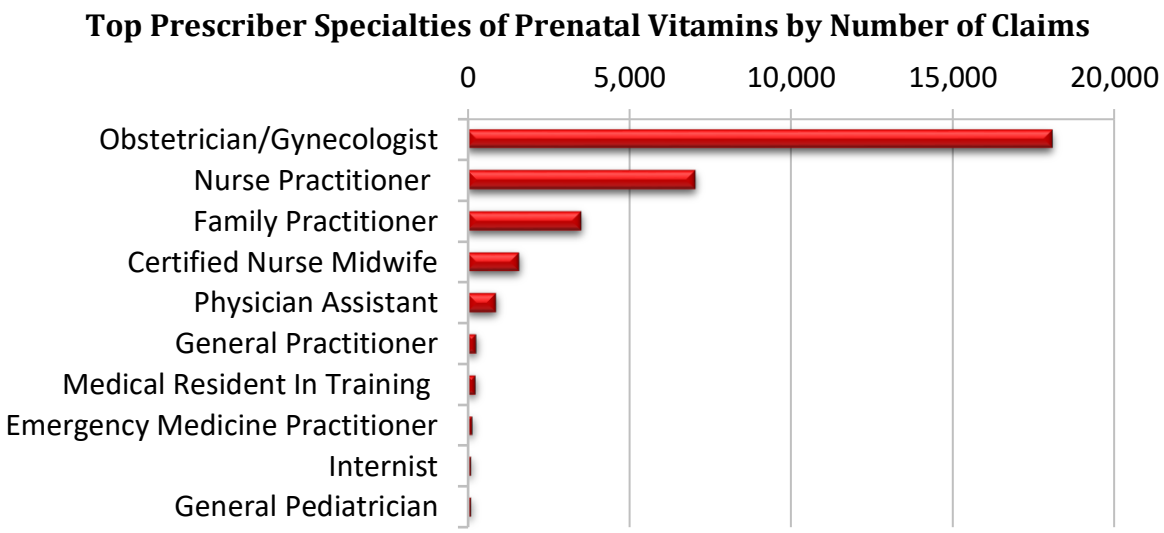
Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	16,339	35,005	$2,743,347.85	$78.37	$1.84	1,684,347	1,493,396
2019	15,010	32,301	$2,989,959.33	$92.57	$2.16	1,646,516	1,386,300
% Change	**-8.1%**	**-7.7%**	**9.0%**	**18.1%**	**17.4%**	**-2.2%**	**-7.2%**
Change	**-1,329**	**-2,704**	**$246,611.48**	**$14.20**	**$0.32**	**-37,831**	**-107,096**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

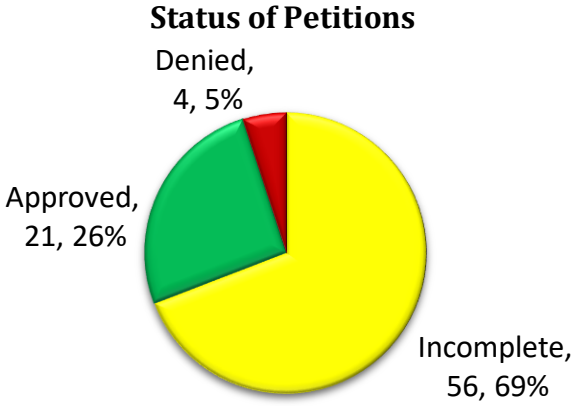
Demographics of Members Utilizing Prenatal Vitamins





Prior Authorization of Prenatal Vitamins

There were 81 prior authorization requests submitted for prenatal vitamins during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.



Recommendations

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

Utilization Details of Prenatal Vitamins: Fiscal Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
VITAFOL CAP ULTRA	7,415	3,198	$1,140,941.67	$153.87	2.32
CONCEPT DHA CAP	4,400	2,250	$202,055.35	$45.92	1.96
VITAFOL CHW GUMMIES	2,516	1,234	$303,915.59	$120.79	2.04
CITRANATAL CAP HARMONY	2,429	1,134	$421,809.30	$173.66	2.14
CITRANATAL MIS 90 DHA	2,322	1,037	$257,827.35	$111.04	2.24
VOL-PLUS TAB	2,079	1,437	$58,186.76	$27.99	1.45

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
FOLIVANE-OB CAP	1,659	1,024	$68,581.10	$41.34	1.62
PRENATAL TAB 27-1MG	1,467	761	$20,437.59	$13.93	1.93
TARON-C DHA CAP	1,198	683	$44,278.59	$36.96	1.75
CONCEPT OB CAP	1,178	736	$55,996.78	$47.54	1.6
PNV PRENATAL TAB PLUS	907	672	$10,254.45	$11.31	1.35
VITAFOL FE+ CAP	715	363	$86,983.94	$121.66	1.97
VIRT-C DHA CAP	652	412	$25,667.66	$39.37	1.58
CITRANATAL PAK ASSURE	568	243	$66,375.62	$116.86	2.34
CITRANATAL PAK DHA	526	254	$58,932.42	$112.04	2.07
PRENATAL VIT TAB LOW IRON	515	334	$6,145.77	$11.93	1.54
VITAFOL-NANO TAB	248	128	$35,950.22	$144.96	1.94
SE-NATAL 19 TAB	221	150	$6,656.88	$30.12	1.47
CITRANATAL MIS B-CALM	207	116	$18,669.99	$90.19	1.78
PROVIDA OB CAP	187	86	$8,662.18	$46.32	2.17
VITAFOL-OB PAK +DHA	139	74	$18,285.56	$131.55	1.88
VITAFOL-OB TAB 65-1MG	124	72	$20,855.58	$168.19	1.72
COMPLETENATE CHW	121	63	$3,311.81	$27.37	1.92
VITAFOL-ONE CAP	88	45	$16,114.50	$183.12	1.96
COMPLETE NAT PAK DHA	83	37	$2,588.85	$31.19	2.24
CITRANATAL TAB BLOOM	64	40	$11,857.30	$185.27	1.6
CITRANATAL TAB RX	63	41	$9,042.16	$143.53	1.54
TRINATAL RX TAB 1	56	32	$932.33	$16.65	1.75
SE-NATAL 19 CHW	34	24	$1,359.23	$39.98	1.42
SELECT-OB+ PAK DHA	25	10	$2,847.19	$113.89	2.5
PRENATA CHW 29-1MG	15	14	$231.07	$15.40	1.07
PRENATAL PLS MIS MV + DHA	15	12	$268.05	$17.87	1.25
VOL-TAB RX TAB	15	9	$364.91	$24.33	1.67
VP-GGR-B6 TAB PRENATAL	14	7	$598.30	$42.74	2
PNV TABS TAB 29-1MG	8	7	$219.63	$27.45	1.14
M-NATAL PLUS TAB	8	7	$114.89	$14.36	1.14
ELITE-OB TAB	6	5	$175.86	$29.31	1.2
PRENAISSANCE CAP PLUS	6	2	$697.28	$116.21	3
PRENATE MINI CAP	3	2	$1,363.36	$454.45	1.5
PROVIDA DHA CAP	2	2	$328.94	$164.47	1
VOL-NATE TAB	1	1	$19.00	$19.00	1
NIVA-PLUS TAB	1	1	$24.71	$24.71	1
ULTIMATECARE CAP ONE	1	1	$29.61	$29.61	1
TOTAL	**32,301**	**15,010***	**$2,989,959.33**	**$92.57**	**2.15**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Fiscal Year 2019 Annual Review of Procysbi® (Cysteamine Bitartrate)

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Procysbi® (Cysteamine Bitartrate) Approval Criteria:

1. An FDA approved diagnosis of nephropathic cystinosis; and
2. A patient-specific, clinically significant reason why the member cannot use the short-acting formulation Cystagon® (cysteamine bitartrate) must be provided.

Utilization of Procysbi® (Cysteamine Bitartrate): Fiscal Year 2019

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	1	2	$5,749.89	$2,874.94	$95.83	360	60
2019	1	2	$5,865.90	$2,932.95	$97.77	360	60
% Change	**0.00%**	**0.00%**	**2.00%**	**2.00%**	**2.00%**	**0.00%**	**0.00%**
Change	**0**	**0**	**$116.01**	**$58.01**	**$1.94**	**0**	**0**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Demographics of Members Utilizing Procysbi® (Cysteamine Bitartrate)

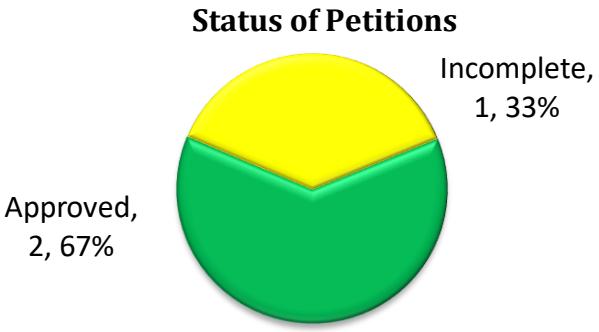
- Due to the small number of members utilizing Procysbi® (cysteamine bitartrate) during fiscal year 2019, detailed demographic information could not be provided.

Top Prescriber Specialties of Procysbi® (Cysteamine Bitartrate) by Number of Claims

- The only prescriber specialty listed on paid pharmacy claims for Procysbi® (cysteamine bitartrate) during fiscal year 2019 was pediatric nephrologist.

Prior Authorization of Procysbi® (Cysteamine Bitartrate)

There were 3 prior authorization requests submitted for 1 unique member for Procysbi® (cysteamine bitartrate) during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.



Market News and Updates

Anticipated Exclusivity Expiration(s):[129]

- Procysbi® (cysteamine bitartrate): August 2036

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

- **February 2020:** The FDA approved Procysbi® (cysteamine bitartrate) delayed-release oral granules in packets for adults and children 1 year of age and older living with nephropathic cystinosis. The new dosage form provides another option in addition to the currently available capsules which both contain microbeads that provide 12 hours of cystine control. Providing oral granules in packets offers a tear-open option for those living with cystinosis who may have difficulty swallowing, need to sprinkle the granules on certain foods or liquids, or administer medication through a gastrostomy tube. Procysbi® oral granules in packets in 75mg and 300mg strengths are expected to be available in the first half of 2020. Procysbi® capsules will continue to be available in 25mg and 75mg strengths.[130]

Recommendations

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

[129] 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/default.cfm?resetfields=1. Last revised 03/2020. Last accessed 03/24/2020.

[130] Horizon Therapeutics. Horizon Therapeutics plc Announces U.S. FDA Approval of New Dosage Form of Procysbi® (Cysteamine Bitartrate) Delayed-Release Oral Granules. *Business Wire*. Available online at: https://ir.horizontherapeutics.com/news-releases/news-release-details/horizon-therapeutics-plc-announces-us-fda-approval-new-dosage. Issued 02/18/2020. Last accessed 03/24/2020.

Fiscal Year 2019 Annual Review of Pulmonary Hypertension Medications

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Adcirca® (Tadalafil) Approval Criteria:

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

Adempas® (Riociguat) Approval Criteria:

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

Generic Ambrisentan (Letairis®) Approval Criteria:

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

Orenitram® (Treprostinil) Approval Criteria:

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

Opsumit® (Macitentan) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension; and
2. Previous failed trials of at least 1 medication in each of the following categories:
   a. Revatio® (sildenafil) or Adcirca® (tadalafil); and
   b. Letairis® (ambrisentan) or Tracleer® (bosentan); and
3. Medical supervision by a pulmonary specialist or cardiologist; and
4. Female members and all health care professionals (prescribers and dispensing pharmacies) must be enrolled in the Opsumit® REMS program; and
5. A quantity limit of 30 tablets per 30 days will apply.

Revatio® (Sildenafil Tablet) Approval Criteria:

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

Revatio® (Sildenafil Suspension) Approval Criteria:

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

Uptravi® (Selexipag) Approval Criteria:

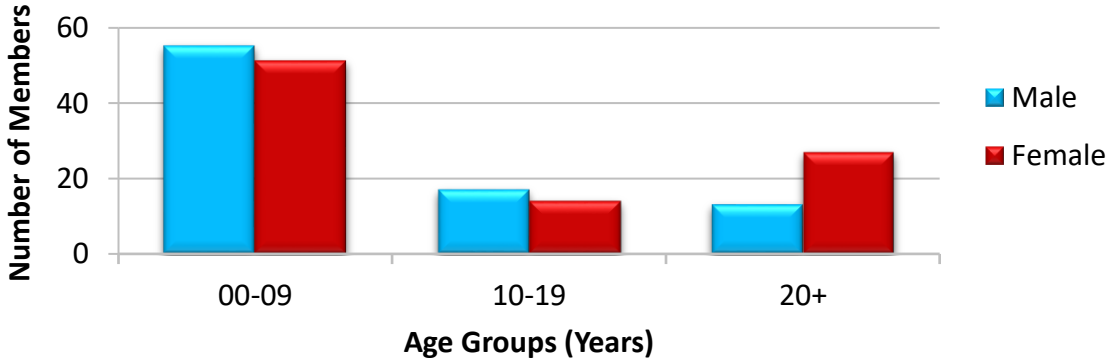
1. An FDA approved diagnosis of pulmonary arterial hypertension; and
2. Member must be 18 years of age or older; and
3. Previous failed trials of at least 1 medication in each of the following categories (alone or in combination):
   a. Revatio® (sildenafil), Adcirca® (tadalafil), or Adempas® (riociguat);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

Utilization of Pulmonary Hypertension Medications: Fiscal Year 2019

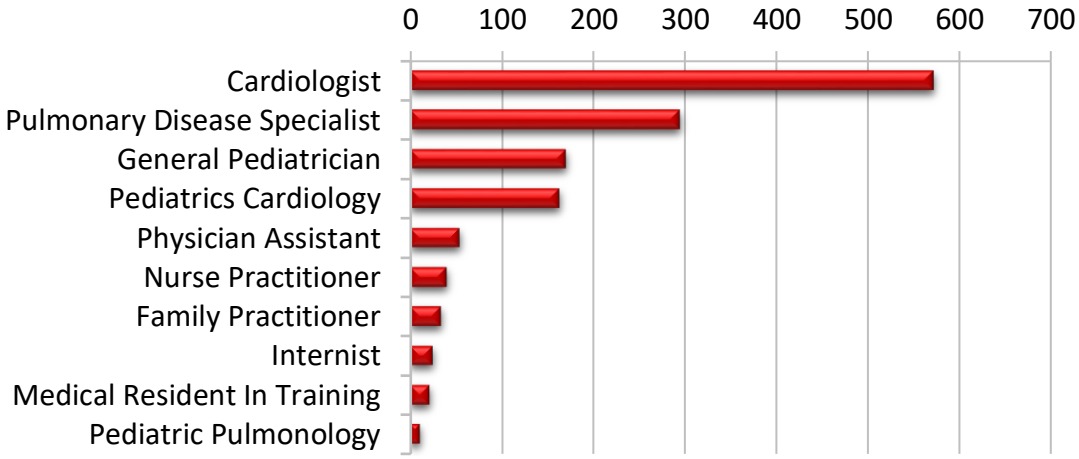
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	146	1,120	$6,540,454.75	$5,839.69	$192.84	96,437	33,917
2019	177	1,400	$9,176,780.73	$6,554.84	$218.72	115,011	41,956
% Change	**21.20%**	**25.00%**	**40.30%**	**12.20%**	**13.40%**	**19.30%**	**23.70%**
Change	**31**	**280**	**$2,636,325.98**	**$715.15**	**$25.88**	**18,574**	**8,039**

*Total number of unduplicated members. Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Demographics of Members Utilizing Pulmonary Hypertension Medications



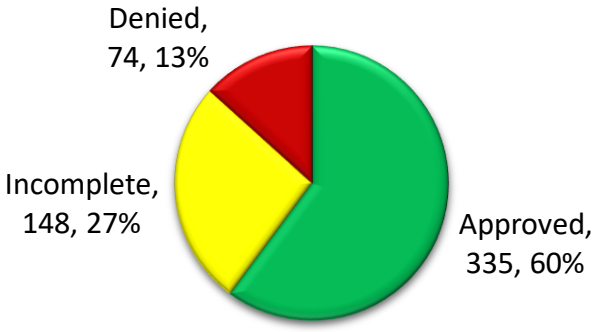
Top Prescriber Specialties of Pulmonary Hypertension Medications by Number of Claims



Prior Authorization of Pulmonary Hypertension Medications

There were 557 prior authorization requests submitted for pulmonary hypertension medications during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[131]

- Adempas® (riociguat): December 2026
- Opsumit® (macitentan): April 2029
- Uptravi® (selexipag): August 2030
- Orenitram® (treprostinil): August 2031
- Letairis® (ambrisentan): October 2031

Generic [Abbreviated New Drug Application (ANDA)] Approval(s):

- **February 2019:** The U.S. Food and Drug Administration (FDA) approved Alyq™ (tadalafil 20mg tablets). Alyq™ is a generic version of Adcirca®, which is manufactured by Teva Pharmaceutical Industries.[132]
- **April 2019:** The FDA approved the first generic versions of Letairis® (ambrisentan) 5mg and 10mg tablets. Generic approvals were granted to Mylan Pharmaceuticals, Watson Laboratories, Sun Pharma Global, and Zydus Pharmaceuticals.[133]
- **May 2019:** The FDA approved the first generic version of Revatio® (sildenafil) 10mg/mL oral suspension. Novitium Pharma was approved for its ANDA as the first therapeutically equivalent generic formulation.[134]

News:

- **March 2019:** The American College of Chest Physicians (CHEST) published an updated guideline and expert panel report on pharmacotherapy for Pulmonary Arterial Hypertension (PAH) in adults. This report updates the 2014 CHEST PAH guidelines. The 2019 CHEST guidelines incorporate a new visual algorithm to enhance the clinical utility of the recommendations. The algorithm provides specific therapeutic recommendations broken down by World Health Organization (WHO) Functional Class (FC) category. Additionally, the 2019 guidelines include new recommendations for combination pharmacotherapy for some patients including:
    - Initial combination therapy with ambrisentan and tadalafil is recommended to improve 6 minute walking distance (6MWD) in treatment naïve patients with WHO FC II or III symptoms.

---

[131] 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/default.cfm?resetfields=1. Last revised 03/2020. Last accessed 03/25/2020.

[132] Duffy S. Alyq, a Generic Version of PAH Treatment Adcirca, Now Available. *MPR.* Available online at: https://www.empr.com/home/news/generics-news/alyq-a-generic-version-of-pah-treatment-adcirca-now-available/. Issued 02/06/2019. Last accessed 03/27/2020.

[133] Duffy S. FDA Approves First Generic Versions of Letairis, Adds New REMS Program. *MPR.* Available online at: https://www.empr.com/home/news/fda-approves-first-generic-versions-of-letairis-adds-new-rems-program/. Issued 04/01/2019. Last accessed 03/25/2020.

[134] Novitium Pharma, LLC. Novitium Pharma Launches Generic Revatio® for Oral Suspension, 10mg/mL. *Globe Newswire.* Available online at: https://www.globenewswire.com/news-release/2019/06/04/1864158/0/en/Novitium-Pharma-Launches-Generic-Revatio-for-Oral-Suspension-10mg-mL.html. Issued 06/04/2019. Last accessed 03/27/2020.

- The addition of tadalafil is recommended to improve 6MWD in stable or symptomatic patients with PAH on background therapy with ambrisentan.[135]

- **February 2020:** The FDA cleared the Remunity™ Pump for usage with Remodulin® (treprostinil). Remunity™ Pump is a subcutaneous delivery system for adults (22 years of age and older) with PAH. The system uses cassettes which arrive from the specialty pharmacy prefilled with drug to last up to 72 hours. This eliminates the need for patients to mix or fill the pump. United Therapeutics expect to launch the Remunity™ Pump in July 2020.[136]

Pipeline(s):

- **Levosimendan:** Tenax Therapeutics is developing levosimendan as a potential treatment for pulmonary hypertension associated with heart failure with preserved ejection fraction (HFpEF). Levosimendan is a calcium sensitizer that improves the contraction of the heart muscles by increasing its sensitivity to calcium and helps dilate blood vessels (vasodilation effects). Tenax is currently conducting the Phase 2 HELP trial in patients with pulmonary hypertension and HFpEF. Tenax provided an enrollment update in January 2020, announcing that 24 patients have been randomized and 16 trial sites have been activated. This should allow for full enrollment in the trial by the first quarter of 2020 with top-line data available by the first half of 2020.[137]

Recommendations

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

Utilization Details of Pulmonary Hypertension Medications: Fiscal Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
PHOSPHODIESTERASE-5 (PDE-5) INHIBITORS						
REVATIO SUS 10MG/ML	432	92	$4,016,486.51	$9,297.42	4.7	43.77%
SILDENAFIL TAB 20MG	332	73	$8,159.02	$24.58	4.55	0.09%
TADALAFIL TAB 20MG	86	20	$153,899.20	$1,789.53	4.3	1.68%
ADCIRCA TAB 20MG	80	17	$185,303.74	$2,316.30	4.71	2.02%
ALYQ TAB 20MG+	2	1	$0.00	$0.00	2	0.00%
SUBTOTAL	**932**	**167***	**$4,363,848.47**	**$4,682.24**	**5.58**	**47.55%**
ENDOTHELIN RECEPTOR ANTAGONISTS (ERA)						
TRACLEER TAB 32MG	82	15	$600,768.62	$7,326.45	5.47	6.55%
LETAIRIS TAB 10MG	68	10	$633,948.16	$9,322.77	6.8	6.91%
OPSUMIT TAB 10MG	62	9	$563,920.57	$9,095.49	6.89	6.15%

[135] Klinger JR, Elliott CG, Levine DJ, et al. Therapy for Pulmonary Arterial Hypertension in Adults: Update of the CHEST Guideline and Expert Panel Report. *Chest* 2019; 155(3):565-586.

[136] United Therapeutics Corporation. Remodulin: Delivery Options. Available online at: https://hcp.remodulin.com/delivery-options/implantable-pump. Last Accessed 03/27/2020.

[137] Tenax Therapeutics, Inc. Tenax Therapeutics Provides Update on Phase 2 Pulmonary Hypertension Clinical Trial. Available online at: http://investors.tenaxthera.com/prviewer/release_only/id/4198696. Issued 01/13/2020. Last accessed 03/27/2020.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TRACLEER TAB 62.5MG	62	11	$247,399.30	$3,990.31	5.64	2.70%
LETAIRIS TAB 5MG	28	4	$344,492.29	$12,303.30	7	3.75%
AMBRISENTAN TAB 10MG	13	7	$19,133.71	$1,471.82	1.86	0.21%
AMBRISENTAN TAB 5MG	5	3	$10,802.37	$2,160.47	1.67	0.12%
BOSENTAN TAB 62.5MG	1	1	$4,224.93	$4,224.93	1	0.05%
SUBTOTAL	**321**	**47***	**$2,424,689.95**	**$7,553.55**	**6.83**	**26.42%**
PROSTACYCLIN VASODILATORS						
REMODULIN INJ 10MG/ML	35	3	$1,022,956.37	$29,227.32	11.67	11.15%
ORENITRAM TAB 1MG	18	3	$127,156.83	$7,064.27	6	1.39%
TYVASO REFIL SOL 0.6MG/ML	12	2	$192,967.91	$16,080.66	6	2.10%
REMODULIN INJ 5MG/ML	11	2	$113,969.03	$10,360.82	5.5	1.24%
ORENITRAM TAB 0.25MG	11	2	$22,956.97	$2,087.00	5.5	0.25%
ORENITRAM TAB 0.125MG	9	2	$8,690.21	$965.58	4.5	0.09%
ORENITRAM TAB 5MG	9	1	$338,692.69	$37,632.52	9	3.69%
REMODULIN INJ 2.5MG/ML	8	2	$79,661.46	$9,957.68	4	0.87%
UPTRAVI TAB 800MCG	6	1	$99,768.66	$16,628.11	6	1.09%
UPTRAVI TAB 600MCG	4	2	$67,917.28	$16,979.32	2	0.74%
VELETRI INJ 1.5MG	4	1	$11,268.76	$2,817.19	4	0.12%
UPTRAVI TAB 200MCG	3	2	$78,784.21	$26,261.40	1.5	0.86%
UPTRAVI TAB 1600MCG	3	1	$52,515.81	$17,505.27	3	0.57%
UPTRAVI TAB 1000MCG	3	1	$45,516.45	$15,172.15	3	0.50%
UPTRAVI TAB 200/800	1	1	$26,260.87	$26,260.87	1	0.29%
UPTRAVI TAB 1400MCG	1	1	$17,505.27	$17,505.27	1	0.19%
ORENITRAM TAB 2.5MG	1	1	$9,211.53	$9,211.53	1	0.10%
REMODULIN INJ 1MG/ML	1	1	$612.37	$612.37	1	0.01%
SUBTOTAL	**140**	**16***	**$2,316,412.68**	**$16,545.80**	**8.75**	**25.24%**
SOLUBLE GUANYLATE CYCLASE (sGC) STIMULATORS						
ADEMPAS TAB 2.5MG	4	2	$41,376.78	$10,344.20	2	0.45%
ADEMPAS TAB 2MG	1	1	$10,344.67	$10,344.67	1	0.11%
ADEMPAS TAB 1.5MG	1	1	$10,344.67	$10,344.67	1	0.11%
ADEMPAS TAB 1MG	1	1	$9,763.51	$9,763.51	1	0.11%
SUBTOTAL	**7**	**2***	**$71,829.63**	**$10,261.38**	**3.5**	**0.78%**
TOTAL	**1,400**	**177***	**$9,176,780.73**	**$6,554.84**	**7.91**	**100%**

*Total number of unduplicated members.

⁺Claims for Alyq® in Fiscal Year 2019 consist of claims for 1 member for which SoonerCare was not the primary payer; therefore, the reimbursed amount is not a true reflection of the cost of the medication for SoonerCare.

Costs do not reflect rebated prices or net costs.

Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Fiscal Year 2019 Annual Review of Qbrexza™ (Glycopyrronium)

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Qbrexza™ (Glycopyrronium) Approval Criteria:

1. An FDA approved diagnosis of primary axillary hyperhidrosis in pediatric patients 9 years of age to 20 years of age; and
2. Documentation of assessment by a licensed behavior specialist or the prescribing physician indicating the member's hyperhidrosis is causing social anxiety, depression, or similar mental health-related issues that impact the member's ability to function in day-to-day living must be provided; and
3. Member must have failed a trial of Drysol™ (aluminum chloride 20%) at least 3 weeks in duration; and
4. Prescriber must verify that the member has received counseling on the safe and proper use of Qbrexza™; and
5. A quantity limit of 1 box (30 cloths) per 30 days will apply.

Utilization of Qbrexza™ (Glycopyrronium): Fiscal Year 2019

Fiscal Year 2019 Utilization

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	1	2	$1,075.09	$537.55	$17.92	60	60

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal year 2019 = 07/01/2018 to 06/30/2019
There was no SoonerCare utilization of Qbrexza™ (glycopyrronium) during fiscal year 2018 (07/01/2017 to 06/30/2018).

Demographics of Members Utilizing Qbrexza™ (Glycopyrronium)

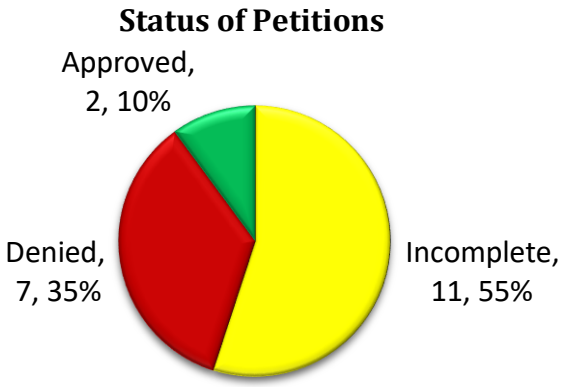
- Due to the small number of members utilizing Qbrexza™ (glycopyrronium) during fiscal year 2019, detailed demographic information could not be provided.

Top Prescriber Specialties of Qbrexza™ (Glycopyrronium) by Number of Claims

- The only prescriber specialty listed on paid claims for Qbrexza™ (glycopyrronium) during fiscal year 2019 was physician assistant. The physician assistant is supervised by a dermatologist.

Prior Authorization of Qbrexza™ (Glycopyrronium)

There were 20 prior authorization requests for 9 unique members submitted for Qbrexza™ (glycopyrronium) during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.



Market News and Updates

Anticipated Patent Expiration(s):

- Qbrexza™ (glycopyrronium): February 2033[138]

Recommendations

The College of Pharmacy does not recommend any changes to the current Qbrexza™ (glycopyrronium) prior authorization criteria at this time.

[138] U.S. Food and Drug Administration (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 12/2019. Last accessed 12/12/2019.

Fiscal Year 2019 Annual Review of Qualaquin® (Quinine Sulfate)

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Qualaquin® (Quinine Sulfate) Approval Criteria:

1. An FDA approved diagnosis of malaria; and
2. Off-label use for the prevention/treatment of leg cramps and other related conditions will not be covered.

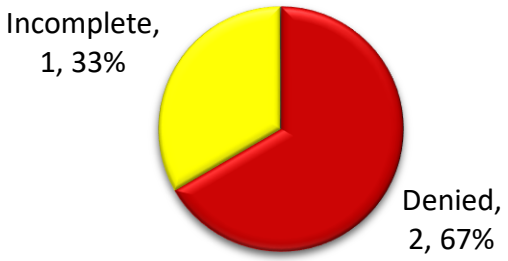
Utilization of Qualaquin® (Quinine Sulfate): Fiscal Year 2019

There was no SoonerCare utilization of Qualaquin® (quinine sulfate) during fiscal year 2019.

Prior Authorization of Qualaquin® (Quinine Sulfate)

There were 3 prior authorization requests submitted for Qualaquin® (quinine sulfate) during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.

Status of Petitions



Recommendations

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

Fiscal Year 2019 Annual Review of Qutenza® (Capsaicin 8% Patch)

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Qutenza® (Capsaicin 8% Patch) Approval Criteria:

1. An FDA approved diagnosis of postherpetic neuralgia; and
2. Documented treatment attempts at recommended dosing or contraindication(s) to at least 1 agent from each of the following drug classes:
   a. Tricyclic antidepressants; and
   b. Anticonvulsants; and
   c. Topical lidocaine; and
3. Qutenza® must be administered by a health care provider; and
4. A quantity limit of no more than 4 patches per treatment every 90 days will apply.

Utilization of Qutenza® (Capsaicin 8% Patch): Fiscal Year 2019

There was no SoonerCare utilization of Qutenza® (capsaicin 8% patch) during fiscal year 2019.

Prior Authorization of Qutenza® (Capsaicin 8% Patch)

There were no prior authorization requests submitted for Qutenza® (capsaicin 8% patch) during fiscal year 2019.

Market News and Updates[139]

Anticipated Patent Expiration(s):

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

Recommendations

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

[139] 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?resetfields=1. Last revised 01/2020. Last accessed 02/13/2020.

Fiscal Year 2019 Annual Review of Ravicti® (Glycerol Phenylbutyrate)

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Introduction[140,141,142,143]

Urea cycle disorders (UCDs) are inherited deficiencies of enzymes or transporters necessary for the synthesis of urea from ammonia. Absence of these enzymes or transporters results in the accumulation of toxic levels of ammonia in the blood, with possible complications of confusion and eventually disorientation, swelling of the brain, brain damage, coma, and death. UCDs occur in 1 in 30,000 newborns in the United States and are often diagnosed when the child is still an infant. Neonatal onset UCDs are caused by severe enzyme deficiencies or complete absence of enzyme function. Individuals with childhood or adult onset disease have partial enzyme deficiencies. The percentage of enzyme function, and therefore ability to rid the body of ammonia varies widely between individuals with partial enzyme deficiencies.

The treatment of UCDs consists of dietary protein management to limit ammonia production in conjunction with medications and/or supplements which provide alternative pathways for the removal of ammonia from the bloodstream. There are 2 medications approved by the U.S. Food and Drug Administration (FDA) for chronic management of UCDs, both of which are "ammonia scavengers", providing alternative pathways for removal of ammonia from the bloodstream and helping to prevent hyperammonemia. Buphenyl® (sodium phenylbutyrate) was FDA approved in 1996 and is available as an oral powder and oral tablets. Sodium phenylbutyrate is dosed based on body surface area (BSA), 3 to 6 times daily with food. The oral powder may be mixed with solid food, liquid food, or water prior to administration. Ravicti® (glycerol phenylbutyrate) was FDA approved in 2013 and is available as an oral solution. Glycerol phenylbutyrate should be given in 3 equally divided doses, each rounded up to the nearest 0.5mL, and should be taken with food. Glycerol phenylbutyrate dosing is based on BSA, previous dose of sodium phenylbutyrate, residual urea synthetic capacity, dietary protein requirements, and/or diet adherence, and the maximum total daily dosage is 17.5mL (19g). These medications are administered multiple times per day in order to ensure continual removal of toxic ammonia from the bloodstream.

---

[140] National Institutes of Health: Rare Diseases Clinical Research Network. Urea Cycle Disorders Consortium: Treatment Guidelines. Available online at: https://www.rarediseasesnetwork.org/cms/ucdc/Healthcare-Professionals/Urea-Cycle-Treatment-Guidelines. Last revised 2005. Last accessed 03/19/2020.
[141] Lee B. Urea Cycle Disorders: Management. *UpToDate®*. Available online at: https://www.uptodate.com/contents/urea-cycle-disorders-management. Last revised 01/09/2018. Last accessed 03/19/2020.
[142] Buphenyl® (Sodium Phenylbutyrate) Prescribing Information. Horizon Pharma. Available online at: https://www.hzndocs.com/BUPHENYL-Prescribing-Information.pdf. Last revised 02/2020. Last accessed 03/19/2020.
[143] Ravicti® (Glycerol Phenylbutyrate) Prescribing Information. Horizon Pharma. Available online at: https://www.hzndocs.com/RAVICTI-Prescribing-Information.PDF. Last revised 11/2019. Last accessed 03/19/2020.

Current Prior Authorization Criteria

Ravicti® (Glycerol Phenylbutyrate) Approval Criteria:

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

Utilization of Ravicti® (Glycerol Phenylbutyrate): Fiscal Year 2019

Comparison of Fiscal Years

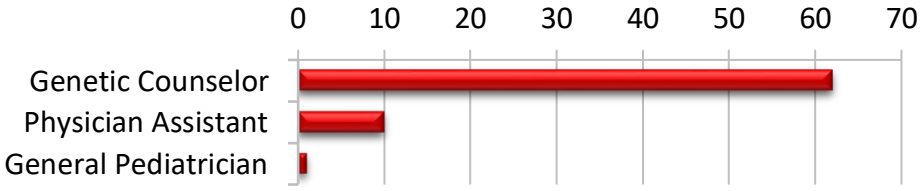
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	6	63	$1,547,010.90	$24,555.73	$876.49	8,800	1,765
2019	8	73	$1,962,374.79	$26,881.85	$929.59	10,475	2,111
% Change	**33.30%**	**15.90%**	**26.80%**	**9.50%**	**6.10%**	**19.00%**	**19.60%**
Change	**2**	**10**	**$415,363.89**	**$2,326.12**	**$53.10**	**1,675**	**346**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Demographics of Members Utilizing Ravicti® (Glycerol Phenylbutyrate)

- There were 8 unique pediatric members utilizing Ravicti® (glycerol phenylbutyrate) during fiscal year 2019; however, due to the limited number of members utilizing Ravicti® (glycerol phenylbutyrate) during fiscal year 2019, detailed demographic information could not be provided.

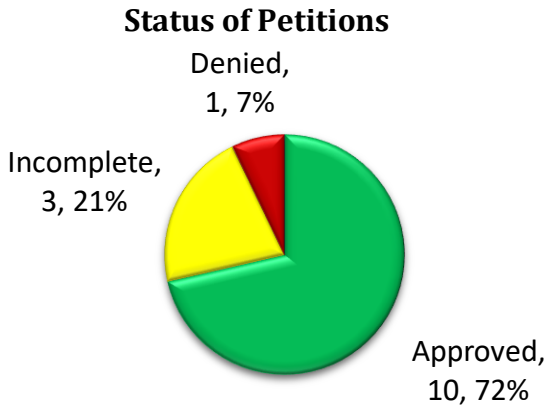
Top Prescriber Specialties of Ravicti® (Glycerol Phenylbutyrate) by Number of Claims



- Upon further research, all prescribers listed as genetic counselors were also classified as general pediatricians specializing in medical genetics and clinical genetics.

Prior Authorization of Ravicti® (Glycerol Phenylbutyrate)

There were 14 prior authorization requests submitted for 8 unique members for Ravicti® (glycerol phenylbutyrate) during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.



Market News and Updates

Anticipated Patent Expiration(s):[144]

- Ravicti® (glycerol phenylbutyrate): March 2032

Pipeline:[145]

- **ACER-001:** Acer Therapeutics is developing ACER-001 for treatment of UCD. ACER-001 is a fully taste-masked, immediate release formulation of sodium phenylbutyrate developed using a microencapsulation process which was designed with the goal of improving patient compliance. Acer Therapeutics is conducting a 2-part pivotal trial of ACER-001 for UCD. Part A of the trial is designed to evaluate the relative bioavailability of different oral suspension formulations of ACER-001 compared to Buphenyl® (sodium phenylbutyrate) and will help determine the optimal formulation for use in Part B of the trial. Part B is designed to evaluate the bioequivalence of ACER-001 compared to Buphenyl® (sodium phenylbutyrate). In October 2019, Acer Therapeutics announced full enrollment in Part A of the trial.

Recommendations

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

[144] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 03/2020. Last accessed 03/19/2020.

[145] Acer Therapeutics. Acer Pipeline: ACER-001 for UCD. Available online at: https://www.acertx.com/rare-disease-research/acer-001-for-urea-cycle-disorders-ucds/. Last accessed 03/19/2020.

Fiscal Year 2019 Annual Review of Smoking Cessation Products

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Smoking Cessation Products Coverage Criteria:

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

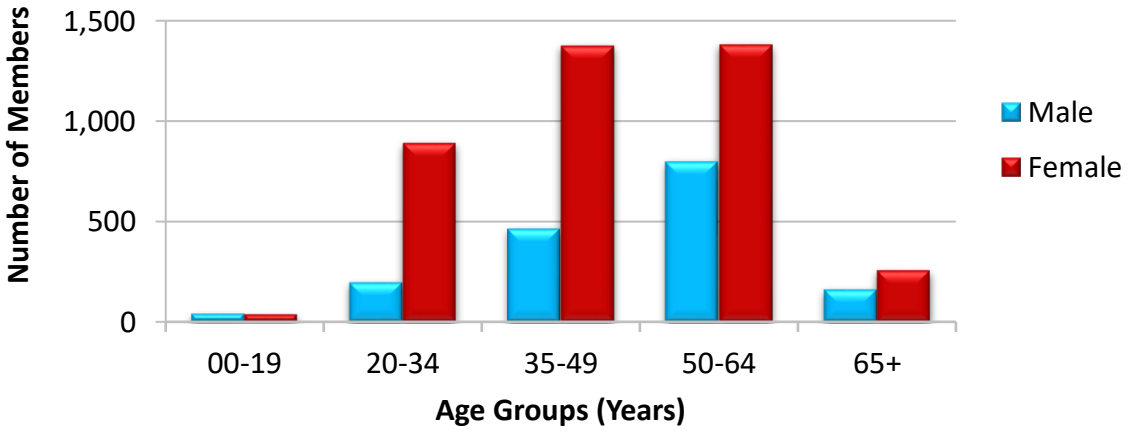
Utilization of Smoking Cessation Products: Fiscal Year 2019

Comparison of Fiscal Years

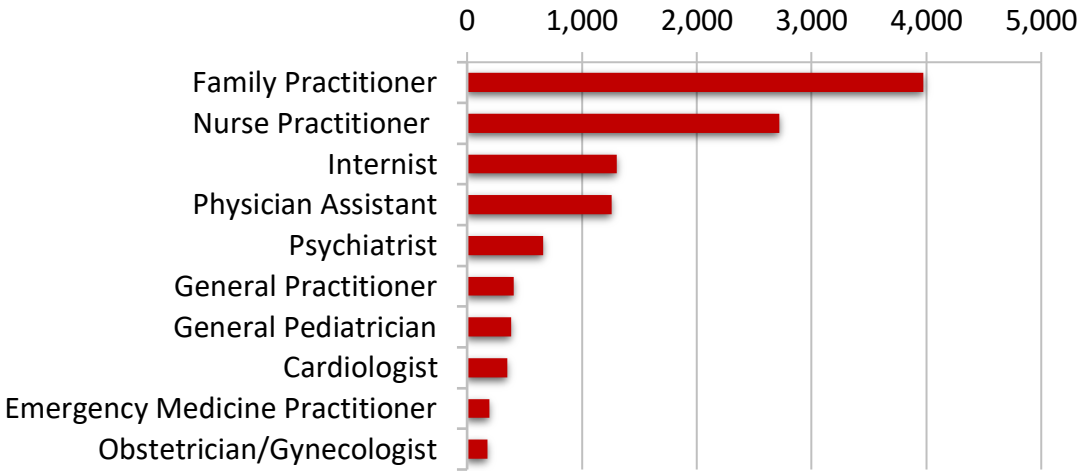
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	5,152	10,894	$2,085,827.32	$191.47	$7.96	500,929	262,037
2019	5,610	12,034	$2,558,726.21	$212.62	$8.78	595,038	291,460
% Change	**8.9%**	**10.5%**	**22.7%**	**11.0%**	**10.3%**	**18.8%**	**11.2%**
Change	**458**	**1,140**	**$472,898.89**	**$21.15**	**$0.82**	**94,109**	**29,423**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Demographics of Members Utilizing Smoking Cessation Products



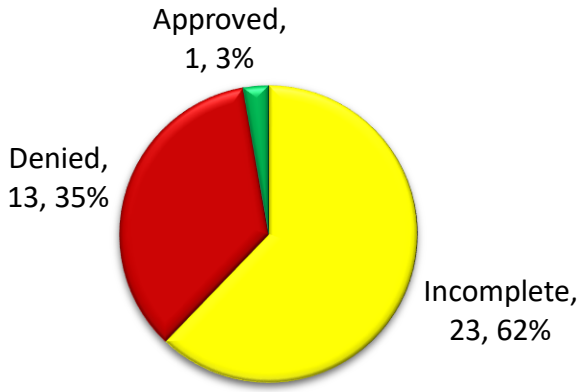
Top Prescriber Specialties of Smoking Cessation Products by Number of Claims



Prior Authorization of Smoking Cessation Products

There were 37 prior authorization requests submitted for smoking cessation products during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[146]

- Chantix® (varenicline tablets): February 2023

News:

- **January 2020:** The Surgeon General released a new report to review and update the evidence on the importance of quitting smoking. This report expands on the findings from the first Surgeon General's report on smoking cessation almost 3 decades ago, as well as past Surgeon General's reports on tobacco, reaching the following major

[146] 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?resetfields=1. Last revised 02/2020. Last accessed 02/18/2020.

conclusions: Smoking cessation benefits persons at any age. Smoking cessation reduces the risk of premature death and can add as much as a decade to life expectancy. Smoking places a substantial financial burden on smokers, health care systems, and society; smoking cessation reduces this burden. More than 3 out of 5 adults in the United States who have ever smoked cigarettes have quit; however, less than one-third used FDA-approved cessation medications or behavioral counseling. Disparities in key indicators of smoking cessation exist among subgroups within the U.S. population including quit attempts, receiving advice to quit from a health care professional, and using smoking cessation therapies. Smoking cessation reduces the risk of many negative health effects, including reproductive health outcomes, cardiovascular (CV) diseases, chronic obstructive pulmonary disease (COPD), and numerous cancers. Cessation medications approved by the FDA and behavioral counseling increase the likelihood of successfully quitting smoking, particularly when used in combination. Insurance coverage for smoking cessation treatment that is comprehensive, barrier-free, and widely promoted increases the use of these treatment services, leads to higher rates of successful quitting, and is cost effective. E-cigarettes, a continually changing and diverse group of products, are used in a variety of ways, and there is presently inadequate evidence to conclude that e-cigarettes, in general, increase smoking cessation. Smoking cessation can be increased by raising the price of cigarettes, adopting comprehensive smoke-free policies, implementing mass media campaigns, requiring pictorial health warnings, and maintaining comprehensive statewide tobacco control programs.[147]

- **February 2020:** A retrospective new-user cohort study assessing the relative CV and neuropsychiatric safety between varenicline and bupropion compared with nicotine replacement therapies (NRT) in adults without a recent history of depression was published in the journal *Addiction*. The retrospective study used U.S. administrative data from 2006-2016, and a total of 618,497 participants were included in the study cohorts. The study found that, compared with NRT, varenicline does not appear to be associated with an increased risk of CV or neuropsychiatric hospitalizations, while bupropion appears to be associated with a lower risk of CV hospitalization and a higher risk of neuropsychiatric hospitalization.[148]

Recommendations

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

[147] U.S. Department of Health and Human Services. *Smoking Cessation: A Report of the Surgeon General—Executive Summary*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2020. Available at: https://www.hhs.gov/sites/default/files/2020-cessation-sgr-executive-summary.pdf. Last accessed 02/18/2020.

[148] Carney G, Bassett K, Maclure M, et al. Cardiovascular and neuropsychiatric safety of smoking cessation pharmacotherapies in non-depressed adults: a retrospective cohort study. *Addiction* 2020; online publication. Available online at: https://doi.org/10.1111/add.14951. Last accessed 02/18/2020.

Utilization Details of Smoking Cessation Products: Fiscal Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	CLAIMS/ MEMBER
NICOTINE REPLACEMENT PRODUCTS						
NICOTINE TD DIS 21MG/24H	2,141	1,344	$102,747.45	$2.09	$47.99	1.59
NICOTINE TD DIS 14MG/24H	1,312	778	$59,957.77	$2.18	$45.70	1.69
NICOTINE TD DIS 7MG/24HR	586	387	$25,000.72	$2.19	$42.66	1.51
NICOTINE POL LOZ 4MG MINT	318	84	$13,128.32	$5.24	$41.28	3.79
NICODERM CQ DIS 21MG/24H	296	185	$12,993.23	$2.18	$43.90	1.60
NICODERM CQ DIS 14MG/24H	244	156	$15,860.37	$3.27	$65.00	1.56
NICOTINE POL GUM 4MG	171	45	$6,669.30	$3.61	$39.00	3.80
NICODERM CQ DIS 7MG/24HR	108	80	$5,246.68	$2.79	$48.58	1.35
NICOTROL INH 10MG	108	84	$48,175.70	$18.17	$446.07	1.29
NICOTINE POL LOZ 2MG MINT	90	25	$4,025.80	$3.92	$44.73	3.60
NICOTINE POL GUM 4MG ORIG	79	37	$3,245.70	$3.96	$41.08	2.14
NICORETTE LOZ 4MG MINT	73	22	$4,355.53	$3.60	$59.66	3.32
NICORETTE GUM 4MG MINT	67	15	$2,721.55	$3.05	$40.62	4.47
HM NICOTINE DIS 14MG/24H	62	33	$2,804.16	$2.14	$45.23	1.88
SM NICOTINE GUM 4MG MINT	50	14	$2,492.59	$2.51	$49.85	3.57
SM NICOTINE DIS 21MG/24H	49	45	$2,509.52	$1.96	$51.21	1.09
NICOTINE POL GUM 2MG	44	26	$1,603.96	$2.53	$36.45	1.69
SM NICOTINE DIS 14MG/24H	41	38	$1,913.36	$1.98	$46.67	1.08
NICOTROL NS SPR 10MG/ML	41	15	$26,920.69	$25.81	$656.60	2.73
HM NICOTINE GUM 2MG MINT	39	10	$1,379.71	$2.38	$35.38	3.90
HM NICOTINE GUM 4MG MINT	30	12	$3,259.99	$4.33	$108.67	2.50
NICOTINE POL GUM 4MG MINT	29	22	$1,239.32	$2.57	$42.74	1.32
NICORETTE LOZ 2MG MINT	27	14	$1,752.63	$4.04	$64.91	1.93
HM NICOTINE LOZ 4MG MINT	26	7	$2,915.94	$4.61	$112.15	3.71
GNP NICOTINE DIS 21MG/24H	26	20	$999.46	$2.30	$38.44	1.30
HM NICOTINE DIS 21MG/24H	22	19	$1,120.16	$2.04	$50.92	1.16
NICORETTE GUM 4MGFRUIT	21	8	$1,243.60	$3.64	$59.22	2.63
SM NICOTINE LOZ 4MG MINT	20	7	$2,272.41	$4.54	$113.62	2.86
NICOTINE POL GUM 2MG ORIG	19	13	$614.81	$1.69	$32.36	1.46
NICOTINE POL GUM 2MG CINN	16	11	$521.07	$1.87	$32.57	1.45
GNP NICOTINE LOZ MINI 2MG	15	3	$672.77	$4.03	$44.85	5.00
NICORETTE GUM 4MG CINN	15	9	$861.74	$4.66	$57.45	1.67
SM NICOTINE DIS 7MG/24HR	14	13	$692.91	$1.98	$49.49	1.08
SM NICOTINE LOZ 2MG MINT	14	12	$641.88	$2.18	$45.85	1.17
SM NICOTINE GUM 2MG	14	9	$326.46	$2.94	$23.32	1.56
NICOTINE POL GUM 2MG MINT	14	8	$383.82	$1.83	$27.42	1.75
NICORETTE GUM 2MG MINT	11	10	$467.61	$3.18	$42.51	1.10
SM NICOTINE GUM 4MG	10	6	$462.07	$2.54	$46.21	1.67
NICORETTE GUM 2MGFRUIT	10	5	$401.14	$3.29	$40.11	2.00
NICOTINE LOZ 2MG MINT	9	5	$351.14	$2.22	$39.02	1.80
HM NICOTINE LOZ 2MG MINT	7	2	$461.47	$8.24	$65.92	3.50
NICOTINE SYS KIT TRANSDER	7	7	$672.16	$1.71	$96.02	1.00

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	CLAIMS/ MEMBER
SM NICOTINE GUM 2MG MINT	6	6	$416.12	$4.29	$69.35	1.00
GNP NICOTINE LOZ 4MG MINT	6	4	$370.93	$5.22	$61.82	1.50
GNP NICOTINE DIS 7MG/24HR	6	3	$248.82	$2.18	$41.47	2.00
GNP NICOTINE GUM 2MG MINT	5	4	$151.81	$1.47	$30.36	1.25
NICORETTE GUM 4MG ORIG	5	2	$611.39	$5.88	$122.28	2.50
NICORETTE ST GUM 2MG ORIG	3	2	$158.57	$2.27	$52.86	1.50
NICORETTE GUM 2MG CINN	3	3	$141.13	$3.53	$47.04	1.00
NICORELIEF GUM 2MG ORIG	3	2	$74.37	$1.14	$24.79	1.50
NICORETTE GUM 2MG ORIG	3	3	$200.01	$2.56	$66.67	1.00
NICORETTE ST GUM 4MG ORIG	2	2	$190.54	$5.44	$95.27	1.00
GNP NICOTINE DIS 14MG/24H	2	2	$68.95	$2.46	$34.48	1.00
HM NICOTINE DIS 7MG/24HR	2	2	$112.88	$2.02	$56.44	1.00
NICORETTE LOZ 4MG CHRY	2	2	$119.78	$3.33	$59.89	1.00
NICORELIEF GUM 4MG MINT	2	2	$121.59	$3.47	$60.80	1.00
NICOTINE LOZ 4MG MINT	1	1	$40.55	$2.70	$40.55	1.00
NICORETTE LOZ 2MG CHRY	1	1	$44.17	$1.47	$44.17	1.00
GNP NICOTINE GUM 2MG ORIG	1	1	$45.94	$3.06	$45.94	1.00
GNP NICOTINE GUM 4MG MINT	1	1	$68.93	$6.89	$68.93	1.00
NICORELIEF GUM 2MG MINT	1	1	$33.05	$3.30	$33.05	1.00
NICORELIEF GUM 4MG ORIG	1	1	$34.37	$1.15	$34.37	1.00
SUBTOTAL	**6,351**	**2,874**	**$369,340.57**	**$2.91**	**$58.15**	**2.21**
VARENICLINE PRODUCTS						
CHANTIX PAK 0.5& 1MG	2,581	2,270	$1,039,639.84	$13.98	$402.81	1.14
CHANTIX PAK 1MG	1,483	841	$600,266.47	$14.23	$404.76	1.76
CHANTIX TAB 1MG	1,215	606	$490,763.57	$13.87	$403.92	2.00
CHANTIX TAB 0.5MG	145	85	$50,448.88	$13.24	$347.92	1.71
SUBTOTAL	**5,424**	**2,797**	**$2,181,118.76**	**$14.01**	**$402.12**	**1.94**
BUPROPION PRODUCTS						
BUPROPION TAB 150MG SR	259	120	$ 8,266.88	$0.93	$31.92	2.16
SUBTOTAL	**259**	**120**	**$ 8,266.88**	**$0.93**	**$31.92**	**2.16**
TOTAL	**12,034**	**5,610***	**$2,558,726.21**	**$8.78**	**$212.62**	**2.15**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Fiscal Year 2019 Annual Review of Strensiq® (Asfotase Alfa)

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Strensiq® (Asfotase Alfa) Approval Criteria:

1. An FDA approved indication for the treatment of patients with perinatal/infantile-onset and juvenile-onset hypophosphatasia (HPP); and
2. Confirmed diagnosis by laboratory testing of:
    a. Low age-adjusted ALP activity; and
    b. Elevated pyridoxal 5'-phophate (PLP) levels; and
3. Member's weight (kg) must be provided and have been taken within the last 4 weeks to ensure accurate weight based dosing; and
4. The 80mg/0.8mL vial should not be used in pediatric patients weighing <40kg.

Utilization of Strensiq® (Asfotase Alfa): Fiscal Year 2019

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	3	36	$1,272,955.80	$35,359.88	$1,262.85	451	1,008
2019	4	34	$1,187,822.70	$34,935.96	$1,247.71	401	952
% Change	**33.30%**	**-5.60%**	**-6.70%**	**-1.20%**	**-1.20%**	**-11.10%**	**-5.60%**
Change	**1**	**-2**	**-$85,133.10**	**-$423.92**	**-$15.14**	**-50**	**-56**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Demographics of Members Utilizing Strensiq® (Asfotase Alfa)

- Due to the small number of members utilizing Strensiq® (asfotase alfa) during fiscal year 2019, detailed demographic information could not be provided.

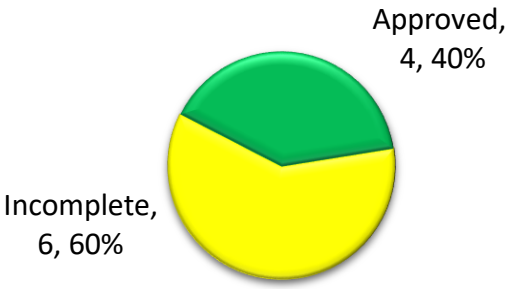
Top Prescriber Specialties of Strensiq® (Asfotase Alfa) by Number of Claims

- The only prescriber specialties listed on paid pharmacy claims for Strensiq® (asfotase alfa) during fiscal year 2019 were general pediatrician and genetic counselor.

Prior Authorization of Strensiq® (Asfotase Alfa)

There were 10 prior authorization requests submitted for Strensiq® (asfotase alfa) during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.

Status of Petitions



Recommendations

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

Utilization Details of Strensiq® (Asfotase Alfa): Fiscal Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	% COST
STRENSIQ 28MG/0.7ML	20	2	$672,887.48	$33,644.37	56.65%
STRENSIQ 40MG/ML	13	2	$446,292.35	$34,330.18	37.57%
STRENSIQ 80MG/0.8ML	1	1	$68,642.87	$68,642.87	5.78%
TOTAL	**34**	**4***	**$1,187,822.70**	**$34,935.96**	**100.00%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Fiscal Year 2019 Annual Review of Symlin® (Pramlintide)

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Symlin® (Pramlintide) Approval Criteria:

1. An FDA approved diagnosis of type 1 or type 2 diabetes; and
2. Member must be using a basal-bolus insulin regimen; and
3. Member must have failed to achieve adequate glycemic control on basal-bolus insulin regimen or are gaining excessive weight on basal-bolus insulin regimen; and
4. Member must be receiving ongoing care under the guidance of a health care professional; and
5. Members meeting any of the following criteria should not be considered for Symlin® (pramlintide) therapy:
    a. Poor compliance with insulin regimen; or
    b. Poor compliance with self-blood glucose monitoring; or
    c. Hemoglobin A1c (HbA1c) >9%; or
    d. Recurrent severe hypoglycemia requiring assistance in the past 6 months; or
    e. Presence of hypoglycemia unawareness; or
    f. Diagnosis of gastroparesis; or
    g. Required use of medications that stimulate gastrointestinal motility; or
    h. Pediatric patients 15 years of age or younger.

Utilization of Symlin® (Pramlintide): Fiscal Year 2019

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Claims/ Member	Total Units	Total Days
2018	1	2	$1,652.03	$826.01	$27.53	6	60
2019	0	0	$0	$0	$0	0	0
% Change	**-100.00%**	**-100.00%**	**-100.00%**	**-100.00%**	**-100.00%**	**-100.00%**	**-100.00%**
Change	**-1**	**-2**	**-$1,652.03**	**-$826.01**	**-$27.53**	**-6**	**-60**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

- There was no SoonerCare utilization of Symlin® (pramlintide) during fiscal year 2019.

Prior Authorization of Symlin® (Pramlintide)

There were no prior authorization requests submitted for Symlin® (pramlintide) during fiscal year 2019.

Recommendations

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

Fiscal Year 2019 Annual Review of Sylvant® (Siltuximab)

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Sylvant® (Siltuximab) Approval Criteria:

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

Utilization of Sylvant® (Siltuximab): Fiscal Year 2019

There was no SoonerCare utilization of Sylvant® (siltuximab) during fiscal year 2019 (fiscal year 2019 = 07/01/2018 to 06/30/2019.

Prior Authorization of Sylvant® (Siltuximab)

There were no prior authorization requests submitted for Sylvant® (siltuximab) during fiscal year 2019.

Recommendations

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

Fiscal Year 2019 Annual Review of Testosterone Products

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Testosterone Products		
Tier-1*	**Tier-2**	**Special PA**
methyltestosterone powder	testosterone enanthate sub-Q auto-injector (Xyosted™)	fluoxymesterone oral tab (Androxy®)
testosterone cypionate IM inj (Depo-Testosterone®)	testosterone nasal gel (Natesto®)	methyltestosterone oral tab/cap (Android®, Methitest®, Testred®)
testosterone enanthate IM inj (Delatestryl®)	testosterone patch (Androderm®)	testosterone buccal tab (Striant®)
testosterone topical gel (Androgel® 1%, 1.62%)+	testosterone topical gel (Fortesta®, Testim®, Vogelxo®)	testosterone pellets (Testopel®)
	testosterone topical solution (Axiron®)	testosterone undecanoate oral cap (Jatenzo®)
	testosterone undecanoate IM inj (Aveed®)	

*Tier-1 products include generic injectable products and supplementally rebated topical products.
+Brand name preferred
PA = prior authorization; IM = intramuscular; inj = injection; sub-Q = subcutaneous; tab = tablet; cap = capsule

Initial Approval Criteria for All Testosterone Products:

1. An FDA approved diagnosis of 1 of the following:
    a. Testicular failure due to cryptorchidism, bilateral torsions, orchitis, vanishing testis syndrome, or orchiectomy; or
    b. Idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary hypothalamic injury from tumors, trauma, or radiation; or
    c. Delayed puberty; or
    d. Advanced inoperable metastatic mammary cancer in females 1 to 5 years postmenopausal, or premenopausal females with breast cancer benefitting from oophorectomy and have been determined to have a hormone-responsive tumor; and
2. Must include 2 labs showing pre-medication, morning testosterone (total testosterone) levels <300ng/dL; and
3. Must include 1 lab showing abnormal gonadotropins and/or other information necessary to demonstrate diagnosis; or
4. Testosterone and gonadotropin labs are not required for authorization of testosterone therapy if documentation is provided for established hypothalamic pituitary or gonadal disease, if the pituitary gland or testes has/have been removed, or for postmenopausal females with advanced inoperable metastatic mammary cancer or premenopausal females with breast cancer benefitting from oophorectomy and that have been determined to have a hormone-responsive tumor.

Testosterone Products Tier-2 Approval Criteria:

1. All diagnoses and laboratory requirements listed in the initial approval criteria for all testosterone products must be met; and
2. A trial of at least 2 Tier-1 products (must include at least 1 injectable and 1 topical formulation) at least 12 weeks in duration; or
3. A patient-specific, clinically significant reason why member cannot use all available Tier-1 products must be provided; or
4. Prior stabilization on a Tier-2 product (within the past 180 days); and
5. Approvals will be for the duration of 1 year; and
6. For Xyosted™ [testosterone enanthate subcutaneous (sub-Q) auto-injector]:
    a. Member must be trained by a health care professional on sub-Q administration and storage of Xyosted™ sub-Q auto-injector.

Testosterone Products Special Prior Authorization (PA) Approval Criteria:

1. All diagnoses and laboratory requirements listed in the initial approval criteria for all testosterone products must be met; and
2. A patient-specific, clinically significant reason why member cannot use all other available formulations of testosterone must be provided; and
3. Approvals will be for the duration of 1 year.

Utilization of Testosterone Products: Fiscal Year 2019

Comparison of Fiscal Years for Testosterone Products: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	148	598	$131,885.82	$220.54	$5.17	21,285	25,513
2019	171	671	$135,158.35	$201.43	$4.54	22,707	29,745
% Change	**15.50%**	**12.20%**	**2.50%**	**-8.70%**	**-12.20%**	**6.70%**	**16.60%**
Change	**23**	**73**	**$3,272.53**	**-$19.11**	**-$0.63**	**1,422**	**4,232**

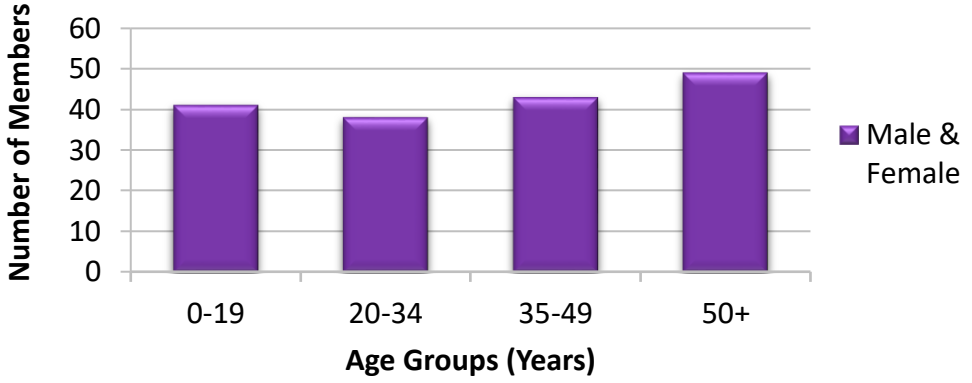
*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Fiscal Year 2019 Utilization of Testosterone Products: Medical Claims

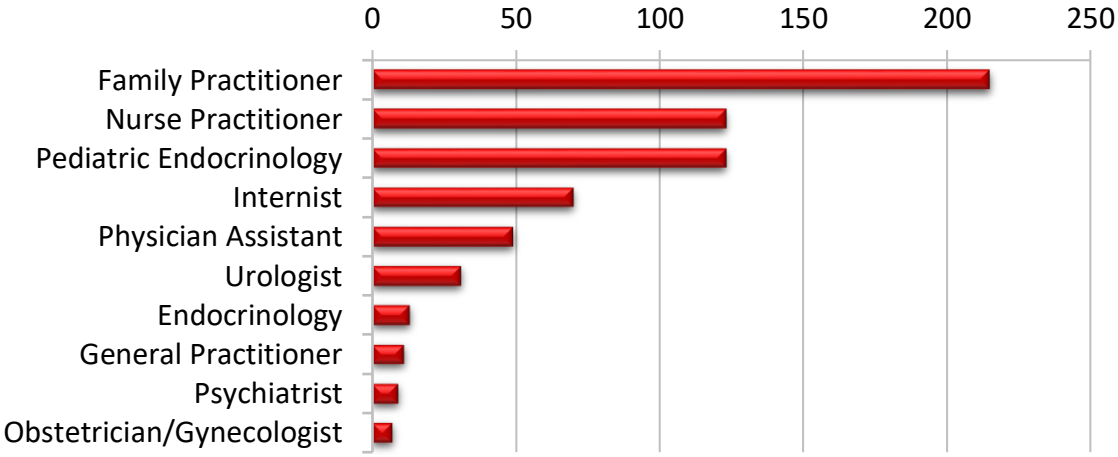
Fiscal Year	*Total Members	+Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2019	29	170	$716.45	$4.21	5.86

*Total number of unduplicated members.
+Total number of unduplicated claims.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Demographics of Members Utilizing Testosterone Products: Pharmacy Claims



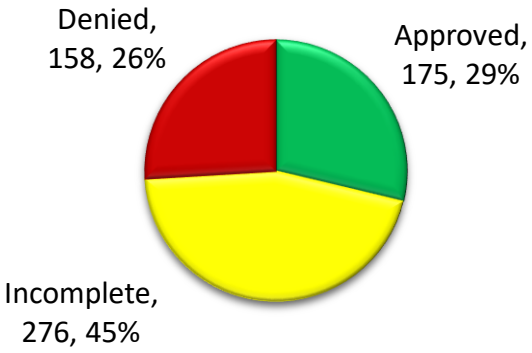
Top Prescriber Specialties of Testosterone Products by Number of Claims: Pharmacy Claims



Prior Authorization of Testosterone Products

There were 609 prior authorization requests submitted for testosterone products during fiscal year 2019. All testosterone products require prior authorization regardless of Tier status in order to evaluate diagnosis and submitted labs. The following chart shows the status of the submitted petitions for fiscal year 2019.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[149]

- Natesto® (testosterone nasal gel): February 2024
- Testim® (testosterone topical gel): January 2025
- Aveed® [testosterone undecanoate intramuscular (IM) injection]: March 2027
- Jatenzo® (testosterone undecanoate oral capsule): December 2030
- Vogelxo® (testosterone topical gel): February 2034
- Xyosted™ [testosterone enanthate subcutaneous (sub-Q) auto-injector]: September 2036

Pipeline:[150,151,152]

- **Tlando™:** Lipocine is currently developing Tlando™, an oral testosterone undecanoate product candidate. In November 2019, the U. S. Food and Drug Administration (FDA) rejected Lipicine's New Drug Application (NDA) for Tlando™, stating that the trial establishing efficacy of the product did not meet the 3 secondary end points for maximal testosterone concentrations.
- **Tlando XR (LPCN 1111):** Lipocine is also developing LPCN 1111 (Tlando XR), a novel, next-generation, oral testosterone therapy product candidate with potential for once daily dosing. LPCN 1111 is a novel ester prodrug of testosterone that uses Lip'ral technology to enhance solubility and improve systemic absorption. Lip'ral is a patented technology based on lipidic compositions which form an optimal dispersed phase in the gastrointestinal environment for improved absorption of an insoluble drug. LPCN 1111 has completed Phase 2 clinical trials and was overall well tolerated with no serious adverse events reported. A Phase 3 trial of LPCN 1111 is planned.

Recommendations

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

---

[149] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 03/2020. Last accessed 03/10/2020.

[150] Lipocine, Inc. Lipocine Pipeline: Tlando™. Available online at: https://www.lipocine.com/pipeline/tlando/. Last accessed 03/16/2020.

[151] Ernst D. FDA Again Rejects NDA for Oral Testosterone Product Candidate. *MPR.* Available online at: https://www.empr.com/home/news/fda-again-rejects-nda-for-oral-testosterone-product-candidate/. Issued 11/12/19. Last accessed 03/16/2020.

[152] Lipocine, Inc. Lipocine Pipeline: Tlando XR (LPCN 1111). Available online at: https://www.lipocine.com/pipeline/tlando-xr-lpcn-1111/. Last accessed 03/16/2020.

Utilization Details of Testosterone Products: Fiscal Year 2019

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TESTOSTERONE INJECTABLE PRODUCTS						
TESTOST CYP INJ 200MG/ML	464	126	$20,956.85	$45.17	3.68	15.51%
DEPO-TESTOST INJ 200MG/ML	18	6	$945.45	$52.53	3	0.70%
TESTOST CYP INJ 100MG/ML	15	8	$726.39	$48.43	1.88	0.54%
TESTOST ENAN INJ 200MG/ML	4	2	$304.62	$76.16	2	0.23%
DEPO-TESTOST INJ 100MG/ML	4	2	$274.01	$68.50	2	0.20%
SUBTOTAL	**505**	**140***	**$23,207.32**	**$45.96**	**3.61**	**17.17%**
TESTOSTERONE TOPICAL PRODUCTS						
ANDROGEL GEL 1.62%	109	24	$80,806.07	$741.34	4.54	59.79%
TESTOSTERONE GEL 1% (50MG)	26	4	$8,195.70	$315.22	6.5	6.06%
ANDROGEL GEL 1% (50MG)	18	4	$17,753.62	$986.31	4.5	13.14%
TESTOSTERONE SOL 30MG/ACT	4	1	$849.27	$212.32	4	0.63%
ANDROGEL GEL 1% (25MG)	3	2	$1,864.92	$621.64	1.5	1.38%
AXIRON SOL 30MG/ACT	2	1	$1,168.04	$584.02	2	0.86%
ANDROGEL GEL 1.62%	2	2	$755.88	$377.94	1	0.56%
TESTOSTERONE GEL 1.62%	2	1	$557.53	$278.77	2	0.41%
SUBTOTAL	**166**	**35***	**$111,951.03**	**$674.40**	**4.74**	**82.83%**
TOTAL	**671**	**171***	**$135,158.35**	**$201.43**	**3.92**	**100%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
TESTOSTERONE CYPIONATE INJ J1071	170	29	$716.45	$4.21	5.86
TOTAL	**170+**	**29***	**$716.45**	**$4.21**	**5.86**

+Total number of unduplicated claims.
*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Fiscal Year 2019 Annual Review of Topical Acne Products

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Aczone® (Dapsone Gel) Approval Criteria:

1. An FDA approved indication of acne vulgaris; and
2. Member must be 20 years of age or younger; and
3. A previous trial of benzoyl peroxide or a patient-specific, clinically significant reason why benzoyl peroxide is not appropriate for the member must be provided; and
4. A previous trial of a topical antibiotic, such as clindamycin or erythromycin, or a patient-specific, clinically significant reason why a topical antibiotic is not appropriate for the member must be provided.

Tazorac® (Tazarotene Cream and Gel) Approval Criteria:

1. An FDA approved indication of acne vulgaris or plaque psoriasis; and
2. Female members must not be pregnant and must be willing to use an effective method of contraception during treatment; and
3. Authorization of tazarotene 0.1% cream will require a patient-specific, clinically significant reason why the member cannot use the other formulations of tazarotene (brand Tazorac® 0.05% cream, 0.05% gel, and 0.1% gel are preferred); and
4. For the diagnosis of acne vulgaris, the following must be met:
    a. Member must be 20 years of age or younger; and
    b. Based on current net costs, Tazorac® 0.05% cream, 0.05% gel, and 0.1% gel will not require prior authorization for members 20 years of age or younger; and
5. A quantity limit of 100 grams per 30 days will apply.

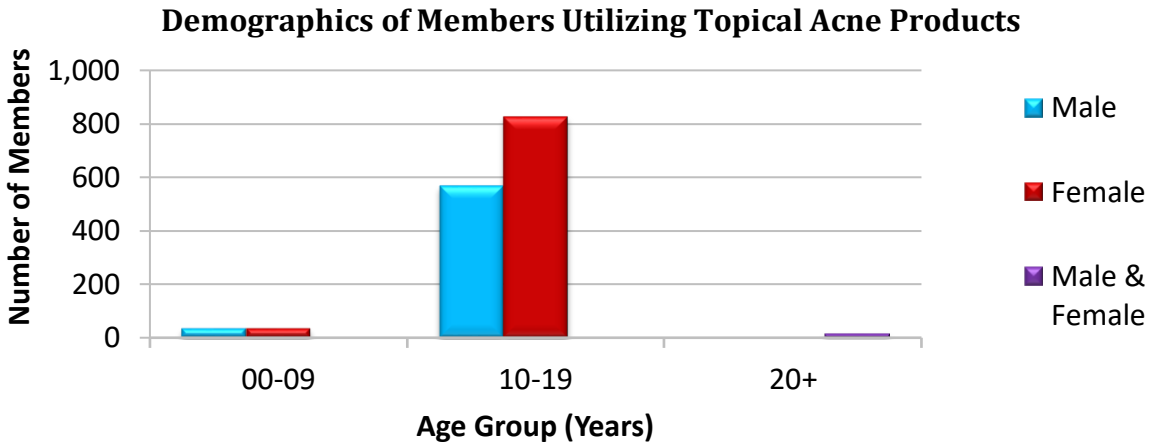
Utilization of Topical Acne Products: Fiscal Year 2019

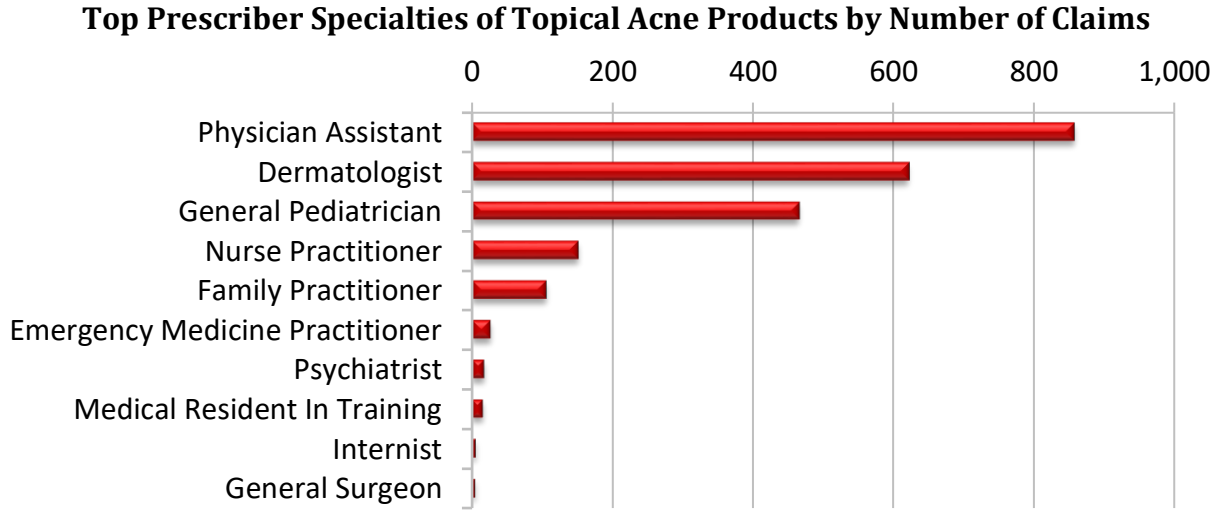
Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	1,467	2,125	$906,152.01	$426.42	$16.65	83,295	54,435
2019	1,481	2,274	$1,055,406.08	$464.12	$17.81	85,640	59,244
% Change	**1.0%**	**7.0%**	**16.5%**	**8.8%**	**7.0%**	**2.8%**	**8.8%**
Change	**14**	**149**	**$149,254.07**	**$37.70**	**$1.16**	**2,345**	**4,809**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

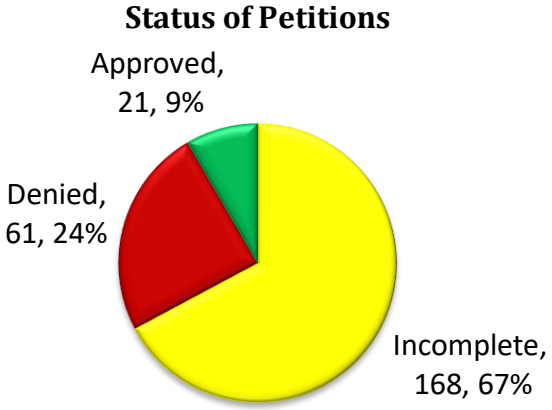
- Please note, Aczone® and Tazorac® both have significant federal rebates and costs included in this report do not reflect rebated prices or net costs.





Prior Authorization of Topical Acne Products

There were 250 prior authorization requests submitted for topical acne products during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.



Market News and Updates

Anticipated Patent Expiration(s):[153]

- Aczone® (dapsone 7.5% gel): November 2033

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

- **September 2019:** Almirall LLC announced that the FDA approved an expanded indication for Aczone® (dapsone 7.5% gel) to include patients 9 to 11 years of age. Aczone® 7.5% gel was previously approved in February 2016 for patients 12 years of age and older for treatment of inflammatory and non-inflammatory acne. The expanded approval was based on data from an open-label safety study to assess safety, pharmacokinetics, and treatment effect of Aczone® 7.5% gel in 101 patients 9 to 11 years of age with acne vulgaris.[154]

Recommendations

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

Utilization Details of Topical Acne Products: Fiscal Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
TAZAROTENE PRODUCTS					
TAZORAC CRE 0.05%	1,483	1,022	$697,319.79	1.45	$470.21
TAZORAC GEL 0.1%	468	302	$210,439.34	1.55	$449.66
TAZORAC GEL 0.05%	273	209	$124,557.15	1.31	$456.25
TAZORAC CRE 0.1%	13	9	$6,987.27	1.44	$537.48
TAZAROTENE CRE 0.1%	9	7	$2,234.87	1.29	$248.32
SUBTOTAL	**2,246**	**1,463**	**$1,041,538.42**	**1.54**	**$463.73**
DAPSONE PRODUCTS					
DAPSONE GEL 5%	13	12	$4,721.16	1.08	$363.17
ACZONE GEL 7.5%	8	6	$4,774.54	1.33	$596.82
ACZONE GEL 5%	7	4	$4,371.96	1.75	$624.57
SUBTOTAL	**28**	**22**	**$13,867.66**	**1.27**	**$495.27**
TOTAL	**2,274**	**1,481***	**$1,055,406.08**	**1.54**	**$464.12**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

- Please note, Aczone® and Tazorac® both have significant federal rebates and costs included in this report do not reflect rebated prices or net costs.

[153] 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 10/2019. Last accessed 10/02/2019.

[154] Almirall. Aczone® (Dapsone) Gel, 7.5% Now Approved for the Topical Treatment of Acne Vulgaris in Patients 9 Years of Age and Older. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/aczone-dapsone-gel-7-5-now-approved-for-the-topical-treatment-of-acne-vulgaris-in-patients-9-years-of-age-and-older-300915589.html. Issued 09/10/2019. Last accessed 10/02/2019.

Fiscal Year 2019 Annual Review of Topical Antibiotic Products

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

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

Tier structure is based on supplemental rebate participation, and/or National Average Drug Acquisition Costs (NADAC), or Wholesale Acquisition Costs (WAC) if NADAC unavailable.
HC = hydrocortisone

Topical Antibiotic Products Tier-2 Approval Criteria:

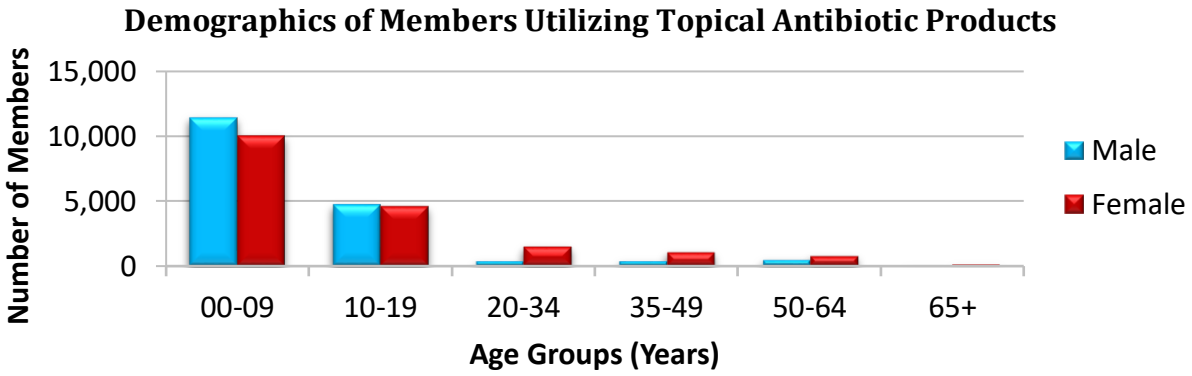
1. A documented 5-day trial of a Tier-1 product within the last 30 days; or
2. Clinical exceptions apply for adverse effects with all Tier-1 products or for a unique indication not covered by Tier-1 products; and
3. Approvals will be for the duration of 10 days.

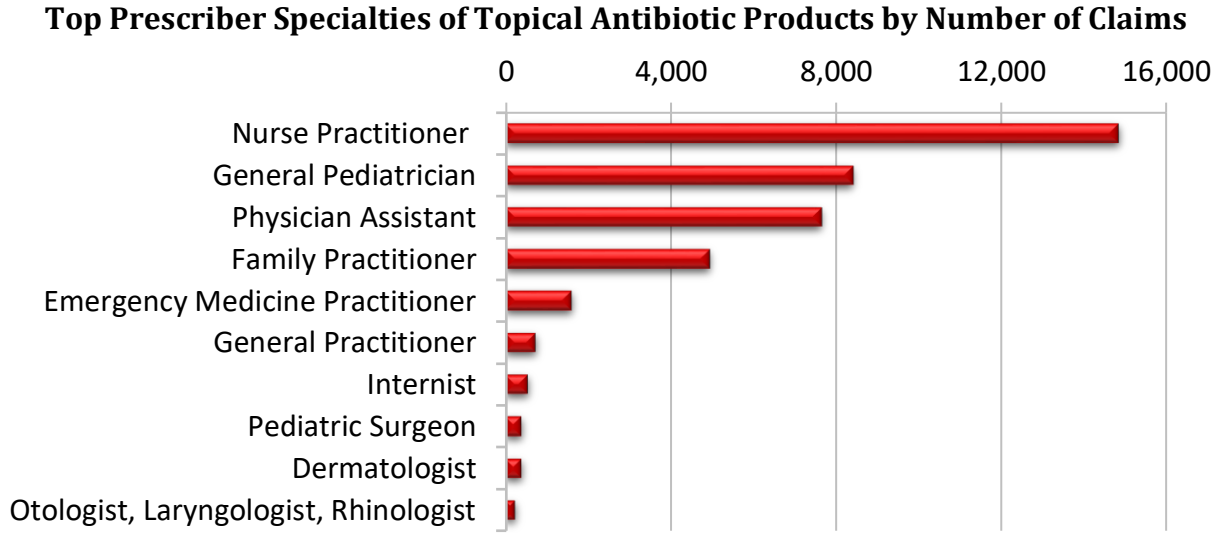
Utilization of Topical Antibiotic Products: Fiscal Year 2019

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	36,505	43,176	$699,380.51	$16.20	$1.54	997,946	453,237
2019	35,157	41,194	$665,435.19	$16.15	$1.53	991,440	435,627
% Change	**-3.7%**	**-4.6%**	**-4.9%**	**-0.3%**	**-0.6%**	**-0.7%**	**-3.9%**
Change	**-1,348**	**-1,982**	**-$33,945.32**	**-$0.05**	**-$0.01**	**-6,506**	**-17,610**

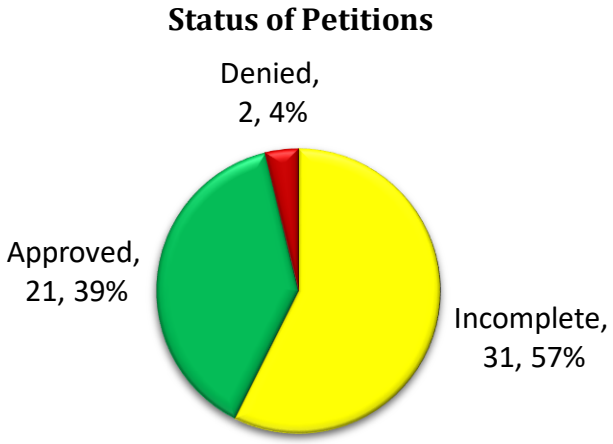
*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019





Prior Authorization of Topical Antibiotic Products

There were 54 prior authorization requests submitted for topical antibiotic products during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.



Market News and Updates

Anticipated Patent Expiration(s):[155]

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

Recommendations

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

Utilization Details of Topical Antibiotic Products: Fiscal Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
TIER-1 PRODUCTS					
MUPIROCIN OIN 2%	40,830	34,992	$620,778.19	$1.44	$15.20
GENTAMICIN OIN 0.1%	225	115	$19,299.88	$6.50	$85.78
GENTAMICIN CRE 0.1%	98	57	$18,945.40	$7.51	$193.32
CORTISPORIN CRE 0.5%	20	14	$2,479.46	$11.59	$123.97
CORTISPORIN OIN 1%	7	7	$1,140.72	$21.94	$162.96
SUBTOTAL	**41,180**	**35,185**	**$662,643.65**	**$1.52**	**$16.09**
TIER-2 PRODUCTS					
MUPIROCIN CRE 2%	13	12	$2,773.44	$19.81	$213.34
CENTANY OIN 2%	1	1	$18.10	$1.21	$18.10
SUBTOTAL	**14**	**13**	**$2,791.54**	**$18.10**	**$199.40**
TOTAL	**41,194**	**35,157***	**$665,435.19**	**$1.53**	**$16.15**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

[155] 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/default.cfm?resetfields=1. Last revised 10/2019. Last accessed 10/02/2019.

Fiscal Year 2019 Annual Review of Topical Antifungal Products

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

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

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

Topical Antifungal Products Tier-2 Approval Criteria:

1. Documented, recent trials with at least 2 Tier-1 topical antifungal products for at least 90 days each; and
2. When the same medication is available in Tier-1, a patient-specific, clinically significant reason must be provided for using a special dosage form of that medication in Tier-2 (e.g., foam, shampoo, spray, kit); and
3. Authorization of combination products nystatin/triamcinolone or clotrimazole/ betamethasone lotion requires a patient-specific, clinically significant reason why the member cannot use the individual components separately, or in the case of clotrimazole/betamethasone lotion, why the Tier-1 cream formulation cannot be used; and
4. For treatment of onychomycosis, a trial of oral antifungals (6 weeks for fingernails and 12 weeks for toenails) will be required for consideration of approval of Penlac® (ciclopirox solution).

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

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

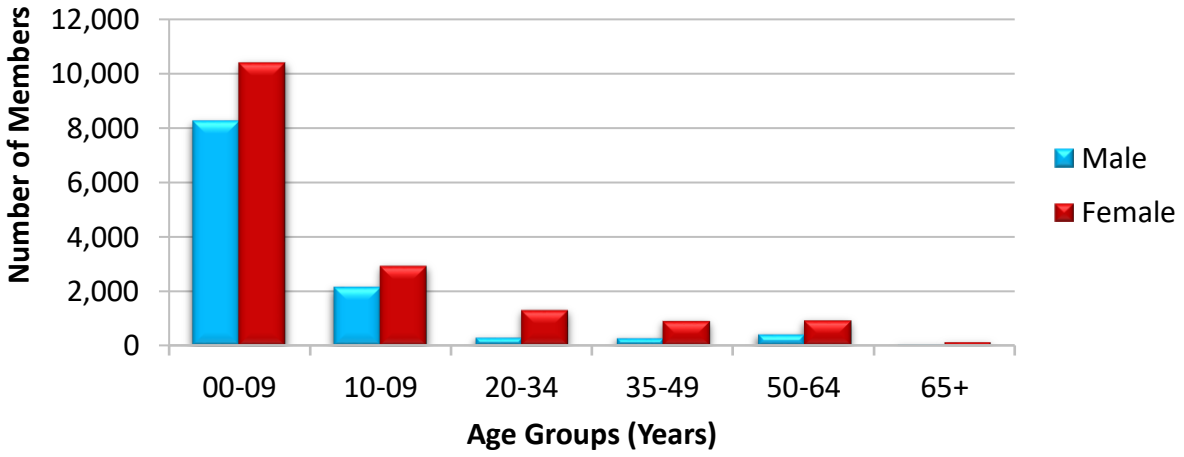
Utilization of Topical Antifungal Products: Fiscal Year 2019

Comparison of Fiscal Years

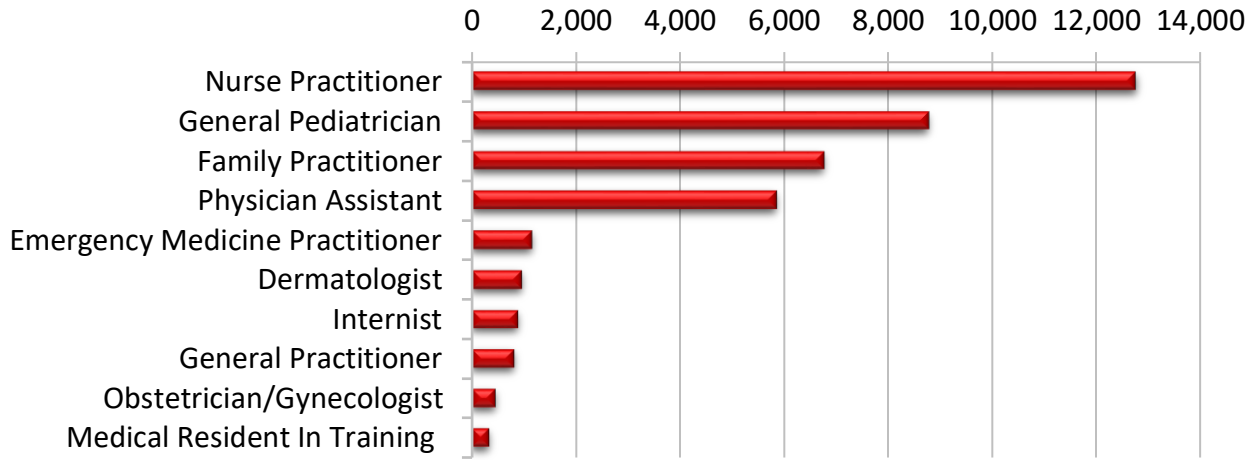
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	28,953	40,914	$891,604.11	$21.79	$1.46	1,570,438	608,874
2019	28,028	39,951	$815,385.22	$20.41	$1.32	1,617,805	615,780
% Change	**-3.2%**	**-2.4%**	**-8.5%**	**-6.3%**	**-9.6%**	**3.0%**	**1.1%**
Change	**-925**	**-963**	**-$76,218.89**	**-$1.38**	**-$0.14**	**47,367**	**6,906**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Demographics of Members Utilizing Topical Antifungal Products



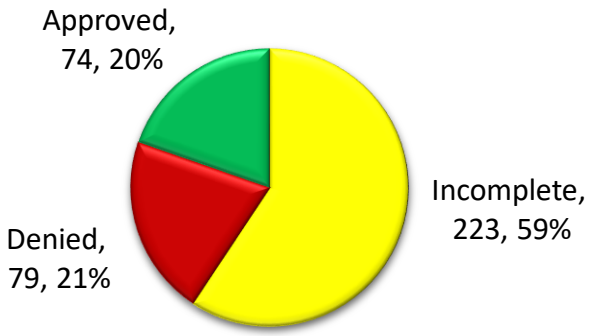
Top Prescriber Specialties of Topical Antifungal Products by Number of Claims



Prior Authorization of Topical Antifungal Products

There were 376 prior authorization requests submitted for topical antifungal products during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[156]

- Xolegel® (ketoconazole gel): November 2020
- Kerydin® (tavaborole solution): November 2027
- Vusion® (miconazole/zinc oxide/white petrolatum ointment): March 2028
- Naftin® (naftifine gel): January 2033
- Luzu® (luliconazole cream): April 2034
- Jublia® (efinaconazole solution): October 2034

[156] 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/default.cfm?resetfields=1. Last revised 02/2020. Last accessed 03/05/2020.

Recommendations

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

Utilization Details of Topical Antifungal Products: Fiscal Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL DAYS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
TIER-1 UTILIZATION						
CICLOPIROX PRODUCTS						
CICLOPIROX CRE 0.77%	396	6,257	322	$7,633.17	$1.22	$19.28
CICLOPIROX SUS 0.77%	19	505	13	$871.93	$1.73	$45.89
SUBTOTAL	**415**	**6,762**	**335**	**$8,505.10**	**$1.26**	**$20.49**
CLOTRIMAZOLE PRODUCTS						
CLOTRIMAZOLE CRE 1%	6,464	87,273	5,494	$109,457.15	$1.25	$16.93
ATHLETE FOOT CRE 1%	35	463	33	$424.16	$0.92	$12.12
SUBTOTAL	**6,499**	**87,736**	**5,525**	**$109,881.31**	**$1.25**	**$16.91**
CLOTRIMAZOLE/BETAMETHASONE PRODUCTS						
CLOT/BETA DIP CRE 1-0.05%	1,487	22,236	1,240	$29,139.84	$1.31	$19.60
CLOT/BETA CRE 1-0.05%	286	4,835	238	$5,849.44	$1.21	$20.45
SUBTOTAL	**1,773**	**27,071**	**1,464**	**$34,989.28**	**$1.29**	**$19.73**
KETOCONAZOLE PRODUCTS						
KETOCONAZOLE CRE 2%	4,530	77,300	3,801	$166,623.41	$2.16	$36.78
KETOCONAZOLE SHA 2%	4,014	123,009	2,454	$70,581.53	$0.57	$17.58
SUBTOTAL	**8,544**	**200,309**	**5,975**	**$237,204.94**	**$1.18**	**$27.76**
NYSTATIN PRODUCTS						
NYSTATIN CRE 100000	12,635	160,778	9,916	$223,836.41	$1.39	$17.72
NYSTATIN OIN 100000	5,805	72,709	4,719	$111,735.06	$1.54	$19.25
NYSTOP POW 100000	1,835	26,191	1,362	$36,378.93	$1.39	$19.83
NYSTATIN POW 100000	1,061	15,138	623	$22,281.15	$1.47	$21.00
NYAMYC POW 100000	722	8,531	361	$14,373.12	$1.68	$19.91
SUBTOTAL	**22,058**	**283,347**	**15,877**	**$408,604.67**	**$1.44**	**$18.52**
TERBINAFINE PRODUCTS						
TERBINAFINE CRE 1%	447	6,886	407	$7,151.06	$1.04	$16.00
ATHLETE FOOT CRE 1%	50	802	44	$949.92	$1.18	$19.00
LAMISIL AT CRE 1%	12	147	12	$181.26	$1.23	$15.11
ATHLETE FOOT CRE AF 1%	9	115	9	$182.06	$1.58	$20.23
SUBTOTAL	**518**	**7,950**	**471**	**$8,464.30**	**$1.06**	**$16.34**
TOLNAFTATE PRODUCTS						
SM ANTIFUNGL CRE 1%	7	138	7	$87.13	$0.63	$12.45
ANTIFUNGAL CRE 1%	5	96	5	$66.43	$0.69	$13.29
TOLNAFTATE CRE 1%	3	41	3	$37.46	$0.91	$12.49
SUBTOTAL	**15**	**275**	**15**	**$191.02**	**$0.69**	**$12.73**
ECONAZOLE PRODUCTS						
ECONAZOLE CRE 1%	51	964	34	$1,577.78	$1.64	$30.94

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL DAYS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
SUBTOTAL	**51**	**964**	**34**	**$1,577.78**	**$1.64**	**$30.94**
TIER-1 SUBTOTAL	**39,873**	**614,414**	**27,995**	**$809,418.40**	**$1.32**	**$20.30**
TIER-2 UTILIZATION						
BUTENAFINE PRODUCTS						
MENTAX CRE 1%	1	14	1	$105.12	$7.51	$105.12
SUBTOTAL	**1**	**14**	**1**	**$105.12**	**$7.51**	**$105.12**
CICLOPIROX PRODUCTS						
CICLOPIROX SHA 1%	8	53	8	$170.46	$0.71	$21.31
CICLOPIROX SOL 8%	5	600	2	$280.52	$3.55	$56.10
SUBTOTAL	**13**	**653**	**10**	**$450.98**	**$1.41**	**$34.69**
CLOTRIMAZOLE PRODUCTS						
CLOTRIMAZOLE SOL 1%	30	542	24	$1,612.77	$2.98	$53.76
SUBTOTAL	**30**	**542**	**24**	**$1,612.77**	**$2.98**	**$53.76**
CLOTRIMAZOLE/BETAMETHASONE PRODUCTS						
CLOT/BETA DIPROP LOT 1/0.05%	3	24	2	$269.09	$11.21	$89.70
SUBTOTAL	**3**	**24**	**2**	**$269.09**	**$11.21**	**$89.70**
NYSTATIN/TRIAMCINOLONE PRODUCTS						
NYSTAT/TRIAM CRE	21	279	11	$781.10	$2.80	$37.20
NYSTAT/TRIAM OIN	5	54	4	$160.06	$2.96	$32.01
SUBTOTAL	**26**	**333**	**15**	**$941.16**	**$2.83**	**$36.20**
OXICONAZOLE PRODUCTS						
OXICONAZOLE NITRATE CRE 1%	1	14	1	$362.66	$25.90	$362.66
SUBTOTAL	**1**	**14**	**1**	**$362.66**	**$25.90**	**$362.66**
TIER-2 SUBTOTAL	**74**	**1,246**	**53**	**$3,741.78**	**$3.00**	**$50.56**
SPECIAL PRIOR AUTHORIZATION (PA) UTILIZATION						
EFINACONAZOLE PRODUCTS						
JUBLIA SOL 10%	4	120	1	$2,225.04	$18.54	$556.26
SPECIAL PA SUBTOTAL	**4**	**120**	**1**	**$2,225.04**	**$18.54**	**$556.26**
TOTAL	**39,951**	**615,780**	**28,028***	**$815,385.22**	**$1.32**	**$20.41**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated members.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Fiscal Year 2019 Annual Review of Ulcerative Colitis (UC) and Crohn's Disease Medications

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Colazal® (Balsalazide Capsule) Quantity Limit Approval Criteria:

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

Giazo® (Balsalazide) Approval Criteria:

1. An FDA approved diagnosis of mildly-to-moderately active ulcerative colitis (UC); and
2. Member must be 18 years of age or older; and
3. Member must be male (the effectiveness of Giazo® was not demonstrated in female patients in clinical trials); and
4. A patient-specific, clinically significant reason why the member cannot use generic balsalazide 750mg capsules or other products available without prior authorization* must be provided; and
5. Approvals will be for the duration of 8 weeks. After 8 weeks of treatment the prescriber must document a patient-specific, clinically significant reason the member needs a longer duration of treatment.

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

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

Uceris® (Budesonide Rectal Foam) Approval Criteria:

1. An FDA approved diagnosis of induction of remission in patients with active, mild-to-moderate, distal ulcerative colitis (UC) extending up to 40cm from the anal verge; and

2. A patient-specific, clinically significant reason why the member cannot use oral aminosalicylates, topical mesalamine, or other topical (rectally administered) corticosteroids available without prior authorization must be provided; and
3. Approvals will be for the duration of 6 weeks in accordance with manufacturer recommended duration of therapy; and
4. A quantity limit of 133.6 grams per 42 days will apply.

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

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

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

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

Canasa® (Mesalamine Suppository) Quantity Limit Approval Criteria:

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

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

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

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

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

Pentasa® (Mesalamine 250mg Controlled-Release Capsule) Quantity Limit Approval Criteria:

1. A quantity limit of 480 capsules per 30 days will apply; and
2. The first 8 weeks of treatment do not require prior authorization; and
3. After 8 weeks of treatment:
    a. Provider must document a patient-specific, clinically significant reason member needs longer duration of treatment.

Pentasa® (Mesalamine 500mg Controlled-Release Capsule) Approval Criteria:

1. An FDA approved indication for the induction of remission or for the treatment of patients with mildly-to-moderately active ulcerative colitis; and
2. A patient-specific, clinically significant reason the member cannot use Pentasa® 250mg controlled-release capsules or other available mesalamine products that do not require prior authorization must be provided; and
3. Approvals will be for the duration of 8 weeks in accordance with manufacturer recommended duration of therapy; and
4. A quantity limit of 240 capsules per 30 days will apply.

Rowasa® (Mesalamine Rectal Suspension Enema) Approval Criteria:

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

Dipentum® (Olsalazine Capsule) Quantity Limit Approval Criteria:

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

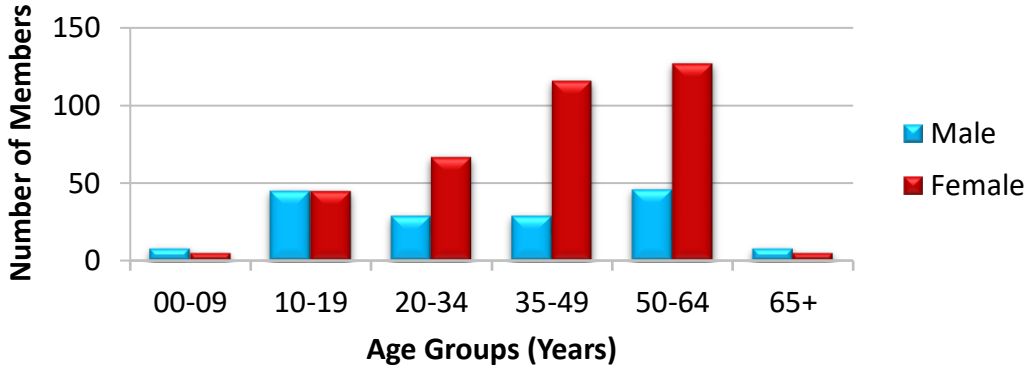
***The following medications do not require prior authorization:** sulfasalazine 500mg tablets, sulfasalazine delayed-release (DR) 500mg tablets, Rowasa® (mesalamine) rectal suspension enemas, Lialda® (mesalamine) DR capsules, Colazal® (balsalazide) capsules, Dipentum® (olsalazine) capsules, Pentasa® (mesalamine) 250mg controlled-release (CR) capsules, Canasa® (mesalamine) suppositories, Apriso® (mesalamine) extended-release (ER) capsules, Delzicol® (mesalamine) DR capsules, and hydrocortisone enemas.

Utilization of UC and Crohn's Disease Medications: Fiscal Year 2019

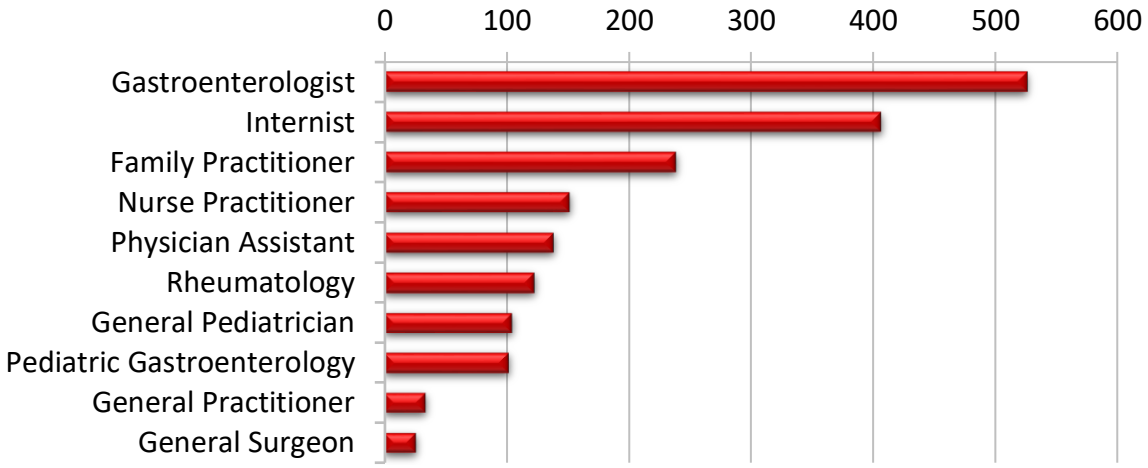
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	500	1,921	$585,833.54	$304.96	$10.20	247,941	57,440
2019	530	1,923	$441,169.38	$229.42	$7.66	236,547	57,613
% Change	**6.00%**	**0.10%**	**-24.70%**	**-24.80%**	**-24.90%**	**-4.60%**	**0.30%**
Change	**30**	**2**	**-$144,664.16**	**-$75.54**	**-$2.54**	**-11,394**	**173**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Demographics of Members Utilizing UC and Crohn's Disease Medications



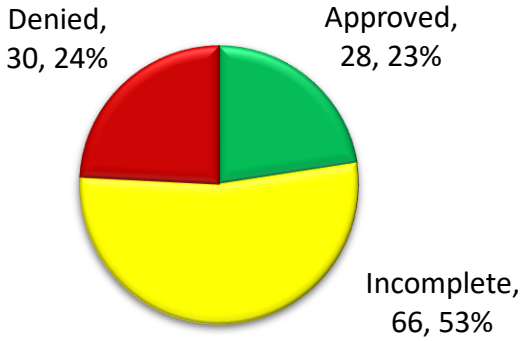
Top Prescriber Specialties of UC and Crohn's Disease Medications by Number of Claims



Prior Authorization of UC and Crohn's Disease Medications

There were 124 prior authorization requests submitted for UC and Crohn's disease medications during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[157]

- Delzicol® [mesalamine delayed-release (DR) tablet]: April 2020
- Lialda® (mesalamine DR tablet): June 2020
- Asacol® HD (mesalamine DR tablet): November 2021
- Canasa® (mesalamine suppository): June 2028
- Apriso® [mesalamine extended-release (ER) tablet]: May 2030
- Giazo® (balsalazide tablets): June 2031

News:

- **February 2019:** The American Gastroenterological Association (AGA) published updated guidelines for the management of mild-to-moderate UC.[158] Mild-to-moderate UC is defined by the AGA as <4-6 bowel movements per day, mild-moderate rectal bleeding, absence of constitutional symptoms, low overall inflammatory burden, and absence of features suggestive of high inflammatory activity. The majority of patients with UC have mild-to-moderate UC and >90% of patients are treated with 5-aminosalicylates (5-ASA) which include mesalamine, sulfasalazine, olsalazine, and balsalazide. Patients who achieve remission on 5-ASA medications typically remain on them for maintenance of remission. A minority of patients with UC require treatment with biologics or immunomodulators. Key recommendations from the AGA 2019 guidelines include:
  - Standard-dose mesalamine (2-3g/day) or diazo-bonded 5-ASA (balsalazide, olsalazine) are preferred over low-dose mesalamine, sulfasalazine, or no treatment for patients with extensive mild-to-moderate UC.
  - Rectal mesalamine is recommended as add-on therapy to oral 5-ASA for extensive or left-sided mild-to-moderate UC.
  - Progression to high-dose mesalamine (>3g/day) plus rectal mesalamine is recommended for patients with suboptimal response to standard-dose mesalamine or diazo-bonded 5-ASA.
  - Standard-dose oral mesalamine or diazo-bonded 5-ASA is preferred over oral budesonide multi-matrix system (MMX) (available in the U.S. as Uceris® tablets and generics) or controlled ileal-release budesonide (generic budesonide DR) for induction of remission.
  - Mesalamine enemas are preferred over rectal corticosteroids for mild-to-moderate ulcerative proctosigmoiditis.
  - Oral prednisone or budesonide MMX is recommended as add-on therapy for mild-to-moderate UC that is refractory to optimized oral and rectal 5-ASA. Trials directly comparing budesonide MMX with systemic corticosteroids such as prednisone have not been identified.

---

[157] 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/default.cfm?resetfields=1. Last revised 03/2020. Last accessed 03/23/2020.

[158] Ko CW, Singh S, Feuerstein JD, et al. AGA Clinical Practice Guidelines on the Management of Mild-to-Moderate Ulcerative Colitis. *Gastroenterology* 2019; 156(3):748-764.

- **March 2019:** The American College of Gastroenterology (ACG) published updated guidelines for the management of adults with UC.[159] The ACG guidelines provide recommendations for patients with UC with mildly active, moderately-to-severely active, and fulminant UC. Management of UC involves appropriate induction therapy followed by maintenance involving a steroid-free strategy. The choice of therapeutic agents for UC are largely in line with recommendations made by the AGA. In general, therapeutic agents should be chosen based on disease activity (active disease vs. remission), severity, extent (proctitis vs. left-sided colitis vs. extensive colitis), and prognosis. The use of disease prognosis to guide therapeutic choices is a new distinction in the 2019 ACG guidelines. Patients who have mild disease severity but poor prognosis should be considered for treatment with agents usually recommended for moderate-to-severe UC. Worse prognosis, measured by the likelihood of colectomy, is indicated by the presence of a greater number of poor prognostic factors. Poor prognostic factors that have been identified for UC include:
    - Age <40 years at diagnosis; and
    - Extensive colitis; and
    - Severe endoscopic disease; and
    - Hospitalization for colitis; and
    - Elevated c-reactive protein (CRP); and
    - Low serum albumin.
- **January 2020:** The AGA published updated guidelines for the management of moderate-to-severe UC.[160] Although the majority of patients with UC have mild-to-moderate disease, about 15% of patients with UC experience an aggressive course and about 20% of those patients require hospitalization for severe disease. Moderate-to-severe UC is defined by the AGA as dependence on or refractory to corticosteroids, severe endoscopic disease activity (ulcers), high risk of colectomy, or Mayo Clinic score of 6-12 with an endoscopic subscore of 2 or 3. Key recommendations from the AGA 2020 guidelines include:
    - Infliximab, adalimumab, golimumab, vedolizumab, tofacitinib, and ustekinumab are all recommended for induction and maintenance of moderate-to-severe UC over no treatment.
    - Infliximab and vedolizumab are preferred for induction over adalimumab for patients who are naïve to biologic agents.
    - Early use of biologic agents with or without immunomodulator therapy is suggested for moderate-to-severe UC rather than gradual step-up after failure of 5-ASA agents.
    - 5-ASA agents are not recommended to be continued in patients who have achieved remission with the use of biologics or immunomodulators.

---

[159] Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG Clinical Guideline: Ulcerative Colitis in Adults. *Am J Gastroenterol* 2019; 114(3):384-413.

[160] Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. *Gastroenterology* 2020. doi: 10.1053/j.gastro.2020.01.006.

Recommendations

The College of Pharmacy does not recommend any changes to the UC and Crohn's disease medications prior authorization criteria at this time.

Utilization Details of UC and Crohn's Disease Medications: Fiscal Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SULFASALAZINE PRODUCTS						
SULFASALAZINE TAB 500MG	575	167	$15,480.70	$26.92	3.44	3.51%
SULFASALAZINE TAB 500MG	403	159	$13,568.88	$33.67	2.53	3.08%
SUBTOTAL	**978**	**326**	**$29,049.58**	**$29.70**	**3**	**6.58%**
MESALAMINE PRODUCTS						
MESALAMINE TAB 1.2GM	307	82	$145,855.17	$475.10	3.74	33.06%
APRISO CAP 0.375GM	136	32	$59,407.19	$436.82	4.25	13.47%
DELZICOL CAP 400MG	94	18	$47,409.00	$504.35	5.22	10.75%
PENTASA CAP 250MG CR	79	23	$50,381.86	$637.75	3.43	11.42%
CANASA SUP 1000MG	20	12	$19,527.77	$976.39	1.67	4.43%
LIALDA TAB 1.2GM	19	4	$20,125.45	$1,059.23	4.75	4.56%
MESALAMINE SUP 1000MG	15	11	$9,569.01	$637.93	1.36	2.17%
MESALAMINE TAB 800MG DR	15	5	$5,820.61	$388.04	3	1.32%
MESALAMINE ENE 4GM	8	6	$1,486.19	$185.77	1.33	0.34%
MESALAMINE CAP 400MG DR	5	5	$2,113.16	$422.63	1	0.48%
SUBTOTAL	**698**	**198**	**$361,695.41**	**$518.19**	**3.53**	**81.99%**
BUDESONIDE PRODUCTS						
BUDESONIDE CAP 3MG DR	190	54	$36,435.26	$191.76	3.52	8.26%
BUDESONIDE CAP 3MG	12	5	$2,179.86	$181.66	2.4	0.49%
BUDESONIDE TAB ER 9MG	4	3	$5,044.52	$1,261.13	1.33	1.14%
UCERIS TAB 9MG	2	2	$3,455.07	$1,727.54	1	0.78%
SUBTOTAL	**208**	**64**	**$47,114.71**	**$226.51**	**3.25**	**10.68%**
BALSALAZIDE PRODUCTS						
BALSALAZIDE CAP 750MG	27	8	$2,120.41	$78.53	3.38	0.48%
SUBTOTAL	**27**	**8**	**$2,120.41**	**$78.53**	**3.38**	**0.48%**
HYDROCORTISONE PRODUCTS						
HYDROCORT ENE 100MG	11	9	$1,167.22	$106.11	1.22	0.26%
COLOCORT ENE 100MG	1	1	$22.05	$22.05	1	0.00%
SUBTOTAL	**12**	**10**	**$1,189.27**	**$99.11**	**1.2**	**0.27%**
TOTAL	**1,923**	**530***	**$441,169.38**	**$229.42**	**3.63**	**100%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Fiscal Year 2019 Annual Review of Vasomotor Symptom Medications

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Bijuva® (Estradiol/Progesterone Capsule) Approval Criteria:

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

Brisdelle® (Paroxetine Mesylate 7.5mg) Approval Criteria:

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

Duavee® (Conjugated Estrogens/Bazedoxifene) Approval Criteria:

1. An FDA approved diagnosis of moderate-to-severe vasomotor symptoms associated with menopause or for the prevention of postmenopausal osteoporosis; and
2. Member must be a female with an intact uterus; and
3. For the diagnosis of moderate-to-severe vasomotor symptoms associated with menopause:
    a. Member must have at least 7 moderate-to-severe hot flushes per day or at least 50 per week prior to treatment; and
4. For the prevention of postmenopausal osteoporosis:
    a. A trial of Fosamax® (alendronate), Actonel® (risedronate), Boniva® (ibandronate), or Reclast® (zoledronic acid) used compliantly for at least 6 months concomitantly with calcium and vitamin D, that failed to prevent fracture or improve bone mineral density (BMD) scores; or
    b. Contraindication to, hypersensitivity to, or intolerable adverse effects with all bisphosphonates indicated for prevention of postmenopausal osteoporosis; and

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

Elestrin® (Estradiol 0.06% Gel) Approval Criteria:

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

Utilization of Vasomotor Symptom Medications: Fiscal Year 2019

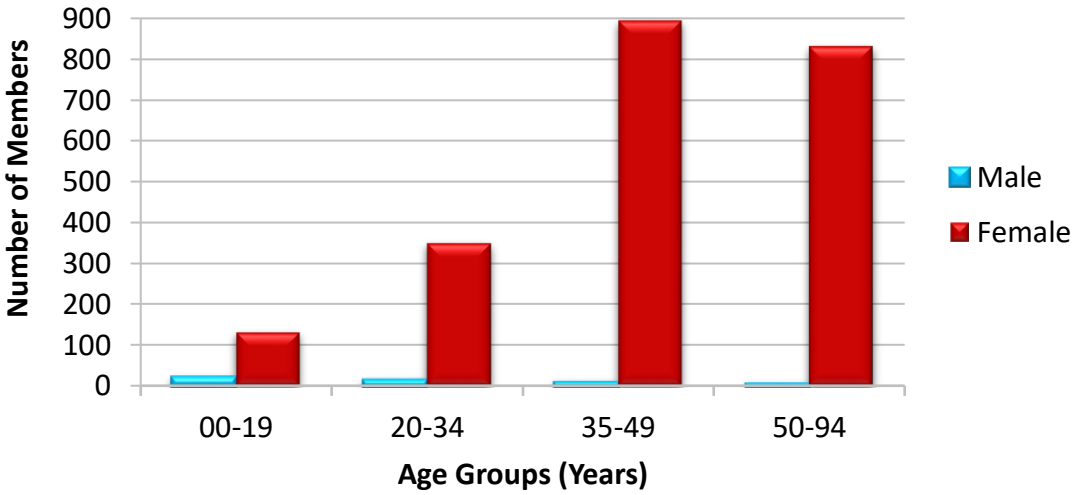
The following utilization data includes vasomotor symptom medications used for all diagnoses and does not differentiate between vasomotor symptom diagnoses and other diagnoses, for which use may be appropriate.

Comparison of Fiscal Years

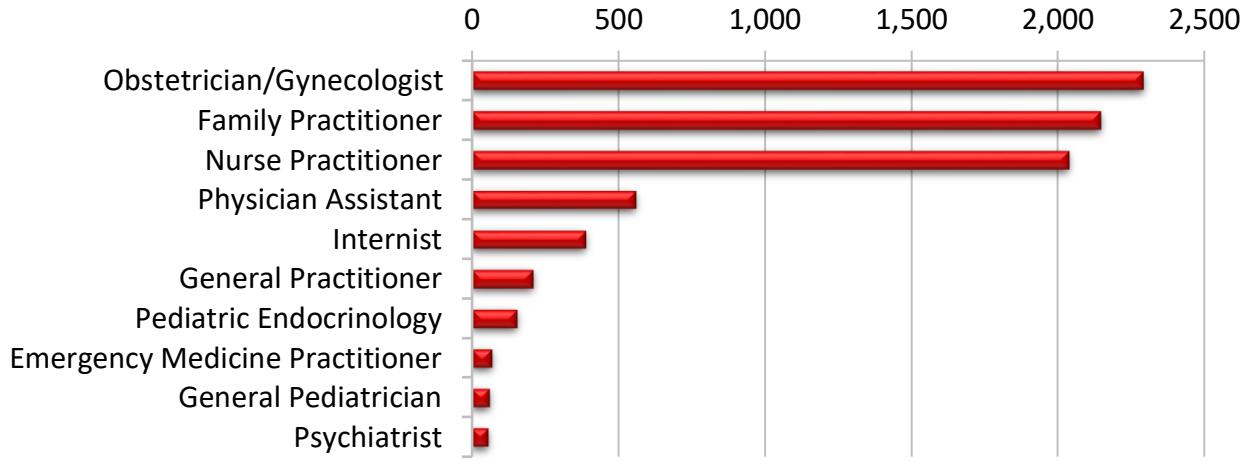
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	2,411	9,008	$875,893.20	$97.24	$2.29	347,420	382,099
2019	2,243	8,210	$798,404.95	$97.25	$2.22	324,874	359,791
% Change	**-7.0%**	**-8.9%**	**-8.8%**	**0.0%**	**-3.1%**	**-6.5%**	**-5.8%**
Change	**-168**	**-798**	**-$77,488.25**	**$0.01**	**-$0.07**	**-22,546**	**-22,308**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Demographics of Members Utilizing Vasomotor Symptom Medications



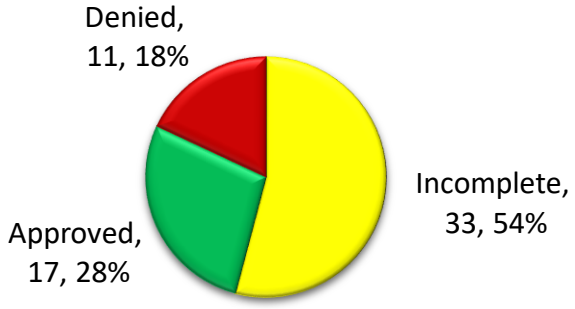
Top Prescriber Specialties of Vasomotor Symptom Medications by Number of Claims



Prior Authorization of Vasomotor Symptom Medications

There were 61 prior authorization requests submitted for vasomotor symptom medications during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[161]

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

News:

- **August 2019:** In an individual participant meta-analysis using data from more than 108,647 women with breast cancer from 58 epidemiological studies worldwide that was published in *The Lancet*, the authors found that all types of menopausal hormone therapy (MHT), except topical vaginal estrogens, were associated with increased risks of breast cancer, which increased steadily with duration of use, and that the risks were greater for users of estrogen/progestin hormone therapy than for estrogen-only hormone therapy. After ceasing MHT, some excess risk persisted for more than 10 years; its magnitude depended on the duration of previous use, with little excess following less than 1 year of MHT use.[162]
- **February 2020:** TherapeuticsMD announced that it submitted a New Drug Application (NDA) prior-approval efficacy supplement for Bijuva® (estradiol/progesterone) 0.5mg/100mg capsules to the U.S. Food and Drug Administration (FDA). The Bijuva® 1mg/100mg dose was approved by the FDA in October 2018 and launched commercially in April 2019. Bijuva® is the only FDA-approved bio-identical hormone therapy combination of estradiol and progesterone in a single, oral capsule. Bijuva® is taken once daily for the treatment of moderate-to-severe vasomotor symptoms (VMS) due to menopause in women with an intact uterus.[163]

Pipeline:

- **Fezolinetant:** Astellas Pharma announced dosing of the first patient in the SKYLIGHT 1 Phase 3 pivotal study for fezolinetant, an investigational oral, non-hormonal compound being studied for the treatment of moderate-to-severe VMS associated with menopause. Fezolinetant is a selective neurokinin-3 (NK3) receptor antagonist. The first trials of the BRIGHT SKY clinical development program will evaluate the efficacy and

---

[161] 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?resetfields=1. Last revised 02/2020. Last accessed 03/05/2020.

[162] Collaborative Group on Hormonal Factors in Breast Cancer. Type and timing of menopausal hormone therapy and breast cancer risk: individual participant meta-analysis of the worldwide epidemiological evidence. *The Lancet* 2019; 394(10204):1159-1168. doi:10.1016/S0140-6736(19)31709-X.

[163] TherapeuticsMD, Inc. TherapeuticsMD Announces Submission of New Drug Application Prior Approval Efficacy Supplement to the U.S. Food and Drug Administration for Lower Dose of Bijuva®. *Business Wire.* Available online at: https://www.businesswire.com/news/home/20200203005141/en/. Issued 02/03/2020. Last accessed 03/05/2020.

safety of 30mg and 45mg once daily fezolinetant in reducing VMS frequency and severity.[164]

- **SJX-653:** SJX-653 is a novel, potent, and selective NK3 antagonist that is currently being developed by Sojournix as a non-hormonal once daily therapy for moderate-to-severe VMS due to menopause. The SJX-653 Phase 2 clinical study is a 12-week, multi-center, randomized, double-blind, placebo-controlled study that is anticipated to enroll approximately 130 postmenopausal women with moderate-to-severe VMS and is designed to evaluate the efficacy of SJX-653 in reducing the frequency and severity of VMS due to menopause, as well as improving measures of sleep and quality of life.[165]

Recommendations

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

Utilization Details of Vasomotor Symptom Medications: Fiscal Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
ORAL ESTROGEN PRODUCTS					
ESTRADIOL TAB 1MG	1,834	632	$23,746.06	$0.28	$12.95
ESTRADIOL TAB 2MG	1,436	472	$20,667.77	$0.32	$14.39
ESTRADIOL TAB 0.5MG	728	255	$9,128.98	$0.27	$12.54
PREMARIN TAB 0.625MG	670	175	$161,994.71	$5.45	$241.78
PREMARIN TAB 1.25MG	556	162	$158,788.49	$5.60	$285.59
PREMARIN TAB 0.3MG	296	86	$73,087.42	$5.64	$246.92
PREMARIN TAB 0.45MG	133	33	$27,508.94	$5.47	$206.83
PREMARIN TAB 0.9MG	127	39	$30,219.17	$5.13	$237.95
ESTROPIPATE TAB 0.75MG	28	7	$804.37	$0.82	$28.73
ESTROPIPATE TAB 1.5MG	17	7	$426.73	$0.84	$25.10
MENEST TAB 0.625MG	10	3	$1,475.08	$2.46	$147.51
MENEST TAB 0.3MG	9	3	$635.24	$1.98	$70.58
SUBTOTAL	**5,844**	**1,714**	**$508,482.96**	**$1.90**	**$87.01**
TOPICAL ESTROGEN PRODUCTS					
ESTRADIOL DIS 0.1MG	333	61	$22,686.00	$2.39	$68.13
ESTRADIOL DIS 0.1MG	238	74	$13,620.44	$2.02	$57.23
ESTRADIOL DIS 0.05MG	165	40	$11,466.70	$2.43	$69.50
ESTRADIOL DIS 0.05MG	152	41	$9,199.87	$2.14	$60.53
ESTRADIOL DIS 0.025MG	104	33	$6,282.32	$2.15	$60.41
ESTRADIOL DIS 0.025MG	98	28	$6,887.15	$1.99	$70.28

[164] Astellas Pharma Inc. Astellas Initiates Phase 3 Clinical Trials for Fezolinetant in Postmenopausal Women with Vasomotor Symptoms. *PR Newswire.* Available online at: https://www.prnewswire.com/news-releases/astellas-initiates-phase-3-clinical-trials-for-fezolinetant-in-postmenopausal-women-with-vasomotor-symptoms-300896688.html. Issued 08/06/2019. Last accessed 03/05/2020.

[165] Sojournix Inc. SJX-653 – A Novel NK3 Antagonist. Available Online at: https://www.sojournixpharma.com/sjx-653. Last accessed 03/05/2020.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
ESTRADIOL DIS 0.0375MG	82	23	$5,558.07	$2.37	$67.78
ESTRADIOL DIS 0.0375MG	68	20	$4,228.21	$2.20	$62.18
ESTRADIOL DIS 0.075MG	57	14	$3,870.56	$2.37	$67.90
DIVIGEL GEL 1MG/GM	32	11	$5,700.27	$5.28	$178.13
ESTRADIOL DIS 0.075MG	21	9	$1,348.46	$2.28	$64.21
DIVIGEL GEL 0.5MG	15	9	$2,034.59	$3.99	$135.64
DIVIGEL GEL 0.25MG	11	4	$1,620.98	$4.16	$147.36
MINIVELLE DIS 0.1MG	10	2	$818.38	$2.92	$81.84
MINIVELLE DIS 0.05MG	9	2	$757.17	$2.91	$84.13
MINIVELLE DIS 0.075MG	9	4	$955.63	$3.78	$106.18
VIVELLE-DOT DIS 0.05MG	8	1	$568.22	$2.46	$71.03
ALORA DIS 0.05MG	5	2	$426.23	$2.92	$85.25
MINIVELLE DIS 0.025MG	5	1	$416.80	$2.87	$83.36
EVAMIST SPR 1.53MG	4	3	$519.34	$1.98	$129.84
ALORA DIS 0.025MG	3	2	$242.64	$2.76	$80.88
ESTRADIOL DIS 0.06MG	3	2	$156.36	$1.86	$52.12
DIVIGEL GEL 0.75MG	1	1	$143.79	$4.79	$143.79
VIVELLE-DOT DIS 0.0375MG	1	1	$132.12	$4.72	$132.12
VIVELLE-DOT DIS 0.025MG	1	1	$68.80	$0.57	$68.80
MENOSTAR DIS 14MCG	1	1	$165.61	$5.52	$165.61
SUBTOTAL	**1,436**	**334**	**$99,874.71**	**$2.37**	**$69.55**
ORAL ESTROGEN/PROGESTIN PRODUCTS					
PREMPRO TAB 0.625-2.5MG	205	51	$56,412.13	$6.64	$275.18
PREMPRO TAB 0.3-1.5MG	135	40	$32,892.11	$6.70	$243.65
PREMPRO TAB 0.45-1.5MG	74	16	$18,165.76	$6.49	$245.48
ESTRA/NORETH TAB 1-0.5MG	55	10	$4,716.27	$2.37	$85.75
PREMPRO TAB 0.625-5MG	52	13	$14,911.92	$6.57	$286.77
ESTRA/NORETH TAB 0.5-0.1MG	36	14	$3,103.71	$2.17	$86.21
MIMVEY TAB 1-0.5MG	12	6	$1,891.43	$2.41	$157.62
NORETH/ETHIN TAB 1MG-5MCG	12	3	$903.85	$1.79	$75.32
PREMPHASE TAB 0.625-5MG	8	2	$3,273.35	$6.49	$409.17
AMABELZ TAB 0.5-0.1MG	8	1	$1,062.49	$2.71	$132.81
NORETH/ETHIN TAB 0.5-2.5MCG	7	6	$789.78	$2.56	$112.83
PREFEST TAB 1-0.09MG	6	1	$824.15	$4.58	$137.36
JEVANTIQUE L TAB 0.5-2.5MCG	5	3	$426.96	$2.18	$85.39
JINTELI TAB 1MG-5MCG	4	3	$386.52	$1.93	$96.63
ANGELIQ TAB 0.5-1MG	3	1	$1,592.43	$6.32	$530.81
ANGELIQ TAB 0.25-0.5MG	3	2	$1,266.30	$6.46	$422.10
FYAVOLV TAB 1-5MCG	1	1	$50.31	$1.80	$50.31
SUBTOTAL	**626**	**163**	**$142,669.47**	**$5.61**	**$227.91**
INJECTABLE ESTROGEN PRODUCTS					
DEPO-ESTRADI INJ 5MG/ML	191	109	$21,851.53	$1.10	$114.41
ESTRAD VAL INJ 200MG/5ML	2	2	$365.66	$1.26	$182.83

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
DELESTROGEN INJ 10MG/ML	2	2	$278.88	$1.64	$139.44
ESTRAD VAL INJ 20MG/ML	1	1	$124.45	$1.38	$124.45
SUBTOTAL	**196**	**113**	**$22,620.52**	**$1.11**	**$115.41**
TOPICAL ESTROGEN/PROGESTIN PRODUCTS					
CLIMARA PRO DIS WEEKLY	44	10	$8,821.99	$7.08	$200.50
COMBIPAT DIS 0.05-0.14MG	34	9	$6,199.82	$6.51	$182.35
COMBIPAT DIS 0.05-0.25MG	5	4	$941.70	$6.54	$188.34
SUBTOTAL	**83**	**23**	**$15,963.51**	**$6.82**	**$192.33**
ESTROGEN/SERM PRODUCTS					
DUAVEE TAB 0.45-20MG	9	1	$1,517.98	$5.62	$168.66
SUBTOTAL	**9**	**1**	**$1,517.98**	**$5.62**	**$168.66**
VAGINAL ESTROGEN PRODUCTS					
FEMRING MIS 0.1MG/24HR	13	5	$5,969.95	$5.18	$459.23
FEMRING MIS 0.05/24HR	3	3	$1,305.85	$4.95	$435.28
SUBTOTAL	**16**	**7**	**$7,275.80**	**$5.14**	**$454.74**
TOTAL	**8,210**	**2,243***	**$798,404.95**	**$2.22**	**$97.25**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019
SERM = selective estrogen receptor modulator

Fiscal Year 2019 Annual Review of Vesicular Monoamine Transporter 2 (VMAT2) Inhibitor Medications

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

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

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

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

1. An FDA approved diagnosis of tardive dyskinesia meeting the following DSM-5 criteria:
    a. Involuntary athetoid or choreiform movements; and

   b. History of treatment with dopamine receptor blocking agent (DRBA); and
   c. Symptom duration lasting longer than 4 to 8 weeks; and
2. Member must be 18 years of age or older; and
3. Austedo® must be prescribed by a neurologist or psychiatrist, or a mid-level practitioner with a supervising physician that is a neurologist or psychiatrist; and
4. Member must not be actively suicidal or have uncontrolled depression and prescriber must verify member will be monitored for depression prior to starting Austedo® therapy and throughout treatment; and
5. Member must not have hepatic impairment; and
6. Member must not be taking monoamine oxidase inhibitors (MAOIs) or have taken an MAOI within the last 14 days; and
7. Member must not be taking reserpine or have taken reserpine within the last 20 days; and
8. Member must not use another vesicular monoamine transporter 2 (VMAT2) inhibitor (e.g., tetrabenazine, valbenazine) concurrently with Austedo®; and
9. For members requiring doses of Austedo® >24mg per day or who are using Austedo® concomitantly with other medications that are known to prolong the QTc interval [antipsychotic medications (e.g., chlorpromazine, haloperidol, thioridazine, ziprasidone), antibiotics (e.g., moxifloxacin), Class 1A (e.g., quinidine, procainamide) and Class III (e.g., amiodarone, sotalol) antiarrhythmic medications, or any other medications known to prolong the QTc interval], the prescriber must agree to assess the QTc interval before and after increasing the dose of Austedo® or other medications that are known to prolong the QTc interval; and
10. The member must not have congenital long QT syndrome or a history of cardiac arrhythmias; and
11. The daily dose of Austedo® must not exceed 36mg per day if the member is taking strong CYP2D6 inhibitors (e.g., paroxetine, fluoxetine, quinidine, bupropion) or if the member is a known poor CYP2D6 metabolizer; and
12. Female members must not be pregnant or breastfeeding; and
13. Prescriber must document a baseline evaluation using the Abnormal Involuntary Movement Scale (AIMS); and
14. Approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment as indicated by an improvement from baseline in the AIMS total score (a negative change in score indicates improvement) or documentation of a positive clinical response to therapy.

Ingrezza® (Valbenazine) Approval Criteria:

1. An FDA approved diagnosis of tardive dyskinesia meeting the following DSM-5 criteria:
   a. Involuntary athetoid or choreiform movements; and
   b. History of treatment with dopamine receptor blocking agent (DRBA); and
   c. Symptom duration lasting longer than 4 to 8 weeks; and
2. Member must be 18 years of age or older; and
3. Ingrezza® must be prescribed by a neurologist or psychiatrist, or a mid-level practitioner with a supervising physician that is a neurologist or psychiatrist; and

4. The daily dose of Ingrezza® must not exceed 40mg per day if the member is taking strong CYP3A4 inhibitors (e.g., itraconazole, ketoconazole, clarithromycin); and
5. Member must not be taking monoamine oxidase inhibitors (MAOIs); and
6. Member must not be taking other vesicular monoamine transporter 2 (VMAT2) inhibitors (e.g., tetrabenazine, deutetrabenazine); and
7. The daily dose of Ingrezza® must not exceed 40mg per day for members with moderate or severe hepatic impairment (Child-Pugh score 7 to 15); and
8. The member must not have congenital long QT syndrome or a history of arrhythmias associated with a prolonged QT interval; and
9. Female members must not be pregnant or breastfeeding; and
10. Prescriber must document a baseline evaluation using the Abnormal Involuntary Movement Scale (AIMS); and
11. A quantity limit of 1 capsule per day will apply; and
12. Approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment as indicated by an improvement from baseline in the AIMS total score (a negative change in score indicates improvement) or documentation of a positive clinical response to therapy.

Xenazine® (Tetrabenazine) Approval Criteria:

1. Authorization of generic tetrabenazine (in place of brand Xenazine®) will require a patient-specific, clinically significant reason why the member cannot use the brand formulation (brand formulation is preferred); and
2. A diagnosis of 1 of the following:
    a. Chorea associated with Huntington's disease; or
    b. Tardive dyskinesia; or
    c. Tourette syndrome; and
3. Xenazine® must be prescribed by a neurologist, or a mid-level practitioner with a supervising physician that is a neurologist; and
4. Member must not be actively suicidal or have uncontrolled depression and prescriber must verify member will be monitored for depression prior to starting Xenazine® therapy and throughout treatment; and
5. Member must not have hepatic impairment; and
6. Member must not be taking monoamine oxidase inhibitors (MAOIs) or have taken an MAOI within the last 14 days; and
7. Member must not be taking reserpine or have taken reserpine within the last 20 days; and
8. Member must not use another vesicular monoamine transporter 2 (VMAT2) inhibitor (e.g., deutetrabenazine, valbenazine) concurrently with Xenazine®; and
9. Member must not be taking medications that are known to prolong the QTc interval concomitantly with Xenazine® [antipsychotic medications (e.g., chlorpromazine, haloperidol, thioridazine, ziprasidone), antibiotics (e.g., moxifloxacin), Class 1A (e.g., quinidine, procainamide) and Class III (e.g., amiodarone, sotalol) antiarrhythmic medications, or any other medications known to prolong the QTc interval]; and

10. Patients who require doses of tetrabenazine >50mg per day must be tested and genotyped to determine if they are poor metabolizers (PMs), intermediate metabolizers (IMs), or extensive metabolizers (EMs) by their ability to express the drug metabolizing enzyme, CYP2D6. The following dose limits will apply based on patient metabolizer status:
    a. Extensive and Intermediate CYP2D6 Metabolizers: 100mg divided daily; or
    b. Poor CYP2D6 Metabolizers: 50mg divided daily; and
11. The daily dose of Xenazine® must not exceed 50mg per day if the member is taking strong CYP2D6 inhibitors (e.g., paroxetine, fluoxetine, quinidine, bupropion); and
12. Approvals will be for the duration of 6 months at which time the prescriber must document that the signs and symptoms of chorea, tardive dyskinesia, or Tourette syndrome have decreased and the member is not showing worsening signs of depression.

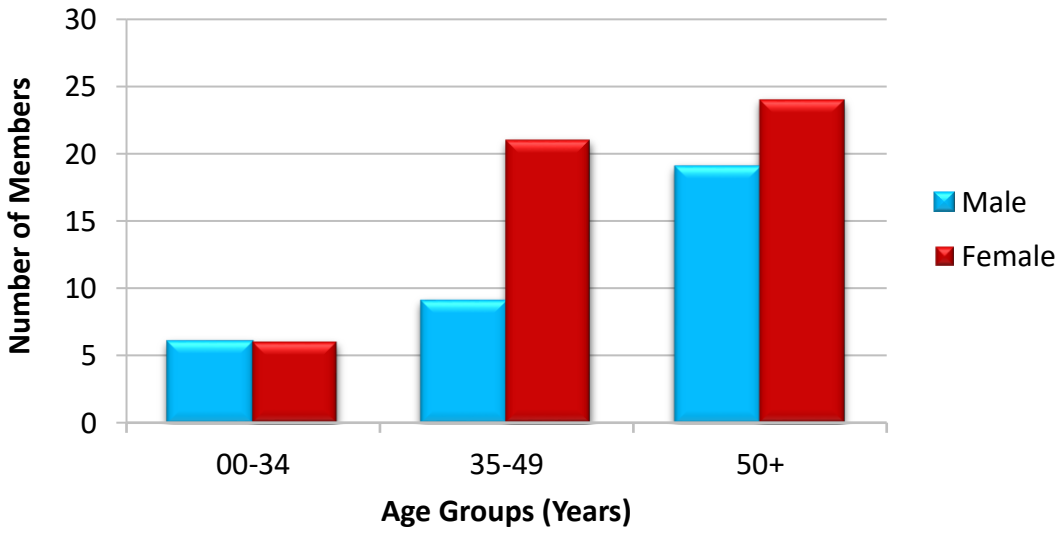
Utilization of VMAT2 Inhibitor Medications: Fiscal Year 2019

Comparison of Fiscal Years

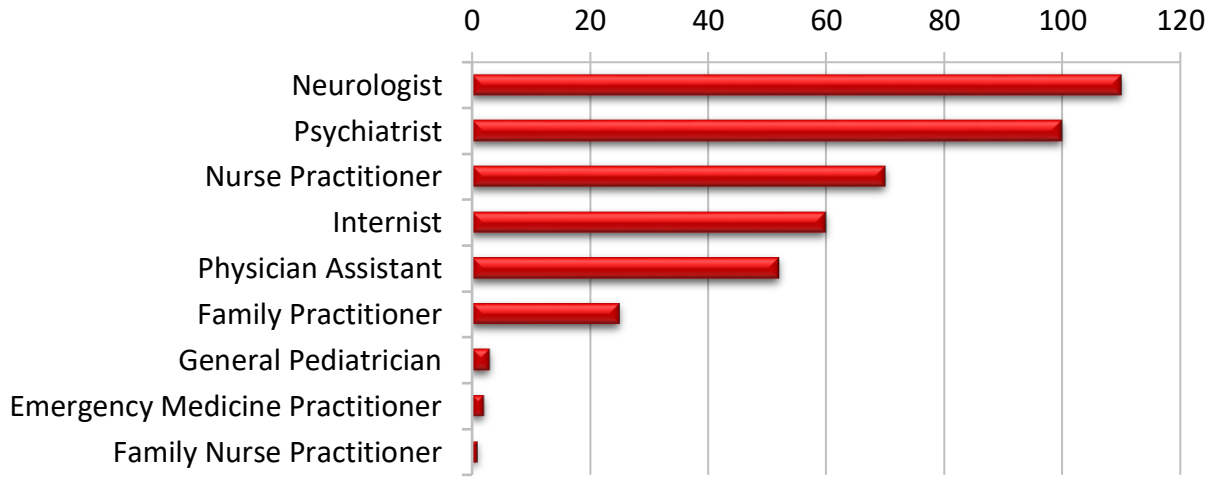
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	27	121	$940,041.02	$7,768.93	$269.43	6,230	3,489
2019	85	423	$2,788,354.40	$6,591.85	$228.72	19,130	12,191
% Change	**214.8%**	**249.6%**	**196.6%**	**-15.2%**	**-15.1%**	**207.1%**	**249.4%**
Change	**58**	**302**	**$1,848,313.38**	**-$1,177.08**	**-$40.71**	**12,900**	**8,702**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Demographics of Members Utilizing VMAT2 Inhibitor Medications



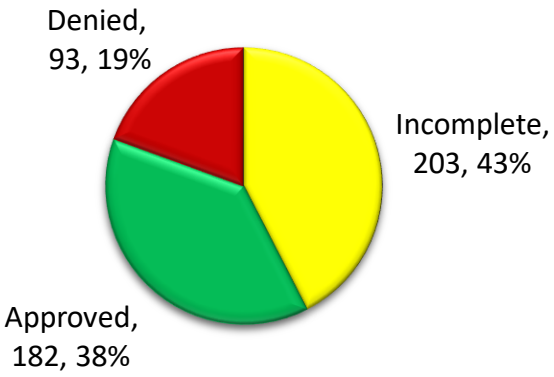
Top Prescriber Specialties of VMAT2 Inhibitor Medications by Number of Claims



Prior Authorization of VMAT2 Inhibitor Medications

There were 478 prior authorization requests submitted for VMAT2 inhibitor medications during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[166]

- Austedo® (deutetrabenazine): September 2033
- Ingrezza® (valbenazine): October 2036

Pipeline:

- **RG6042:** RG6042, formerly called IONIS-HTTRx, a potential first disease-modifying therapy for Huntington's disease, is now in a Phase 3 trial expected to end in 2022. RG6042 is an antisense oligonucleotide (ASO), or gene silencing therapy, designed to

[166] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 03/2020. Last accessed 03/20/2020.

bind to mutated forms of the huntingtin (mHTT) mRNA targeting it for degradation. RG6042 is currently being tested in a worldwide Phase 3 clinical trial (NCT03761849), called the GENERATION HD1. This study is evaluating the efficacy, safety, and biomarker effects of RG6042, compared with placebo, in up to 909 patients with Huntington's disease. A Phase 1/2a clinical trial (NCT02519036), testing RG6042 in 46 adults with early stage Huntington's, has been published and showed a reduction in the levels of mHTT in the cerebral spinal fluid by up to 60%.[167]

- **AMT-130:** AMT-130 is an experimental gene therapy that works by inhibiting the production of the mHTT protein, the underlying cause of Huntington's disease. The therapy has shown promising results in preclinical studies and has been granted Orphan Drug and Fast Track designations by the U.S. Food and Drug Administration (FDA). New preclinical data that were shared recently in 4 presentations at the 15th Annual CHDI Huntington's Disease Therapeutics Conference, continue to support the use of AMT-130 for Huntington's disease. Results revealed that the therapy lowered the levels of mHTT in nerve cells derived from Huntington's patients as well as in mouse, mini-pig, and non-human primate models of the disease.[168]

Guideline Update(s):

- **May 2019:** The American Academy of Neurology (AAN) published a new guideline for treating Tourette syndrome and other chronic tic disorders. The guideline recommends that when a patient has tics that are not causing physical impairment, pain, emotional distress, or social embarrassment, watching and waiting is an acceptable management strategy when also combined with patient education. If symptoms affect a patient's daily life, the guideline recommends that health care providers first consider Comprehensive Behavioral Intervention for Tics (CBIT), which is effective in both children and adults and has no major side effects. The guideline recommends that patients with tics are evaluated for attention deficit hyperactivity disorder (ADHD), obsessive-compulsive disorder (OCD), and mood and anxiety disorders, since treatment for these disorders may also be needed. Alpha-2 adrenergic agonists can improve symptoms of both tic disorders and ADHD, and antipsychotic medications can be prescribed for tics provided that side effects are discussed and monitored. There is limited evidence for the use of botulinum toxin, and adults with severe Tourette syndrome who are resistant to medical and behavioral therapy may benefit from deep brain stimulation (DBS), but that they must first be screened by a mental health professional and continue to be monitored throughout DBS treatment.[169]

---

[167] Bryson, S. RG6042, Potential DMT in Phase 3 Trial, Named Orphan Drug in Japan. Huntington's disease News. Available Online: https://huntingtonsdiseasenews.com/2020/03/05/rg6042-potential-dmt-in-phase-3-trial-named-orphan-drug-in-japan/. Issued 03/05/2020. Last Accessed 03/26/2020.

[168] Inacio, P. UniQure Presents More Data Supporting the Effectiveness of Gene Therapy Candidate AMT-130. Huntington's disease News. Available Online: https://huntingtonsdiseasenews.com/2020/03/10/uniqure-preclinical-data-gene-therapy-amt-130-huntingtons-diesease/. Issued 03/10/2020. Last Accessed 03/26/2020.

[169] American Academy of Neurology (AAN). Practice Guideline: The treatment of tics in people with Tourette syndrome and chronic tic disorders. Available Online at: https://www.aan.com/Guidelines/Home/GuidelineDetail/958. Last Revised 05/2019. Last Accessed 03/26/2020.

Recommendations

The College of Pharmacy recommends updating the Ingrezza® (valbenazine) approval criteria based on the *Drug Interactions* section of the Ingrezza® Prescribing Information, to be consistent with the approval criteria for the other VMAT2 inhibitor medications (changes shown in red):

Ingrezza® (Valbenazine) Approval Criteria:

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

Utilization Details of VMAT2 Inhibitor Medications: Fiscal Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
TETRABENAZINE PRODUCTS						
XENAZINE TAB 25MG	39	4	$562,337.41	$480.63	$14,418.91	20.17%
XENAZINE TAB 12.5MG	1	1	$3,405.81	$113.53	$3,405.81	0.12%
TETRABENAZIN TAB 12.5MG	1	1	$1,182.53	$42.23	$1,182.53	0.04%
SUBTOTAL	**41**	**6**	**$566,925.75**	**$461.67**	**$13,827.46**	**20.33%**
VALBENAZINE PRODUCTS						
INGREZZA CAP 80MG	164	39	$1,039,928.45	$213.63	$6,341.03	37.30%
INGREZZA CAP 40MG	72	26	$370,773.10	$196.80	$5,149.63	13.30%
SUBTOTAL	**236**	**51**	**$1,410,701.55**	**$208.93**	**$5,977.55**	**50.59%**
DEUTETRABENAZINE PRODUCTS						
AUSTEDO TAB 12MG	94	26	$634,223.35	$217.42	$6,747.06	22.75%
AUSTEDO TAB 6MG	26	12	$103,963.93	$153.57	$3,998.61	3.73%
AUSTEDO TAB 9MG	26	10	$72,539.82	$117.57	$2,789.99	2.60%
SUBTOTAL	**146**	**31**	**$810,727.10**	**$192.53**	**$5,552.93**	**29.08%**
TOTAL	**423**	**85***	**$2,788,354.40**	**$228.72**	**$6,591.85**	**100%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Fiscal Year 2019 Annual Review of Vimizim® (Elosulfase Alfa)

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Vimizim® (Elosulfase Alfa) Approval Criteria:

1. An FDA approved diagnosis of Morquio A syndrome (mucopolysaccharidosis type IVA; MPS IVA) confirmed by:
   a. Enzyme assay demonstrating a deficiency of N-acetylgalactosamine-6-sulfatase (GALNS) enzyme activity; or
   b. Molecular genetic testing to confirm biallelic pathogenic variants in GALNS; and
2. Vimizim® must be administered by a health care professional prepared to manage anaphylaxis; and
3. Initial approvals will be for the duration of 12 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment; and
4. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling.

Utilization of Vimizim® (Elosulfase Alfa): Fiscal Year 2019

There was no SoonerCare utilization of Vimizim® (elosulfase alfa) during fiscal year 2019 (fiscal year 2019 = 07/01/2018 to 06/30/2019).

Prior Authorization of Vimizim® (Elosulfase Alfa)

There were no prior authorization requests submitted for Vimizim® (elosulfase alfa) during fiscal year 2019.

Recommendations

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

Fiscal Year 2019 Annual Review of Xgeva® (Denosumab)

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Xgeva® (Denosumab) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. Prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors; or
    b. Treatment of adults and skeletally mature adolescents with giant cell tumor of the bone (GCTB) that is unresectable or where surgical resection is likely to result in severe morbidity; and
        i. Prescriber must document that tumor is unresectable or that surgical resection is likely to result in severe morbidity; or
    c. Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy; and
        i. Member must have albumin-corrected calcium >12.5mg/dL (3.1mmol/L) despite treatment with intravenous bisphosphonate therapy in the last 30 days prior to initiation of Xgeva® therapy.

Utilization of Xgeva® (Denosumab): Fiscal Year 2019

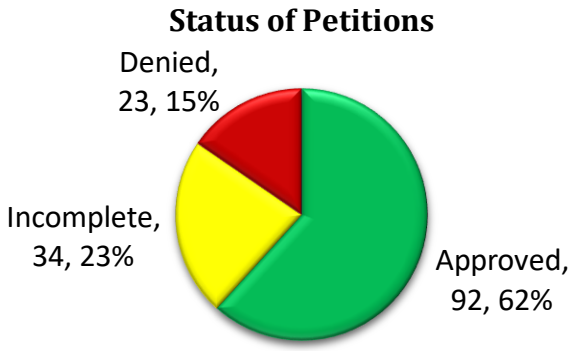
Xgeva® (Denosumab) Comparison of Fiscal Years: Medical Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim
2018	57	268	$513,738.28	$1,916.93
2019	55	286	$641,384.52	$2,242.60
% Change	**-3.51%**	**6.72%**	**24.85%**	**16.99%**
Change	**-2**	**18**	**$12,7646.24**	**$325.67**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Prior Authorization of Xgeva® (Denosumab)

There were 149 prior authorization requests submitted for Xgeva® (denosumab) during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.



Recommendations

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

Fiscal Year 2019 Annual Review of Xiaflex® (Collagenase Clostridium Histolyticum)

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

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

1. An FDA approved indication 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. The member must not be a candidate for needle aponeurotomy; and
4. The 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. A 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® REMS program; and
7. A maximum of 8 injection procedures will be approved.

Utilization of Xiaflex® (Collagenase Clostridium Histolyticum): Fiscal Year 2019

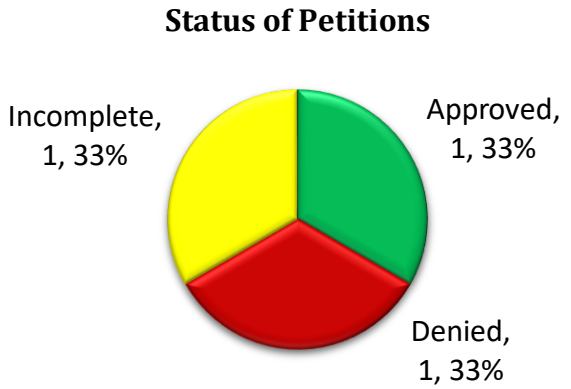
Fiscal Year 2019 Utilization: Medical Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Total Units
2019	1	2	$4,115.00	$2,057.50	148

*Total number of unduplicated members. Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Prior Authorization of Xiaflex® (Collagenase Clostridium Histolyticum)

There were 3 prior authorization requests submitted for Xiaflex® (collagenase clostridium histolyticum) during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.



Market News and Updates

News:[170]

- **September 2019:** Endo International announced that the company has submitted a Biologics License Application (BLA) for Xiaflex® (collagenase clostridium histolyticum) to the U.S. Food and Drug Administration (FDA) for the treatment of cellulite in the buttocks.

Recommendations

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

[170] Zacks Equity Research. Endo International Files BLA for Label Expansion of Xiaflex. *Zacks*. Available online at: https://www.zacks.com/stock/news/509478/endo-international-files-bla-for-label-expansion-of-xiaflex. Issued 09/09/2019. Last accessed 12/13/2019.

Fiscal Year 2019 Annual Review of Xuriden® (Uridine Triacetate)

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Xuriden® (Uridine Triacetate) Approval Criteria:

1. An FDA approved diagnosis of hereditary orotic aciduria defined by at least 1 of the following:
    a. Assay of the orotate phosphoribosyltransferase and orotidylic acid decarboxylase enzymes in the member's erythrocytes showing deficiency in both enzymes or deficiency in orotidylic acid decarboxylase alone; or
    b. Evidence of megaloblastic anemia; and
        i. Normal serum folate and vitamin B12 levels; and
        ii. No evidence of transcobalamine II deficiency; or
    c. Orotic acid crystals visualized in the urine via microscopy; and
2. The member's current weight must be provided on the prior authorization request; and
    a. Weights should be reassessed every 6 months to ensure proper dosing and effectiveness; or
    b. Prescriber can indicate urine orotic acid levels are within normal ranges and dosing remains appropriate; and
3. The prescriber must verify that the member or caregiver is able to properly measure and administer medication; and
4. A quantity limit of 4 packets per day will apply.

Utilization of Xuriden® (Uridine Triacetate): Fiscal Year 2019

There was no SoonerCare utilization of Xuriden® (uridine triacetate) during fiscal year 2019 (fiscal year 2019 = 07/01/2018 to 06/30/2019).

Prior Authorization of Xuriden® (Uridine Triacetate)

There were no prior authorization requests submitted for Xuriden® (uridine triacetate) during fiscal year 2019.

Market News and Updates

Anticipated Patent Expiration(s):

- Xuriden® (uridine triacetate): July 2023[171]

[171] U.S. Food and Drug Administration (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 12/2019. Last accessed 12/14/2019.

Recommendations

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

Fiscal Year 2019 Annual Review of Zinplava™ (Bezlotoxumab)

Oklahoma Health Care Authority
Fiscal Year 2019 Print Report

Current Prior Authorization Criteria

Zinplava™ (Bezlotoxumab) Approval Criteria:

1. An FDA approved diagnosis of *Clostridium difficile* infection (CDI) in patients 18 years of age or older who are receiving antibacterial drug treatment of CDI and are at a high risk for CDI recurrence; and
    a. Prescriber must document the member has ≥1 of the following risk factors for high risk of CDI recurrence:
        i. Age 65 years or older; or
        ii. ≥1 episode(s) of CDI within the 6 months prior to the episode under treatment; or
        iii. Need for ongoing therapy with concomitant antibiotics during treatment for CDI; or
        iv. Severe underlying medical disorders; or
        v. Immunocompromised; or
        vi. Clinically severe CDI (Zar score ≥2); and
2. Current or planned antibacterial drug for CDI must be provided on the prior authorization request to ensure medication is within standard of care; and
3. Prescriber must document that Zinplava™ (bezlotoxumab) will be administered while the member is receiving antibacterial drug treatment of CDI; 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 Zinplava™ (Bezlotoxumab): Fiscal Year 2019

Comparison of Fiscal Years: Medical Claims

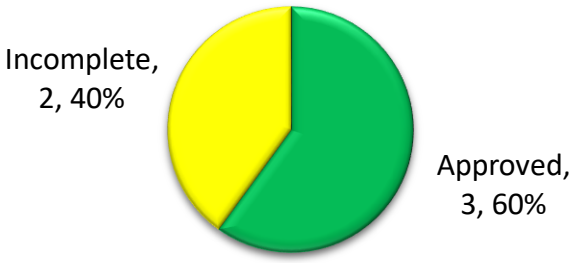
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Total Units
2018	1	1	$3,800.00	$3,800.00	100
2019	1	1	$2,698.00	$2,698.00	71
% Change	**0.00%**	**0.00%**	**-29.00%**	**-29.00%**	**-29.00%**
Change	**0**	**0**	**-$1,102.00**	**-$1,102.00**	**-29**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2018 = 07/01/2017 to 06/30/2018; Fiscal Year 2019 = 07/01/2018 to 06/30/2019

Prior Authorization of Zinplava™ (Bezlotoxumab)

There were 5 prior authorization requests submitted for 2 unique members for Zinplava™ (bezlotoxumab) during fiscal year 2019. The following chart shows the status of the submitted petitions for fiscal year 2019.

Status of Petitions



Market News and Updates

News:

- **February 2019:** The U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy designation to CP101 for the treatment of patients with recurrent *Clostridium difficile* infection (CDI). CP101 is an investigational oral full-spectrum microbiota (FSM) product being developed to prevent recurrent CDI. It contains various functional microorganisms which may engraft in the host microbiome and help restore gut flora. Currently, a Phase 2 randomized, placebo-controlled study (PRISM3) is underway and actively enrolling patients.[172]

Pipeline:

- **SER-109:** Seres Therapeutics presented new data for SER-109, a microbiome candidate in Phase 3 development, at the IDWeek 2018 conference in October 2018. The findings presented provide support for SER-109 as a potential new treatment option for the treatment of recurrent CDI and for the continued development of SER-109. Seres Therapeutics also indicated that the data found suggest that SER-109 may have important broader public health benefits by reducing the spread of antibiotic resistance.[173]

Recommendations

The College of Pharmacy does not recommend any changes to the current Zinplava™ (bezlotoxumab) prior authorization criteria at this time.

---

[172] Han DH. CP101 Designated Breakthrough Tx for Recurrent *C. difficile* Infection. *MPR*. Available online at: https://www.empr.com/home/news/drugs-in-the-pipeline/cp101-designated-breakthrough-tx-for-recurrent-c-difficile-infection/. Issued 02/08/2019. Last accessed 12/16/2019.

[173] Seres Therapeutics. Seres Therapeutics to Present New Data Supporting SER-109 Clinical Activity at IDWeek 2018. *Business Wire.* Available online at: https://www.businesswire.com/news/home/20181003005055/en/Seres-Therapeutics-Present-New-Data-Supporting-SER-109. Issued 10/03/2018. Last accessed 12/16/2019.